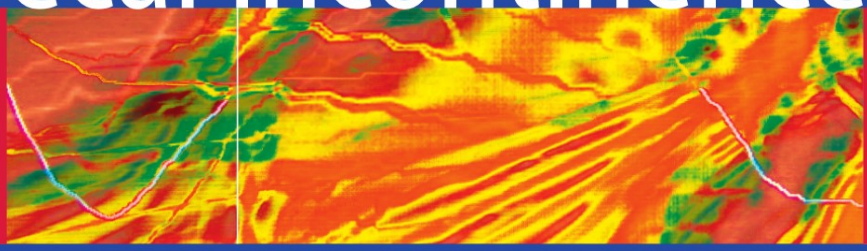
Horst-Dieter Becker · Arnulf Stenzl
Diethelm Wallwiener · Tilman T. Zittel
Editors

Urinary and Fecal Incontinence



An Interdisciplinary Approach

Springer

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With 95 Figures, 43 in Color and 89 Tables

Springer

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Part I

Epidemiologic and Health Costs of Incontinence

Chapter 1

Epidemiology of Urinary Incontinence

1

Steinar Hunskaar

Contents

1

The understanding of epidemiology – the study of the distribution and determinants of disease – is critical in the search for the risk and protective factors that lead to primary or secondary disease prevention. This chapter reviews some of the knowledge of the epidemiology of urinary incontinence (UI). The review uses only a fraction of the high-quality, population-based studies available. More comprehensive reviews have been published (Hampel et al. 1997; Thom 1998; Hunskaar et al. 2000, 2002).

1.1 Definitions

Studies of disease frequency should rely on a very specific definition of the condition under investigation. The lack of unifying definitions for UI is a fundamental problem in assessing and comparing the findings in different studies. The International Continence Society (ICS) previously defined "urinary incontinence" as "a condition where involuntary loss of urine is a social or hygienic problem and is objectively demonstrable." From 2002 the definition reads "The complaint of any involuntary leakage of urine." The old definition was not achievable outside clinical settings. It added a subjective aspect ("problem") and therefore confounded the analyses of prevalence and risk factors. The new definition is well suited for epidemiological studies, but not appropriate for defining a patient. It should therefore be combined with validated instruments for type, severity, and QoL, in addition to investigations, for the clinical setting.

"Prevalence" is defined as the probability of being incontinent within a defined population and at a defined point in time. The concept is important for establishing the distribution of the condition in the population and for projecting the need for health and medical services. "Incidence" is defined as the probability of developing the condition under study during a defined time period. Incidence is usually reported for 1-, 2-, or 5-year time intervals. Epidemiological surveys must often take a pragmatic approach and therefore define "incontinence type" based on the symptoms alone. The classification can be made either by researchers or by the respondent's confirmation of a typical description. Clinical assessment allows for more differentiation of subtypes, but is difficult to perform on a large-scale basis. Severity of incontinence is another important factor for the estimate of prevalence. "Severity" can be defined by factors such as frequency, amount, and subjective bother (Sandvik et al. 2000).

1.2 Epidemiology of Nocturnal Enuresis

Most epidemiological studies link primary and secondary enuresis together and may include both monosymptomatic and polysymptomatic cases. Also, enuresis is defined in different ways, and in many papers there is no frequency defined at all. The best studies are longitudinal cohort studies, but many are cross-sectional (Krantz et al. 1994). In some cultures, parents are more complacent about bedwetting than in others and do not regard it as a problem requiring attention.

Nocturnal enuresis is caused by relative nocturnal polyuria and/or nocturnal bladder overactivity combined with lack of arousal at the time when the bladder needs to be emptied. These factors have a different weight in different enuretic children. The pathophysiology is thus a mixed mechanism, which explains difficulties encountered when trying to define enuresis in a consistent way. Stringent epidemiological studies would need to evaluate nocturnal urine production, nocturnal bladder activity, sleep

and arousal in each of the probands. Needless to say, there is no large population-based study using such diagnostic evaluation.

1.2.1 Survey Studies

Prevalence of nocturnal enuresis at age 7 years is significant since many children start school then, meaning more exposure to the environment and thus a greater awareness of the problem. At this age, the prevalence of nocturnal enuresis seems to be between 7% and 9% (Spee-van der Wekke et al. 1998; Hunskaar et al. 2002). In the early ages, the prevalence in boys is reported to be higher than in girls by a 2 : 1 ratio in Western countries. In studies from other countries, the figures are more similar in boys and girls, but there is always a predominance of boys. It seems that the sex difference diminishes with age and becomes less obvious among older children. In a French study (Lottmann 1999), the severity and consequences of enuresis were reported: 66% had more than one wet night per month, 37% more than one wet night per week, and 22% wet the bed every night. Regarding consequences, 42% were "bothered a lot" while 15% were "not bothered at all" by their enuresis. In contrast, 92% of the mothers declared that the enuresis had no significant effect on family life or the child's behavior at school. Fourteen percent of mothers punished their child and only 13% intended to seek treatment for their child. Even if there are some ethnic and cultural differences in the prevalence of enuresis, with higher rates generally reported from Eastern countries, there is nonetheless a remarkable similarity of prevalence rates of nocturnal enuresis in populations from all parts of the world.

1.2.2 Remission and Natural History

Primary nocturnal enuresis usually remits with age. The spontaneous cure rate seems to be around 15% annually between the ages of 5 and 19. The risk for an enuretic 7-year-old boy to remain enuretic throughout life may be calculated at 3%. In a largely untreated adult population, the prevalence is around 0.5%.

1.2.3 Potential Risk Factors of Nocturnal Enuresis

Several risk factors have been established or suggested by epidemiological studies; the most important are shown in Table 1.1

1.3 Epidemiology of Urinary Incontinence in Women

Differences in sample, definition and measurement, and survey methodology continue to make reviews challenging.

1.3.1 Prevalence

More epidemiological research is available on older women of all ages because UI is considered to be a health condition of older age. Reviews of several European and

Table 1.1. Risk factors of nocturnal enuresis and day and day/night wetting

Nocturnal enuresis
Family history
Behavioral disturbances
Nocturnal polyuria
Sleep and arousal
Nocturnal bladder dysfunction
Other factors
Day and day/night wetting
Family history
Psychological disorders and sexual abuse
Disorders of bladder-sphincter nerve control
Urinary tract infections
Infravesical obstruction
Epispadias

American epidemiological studies of women living in the community identify a 10%–40% range of prevalence estimates of the experience of any UI and suggest a UI prevalence of 40% or even greater in the elderly. These studies also suggest that the wide range can be attributed to the definition of UI and the sample and potentially to the format of the questions about UI.

The median level of prevalence estimates gives a picture of increasing prevalence during young adult life (prevalence, 20%–30%), a broad peak around middle age (prevalence, 30%–40%), and then a steady increase in the elderly (prevalence, 30%–50%). Two recent studies of European women of all ages illustrates these findings (Fig. 1.1) (Hannestad et al. 2000; Hunskaar et al. 2004).

Prevalence has always been higher in institutions because the residents tend to be older and more impaired than community-residing women. Several recent studies from around the world suggest prevalence of 50% or higher.

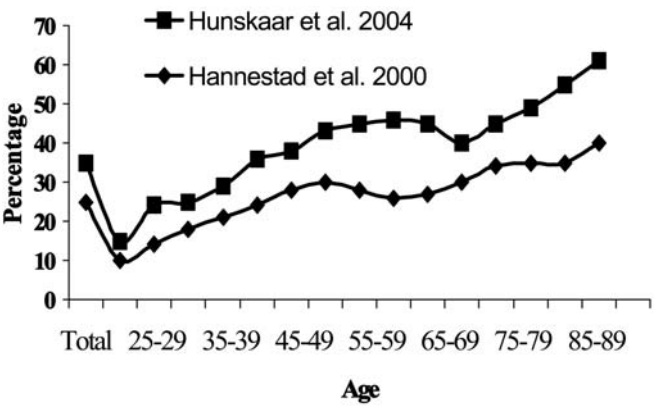

Fig. 1.1. Prevalence of urinary incontinence in women by age. Data from Hannestad et al. (2000) and Hunskaar et al. (2004)

1.3.2 Type

Only symptoms can be recorded in surveys based on questionnaires or interviews. Typically, stress incontinence is identified when the respondent reports UI to occur with physical activity and urge incontinence when it occurs in the context of a sudden urge to urinate. Proportions of types of UI differ with age. In general, studies indicate that approximately half of all incontinent women are classified as stress incontinent, making this group the largest among urge, mixed, and stress types. A smaller proportion is classified as mixed incontinent, the smallest one as urge incontinent. An analysis of type distribution in 15 studies showed median values of 49% for stress, 21% for urge, and 29% for mixed type. In a recent European study, the figures were 46%, 26%, and 28%, respectively (Hunskaar et al. 2004).

Unfortunately, not all studies have carefully assessed the different types (and even fewer have examined their correlates). Therefore, proportions of stress, urge, and mixed types among women are difficult to estimate and estimates vary considerably. But there are intriguing differences between the different types, which suggests that the types may reflect quite different pathologies and that differentiating the types in future research might prove useful.

1.3.3 Severity

The characterization of severity has been made using two methods. The first approach is a simple attempt to operationalize the frequency of urine loss, where severe incontinence is defined by weekly or more frequent loss. The second approach uses quantity of loss, as well as perception differences, personal hygiene, and coping ability. Typically, slight incontinence denotes leakage of drops a few times a month, moderate incontinence daily leakage of drops, and severe incontinence larger amounts at least once a week (Sandvik et al. 2000).

The severity of incontinence varies between the different types. The fraction of severe incontinence is much lower in the stress group compared to the urge and mixed groups. In one major study, slight incontinence was found in 53% of the stress group, 39% of the urge group, and 31% of the mixed group. Within each type of incontinence, severity increased with increasing age (Hannestad et al. 2000).

Prevalence is also dependent on thresholds for diagnosis or severity. For example, one researcher found that nearly 50% of cases were classified as slight incontinence and only 27% as severe (Sandvik et al. 1993). Studies also investigated the "bother" factor and found that different levels of bother significantly affected the prevalence estimates and that approximately one-fifth of incontinent women suffer from severe incontinence, if only moderate or severe incontinence and an indication of bother is considered (Sandvik et al. 1993; Hannestad et al. 2000).

Even though the definition of severe or significant UI varies between authors, its prevalence is considerably less variable across different studies than prevalence of any UI. Most prevalence estimates vary between 6% and 10%. The lesser variance among these estimates suggests that severe incontinence is less easy to deny and better understood by participants than any incontinence and thus may represent a more reliable figure.

1.3.4 Incidence, Remission, and Natural History

Very few studies have reported on the incidence of UI. A study of community-dwelling women aged 60 years or older found that 20% of the originally continent women had developed some level of UI during the 1-year study period. In another study, a cohort of healthy middle-aged women was examined over 3 years. Of the previously continent women, 8% reported at least monthly leakage; higher rates have been found in the elderly. One-year incidence rates of 6% and 3% have been reported for young and middle-aged women, respectively (Hunskaar et al. 2002).

Similarly, rates of remission (the probability of becoming continent among previously incontinent women) vary considerably across the few studies that have investigated them, ranging over 1 year between a maximum of 38% to a minimum of 6% among middle-aged and younger women, and 10% for older women. It is not clear whether the level of remission reflects active treatment or intervention or whether it is part of the natural course of incontinence.

1.3.5 Racial and Ethnic Differences

Most epidemiological studies of UI have been conducted on white populations. Research on other populations shows a wide variation in prevalence. These studies have used different methods and definitions, and the quality is mixed. Therefore, the results are difficult to compare, and most of the studies do not lend themselves easily to cross-cultural or cross-national comparisons. Some data for black women exist, and they indicate that white women may be more susceptible to UI than black women. US clinical data suggest that black women have higher urethral closure pressure, larger urethral volume, and greater vesical mobility.

1.3.6 Potential Risk Factors

Epidemiological studies conducted in various populations reveal a number of variables related to UI, including several possible risk factors or contributing variables (Table 1.2) (Brown et al. 1996; Hunskaar et al. 2002). Most of the data regarding risk fac-

Table 1.2. Proposed risk factors for urinary incontinence

Established factors	Suggested factors
Age (Fig. 1)	Menopause
Pregnancy	Hysterectomy
Childbirth (Fig. 2)	Caffeine intake
Obesity	Cognitive impairment
Lower urinary tract symptoms	Family history and genetics
Functional impairment	Exercise
	Smoking
	Respiratory problems
	Constipation

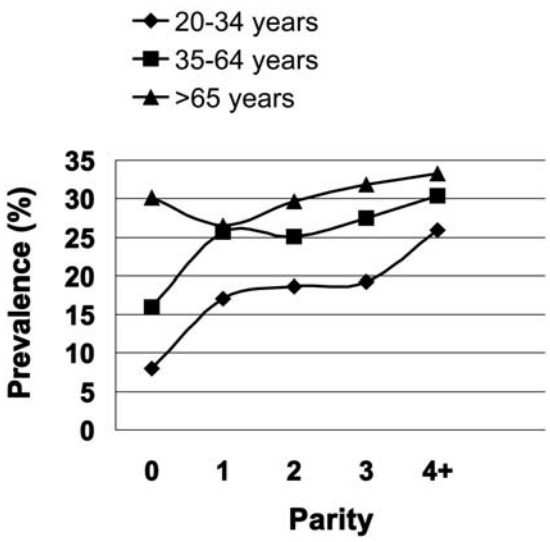

Fig. 1.2.
Prevalence of urinary incontinence by age groups and parity. Data from Rortveit et al. (2001)

tors for the development of UI have been derived from cross-sectional studies of volunteer and clinical subjects. Risk factors such as smoking (Hannestad et al. 2003), menopause (Brown et al. 1999), restricted mobility, chronic cough, chronic straining for constipation, and urogenital surgery (Thom and Brown 1998) have not been as rigorously studied as age (Hannestad et al. 2000; Hunskaar et al. 2004), parity (Fig. 1.2) (Rortveit et al. 2001, 2003), and obesity (Mommsen and Foldspang 1994; Hannestad et al. 2003). This provides us with information of limited generalizability and restricts the level of inference regarding causality.

1.4 Epidemiology of Urinary Incontinence in Men

The epidemiology of UI in men has not been investigated to the same extent as for females. In almost all studies, the prevalence rates of UI continue to be reported to be less in men than in women by a 1:2 ratio. The type and age distribution are much different between the sexes, and risk factors, although less investigated in men, seem to be different. It is also important not to consider UI as an isolated problem in men, but rather as a component of a multifactorial problem, including postprostatectomy incontinence. Often other urogenital symptoms such as weak stream, hesitancy, dribbling or impotence exist.

1.4.1 Prevalence

Some of the major reviews also discuss the prevalence of UI in men (Fultz and Herzog 1996; Hunskaar et al. 2002), ranging from 3% to about 10%. There are no studies reporting prevalence for men according to the ICS definition. But for any definition, there is a steady increase in prevalence with increasing age.

1.4.2 Type and Severity

Due to differences in the pathological anatomy and pathophysiology of UI in men, there is a different distribution in incontinence subtypes. Recent studies confirm the predominance of urge incontinence (40%–80%), followed by mixed forms of UI (10%–30%), and stress incontinence (<10%). The increasing prevalence of UI as age increases observed in men is largely due to the contribution of the urge incontinence rather than stress incontinence. One study demonstrated an increasing rate of urge UI from 0.7% in respondents between age 50 and 59 years, 2.7% between 60 and 69 and 3.4% for 70 years and older. Stress UI was steady at 0.5%, 0.5% and 0.1% for the above groups, respectively (Ueda et al. 2000). One survey found an overall prevalence of overactive bladder with urge incontinence of 2.6% in men 18 years and older, increasing with age from less than 1% in the age group 18–44 to 9% in age group 65+.

Most studies have a large fraction of other and unclassified types. One recent study found that constant dribbling was reported by 7.4% of their respondents. Terminal dribbling or postvoid dribbling is another type of leakage in men that is difficult to assign to the conventional subtypes of UI (Hunskaar et al. 2002).

When it comes to severity, the sex differences do not seem to be different from those for any incontinence. Estimates for severe UI in older women tend to be more than twice as high as for older men.

1.4.3 Potential Risk Factors

There is relatively little research concerning conditions and factors that may be associated with UI in men, and clear risk factors are scientifically documented less often. However, a few available studies have identified the following potential risk factors: age, lower urinary tract symptoms (LUTS), functional and cognitive impairment, neurological disorders, prostatectomy, and some other factors.

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Chapter 2

Epidemiology of Faecal Incontinence: A Review of Population-Based Studies

2

Catherine W. McGrother

Contents

2.1 Introduction

Two recent reviews provide perspective on the prevalence of faecal incontinence. Matibag et al. (2003) suggest a range of 1%–11% in population-based studies and 4%–50% in other, mainly clinic-based studies. Harrari (2002) suggests a range of 2%–18% in the community as distinct from 13%–54% in long-term care. The issues raised by these and other reviews (Tariq et al. 2003) include a lack of definition of concepts and indicators, inconsistent age and gender relationships, lack of information on social groups and differences in health-related risk factors identified. The aim of this paper is to review all the evidence from population-based studies and thereby clarify the epidemiology of faecal incontinence.

The search strategy included electronic search of Medline and Embase for English language papers concerning 'faecal incontinence'. Separate searches were carried out for 'prevalence' (1984–2003) and 'risk factors', 'correlates' or 'predictors' (1996–2003). Exclusion criteria for prevalence studies were: non-population-based; response rate of less than 60%; data collection from third parties; and lack of definition of faecal incontinence as a whole and as distinct from anal incontinence. Studies concerning risk factors were excluded if they concerned selected groups (e.g. clinical series and long-term care), local conditions affecting the pelvic floor (e.g. obstetric factors and cancer), or children. All eligible studies were methodologically evaluated for potential biases. Information on prevalence and risk correspond to levels of evidence II-3 and II-2, respectively (Canadian Task Force on Preventive Care).

Table 2.1. Threshold ratings for terms used to describe the severity of faecal incontinence

Minor	Moderate	Major
1. Any, ever, yearly Leakage Staining Loss Accident Release Wet Liquid	1. Monthly Leakage staining, etc.	1. Weekly or more Leakage
2. Occasional Incontinence Solid Problem Control Difficulty Trouble Loss	2. Any, ever, yearly Soiling Solid Problem Control Difficulty Trouble Loss	2. Monthly or more Soiling
3. Regular Incontinence	3. Frequent Incontinence	

For the purposes of this review, faecal incontinence (FI) was conceptualised as involuntary leakage of liquid or solid from the bowel, and severity as frequency volume. Reported definitions were rated into thresholds of minor, moderate or major incontinence based on the implicit and explicit severity of the wording (Table 2.1). For example, 'any', 'yearly' and 'ever' were rated as similar and less severe than 'monthly', 'weekly' or 'daily'. Descriptors such as 'leakage' and 'staining' were rated as similar and less severe than 'difficulty in control' and 'soiling'. This approach was based on experience with piloting and interviewing in a variety of population groups using such terms (McGrother et al. 1996, 2004; Peet et al. 1995, 1996).

2.2 Prevalence

A total of 15 eligible population-based studies were identified between 1984 and 2003, and these are profiled for potential methodological sources of variation in Table 2.2. There was little suggestion of association with response rate or postal/interview type of approach. There was some suggestion that studies based on total populations (i.e. including elderly people in long-term care) provided slightly higher estimates compared to community-based studies. Similar estimates excluded from this analysis also fell within the range (Nuotio et al. 2003; Nelson et al. 1995; Drossman et al. 1993) or could not be equated because traits of solid or liquid were reported rather than faecal incontinence as a whole (Eva et al. 2003).

These 15 studies provided 21 prevalence estimates for individual thresholds (Table 2.3). The overall range of prevalence was 0.7%–13.1% for adults of various ages. Full ranges for specific thresholds were: minor, 6.2%–13.1%; moderate, 2.8%–10%; and major, 0.7%–3.8%. Overall, there was good correlation between threshold rating and prevalence. There was evidence of correlation with age within the major threshold, but no suggestion of any correlation with either place or time of reporting studies.

Age Group. Among those studies that considered age, all described some degree of increase in prevalence with age. All but one study (Roberts et al. 1999) showed a continuing increase with advancing age. The increase was present to a slightly greater extent for women compared to men (Figs. 2.1 and 2.2). Some apparent decline in prevalence in extreme old age was reported (Talley et al. 1992), but the estimate was based on very small numbers.

Gender. Among studies that considered gender, the overall range of female : male ratios was 0.36–4.0. In the majority (85%) of studies, the range was considerably narrower, 0.73–1.43, and consistent with no difference between the two. Other than sampling error, there was no clear explanation for the variation, although females possibly predominated at minor levels and males at major levels of FI: Comparing F : M ratios age-specifically, males consistently predominated at younger ages but there was some variability in the degree of predominance of females in old age (Fig. 2.3). Taking into account issues of sample size and type, it seems likely that the prevalence in elderly women exceeds that in men slightly in the total population, i.e. including long-term care.

There were substantial increases in prevalence with age for daily, weekly and monthly leakage but little increase for yearly leakage in a recent large-scale community study, suggesting monthly leakage may provide a threshold for abnormality or impairment (Fig. 2.4).

Table 2.2. Methodological features of population-based prevalence studies of faecal incontinence, 1984 and 2003

Author	Threshold[a]	Population	*N* subjects	Approach	Response %	Age group	Prevalence
Roberts et al. (1999)	Minor	Mayo Clinic	1,540	Postal	66	50+	13.1
Kalantar et al. (2002)	Minor	Total	651	Postal	66	18+	11.2
Crome et al. (2001)	Minor	Total	1,608	Interview	79–94	70+	10.0
Walter et al. (2002)	Minor-mod	Total	1,610	Postal	80	31–76	10.0
Clarke et al. (1984)	Minor-mod	Community	1,201	Interview	95	75+	9.4
Wetle et al. (1995)	Moderate	Community	3,809	Interview	85	65+	8.1
Lam et al. (1999)	Minor-mod	Population	618	Postal	71	20+	7.8
Nakanishi et al. (1997)	Minor	Total	1,405	Interview	95	65+	7.5
Kok et al. (2002)	Minor	Community	719	Postal	69	60+	7.2 F
Perry et al. (2002)	Minor	Community	1,0116	Postal	70	40+	6.2
Talley et al. (1992)	Major	Mayo Clinic	328	Postal	77	65+	3.7
Campbell et al. (1985)	Moderate	Community	555	Interview	95	60+	3.1
Edwards and Jones (2001)	Moderate	Community	2,818	Interview	94	65+	3.0
Chen et al. (2003)	Moderate	Population	1,253	Interview	79	20+	2.8 F
Thomas et al. (1984)	Mod-major	Community	14,844	Postal	89	15+	1.4

[a] Minimum threshold.

■ **Residence.** Several studies of isolated care facilities suggest relatively high prevalence in long-term care (Harrari 2002). However, only one study compared type of residence within a total population (Crome et al. 2001). For people aged 70 or more, this study in the UK shows occasional (minor) incontinence affects 6.5% of people who owned their own home, 8.5% of people living in public rented homes, 9.6% of people living in sheltered housing, 19.2% of people living with relatives, and 45.2% of people living in residential or nursing homes. The corresponding rates for frequent (major) incontinence were 2.5%, 2.5%, 3.8%, 7.7% and 21.0%, respectively.

These results are consistent with other recent estimates identified for long-term care facilities in the UK (13%–52%) (Peet et al. 1995; Brocklehurst et al. 1999), the US and Canada (17%–46%) (Harrari et al. 1994; Johanson et al. 1997) and France 54% (Chassagne et al. 1999). Dependency levels are highly correlated with prevalence (Peet

Table 2.3. Prevalence variations in time, place and person for different thresholds of faecal incontinence

Author	Year	Place	Threshold	Age group	Prevalence %			F : M ratio
					All	Female	Male	
Roberts et al.	1999	USA	Minor	50+	13.1	15.2	11.1	1.37
Kalantar et al.	2002	Sydney, Australia	Minor	18+	11.2	11.6	10.8	1.07
Crome et al.	2001	UK	Minor	70+	10.0	11.3	7.9	1.43
Clarke et al.	1984	UK	Minor to moderate	75+	9.4	–	–	No difference
Lam et al.	1999	Sydney, Australia	Minor to moderate	20+	7.8	4.5	12.4	0.36
Nakanishi et al.	1997	Japan	Minor	65+	7.5	6.6	8.7	0.75
Kok et al.	1992	Netherlands	Minor	60+	7.2 F	7.2	–	Not available
Perry et al.	2002	UK	Minor	40+	6.2	5.7	6.2	0.92
Walter et al.	2002	Sweden	Moderate	31–76	10.0	10.9	9.7	1.12
Wetle et al.	1995	USA	Moderate	65+	8.1	7.8	8.5	0.91
Perry et al.	2002	UK	Moderate	40+	3.3	3.1	3.6	0.86
Campbell et al.	1985	New Zealand	Moderate	65+	3.1	–	–	<1
Edwards and Jones	2001	UK	Moderate	65+	3.0	4	1	4
Chen et al.	2003	Taiwan	Moderate	20+	2.8 F	2.8	–	Not available
Crome et al.	2001	UK	Major	70+	3.8	3.7	4.0	0.93
Talley et al.	1992	USA	Major	65+	3.7	3.1	4.5	0.69
Nakanishi et al.	1997	Japan	Major	65+	2.0	2.2	1.8	1.22
Perry et al.	2002	UK	Major	40+	1.9	1.7	2.2	0.77
Lam et al.	1999	Sydney, Australia	Major	20+	1.8	1.1	2.7	0.41
Thomas et al.	1984	UK	Major to moderate	15+	1.4	1.39	1.46	0.95
Walter et al.	2002	Sweden	Major	31–76	0.7	1.4	0.4	3.5

et al. 1995), suggesting prevalence may vary between different facilities because of differences in selection criteria.

■ **Social Group.** Few population-based studies have considered socio-economic factors. Crome et al. (2001) showed a slightly higher prevalence for occasional (minor) incontinence in public rented (8.5%) compared to own homes (6.5%) but the levels were similar for frequent (major) incontinence. Secondary analysis of the MRC Incontinence Study (UK) suggests that the prevalence of monthly (moderate) leakage increases with worsening socio-economic status (Table 2.4). There were no statistically significant differences between white and South Asian groups either before or after adjusting for other social factors.

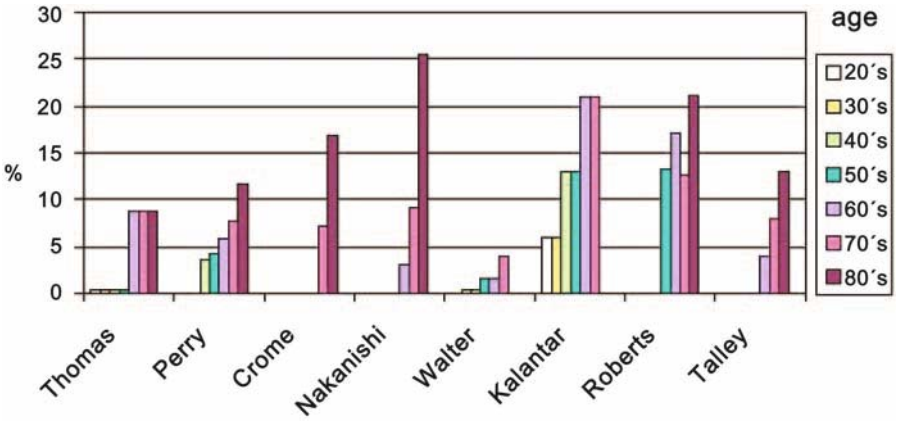

Fig. 2.1. Prevalence of faecal incontinence in women – population studies

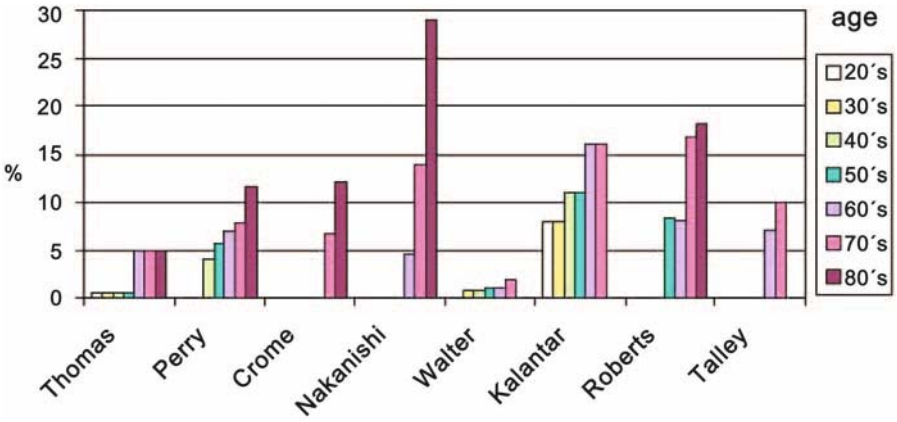

Fig. 2.2. Prevalence of faecal incontinence in men – population studies

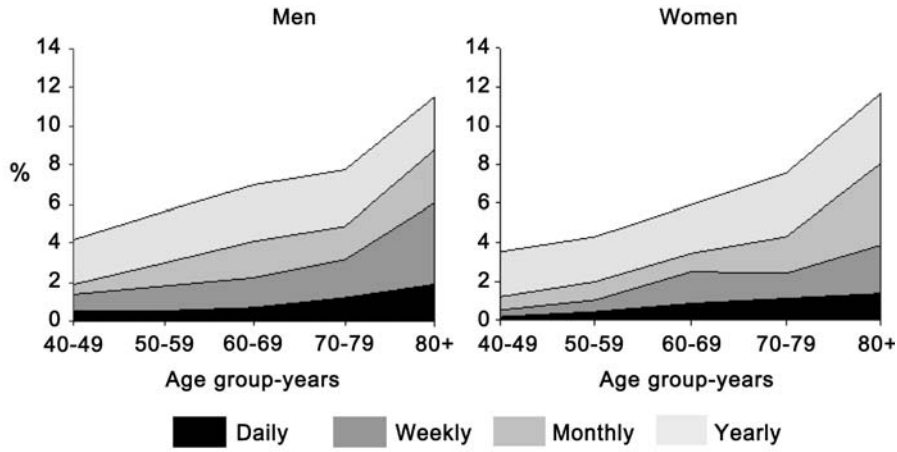

Fig. 2.3. Prevalence of faecal incontinence by frequency of leakage

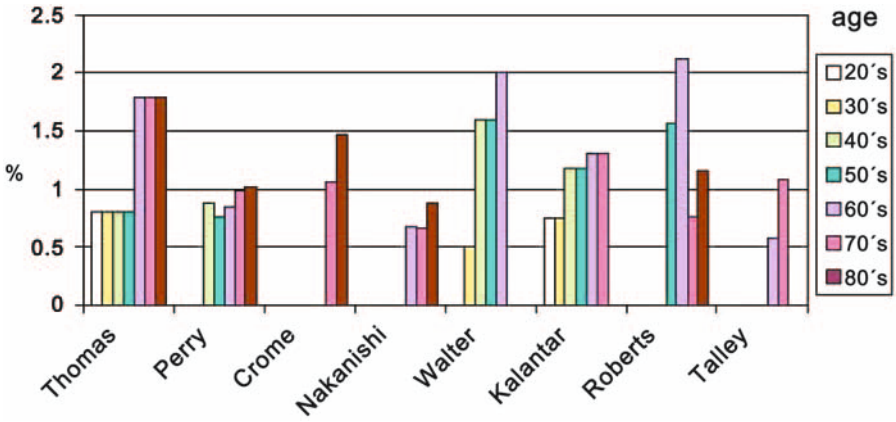

Fig. 2.4. Female : male prevalence ratios by age group – population studies

Table 2.4. Social groups associated with faecal incontinence in Leicestershire, UK

	Social group	Univariate	Multivariate
Socio-economic group	Homeowner	1.0	1.0
	Private rental	1.55*	1.51**
	Public rental	1.75**	1.44**
Ethnic group	White	1	–
	South Asian	0.75	
Gender	Female	1.0	1.0
	Male	1.23**	1.32**
Age	40–49	1.0	1.0
	50–59	1.31*	1.28*
	60–69	2.04**	1.98**
	70–79	2.64**	2.49**
	80*	3.99**	3.61**

* $p<0.01$, ** $p<0.001$.

Disability. Information concerning people with learning disability (LD) is available from the Leicestershire population-based Learning Disability Register (McGrother et al. 1996). Comparison of the prevalence of faecal incontinence with the general population in Leicestershire (Perry et al. 2002) shows a greater than sevenfold higher rate for those aged over 40 years (Table 2.5). A threefold increase is present for the mobile sub-group with relatively normal physical functioning, compatible with independent living. Prevalence among non-mobile people with LD is similar to that in elderly people in long-term care facilities in Leicestershire (Arthur et al. 2002).

Table 2.5. Prevalence of faecal incontinence[a] in people with learning disability and the general population in Leicestershire UK

Age	Learning Disability			General population	
	Mobile[b]	Non-mobile	All	Community	Long-term care
40–49	3.8	30.3	9.1	0.7	–
50–59	4.4	21.8	8.9	1.1	–
60–69	7.4	24.5	12.0	1.5	37.2[c]
70+	–	18.5	7.7	2.4	28.7
All	4.4	25.4	9.4	1.4	29.1

[a] Weekly leakage.
[b] Walks unaided.
[c] 65–69 years age group.

2.3 Associated Factors

Urinary Incontinence. Faecal incontinence is consistently associated with urinary incontinence in adults (Table 2.6). In the general population in women, across a variety of age groups over 20, the strength of association ranged from an odds ratio of 1.5 to 17 (adjusted for age). The association was convincing for urge incontinence but marginal for stress incontinence. In men, similar overall estimates ranged from 3.0 to 5.1. Non-age adjusted estimates showed similar ranges for women (2.1–11.5) and men (2.1–3.1). Residents in long-term care showed relatively strong associations between 10.4 and 20.5 for multivariate analyses and 25 for non-age adjusted odds ratios (Aggazzotti et al. 2000; Nelson et al. 1998; Ouslander et al. 1993).

Health Factors. There was consistent evidence from population-based studies with multivariate analyses to support associations between FI and poor health (Kalantar et al. 2002; Crome et al. 2001; Nakanishi et al. 1997; Nelson et al. 1995), poor physical func-

Table 2.6. Association between urinary and faecal incontinence in population studies

Author	Age	OR men	OR women	Type	Adjustment
Koskimaki et al. (2001)	50, 60, 70	–	17 (7.5, 40)	Urge	Age
Nuotio et al. (2003)	'older'	NS	7.84	Urge	Age
McGrother et al. (2005)	40+	5.1 (3.9–6.5)	5.3 (3.9–7.2) 1.8 (1.2–2.7)	OAB SUI	Age
Roberts et al. (1999)	50+	3 (1.9–4.8)	1.8 (1.2–2.7)	All	Age
Chen et al. (2003)	20+	–	3.2 (1.6) 1.5 (0.7–3.0)	Urge SUI	Multivariate
Edwards and Jones (2001)	65+	–	11.5 (p<0.0001)	All	Unadjusted
Kok et al. (1992)	60–84	–	5.8 (1.6–21.0)	All	Unadjusted
Diokno et al. (1990)	60+	3.2 (p=0.001)	2.5 (p=0.0005)	All	Unadjusted
Wetle et al. (1995)	65+	2.1–7.9[a]	2.1–7.9 [a]	All	Unadjusted

[a] Varying with age, sex and severity.

tioning (Crome et al. 2001; Talley et al. 1992; Edwards and Jones 2001), depression (Edwards and Jones 2001; Crome et al. 2001; Black et al. 1998), anxiety (Edwards and Jones 2001; Crome et al. 2001) and diarrhoea or loose stool (Talley et al. 1992; Kalantar et al. 2002). Other health factors identified in lone studies were constipation (Lam et al. 1999), incomplete defaecation and urgency (Kalantar et al. 2002), bodily pain (Crome et al. 2001), and stroke (Nakanishi et al. 1997). Diabetes and dementia were also associated with isolated and double FI, respectively (Nakanishi et al. 1997). Although beyond the scope of the systematic review, consistent evidence was also observed from prospective studies that instrumental vaginal delivery and sphincter damage were associated with FI (Macarthur et al. 1997; Faltin et al. 2001; Eason et al. 2002; de Leeuw et al. 2001). Among residents in long-term care, there was consistent evidence for association with poor mobility and dementia, and some indication of links with neurological disease and diarrhoea (Chassagne et al. 1999; Johanson et al. 1997).

2.4 Conclusions

The results of this review are consistent with earlier reviews concerning the range of prevalence for faecal incontinence in the general population. There was a reasonable degree of consistency between individual studies on the prevalence of age-related moderate or more faecal incontinence affecting between 2.8% and 10.0% of adults, similarly in men and women, increasing with age. Males predominated at a younger age, whereas females had higher prevalence at old age, but the differences were slight. There was little evidence of differences in prevalence over time or between countries. Prevalence in long-term care was much higher than in the community, especially for major incontinence, and people with learning disability also experienced high rates. There was evidence of a link with adverse socio-economic status, but no difference was observed between whites and South Asians. There was a strong link between urinary and faecal incontinence. Faecal incontinence was also consistently related to poor perceived health, including depression, anxiety, diarrhoea and physical functioning in the general population. There was also consistent evidence for an association with instrumental vaginal delivery.

Methodologically, it appeared that prevalence estimates were primarily dependent on the frequency and implicit severity of the wording of questions used plus the inclusion of people in long-term care. On the basis of this review, faecal incontinence could be defined conceptually as 'any involuntary leakage of faeces (liquid or solid) from the bowel. However, the word 'involuntary' implies a degree of severity and 'faeces' is not a common term. Also, different thresholds are needed for particular purposes (e.g. for health promotion or care). Therefore practical translation into a question would be 'do you ever leak (liquid or solid) from your bowel when you don't mean to (day or night), with responses 'continuously, daily, weekly, monthly, yearly or never'.

Faecal incontinence may be an effective marker for impairment but the coherent whole that it represents is unclear and likely to involve other lower-bowel symptoms such as urgency and constipation, representing disorder of the lower-bowel system. Within such an umbrella, research measuring the public health burden and identifying causes and effects is likely to focus on the whole lower-bowel system including the following elements:

(a) Burden, the presence and severity of faecal incontinence (and related lower-bowel symptoms); impact (as a whole) on QOL; clinically significant disorder (as a whole); and felt need (i.e. use or want care)

(b) Causes and effects, the type and severity of faecal incontinence and related lower bowel symptom syndrome; clinical management group and underlying pathophysiological process.

Realistic conceptual and terminological standards for each element are needed as a basis for investigation, together with validated assessment and procedural standards for research including reporting for meta-analysis purposes. Effective multidisciplinary research depends on knowledge of the relationship between these elements rather than the primacy of one over another.

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Chapter 3

Economic Costs of Urinary Incontinence in Germany

3

Günter Neubauer, Sandra Stiefelmeyer

Contents

3.1 Prevalence and Social Importance

Urinary and fecal incontinence is a frequent public health problem with negative social consequences. Failure to control the elimination of urine or stool causes psychological problems, complicates medical illness, makes management difficult and produces major economic consequences. Susceptibility is the result of anatomical, social, economic and cultural factors. Also, urinary incontinence is a major clinical problem that has a profound effect on quality of life and activities of daily living (Hollywood and O'Dowd 1998) and isolates the affected person from friends and family. Women with urinary incontinence report fear, frustration, shame and humiliation, and worry about the odor of urine from pads and wet underclothing. Urinary incontinence is physically debilitating and socially incapacitating, and is associated with loss of self-confidence, feelings of helplessness, depression and anxiety.

The probability of incontinence increases with age. The nature of incontinence changes from stress incontinence to urge incontinence with age as a result of an increasing prevalence of multiple disorders and organ dysfunction. This change has a significant implication for clinical management. While stress incontinence is typically managed with strengthening exercises for pelvic floor muscles, with or without neuromuscular electrostimulation and surgery, management of urge incontinence also include a bladder training program, drugs and transcutaneous electrostimulation aimed at the spinal micturition reflex center.

Studies regarding the prevalence of urinary incontinence suggest that this problem is widespread among women and men of all ages. The prevalence of urinary incontinence ranges from 10% to 60%, depending on the country and population studied. Women are much more susceptible to urinary incontinence than men. Anatomical and physiological differences, such as reproductive and hormonal changes associated with pregnancy and menopause, explain the differences prevailing between male and female. It is highly probable that socioeconomic and cultural factors play a crucial role in urinary incontinence. However, the extent of the influence of these factors on women's health remains relatively unknown. In contrast, fecal incontinence is less investigated and only few data are reported, mainly from clinical experience with patients with this disorder. These studies are methodologically rather weak in information. They generally focus on a narrow part of the problem that cannot be extrapolated to the entire population with incontinence.

The costs of urinary and fecal incontinence is not adequately described by the dollars spent in the healthcare system. Nonetheless, in the current climate of economic healthcare rationalization, it remains useful to calculate the measurable costs of a disorder, as least to justify expenditure on this rather than upon some other medical problem. The costs of an illness comprises three components: direct costs, which include personal costs (pads, replacement of urine-soaked clothes) and treatment costs (met by patients and by several government subsidies); indirect costs, which include lost productivity both in the home and in outside employment; and intangible costs, which are most difficult to measure financially, but include psychological distress and impaired physical or mental health.

3.2 From a Medical to an Economic Approach

The medical impact of urinary and fecal incontinence is mainly based on prevalence and necessary diagnostics and treatment (Fig. 3.1). In terms of economic impact, the number of treatments and costs per patient are derived. Standardized procedures and mean treatment costs as defined in DRGs (diagnosis-related groups) can be utilized to determine the direct costs. Additionally, indirect costs such as lost productivity have to be considered to derive the economic impact. Of course the intangible costs cannot be calculated but are reflected in, for example, quality of life (Neubauer 1989).

3.3 Direct Costs

Urinary incontinence has a considerable financial impact on both individuals and the healthcare system. One United States study has reported costs of US $26.3 billion in 1995 for individuals aged 65 years and over, or US $3,565 per incontinent individual (Wagner and Hu 1998).

In 1990, Hu estimated the costs of incontinence in the USA to 10 US $billion (US $41 per inhabitant), not including indirect costs (Hu 1990). According to Milsom and coworkers, the major contributors to the economical impact are care for incontinent persons in nursing homes and the use of incontinence aids (Milsom et al. 1993). Milsom et al. (1993) have estimated the costs for managing urinary incontinence in Sweden to almost 2 billion Swedish krone in 1990, 2% of the total health expenses (US $38 per inhabitant). Several studies have demonstrated that urinary incontinence is an important factor predicting institutionalization of geriatric or demented patients, and according to Ouslander and Kane urinary incontinence accounts for 3%–8% of the costs of nursing home care (Ouslander and Kane 1984). Another study on costs in nursing homes calculated direct costs of incontinence of US $17.21 per resident per day (US $6,282 per resident per year) (Frenchmann). In Norway the National Insurance spends

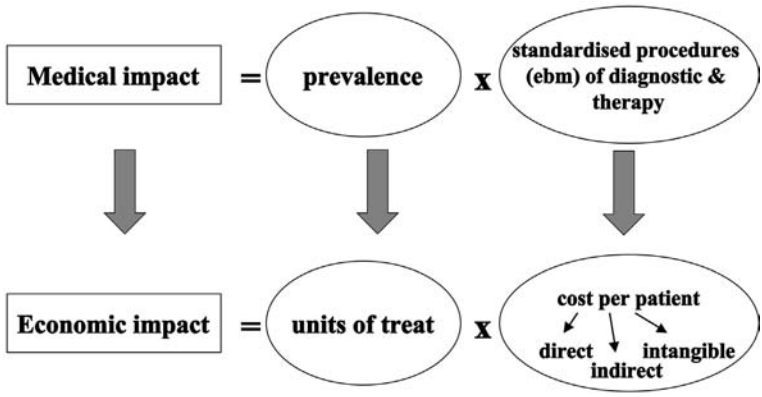

Fig. 3.1. From a medical to an economic approach**.** Medical impact of incontinence is mainly based on prevalence and necessary diagnostics and treatment. Standardized procedures and mean treatment cost as defined in DRGs (diagnosis related groups) help in deriving the direct costs. Additionally, the indirect costs such as lost productivity and intangible costs must be considered to derive the economic impact

approximately over 200 million Norwegian krone on incontinence pads (US $7 per inhabitant) (Sandvik et al. 1993). However, the costs of urinary incontinence go beyond the money spent.

A recent study (Dowell et al. 1999) developed the Dowell-Bryant Incontinence Cost Index (DBICI) to measure the total direct costs of urinary incontinence. This study applied the DBICI to 100 consecutive community-dwelling women attending continence clinics for treatment of their urinary incontinence. Personal cost estimates included weekly expenditure on pads, incontinence-related laundry and miscellaneous costs (clothing, dry cleaning, replacement of urine-soaked carpets), while costs for treatment estimates included visits to healthcare professionals, surgical procedures, medications and costs associated with travel and time off work in the previous year (Dowell et al. 1999).

Similar to this study an Australian study estimated the total annual costs of this urinary incontinence at about Australian $710.44 million, or Australian $387 per incontinent woman, comprising Australian $338.47 million in treatment costs and Australian $371.97 million in personal costs. An estimated 60% of women with incontinence in 1998 were aged 40 years or over. Assuming the prevalence of incontinence remains constant and allowing for inflation, they project that the total annual costs in 20 years' time will be Australian $1,267.85 million, 93% of which will constitute costs associated with women aged over 40 years (Doran et al. 2000).

In Fig. 3.2 the results of all given studies are summarized showing cost differences per country ranging from US $7–41 per incontinent person and day.

3.4 Indirect Costs

Unfortunately the indirect costs of incontinence (urinary and fecal) have not been evaluated scientifically but are believed to be larger than direct costs. They include the payment of disability claims for patients with incontinence who are no longer able to work and lost wages related to quitting work or retiring prematurely. Also included are family members or friends who help the patient with incontinence. The total amount of these costs may exceed several hundreds of millions of US dollars per year.

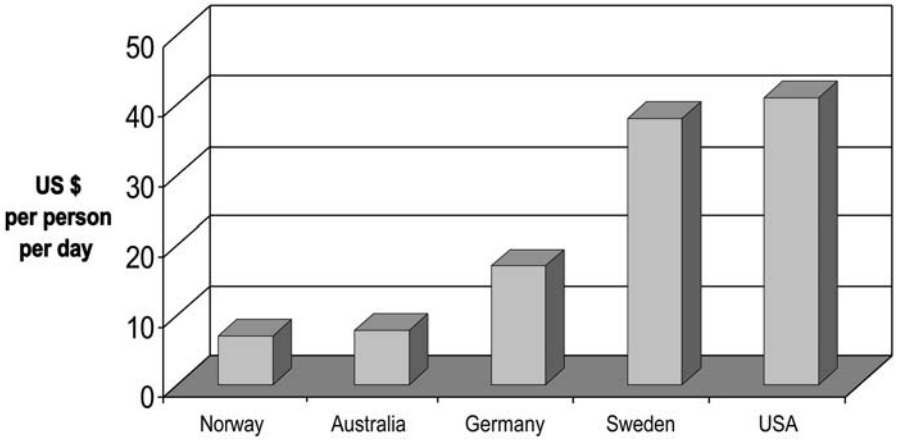

Fig. 3.2. Direct incontinence costs for different countries. The costs per incontinent person per day vary from US $7 to 41 per day depending on the country

3.5 Economic Impact in Germany

Healthcare costs for incontinence in individuals are difficult to estimate because most affected individuals do not seek help in healthcare. Germany estimated in the year 2002 that there were 3.5 million people with a urinary incontinence disorder that required help or treatment. Over 1 million women between 12 and 65 years and 0.2 million men suffer from incontinence. In the age group above 65 years, there are 1.5 million women and 0.4 million men suffering from incontinence.

With an increasing proportion of older people in a population, the frequency of incontinence is growing. In people over 60 years of age, incontinence is even more frequent than cardiovascular disease and high blood pressure. More than 30% in a population over 40 years have problems with incontinence. The prevalence is remarkably increasing in older persons, especially in women.

To investigate the costs in the German Healthcare System concerning incontinence, we used data from the German nursing status, where four nursing care categories are distinguished, ranging from 0 to 3 depending on the amount of help needed. Each nursing care category is defined by the necessary time of care per patient and the severity of disability. Reimbursement varies with care status but does not cover all costs.

In German nursing homes, the supply per incontinent person is 7.4 min a week for nursing status 0 and goes up to 42.6 min per week for nursing status 4. Based on these nursing data, we calculated the nursing time per day, which range from 1.06 min per day and incontinent person for nursing status 0 to 6.09 min for nursing status 4. The costs for personal care per day range from 2.24 euros (nursing status 0) to 15.69 euros (nursing status 4) per day. The costs for material such as pads average 2.56 euros per day. According to these data, a total amount of 201.57 million euros per year is calculated for caring for the incontinent patient (Table 3.1).

For the estimated costs of incontinence for the entire health system (public and private health system) in Germany we calculated 3,970 million euros based on the year 2002. Total costs in different countries differ from US $1 million to US $10 billion in the year 2002. Considering the demographic shift up to 2050, the German health care

Table 3.1. German prevalence and costs of incontinent persons in long-term public care insurance

Different costs and times of nursing for incontinent persons					
Nursing status	**0**	**1**	**2**	**3**	**4**
h =	45,196	4,713	14,387	10,683	549
Time of nursing (min)	1.06	1.69	3.07	4.21	6.09
∅ Time of intervention (min)	3.2	2.8	3.5	4.5	3.9
Total time of nursing per day and case (min)	3.39	4.73	10.75	18.95	23.75
Costs for personal per day/case (euros)	2.24	3.12	7.09	12.51	15.68
Cost of material per day/case (euros)	2.56	2.56	2.56	2.56	2.56
Total expenditure per day/case (euros)	4.8	5.68	9.56	15.07	18.24
Total expenditure (million euros) within 1 year	79.18	9.77	50.2	58.76	3.66

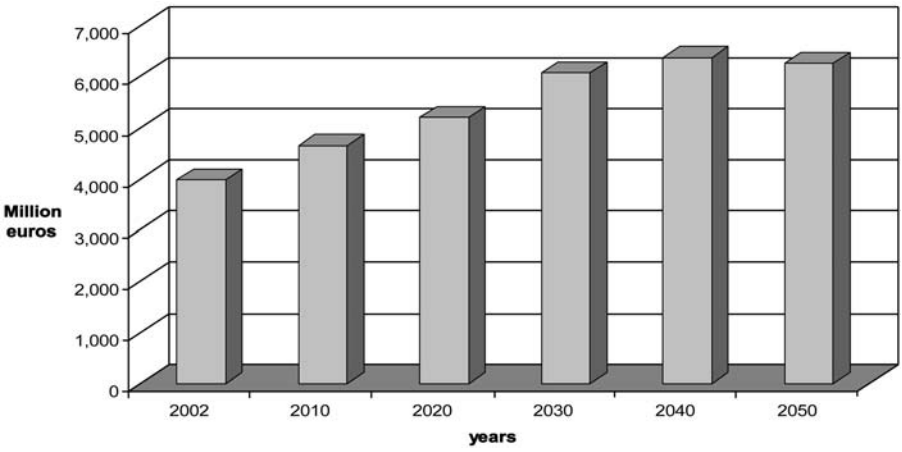

Fig. 3.3. Development of incontinence costs in German health care system in the future. Increasing costs of incontinence due to population until 2050. In the total cost the cost of personnel is included: per minute (gross expenditure of the employer): 0.66 euros (median over all qualifications)

system will have to invest at least 6,266 million euros just for incontinence even with constant costs assumed (Fig. 3.3). This means a doubling of the costs in 50 years only based on at the demographic shift.

3.6 From Treating to Healing

The total costs of nearly 7 billion euros for the year 2050 is a conservative estimate of the costs of resources used in treatment and care with urinary incontinence. If we were to consider the reduced quality of life, lost earnings and the burden imposed on family, friends and care-takers, the total costs would be considerably higher, presumably doubling the costs.

From a patient's perspective, there are substantial personal costs involved in managing urinary and fecal incontinence. Research has found that patients are willing to pay considerable amounts to reduce the symptoms of urinary incontinence. From a health system perspective, the high costs of treatment and care of urinary and fecal incontinence clearly demonstrates that this is a serious medical condition that imposes a considerable drain on scarce healthcare resources.

Philip and Miner (2004) conducted an investigation to improve the medical management algorithms of outpatient care designed to decrease urinary and fecal incontinence. They also request maximizing the utilization of available resources to medical facilities such as skilled nursing centers and nursing homes, without forgetting that inpatient management algorithms in short-term and long-term care facilities should be improved to decrease the economic burden of personnel and supplies while improving physical and psychological outlook.

We need more and better information about the economic impact directly on patients and their families and social issues such as lost wages, disability insurance and nursing homes on the consequences of urinary and fecal incontinence so that we do not have to make as many assumptions to estimate economic impact. In particular, we

need to know the effect on quality of life and the potential benefits from reducing the prevalence of urinary and fecal incontinence. Given the demographic shift towards an older population and the escalating costs of healthcare provision and technology, this has become urgent.

To solve the problem of incontinence and its great financial costs, the World Health Organization (WHO) has recently focused on it. At the first international WHO consultation on incontinence 1998, a team of 24 committees considered the best way to eradicate incontinence. The issue of costs, and our poor knowledge of the magnitude of the problem, was a major concern. The WHO concluded that incontinence should be considered a disease rather than a condition, in view of its debilitating effects upon health and wellbeing. This implies greater focus on adequate treatment of this disease. However, further research regarding the epidemiology and treatment of incontinence is needed to reduce the costs and personal impairment of affected patients.

Acknowledgement

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Chapter 4

Perception of Incontinence in and by Society

4

Paul Enck, Sibylle Klosterhalfen

Contents

4.1 Background

The public appearance of the topic incontinence – either urinary or fecal or both – in the media (TV, newspapers, journals) has undoubtedly increased over the last decade, and has led to increased numbers of patients consulting for diagnosis and therapy of incontinence symptoms in specialized medical centers, usually university hospitals.

However, given the epidemiological estimates of the annual incidence and overall prevalence of incontinence in the adult population (Nelson 2004), it is also evident that only a minority of patients seek and receive diagnosis and treatment in institutions of primary or secondary care.

One frequently cited reason for this discrepancy between the needs and the supply for incontinence management in any society is the taboo incontinence carries, similar to other common topics in society that are difficult to communicate, for example, sexuality and sexual preferences.

Taboo topics share several characteristics when it comes to estimating the number of people affected: usually these numbers, for example in epidemiological surveys on prevalence and incidence, are underestimating rather then overestimating the true occurrence. This is because even with full anonymity guaranteed, only a fraction of those affected are willing to acknowledge that they suffer – or enjoy in case of sexuality – from this condition.

Why the lack of continence is a taboo is a secondary question and may relate to the fact that proper control of evacuation functions is regarded as appropriate and normal once is has been achieved during childhood hygiene training; any abnormality in this respect later in life may indicate that loss of control is indicative of loss of other functions as well, and may be associated with the fear of becoming socially dependent.

To answer the question of how incontinence is regarded in and by our society, and whether this perception has changed over the last decades, it needs direct and indirect indicators of attention, and public appearance of the topic in the media may be but one. In the following, we have chosen three such indicators: number of incontinence papers in the scientific literature, the number of treatment options available, and the medical knowledge of the health care system agencies on patients with incontinence. They are based on publicly available knowledge, in contrast to privately owned data such as the sales numbers of incontinence care products.

4.2 Incontinence Citations in PubMed

Over the last 50 years, between 1954 and 2003, a total of more than 22,000 papers have been published and listed in PubMed related to incontinence – both fecal and urinary. This includes all data papers and reviews, but also editorials, letters, and comments. The distribution of these citations over the 50 years clearly follows an logarithmic function (Fig. 4.1a, b), with the majority of papers published in the last 10 years.

While at a first glance this may indicate a dramatic increase in interest in this topic in the scientific community, a second look casts doubts: when the numbers of PubMed citations for another disease, irritable bowel syndrome, were plotted in the same graph, the same steep, logarithmic increase is clear, also seen when disease-unspecific medical research topics (e.g., placebo) were evaluated in PubMed (Klosterhalfen et al. 2004). Consequently, it can be concluded that the scientific increase in incontinence as a research subject is probably the result of an increased number of publication pos-

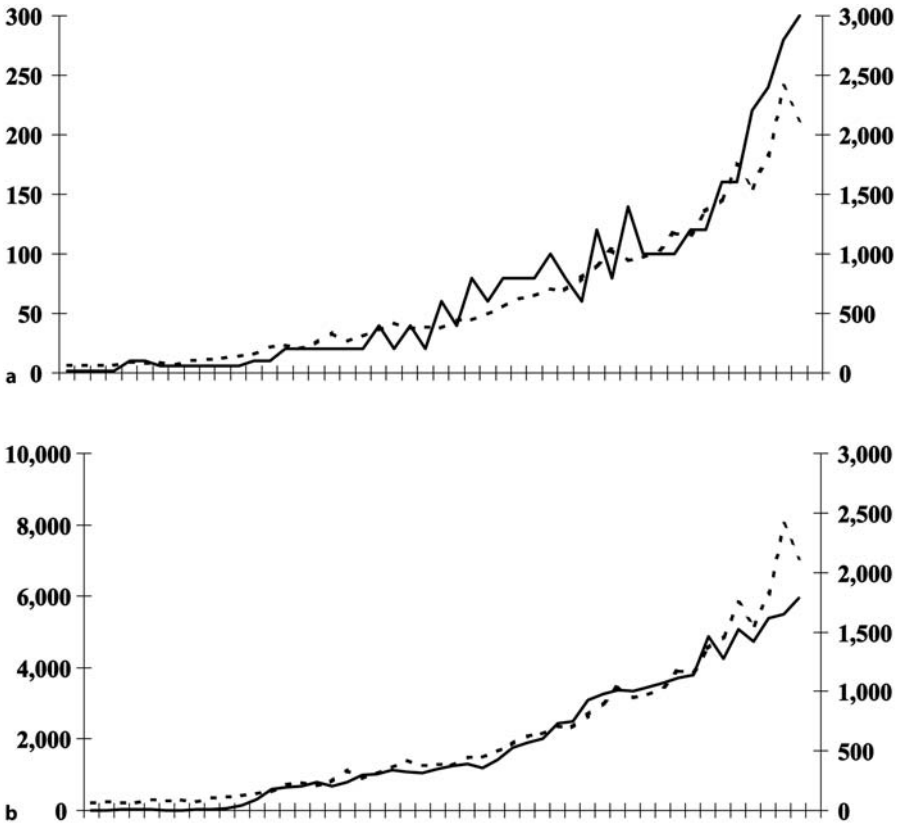

Fig. 4.1. a Number of publications according to PubMed for incontinence (*dotted line, right Y-axis*) and irritable bowel syndrome (*solid line, left Y-axis*) between 1954 and 2003. **b** Number of publications for incontinence (*dotted line, right Y-axis*) and placebo (*solid line, left Y-axis*)

sibilities available. However, it may also indicate an increased awareness on the part of the scientific community for the needs of patients suffering from incontinence, and thus may reflect an altered perception on the part of the society as well.

4.3 Available Therapeutic Tools

Milestones in the development of therapeutic tools for treatment of fecal and urinary incontinence are drugs that became available (e.g., trospium chloride for urinary incontinence, loperamide for fecal incontinence), other conservative treatment options (biofeedback therapy, electrostimulation), or surgical procedures that became routine (e.g., anal repair, gracilis muscle transplant, sacral nerve stimulation). With the exception of surgical procedures that are often not easy to identify for their origin, that are often modified from one surgeons to another, and whose outcome depends very much on the individual skills of an individual surgeon, many of these milestones can be listed according to the year they became available to the general medical public (Fig. 4.2).

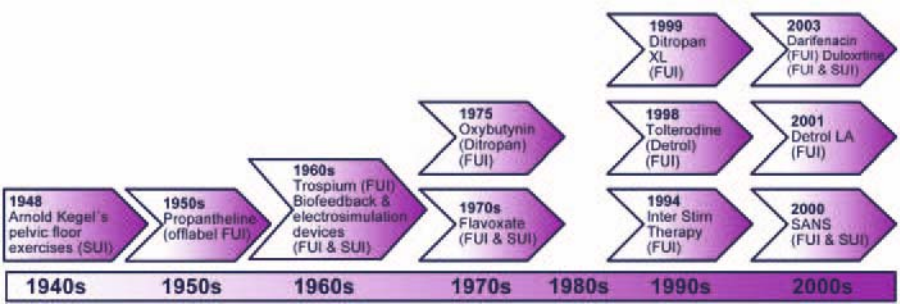

Fig. 4.2. Milestones in urinary incontinence therapy (according to Buddrus 2002)

As can bee seen, these milestones are rather equally distributed over the last 50 years and do *not* indicate – at least not by numbers – an increased attention given to incontinence therapy in this period.

The picture changes dramatically, however, when drugs in development, which are not yet available on the market but will be in the near future, are taken into account. More then 35 drugs are in the pipeline within different drug companies around the world, at different stages of drug development (Table 4.1), and even if only half of them make it into the clinics, it will improve the situation of patients seeking treatment for urinary incontinence.

This increase in the number of potential drugs for treatment of urinary incontinence is probably highly indicative of the (economic) estimate of the drug industry of potential patients asking for treatment in the future.

4.4 Incontinence Knowledge in Traditional Health Care

In a landmark paper by Leigh and Turnberg (1982), the authors noted that less then 50% of their patients seen for diarrhea suffered from fecal incontinence but did not disclose this condition to their physician at the initial visit, and only on specific questioning. The authors cite "the apparent reluctance of patients to complain of incontinence may be compounded by the reluctance of medical attendants to embarrass patients by asking about it. . ." (Leigh and Turnberg 1982, p 1351) – both may be hindered by the taboo.

Some 10 years later, we wondered whether this had changed at all over the years, and how deep-rooted the reluctance of doctors is. We raised three questions:

- Do family physicians (*Hausärzte*) know when their patients have incontinence?
- How accurate are medical charts in highly specialized outpatient clinics with regards to incontinence?
- Do the files of health insurance organizations/HMOs (*Krankenkassen*) contain adequate incontinence information?

Table 4.1. Drugs in development for treatment of urinary incontinence

Drug type	Product (generic name)	Originator	Status
Anticholinergics	Urespan (temiverine hydrochloride)	Nippon Shinyaku	Preregistration (Japan)
	Vesicare (solifenacin)	Yamanouchi	Preregistration
	Enablex (darifenacin)	Novartis	Preregistration
	S-Oxybutynin	Sepracor	Phase III
	Darifenacin	Phizer (Novartis)	Phase III
	Fesotoderine	Schwarz Pharma	Phase III
	Intravesical Trospium	Pfleger	Phase II
	Oxybutynin ring	Barr Laboratories	Phase II
	KRP-197/ONO-8025	Kyorin	Phase II
	Oxybutynin	Labopharm	Phase I
	RO-32–02904	Roche	Preclinical
	Trospium ext. release	Shire	Preclinical
	Urespan (temiverine HCl)	Nippon Shinyaku	Preregistration (Japan)
Antidepressants	Cymbalta (duloxetin)	Eli Lilly	Preregistration, phase II
	5-HT 1a antagonist	Recordati	Preclinical, phase I
Antiadrenergics	Tamsulosin (α-antag)	Yamanouchi	Phase III
	RO-450 (α-agonist)	Roche	Phase II
Tachykinins	Cizolirtina	Esteve	Phase II
	Saredutant	Sanofi	Phase II
	UK-22671	Pfizer	Phase I
	AZD-5106	AstraZeneca	Preclinical
Potassium channel openers	NS-8	Nippon Shinyaku	Phase II
	ZD-0947	AstraZeneca	Phase II
	ABT-598	Abbott	Phase I
	NS-4591	NeuroSearch	Preclinical
Vasopressin agonists	OPC-518013	Otsuka	Phase II
	FE106 483	Ferring	Phase I
Aromatase inhibitor	Finrozole	Hormos Medical	Phase II
C-fiber inhibitor	KW-7185	Kyowa Hakko	Phase II
COX inhibitor	Nitroflurbiprofen	NicOx	Phase II
Vanilloid receptor agonists	Resiniferatoxin	Afferon	Phase II
(Unknown)	AA-10020	Araqchnova	Phase I
(Unknown)	DRP-001	Sosel	Phase I
(Unknown)	KUC-7483	Kissel	Phase I
Delta opioid agonist	DPI-221	Ardent	Preclinical

According to Barry 2003.

Three studies were performed (Enck et al. 1991a,b):

- We retrospectively evaluated by telephone interview whether and since when the family physicians of 120 consecutive adult patients with fecal incontinence seen at a university hospital incontinence outpatient clinic were aware of the patients' incontinence condition, and when this was first marked in the patient's chart
- We retrospectively evaluated whether the medical charts of patients seen at various specialized university outpatient clinics (IBD, upper and lower GI, diabetes) contained information about incontinence – at the same time, patients were given a questionnaire prospectively asking for the presence and severity of fecal incontinence symptoms.
- We retrospectively evaluated whether the files of patients with proven incontinence at the level of a health insurance organization/HMO (Krankenkasse: AOK) contained correct information on incontinence, by asking family physicians (see above) whether they had reported the patients' incontinence to the HMO. We also analyzed two HMO samples (n=280, n=2,080) from a large HMO (AOK Dortmund) and compared prevalence data with that of population sample.

The results of these surveys can be summarized as follows: the number of undisclosed cases (*Dunkelziffer*) was lowest at the level of the family physician: two out of three of the physicians did know about their patients' incontinence. Highly specialized outpatient clinics at a tertiary center contain the lowest information regarding incontinence (between 0 and 3% of cases only!), and HMOs are usually uninformed – despite or because giving the diagnosis incontinence is usually associated with reimbursement of cost for incontinence care products.

The rather low rates of knowledge about incontinence symptoms in affected patients, at least at the level of medical specialists and HMOs, indicates that little has changed in the incontinence awareness of the medical community since Leigh and Turnberg's statement 20 years ago. It is unlikely that public awareness will improve without it or that it will proceed independently.

4.6 Summary

Using indirect indicators of awareness of incontinence in the (scientific) community such as the number of publications, the number of therapeutic tools available, or the specific knowledge of health care institutions about patients with incontinence, we estimate that the perception of incontinence in and by society has not changed very much, that the gap between the patient needs and supply in terms of care for those suffering from incontinence is still large, but that the near future may bring about a variety of new drugs that may – via increased economic demand for these treatment options – call increased public attention to this condition.

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Part II

Pelvic Anatomy, Physiology and Etiology of Incontinence

II

Chapter 5

The Rodent Animal Model to Explain Stress Urinary Incontinence

5

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Contents

5.1 Introduction

Urinary incontinence is a common problem among women, but its cause is not well understood. It has been shown that childbearing increases the risk of incontinence, and it appears that the female pelvic floor loses tone with increasing age (Densmore 1982). Despite the large social, psychological and economic implications of this problem, it has received little public attention. Although many women report incontinence shortly after vaginal delivery, it persists after 12 months in only a small percentage (2%–3%) of women (Meyer et al. 1993). Women of all ages (5 to over 85 years) have an 8.5% probability of incontinence during a specific period of their lives. A high rate has been reported in women aged 45–54 years, who have had four or more vaginal deliveries (Thomas et al. 1980). In another study, all women who underwent vaginal delivery had lower urethral pressure and functional length at 8 weeks postpartum than in early pregnancy and lower also than in healthy nulliparous women in the follicular phase of the cycle (van Geelen et al. 1982). The inherent weakness of the urethral sphincter mechanism in women and the stress of vaginal delivery have been suggested as important factors in the pathogenesis of stress urinary incontinence (van Geelen et al. 1982). In addition, a transvaginal ultrasound study demonstrated an open bladder neck in 21% of nulliparous females. These women may have a higher risk of developing stress incontinence if the integrity of the distal sphincter is compromised during vaginal delivery (Chapple et al. 1989).

In fact, incontinence often develops many years after the last delivery and usually after menopause (Tapp et al. 1988; Buzelin 1998). Pudendal neuropathy, secondary to vaginal delivery, has also been proposed as a contributing factor (Shooks and Swash 1984, 1985a,b).

Because of the problems inherent in obtaining tissue from human female volunteers, studies of the effect of parity and age on the continence mechanism are lacking. Lin et al. (1998) showed virgin rats experience incontinence after 4 h of vaginal balloon inflation. After looking into the effect of labor (Bakircioglu et al. 2000) in Part 1 of this chapter, we studied the effect on the modified animal model of Lin et al. (1998) by using nulliparous pregnant rats to investigate the effects of prolonged second stage of vaginal delivery, intravaginal balloon inflation, and hormone deficiency on the pelvic floor, bladder, bladder neck and urethra. The inflation of the balloon in the vagina simulates the effects of heavier childbirth injury, and ovariectomy simulates the hormone deficiency that occurs after menopause – two factors known to play an important role in female incontinence. In an attempt to correlate the functional and structural changes, we also performed ultrastructural examinations with light microscopy, electron microscopy and RT-PCR.

Caveolae are small bulb-shaped invaginations located at or near the cell surface (Svers 1988; Song et al. 1996) that represent a microdomain or subcompartment of the plasma membrane. It has been demonstrated that the plasmalemmal Ca^{2+}-pump is preferentially localized in the caveolae (Fuji et al. 1985). Recent biochemical and morphological studies have implicated caveolae in a subset of transmembrane signaling events, including G-protein-coupled signaling (Severs 1988).

Caveolin, a 21- to 24-kDa integral membrane protein, with different subgroups such as caveolin-1 (smooth muscle) (Glenney 1992; Lisanti et al. 1994) and caveolin-3 (striated muscle), is an important structural and regulatory component of the caveolae membrane. It is known that caveolin interacts directly with several structurally dis-

tinct signaling proteins in caveolae, including G proteins (Li et al. 1996) and cellular oncogenes (Koleske et al. 1995) as well as endothelial nitric oxide synthase (eNOS) and neuronal nitric oxide synthase (nNOS) (Michel et al. 1997; Venema et al. 1997). Although the function of caveolins is still under investigation, caveolin-3 has been shown to colocalize with dystrophin and to be increased in Duchenne muscular dystrophy (Hoffman and Kunkel 1989).

Nitric oxide has been implicated as one of the neurotransmitters involved in urethral relaxation (Andersson and Persson 1994). Interestingly, the urethral pressure during micturition is reduced by a nitric oxide synthase (NOS) inhibitor in female rats (Bennett et al. 1995).

Besides muscular intracellular function, research has focused on the different effects of various neuropeptides in normal tissue. This is an important step in understanding the complex function of the lower urinary tract, especially the continence and micturition mechanisms.

Tyrosine hydroxylase (TH) seems to be the most important peptide in mediating adrenergic innervation to the lower urinary tract. Nitric oxide (NO; a nonadrenergic, noncholinergic (NANC) mediator synthesized by NOS) as well as substance P (SP) (tachykinins), neuropeptide Y (NPY), and calcitonin gene-related peptide (CGRP) have also been found to have a role in regulation of the continence mechanism (Watts and Cohen 1991; Werkstrom et al. 1998). Besides being classified into families, peptides have also been subcategorized as afferent- and efferent-specific neuropeptides, although this clear line seems to diminish with increased knowledge and more specific staining (for example, VIP [Sjogren et al. 1985; Persson et al. 1995], NOS [Burnett 1995; Vizzard et al. 1994], TH [Persson et al. 1997]).

The present study examines the muscular and neuronal changes in a rodent model after delivery, ovariectomy, ballooning, and a combination of the three, to evaluate relationships between the functional and histological changes.

5.2 Part I

5.2.1 Experimental Set-up

Six virgin and 18 timed-pregnant Sprague Dawley rats (age, 3–4 months) were used. Cystometric studies were performed before sacrifice in virgins and in pregnant rats at gestation day 19 and postpartum day 2 and week 6. Tissue samples were taken from the anterior wall of the bladder and mid-portion of the urethra.

5.2.2 Statistical Analyses

Statistical analyses were performed with parametric ANOVA and Mann-Whitney U test, with StatView 4.02 software (Abacus Concepts, Berkeley, CA) for unpaired samples. Values were considered significant at $p<0.05$.

5.2.3 Functional Evaluation

Cystometry and Leak-point Pressure Measurement

The animals were anesthetized with an intramuscular injection of ketamine (50–60 mg/kg body weight; Ketamine HCL Injection, Sanofi Winthrop Pharmaceuticals, New York, NY) or pentobarbital and placed supine on a warming mattress (37°C). A transurethrally placed 22G Intracath was used for filling and recording via a three-way stopcock. The tubing was connected to a pressure transducer (Baxter Uniflow, Baxter Healthcare Corp., Irvine, CA) in line with a Harvard infusion pump (Harvard Pump Model 22, Millis, MA). Saline (37°C) was infused at 0.1 ml/min after the pressure transducer was zeroed to atmosphere. A customized Macintosh Quadra 800 was used to acquire the data with LabVIEW 4.0 (National Instruments Corp., Austin, TX). Measurement began 15 min after catheter placement and immediately after the last bladder emptied. Upon infusion, capacity was determined as the actual bladder volume. The first urine drop at the urethral meatus determined the modified leak-point pressure (mLPP). The residual bladder volume was determined by aspiration. At least three measurements per animal were obtained and the mean value was used for analysis.

Cystometric Results

Parametric ANOVA indicated significant differences in the bladder capacity ($p<0.01$), micturition pressure ($p<0.001$), and residual volume ($p<0.05$) among the groups (Table 5.1). Bladder capacity was larger and micturition-pressure significantly lower on gestation day 19 and postpartum day 2 than in the control virgins or at 6 weeks postpartum. No difference in these values was found between the control and 6-week groups. In the pregnant group, 0.61±0.23 ml of residual volume was detected after micturition.

Table 5.1. Cystometric evaluation

	Virgin	Pregnant	Postpartum day 2	Postpartum week 6
Bladder capacity (ml)	1.47±0.18	1.97±0.47*	2.08±0.42*	1.55±0.31
mLPP (cm H2O)	50.15±5.4	35.05±5.05*	30.23 ± 4.49*	49.67±7.12
Residual volume (ml)	0.35±0.1	0.61±0.23*	0.39 ± 0.15	0.33±0.11

Values are presented as mean ± SD. $N=6$ for each group. *$p<0.05$ compared with virgin.

5.2.4 Histological Evaluation

5.2.4.1 Immunohistochemical Staining

Tissue Preparation for Immunohistochemical Staining

Tissue was collected immediately after sacrifice. PE10 tubing (Polyethylene Tubing Intramedic, Becton Dickinson, Sparks, MD) was inserted transurethrally, and the symphysis was cut to expose the pelvic floor, which was removed carefully to preserve the original muscle orientation. The lower urinary tract was dissected and processed for examination.

Immunohistochemical Staining

Paraffin-embedded urethra and bladder sections were stained with caveolin-1 and caveolin-3 antibodies (Transduction Laboratories, Lexington, KY) with an avidin-biotin-enzyme complex (ABC) staining kit (Vectastain, Vector Laboratories, Burlingame, CA). Briefly, tissue sections were incubated with 3% goat serum for 2 h and then with 1:5,000 dilution of caveolin-1 and caveolin-3 antibody overnight. Tissue sections were then incubated sequentially with biotinated secondary antibody (Vector Laboratories), peroxidase-conjugated avidin, and diaminobenzidine. Finally, these sections were counterstained with hematoxylin (bluish staining of all cell nuclei), while positive (antigen-expressing) cells were stained with diaminobenzidine (brown color).

For control purposes, some sections were incubated as above, but without primary antibody. No immunostaining was seen under this condition.

Immunostaining Results

With immunostaining, caveolin-1 was localized to the sarcolemma of the smooth muscle cells of the bladder and urethra; in contrast, caveolin-3 was localized in the sarcolemma of striated muscle cells in the intrinsic sphincter.

In the urethra of virgin rats, immunohistochemical staining for caveolin-1 revealed densely packed smooth muscle cells with well-defined sarcolemma and centrally situated nuclei. In contrast, in pregnant rats expression of caveolin-1 was lower, with a concomitant loss of muscle cell architecture. Furthermore, in virgin rats, the smooth muscle cells appeared uniform in size with little intercellular space. In the 2-day postpartum rats, caveolin-1 staining was very dense. Many of the smooth muscle cells were distorted, which could represent either distortion of the individual smooth muscle cell or "internalization of the caveolae" as described by Thyberg et al. (1997). There was a large amount of intercellular space among bundles of smooth muscle, suggestive of interstitial edema shortly after delivery. In the urethra of 6-week postpartum rats, the staining density was similar to that of the virgin rats. However, many of the smooth muscle cells still appeared distorted, which again may represent distortion of the sarcolemma or internalization of the caveolae. In the bladder of pregnant and 2-day postpartum rats, immunohistochemical staining for caveolin-1 revealed that the smooth muscle cells were arranged in small groups with larger intercellular spaces as opposed to the virgin and 6-week postpartum rats.

Caveolin-3 staining was seen only in the sarcolemma of the striated muscle of the intrinsic urethral sphincter, and no significant difference in staining pattern among the groups was noted.

5.2.4.2 Electron Microscopy

Tissue Preparation for Electron Microscopy

Tissue samples (bladder and mid-urethra) were immersion-fixed in 2.5% glutaraldehyde, 2.0% paraformaldehyde in 0.15 M sodium cacodylate buffer, pH 7.4. After postfixation in 2% osmium tetroxide, the tissue was dehydrated in graded ethanol and propylene oxide and subsequently embedded in Epon 812. Thick sections (1 μm) were cut on a Sorvall MT 2-B microtome, stained with 1% methylene blue, and examined by Leitz Laborlux S light microscope (Leica Mikroskope und Systeme GmbH, Wetzlar, Germany). Thin sections (~900 Å) were mounted on 200-mesh copper grids and stained with 10% uranyl acetate and lead citrate. Ultrastructural examination was performed with a Zeiss transmission electron microscope Model 10.

Electron Microscopy Results

As reported by others (Elbadawi 1995), the smooth muscle cells in the bladder are larger than those in the urethra. The morphology of bladder smooth muscle cells varies from polygonal to cylindrical, depending on the plane of sectioning. In addition, they pack together with minimal intercellular space (Fig. 5.1). The sarcolemma of the smooth muscle cell contains thick electron-dense zones and thinner zones. The latter contain varying numbers of sarcolemmal caveolae. In our study, after delivery, most bladder smooth muscle cells showed increased mitochondrial aggregation and more vacuoles than those in virgin rats (Table 5.2), and the number of sarcolemmal caveolae was significantly less in pregnant and postpartum rats (Table 5.3).

The urethra contains two layers of smooth muscle, an inner longitudinal and an outer circular layer. In addition, an outer layer of striated muscle is present in the mid-

Table 5.2. Bladder changes on electron microscopy

	Virgin	Pregnant	Postpartum day 2	Postpartum week 6
Shape	Irregular	Polygonal	Polygonal	Polygonal
Vacuoles	Rare	Slight increase	Moderate increase	Moderate increase
Intercellular Space	Small	Slight increase	Slight increase	Slight increase
Mitochondria				
Location	Near nucleus	Scattered	Scattered	Scattered
Swelling	No	Slight increase	Moderate increase	Moderate increase
Vacuolar deg.	No	Increase	Moderate increase	Moderate increase
Aggregation	Scattered	Increase	increase	increase

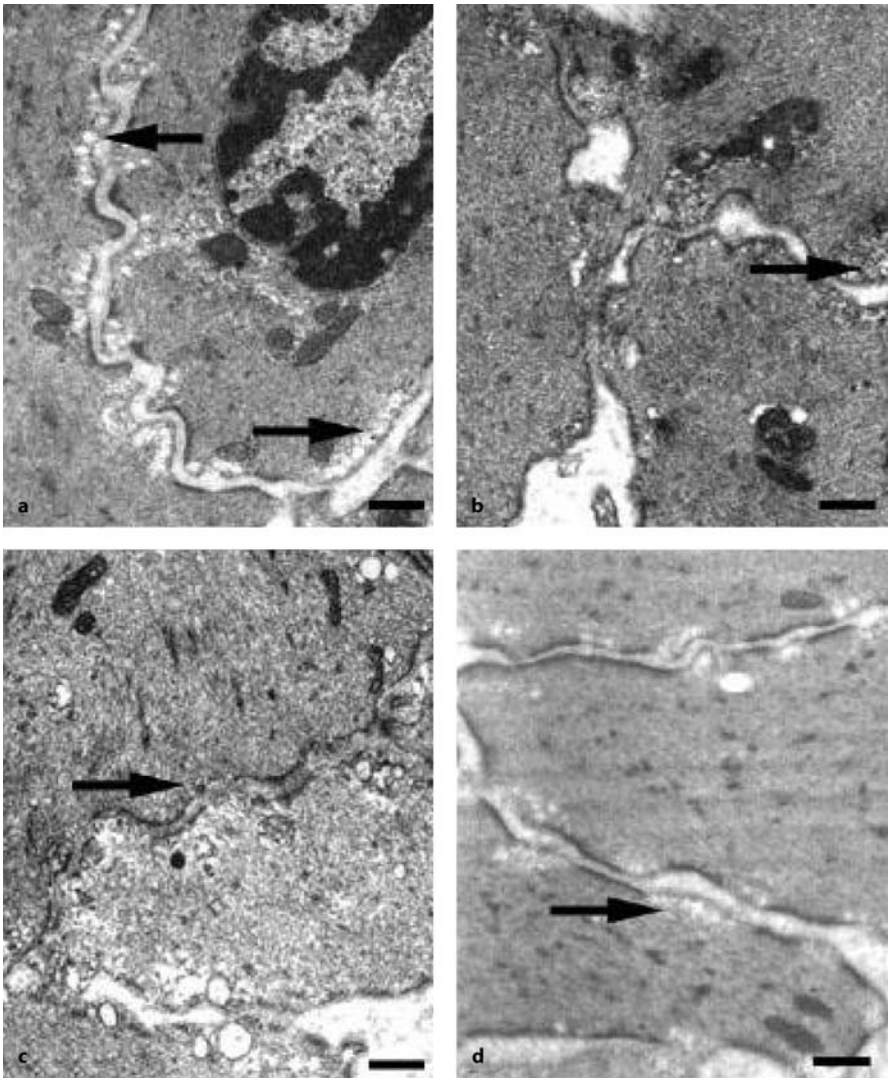

Fig. 5.1a–d. Electron micrographs of (**a**) virgin, (**b**) pregnant, (**c**) 2nd-day, and (**d**) 6-weeks-postpartum rats' bladder smooth muscle cells. Note decreased caveolae (*arrows*) in (**b**) and (**c**) (20,000 × magnification). Scale bar = 500 nm

Table 5.3. Number of caveolae in urethra and bladder smooth muscle cells

	Virgin	Pregnant	Postpartum day 2	Postpartum week 6
Urethra	22.1±2.7	15.3±3.8*	16±2.3*	19.4±1.6
Bladder	16.5±2.3	10.6±4.5*	10.3±3.9*	15.4±2.4

* $p<0.05$ compared with virgin.

urethra. The urethral smooth muscle cells are arranged in small groups with large intercellular spaces. The individual smooth muscle cell appears irregular in shape and contains many finger-like processes (Fig. 5.2). In a separate pharmacological experiment (data not shown), phenylephrine pretreatment produced an irregular cell shape and indented nucleus, while papaverine pretreatment produced a relatively smooth cellular outline. Therefore, the irregular shape of the urethral smooth muscle cells in-

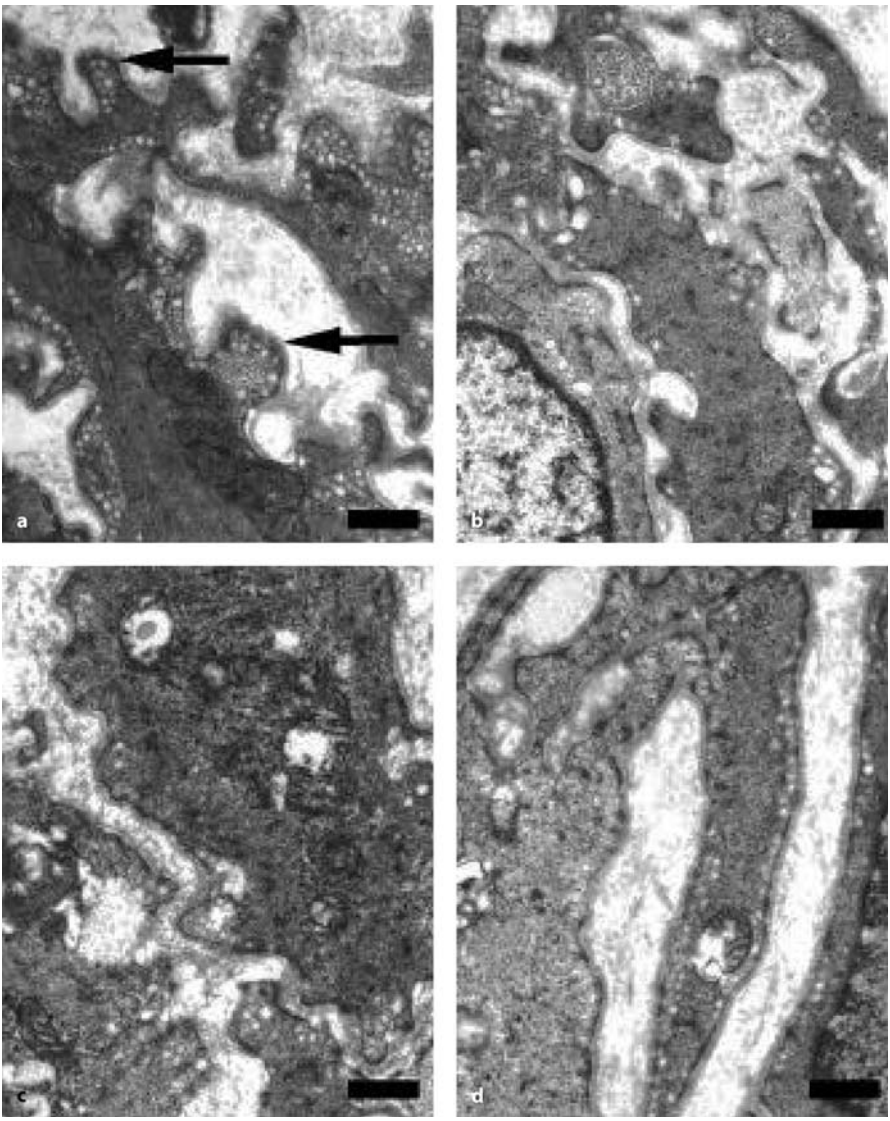

Fig. 5.2a–d. Electron micrographs of (**a**) virgin, (**b**) pregnant, (**c**) 2nd-day, and (**d**) 6-weeks-postpartum rats' urethral smooth muscle. Note the finger-like processes (*arrows*) and the numerous caveolae in the plasma membrane of smooth muscle cells of (**a**). Note the round shape of smooth muscle cells and decreased number of caveolae in the plasma membrane as well as increased vacuoles in (**c**) (20,000 × magnification). Scale bar = 500 nm

Table 5.4. Urethral changes on electron microscopy

		Virgin	Pregnant	Postpartum day 2	Postpartum week 6
Striated muscle	Mitochondria				
	Sarcolemmal accumulation	Rare	Moderate	Moderate	Moderate
	Giant mitochondria	Rare	Slight increase	Moderate increase	Moderate increase
	Vacuolar deg.	No	Slight increase	Moderate increase	Moderate increase
	Lipid droplets	No	Moderate increase	Slight increase	Slight increase
	Z-disk deg.	No	Few	Moderate	Moderate
	Whole cell deg.	No	Few	Few	Moderate
Smooth muscle	Shape	Irregular/ contracted	Polygonal/ cylindrical	Polygonal/ cylindrical	Polygonal/ cylindrical
	Vacuolar deg.	No	Slight increase	Moderate increase	Moderate increase
	Mitochondria accumulation	Rare	Slight increase	Slight increase	Slight increase

dicates that most of the urethral smooth muscles are contracted. In contrast, the bladder smooth muscles are in a relaxed state with smooth cellular perimeters.

The urethral smooth muscle cells in virgin rats were more irregular in shape (Table 5.4) and possessed more sarcolemmal caveolae than in pregnant and postpartum rats (Table 5.3). In the latter, the numbers of finger-like processes and caveolae markedly decreased. In addition, swelling and aggregation of mitochondria were observed, as well as vacuolar degeneration. Mitochondria were located near the nucleus in virgin rats, but were scattered in the cytoplasm in pregnant and postpartum rats. The interstitial connective tissue in the smooth muscle cells of the urethra and bladder was more abundant in pregnant and 2-day postpartum rats than in the virgin rats. At 6 weeks after delivery, increased vacuoles were observed.

In the external sphincter, striated muscle cells were mostly composed of slow-twitch myofibers showing more mitochondria, thin Z-disks and fewer glycogen particles (Fig. 5.3a). In pregnant and postpartum rats, lipid droplets and large vacuoles were noticed, especially in the I-band and between the myofibers where the mitochondria accumulate (Fig. 5.3b, c). Although lipid droplets were mostly recognized in striated muscle cells of pregnant rats, vacuoles were mostly seen 6 weeks after delivery. Moreover, numerous subsarcolemmal mitochondria were observed in striated muscle cells of pregnant and 2-day postpartum groups; whole cell degeneration and Z-disk degeneration were noticed in striated muscles of the rats 6 weeks after delivery (Table 5.4, Fig. 5.3d).

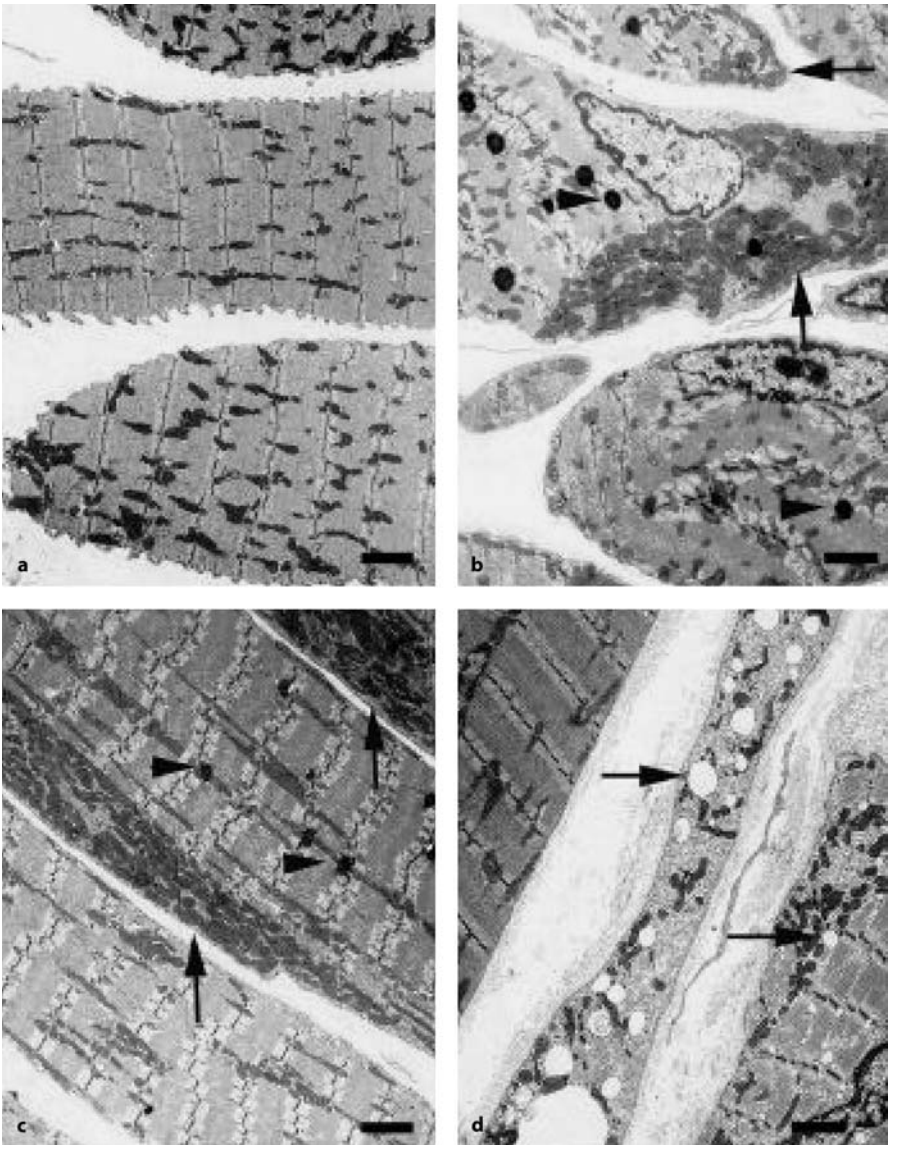

Fig. 5.3a–d. Electron micrographs of urethral striated muscle cells in (**a**) virgin, (**b**) pregnant, (**c**) 2nd-day, and (**d**) 6-weeks-postpartum rats. Note the subsarcolemmal mitochondria accumulation (*arrows*) and lipid droplets in (**b**) and (**c**) (*arrowheads*), and vacuolar degeneration (*arrows*) in (**d**). Scale bar = 2.5 μm

5.2.5 RT-PCR

Western Blot Preparation

Freshly obtained samples from bladder and urethra were homogenized in ice protein lysis buffer. Insoluble materials were removed by centrifugation. Protein concentration was determined by the BCA method (Pierce Chemical Company, Rockford, IL). An equal amount (20 μg) from each sample was electrophoresed in SDS-PAGE. The fractionated proteins were then transferred to PVDF membrane. The membrane was stained with Ponceau S to verify the integrity of the transferred proteins and to monitor the unbiased transfer of all protein samples. The membrane was then subjected to either the ECL (Amersham Life Sciences Inc., Arlington Heights, IL) or the AP procedure (Promega Corp., Madison, WI) for the detection of caveolin-1. A 1:1,000 dilution of caveolin-1 and -3 antibodies was used for Western blotting.

Western Blot Results

Expression of caveolin-1 in the urethra and bladder was less in pregnant rats than in virgin controls, but markedly increased in the 2-day postpartum rats. At 6 weeks postpartum, expression had returned to the level in the virgin rats (Fig. 5.4). No significant difference was detected in caveolin-3 expression in the urethra of the four groups (Fig. 5.5).

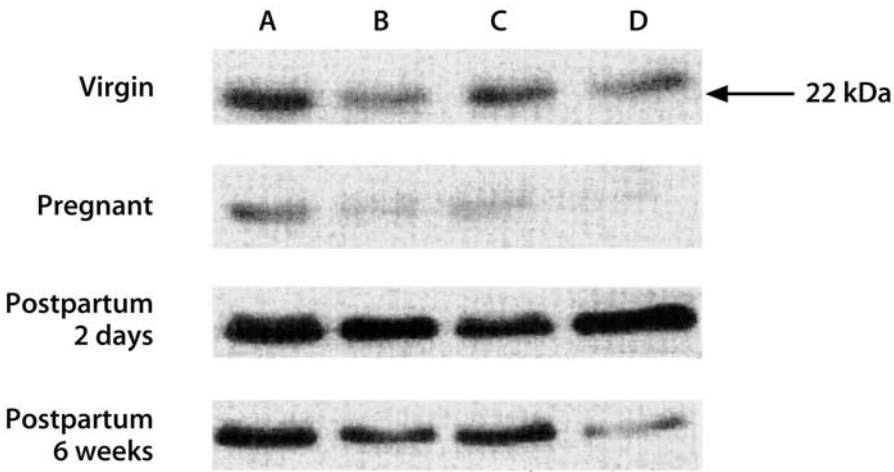

Fig. 5.4. Immunoblot shows caveolin-1 protein expression in the bladder (*line A and C*) and urethra (*line B and D*) in virgin, pregnant, 2nd-day-postpartum, and 6-weeks-postpartum rats. Note high protein expression in 2nd-day-postpartum and low protein expression in pregnant rats' bladder and urethra

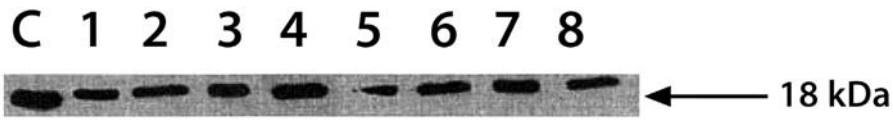

Fig. 5.5. Immunoblot shows caveolin-3 protein expression in the urethra of virgin (*1, 2*), pregnant (*3, 4*), 2nd-day (*5, 6*), and 6-weeks-postpartum rats (*7, 8*). Rat muscle lysate was used as control (*C*). No difference was noted among the groups

5.3 Part II

5.3.1 Experimental Set-up

Three-month-old female virgin (n=12; mean weight, 249.2 g) and primiparous pregnant Sprague-Dawley rats at gestational day 16 (n=48; mean weight, 266.5 g) were obtained from the vendor. They were housed at 16°C constant room temperature and 47% humidity with a 12-h light–dark cycle and free access to standard laboratory chow and tap water.

Immediately after parturition, cystometry and stress/sneeze testing were performed in all rats to serve as the baseline for future evaluations. Animals were separated into two groups, with half in each group undergoing balloon dilation. (Virgin rats were also evaluated to establish control values.) One month after parturition, every second animal of each group underwent ovariectomy, resulting in four groups (I = delivered, II = delivered and ballooned, III = delivered and ovariectomized, IV = delivered, ballooned and ovariectomized).

Approximately 9 weeks after the animals were obtained from the vender, - 2 months after parturition – all animals were evaluated by transurethral urodynamic and stress/sneeze test before sacrifice (Fig. 5.6). The lower urinary tract (bladder, bladder

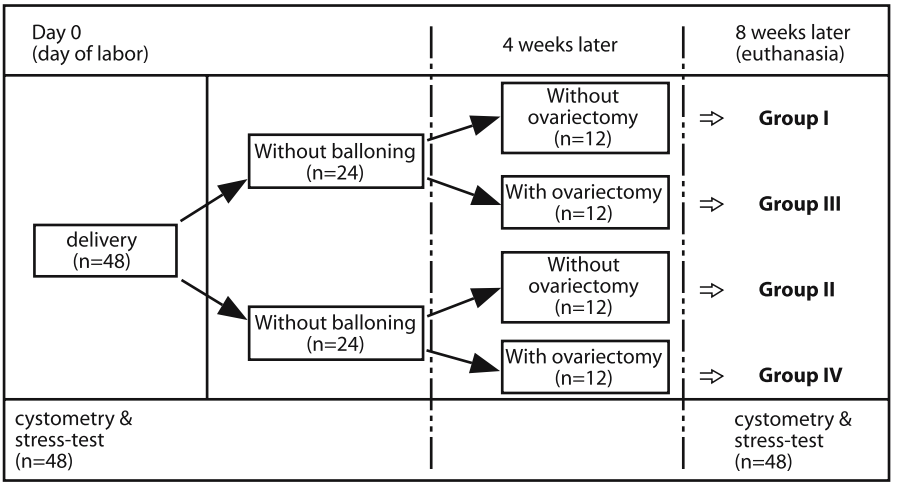

Fig. 5.6. Illustration of the experimental protocol

neck, mid-urethra and levator muscle) was then removed and specimens were processed for light or electron microscopy.

Intravaginal Balloon Inflation

Immediately after parturition, half of the animals were anaesthetized with 18–20 mg/kg intraperitoneal pentobarbital (groups II and IV). The bladder was emptied via a transurethrally placed 22G Intracath (Becton Dickinson, Sandy, UT). A modified 22°F Foley catheter (entire weight, 130 g) was inserted intravaginally and inflated with 5 ml distilled water. The rat was placed in a fixed prone position, the symphysis at the table edge for 3 h. The symphysis became a fulcrum for the catheter, which hung freely without touching the table (Fig. 5.7). (The pulling directed the pressure downward to simulate the pressure of a large fetus on the pelvic floor and lower urinary tract during a prolonged second stage of labor.)

5.3.2 Statistical Analysis

Functional evaluation of bladder capacity, modified leak-point pressure (mLPP), bladder pressure, and residual volume was repeated at least three times and the mean was used for further analysis. The values of different groups were compared with those of the virgin rats. The Mann-Whitney U test was used for statistical analysis. The stress/ sneeze test, used as the indicator for incontinence, was verified by convergence tables.

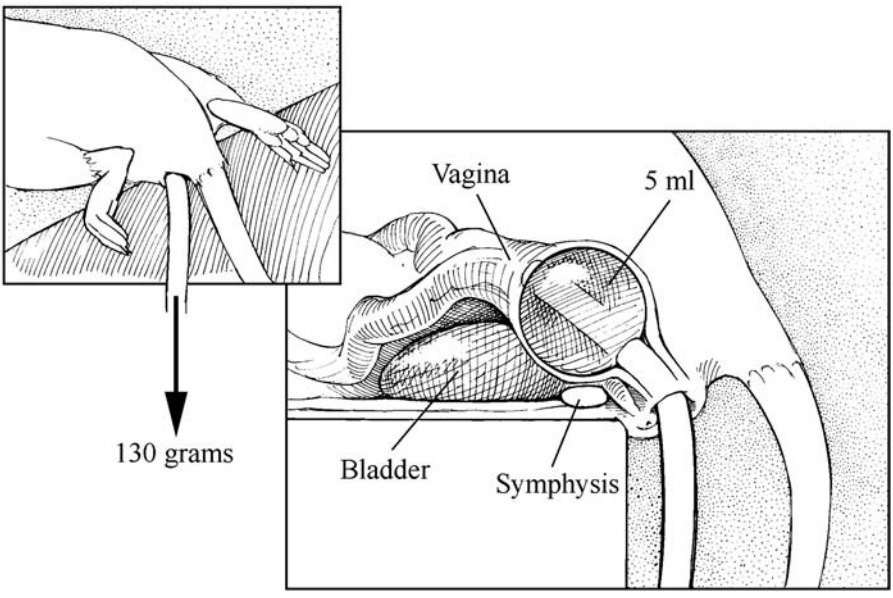

Fig. 5.7. Intravaginally placed Foley catheter. The force of the balloon is directed to the pelvic floor to simulate human labor

5.3.3 Functional Evaluation

Cystometry and Leak-point Pressure Measurement

Cystometry and leak-point pressure measurements were performed as described in Sect. 5.2.3.

Urodynamic Results

Bladder capacity on the day of delivery was significantly increased (mean bladder capacity 2.1±0.2 ml [delivered] vs 1.3±0.2 ml [virgin], $p<0.005$). In group I, the bladder capacity remained the same 8 weeks after delivery, but a decrease was noted in groups II–IV. The mLPP decreased significantly at the day of delivery (28.9±1.3 cm H_2O) and returned to the level of virgin rats (49.7±2.4 cm H_2O) after 8 weeks. Animals under ketamine anesthesia had higher mLPPs than did those under pentobarbital anesthesia (data not shown). There was an increase in residual volume in group I rats (mean, 1.1±0.4 ml) when compared with virgin rats (mean, 0.3±0.1 ml) ($p<0.05$) (Table 5.5).

Stress/Sneeze Test

After cystometry, the bladder was filled to half capacity with saline solution (0.9%; 37°C) mixed with one drop of methylene blue to facilitate the determination of urinary leakage. After removal of the catheter, a rat whisker was inserted into the nostril and moved to induce sneezing, and the urethral meatus was observed for urinary leakage. The test was repeated twice to verify the findings.

Table 5.5. Urodynamic results

	Virgin	Day 0 Delivery	Group I 8 weeks after delivery	Group II	Group III	Group IV
	n=10	*n*=48	*n*=12	*n*=12	*n*=12	*n*=11
Bladder capacity (ml)	c=1.4 i=2.5*	c=2.5* i=1.6	c=2.0* i=1.5	c=2.1* i=1.6	c=1.1 i=1.6	c=1. 3
mLPP (cmH_2O) (ketamine)[a]	c=49.7 i=23.2*	c=27.3* i=46.5	c=48.3 i=38.3	c=43.0 i=42.0	c=49.6 i=38.3	c=59.0
Residual volume (ml)	c=0.3 i=0.8	c=0.3 i=0.8	c=1.2* i=0.5	c=0.8 i=0.8	c=0.7 i=0.6	c=0.7
Incontinent stress test + (%)	0	29.2*	16.7*	58.3*	16.7*	72.7*

c continent rats, *i* incontinent rats.

* $p<0.05$ compared with virgin.

[a] The mLPP results under pentobarbital sedation showed a similar trend among groups, although with a lower pressure (virgin=35.0±2.2, group I=42.5±4.4, II=36.2±4.4, III=36.8±3.6 and IV=33.8±2.1; mean values of the whole group).

Stress Test Results

In the stress/sneeze test, all virgin controls were continent. After delivery, 29% were incontinent, whereas, at 8 weeks postpartum, the incontinence rates were as follows: group I, 16%; group II, 58%; group III, 16%; and group IV, 72%. The percentages were derived by using the mean of both anesthesia medications (one-half of rats under ketamine, one-half under pentobarbital). The increase in incontinence for groups II and IV was statistically significant by the convergence tables. Additionally, under pentobarbital anesthesia, incontinence rates were higher in all four groups (results not shown) (Table 5.5).

5.3.4 Histological Evaluation

5.3.4.1 Muscle Changes

Light Microscopy

Tissue Preparation. Tissue was prepared as described in Sect. 5.2.4.1.

Fixed Frozen Tissue. Specimens (pelvic floor, bladder, bladder neck and mid-urethra) were fixed (2% formaldehyde, 0.2% saturated picric acid in 0.1 M phosphate buffer, pH 8.0) for 2 h before transfer to 15% sucrose in buffer for 24 h. The specimens were embedded in Tissue-Tek O.C.T. Compound (Sakura Finetek USA, Torrance, CA), frozen in liquid nitrogen, and stored at –80°C until use.

Tissue Preparation for Immunohistochemical Staining. Fixed frozen tissue specimens were cut at 8 μm, adhered to charged slides (SuperFrost Plus, Fisher Scientific, Pittsburgh, PA), and air-dried. To block endogenous peroxidase activity, slides were placed in 0.3% H_2O_2/methanol for 10 min. After rinsing, sections were treated with either 3% horse serum or 3% goat serum in PBS/0.3% Triton X-100 for at least 60 min to eliminate nonspecific protein binding. Slides were incubated overnight at room temperature with mouse monoclonal antibodies to caveolin-1 or caveolin-3 (1:5,000 dilution; Transduction Laboratories, Lexington, KY) or with rabbit polyclonal antibody to nNOS (1:5,000 dilution; Santa Cruz Biotechnology, Santa Cruz, CA). After washing with buffer, sections were immunostained according to the avidin-biotin peroxidase method (Vectastain Elite Kit, Vector Laboratories, Burlingame, CA) with 3,3′-diaminobenzidine plus hydrogen peroxide as the chromogen. Sections were counterstained with hematoxylin, dehydrated to xylene, and mounted.

For control purposes, some sections were incubated as above, but without primary antibody. No immunostaining was seen under this condition.

Statistical Analysis

The muscular structure was divided into two substructures (inner muscular layer and outer muscular layer). For each substructure, four randomly chosen fields were analyzed at 400 × light microscope magnification (Leica light microscope DM RB attached

to a digital camera [Nikon N 90]). The changes of caveolin-1, caveolin-3 and nNOS were quantified with Adobe Photoshop 4.0 (Adobe Systems Incorporated, Mountain View, CA) installed on a Power Macintosh 7500/100 (Apple Computer, Inc. Cupertino, CA). The ratio of the caveolin-1-, caveolin-3-, or nNOS-stained pixels to the total number of pixels yielded a percentage.

Immunostaining Results. Caveolin-1 is located mainly in the sarcolemma of smooth muscle cells in the bladder, bladder neck and urethra as well as in smooth muscle cells of blood vessels (Table 5.6).

In the bladder tissue of group I, caveolin-1 was decreased, but not significantly. In groups II–IV caveolin-1 staining diminished significantly. The well-arrayed architecture of the muscle bundles seen on histological examination of the virgin controls was lost in groups II–IV (Figures 5.8a, 5.8b).

In the urethra of virgin rats, densely packed smooth muscle cells with a well-defined sarcolemma and a centrally situated nucleus were seen (Fig. 5.8c, d). Caveolin-1 was significantly less in smooth muscle bundles of the urethra in groups I–IV than in virgins (Fig. 5.8 e–h).

Regardless of location, smooth muscle cells of groups II–IV appeared to be less well defined and unequal in size when compared with the virgin controls (Fig. 5.8d, f–h). Ovariectomized animals (group III) had decreased smooth muscle cell size.

Table 5.6. Caveolin-1, -3 and neuronal nitric oxide synthase staining results

	Virgin (n=10)	Group I (n=8)	Group II (n=8)	Group III (n=8)	Group IV (n=8)
Cont.:incont.	c:i	c:i	c:i	c:i	c:i
Caveolin-1					
Urethra					
Inner (%)	17.1:–	9.9:8.3[a]	8.2:3.3[a]	8.2:3.3[a]	9.3:3.3[a]
Outer (%)					
Bladder neck					
Inner (%)	11.6:–	10.1:7.2	15.2:11.2	14.44:7.90	18.40:8.63
Outer (%)	13.7:–	14.5:13.8	13.3:12.1	14.8:12.6	15.7:13.5
Bladder					
Inner (%)	16.1:–	12.7:12.2	12.7:12.6[a]	8.7:9.2[a]	4.4:5.2[a]
Outer (%)	21.7:–	18.7:15.6	18.2:9.9[a]	10.5:5.5[a]	14.9:6.3[a]
Caveolin-3					
Urethra					
Inner (%)					
Outer (%)	20.6:–	14.4:12.3	14.8:9.18[a]	7.2:3.0[a]	8.9:7.5[a]
n-NOS					
Urethra					
Inner (%)	1.0:–	0.9:n.i.	n.i.	n.i.	n.i.
Outer (%)	5.5:–	2.5:0.5[a]	1.7:n.i.[a]	1.9:n.i[a]	1.3:n.i.[a]

[a] Versus virgin.
$p<0.05$.
n.i. Non-immunoreactive.

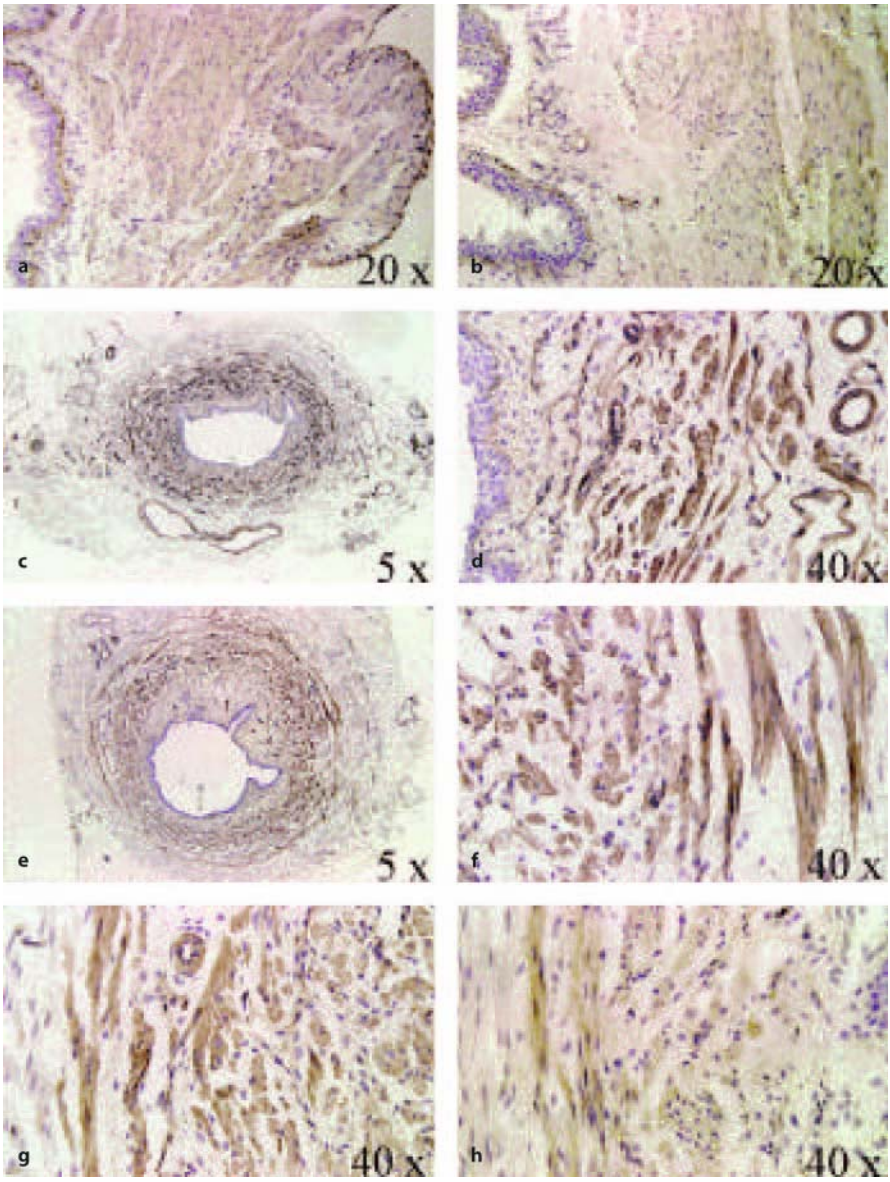

Fig. 5.8a–h. Caveolin-1 staining of the bladder from a virgin (**a**) and a group IV rat (**b**) (delivered + ballooned + ovariectomized). The staining of group IV bladder muscle was significantly decreased. Caveolin-1 staining of the urethra revealed inner longitudinal and outer circular layers with dense staining in the virgin (**c** and **d**). After ballooning (group II), a decreased intensity of staining was noted (**e** and **f**). Further decrease in caveolin staining was noted in groups III (delivered + ovariectomized) (**g**) and IV (delivered + ballooned + ovariectomized) (**h**)

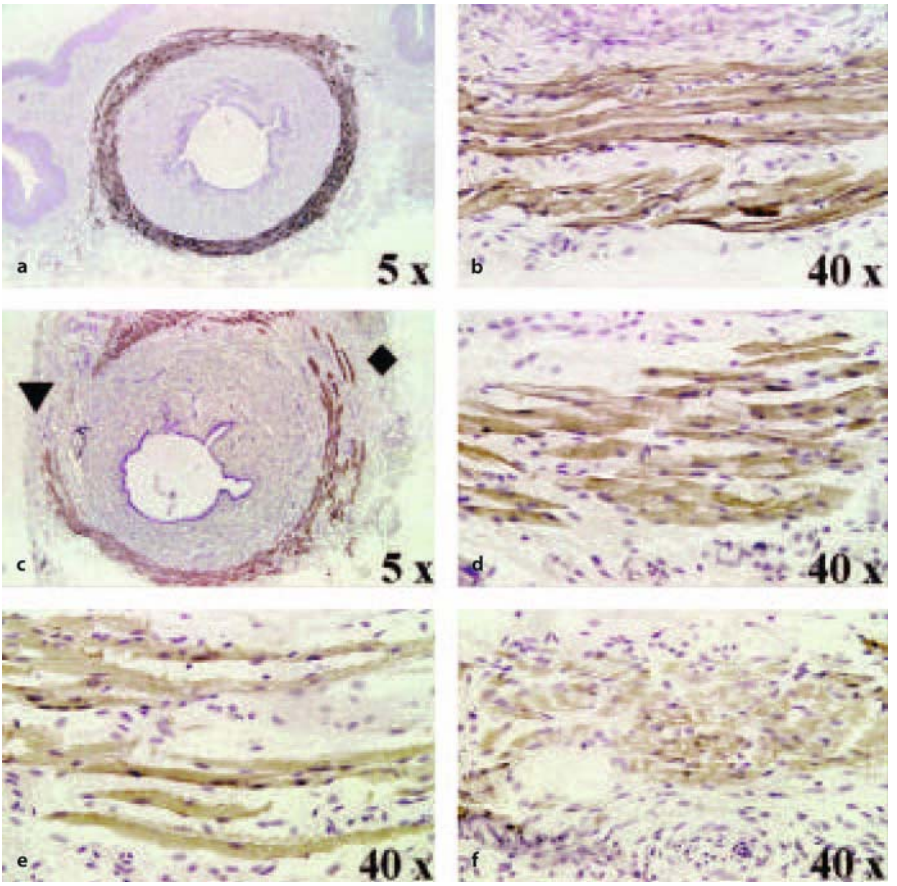

Fig. 5.9a–f. In the virgin rat, **a** a completely circular striated muscle ring of the urethral outer muscular layer is clearly seen after caveolin-3 staining; **b** the caveolin-3 staining is located predominantly in the sarcolemma. **c** The muscle layer after ballooning in a group II rat (◆ towards the symphysis, ▼ toward the vagina); **d** distribution of caveolin-3 staining is even, rather than the sarcolemmal distribution in (**b**). **e** A further decrease in caveolin-3 staining and irregular arrangement of striated muscle were noted in rats from group III (delivered + ovariectomized) and **f** group IV (delivered + ballooned + ovariectomized)

Caveolin-3, which stained the sarcolemma of the striated muscle of urethra and levator, was significantly decreased in groups II–IV (Fig. 5.9a, b). The architectural derangement in the smooth muscle layer was not seen in the striated muscle layer, where the orientation was retained regardless of treatment (Fig. 5.9b, d, e, g). There was no increase in connective tissue at the light microscopy level.

In treated rats, nNOS in the urethral striated muscle bundles showed a significant decrease (Fig. 5.10a, b).

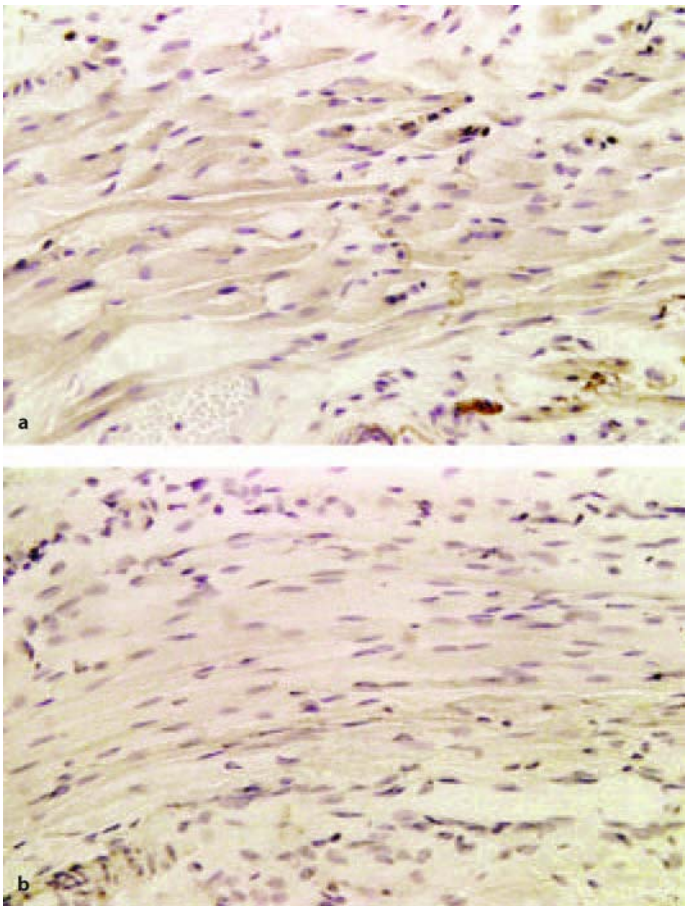

Fig. 5.10a, b. nNOS staining of the urethral striated muscle in (**a**) virgin and (**b**) group IV rats (delivered + ballooned + ovariectomized). Note the less well-defined individual muscle cells and the decreased staining in (**b**)

Electron Microscopy

Tissue Preparation for Electron Microscopy. Tissue samples (bladder, bladder neck, mid urethra and levator muscle) were immersion-fixed in 2.5% glutaraldehyde, 2.0% paraformaldehyde in 0.15 M sodium cacodylate buffer, pH 7.4. After postfixation in 2% osmium tetroxide, the tissue was dehydrated in graded ethanol and propylene oxide and subsequently embedded in Epon 812. Thick sections (1 μm) were cut on a Sorvall MT 2-B microtome, stained with 1% methylene blue, and examined by Leitz Laborlux S light microscope (Leica Mikroskope und Systeme GmbH, Wetzlar, Germany). Thin sections (~900 Å) were mounted on 200-mesh copper grids and stained with 10% uranyl acetate and lead citrate. Ultrastructural examination was performed with a Zeiss transmission electron microscope Model 10.

Table 5.7. Electron microscopy findings[a]

	Virgin (n=10)	Group I (n=8)	Group II (n=8)	Group III (n=8)	Group IV (n=8)
Cont.: incont.	c:i	c:i	c:i	c:i	c:i
Caveolae					
Urethra	282.6:–	301.0:249.8	150.0:76.6[b]	103.0:77.0[b]	41.5:16.3[b]
Bladder neck	79.0:–	75.0:60.5	81.0:38.0	120.0:186.0[b]	50.0:39.3
Bladder	190.5:–	150.0:114.3[b]	75.5:65.3[b]	61.5:47.7*	23.5:9.6[b]
Cell Number					
Urethra	17.7:–	15.0:12.3	23.0:20.3	19.0:15.0	18.0:19.3
Bladder neck	21.8:–	19.0:17.3	18.0:13.7	30.0:15.3	21.0:15.0
Bladder	20.0:–	16.0:13.67*	24.0:15.3	20.0:24.7	22.0:33.3*
Connective Tissue					
Urethra (%)	10.5:–	11.0:12.0	11.0:14.5	9.9:12.8	11.2:14.7
Bladder neck (%)	6.8:–	7.2:6.7	8.1:13.3	7.0:7.83	10.0:12.3[b]
Bladder (%)	7.5:–	7.4:7.3	7.5:9.1	6.6:8.5	7.6:9.8

$p<0.05$.

[a] The number of caveolae was already decreased in the bladder by labor. In the mid-urethra, the influence of ballooning and/or ovariectomy was seen. The number of cells per field increased with each additional treatment. The exception is the bladder neck with a decrease in smooth muscle cells but an increase in connective tissue. The changes in cell number and connective tissue were more obvious by further subdividing each group into continent (c) and incontinent (i). The differences, when compared with the results of virgin controls, became obvious (data not shown). However, because of the small numbers of incontinent/continent rats in each subgroup, statistical comparison with Mann-Whitney U test could not be performed.

[b] Versus virgin,

Electron Microscopy Results. Smooth muscle cells were observed under electron microscopy, confirming the results of caveolin-1 immunostaining. In the urethra, a decrease of caveolae in groups II–IV was seen (Fig. 5.11a, b). In the bladder, the number of caveolae decreased significantly in groups I–IV when compared with virgin rats (Table 5.7).

Bladder specimens of groups II and IV had a significant increase in smooth muscle cells per field, suggestive of muscle atrophy (Fig. 5.11b); group I showed a significant decrease, which may be indicative of cell swelling.

A significant increase in connective tissue between the smooth muscle bundles, in relation to the entire scanned field, was observed only in the bladder neck of groups II and IV.

In group I striated muscle cells, some levator muscle fibers showed thinner or deficient Z-bands (Fig. 5.12b). Besides a decrease of T-tubules, large vacuoles were noted, which, in virgin animals, were occupied by mitochondria. (Fig. 5.12a: for normal T-tubuli, Z-bands and mitochondria). Urethral striated muscle bundles showed slow-twitch myofibers. Group I specimens showed an increased number of swollen mitochondria (Fig. 5.13b) and normal muscle cells. In ovariectomized animals (group III), hyperdense vacuoles (perhaps attributable to calcification) were seen (Fig. 5.13c). A decrease in mitochondria in muscle cells was seen in groups II–IV (Fig. 5.13).

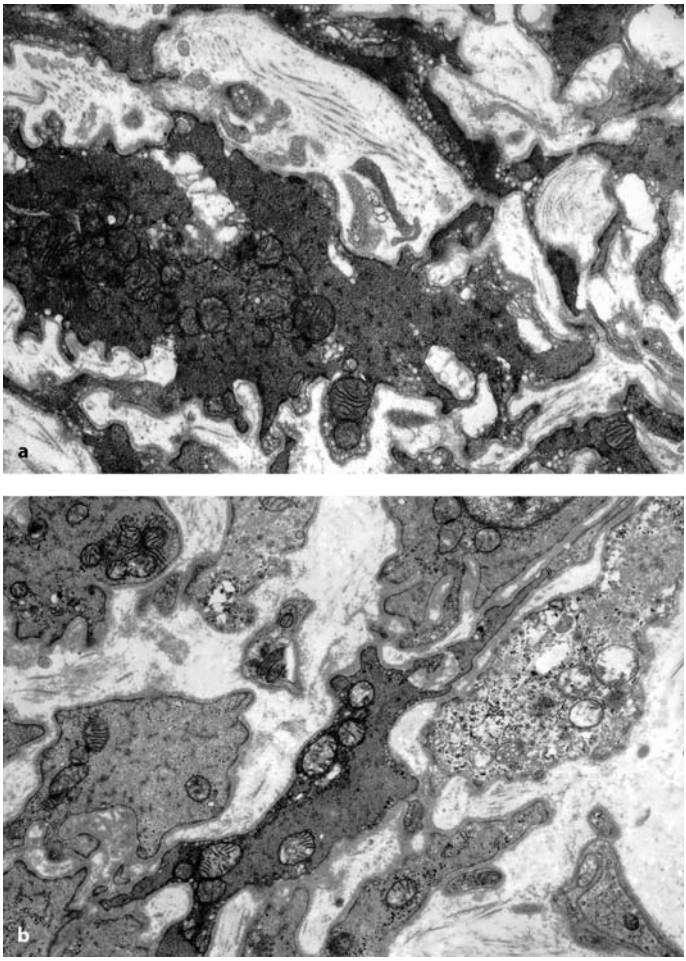

Fig. 5.11a, b. Urethra from virgin rat (**a**) shows irregular and serrated smooth muscle cells with abundant caveolae. Urethra from group IV (delivered + ballooned + ovariectomized) rat (**b**) reveals a significant change in the shape and number of caveolae. (12,550 × magnification)

Statistical Analysis. The method, as described in "Statistical Analysis" above, was also used to analyze the amount of intercellular tissue of muscle bundles by electronic microscopy (EM). These pictures were scanned using a ScanJet 3c (Hewlett Packard). The mean of four areas (area of 5×5 cm^2; EM-magnification, 4125 ×) was used to compare the differences between the virgin and the various groups with the Mann-Whitney U test (GB-STAT, Dynamic Microsystems Inc., Silver Spring, MD). Values were considered significant at $p<0.05$ and highly significant at $p<0.005$.

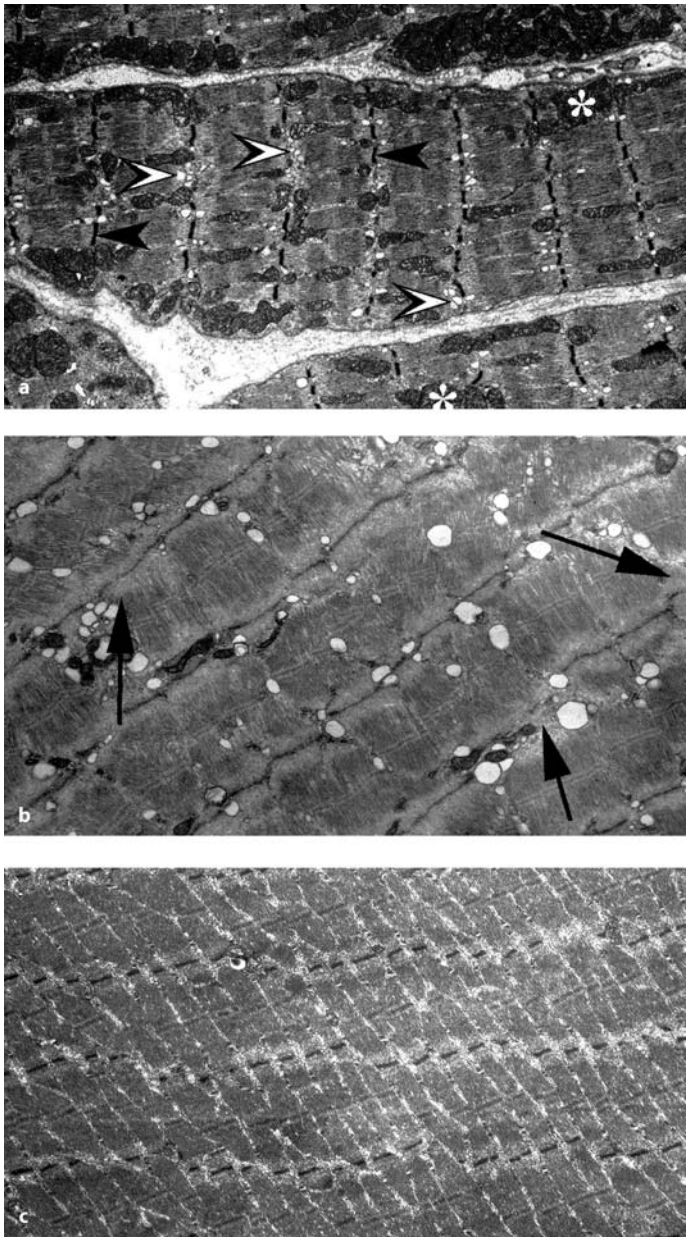

Fig. 5.12a–c. Striated muscle of the levator from (**a**) virgin rats. Note the T-tubules (*arrowheads*), Z bands (*arrows*) and mitochondria (*asterisks*). **b** Group I (delivered) rats: large vacuoles, a decrease in mitochondria and glycogen, and deficient Z-bands (*arrows*) are noted. **c** In group IV (delivered + ballooned + ovariectomized) rats, there was a marked loss of mitochondria and a reduction in the diameter of individual muscle cells. This phenomenon is seen only in ovariectomized rats (12,550 × magnification)

Fig. 5.13a, b. Striated muscle of mid-urethra in rats from **a** virgin, **b** group II (delivered + ballooned) and **C** group IV (delivered + ballooned + ovariectomized). In group II, large vacuoles replacing mitochondria were noted and the number of mitochondria was significantly decreased. Further decrease in the number of mitochondria and calcifications (*black dots*) are seen in group IV (12,550 × magnification)

5.3.4.2 Neural Changes

Light Microscopy

■ **Tissue Preparation for Light Microscopy.** Tissues were prepared as described in "Electron Microscopy" above.

■ **Fixed Frozen Tissue.** Frozen tissue samples were prepared as described in "Fixed Frozen Tissue" above.

■ **Staining.** Fixed frozen tissue specimens were cut at 8 μm, adhered to charged slides (SuperFrost Plus Fisher Scientific, Pittsburgh, PA) and air-dried. For immunohistochemistry, endogenous peroxidase activity was blocked by placing slides in 0.3% H_2O_2/methanol for 10 min. After rinsing, sections were treated with 3% goat serum in PBS/0.3% Triton X-100 for at least 60 min to eliminate nonspecific protein binding. Slides were incubated with specific antibodies (anti-protein gene product 9.5 [PGP 9.5], 1:8,000 [Accurate Chemical & Scientific Corporation, Westbury, NY]; anti-calcitonin-gene-related-peptide [CGRP], 1:1,800; anti-substance P [SP], 1:8,000; anti-neuropeptide Y [NPY], 1:6,000; anti-vasoactive intestinal polypeptide [VIP], 1:6,000 [Peninsula Laboratories Inc., Belmont, CA]; anti-neuronal nitric oxide synthase [nNOS], 1:5,000 [Santa Cruz Biotechnology, Santa Cruz, CA], anti-tyrosine hydroxylase [TH], 1:20, [Newcastle-Upon-Tyne, UK]). All sections were incubated at room temperature overnight, except for CGRP for which sections were incubated for 60 min. After washing with buffer, sections were immunostained according to the avidin-biotin peroxidase method (Vectastain Elite Kit, Vector Laboratories, Burlingame, CA) with 3,3′-diaminobenzidine with hydrogen peroxide as the chromogen. Sections were counterstained with hematoxylin, dehydrated to xylene, and mounted.

For control purposes, some sections were incubated as above without primary antibody. No immunostaining was seen under this condition.

Acetylcholinesterase (ACEase) staining was performed according to the method of Goto et al. (1984). Tissue sections were incubated for 60 min with 0.065 M maleate buffer, pH 6.0, containing sodium citrate (5 mM), copper sulfate (3 mM), potassium ferricyanide (0.5 mM) and acetylthiocholine iodine (1.7 mM). To serve as control, some sections were incubated in a mixture without acetylthiocholine iodine. Sections were briefly rinsed with water, then incubated for 2–10 min with a mixture of 8% sodium acetate and 0.02% rubeanic acid. Tissues were lightly counterstained with eosin, dehydrated, and cover-slipped. Acetylcholinesterase-stained nerves appeared as black fibers against the eosin background.

■ **Statistical Analysis.** Specimens were divided into five structural categories: epithelium and basal membrane (EBM); submucosa (SM); inner muscular layer (iM); outer muscular layer (oM); and adventitia (AD). For each substructure, four randomly chosen fields (one main field is subdivided in 5 × 5 subfields = 25 subfields) were counted at 400× magnification (Leica light microscope DM RB attached to a digital camera [Nikon N 90]). Because the amount of ACEase positive staining was not countable, as the other nerve quantities, the ACEase stain changes were quantified with Adobe Photoshop 4.0 (Adobe Systems Incorporated, Mountain View, CA) installed on a Power Macintosh 7500/100 (Apple Computer, Inc. Cupertino, CA). The ratio of ACEase-positive pixels to the total number of pixels yielded a percentage. The mean of four areas

was used to compare the differences among groups with the Mann-Whitney U test (GB-STAT, Dynamic Microsystems Inc., Silver Spring, MD). Values were considered significant at $p<0.05$ (In Tables 8–15 significant results are marked by $*p<0.05$; – = no animals in this subgroup, whereas 0 = no immune reactive (IR) nerve stain was seen).

Light Microscopy Staining Results: PGP 9.5. *Virgin Controls*. The urothelial surface and the basal membrane were strongly stained in all specimens. Therefore, the staining pattern in the epithelium and basal membrane was not analyzed because it was impossible to recognize individually stained nerves (Table 5.8).

In all specimens, PGP 9.5-IR-positive nerves were seen surrounding small vessels, and were present in higher numbers around larger veins in the bladder neck and mid-urethra. Within the smooth muscle, more nerves were noted in the mid-urethra, fewer in the bladder neck, and fewer still in the bladder. A higher number of IR-positive nerves was found in the inner muscle layer in the bladder neck and mid-urethra and in the outer muscle layer of the bladder. In the mid-urethra, more PGP 9.5-IR-positive nerves were seen in the smooth muscle than in the striated muscle (Table 5.8, virgin).

Groups I–IV. In the bladder, a statistically significant decrease was noted in both inner and outer layers of the muscle in groups II, III and IV. Both ballooning (group II) and ovariectomy (group III) decreased PGP 9.5-IR-positive nerves. The combination of ballooning and ovariectomy (group IV) eliminated PGP 9.5 completely (Table 5.8a).

Table 5.8. Protein gene product 9.5

Bladder	EBM[a] c:i	SM c:i	iM c:i	oM c:i	AD c:i
Virgin	0:–	0:–	15:–	29:–	1:–
Group I	0:0	1:1	16:13.5	19:7	3:0
Group II	0:0	0.5:3.3	6:7.3	6:7.7	1:0.3
Group III	0:0	0:0	6:4.5*	3.5:6.5*	0:1
Group IV	0:0	0:0	0:0*	0:0*	0:0
Bladder neck	**EBM c:i**	**SM c:i**	**iM c:i**	**oM c:i**	**AD c:i**
Virgin	0:–	5:–	37:–	14.5:–	6.0:–
Group I	0:0	0:0*	12.7:8*	20:8	4.7:4
Group II	0:0	0:0*	2:2.3*	4:7*	1:2*
Group III	0:0	0:0*	6.5:6*	7.5:8*	2.5:1*
Group IV	0:0	0:0*	3:0*	4:3*	1:1*
Mid-urethra	**EBM c:i**	**SM c:i**	**iM c:i**	**oM c:i**	**AD c:i**
Virgin	0:–	9.5:–	52:–	13.5:–	6:–
Group I	0:0	4.3:2*	40:12	8:10	7.3:0
Group II	0:0	1.5:4.3*	31.5:32.6	8:4.3	4:3.3*
Group III	0:0	2:–*	12.5:29*	10.5:12	4.5:4*
Group IV	0:0	0:3.5*	10:21*	3:3.5*	4:3*

* $p<0.05$ compared with virgin.
For descriptions of the groups, see text.
[a] Anti-PGP 9.5 immunoreactivity was strongly positive in the epithelium and basal membrane of all three anatomic sections, although no nerves were observed.

In the bladder neck, PGP 9.5-IR-positive nerves were significantly decreased in the submucosa and inner muscle layer in all groups. A significant change was also noted in the outer muscle layer and adventitia of groups II, III and IV (Table 5.8b).

In the mid-urethra, there was a significant decrease in PGP 9.5-IR-positive nerve fibers in the submucosa of groups I–IV and a significant decrease in all layers in group IV (Table 5.8C).

Light Microscopy Staining Results: CGRP. *Virgin Controls*. In the muscle layers the number of PGP 9.5-IR-positive nerves, as noted above, was higher than the number of CGRP-IR-positive nerves. However, directly beneath the basal membrane a large number of CGRP-IR-positive nerves were apparent in the three sections, as opposed to very few PGP 9.5-IR-positive nerves or none. The nerve trunks, which demonstrated high immunoreactive positive PGP 9.5 staining in the muscle layers and adventitia, had a lower percentage of CGRP-IR-positive nerves (Table 5.9).

IR-positive nerves were mainly seen in the smooth muscle bundles, less frequently around the striated muscles in the urethra and very infrequently around vessels. When comparing the three tissue sections, more CGRP-IR-positive nerves were seen in the bladder neck and mid-urethra than in the bladder (Table 5.9, virgin, Figs. 5.14a, 5.15a).

Groups I–IV. In the bladder, CGRP-IR-positive nerves were significantly decreased in the inner muscle layer of all groups (I–IV) and in the outer muscle layer of groups II–IV. IR-positive stained nerve trunks showed a decrease in CGRP. The submucosa

Table 5.9. Calcitonin gene-related peptide

Bladder	EBM c:i	SM c:i	iM c:i	oM c:i	AD c:i
Virgin	6.5:–	5:–	9:–	9:–	5:–
Group I	8.6:5	5.3:4	6:6*	10.6:6	4:2
Group II	4:3.3	7:4.7	5:4.7*	7:5	3.5:3.3
Group III	9.3:3	2.3:2*	5:6*	4.7:4*	4.7:5
Group IV	5:2	3:2.5*	5:3.5*	6:5*	1:2.5
Bladder neck	**EBM c:i**	**SM c:i**	**iM c:i**	**oM c:i**	**AD c:i**
Virgin	25.5:–	12:–	18.5:–	11:–	5.5:–
Group I	23.7:18	12.3:9	11.3:7*	8:5*	5:4
Group II	20:23.3	5.5:8.7	5:5.3*	8.5:7*	5.5:5.7
Group III	26:20	11:11	6.5:6*	7.5:8*	3:3
Group IV	31:7.5	11:8	8:6*	7:7	3:5
Mid-urethra	**EBM c:i**	**SM c:i**	**iM c:i**	**oM c:i**	**AD c:i**
Virgin	20.5:–	15.5:–	13.5:–	11.5:–	6.0:–
Group I	26.3:17	18.3:18	8.3:6*	10.3:8	11:4
Group II	11:7.7*	11:15	5.5:5*	4:4.7*	4.5:5.7
Group III	10.3:15*	14.3:18	3.7:5*	2.3:4*	1.3:5
Group IV	10:13.5*	14:12.5	5:4*	4:2.5*	4:5.5

*$p<0.05$ compared with virgin.
For descriptions of the groups, see text.

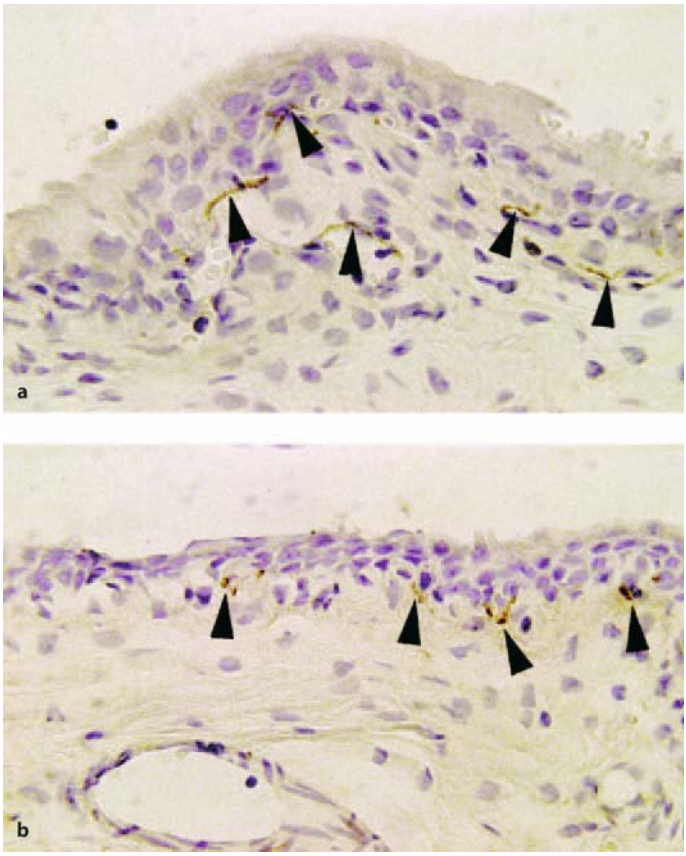

Fig. 5.14a, b. Basal membrane of the bladder comparing CGRP-positive nerves (*arrowheads*) of virgin (**a**) and group II animals (delivered + ballooned) (**b**) where no difference is seen. (*arrowheads* point towards the nerves, magnification 63×)

demonstrated a decrease in CGRP-IR-positive nerves in groups III and IV, suggesting an influence from ovariectomy (Table 5.9a, Fig. 5.14b).

In the bladder neck, there was a significant decrease in CGRP-IR-positive nerves in the muscle layers of groups I–IV (Table 5.9b). Similar results were seen in the mid-urethra. Additionally, the number of IR-positive nerves was significantly reduced beneath the basal membrane of groups II–IV (Table 5.9c, Fig. 15b).

■ **Light Microscopy Staining Results: SP.** *Virgin Controls*. SP-IR-positive nerves were seen in similar locations as CGRP-IR-positive nerves, but in much lower numbers. Higher numbers of SP-IR-positive nerves were counted in the muscle bundles of the bladder neck than the mid-urethra (Table 5.10, virgin, Fig. 5.16a).

Groups I–IV. A statistically significant decrease in SP-IR-positive nerves was seen in the inner muscle layers of the bladder in all groups. A significant decrease in SP directly beneath the basal membrane (Table 5.10), which was not demonstrable with the other stains, was noted in all four groups. Similar results were seen in the bladder neck (Table 5.10).

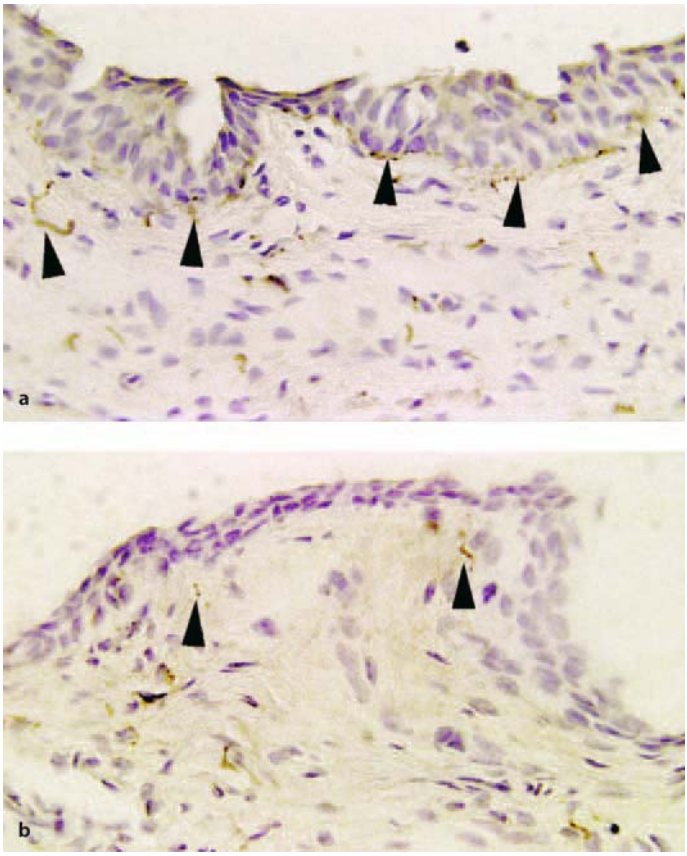

Fig. 5.15a, b. Basal membrane of the urethra comparing CGRP-positive nerves (*arrowheads*) of virgin (**a**) and group II animals (delivered + ballooned) (**b**) where the number of nerves is significantly reduced (magnification 63×)

In the urethra, the number of SP-IR-positive nerves beneath the basal membrane and in the submucosa decreased in groups II–IV, with the exception of the submucosa of group III. The changes in the submucosa seem to be related to ballooning (groups II and IV) (Table 5.10, Fig. 5.16b).

■ **Light Microscopy Staining Results: nNOS.** Neuronal NOS-IR-positive nerves were seen in the bladder neck and mid-urethra, but rarely in the bladder.

Virgin Controls. In the bladder neck, nNOS-IR-positive nerves were mainly observed in the smooth muscle layer as terminals accompanying the muscle bundles. In addition to the high concentration in the inner smooth muscle layer of the mid-urethra, n-NOS-IR-positive nerves were detected around circular smooth muscle cells and only a few around the striated muscle cells (Table 5.11, Fig. 5.17a).

Groups I–IV. In the bladder neck, nNOS-IR-positive nerves were decreased in all four groups, except in group III. In group II only a few nNOS-IR-positive nerves were observed (Table 5.11).

Table 5.10. Substance P

Bladder	EBM c:i	SM c:i	iM c:i	oM c:i	AD c:i
Virgin	7.3:–	3:–	1.6:–	5:–	2:–
Group I	1.6:0*	1.6:0	1.3:1*	3.3:2	0.7:0
Group II	0.5:1.6*	0:1.3	1:1.6*	1.3:1.3	0:0.3
Group III	1:0*	0.6:0	1.6:0	1.6:0*	0:0
Group IV	3:0.5*	2:0	2:0.5*	3:2	4:0
Bladder neck	**EBM c:i**	**SM c:i**	**iM c:i**	**oM c:i**	**AD c:i**
Virgin	14:–	5:–	6.3:–	13.3:–	1.3:–
Group I	8:5*	3.3:2	2:1*	5:3*	2.3:0
Group II	7:6.6*	2.3:2.3	1.2:2.3*	3:5*	1:1.3
Group III	6.6:9*	2:2	1.6:3*	4.3:4*	1.6:1
Group IV	7:7.5*	3:3	3:1*	6:4.5*	1:2.5
Mid-urethra	**EBM c:i**	**SM c:i**	**iM c:i**	**oM c:i**	**AD c:i**
Virgin	15.6:–	7:–	3.3:–	2.6:–	0.3:–
Group I	9:5	7:2	3.6:3	5.3:2	2.6:0
Group II	2:5.3*	1.5:3.6*	0.5:2.3	0:1.6	0:0.3
Group III	3:5.3*	5.5:7	2.5:3	1.5:1	1.5:2
Group IV	0:1*	2:1.5*	1:1.5	1:1	0:1

*$p<0.05$ compared with virgin.
For descriptions of the groups, see text.

The findings in the mid-urethra were similar. The decrease in nNOS was seen not only in the muscle bundles but also around the arteries. The basal membrane did not show any nNOS-IR-positive nerves in groups I–IV (Table 5.11, Fig. 5.17 b).

Light Microscopy Staining Results: NPY. *Virgin Controls*. In the bladder, all substructures demonstrated NPY immunoreactivity. The highest concentration was seen in the muscle layers (equally in inner and outer layers). In the bladder neck and mid-urethra, the number of NPY-IR-positive nerves was higher than in the bladder, as seen in most of the previously described neuropeptides. NPY terminals surrounded arteries in all specimens (bladder, bladder neck and urethra). The bladder neck, and especially the urethra, demonstrated large venous plexuses with terminal nerve endings. The striated muscle of the outer muscular layer had far fewer NPY-IR-positive nerves than did the smooth muscle bundles of this layer. Mainly NPY-IR-positive nerve trunks of the adventitia passed through the outer muscle layer and some through the inner muscle layer to innervate the submucosa and basal membrane (Table 5.12, virgin).

Groups I–IV. In the bladder, NPY-IR-positive nerves in the muscle layers decreased significantly in all four groups (Table 5.12).

In the bladder neck and mid-urethra, a significant decrease in NPY-IR-positive nerves was seen in the muscle layers and the submucosa, specifically around small vessels (Table 5.12).

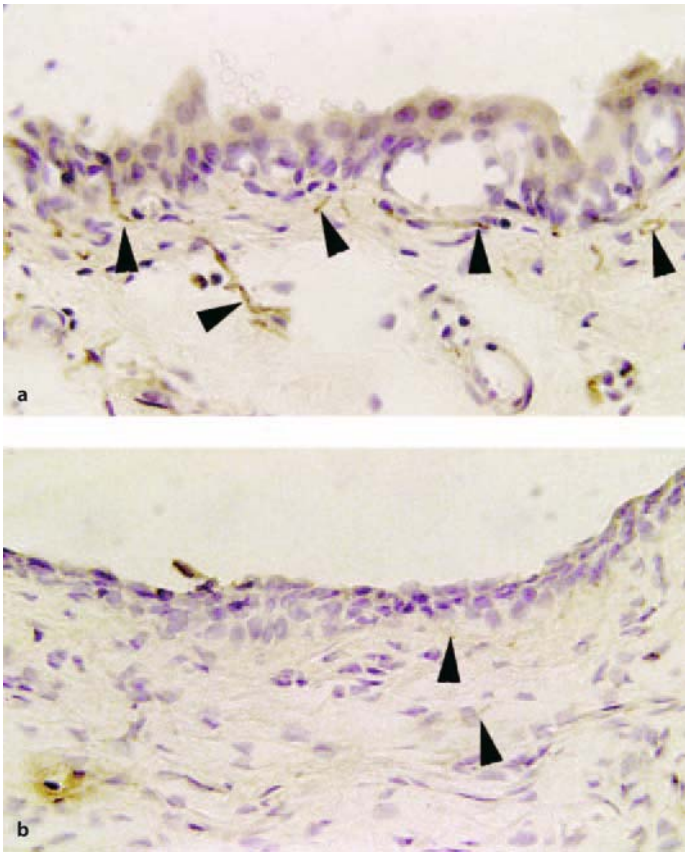

Fig. 5.16a, b. SP-IR-positive nerves (*arrowheads*) beneath and in the basal membrane of the urethra of virgin animals (**a**) were remarkably reduced by treatments, as shown in group IV (delivered + ballooned + ovariectomized) (**b**) (magnification 40 ×)

In the urethra, the NPY terminals were significantly reduced directly beneath the basal membrane in groups I–IV (Table 5.12).

■ **Light Microscopy Staining Results: VIP.** *Virgin Controls*. Very few VIP-IR-positive nerves were observed in the bladder and the bladder neck, which were small in diameter (Table 5.13, virgin). The main location was beneath the basal membrane and in the muscle layer. In the mid-urethra, as in the bladder neck, a similar ratio between the single substructures was demonstrated. The main VIP-IR-positive nerves were seen in the wall of small arteries and around the smooth muscle bundles. Large veins around the outer muscular layer did not demonstrate any nerve terminals. The numbers of VIP-IR-positive nerves were lower than nNOS- and NPY-IR-positive nerves.

Groups I–IV. In the inner muscular layer of the urethra, delivery (group I) caused a significant decrease in VIP with an additional slight decrease after ballooning (groups II and IV). The ballooning decreased VIP-IR-positive nerves beneath the basal membrane and the submucosa, whereas in the outer muscular layer, a significant decrease was recognized for groups II–IV. As noted in virgin animals, VIP nerves were rarely

Table 5.11. Neuronal nitric oxide synthase

Bladder	EBM c:i	SM c:i	iM c:i	oM c:i	AD c:i
Virgin	0:–	0:–	0:–	0:–	0:–
Group I	0:0	0:0	0:0	0:0	0:0
Group II	0:0	0:0	0:0	0:0	0:0
Group III	0:0	0:0	0:0	0:0	0:0
Group IV	0:0	0:0	0:0	0:0	0:0
Bladder neck	**EBM c:i**	**SM c:i**	**iM c:i**	**oM c:i**	**AD c:i**
Virgin	14.3:–	5:–	18:–	15.6 / -	4.6:–
Group I	2:0*	0:0*	4.5 / 6*	3.5 / 1*	0.5 / 2*
Group II	0:0	0:0	0:0	0:0	0:0
Group III	9:10*	1:1*	2:4*	5:9	0:0*
Group IV	4:3.5*	0:0*	0:0*	2:1*	3:0*
Mid-urethra	**EBM c:i**	**SM c:i**	**iM c:i**	**oM c:i**	**AD c:i**
Virgin	12:–	15.3:–	29.3:–	33.6:–	5.6:–
Group I	0:0*	2:3*	2:6*	6:3.3*	1:2
Group II	0:0*	0.5:0.5*	3:5*	1.5:3.5*	1.5:2*
Group III	0:0*	1:0*	3.6:1*	1.6:0*	1:1*
Group IV	0:0*	1:0.5*	0:2.5*	1:1.5*	0:1.5*

*$p<0.05$ compared with virgin.
For descriptions of the groups, see text.

seen in all groups. When present, they were found especially around small arteries (Table 5.13).

■ **Light Microscopy Staining Results: ACEase.** *Virgin Controls*. A large number of ACEase-positive nerves was found, with similar distributions in the bladder, bladder neck and mid-urethra. In the musculature, ACEase-positive nerves supplied the muscle bundles, equally in the smooth and striated muscle of the urethra, encircling small arteries or running along the urothelium. ACEase-positive nerve trunks from the adventitia were seen traversing between the muscle bundles. The number of ACEase-positive nerves was similar to the number of PGP 9.5-IR-positive nerves, but they were seen additionally as individual nerves directly beneath the basal membrane. Because of the staining on the endplates in the muscular layers, which made comparison difficult, PhotoShop was used for analysis (Table 5.14, Fig. 5.18a).

Groups I–IV. No significant change was noted in the bladder (Table 5.14a). A significant increase directly beneath the basal membrane of groups III and IV (Table 5.14b) was noted in the bladder neck. In the mid-urethra, both muscle layers showed a significant decrease in ACEase in groups I–IV (Table 5.14, Fig. 5.18b).

■ **Light Microscopy Staining Results: TH.** *Virgin Controls*. TH-IR-positive nerves were mainly seen within the smooth muscle bundles and vessel wall. They were occasionally seen around the striated muscles in the mid-urethra. More TH-IR-positive

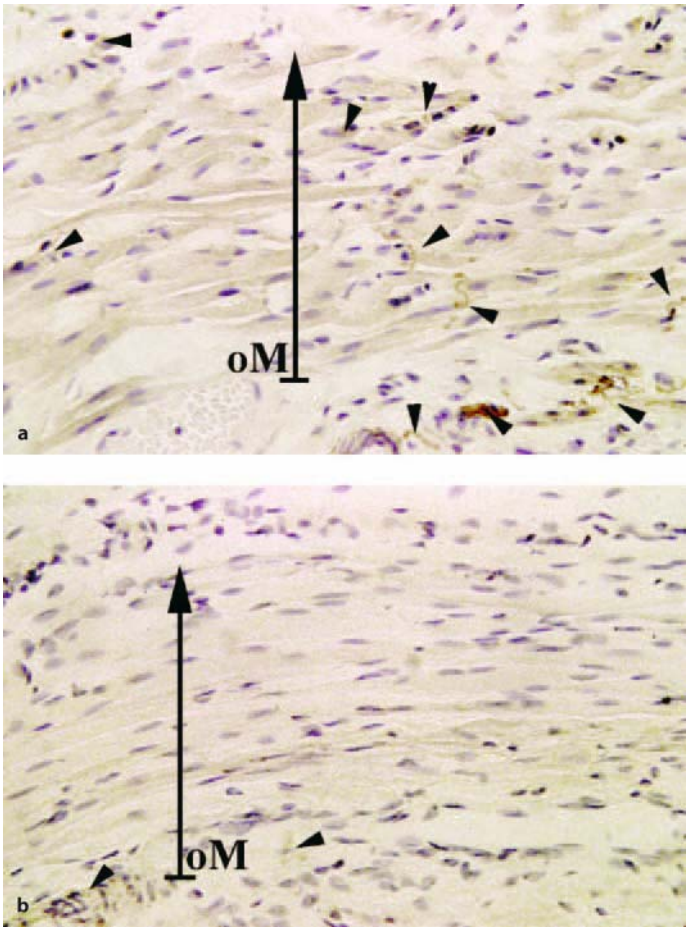

Fig. 5.17a, b. The treatment of group IV (delivered + ballooned + ovariectomized) (**b**) caused nearly a complete loss of nNOS-IR-positive nerves (*arrowheads*), which were demonstrated in the urethra of virgin animals (**a**). The *arrows* mark the direction through the outer muscle layer (oM) (magnification 63×)

nerves were seen in the mid-urethra (Table 5.15, virgin, Fig. 5.19a) and bladder neck than in the bladder.

Groups I–IV. In the bladder, TH-IR-positive nerves were significantly decreased in both muscle layers of all groups (I–IV). In the submucosa, a decrease in TH-IR-positive nerves was noted in groups I, II and IV (Table 5.15).

In the bladder neck, there was a significant decrease in TH-IR staining in both muscle layers of groups I–IV (Table 5.15).

In mid-urethra, the main change was seen in the smooth muscle cells of groups II and IV as the result of the ballooning. The most striking change was the almost complete loss of TH-IR-positive nerves in the circular smooth muscle layer (Table 5.15, Fig. 5.19b).

Table 5.12. Neuropeptide Y[a]

Bladder	EBM c:i	SM c:i	iM c:i	oM c:i	AD c:i
Virgin	4.3:–	0.6:–	31:–	27:–	2:–
Group I	1:0	1.6:1	3.3:2*	4.6:3*	3.3:0
Group II	0:0.3	0.5:1.3	2:3.6*	1:6*	0:0.3
Group III	0.6:0	1.6:1	3.6:2*	4:5*	1.6:0
Group IV	1:0	1:1	2:2.5*	2:2*	0:1.5
Bladder neck	**EBM c:i**	**SM c:i**	**iM c:i**	**oM c:i**	**AD c:i**
Virgin	4:–	4:–	40.3:–	14.6:–	3.6:–
Group I	3:2	1.3:1*	5:5*	7.3:10*	2.6:4
Group II	1:2	0.5:0.5*	2.5:2.5*	8:8*	0.5:1.5
Group III	4:1	1.3:1*	3.3:4*	7.3:10*	2.6:2
Group IV	3:3	1:1.5*	4:5*	7:7.5*	2:2.5
Mid-urethra	**EBM c:i**	**SM c:i**	**iM c:i**	**oM c:i**	**AD c:i**
Virgin	7:–	9.3:–	53.6:–	7.3:–	3.6:–
Group I	3.6:1*	1.6:1*	22.6:17*	1.6:3	3.3:3
Group II	3.5:3	1.5:1*	21:18.5*	2.5:1.5	1:1.5*
Group III	1:2*	1:3*	20.6:21*	0.6:2*	1.3:2
Group IV	3:2.5*	1:2*	18:18.5*	2:1*	0:2.5

* $p<0.05$ compared with virgin.
For descriptions of the groups, see text.
[a] NPY, mainly seen in the muscle layers of all three tissue-sections, was significantly decreased by labor (group I). In the urethra, results became significant after additional of ovariectomy (group III). Fewer NPY-positive nerves around vessels caused the changes in the submucosa.

5.4 Discussion

A rat model to study stress urinary incontinence was first reported by Lin et al. (1998). However, the model has been criticized because the study was performed in virgin rats and balloon dilation was not modified: i.e., the direction of the force of the balloon in a quadruped might reasonably be expected to differ from the force a fetus exerts in a woman. In the present study, pregnant rats were used for the experiments and the balloon was attached to weighted traction to direct the force to the pelvic floor. To permit normal delivery, the balloon dilation was performed immediately after birth when the tissue in the pelvis was still relaxed. One may argue that this differs from a prolonged second stage of labor that occurs in humans. However, we believe this modified model is adequate for studying the effect of delivery, difficult labor, and ovariectomy on the continence mechanism.

The effect of birth trauma and menopause on the urinary tract is well known. Clinically, symptoms such as frequency, urgency, retention, and incomplete voiding occur often. After vaginal delivery, a large percentage of women experience stress urinary incontinence; in some cases, this persists even after 12 months.

Table 5.13. Vasoactive intestinal polypeptide

Bladder	EBM c:i	SM c:i	iM c:i	oM c:i	AD c:i
Virgin	0:–	0:–	0.6:–	1:–*	0:–
Group I	0:0	0:0	0:0	0:0	0:0
Group II	0:0	0:0	0:0	0:0	0:0
Group III	0:0	0:0	0:0	0:0	0:0
Group IV	0:0	0:0	0:0	0:0	0:0
Bladder neck	**EBM c:i**	**SM c:i**	**iM c:i**	**oM c:i**	**AD c:i**
Virgin	3.3:–	0.6:–	2:–	0.3:–	0:–
Group I	0:0	0:0	0:0	0:0	0:0
Group II	0:0	0:0	0:0	0:0	0:0
Group III	0:0	0:0	0:0	0:0	0:0
Group IV	0:0	0:0	0:0	0:0	0:0
Mid-urethra	**EBM c:i**	**SM c:i**	**iM c:i**	**oM c:i**	**AD c:i**
Virgin	8:–	4.3:–	20.6:–	2.6:–	0:–
Group I		4.3:3	4.5:4	2.5:3	3:0
Group II	1:0.5	2:1.5	4:2.5*	1:1*	1:1
Group III	4.3:6	3.3:5	4.3:4*	0.3:1*	1:1
Group IV	1:2.5*	0:2.5	2:4*	1:0.5*	0:1.5

* $p<0.05$ compared with virgin.
For descriptions of the groups, see text.

In Part I of this study, increased bladder capacity, decreased micturition pressure, and higher residual volume were observed during pregnancy. On the other hand, residual volume was decreased in 2-day postpartum rats. In Part II, incontinence was noted in 29% of rats on the day of delivery, and this decreased to 16% at 8 weeks postpartum. However, in group II (delivery and ballooning) and group IV (delivery, ballooning, and ovariectomy), the rate of incontinence increased to 58% and 71%, respectively (Part II, Table 5.5). One might hypothesize that, although the injury to the continence mechanism is relatively minor after a normal delivery, the ischemia caused by prolonged pressure and intravaginal ballooning can aggravate the injury and cause irreversible damage to the urethra and levator. Interestingly, delivery and ovariectomy did not result in a higher incontinence rate than did delivery alone.

The effect of hormone deficiency is intriguing. It is possible that a relatively healthy continence mechanism can be compensatory. However, if tissue damage is severe enough, the added hormone deficiency may significantly impact the continence mechanism. This may explain some of the inconsistent reports in women given hormone therapy for incontinence. Nevertheless, the exact mechanism requires further investigation.

In 20 patients, in whom Kerr-Wilson et al. performed cystoscopy and cystometry at 48 h postpartum (Kerr-Wilson et al. 1984), those who had undergone vaginal delivery had greater bladder capacity and lesser bladder tone than those who had undergone cesarean section. In an experimental study, Hsia et al. found that pregnant rats had higher bladder compliance and capacity than non-pregnant rats (Hsia and Shortliffe

Table 5.14. Acetylcholinesterase (ACEase)

Bladder	EBM c:i	SM c:i	iM (%) c:i	oM (%) c:i	AD c:i
Virgin	0.3:–	3.3:–	9.6:–	6.2:–	1.3:–
Group I	0.6:0	2:2	9:6.5	6.4:2.2	1:0
Group II	0.5:0	2:1.6	7.7:9.2	9:11.4	0:0.6
Group III	0.6:0	1.3:0	9.7:6.7	6.8:5.5	2:0
Group IV	0:0	2:1	12.6:9.6	5.3:4.3	0:0.5
Bladder neck	**EBM c:i**	**SM c:i**	**iM (%) c:i**	**oM (%) c:i**	**AD c:i**
Virgin	2.5:–	3:–	4.1:–	8.2:–	3:–
Group I	7:3	2.6:2	4.8:4.1	7.2:2.8	3.6:3
Group II	6:5.3	2:2.3	2.8:10.6	5.2:6.1	3:3.6
Group III	6.3:7*	2.6:3	4.6:14.1	4.3:10.6	3:3.6
Group IV	5:7.5*	2:3	7.8:4.5	3.2:4.9	5:2.5
Mid-urethra	**EBM c:i**	**SM c:i**	**iM (%) c:i**	**oM (%) c:i**	**AD c:i**
Virgin	2.5:–	3:–	8.6:–	8.6:–	4.3:–
Group I	3:2	4.6:3	2.7:1.8*	1.4:3.4*	5.3:5
Group II	1:0.3	3.5:2	4:2.5*	3:4.1*	3.5:3.3
Group III	1.3:2	4.7±0.3	5.4:5.6*	3.7:4.8*	4.6:3
Group IV	1:1	2:3.5	2.7:2.7*	3.5:3*	6:3.5

* $p<0.05$ compared with virgin.
For descriptions of the groups, see text.

1995), and they suggested that this finding might result from hormonal changes rather than from the obstructive effect of the uterus. Kostrzewska further suggested that hormones relax the smooth muscle of the urinary tract (Kostrzewska et al. 1993). In our study, we observed increased bladder capacity and decreased modified leak-point pressure (mLLP) on the day of delivery in all rats (Part II, Table 5.1). Except in group I, both the bladder capacity and mLPP returned to levels similar to those in virgin rats after 8 weeks. Why bladder capacity increased in group I rats is unknown. Although mLPP here is a measurement at the time of overflow incontinence, it nevertheless provides a consistent method of continence assessment in addition to the stress/sneeze test. Electrostimulation of the pelvic nerve and conscious voiding were not performed because the study by Lin et al. showed damage to the pelvic ganglion in ballooned rats and comparison between different groups would be difficult (Lin et al. 1998).

After finding similar results in the female human and even being able to increase the functional damage, as after heavy labor, the main change was expected to be in the muscle cell. Therefore we investigated caveolae and its component caveolin as an imported cell organ at the cell membrane. Caveolae are 50- to 100-nm membrane microdomains representing a subcompartment of the plasma membrane (Lisanti et al. 1994; Yamada 1955). These microdomains can sequester membrane-bound ligands away from the extracellular space and facilitate their delivery to the cytoplasm of the cell. This process is called potocytosis (Anderson et al. 1992). What distinguishes it from other endocytic pathways is the use of glycosylphosphatidylinositol (GPI)-anchored membrane proteins to concentrate low-molecular-weight molecules and ions in the

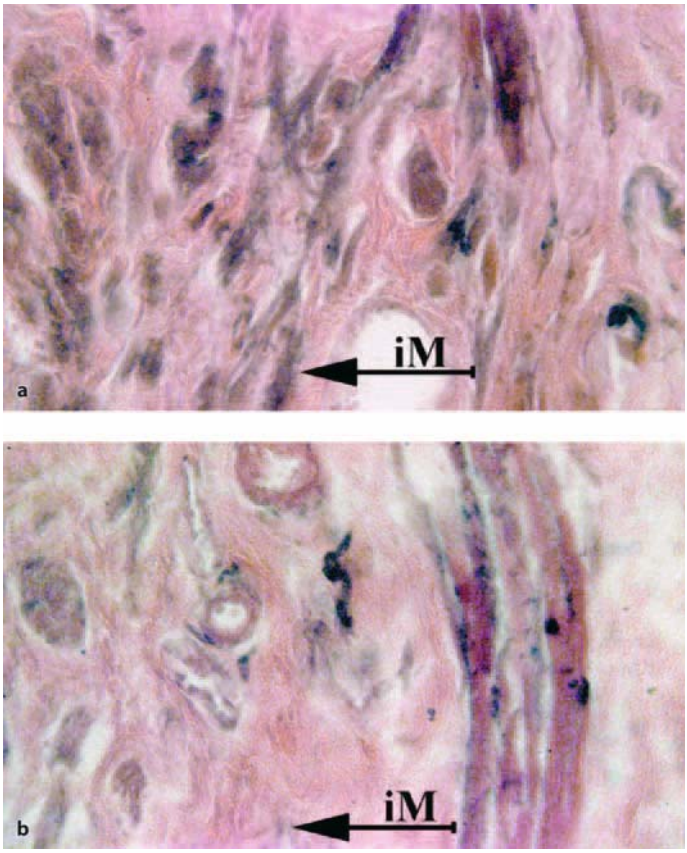

Fig. 5.18a, b. A comparison between virgin (**a**) and group IV (delivered + ballooned + ovariectomized) (**b**) urethral muscle layers (magnification 40×). The *arrows* mark the beginning of the inner muscle layer (iM). The loss of ACEase is demonstrated in group IV

closed caveolae. Another potential function for potocytosis is to receive or transmit various kinds of cellular signals such as signaling molecules derived from GPI-anchored membrane molecules. GPI-anchored membrane proteins have been implicated as the source of inositolphosphoglycans, which act as second messengers for a variety of hormones (Romero et al. 1988; Saltiel and Sorbara-Cazan 1987). In addition, 1,4,5-triphosphate (IP_3)-sensitive calcium channels and an adenosine triphosphate-dependent calcium pump have recently been localized to caveolae, which suggests a role for potocytosis in calcium signaling (Fujimoto 1993). The present results showed a decreased number of sarcolemmal vacuoles in groups II–IV in both the bladder and urethral smooth muscles. By impairing calcium signaling, the decrease in caveolae may contribute to a higher incontinence rate. Interestingly, in group III, the number of caveolae increased significantly in the bladder neck, corresponding to the lower rate of incontinence in this group. This compensatory increase in caveolae in the ovariectomized rats warrants further investigation.

Caveolin is a 21- to 24-kDa integral membrane protein and is an important structural and regulatory component of caveolae membranes that was first identified as a major-scr substrate in Rous sarcoma virus-transformed cells (Rothberg et al. 1992). Cave-

Table 5.15. Tyrosine hydroxylase[a]

Bladder	EBM c:i	SM c:i	iM (%) c:i	oM (%) c:i	AD c:i
Virgin	–:–	4.3:–	8.0:–	13:–	9.3:–
Group I	–:–	1.3:0*	3.3:1*	3:0*	2.3:0*
Group II	–:–	1:0.3*	0:0*	0:0.7*	0:1*
Group III	–:–	2.5:3	0.5:1*	2:2*	1:2*
Group IV	–:–	1:1.5*	1:1*	0:2*	2:0.5*
Bladder neck	**EBM c:i**	**SM c:i**	**iM (%) c:i**	**oM (%) c:i**	**AD c:i**
Virgin	–:–	13:–	16.7:–	11.7:–	7:–
Group I	–:–	2:1*	1:0*	1:0*	1.6:0*
Group II	–:–	1.5:1.5*	0:0*	1:1*	1:0.5
Group III	–:–	4.5:10	0.5:1*	1/3*	1:2
Group IV	–:–	8:3.5*	0:1*	1:2.5*	0:3*
Mid-urethra	**EBM c:i**	**SM c:i**	**iM (%) c:i**	**oM (%) c:i**	**AD c:i**
Virgin	–:–	1.7:–	44.7:–	4:–	7:–
Group I	–:–	0.3:1	34.7:22	1:1	2.7:3*
Group II	–:–	0:0*	19.5:18.7*	1:1.7	0.5:1.3*
Group III	–:–	1.5:1	36.5:23.5	2.5:3	4.5:1
Group IV	–:–	1:1	17.5:14*	2.5:2	2:2*

* $p<0.05$ compared with virgin.
For descriptions of the groups, see text.
[a] Although labor seemed to decrease the number of TH-positive nerves in the bladder and bladder neck, the main change was seen in the mid-urethra, where almost no TH-positive nerves were observed after labor in the circular smooth muscle layer.

olin may also act as a scaffolding protein within caveolae membranes and may represent an important structural protein for directing their formation (Fujimoto 1993). Caveolin copurifies with a number of lipid-modified cytoplasmic signaling molecules, including G-protein, protein kinase Ca^{2+}, scr-family tyrosine kinases and ras proteins (Tang et al. 1997). Recently, the family of caveolin-related proteins grew: caveolin-1 (with the isoforms a and b), -2, and -3. Caveolin-1 is found in endothelial cells, fibroblasts, adipocytes and smooth muscles, while caveolin-3 is selectively expressed only in heart and skeletal muscle tissues (Glenney 1992; Romero et al. 1988; Breton et al. 1998; Tang et al. 1996).

A change in the staining pattern of caveolin-1 and a decrease in immunoreactivity was noted in urethral and bladder smooth muscle cells (in the urethra of groups I–IV and bladder of groups II–IV). The decrease in both the caveolin-1 protein and the number of caveolae in the above groups might be the reason for the decrease in muscle contraction force in the bladder and urethra. It should be noted that neither the percentage of caveolin-1 stain nor the architecture and staining pattern of the smooth muscle cells in the experimental rats returned to the condition of the virgin rats after 8 weeks.

Immunostaining demonstrates that caveolin-3 is localized to the sarcolemma of striated muscles and coincides with the distribution of dystrophin (Song et al. 1996; North et al. 1993). In the present study, caveolin-3 (analyzed in the mid-urethra) de-

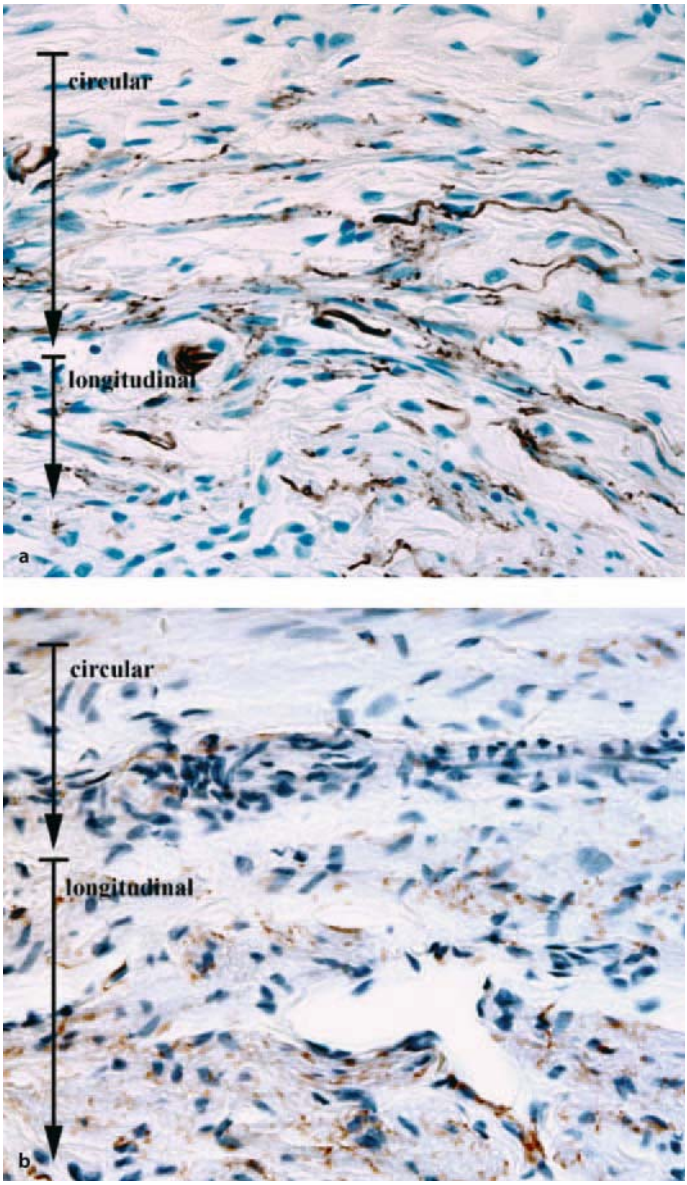

Fig. 5.19a, b. A comparison between virgin (**a**) and group II (delivered+ballooned) (**b**) urethral muscle layers (magnification 40 ×). The *arrows* mark the longitudinal and circular running layer of the smooth muscle (**b**), demonstrating the loss of TH-IR-positive nerves in group II as a result of the ballooning

creased significantly in groups II–IV, but not in group I. The significance of caveolin-1 and caveolin-3 in the continence mechanism is unknown. The demonstrated changes may contribute to stress incontinence: a decrease in membrane caveolae, caveolin-1 and -3, and smooth muscle cells as well as an increase in collagen content in the bladder neck and urethra.

As found on immunostaining, the decrease in caveolae in the smooth muscle cells was also demonstrable by electron microscopy. One of the most striking features of the urethral smooth muscle of virgin rats was the rich presence of caveolae in the sarcolemma. Because the function of the caveolae is signal transduction and calcium transport (Fujimoto 1993; Tang et al. 1996; Sargiacomo et al. 1995), the abundance of caveolae and caveolin-1 assures adequate intracellular concentration of calcium ions and strong bladder and sphincter contraction. In pregnant rats, decreased caveolin-1 staining and protein expression may decrease the force of urethral muscle contraction and render the urethra more compressible by the enlarged uterus. The increase in protein expression and staining of caveolin-1 in the 2-day postpartum rats is intriguing. It may represent either a tissue response to the relief of mechanical compression or a change in hormonal environment. In the 6-week postpartum rats, although the caveolin staining and protein expression returned to the levels seen in virgin rats, the architecture of the urethral wall remained somewhat distorted. In contrast, overall intercellular space between smooth muscle groups returned to that found in virgin rats. Ultrastructural analysis also showed that the urethral smooth muscle cells from virgin rats were irregular and serrated, with narrow intercellular spaces. Wider intercellular spaces in the urethra of pregnant and postpartum rats may impair signal propagation and coordination among smooth muscle cells, which are important in the continence mechanism. Besides cell atrophy, an increase in connective tissue was demonstrated in groups II–IV.

The striated muscle of the external sphincter showed lipid droplets in the I-band and subsarcolemmal accumulation of mitochondria in the pregnant and 2-day postpartum rats. In one reported experimental study, the number and the size of subsarcolemmal mitochondria increased after 6–24 h of ischemia (Hanzlikova and Schiaffino 1977), and the authors concluded that an adaptation reaction of growth and multiplication occurs under extreme circumstances. The present results may represent a response to the stress of pregnancy and delivery.

Lipid droplets are not membrane-bound, and their number and size may vary considerably among different muscle types and in the same type of muscle in different areas of the body. They are frequently associated with mitochondria, and are sometimes completely encircled by a mitochondrion (Jennekens et al. 1981). It has been shown that experimental enzyme deficiencies in mitochondrial energy metabolism induce accumulation of giant mitochondria and numerous lipid droplets (Jennekens et al. 1981). This has led to the suggestion that mitochondria may use lipids as a source of energy for muscular contraction. The increased number of lipid droplets in the pregnant rats indicates that lipids may be an important energy source for striated muscle during pregnancy. With additional manipulation, the damage to the striated muscle cells became more obvious: e.g., a decrease in T-tubules and, in group IV, significantly fewer mitochondria and almost no lipid droplets.

Recent studies have shown that eNOS is associated with caveolin-1 in endothelial cells and nNOS with skeletal muscle caveolin-3 (Venema et al. 1997; Michel and Feron 1997). A dynamic model of the NOS-caveolin/calmodulin cycle has been proposed by Michel and Feron (1997): in the resting cell, the formation of the inhibitory NOS-caveolin complex suppresses NOS enzyme activity. After activation, the increase in intracellular calcium promotes calmodulin binding to NOS and dissociation of caveolin from NOS. The activated NOS-calmodulin complex synthesizes NO until intracellular calcium decreases to a point where calmodulin dissociates and the inhibitory NOS-caveolin complex reforms. The nNOS isoform is highly expressed in skeletal muscle, and thus it appears to be involved in modulating contractile force. Neuronal NOS has also

been postulated as one of the neurotransmitters involved in the relaxation of urethral sphincter muscle (Burnett 1995). The present study reveals a significant decrease in nNOS-IR-staining (groups I–IV), which suggests a decrease in enzyme activity. The nNOS isoform is highly expressed in skeletal muscle, and thus it appears to be involved in modulating contractile force. The significance of caveolin-1 and -3 in the continence mechanism is unknown. Theoretically, a decrease in caveolin would impair calcium transport and enhance NO production – both of which decrease sphincter function – and thus might contribute to urinary incontinence.

The present results of nerve locations for specific stains were similarly reported by other authors (Persson et al. 1995; Alm et al. 1995; Gosling 1985; el-Badawi and Schenk 1966; Radziszewski et al. 1996). PGP 9.5 is a general cytoplasmic nerve marker, which should be present in all types of efferent and afferent nerve fibers (Gulbenkian et al. 1987). In this study, PGP 9.5 was present in most nerve fibers, except beneath the basal membrane where heavy staining in the urothelium may have masked it. These findings are similar to the results of Alm et al. (1995). In addition, almost complete elimination of PGP 9.5-IR-positive nerves was noted in the muscular layer of the bladder and bladder neck after both ballooning and ovariectomy, although staining was positive for other neuropeptides.

The finding of nNOS-IR staining in the urethra and the bladder neck of virgin rats is comparable to reports by others (Alm et al. 1995; Andersson and Persson 1995; Burnett et al. 1992). However, as opposed to their description of low NOS immunoreactivity (Alm et al. 1995), a high number of nNOS-IR-positive nerves was seen in the smooth muscle bundles (inner and outer layers) of the urethra and bladder neck. In the delivered rats, a strong decrease in nNOS was noted in the bladder neck and urethra. The significance of these findings is unknown because the role of NO in urethral relaxation remains controversial (Werkstrom et al. 1998; Zhou and Ling 1999).

Comparison between ACEase and the immunostains was not useful because we analyzed ACEase content with Photoshop, which resulted in a percentage of the analyzed picture in the muscle layers.

The results of the double stain for TH and NOS were not found to coincide in exactly the same nerves (Werkstrom et al. 1998; Vizzard et al. 1994). The ballooning caused a significant decrease in TH-IR-positive nerves. In a previous report by others, treatment with 6-hydroxydopamine (6-OHDA) resulted in the complete absence of all TH-IR-positive nerves, mainly in the bladder base and urethra (Persson et al. 1997). The changes demonstrated here, especially the almost complete loss of TH-IR-positive nerves in the circular smooth muscle of the outer mid-urethral muscular layer, might be strong contributory factors in the functional origins of incontinence.

In the elegant study of Alm et al., the distribution of nitrergic, adrenergic, peptidergic, and cholinergic nerves in the lower urinary tract of the female rat is described in detail, as are the changes after bilateral pelvic cryoganglionectomy, preganglionic decentralization and intravesical obstruction. They report an almost complete loss of all nerves in the bladder and urethra after bilateral pelvic ganglionectomy and a selective decrease in CGRP after preganglionic decentralization. Intravesical outlet obstruction caused a significant decrease in PGP 9.5 and a nearly complete loss of NOS above the obstruction (Alm et al. 1995).

In animal studies with intravesical outlet obstruction, the results of sensory neuropeptide (VIP, CGRP, SP and NPY) changes are not consistent. Chapple et al. (Chapple et al. 1992) saw a reduction in the density of innervation of VIP, CGRP, and SP with no changes for NPY, whereas Lasanen et al. (1992) reported an increase in VIP-, NPY-, and SP-IR-positive nerves. As opposed to the obstructed animal model, no previous work

in an incontinence animal model has been described. Nevertheless, Gu et al. (1983) described a marked reduction of VIP in the bladder muscle layer of patients with idiopathic detrusor instability.

It is interesting that the present results are similar to those of Alm et al. (1995). As with bilateral pelvic cryoganglionectomy, a decrease was apparent in the staining of many of the neuropeptides studied. Because they did not describe the results in the substructures, a comparison is difficult to make. From the present results, it is apparent that delivery, ballooning and ovariectomy decrease the number of nerves in the bladder, bladder neck and urethra. Delivery and ballooning seem to have a damaging effect similar to that of pelvic cryoganglionectomy, but not as severe. In the previous study in virgin rats of Lin et al., the number of ganglion cells in the neural plexus posterolateral to the vagina was significantly decreased after ballooning (Lin et al. 1998). This may explain the similarity between the present results and those after pelvic cryoganglionectomy in the report of Alm et al. (1995).

Surprisingly, even a normal delivery (group I) altered the staining patterns both quantitatively and qualitatively. The effect was more pronounced in the mid-urethra and bladder neck, especially in the inner muscular layer where almost all the nitrergic and peptidergic nerve fibers were affected (PGP 9.5, CGRP, SP, nNOS and NPY in the bladder neck and CGRP, nNOS, NPY, VIP and cholinergic in the mid-urethra). Because the staining pattern in pregnant rats was not studied, one may argue that these changes may be attributed to pregnancy alone – and this cannot be totally excluded. However, in the previous study of Bakircioglu et al. (2000), no damage to the pelvic ganglion was noted during pregnancy. In addition, since similar decreases in IR-staining patterns for PGP 9.5, CGRP, SP, nNOS and NPY were noted after ballooning (group II), one may postulate that a normal delivery has a mini-ballooning effect on the continence mechanism, which explains the high incidence of incontinence immediately after birth in female rats and humans.

The present results fail to show a specific pattern of neuronal change associated with pregnancy, delivery, ovariectomy or a combination. Although a decrease in SP in the submucosa and a decrease in VIP in the basal membrane of the mid-urethra seem to correlate with ballooning, and a decrease in CGRP in the bladder submucosa suggests an influence from ovariectomy, these findings may be simply coincidental. Nevertheless, the most striking effect is the significant decrease in nNOS in all tissue layers in the bladder neck and mid-urethra in groups I–IV, making it the most sensitive indicator of tissue or nerve injury. The almost complete loss of TH-IR-positive nerves in the circular layer of the mid-urethra could also be contributory.

In summary, functional studies in a pregnant rat model demonstrated a large increase in the rate of incontinence in group II (delivery and ballooning) and group IV (delivery, ballooning and ovariectomy) animals. Ovariectomy appeared to have no effect when combined with delivery alone, but significantly increased the incontinence rate in rats that underwent delivery and ballooning. Ultrastructural and immunohistochemical studies revealed various degrees of changes in plasma membrane caveolae, caveolin-1 and -3 and nNOS. The increase of stress test-positive animals and the decrease of caveolin-1 and -3 – hypothesized to be important for the contractility of muscle cells (at least as it relates to calcium channels) – and the demonstrable increase in connective tissue caused by heavy birth trauma may explain the lack of necessity for further muscle relaxation. This may likewise explain the decrease in nNOS, i.e., a reaction to the caveolin decrease, and not a direct result of additional treatment(s).

The functional changes observed should not be directly attributed to the changes in immunostaining, which only demonstrate the quantitative changes in the nerve fiber

containing a particular neuropeptide. Given the complexity of the innervation of the lower urinary tract as well as the co-localization, co-transmission, cross-talk, and pre- and postsynaptic modulation of these neuropeptides, it is short-sighted to infer definitive functional significance. Nevertheless, this study may provide a stepping-stone for further exploration of the significance of neuropeptides in urinary incontinence.

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5

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Chapter 6

Birth Trauma and Incontinence

6

Ralf Tunn, Ursula Peschers

Contents

6.1 Morphological Canges of the Continence Controlling System of Urethra and Anus Caused by Pregnancy and Delivery

Morphofunctional causes for pregnancy- and delivery-related functional reduction of the urinary stress-continence controlling system and of the anal continence system can result from changes in the pudendal nerve conduction, a reduced contraction force of the pelvic floor muscles, a changed mobility of the bladder neck as a result of collagen tissue weakness, a changed resting tonus of the urethra or anus, continuity defects of the sphincter ani externus and/or internus or myotrophic changes of the sphincter ani internus muscle.

Retrospective histological examinations of cadavers have shown changes of morphology of the pelvic floor and urethra in correlation to parity, at which constitutional or age-related changes come in and cannot be distinguished. For the first time, magnetic resonance imaging makes it possible to examine the course of physiological and pathological changes in morphology of the urinary stress-continence system and the anal continence controlling system in the context of pregnancy and delivery. Therefore the following concentrates on results of the magnetic resonance imaging.

6.1.1 Urethra

No correlation could be found between parity and urethral diameter in urogynecologically healthy women with stress urinary incontinence (Tunn et al. 1998b). Six months after spontaneous delivery no significant changes in the anatomical length of the urethra, independent of parity, could be found (Hayat et al. 1996). There were no examinations to be found on the delivery-related changes of the zonal anatomy of the urethra.

6.1.2 Levator ani Muscle

Sequel examinations of the signal intensity of the levator ani muscle postpartum in correlation with the obturatorius internus (first day postpartum, 1,2 and 6 weeks postpartum) showed an increased signal intensity in the levator ani on the first day postpartum, a signal intensity expressing its chemical compound (Tunn et al. 1999). Some explanations for the increase in signal intensity are known: an elevated proportion of water or fat in muscle tissue, an increase in extracellular fluid or a glycogenolysis-related accumulation of tissue lactate (Fleckenstein et al. 1992, 1993; Schedel et al. 1995). By correlating histological examinations and those done by magnetic resonance imaging on striated muscle tissue, a heightened signal intensity could be shown as a result of a widened extracellular space and incomplete muscle fiber regeneration (Gejo et al. 2000), meaning reversible tissue changes. Signal intensity in primiparae diminished 6 weeks after delivery to values comparable to those of the obturatorius internus muscle through reconvalescence of the levator ani. In multiparae the starting point of signal intensity was reached again after 6 months only (Tunn et al. 1999). Comparable findings have been seen on striated muscle tissue after denervation and reinnervation (Uetani et al. 1993). In several observations, persistence of heightened signal intensity and total loss of the levator ani seemed possibly to be expressing the loss of striated muscle fibers after laceration, infarction or denervation, respectively, as has been seen in skeletal muscles by MRI (de Smet 1993; Khoury et al. 1997).

In the same observation period, there was no significant decrease in the thickness of the levator ani muscle, measured in transversal sections paravaginally at the level of the middle and proximal urethra (Tunn et al. 1998b).

6.1.3 Endopelvic Fascia

Delivery-caused changes of the endopelvic fascia that influence the preservation of continence are to be found between the lateral vaginal wall and the levator ani muscle at the level of the middle part of the urethra. They have to be examined with high-dissolution magnetic resonance imaging. Using examinations with MRI, Tunn et al. (1998a) observed that in the above-mentioned part of the endopelvic fascia, changes in signal intensity are caused by pregnancy and delivery. When high signal intensity was found with nulliparae in the tissue structures between the lateral vaginal walls and the levator ani muscle at the level of the middle part of the urethra, after spontaneous delivery they showed less signal intensity. These observations led the authors to hypothesize that the musculofascial connection between the lateral vaginal wall and the levator ani muscle develops this tissue quality only through pregnancy and delivery, whereas in nulliparae there are loose collagenous tissue structures found by MRI criteria. This hypothesis is supported by histomorphological findings in embryos and newborns, where a musculofascial connection in the sense of pubovaginal muscle could not be detected (Fritsch and Frohlich 1994). The missing transformation of the tissue quality could represent a predisposition for the development of stress urinary incontinence, as no musculofascial structure was detectable by MRI criteria in 25% of the examined women with stress urinary incontinence without genital descent and even in 40.9% of women with additional urogenital descent (Tunn et al. 1998b). No answer was found concerning whether the lateral defects of the endopelvic fascia are caused by delivery trauma or development failure.

6.1.4 Anal-Sphincter System

The anal-sphincter apparatus describes a functionally very complex system. Changes caused by traumatic delivery are mainly interpreted as endoanal sonographically detectable defects of the sphincter ani externus and internus muscle. In everyday clinical routine, large defects can even be detected by inspection when finding a missing anal rosette, a weak sphincter tension can be noted by digital examination; often the morphological defect can even be palpated. Within the scope of extended diagnostics, a changed conduction speed of the pudendal nerve can lead to the neurogenic cause of the anal incontinence. The puborectal sling greatly helps the preservation of anal continence; functional restrictions can be clinically interpreted as one- or two-sided levator weakness, without the possibility of discriminating it from the ventral parts of the levator. Therefore morphological changes of the puborectal sling caused by pregnancy and delivery are equal to those of the ventral parts of the levator ani, as described above.

6.2 Birth Trauma and Prevalence Incontinence

6.2.1 Prevalence of Urinary Incontinence

The prevalence of urinary incontinence after pregnancy and delivery is given at 3.7%–15.2% as shown by analysis of the English Medline literature (analysis period from 1983 to 1997; Schuessler and Baessler 1998). This literature rarely distinguishes the influence of pregnancy and delivery separately from each other after vaginal delivery. In the course of the Norwegian EPINCONT study, Rortveit et al. (2003b) stated higher prevalence rates, probably because of the age of the questioned participants: 21% of the women questioned complained of urinary incontinence in connection with vaginal deliveries (odds ratio, 2.3), 8.7% were classified with severe urinary incontinence, after cesarean section the rate rose to 15% and 6.2%, respectively (odds ratio, 1.5). In the nullipara comparison group 10% and 3.7%, respectively, of the questioned participants had comparable complaints. Multiparae had a high relative risk of 3.3 at the age of 35– 64 years, wherein the influence of the first delivery was decisive (Rortveit et al. 2001).

As early as 1980, Stanton et al. reported a very high rate of urinary incontinence during pregnancy (Stanton et al. 1980); they found no substantial difference between primiparae (38.6%) and multiparae (41.7%). After delivery, the frequency of urinary incontinence was only 5.8% in primiparae, whereas it amounted to 10.6% with multiparae. Chaliha et al. (1999) and Viktrup et al. (1992) confirmed the high rate of urinary incontinence complaints during pregnancy (43.7% vs 32%); after delivery 14.6% vs 7% remained. The high percentage of urinary incontinence during pregnancy cannot be explained neither by pregnancy-related pressure on the bladder nor by hormone-induced relaxation of collagenous tissue. On the other hand, these changes can entertain a postpartum urinary incontinence, which is reflected in the incidence of urinary incontinence after cesarean section. Therefore Faundes et al. (2001) could prove that compared to nulliparae, women after cesarean section have 3.5 times higher risk and women after spontaneous delivery a 4.3 times higher risk of urinary incontinence. Further research is still necessary to reveal the causes.

6.2.2 Prevalence of Anal Incontinence

The influence of pregnancy and delivery on the anal sphincter can be interpreted either by morphology or function, which only partly correlate with each other. Even the interpretation of literature on functional disorders is difficult, as nomenclature is not always used in the same way. Anal incontinence represents a collective term for all functional disorders of the anal sphincter apparatus and occurs in 8% of women after spontaneous delivery and 5% after cesarean section according to Lal et al. (2003). How far cesarean section has an influence on functional disorders of the anal sphincter is often unclear as the questioned women are seldom distinguished on basis of pre-pregnancy history. In addition, the differentiation between primary and secondary cesarean section is often missing. Flatus incontinence is given by Hall et al. (2003), with 24%, and even with 25% by Nazir et al. (2002). Nazir et al. stress that two-thirds of afflicted postpartum women recover spontaneously. Franz et al. (1999) report 19% vs 22% of flatus incontinence after spontaneous delivery without and with episiotomy respectively; 8% and 12%, respectively, of the controls examined complained of stool incon-

tinence. Hall et al. (2003) had similar results with 10% for stool incontinence, Nygaard et al. (1997) even found 26% stool incontinence after spontaneous delivery with episiotomy, 28% after grade three perineal lacerations and 15% after cesarean section. Chaliha et al. (1999) asked about fecal urgency, which was affirmed in 7.3% after spontaneous delivery and in 3.1% after cesarean section.

6.3 Risk factors for the Development of Urinary and Anal Incontinence

Through pregnancy and especially through delivery, a wide variety of factors influence the genesis of pelvic floor trauma. In most cases, this represents a multifactor generated event, meaning that individual factors cannot be defined easily. Augmenting this problem, morphological damage to the pelvic floor can heal by reparatory mechanisms and morphological defects can come with or without functional restrictions. Within the EPINCONT, study risk factors such as age at delivery, body mass index, parity and birth weight above 4,000 g were defined (Rortveit et al. 2003). Meyer et al. (1998) proved that after forceps deliveries, urinary incontinence complaints occurred more often (36% vs 21% after spontaneous delivery). Viktrup and Lose (1993) observed a higher risk when peridural anesthesia is administered (7% with PDA and 3% without PDA). There is a high degree of discrepancy in the discussion of factors such as episiotomy and perineal massage. On one hand mediolateral episiotomy is supposed to avoid defects to the sphincter ani externus, on the other traumatization to the pelvic floor by the procedure is considerable. Its use should be individually justified for every case (fetal indication, avoidance of uncontrolled perineal laceration). Median episiotomy should not be used routinely as it provokes higher grades of perineal lacerations. (Signorello et al. 2000; Myers-Helfgott and Helfgott 1999; Zetterström et al. 1999; Jander and Lyrenas 2001). If perineal massage is being performed during pregnancy, birth injuries are avoided and episiotomy rates lessened (Eason et al. 2000). However, when begun as late as in the delivery room, it has no positive influence on avoiding traumatization of the birth canal (Stamp et al. 2001).

A small pubic angle (>90°) causes a prolonged second stage of labor (Frudiger et al. 2002), the baby's head circumference correlates with flatus incontinence (Nazir et al. 2002) and a forceps delivery has a correlation with low sphincter ani pressure (Meyer et al. 2000).

The most important statement for delivery room management may be this: after occurrence of a third-degree perineal laceration, the rate of anal incontinence can be diminished by performing an elective cesarean section at the next delivery (2.3 cesarean sections avoid one case of anal incontinence; McKenna et al. 2003).

6.4 Summary

Incontinence and birth trauma are both events seen in the literature and daily practice. Several facts render a standardization of pelvic floor protective proceedings in the course of pregnancy and delivery very difficult: urinary incontinence occurs already during pregnancy, it is not comparable to postpartum complaints. After cesarean section urinary and stool incontinence can also occur.

Pelvic floor consciousness training and conditioning should be established in a standardized way before, during and after pregnancy, independent of functional dis-

orders as the influence of giving birth continues even as late as after menopause. Delivery management must be adapted individually to each case and situation anew. Despite all attempts to protect the pelvic floor, stool and urinary incontinence cannot be avoided entirely. Even prospective randomized studies with large case numbers will be able to elucidate this subject only in part, as the genesis of stool and urinary incontinence is multifactorial.

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Chapter 7

Neurogenic Urinary Incontinence

7

Helmut Madersbacher

Contents

7.1 Introduction and Aims

The prevalence of neurogenic urinary incontinence with different neurological diseases is between 20% (cerebral hemorrhage) and 90% (para- and tetraplegics after spinal cord injury). Altogether in Germany an estimated 2.6 million people are affected. In this regard, one has to consider that over the age of 40, each individual acquires one neurological disease every decade (Gerstenbrand 1995).

Neurogenic lower urinary tract (LUT) dysfunction is characterized by the detrusor and sphincter becoming either overactive or underactive. Mostly both the detrusor and sphincter are affected; however, a normal function of the counterpart is also possible. Most patients have a storage problem, causing incontinence, as well as an emptying problem causing impaired voiding. The aims of urological care in neurogenic LUT dysfunction are (1) to protect the upper urinary tract by achieving a urodynamically safe situation: a bladder with sufficient capacity, filling at low pressure, emptying completely without hyperpressure and without outflow obstruction. This issue is important for the life expectancy of these patients. (2) The second aim is to manage urinary incontinence or possibly to restore continence, which is of paramount importance for quality of life.

Both aspects are for the most part closely related to each other and both have to be considered in planning therapy. In patients suffering from neurogenic urinary incontinence, therefore, the type of bladder emptying before and with incontinence therapy must also be taken into account.

7.2 Pathophysiology of Neurogenic Urinary Incontinence

Neurogenic urinary incontinence may be due to dysfunction of the detrusor or dysfunction of the sphincter; however often both conditions are present simultaneously.

Detrusor overactivity causes overactivity incontinence, previously called urge or reflex incontinence depending on whether the urge to void is present or not. Likewise, the underactive detrusor, which in this context means detrusor weakness resulting in a hypocontractile detrusor, may also cause overflow incontinence in patients without adequate management of bladder emptying. Detrusor overactivity occurs in supraspinal and suprasacral spinal lesions; however underactivity is mostly a consequence of sacral and subsacral lesions.

Sphincter dysfunction comprises again overactivity, which means sphincter spasticity, also called detrusor-sphincter dyssynergia (DSD) if it occurs together with a detrusor contraction. It is then a characteristic sign for suprasacral spinal cord lesions. The overactive (spastic) sphincter or detrusor-sphincter dyssynergia, mostly cause functional infravesical obstruction with consequences for the urinary tract if not treated properly. Chronic urinary retention with overflow incontinence may then occur. Underactivity of the sphincter is seen with a sacral or subsacral neurogenic lesion and lowers urinary tract innervation, causing neurogenic stress incontinence. Depending on the etiology of the lesion, these different types of incontinence may be present at the same time in a significant proportion of patients.

A targeted clinical investigation should comprise evaluation of sacral reflexes (anal and bulbocavernosus reflex) as well as the tone of the anal sphincter and the ability of the patient to squeeze it. In sacral and subsacral lesions, pudendal reflexes are absent

or weakened. Anal tone is decreased and the ability to squeeze it may be compromised. However, in suprasacral spinal lesions these reflexes and anal tone may be enhanced. The ability to squeeze the anal sphincter depends on the incompleteness of the lesion. However, these findings do not always reflect what really happens during the emptying phase.

For the evaluation of neurogenic LUT disorders, urodynamic investigations are mandatory to define the pattern of neurogenic detrusor-sphincter dysfunction in the individual patient. Figure 7.1 shows the eight most frequent patterns observed in patients with neurogenic lower urinary tract dysfunction.

The underlying urodynamic pattern is decisive for selecting the treatment strategy, which is also the case in incontinent patients to achieve continence with various conservative and operative therapeutic options. Last but not at least, the urodynamic pattern determines the risk for upper urinary tract function and morphology deterioration.

Nervous control of continence and micturition is organized on a cerebral, spinal and peripheral level, all three are cross-linked, and the circuiting is complex and contentious.

As will be described, there are numerous treatment options, their application depends on the type of neurogenic LUT dysfunction, the etiology and the social situation of the individual patient. In the following the clinical symptomatology and the treatment strategies are described in (1) suprapontine, (2) suprasacral spinal and (3) spinal sacral and subsacral (cauda equina and peripheral nerve) lesions.

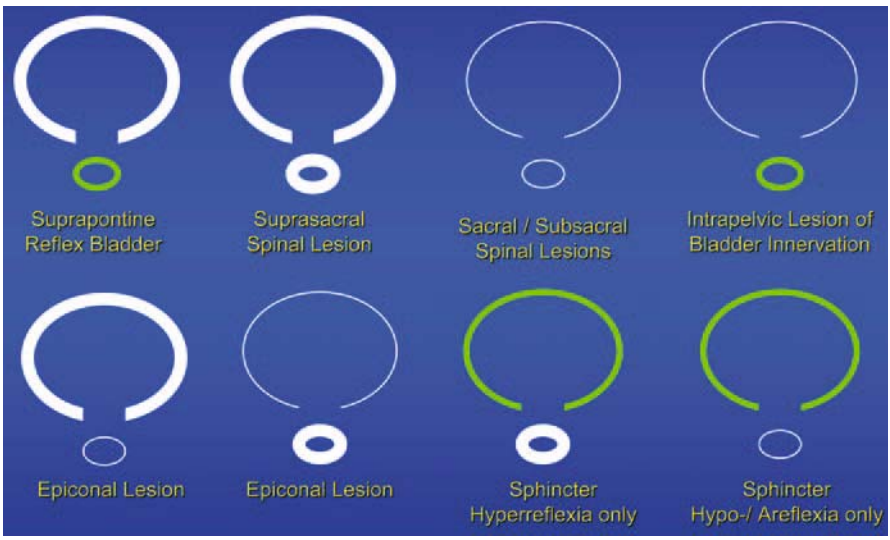

Fig. 7.1. Patterns of neurogenic lower urinary tract dysfunction. Each of the drawings symbolizes the bladder and sphincter. Structures drawn with *heavy lines* symbolize overactivity, structures drawn with *thin lines* represent underactivity, those with *intermediate lines* normal function. The drawings represent the eight most frequent neurogenic dysfunctional patterns in the lower urinary tract (for further explanations, see text).

7.3 Therapeutic Options for Neurogenic Urinary Incontinence

7.3.1 Urinary Incontinence Due to Suprapontine Lesions

The detrusor reflex to empty the bladder is a brainstem reflex that is controlled by various suprapontine centers including the frontal lobe and basal ganglia. Clinically, suprapontine lesions therefore cause frequency, urgency and incontinence due to detrusor overactivity caused by damage to cerebral inhibitory centers. Urodynamically we see detrusor overactivity either of the phasic or more often of the terminal type (see Fig. 7.2). During the storage phase, the urge to void comes up usually late without warning and is accompanied by a uncontrollable detrusor contraction causing detrusor overactivity incontinence.

The coordination between detrusor and sphincter is located in the brainstem. Therefore in suprapontine lesions, the coordination between detrusor and sphincter is preserved and bladder emptying is without residual urine unless other reasons for infravesical obstruction such as an obstructive, enlarged prostate are present.

Unless the neurological disease causing LUT dysfunction cannot be eliminated, neurourological therapy is mostly symptomatic or activates reserve functions to compensate the defect.

Terminal detrusor overactivity can only be brought under control by adequate *toilet training* based on the records of a micturition protocol: the patient has to go or has to be brought to the toilet regularly before the urge to void occurs. The exact

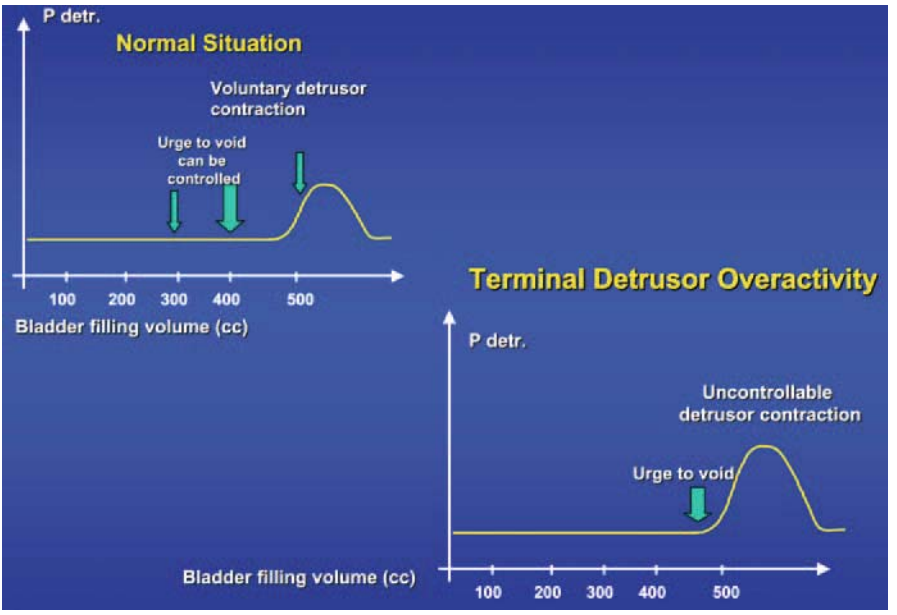

Fig. 7.2. Terminal detrusor overactivity. In the majority of elderly patients with symptoms of the overactive bladder, terminal detrusor overactivity can be found. At a certain filling volume, which may be small or large, suddenly, without warning, the urge to void comes up together with the detrusor contraction, which the patient is unable to control: The consequence is overactivity incontinence.

timing is based on the records of the micturition protocol. The timing of micturition has to be adjusted to the bladder capacity and prompted voiding has to occur before uncontrolled detrusor contractions cause incontinence. If the bladder capacity is below 250 cc *anticholinergic therapy* is indicated in order to increase bladder capacity.

A retrospective analysis in patients with Parkinson's disease (Holliger et al. 2002) reveals that detrusor overactivity increases and bladder capacity decreases with duration and severity of the disease. Only recently Seif et al. (2003) demonstrated in Parkinson patients with an implant for deep brain stimulation the inhibiting influence of the basal ganglia on the detrusor reflex: STN stimulation normalizes detrusor hypersensitivity in Parkinson patients, whereas with stimulation off hypersensitivity occurs again.

7.3.2 Suprasacral Spinal Cord Lesions

In suprasacral lesions (also known as upper motor neuron lesion or spinal reflex bladder) the sacral reflex arc (bladder → afferent neurons → S2-S4 sacral cord → efferent neurons → bladder) remains intact. However, at least on the afferent side, this reflex is mediated not as normally by A-delta afferent neurons but by unmyelinated C-fibers (= *C*apsaicin sensitive), which originate in the vanilloid receptors within the bladder. In complete suprasacral lesions, at a certain point the filling volume of the bladder triggers the sacral micturition reflex. The patient himself has lost the ability to feel bladder filling and the urge to void and is therefore unable to control it. The patient suffers from neurogenic detrusor overactivity incontinence (previously called reflex incontinence). As the reflex for bladder emptying is limited to the spinal cord, the coordination between detrusor and sphincter mediated in centers of the brainstem area is lacking and detrusor-sphincter dyssynergia occurs. DSD presents a functional infravesical obstruction that may cause severe damage to the lower and upper urinary tracts. A high-pressure situation within the bladder with ureterorenal reflux, hydronephrosis and pyelonephritis can result.

The therapeutic strategy is based (1) on regular bladder emptying before neurogenic detrusor overactivity occurs, achieved nowadays primarily by intermittent (self-) *catheterization*, in some patients also by triggered reflex voiding; and (2) by inhibiting the overactive detrusor with *pharmacotherapy*, *electrical neuromodulation*, *sacral deafferentation* or *bladder augmentation*.

If incontinence persists, condom catheters in men and pads in women are useful. A transurethral or suprapubic indwelling catheter should be avoided if possible.

Pharmacotherapy in neurogenic detrusor overactivity comprises (1) *anticholinergics*, which act in the periphery on the efferent side, (2) substances blocking the receptors of the afferent nerves within the bladder, primarily by blocking vanilloid receptors by instillation of capsaicin or *resiniferatoxin* into the bladder or by paralyzing the detrusor muscle by injecting botulinum toxin A into the detrusor.

In incomplete lesions, *noninvasive neuromodulation* of the detrusor reflex preferably by stimulating the pudendal afferents via the dorsal penile or clitoridal nerve is an alternative, especially when anticholinergics are either not effective or not tolerated in adequate dosages.

In complete lesions caused by a spinal cord trauma, electrical stimulation of the anterior sacral nerves using the *Brindley implant* is another alternative; however, balanced voiding and continence can mostly only be achieved if this procedure is com-

bined with sacral deafferentation which means posterior sacral root rhizotomy of S2–S5 bilaterally (see following paragraph).

For patients in whom neurogenic detrusor overactivity incontinence cannot be managed adequately by conservative means, two operative options are available to achieve the aims: One is *sacral deafferentation* (rhizotomy of the dorsal sacral roots S2–S5 bilaterally), which abolishes any sacral reflex activity and therefore provides continence. However, in order to empty the bladder the patient either has to perform intermittent (self-) catheterization or at the time of operation simultaneously an anterior root stimulator (Brindley device) is implanted. According to our and others' experience over the long term, 85% of the patients became and remained continent and the same percentage achieved balanced electrically driven micturition with tolerable pressures.

In patients with incomplete lesions, *sacral electrical neuromodulation* is able to reduce detrusor overactivity with beneficial clinical effect in patients in whom the non-invasive technique is not effective: special electrodes are directly implanted to the S3 root after a trial period.

For both complete and incomplete lesions, *bladder augmentation*, preferably using *clam-ileo-cystoplasty*, is an alternative with good long-term results to achieve continence; however, bladder emptying has to be accomplished by intermittent catheterization in almost all patients.

Transurethral sphincterotomy can relieve infravesical functional obstruction caused by detrusor-sphincter dyssynergia; however, the second aim, the achievement of continence, is not achieved.

7.3.3 Spinal Sacral and Subsacral Lesions

In complete spinal sacral and subsacral (cauda equina and peripheral) lesions (lower motor neuron lesion), the detrusor and sphincter become underactive, resulting in neurogenic detrusor acontractility and flaccid paresis of the pelvic floor musculature and the striated sphincter. The problem for the patient again is twofold: there is a failure to empty and, because of flaccid paresis of the striated sphincter and the pelvic floor, also a failure to store, resulting in neurogenic stress incontinence.

Bladder emptying is best achieved by intermittent (self-) catheterization. Emptying by abdominal straining carries certain risks and demands careful urodynamic investigation before it can be recommended.

Conservative treatment is rarely successful in neurogenic stress incontinence; however, regular fluid intake and regular bladder emptying may improve the situation to a certain extent. Pharmacological agents are not effective in this type of lesion. The method of choice is still the *implantation of the artificial urinary sphincter* with a 90% success rate, however, with the disadvantage of a 30% re-operation over time and a change in the system between 10 and 15 years after implantation because of material fatigue.

Sling procedures may be an alternative; however, no long-term results have been published so far and there is almost no experience with suburethral slings of the new type (tension-free vaginal tape and others) in patients with neurogenic stress incontinence. It is questionable whether the therapeutic concept for these slings, which is effective in non-neurogenic stress incontinence, also works in these patients. In incomplete lesions, electrical stimulation of the pelvic floor over several months may improve the situation, although no evidence-based data are available.

7.4 Conclusions

Neurogenic lesions are a frequent cause of urinary incontinence, especially in the elderly. Numerous treatment options are available for neurogenic incontinence, but their application depends on the underlying pathophysiology and the individual situation of the patient in regards to disability and social situation. The mainstays for neurogenic detrusor overactivity incontinence in suprapontine lesions is behavioral treatment combined with anticholinergic therapy if bladder capacity is reduced. In patients with spinal lesions, mostly urinary incontinence is combined with an emptying problem; therefore both aspects have to be looked after at the same time. In suprasacral spinal lesions, intermittent catheterizations in combination with pharmacotherapy (anticholinergics, botulinum toxin A) is the method of choice; operative alternatives are in complete lesions sacral deafferentation together with the implantation of the anterior sacral root stimulator (Brindley) or in complete and incomplete lesions bladder augmentation. Some patients with incomplete lesions may benefit from noninvasive or invasive sacral neuromodulation.

In sacral and subsacral lesions, neurogenic stress incontinence can only be cured thus far by operative procedures. The implantation of the artificial urinary sphincter is the method of choice; alternatives may be sling procedures, although no long-term data are available and there is almost no experience with suburethral slings of the new type.

Chapter 8

Fecal Incontinence After Rectal and Perianal Surgery

8

Alan G. Thorson

Contents

8.1 Introduction

The following discussion will focus on several specific aspects of postoperative fecal incontinence. We will first identify the most common anal and rectal operations that are associated with the unintended consequence of fecal incontinence. We will next try to quantitate the relative risks for incontinence for those procedures, identify specific groups of patients who appear to be at particularly high risk and determine if there are any procedures where some degree of incontinence should be an expected outcome. We will then look at the etiology of incontinence in these patients and evaluate the current literature for contributing factors within these operations that could potentially be changed in order to decrease the risk of incontinence. Finally, any current outcomes data with respect to specialist and volume data will be reviewed.

8.2 At-risk Procedures

Alterations in continence have been reported following many different procedures performed on the anorectum. There are four general types of operations that have an impact on continence. These include: (1) Procedures performed for anal diseases that have a direct impact on the anal sphincter, (2) Procedures performed for colonic or rectal conditions that secondarily impact continence, (3) Procedures for prolapse and (4) Miscellaneous procedures, including those performed for the management of incontinence or other conditions.

The most obvious risks are associated with procedures done for controlling symptoms of anal pain and bleeding and the management of acute and chronic anal suppurative disease. The most common of these procedures related to postoperative incontinence include the many operations for hemorrhoidectomy (stapled and excisional), sphincterotomy, anal dilatation, drainage of abscesses and the various operations for anal fistula. The latter includes fistulotomy and fistulectomy with or without seton, advancement flaps and the use of fibrin glue. The operation of sphincterotomy and those for fistula, which often entail an actual division of at least a portion of the sphincter, are at particular risk for causing incontinence.

Procedures performed for colonic or rectal conditions that secondarily impact continence include those performed for cancer and inflammatory bowel disease. These operations include low anterior resection, proctectomy with or without colonic J-pouch or coloplasty–anal anastomosis and ileal pouch anal anastomosis (IPAA). There are also reports dealing with the effects on continence following the transanal excision of rectal tumors, including the technique of transanal endoscopic microsurgery (TEM).

The procedures for rectal prolapse can be divided into abdominal and perineal approaches. The abdominal approaches may have an impact on continence due to the correction of a preexisting anatomic problem. This effect is usually positive, although reduction of the intussusception, when chronic dilation of the prolapse has significantly weakened the sphincter mechanism and stretching of the pudendal nerves has caused a neuropathy, may worsen continence. These approaches include the Loygue procedure and rectopexy by suture, mesh (Ripstein) or Ivalon sponge and may be with or without sigmoid colon resection. Generally, the abdominal approaches for prolapse have less dramatic effects on continence than do the perineal operations. The Altemeier perineal rectosigmoidectomy results in a proctectomy, while the Delorme proce-

dure represents a rectal mucosectomy with preservation of the muscular wall of the rectum.

Miscellaneous procedures that can affect continence include rectocele repair and anterior sphincteroplasty. The latter is an operation that is performed specifically for the management of fecal incontinence but that has an incidence of incontinence as a consequence.

8.3 Procedure-specific Risks

8.3.1 Procedures for Anal Diseases

8.3.1.1 Hemorrhoidectomy

The reported incidence of incontinence following hemorrhoidectomy is highly variable. Many factors confound the establishment of a true figure. These include the type of procedure performed and the definition of incontinence utilized in the postoperative evaluation. No large studies have examined this question using the newer fecal incontinence scales that are now available. Randomized series comparing differing techniques are not common.

Having said this, in general complaints of significant continence issues following a well-performed hemorrhoidectomy are low. The exception is for utilization of Lord's dilatation procedure for hemorrhoid management. In the long-term follow-up of 153 patients randomized between operative hemorrhoidectomy and Lord's dilatation, Konsten and Baeten (2000) found the risk of incontinence following dilatation to be as high as 52% 17 years after the procedure. In a study evaluating transanal ultrasonographic evidence of sphincter injury following anorectal procedures, Stamatiadis found a 76% incidence of internal sphincter injury and a 24% incidence of external sphincter injury following anal dilatation (Stamatiadis et al. 2002).

In comparing technical modifications, there is little difference whether a stapler, laser, ultrasonic scalpel, bipolar cautery, standard cautery or a cold blade is used. Ravo described a 0.2% risk of flatus and fecal incontinence in a review of 1,107 patients from 12 Italian centers undergoing stapled hemorrhoidectomy (Ravo et al. 2002). In a randomized prospective trial of 119 patients undergoing stapled vs conventional hemorrhoidectomy, Ho found a minor incontinence rate of 3.7% for stapled hemorrhoidectomy and 3.2% for conventional hemorrhoidectomy at 3 weeks (Ho et al. 2000). At 3 months the residual rates were 0% and 1.6% respectively.

Khan examined the results of hemorrhoidectomy utilizing the ultrasonic scalpel. In a prospective trial, 30 patients were randomized to either excisional hemorrhoidectomy using electrocautery or by ultrasonic device. Incontinence was compared to flatus only and did not differ between the groups (Khan et al. 2001).

McConnell and Khubchandani (1983) reported on closed hemorrhoidectomy in 441 patients. With follow-up of up to 7 years, they reported a lasting incontinence rate of 0.5%. Johannsson reviewed the long-term results of patients undergoing Milligan-Morgan hemorrhoidectomy. Over a follow-up period ranging from 7 to 14 years, 507 patients reported a 33% incidence of impaired continence. However, only 29% of these, or 8% of the total, said that their incontinence was directly related to the operation of hemorrhoidectomy (Johannsson et al. 2002).

Overall the risk for incontinence is probably less with the stapled procedures as there is minimal risk to division of the sphincter. Both conventional and stapled hemorrhoidectomies do result in some dilatation of the sphincter with a resultant undefined continence risk. Depending upon the patient population being studied and the type of hemorrhoidectomy, continence risks range from 0% to an excess of 30%. However, when taking into consideration the size of the various studies, the overall rate of incontinence following hemorrhoidectomy is probably somewhere between 0.5% and 5%.

8.3.1.2 Sphincterotomy

The operation of lateral internal sphincterotomy (LIS) entails the partial division of the internal sphincter. With a planned division of the sphincter, it is not surprising that there is a reported incidence of incontinence following the procedure. The extent of the incontinence could be related to a number of variables, including the length of the muscle divided, the preoperative manometric pressures and the operative technique utilized.

Garcia-Aguilar compared the technique of open vs closed LIS. In a retrospective review of 864 patients, 90% expressed satisfaction with their operation; however, there were statistically significant differences between the operations with respect to incontinence. With the open procedure, there was a persistent incontinence to gas in 30.3%, soiling of underclothing in 26.7% and accidental bowel movements in 11.8%. The comparable figures for the closed procedure were 23.6% for problems controlling gas, 16.1% for soiling of underclothing and 3.1% for accidental bowel movements (p=0.062 for gas, less than 0.001 for soiling underclothing and accidental bowel movements). These figures suggest a significant risk for continence issues following either operation (Garcia-Aguilar et al. 1996).

Three other studies have also shown a significant risk of continence issues with LIS. Pernikoff and associates reviewed 500 patients in a retrospective manner. Although the fissure healing rate was 99%, 8% of patients experienced "impaired fecal incontinence" (Pernikoff et al. 1994). In a retrospective review of 1,355 patients, Khubchandani found an incidence of incontinence to flatus of 35.1%, soiling 22% and accidental bowel movements 5.3%. A significantly higher proportion of patients having accidental bowel movements were over age 40 (Khubchandani and Reed 1989). Lewis retrospectively reviewed 350 patients undergoing either open or closed LIS for anal fissure. A total of 60 patients (17%) complained of incontinence to flatus or feces, which was transient in two-thirds. Thus the long-term incontinence rate was about 6% (Lewis et al. 1988). Overall, these studies suggest a risk of incontinence of at least some degree following LIS, ranging generally from 6% to 30%.

8.3.1.3 Operations for Fistula-in-ano

The are many variables that confound attempts to assess the risk of continence following procedures for anal fistula. These include the type of fistula, the underlying disease state and the operation utilized.

The type of fistula refers to the extent of muscle involvement by the tract as it extends from the internal to the external opening. Parks' classification of anal fistula is the most commonly used today. This classification includes submucosal fistulas (no

muscle involvement), intersphincteric fistulas (between the internal and external sphincters), as well as transsphincteric, extrasphincteric and suprasphincteric fistulas (indicating a variable extent of involvement of the external sphincter). Continence risk increases with increasing involvement of the external sphincter in the process.

The underlying disease state can markedly affect the success or failure of fistula surgery. Variables include Crohn's and other granulomatous diseases, immune suppression, radiation history and fistulas of anal gland origin. Most anal fistulas arise according to the theory of cryptoglandular origin. In its simplest form, this states that infection originates in one of the anal glands with subsequent extension to any one of the various anorectal spaces as an abscess in the acute state with subsequent evolution to a fistula in the chronic state of anal suppurative disease. For the purposes of this discussion, we will confine ourselves to fistulas of anal gland origin.

The basic premise of fistula treatment involves two steps. First the inciting gland must be destroyed and secondly, the tract must be eliminated through unroofing (with wound healing by secondary intention), excision or filling. The latter refers to the use of fibrin glue. Protection of the external sphincter can be enhanced by maneuvers meant to avoid division altogether (fibrin glue and advancement flaps) or by the use of setons in an attempt to minimize long-term sequelae of muscle division.

A seton is a large suture or circular drain that may consist of silk, vascular loops, flat latex or other material selected by the surgeon. It is placed through the internal opening, follows the fistula tract and is then brought out the external opening and tied back upon itself in a loop so that it stays in place. Setons can take several forms. A cutting seton is designed to be serially tightened over time so that it slowly divides the contents of its loop (the external sphincter) allowing healing behind the seton as it is withdrawn. The concept is that the slow staged process minimizes separation of the muscle as it is divided, thus protecting continence.

A draining seton is used when there is no immediate anticipation of dividing the muscle. It allows continued drainage of the suppurative process so that repeated abscess formation is not a threat. Draining setons are frequently used in the management of anal Crohn's disease.

A staging seton is meant to be placed following destruction of the inciting gland. It is utilized when the amount of external sphincter contained within the loop is of such magnitude that it is felt that immediate division of the sphincter would result in significant continence issues. Utilizing a highly reactive material such as silk, a seton is left in place for 8 weeks or longer to create fibrosis around the tract. The subsequent fibrosis is meant to protect the muscle from wide separation at time of division to complete the unroofing process.

There are many studies looking at various aspects of fistula surgery. The complexity of trying to evaluate the results in the overall context of continence risk is confounded by the many variables introduced in the above discussion. However, we will look at a few representative studies to get a general feel for the risks of incontinence and opportunities for risk reduction.

A retrospective review of 312 patients by van Tets, including all comers for fistula surgery and various operative approaches, revealed minor continence issues in 24% with no frank incontinence. Factors that increased the risk of continence issues included the presence of a posterior fistula opening, a high fistula and fistula extensions (van Tets and Kuijpers 1994).

Vasilevsky and Gordon retrospectively reviewed 160 patients with intersphincteric, transsphincteric and suprasphincteric fistulas. The rate of postoperative incontinence was 6% overall. In further evaluation, it was found that in the acute postoperative pe-

riod 2.6% of patients suffered incontinence to flatus, 1.3% to liquid stool and 0.7% to solid stool. Permanent loss of control of flatus was noted in only 0.7% of patients and permanent loss of control of liquid stool was noted in only 0.7%. No one had permanent loss of control to solid stool (Vasilevsky and Gordon 1985).

Thus it would appear that the *overall* risk to continence from fistula surgery is between 10% and 20%, with most issues being of minor degree. However, the degree of variability with respect to the type of fistula and operative technique can be more fully appreciated by looking at a few additional studies.

Theerapol retrospectively reviewed a series of 47 patients who were treated by seton placement only. A minimum of two setons were placed in each case. One was tied tightly as a cutting seton and then sequentially tightened over time. There was at least one additional seton tied loosely as a draining seton in each case. No patients developed fecal incontinence (Theerapol et al. 2002).

In a retrospective review of 100 patients undergoing staged seton placement for high fistulas, Pearl showed a 5% risk of incontinence severe enough that patients required a pad for protection (Pearl et al. 1993). The use of staging setons in complex, high fistulas was completed in a retrospective fashion by van Tets. Thirty-four patients underwent staging setons for 16 extrasphincteric and 18 transsphincteric fistulas. Overall, there was a 59% risk of various degrees of incontinence. These included 17% risk of flatus incontinence, a 38% risk of incontinence to liquid stool and a 3% risk of constant leakage. The use of staging seton for fistulas with high internal openings was not recommended, presumably in deference to the use of a cutting seton in these instances (van Tets and Kuijpers 1995).

Graf reported retrospectively on the use of setons in 29 patients with similar high transsphincteric fistulas. The rate of incontinence following treatment was 44%. He noted that the risk of incontinence appeared to be greater in patients in whom there was less fibrosis resulting from the use of the seton, suggesting that some of the muscle divisions may have been premature (Graf et al. 1995).

Hasegawa reviewed the use of cutting setons in 32 patients with high transsphincteric fistulas. He found that there was a 22% incidence of worsening incontinence following the use of cutting setons in these situations. However, major incontinence occurred only in women with previous vaginal delivery. There was also a 29% risk of recurrence (Hasegawa et al. 2000). Hamalainen reviewed an experience with 44 similar patients with high transsphincteric, extrasphincteric and suprasphincteric fistulas and noted a 41% risk of worsened continence with a cutting seton. He advised a preference for management of high transsphincteric fistulas with techniques that would avoid muscle division (Hamalainen and Sainio 1997).

In a slight modification of the standard cutting seton, McCourtney and Finlay reviewed a series in which they avoided the use of an internal sphincterotomy at the time of the cutting seton. They found that this simple modification decreased the risk of incontinence related to cutting setons to 19%. In their series, all patients who experienced some deterioration in continence in the long term were women with rectal-vaginal fistulas. Other alternatives to the division of the sphincter include the use of fibrin glue and the utilization of advancement flaps.

In a prospective review, Sentovich evaluated the results of fibrin glue management of anal fistula in 48 patients. Treatment consisted of destruction of the inciting anal gland and placement of a draining seton. Two months later, the draining seton was removed and the internal opening closed with a single suture. The tract was then filled with fibrin glue through the external opening. The overall healing rate was 69% with no alteration in continence (Sentovich 2003).

Advancement flaps offer another alternative to sphincter division in selected patients. In a prospective study, Ortiz examined the results of the endorectal advancement flap with core fistulectomy in 103 patients with high transsphincteric and suprasphincteric fistulas. The overall healing rate was 93%. Some "continence disturbance" was noted in 8% of patients (Ortiz and Marzo 2000). Miller retrospectively reviewed 25 patients undergoing core fistulectomy with the endorectal advancement flap for high transsphincteric fistula. the primary healing rate was 80% with no alteration in continence (Miller and Finan 1998). In contrast, Schouten reported in a retrospective study of 44 patients undergoing advancement flap surgery without fistulectomy and found that 35% of patients had some deterioration in continence following the procedure. Successful healing was noted in 87% of patients who had one or fewer previous attempts at repair (Schouten et al. 1999).

It would be reasonable to conclude that although the *overall* risk of incontinence due to fistula surgery may be in the range of 10%–20%, the more significant risks lie in fistulas that are high and complex. These risks are probably related to the amount of muscle that is divided at the time of operation. There are alternatives that decrease the amount of muscle that needs to be divided. These appear to lower the risk of incontinence in these procedures.

8.3.2 Procedures with Secondary Impact on Continence

Operations done primarily above the level of the sphincter can have a significant impact on subsequent continence. Just what that impact is results from a number of factors. Normal continence requires not only an anatomically intact sphincter, but that sphincter must also be able to function in a dynamic manner. This means there must be proper innervation. The rectum must remain pliable and distensible to allow for accommodation. Loss of reservoir capacity can lead to increased frequency of stool. Sensation must be kept intact to provide for discrimination and allow adequate reaction time for contraction of the voluntary sphincter.

A number of steps that are taken in the process of managing colorectal conditions such as rectal cancer and inflammatory bowel disease (IBD) can have profound effects on these factors. Potential effects can include the fibrosis and loss of distensibility that may result from radiation. This may include fibrosis and impaired function of the sphincter itself. Rectal reservoir size is frequently decreased by resection. In some cases, the native reservoir is totally eliminated. Loss of sensation accompanies mucosectomy for IBD. The following section will consider these issues as they relate to the operations of anterior resection and IPAA.

8.3.2.1 Anterior Resection

Low anterior resection, with or without a neorectum, results in rather profound changes in bowel function. Small frequent stools in a pattern known as fragmentation frequently manifest as the stooling pattern. Loss of sensation with leakage, particularly at night, is common. These manifestations generally improve with time and have usually stabilized by 2 years following resection. Rasmussen, in a review of 43 patients, found 49% to be incontinent following low anterior resection (LAR), including 26% incontinent to flatus and 23% incontinent to stool (Rasmussen et al. 2003). In the evaluation of 315 patients following various colon resections, Ho found that defecation problems

occurred in 28.4% of patients following LAR (Ho et al. 2003). In a review of 43 patients undergoing LAR, Chatwin reported some degree of incontinence in 47% (Chatwin et al. 2002). Lewis and colleagues from Leeds reviewed 73 patients following LAR and found that 60% experienced some form of bowel dysfunction (Lewis et al. 1995). Overall, some element of incontinence is present in 30%–50% of patients following LAR for rectal cancer.

The reasons for some of the continence manifestations following anterior resection seem obvious. The amount of residual native rectal reservoir is directly related to the level of the anastomosis. The higher the anastomosis, the more native rectum remains in situ. To help obviate this loss of rectal capacity with very low rectal and coloanal anastomoses, alternatives have been designed to provide neo-reservoirs. Options include coloplasty and colonic J-pouch. Studies have shown that a J-pouch functions better than a straight coloanal anastomosis in the postoperative period.

Ho and colleagues evaluated the long-term efficacy of the J-pouch in a prospective randomized trial of straight vs J-pouch anastomosis. At 6 months, patients with a J-pouch had significantly fewer stools and less soiling than their counterparts with a straight anastomosis. However by 2 years, this difference had been lost. Rectal sensory testing showed impairment at 6 months but recovery at 2 years, suggesting that postoperative recovery of residual afferent sympathetic nerves may play a role in functional recovery (Ho et al. 2001).

In another prospective study, Ho randomized 88 patients to receive either a J-pouch or coloplasty anal anastomosis following anterior resection for rectal cancer. At 4 months, J-pouch patients had 10.3% less stool fragmentation but poorer stool deferment and more nocturnal leakage. However by 1 year, there were no differences in bowel function, continence scores or quality of life (Ho et al. 2002). At the present time, coloplasty is generally reserved for those patients in whom a J-pouch cannot be formed because of a narrow pelvis or lack of bowel length.

Radiation is known to impact pelvic tissues through the potential for postradiation fibrosis and chronic radiation proctitis. Either effect can result in loss of rectal distensibility, reduced accommodation and decreased elasticity of the sphincter. Gervaz, in a retrospective study involving 45 patients having proctectomy with colonic J-pouch anal anastomosis, compared results between 28 patients receiving surgery alone and 13 patients receiving preoperative and four patients receiving postoperative adjuvant chemotherapy and radiation. The patients receiving radiation were found to have more frequent incontinence to gas (76% vs 43%, p=0.03), liquid stool (64% vs 25%, p=0.01), and solid stool (47% vs 11%, p=0.01). Irradiated patients also reported more frequent pouch-related specific problems such as fragmentation (82% vs 32%, P=0.001) and sensation of incomplete evacuation (82% vs 32 *percent*, p=0.001). Regression analysis demonstrated that radiation-induced sphincter dysfunction was progressive over time (Gervaz et al. 2001).

There has also been evidence that postoperative radiation has a greater negative impact on function than preoperative radiation. From an empiric standpoint this would stand to reason. When radiation therapy is given in the preoperative period, the bowel used for the neorectum is nonirradiated, while the same neorectum would be radiated if therapy is delivered postoperatively, subjecting the neorectum to radiation induced changes with potential for negative functional impact. Either way, the sphincter remains at risk. This has served as a basis for seeking exclusion of the anal canal from the radiation field in patients where sphincter preservation is anticipated.

8.3.2.2 Ileal Pouch Anal Anastomosis

The operation of ileal pouch anal anastomosis has the potential for rather profound effects on continence. The entire native rectal reservoir is resected, sensation is altered through the elimination of varying amounts of the sensate anal canal, the sphincter is at direct risk of injury through stretching and/or unintended excision and normal stool consistency is profoundly altered. It is no surprise then that some degree of incontinence is common. Taking the literature as a whole, one might expect that generally patients with an IPAA would expect a 20%–30% risk of daytime leakage, a 30%–50% risk of nighttime leakage and a 3%–8% risk of frank incontinence.

Longitudinal studies have quantified long-term expectations for function of the IPAA. Fazio, in a retrospective review of one of the largest series of IPAA (977 patients), found that perfect continence increased from 75.5% before surgery to 82.4% some 2 years after IPAA. There was some deterioration in function and continence after 2 years postoperatively, but incontinence did not return to preoperative levels. Therefore total incontinence risk in the long term was estimated at 17.6% (Fazio et al. 1999).

8.3.2.3 Transanal excision

Transanal excision of rectal cancer in selected patients has the potential to improve postoperative functional results compared to anterior resection since the native rectal reservoir is spared and, in most cases, the sensate anal canal is not altered. The theoretical risks to continence are largely related to risks associated with stretching of the anal sphincter mechanism at time of excision. This has been the focus of attention for a number of studies on the effects on continence of transanal endoscopic microsurgery (TEM), where a 4 cm operating anoscope is utilized.

In a prospective study of 18 patients, Kennedy found that TEM resulted in a significant decrease in mean resting pressures for up to 6 weeks postoperatively, the magnitude of which was directly related to the length of the operative procedure. However, there was no effect on continence scores (Kennedy et al. 2002). Kreis, in a prospective evaluation of 42 patients undergoing TEM, found both manometric and functional deterioration at 3 months but full recovery by 1 year (Kreis et al. 1996). Herman prospectively followed 33 patients for 6 months after undergoing TEM and compared them to 20 normal controls. Twenty-nine percent of patients had internal sphincter defects diagnosed by ultrasound following TEM. Fifty percent of patients experienced some sphincter dysfunction at 3 weeks but only 21% had persistent dysfunction at 6 months. Dysfunction was associated with low preoperative resting pressures, postoperative internal sphincter defects and extent (greater than 50% circumference) and depth of (full thickness) excision (Herman et al. 2001). In summary, dysfunction and incontinence related to TEM is largely minor and temporary.

8.3.3 Procedures for Prolapse

8.3.3.1 Abdominal Procedures

With the exception of anterior resection, abdominal operations for rectal prolapse preserve and fix the rectal reservoir. Consequently, there is little direct effect on continence related to these procedures other than anterior resection. Anterior resection risks some of the same changes in continence already discussed above due to resection of a part of the rectal reservoir. Since the procedure does not improve recurrence rates for prolapse, it is best not utilized for this indication if continence is to be maximally preserved.

The procedures that fix the rectum can do so with suture, mesh (Ripstein) or Ivalon sponge and may or may not include a sigmoid colon resection. The addition of sigmoid colon resection likely has little effect on continence issues. Generally, rectal fixation and correction of the prolapse improves continence but there is an incidence of worsening continence. This is most likely related to preexisting damage to the sphincter resulting from chronic dilation from the prolapse itself and stretching of the pudendal nerves leading to neuropathy.

Huber reported continence improved from a rate of 66% to 23% with resection rectopexy in 42 patients (Huber et al. 1995). Apropos to the above discussion, Winde, in a prospective data base of 47 patients, found that 51% of patients who were incontinent before surgery improved following surgery but 12% of those that were continent preoperatively became incontinent (Winde et al. 1993). Similar findings with regard to continence are reported with the Ripstein and Ivalon sponge procedures.

8.3.3.2 Perineal Procedures

Of the perineal procedures, the Delorme has the most positive outcome with regards to continence. Tsunoda demonstrated a significant increase in both resting and squeeze pressures and improved continence scores in a prospective study of 31 patients. Short-term recurrence was 13% (Tsunoda et al. 2003). Kling reported improved continence in 67% of six patients (Kling et al. 1996). Lechaux retrospectively reviewed 85 patients and found that 69% improved with regard to continence and no one worsened. There was a 14% recurrence rate (Lechaux et al. 1995). Tobin prospectively followed 43 patients. Fifty percent of 40 patients with incontinence were rendered continent. The recurrence rate was 22% (Tobin and Scott 1994).

The Altemeier procedure differs in that the rectum and a portion of the sigmoid colon are resected with construction of a coloanal anastomosis. In a prospective study, Deen randomized 20 patients with rectal prolapse to abdominal rectopexy with resection or to Altemeier perineal rectosigmoidectomy. The stool leakage rate following rectopexy was 20% and after perineal rectosigmoidectomy 60% (Deen et al. 1994). Perineal rectosigmoidectomy in the management of rectal prolapse carries a higher risk of fecal incontinence than other alternatives for management.

8.3.4 Miscellaneous Procedures

8.3.4.1 Rectocele Repair

In a prospective series of 89 patients followed after repair of rectocele, van Dam showed an 8% risk of deteriorating continence. This clinical finding was associated with acute decreases in resting and squeeze pressures and gradual recovery of the resting pressures but not squeeze pressures during a 24-month follow-up period (van Dam et al. 2000).

8.3.4.2 Sphincteroplasty

The success rate of anterior sphincteroplasty for anal incontinence is approximately 70%–80% in the early postoperative period. However, recent studies have shown a significant decline in continence status in the ensuing 5–10 years after repair. The reasons for these declines in functional outcome are not clear. This issue is more thoroughly addressed in the discussion on sphincteroplasty in this text and will not be further discussed here.

8.4 High-risk Procedures

Based on the previous assessments, procedures at particularly high risk for postoperative incontinence are those where there is planned division of the sphincter mechanism and those where multiple continence mechanisms are altered. Thus the operations for anal fistula and anal fissure fit the definition of high risk based on planned division of the sphincter muscle. The data presented above confirm this.

IPAA and anterior resection operations, including coloanal anastomosis, fulfill the definition of high-risk procedures for incontinence based on the number of continence mechanisms affected by the procedures. These procedures affect reservoir size, accommodation and sensation. They can also alter sphincter function, and they can change stooling patterns. Once again, the data presented in the preceding discussion confirms these risks.

8.5 Etiology of Postoperative Incontinence

The discussions in the preceding sections have partially addressed the etiology of postoperative incontinence. Risk factors include the loss of rectal capacity, distensibility and sensation, the division or stretch injury of sphincter muscle and the alteration of stool consistency. However, the literature supports additional comment.

In a prospective randomized trial assessing the use of anal retractors for hemorrhoidectomy, van Tets demonstrated a risk of sphincter injury with retractor use. In his study of 40 patients, the use of a retractor was associated with a significant decrease in mean resting pressures following operation (van Tets et al. 1997). Zimmerman reported similar detrimental effects from retractor use in a trial of 30 patients randomized to a Parks retractor or a Scott retractor for fistulotomy. The Parks retractor was associated with a much higher risk of incontinence (Zimmerman et al. 2003).

Unrecognized sphincter injury can aggravate incontinence. In evaluating 123 symptomatic and asymptomatic patients with endorectal ultrasound following anorectal surgery, Stamatiadis found a 5.5% incidence of internal anal sphincter (IAS) injury but no external sphincter (EAS) injury after conventional hemorrhoidectomy. The comparable figures following fistulotomy were 57% for IAS and 29% for EAS injury, and following anal dilation they were 76% and 24%, respectively. However, only 25% of IAS-injured patients and 38% EAS-injured patients reported disorders of continence (Stamatiadis et al. 2002). Felt-Bersma described similar findings in 50 patients. Only 30% were symptomatic for incontinence (Felt-Bersma et al. 1995). Thus sphincter defects may be associated with but are not diagnostic of clinical incontinence. In addition, patients who are asymptomatic with regards to continence, but who are being considered for anal or rectal surgery for other indications, may harbor occult sphincter injuries that could affect continence status postoperatively.

Becker examined resected specimens for the extent of smooth muscle following mucosectomy in 79 IPAA patients. Increased smooth muscle in the specimen correlated with decreased resting pressure. Decreases in resting pressure were related, in turn, to increased stool frequency. Stool frequency was also inversely related to volume of the ileal pouch. Multivariate analysis confirmed that resting pressure and pouch volume were both significant determinants of stool frequency. Increased stool frequency correlated with decreased pouch volume and with nighttime incontinence exhibit the complex interactions at play in continence (Becker et al. 1997).

Hayne has reviewed the risks of pelvic radiation, including the risks to continence both in the acute and chronic phases. Up to 5% or patients are at risk for stricture, fistula and disabling incontinence, adding to the risk associated with resection of rectal cancer (Hayne et al. 2001).

In a review of 24 patients with rectal prolapse, Birnbaum showed that prolonged pudendal nerve terminal motor latencies (PNTMLs) were associated with incontinence following repair. Bilateral neuropathy was associated with an 83% risk, unilateral neuropathy with a 38% risk and normal PNTMLs with a 20% risk of incontinence (Birnbaum et al. 1996).

In following 15 patients after anterior resection, Rao and colleagues determined that anterior resection syndrome, with its attendant continence issues, is compatible with sympathetic denervation of the inferior mesenteric and hypogastric plexuses. With an anastomosis at and below 3 cm from the puborectalis, the rectoanal inhibitory reflex showed a sustained drop in mid-anal canal pressures as opposed to normal recovery with an anastomosis above this level (Rao et al. 1996).

8.6 High-risk Patient Groups

Certain groups of patients can be identified as at high risk for incontinence following colorectal surgery. Beyond what can be inferred from the previous discussions, several additional points can be made. Sultan showed that females have shorter anal canals than males. During LIS, a given length of sphincter division tends to represent a greater proportion of the sphincter and thus increased risk of incontinence. He recommended that, especially in females, care should be taken to keep the length of the sphincterotomy shorter. Females also are at risk for incontinence related to anterior fistulas due to the relative decreased sphincter in the rectovaginal septum. Johannsson found an increased risk in females following hemorrhoidectomy (Johannsson et al. 2002).

Patients who have a history of pelvic radiation present with increased risks for incontinence following colorectal surgery. Gervaz et al. (2001) in reviewing 74 patients, Matzel et al. (2003) in reviewing 139 patients and Welsh et al. (2003) reviewing 124 patients following anterior resection all demonstrated increased rates of incontinence and/or poorer incontinence scores in patients who had a history of radiation.

Patients with a history of previous anorectal surgery frequently harbor occult sphincter injuries that may impact continence following additional anorectal surgery. Thus patients with previous anorectal surgery represent a high-risk group. High transsphincteric and suprasphincteric fistulas increase risk of incontinence following operation for fistula-in-ano, as do posterior fistulas and those with extensions.

Several reports suggest that advancing age has a negative impact on continence following anorectal surgery. Khubchandani found this to be true following LIS (Khubchandani and Reed 1989). This has also been reported with regard to IPAA, anterior resection and hemorrhoidectomy.

8.7 Decreasing the Risk of Fecal Incontinence Following Rectal and Perianal Surgery

The previous discussions have identified numerous opportunities for improving the outcomes for continence following anal and rectal surgery. However, in general, there are certain principles that can be followed. Muscle injury should be minimized. Avoid stretching of the sphincter with prolonged retraction or dilation with instrumentation. Consider the use of fibrin glue and advancement flaps in the management of fistulas. Abandon the Lord's procedure for hemorrhoids and fissures. Minimize the length of the sphincterotomy in the treatment of fissures, especially in female patients.

When possible, preserve as much of the native rectum as is technically feasible. Consider nonresective surgery for rectal prolapse. When possible, avoid radiating the anal canal when treating rectal cancer with the intent of sphincter preservation. Consider preservation of the anal transition zone when performing IPAA, while recognizing risks for dysplasia and persistent inflammatory bowel disease in the retained cuff. Consider the choice of pouch construction, recognizing that larger pouch configurations (S, W) have been associated through randomized trials with improved functional status in the early postoperative period. When possible, preserve as much colonic function as is feasible for the given surgical indication so that stool consistency can be kept as normal as possible.

When proposing a rectal operation on a patient with a history of previous anorectal surgery, consider a physiologic assessment for occult injuries. The finding of an unsuspected, asymptomatic injury may alter your approach to the presenting problem or may allow for a frank discussion with the patient regarding expectations of functional outcome.

8.8 Outcomes Data

There are currently no outcomes data assessing the effect of training or case volume on the postoperative incontinence rates following the procedures discussed in this review. We have only recently seen the establishment of standardized fecal incontinence scores; however, no single score has achieved acceptance by all groups studying fecal

incontinence. Only quality of life incontinence scores have been validated. The result is a body of literature in which comparisons are difficult to make.

There is really no process for comparing the results from specialized centers or specially trained surgeons to nonspecialty centers and surgeons. Such data is only available in limited form for malignant disease through national cancer databases. Until there is a concerted effort to generate outcomes data through the development of uniform reporting mechanisms and the establishment of a compelling reason for all surgeons and centers to participate, these questions will remain unanswered.

8.9 Conclusion

Most operations performed on the anorectum risk postoperative continence. As we have seen, some operations pose a greater risk than others, particularly those that result in division of the sphincter and those that significantly alter the rectal reservoir. However, there are steps that can be taken to minimize risks to continence posed by these procedures. Any surgeon operating on the anorectum should be thoroughly familiar with options that decrease risk. Outcomes data relating to fecal incontinence are lacking but sorely needed and represent an area for potential study and research with regard to fecal incontinence.

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Part III

Diagnostic Methods to Detect Incontinence

III

Chapter 9

Evaluation of Anorectal and Pelvic Floor Muscle Function

9

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Contents

9.1 Anatomical Background

The lower end of the gastrointestinal tract is fitted to control fecal continence and evacuation. Fecal continence is maintained by two key mechanisms: the rectal reservoir function and the muscular closure of the anal canal (Rasmussen et al. 1990; Whitehead and Schuster 1987; Diamant et al. 1999; Azpiroz et al. 2002).

Muscular closure of the anal canal is achieved by three components: the internal anal sphincter, the external anal sphincter and the pelvic floor muscles. The internal sphincter is a smooth muscle cylinder that surrounds the anal canal. The internal sphincter can be considered a thickening of the circular muscle layer of the rectum and exerts a continuous tonic contraction that keeps anal closure during basal conditions. The external anal sphincter is a striated muscle cylinder that surrounds the internal sphincter. The external sphincter exerts voluntary phasic contractions that provide additional closure to the anal canal at demand. The pelvic floor muscles constitute a striated muscular diaphragm, the levator ani, of which the most important component, both from a functional and surgical point of view, is the puborectalis muscle. The puborectal is a muscular sling with two well-developed parallel fascicles that insert anteriorly in the pubis and fusion together behind the rectum at the top of the anal canal. The traction of the puborectalis sling maintains the anorectal angulation. The other components of the levator ani are two thin sheets of muscle, which complete the pelvic diaphragm, the iliococcygeus and the pubococcygeus, although different anatomical arrays have been described (Morgan 1949; Milligan and Morgan 1934; Strohbehn 1998). The external anal sphincter and the pelvic floor muscles exhibit both type I fibers, with high resistance to fatigue, as well as rapid contracting type II fibers. The proportion of both types of fibers depends on several factors, such as sex and age, but the proportion of type II fibers is higher in pelvic floor muscles than in the external sphincter, and hence the former is more of a tonic-type contraction muscle (Beersiek et al. 1979).

Anoperineal muscle function is controlled by intrinsic and extrinsic neural pathways (Parks et al. 1962; Percy et al. 1981). The internal anal sphincter is innervated by the myenteric plexus, but also receives modulatory innervation from the sympathetic and parasympathetic nervous system. Alpha adrenergic receptors produce contraction and beta receptors relaxation. Parasympathetic cholinergic innervation exerts an inhibitory effect. The external sphincter and pelvic floor muscles receive motor innervation from sacral segments II–IV, but whereas the external sphincter is innervated by the pudendal nerves, the levator ani receives innervation directly from the sacral roots. Both the external sphincter and the pelvic floor muscles are under voluntary control via corticospinal descending motor pathways as well as under spinal reflex control via sacral reflex pathways, and these reflexes are preserved in patients with complete spinal transection when the lesion is above the sacral segments.

9.2 Functional Parameters and Evaluation Techniques

It is important to keep is mind that incontinence is multifactorial, and hence incontinent patients require a comprehensive evaluation of all the factors that determine continence, including rectal reservoir function, anal closure and innervation pathways (Meunier 1991; Diamant et al. 1999; Azpiroz et al. 2002). Furthermore, even though it may seem paradoxical, in patients with anal incontinence it is important to evaluate

the defecatory function. Normally, perception of rectal filling is followed, when the conditions are appropriate, by the defecatory maneuver, which completely empties the rectum. In some patients, the defecatory maneuver is abnormal, resulting in incomplete rectal evacuation. Fecal residues remaining in the rectum may leak, particularly if anal contraction is weak. The defecatory maneuver consists in an abdominal compression associated to anal relaxation, which allows evacuation of the fecal bolus. Some patients fail to completely relax the anus during straining, and this results in a functional outlet obstruction. These patients usually compensate their impaired anal relaxation by excessive straining, and this repeat, forceful abdominal compression may in the long term damage the pelvic floor and deteriorate the mechanisms of continence.

9.2.1 Rectal Reservoir Function

The rectal wall is distensible and allows accommodation of the fecal mass. Furthermore, fecal distension activates afferent neural pathways that induce conscious sensation of rectal filling. Evaluation of these two rectal parameters, compliance and sensitivity, provide important information in patients with anal incontinence.

9.2.1.1 Compliance

Rectal compliance reflects both the size and the distensibility of the rectal wall (Rasmussen et al. 1990; Sun et al. 1990b). Compliance is related to the size (capacity) of the rectum, e.g., patients with megarectum have a very high compliance. On the other hand, compliance is also determined by the tonic muscular contraction of the rectal wall (rectal tone), and this can be seen by administration of a relaxant such as glucagon, which increases compliance. Compliance also depends on the elastic vs viscous properties of the rectal wall, and on the mobility of the pelvic organs to allow rectal expansion; for instance, rectal fibrosis or pelvic irradiation may produce a rigidity of the rectal wall with a stiff rectum compliance curve.

Compliance can be measured as the pressure–volume relationship during distension (Diamant et al. 1999; Distrutti et al. 2004). Compliance measured by means of elastic balloons requires corrections in relation to the intrinsic elastic properties of the balloon. Flaccid and oversized bags do not interfere with the measurements and seem more reliable. Compliance can be evaluated by injecting air into the intrarectal bag and measuring the pressure, or alternatively, using a barostat that distends the rectum to given pressure levels, and determines the volume at each distending step. With either technique, each distending level should be maintained for several seconds before making the measurements, because rapid distension may require some time before the rectum stabilizes. Both systems should give the same result. The compliance curve is not linear, and hence it is not possible to compile all the information in a single index; rather a graphical plot seems more advisable (Kellow et al. 2000). The position of the subject during the test determines the extrinsic pressure to the rectum (intra-abdominal pressure at that site), and hence influences compliance. Compliance measurements should ideally be performed in the lateral or prone position, to minimize the intra-abdominal pressure at the pelvic level. Otherwise abdominal viscera laying on top of the rectum will interfere with the measurements.

9.2.1.2 Perception of Rectal Filling

The rectum has a sensory innervation that provides conscious recognition of rectal content. Rectal sensitivity can be evaluated by measuring perception in response to rectal distension. For clinical purposes, the methods described above to measure rectal compliance may be appropriate. Indeed, perception has to be evaluated considering compliance: a patient with megarectum requires very large volumes for perception, and conversely, in patients with a small, stiff rectum, very small volumes induce discomfort. Several responses can be measured such as the first perception and the urge to defecate. At this stage, the mechanisms (type of receptors) of these responses are unclear. However, it has been shown that impaired ability to perceive rectal distension is a risk factor for fecal incontinence (Wald and Tunuguntla 1984). Some recent data suggest that perception is directly related to the tension of the rectal wall, which can be calculated based on the intrarectal pressure and volume, by applying Laplace's law. These data would indicate that rectal distension procedures could be best standardized using fixed tension levels, by means of a tensostat (Distrutti et al. 2004). However, for routine clinical evaluation rectal distension at fixed volumes would suffice.

The distension paradigm may influence perception. Particularly, very rapid distensions such as those used for studying evoked potentials may give different responses than slower distensions. However, it is not clear whether this type of rapid distension also stimulates other types of pelvic structures that contribute to perception. At this stage, there are no data to recommend any specific technique for measuring perception, but for clinical purposes stepwise rectal distension seems acceptable for providing the relevant information.

9.2.2 Anal Sphincter Function

Anal sphincter function is usually evaluated by manometry, measuring the pressure in the anal canal (Meunier 1991; Diamant et al. 1999). Anal canal manometry does not reflect the activity of the levator ani. Anal manometry can be performed using low perfusion systems (3 ml/min or less) and commercially available probes of less than 5 mm in diameter provide reliable measurements. High perfusion rates may induce motor responses due to mucosal or skin stimulation. Manometric probes may allow measurement of radial pressures, which may be of clinical utility by detecting asymmetries. Solid state microtransducers are reliable, but do not allow the use of multiple recording sites at short distances and with flexible probes. Pressures should be measured along the anal canal from the rectum to the anal verge. A stationary pull-through technique is recommended, allowing a few seconds for accommodation at each station before measuring the basal pressure. At each step, the squeeze pressure produced by voluntary anal contraction should also be measured. The dynamic pull-through technique seems unadvisable, because the stimulation of the anal canal by the probe movement induces a contraction of the external anal sphincter, resulting in artifactually increased basal pressures. Alternatively, a manometric probe with multiple, close, special (5–10 min) recording sites could be used to measure simultaneously the pressures at different levels of the anal canal from the rectum to the anal verge. Basal pressure reflects by-and-large the activity of the internal anal sphincter. Manometric studies in patients during pudendal block and other interventions demonstrated that 30% or more of the basal anal resting pressure can be attributed to the external sphincter (Du-

thie and Watts 1965). Voluntary contraction of the external anal sphincter is evaluated by asking the patient to squeeze while the pressure increment at different levels of the anal canal is being measured. To evaluate squeeze pressure, it is important to make sure that the patient does not increase simultaneously intra-abdominal pressure, because this may trigger extrinsic reflexes and confound the results.

9.2.3 Neural Reflexes

9.2.3.1 Rectoanal Inhibitory Reflex

This reflex is used to evaluate the function of the intrinsic innervation of the internal anal sphincter. Normally, distension of the rectum elicits an intrinsic reflex (i.e., via the myenteric plexus), which produces a relaxation of the internal anal sphincter (Whitehead and Schuster 1987; Schuster et al. 1965; Burleigh 1992). This reflex can be elicited by inflating a rectal bag or balloon, and the anal response can be measured using a manometric probe. This technique has replaced the Schuster double balloon method initially developed for that purpose (Schuster et al. 1965). Before testing this reflex, the presence of a basal anal tone (basal pressures) should be demonstrated. Several technical aspects should be also taken into account such as the application of an appropriate stimulus that is able to distend the rectum even in case of megarectum. For that purpose, it is important to monitor the intraballoon (intrarectal) pressure. The rectum should be free of feces, otherwise the balloon may displace the fecal mass without a real stimulation of the rectal wall. It is also advisable to use several manometric ports along the anal canal, because inflation of the balloon may produce an interiorization of the probe with a pressure drop at the orad port. Other potential technical pitfalls are related to the contraction of the external anal sphincter induced by the perceived rectal distension, which may obscure the relaxation of the internal anal sphincter. In this case, a pudendal block would reveal the presence of the normal reflex.

9.2.3.2 Cough Reflex

This reflex is used to evaluate sacropudendal reflex pathways. Normally, an intra-abdominal pressure increment induces a reflex contraction of the external anal sphincter. This is a multisynaptic sacral reflex, which prevents anal leakage during abdominal compression (Parks et al. 1962; Sun et al. 1990a). Conceivably, this reflex is voluntarily inhibited during the defecatory maneuver via descending inhibitory pathways. The term "cough reflex" implicitly excludes other techniques involving sustained abdominal compression. Indeed, this reflex can be elicited by asking the patient to blow against a fixed pressure level into a manometer, to blow up a balloon or simply to cough. Also, with a gradual increase in intra-abdominal compression, one may elicit a reflex inhibition (and not a reflex contraction) in pelvic floor muscles and anal canal pressure as seen in response to the defecatory maneuver. Hence, cough or very rapid increase in intra-abdominal pressure is recommended to elicit the cough reflex in a clinical setting.

This reflex can be tested using a manometric probe. The intra-abdominal pressure increment should be monitored either using an intrarectal balloon or a manometric port. The response in the anal canal should be monitored using multiple ports spaced

along the anal canal, because the abdominal compression may produce a displacement of the probe. The double balloon technique may register a different type of response. For the evaluation of this reflex, the pressure increment in the abdomen and in the anal canal should be compared, and in normal conditions the latter should be higher. Another parameter in evaluating this reflex is the duration of the reflex anal contraction (increment in anal pressure), which should be longer than the intra-abdominal pressure peak. This parameter is particularly useful in case of damage of the external anal sphincter resulting in muscular weakness. Nevertheless, the evaluation of the cough reflex requires the presence of some manometric activity of the external anal sphincter, and in some cases the interpretation may be difficult. Alternatively, the anal response may be monitored by electromyography. The precise timing of the anal response in relation to the intra-abdominal pressure increment has not been clearly established. Some data suggest that the anal increment precedes the actual intra-abdominal pressure rise. However, this anticipatory response may reflect learning (i.e., Pavlovian conditioning) rather than reflex activity.

9.2.3.3 Anocutaneous Reflex

This reflex has been used as an alternative method to evaluate the reflex innervation of the external anal sphincter: scratching the perianal skin elicits a reflex contraction (Diamant et al. 1999). The use of this reflex is limited, because it requires a relaxed external anal sphincter for the response to be seen; tense subjects may not display a recordable response. Furthermore, this reflex can be inhibited by voluntary efforts or by asking the subject to relax. However, this reflex is not a conditioned (i.e., learned) response, because it can be elicited in patients with high spinal cord lesions. At present the clinical relevance of this reflex has not been established, and it is not used for routine clinical testing.

9.2.4 Defecatory Function

Defecation is normally produced by an abdominal compression associated with anal and pelvic floor relaxation, which results in perineal descent and evacuation of the fecal bolus through the anal canal. It is not clear whether defecation in humans also involves rectal contractions. There is no agreement on the technique to evaluate the defecatory maneuver. It seems important to measure the abdominal compression, for instance by intrarectal pressure recording, and anal relaxation, without interfering with the normal conditions to prevent artificially abnormal responses. The defecatory maneuver is usually studied with some degree of rectal distension by means of a balloon, but both rectal compression and anal relaxation can also be observed without any kind of rectal distension. Laboratory tests do not tell what happens during real defecation, but may provide useful information for the management of the patient. The effect of the various degrees of lack of privacy and the position of the patient during the test (left lateral decubitus vs sitting on a commode) has not been clearly established (Duthie and Bartolo 1992).

The defecatory maneuver can be evaluated using a manometric technique. Abdominal compression can be measured by recording intrarectal pressure, usually using a balloon. The anal relaxation can be measured by pressure recordings along the anal canal. Manometric evaluation of anal relaxation requires multiple, closely spaced re-

cording ports along the anal canal, because during straining the anal canal shortens progressively until the final diaphragm opens completely, and these morphological changes may displace the probe. If both intrarectal and anal pressure recordings are combined, it is important to locate the most orad anal manometric port very close (<5 mm) to the rectal balloon, otherwise a short nonrelaxing segment of the anus may be missed. The relaxation of the anal canal can be also evaluated by surface electromyography (inhibition of striated muscle activity). The correlation between manometry and electromyography seems very good. The perineal descent may be measured separately by perineometry.

9.2.4.1 Expulsion Tests

The evacuation capability is generally evaluated by specific expulsion tests. Different techniques have been used to evaluate the capability of expulsion, and there is no agreement on a standard test. Large (100 ml or 50 ml) deformable balloons made of condoms, as well as small rigid balloons (Foley balloon inflated with 5 ml of water) have been used. In general, larger balloons are easier to evacuate. These tests try to establish the specific condition, in terms of balloon size and time, under which the normal population would achieve evacuation, but not patients with functional outlet obstruction (Rao et al. 1999). The problem here is that some patients in the normal population may have subclinical, undetected functional outlet obstruction, and conversely, patients with functional outlet obstruction may have normal expulsion due to compensatory mechanisms. This could also explain the relatively poor correlation of the results of the different techniques, and may warrant a systematic investigation of the physiological mechanisms of defecation. Nevertheless, the information about the different parameters related to defecation (abdominal compression, anal relaxation, perineal descent, expulsion capability) should be analyzed together. In some laboratories a combination of techniques is used, by measuring intraballoon pressure during expulsion (defecometry), which gives an integrated view of the abdominal contraction and the resistance of the anal canal (anal compression of the balloon), but these data may be even more difficult to interpret.

9.2.5 Pelvic Floor Muscle Function

9.2.5.1 Perineometry

The activity of the puborectalis can be indirectly tested by the perineometer, which measures the level of the perineum with respect to the ischial hypophysis. The pelvic floor physiologically ascends during anoperineal muscle contraction, and descends during straining associated with anoperineal relaxation. In general, it is felt that these measurements are difficult to perform, and the reproducibility is poor. Some patients with functional outlet obstruction have, in association with their impaired anal relaxation (or paradoxical contraction), impaired relaxation of the puborectalis muscle with minimal perineal descent, featuring a true abdominoperineal dyssynergia. Other patients with functional outlet obstruction and compensatory forceful training produce excessive perineal descent. This perineal dysfunction is related to descending perineum syndrome and may also be associated with pudendal damage due to nerve stretch.

9.2.5.2 Levator Ani Contraction

The voluntary muscular contraction of the levator ani can be measured using a perineal dynamometer. With the patient positioned in lateral decubitus, the system measures the traction exerted by the levator ani on an intrarectal balloon catheter. The balloon is inflated with a fixed volume of water and connected by a nondistensible rope to an electronic isometric dynamometer. The external dynamometer is positioned perpendicular to the anal canal axis, by means of an articulated support. The support consists of three articulated arms made of methacrylate. The anterior and posterior arms are adjusted and fixed in each subject to be in apposition to the pubis and the posteroinferior aspect of the sacrococcygeal junction, respectively. Phasic contraction of the levator ani are measured by asking the subjects to produce a maximal anal squeeze (Fernández-Fraga et al. 2002).

An important aspect in this system is the 90° angulation between the axis of the anal canal and the dynamometer, and this is carefully accomplished by means of the articulated support fixed to the pelvic bones. Nevertheless, deviations from this angle may not be critical, for instance, 10° deviation, which is a substantial error, would theoretically underestimate the actual traction only by 1.6% ($\mathbf{b} = \mathbf{a} \cdot \cos\alpha$; where **b** is the force measured, **a** the actual traction, and α the angle of deviation). The reproducibility of this method has been carefully validated by repeat measurements on the same and different days. A similar approach has been previously used to evaluate anal continence by measuring the strength required to pull out intrarectal rubber balls or spheres (Diamant and Harris 1969). This is an experimental technique, whose clinical value remains to be established.

9.3 Outcome Measures and Clinical Relevance

The information of the different tests is complementary and interpretation depends on the integration of all the data (Meunier 1991). Some tests (i.e., the rectoanal inhibitory reflex and the cough reflex) are basically qualitative, whereas other tests (e.g., anal canal pressure and sensory thresholds) provide quantitative information. However, the range of normal values has not been established. Furthermore, the clinical significance of normal and abnormal values remains unclear. Considering each functional parameter independently, subjects with values outside the normal range may not have clinical symptoms, because, given the great capability for functional compensation, an isolated dysfunction may not have clinical relevance. The pathophysiology of most clinical conditions is multifactorial, so that symptoms may only occur when multiple parameters are affected. On the other hand, since anorectal dysfunctions may have different causes, in patients with clinical problems some parameters may be similar to those in healthy subjects.

9.3.1 Rectal Reservoir

Reduced rectal compliance may be an important pathophysiological factor in some patients with incontinence, due to the lack of rectal reservoir function, specially if they also have another factor such as weak sphincters. It is frequently associated with rec-

tal hypersensitivity. Hypersensitivity with reduced threshold for the urge to defecate may be important in patients with urge incontinence and can be seen in patients with proctitis.

Impaired rectal perception may be an important pathophysiological factor in fecal incontinence. Indeed, high threshold for first perception has been proposed to be of clinical value patients with incontinence (Caruana et al. 1991; Whitehead et al. 1981). Patients with a neurological deficit may have constipation and incontinence, and in them rectal sensitivity can be considerably improved by means of biofeedback techniques (Musial and Enck, in press).

Increased thresholds for urge to defecate can be also observed in patients with constipation. Usually these patients also have a large rectum with increased compliance. It is not known whether a large, atonic rectum is a contributing cause of fecal impaction or whether it is a passive consequence of recurring fecal impaction. In patients with functional outlet obstruction, continuous fecal distension of the rectum abolishes the sensation of rectal filling and the desire to evacuate, but these sensations are recovered after successful retraining (di Medici et al. 1989).

9.3.2 Anal Sphincters

The clinical value of anal pressures considered alone is limited, because patients with abnormal low pressures may have normal continence, and conversely, patients with incontinence may have normal pressures. Furthermore, the normal values of pressures in the anal canal has not been established. However, basal pressures below 20 mmHg and above 100 mmHg, as well as squeeze pressure increments lower than 20 mmHg may be considered abnormal.

9.3.2.1 Weak Sphincters

Low basal pressures are pathophysiologically important in patients with incontinence, but have to be considered with the rest of the functional findings, because a patient with very low basal pressures may be perfectly continent. The length of the anal canal may seem theoretically important, in analogy to the lower esophageal sphincter, but there seems to be little evidence to support it. A long anal canal has no clinical relevance, and a short canal may be seen in patients with surgical or traumatic injures. Twenty-four-hour manometric studies in healthy subjects have demonstrated spontaneous pressure drops in the anal canal, down to atmospheric level (Enck et al. 1991). These relaxations are more prominent in the recumbent position after awakening in the morning before breakfast, when they can reach a roughly one per minute frequency. They seem not related to rectal activity, and their relationship to rectal content is not clear. During a routine clinical manometry, spontaneous relaxations are usually not seen, except in patients with diabetes, where they appear more frequently. Spontaneous relaxation has been also observed in the following conditions: (a) patients with anal gape during the examination (i.e., patulous anus), (b) female patients with incontinence during intercourse, (c) patients with nocturnal incontinence, and (d) during overnight studies in patients with ileal pouches, where they are associated with leakage. Overall in incontinent patients, spontaneous relaxation seems not to be increased, and their pathophysiological role in incontinence has not been established. Anal pres-

sures decrease during night sleep. Some patients, particularly with incontinence, exhibit unstable pressures during the clinical manometry, but overall there is little experience on this particular topic.

A weak squeeze pressure is an important factor, particularly in patients with incontinence. Weak squeeze pressures may indicate sphincter damage, neurological damage of the motor pathways, or simply a poorly compliant patient. Some patients have poor voluntary control of this muscular activity or are not compliant with the instructions. For instance, it has been reported that sexually abused patients have a weak squeeze pressure even without any lesion (Leroi et al. 1995). Poorly compliant patients in general can be easily trained to produce normal contractions by providing visual feedback of the manometric activity. Squeeze pressure should be evaluated together with the reflex contraction of the external anal sphincter in response to coughing (cough reflex). Impaired squeeze pressure and a normal cough reflex may indicate neurological damage of the central motor pathways (above the sacral segments) or just poor compliance. Conversely, an abnormal cough response suggests damage to the sacral reflex arch (pudendal nerves or sacral segments). When the squeeze pressure is decreased, it may be important to determine whether it is due to muscular or neural damage, using either endosonography to detect muscle defects, or external sphincter electromyography, which may suggest a muscular defect in case of normal electrical response in the presence of low squeeze pressures.

The duration of the maximal squeeze pressure depends on the proportion of type I and II fibers in the external anal sphincter, which is related to age. Healthy subjects maintain the maximal squeeze pressure for 45–50 s (Chiarioni 1993), and the voluntary contraction is followed by a refractory period. It has been proposed that the inability to sustain the maximal squeeze pressure for 10 s may reflect a decreased number of tonic fibers, and that this may favor incontinence, even with appropriate initial magnitude of squeeze pressures. The duration of squeeze pressure and the refractory period could be important in planning biofeedback therapy, but really the clinical relevance of measuring the duration of squeeze pressure has not been clearly established to date. Radiological studies (Grimaud et al. 1991) using simulated solid stools have shown that sustained anal squeeze produces a retropulsion of rectal content into more proximal parts of the colon, but retropulsion does not occur with liquid feces.

9.3.2.2 Hyperactive Sphincters

Basal pressures above the normal range can be seen in healthy asymptomatic subjects, and hence this finding per se has no clinical value. Most patients with anal fissure have pressures in the upper limit of the normal range or above. However, some fissures appear in patients with normal or even low pressures. The pathophysiology in these two situations may be different. Some surgeons require evidence of high basal pressures before indicating sphincterotomy in patients with anal fissure, and would not recommend this procedure otherwise (Cerdan et al. 1982). High anal pressures have also been seen in patients with anal pain. Interestingly, high pressures in some of these cases have been observed to correspond to striated muscle activity using electromyography. Smooth muscle spasm can be differentiated from striated muscle spasm as a cause of high resting pressure by giving sublingual nitroglycerine (10 mg): this causes the internal anal sphincter to relax within 5 min with recovery by 15 min. Striated muscle spasm is unaffected by nitroglycerine. High magnitudes of squeeze pressures have

been observed in male patients with prostatic-type chronic pelvic pains and impaired anal relaxation during straining.

Ultraslow waves of 1–2 cycles per minute are usually associated with high basal pressures; slow waves in the 8–12 cycles per minute range and fast waves have been also described. There is no known pathophysiological role for these events. Brief episodes lasting a few minutes with increased anal pressures, featuring a kind of anal spasm, have been described during proctalgia attacks in patients with a particular form of internal sphincter myopathy. In patients with proctalgia fugax, the relationship of anal pressures to the pain is not clear, and in some pain episodes increased rectal activity with normal anal pressures has been observed.

9.3.3 Reflex Activity

9.3.3.1 Anorectal Inhibitory Reflex

Presence of the rectoanal inhibitory reflex indicates a functioning myenteric plexus, and hence absence of Hirschsprung's disease. Sometimes the external anal sphincter contracts during rectal distension. This is an automatic, but not a reflex response, that may sometimes be abolished by asking the subjects to relax (Whitehead et al. 1982). This response can be observed more frequently using the double-balloon probe than with perfused manometry, and probably depends on the anal stimulation caused by the diameter of the probe. It can also be seen in patients who are tense or with anal irritation.

The definition of an incomplete relaxation is unclear, and it could be theoretically caused by increased activity of the external anal sphincter or to impaired inhibitory input to the internal anal sphincter. Studies under general anesthesia suggest that this reflex produces a complete inhibition of the internal anal sphincter. Incomplete or irregular responses (lack of dose–response relationship) have been observed in neurological disorders, rectal ischemia, scleroderma, myelomeningocele, and trauma to the cauda equina. A pronounced rebound contraction after deflating the rectal balloon has been observed in dystrophia myotonica in the myotonic stage, and in patients with anal fissure. In the latter case, it has been shown by electromyography that this contraction corresponds to the internal anal sphincter. Occasionally this rebound contraction has also been observed in patients with proctalgia without fissure. The clinical value of incomplete relaxation and rebound contraction have not been established.

Absence of the rectoanal inhibitory reflex is most frequently due to technical aspects. Absence of the reflex in repeat explorations may indicate Hirschsprung's disease (Meunier et al. 1978). However, Hirschsprung's disease is a pediatric disorder, and it is extremely rare to find this disease undiagnosed in adults. Nevertheless, in case of constipation with radiological evidence of megarectum and a narrow aganglionic transitional zone, one should perform a rectal biopsy to confirm the absence of ganglionic cells. The existence and clinical significance of ultrashort Hirschsprung's disease is debatable, because these patients do not have megarectum; evidence of a narrow segment is not definitive, and even the biopsy may not be conclusive, because this caudal zone lacks ganglionic cells. It is also not clear how an ultrashort aganglionic segment could impair defecation. Absent rectoanal inhibitory reflex has also been observed in patients with visceral neuropathies, and some subjects have absent reflex without megarectum or constipation.

9.3.3.2 Cough Reflex

The following parameters indicate that this reflex may be impaired: (a) magnitude of the anal contraction lower than the intra-abdominal pressure increment, (b) in case of weak sphincter, anal contraction lower than the maximal anal squeeze pressure, and (c) duration of the anal response not exceeding the intrarectal pressure increment. Other parameters such as delayed onset remain to be validated. An abnormal reflex response in the presence of normal squeeze pressure indicates neural damage of the sacral arc, either of the spinal sacral segments or the pudendal nerves. The presence of the normal squeeze pressure with abnormal cough reflex may be explained either by a larger number of efferent pathways activated by a voluntary contraction as compared to the reflex response, or alternatively, by selective damage of the afferent reflex path. Usually these patients have stress incontinence and may either have a spinal sacral lesion (cauda equina), a pudendal neuropathy, or a disease involving peripheral neuropathies such as diabetes. However, this reflex is preserved in patients with spinal lesions above the sacral level (Sun et al. 1990a). These latter patients have impaired or even abolished anal squeeze pressure, but have a normal cough reflex. The presence of an abnormal reflex in a normal subject could be interpreted either as a false-positive or as a subclinical neuropathy, and so far there are no data on the specificity of this reflex.

9.3.4 Impaired Defecation

Impaired anal relaxation during straining is usually associated with reduced expulsion capability in patients with constipation (Whitehead et al. 1999). Some patients may even exhibit anal pressure increment during straining because of a paradoxical contraction of the external anal sphincter. The main criticism to the clinical usefulness of this parameter has been that it may be seen in healthy subjects. Again there are no data to clarify whether these are simply false-positives or whether these are subclinical dysfunctions in apparently healthy subjects, in which the alteration is compensated by another mechanisms such as undetected or unrecognized excessive straining or decreased stool consistency. Another potential criticism is the poor reproducibility of this maneuver in some patients. However, the inconsistency of the maneuver probably reflects some degree of dysfunction. The lack of relaxation of the anal canal during straining has been called animus, pelvic floor dyssynergia, or functional outlet obstruction. In these patients, frequently also with weak sphincters, fecal retention may lead to anal leak and incontinence.

Some patients with impaired anal relaxation exhibit very high intrarectal pressures during straining, which probably reflect an extra effort to attempt expulsion. In some cases, the extra effort compensates for the defective anal relaxation and the expulsion capability is preserved, but in other cases the compression is still insufficient and the expulsion is defective. Excessive abdominal compression conceivably produces a perineal stress, which may have long-term consequences (i.e., traction injury to the pudendal nerve or enterocele). In some patients with incontinence and normal expulsion capability, the abdominal compression is excessive. There are no data to support whether these are false-positives or whether these patients initially had a functional outlet obstruction that has been resolved after the muscle has been damaged by repeated stress. However, it has been recently shown that history of constipation is the only

physiological factor predictive of a poor response to biofeedback treatment in patients with incontinence (Fernández-Fraga et al. 2003).

Children with paradoxical contraction during straining may be unable to voluntarily evacuate the rectum, and have fecal overflow (encopresis). Some patients with impaired anal relaxation during straining have a global dysfunction both of the puborectalis muscle and the external anal sphincter. However, other patients have an isolated dysfunction of the external anal sphincter with normal or even exaggerated perineal descent. Sometimes only a narrow segment of the most distal part of the external anal sphincter does not relax. It is not clear whether the reverse is also true, that is, whether a normal and complete relaxation of the external anal sphincter during straining can be associated with a lack of relaxation of the puborectalis muscle. The dissociation of these two muscles can also be detected by needle electromyography.

Impaired relaxation may be also associated with anal fissure, but it is not clear whether the outlet obstruction plays a pathophysiological role in the development of the anal fissure, or whether the pain associated with the fissure inhibits the normal defecatory maneuver. This dysfunction has also been reported in sexually abused patients (Leroi et al. 1995) and in patients with neurological disorders, the latter probably due to injuries to the voluntary inhibitory pathways. Detection of this dysfunction may be important, because it may be successfully treated with biofeedback using either manometric or electromyographic techniques. In the presence of a functional outlet obstruction, colonic transit times measured by radiopaque markers are difficult to interpret.

Patients with neurological or skeletal muscle disorders (Roberts et al. 1992) may exhibit weak abdominal compression, reflected by low intrarectal pressures during straining, and this may be the cause of incomplete rectal evacuation.

9.3.5 Weak Levator Ani

Levator ani contraction is elicited by asking the patients to squeeze, the same maneuver that produces contraction the external anal sphincter, and conceivably a global contraction of the pelvic floor musculature (Whitehead and Schuster 1987; Diamant and Harris 1969). However, levator ani performance is distinctly different from that of the external sphincter, both in physiological and in pathophysiological conditions. It has been shown that overall, the levator ani and the external sphincter correlate well, but in some patients failure of one muscle coexists with a normal function of the other. This dissociation may be more frequent than observed, because patients with sphincter damage, but preserved levator ani, may not develop incontinence in the absence of other pathophysiological factors. Likewise, the rheological properties of the levator ani are different, with a slower reaction and significantly less fatigability, probably related to the different tissue structure and innervation

In a cohort of healthy subjects and constipated patients, levator ani contraction force was found to be around 500 g (95th percentile values between 361 g and 725 g), and a large proportion of patients with anal incontinence, approximately 60%, had impaired levator ani contraction (Fernández-Fraga et al. 2002). It has been recently shown that levator ani contraction is the independent variable with the strongest relation to the severity of incontinence, as well as the strongest predictive factor of the response to treatment. Furthermore, in contrast to other physiological parameters, a marked and significant levator ani strengthening was associated with clinical improvement in response to biofeedback therapy (Fernández-Fraga et al. 2002).

9.4 Indications

Within the context of this chapter, the indications for a formal evaluation of anorectal function will be divided into two sections: patients in whom neuromuscular function seems to be impaired, and those with other type of anorectal symptoms.

9.4.1 Patients with Incontinence and/or Pelvic Floor Dysfunction

Anal incontinence either to solid feces, liquids or gas, is not normal and should be always investigated. A proper evaluation in patients with incontinence provides a good guideline for individualized treatment planning. If on the basis of the antecedents (obstetric or iatrogenic injury, trauma) and the physical exam (asymmetries, rigidities, scars) anatomical damage is suspected, evaluation by imaging techniques is indicated. Significant muscular disruptions may require surgical repair, but minor tears usually do not have clinical relevance and should be treated conservatively. In patients undergoing surgical treatment, a proper evaluation of the functional status before and/or after surgery may be valuable for a comprehensive treatment. Indeed, the results of surgical repair in these cases may considerably improve when the concomitant functional abnormalities are identified and treated.

Pelvic floor damage includes a series of urological, gynecological and proctological disorders such as rectocele, cystocele, various prolapses, descending perineum, and urinary incontinence. Functional evaluation identifies putative etiological mechanisms such as functional outlet obstruction and provides a clear idea of the neuromuscular status.

Before major anorectal surgery, evaluation of anorectal function helps to establish a prognosis and define the putative risk of postoperative incontinence. Some patients after surgery exhibit symptoms such as incontinence, defecatory urgency, or insidious tenesmus, which may improve once the pathophysiological mechanism is identified and corrected.

Patients with diseases potentially associated with neuromyopathies may present constipation, incontinence or may be asymptomatic. Functional evaluation can determine anorectal involvement and its functional repercussion.

9.4.2 Other Indications Not Primarily Related to Pelvic Floor Damage

A large proportion of patients with constipation not responding to dietary corrections and mild osmotic laxatives present a functional outlet obstruction that once identified may be corrected by biofeedback treatment. Over the long term, excessive straining in these patients may damage the pelvic floor, and this may be also prevented.

In the case of suspected Hirschsprung's disease, the identification of the rectoanal inhibitory reflex rules out the diagnosis. If the reflex is repeatedly absent, a deep rectal biopsy should be performed.

Most patients with megacolon have constipation caused by functional outlet obstruction that conceivably has been the cause of the colonic dilatation due to fecal retention over the years. After biofeedback treatment, these patients may become

asymptomatic. In other patients, megacolon is a fortuitous finding, possibly because the original defect resolved.

A heterogeneous group of conditions such as proctalgia, perineal discomfort, solitary rectal ulcer and rectal bleeding of unknown origin may be the consequences of anorectal traumatism related to functional outlet obstruction and excessive straining. Proper diagnosis and correction of the abdominoperineal incoordination (impaired anal relaxation with compensatory straining) may resolve the clinical problem.

9.5 Conclusion

Nowadays the anorectal physiologist has an array of techniques that allow systematic testing and comprehensive evaluation of pelviperineal muscle function. The identification of pathophysiological mechanisms in patients with anal incontinence, pelvic floor damage and other related conditions allows individualized mechanistic treatment planning. In a large proportion of patients, conservative treatment is effective, but if surgical intervention is indicated, a proper neuromuscular balance status provides a helpful guide for the surgeon.

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Chapter 10

Imaging of the Pelvic Floor – Videoproctography and Dynamic MRI of the Pelvic Floor

10

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Contents

10.1 Introduction

Pelvic floor disorders are manifold. Outlet obstruction, anismus, inertia recti, descending perineum syndrome, dyskinesia of the puborectal muscle, intussusception, prolapse of the anus and rectum, vaginal prolapse, rectocele, cystocele and enterocele are common diagnoses in proctology. Besides constipation, problems with incontinence for stool or urine are the most common symptoms. Women are affected at a significantly higher rate (ratio 9:1) (Winkler and Otto 1997). Patients usually seek help from gynecologists, urologists, dermatologists and proctologists. Therefore, diagnostic and therapeutic strategies for an interdisciplinary approach are needed.

A thorough medical history and proctologic examination (inspection, palpation, rectoscopy, proctoscopy) along with manometry and endosonography are the basic diagnostic tools in complex pelvic floor disorders, and evacuation proctography may yield additional information (Herold et al. 1999).

With the improvement of magnetic resonance imaging (MRI) technology, dynamic MRI of the pelvic floor has become an alternative option in the diagnostic process of combined pelvic floor disorders. Since its introduction by Yang et al. (1991) and Kruyt et al. (1991) in 1991, MRI is increasingly replacing evacuation proctography first described in 1952 by L. Walldén (1952) for the evaluation of outlet obstruction.

In the evaluation of enteroceles and uterovaginal prolapses, MRI of the pelvic floor seems to be favorable in some aspects compared to clinical examination and evacuation proctography (Yang et al. 1991; Kruyt et al. 1991; Goodrich et al. 1993; Healy et al. 1997a,b; Lienemann et al. 1997, 2000). In addition, examination series in MRI can be repeated without any ionizing radiation. This may increase the chances of detecting pathological findings in some patients (Lienemann et al. 1997).

On the other hand, the horizontal position of the patient during MRI may influence pelvic floor physiology. Therefore, some authors consider videoproctography to have advantages over MRI in the diagnosis of enteroceles or rectoceles (Delemarre et al. 1994; Vanbeckevoort et al. 1999).

So far, patient preparation, examination technique and reference lines for the evaluation of MRI have not been standardized and findings differ widely in the published studies. Most of the studies did not examine the defecation process. Normal findings and normal values were defined in small control groups and therefore were only applicable in the actual study setting. For these reasons, MRI cannot yet replace videoproctography in the evaluation of pelvic floor disorders.

10.2 Technical Necessities to Perform Defecography

Videoproctography is performed as usual in lateral projection with patients in the upright position sitting on a specially designed commode. The rectum is filled with 150–200 ml of a barium paste. The visualization of a cystocele or a vaginal prolapse requires filling the bladder with contrast medium and inserting a vaginal tampon, respectively. To visualize an enterocele, the oral administration of contrast medium is necessary. Patients first are asked to relax the pelvic floor and then to empty the rectum as completely as possible. Images are obtained at a frequency of one per second during defecation.

10.3 Radiation Dose of Defecography

Radiation exposure of the patient during defecography is an important point. Most patients referred to the radiologist for defecography are women and some are still of childbearing age. Therefore, the possibility of potential genetic damage is an important issue. Since defecography is a dynamic investigation, a series of images is necessary. There are three options to perform a conventional defecography:

- Use of 100-mm image intensifier photography with frequent single shots or with the serial technique. Ovarian dose measurements of 15±5 mSv were published by Goei and Kemerink in 1990.
- Video recording has the disadvantage of a poorer image quality. Brühlmann and Müller-Duysing measured doses of 9 mSv for the ovary proximal to the X-ray tube. Ovarian doses of 4–16 mSv were published from other investigators.
- Cineradiography combines image quality with good temporal resolution. However, ovarian doses of 60 mSv were measured, which are unacceptably high doses to women of childbearing age.

New digital imaging techniques can reduce the dose resulting in an approximately twofold lower dose–area product (Broadhead et al. 1995). Additionally low-dose digital programs with added copper filtration have the lowest dose showing still adequate image quality (Hare et al. 2001).

10.4 Standards of Evaluation

The reference line was the pubococcygeal line (Fig. 10.1), movement of pelvic floor organs was measured as the vertical distance to this line. Above the pubococcygeal line values were marked positive (+), values below this line were marked negative (–).

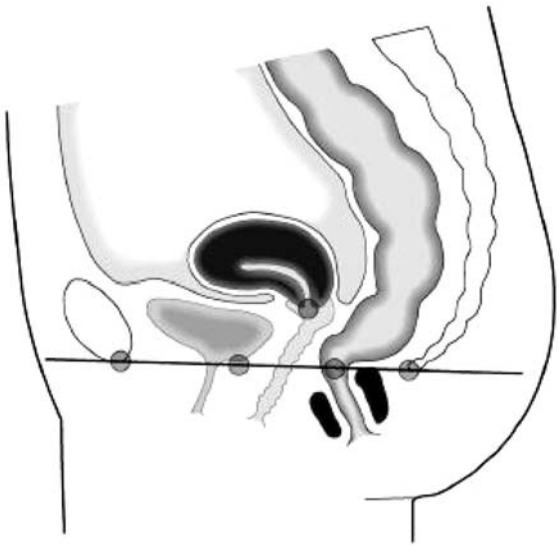

Fig. 10.1.
Diagram of the pubococcygeal line (*black*) joining the most inferior part of the pubic symphysis and the last coccygeal joint. Additionally this figure shows the bladder base, uterocervical junction and the anorectal junction (*gray dots* from left to right)

Data were recorded in resting position as well as during the defecation process with maximal straining. All data (except those typified) are mean values with corresponding standard deviations.

The anorectal junction was defined as the intersection point of the central axis of the anal canal and a line along the posterior rectal wall. The anorectal angle was measured between these two lines (Yang et al. 1991; Healy et al. 1997a; Lienemann et al. 1997).

According to the literature, based on different evaluation techniques, a rectocele is defined as a bulge of the anterior rectal wall of approximately 20–30 mm (Delemarre et al. 1994). For data analysis of the videoproctography and MRI, we applied the method described by Delemarre et al. (1994), who defined a rectocele as the distance from the anorectal junction to the tip of the protrusion of the anterior rectal wall.

Due to the imaging technique, only MRI revealed data on the position of the bladder base, the uterocervical junction and the vagina. Also, an enterocele could only be assessed by MRI.

A cystocele and a uterovaginal prolapse were diagnosed if the bladder base or the uterocervical junction fell below the pubococcygeal line during defecation (Lienemann et al. 1997, 2000). Widening of the rectovaginal space or a descent of mesenteric parts, small bowel or sigmoid colon beyond the pubococcygeal line during defecation was defined as an enterocele (Healy et al. 1997b; Lienemann et al. 2000).

During the stages of defecation, the following parameters should be considered:

- The anorectal angle: the angle between the axis of the anal canal and the line along the posterior border of the distal rectal wall
- The position of the anorectal junction in relation to the pubococcygeal line
- The movement of the anorectal junction from rest to squeezing and from rest to straining
- The amount of rectal emptying
- The morphological changes of the rectal wall

10.5 Information from a Correctly Performed Defecography

The main application of defecography is for the detection of anatomical abnormalities as the possible cause of defecation disorders. The following findings of defecography are common:

- Intussusception (Fig. 10.2)
- Rectocele (Fig. 10.3)
- Prolapse
- Descending perineum syndrome
- Solitary rectal ulcer
- Spastic pelvic floor syndrome
- Evacuation disorders

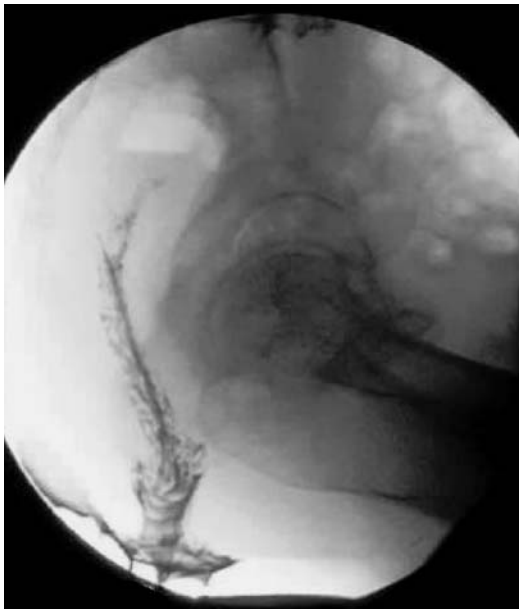

Fig. 10.2.
Intussusception of the rectal wall at the end of defecation

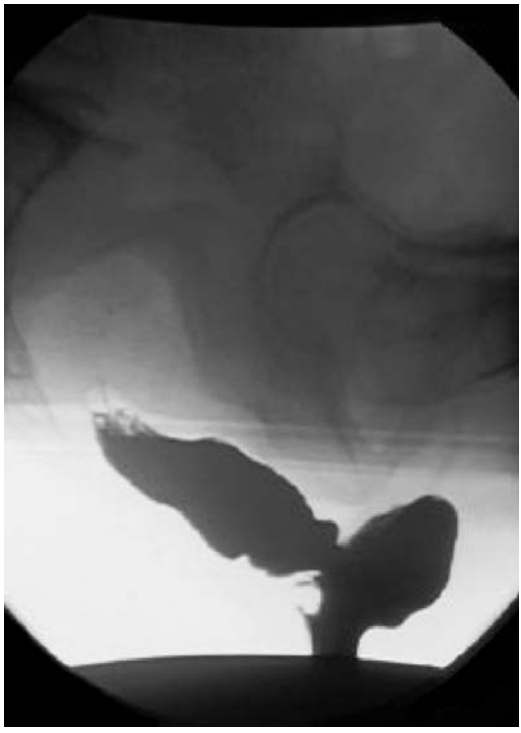

Fig. 10.3.
Rectocele shown by a conventional videoproctography

There is a wide interobserver variation in the measurements of defecography and also a wide variation among healthy individuals. In addition, a great proportion of healthy people show abnormalities at defecography with no clinical symptoms. Therefore, the results of a defecography should be interpreted very carefully must be consistent with the clinical findings.

10.6 Technical Necessities to Perform a Dynamic MRI of the Pelvic Floor

Dynamic imaging requires scanners that allow the acquisition of sequences with a frame rate of approximately 1/s. Normally the modern generation of MR scanners with a field strength of 1–1.5 T and an slew rate of 50 T/m/s and more fulfill this condition. T2-weighted gradient echo sequences called RARE, Haste or True Fisp are utilized (Gufler et al. 1999; Paetzel et al. 2001). Dynamic images are acquired in a median sagittal plane, for example with a True Fisp single-slice sequence with a slice thickness of 5–6 mm (TR, 5.8 ms; TE, 2.5 ms; flip angle, 70°; matrix, 256×256; field of view, 270 mm; total measurements of approximately 30–50 s; in-plane resolution, 1.02 mm) (Gufler et al. 1999; Paetzel et al. 2001).

10.7 How to Perform Dynamic MRI

Patient preparation plays an important role in the comparison of both procedures. Patients were asked to urinate 3 h before examination to achieve a medium filling of the urinary bladder during MRI. The rectum was filled with 180 ml of a gadolinium-based ultrasound gel mixture (Gd-DTPA-GEL-Mixture, 1%). MRI (1.5-T, Magnetom Symphony, Siemens, Erlangen, Germany) was performed in a supine position with hips and knees bent at 45°. The pelvic floor was visualized in three planes (transversal, coronary, sagittal, T1 and T2) to find the appropriate sagittal plane in which pelvic floor organs during defecation were recorded over 50 s at a frequency of one shot per 0.8 seconds (true FISP). Scan progression was 6 mm (format, 270×270 mm). During the ex-

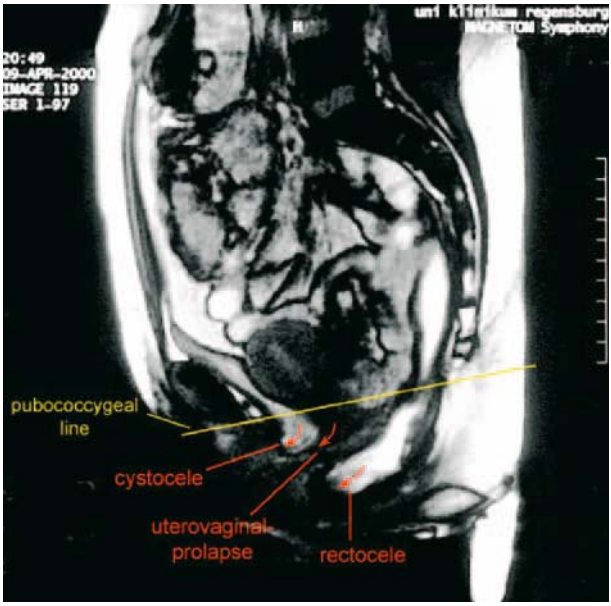

Fig. 10.4. Descending perineum including a cystocele, uterovaginal descensus and rectocele shown by dynamic MRI

amination, patients were instructed via headphones. They first were asked to relax and then to perform repeated straining maneuvers to empty the rectum as completely as possible. The sequences were recorded digitally and analyzed cinematographically (Gufler et al. 1999; Paetzel et al. 2001).

Evaluation was also simplified without missing diagnostic tools. The lower pubococcygeal line was used in both procedures to visualize relative movements of the pelvic organs during defecation (Fig. 10.4). The anorectal junction and the anorectal angle were determined by the central axis of the anal canal and a line along the posterior wall of the rectum (Healy et al. 1997b; Lienemann et al. 1997, 2000). According to Delemarre et al. (1994), rectoceles were measured from the anorectal junction to the tip of protrusion of the anterior rectum wall (Table 10.1).

10.8 Indication for Dynamic MRI

Combined and complex pelvic floor disorders may indicate dynamic pelvic MRI. A host of combined diagnoses and symptoms such as descending perineum syndrome, rectocele, cystocele, enterocele, uterine and vaginal descensus, anal and rectal prolapse, outlet obstruction, anismus, inertia recti and intussusception can be visualized with one diagnostic procedure.

Besides descent of the perineum and constipation, problems with incontinence for stool or urine are the most common symptoms. Women are affected at a significantly higher rate (ratio, 9 : 1; Winkler and Otto 1997). Patients usually seek help from gynecologists, urologists, gastroenterologists and proctologists. Therefore, a visualizing procedure which includes all anatomical structures of the pelvis is attractive.

Indications for dynamic MRI of the pelvis:

- Descending perineum syndrome
- Rectocele
- Cystocele
- Enterocele
- Uterine and vaginal descensus
- Anal and rectal prolapse
- Outlet obstruction
- Anismus
- Inertia recti
- Intussusception

10.9 Costs of Conventional Defecography and Dynamic MRI

It seems to be difficult to assess the real cost of a pelvic MRI in patients during their stay at the hospital. The material used for an examination (Gd-DTPA 2 ml, ultrasound gel) are not worth mentioning. The MRI scanner time of approximately 20 min is comparable to the conventional fluoroscopically performed examination. It is still difficult

Table 10.1. Patient preparation, evaluation techniques, normal values and findings as described by other authors

	Yang et al. (1991)	Kruyt et al. (1991)	Vanbeckevoort et al. (1999)	Lienemann et al. (1997)	Healy et al. (1997a)	Hutzel et al. (2002a)
Defecation	No	No	No	No	No	Yes
Rectal contrast	No	No	100 ml ug	200 ml ug	Plastic tube	180 ml ug
Bladder contrast	No	No	No	60 ml NaCl	No	No
Vaginal contrast	No	No	No	50 ml ug	Plastic tube	No
Position	Horizontal	Prone	Horizontal	Horizontal	Horizontal	Horizontal
Reference line	Pubococcygeal	Symphysiosacral	Pubosacral	Pubococcygeal	Pubococcygeal	Pubococcygeal
Anorectal junction	–25 mm	–30 to –40 mm	–25	No information	–20 mm	Discussed
Bladder base	–10 mm	No information	±0	±0	–10 mm	Discussed
Uterocervical junction	+10 mm	No information	No information	+0	±0	Discussed
Rectocele (evaluation)	No information	No information	Yoshioka	Yoshioka	Yoshioka	Delemarre
Rectocele (size)	No information	No information	<30 mm	<30 mm	No information	Discussed
Anorectal angle	No information	<130° (rest)	No information	No information	No information	Discussed
Enterocele	No information	No information	w. RVS	w. RVS	w. RVS	w. RVS

ug, customary ultrasound gel; Gd 1%, mixture with gadolinium 1%; NaCl, isotonic saline solution; w. RVS, widened rectovaginal space.

Data for anorectal junction, bladder base and uterocervical junction: normal values were defined as positions cranial to the individual reference lines.

Measurement of rectoceles according to Yoshioka (Gufler et al. 1999) : from the assumed anterior wall of the anal canal to the maximal anterior protrusion of the rectocele; according to Delemarre et al. (1994): from the anorectal junction to the maximal anterior protrusion of the rectocele.

Size of the rectocele and anorectal angle: normal findings had to be below the given values

to assess the occupation of different modalities correctly. The presence of a physician seems to be slightly shorter in MR imaging. On an outpatient basis, a conventional defecography is covered with 58.29 euros, a dynamic pelvic MRI with 303.09 euros (in Germany: GOÄ – E 3003.09).

10.10 Discussion

Dynamic MRI of the pelvic floor is increasingly used in the diagnosis of complex pelvic floor disorders and is replacing videoproctography more and more. Different specialties (radiology, urology, gynecology and surgery) are engaged with the interpretation and comparability of findings and with the definition of normal values and reasonable reference lines.

Since there is a lack of standardized comparative studies, special emphasis was laid on simplification and standardization of the examination technique. In 1991, Kruyt et al. was one of the first who used magnetic resonance to study functional aspects of the anorectal region. Also in 1991, Yang et al. introduced the dynamic MRI as a new method in the diagnosis of descending perineum in women. Values were recorded under various degrees of straining maneuvers. Defecation itself was not studied since the rectum was not filled with a contrast medium. As in the present study, the lower pubococcygeal line was taken as reference line to evaluate the descent of the pelvic organs.

Another study comparing clinical examination, videoproctography and dynamic MRI in the diagnosis of anterior rectoceles was published by Delemarre et al. (1994). In this study patients were examined in the prone position without rectal filling, which made evaluation of the defecation process impossible. The pubosacral line reaching from the most inferior part of the pubic symphysis to the lower part of the sacrum was chosen as the reference line in MRI. Measurements were performed at rest and during straining for both imaging techniques. Healy et al. (Healy et al. 1997b; Hilfiker et al. 1998) analyzed various aspects of pelvic floor disorders in patients and healthy volunteers, comparing videoproctography and dynamic MRI. For MRI, patients were placed in the supine position; defecation was not recorded. In contrast to other studies (Lienemann et al. 1997, 2000; Vanbeckevoort et al. 1999), instead of a contrast medium, a tampon was placed in the rectum to mark the rectal lumen. Measurements were performed during maximal straining; the reference line was the lower pubococcygeal line.

Tacke et al. (Bertschinger et al. 2002) tested a new method of dynamic MRI with radial real-time imaging and a reduced image area for defecography. Patients were asked to void a condom filled with a gadolinium-based contrast gel in the supine position. The authors themselves discussed this form of rectal filling critically, as it may mask an intussusception or a latent incontinence.

Vanbeckevoort et al. (1999) compared colpocystoproctography (videoproctography with opacification of vagina and bladder) and dynamic MRI in the supine position. For MRI, the rectum was filled with 100 ml of ultrasound gel that was not meant to be voided. Measurements were taken during maximal straining, the reference line was a line from the most inferior part of the pubic symphysis to the lower part of the sacrum, which was also called pubococcygeal line (corresponding to the pubosacral line according to Delemarre et al. 1994).

Lienemann et al. (2000) compared colpocystoproctography and MRI in the diagnostic of enteroceles. In MRI, patients and healthy volunteers were placed in a supine position and the rectum was filled with 200 ml of ultrasound gel which was to be def-

ecated during the imaging. The study does not reveal data on frequency and completeness of the defecation process. Reference line was the lower pubococcygeal line.

In a technically equal approach, Lienemann et al. (1997) examined 44 female patients and five asymptomatic volunteers for descent of the pelvic floor. Also in this study patients and volunteers were asked not to void the gel. There was no discussion of the findings of the healthy volunteers in this study.

Schoenberger et al. (1998) and Hilfiker et al. (1998; Bertschinger et al. 2002) presented an open-system MRI where patients were examined in an upright position analogous to videoproctography. In the study of Schoenberger et al. (1998) the findings of 15 patients examined with videoproctography and this new form of open configured MRI were compared. Five healthy volunteers were included for the definition of normal values, which are not mentioned in the paper so that comparison with other studies is not possible.

This overview illustrates the problems of introducing a new examination technique. So far, dynamic MRI is widely accepted as a promising technique in the diagnosis of the pelvic floor (Yang et al. 1991; Kruyt et al. 1991; Goodrich et al. 1993; Lienemann et al. 1997, 2000), particularly for functional aspects of pelvic floor disorders, since pelvic organs and muscles can be visualized and evaluated without invasive opacification or exposure to radiation. Still, without standardization of patient preparation, examination technique and evaluation of the data according to standardized reference lines and landmarks, it may not yet replace a well-established technique like videoproctography (or colpocystoproctography). We believe that a comparison of both procedures has to take place under standardized conditions. In this context, the documentation of the defecation process is most important for subsequent comparability of both techniques. Vanbeckevoort et al. (1999) compared the results of 35 patients examined with colpocystoproctography with and without defecation with the findings of dynamic MRI without defecation. For colpocystoproctography, the urinary bladder and the small bowel were filled with a contrast medium. In their analysis, colpocystoproctography including defecation was by far superior to the same technique without defecation. Based on the observation that the pelvic floor reached its maximal downward movement only during defecation and supported by the fact that patients are placed in a horizontal position in MRI, the authors concluded that colpocystoproctography including defecation may also be superior to MRI without defecation. In our opinion, this is a further argument for the examination of the defecation process in MRI. Our own findings also showed that in patients and healthy volunteers the formation of a rectocele, enterocele and cystocele as well as the maximal descent of the anorectal junction and of the uterocervical junction was only completely visible towards the end of the defecation process but not during straining alone.

Besides the descent of the anorectal junction (Fig. 10.5), changes in the anorectal angle (Fig. 10.6) are commonly used as an indicator for the functional status of the pelvic floor. A narrowing of the anorectal angle may indicate a disorder of the puborectal muscle. This may lead to constipation with subsequent straining leading to a rectal intussusception, rectocele and a mucosal prolapse with a solitary ulcer of the rectum, as postulated by several authors. If the anorectal angle is already widened at rest, this may be a sign of weakness of the pelvic floor and is commonly observed along with incontinence and a rectal prolapse. Normal values in the literature vary enormously. For videoproctography normal values were indicated between 60° and 105° at rest, whereas the findings of other groups relying on control groups with up to 150 volunteers show values between 90° and 104° at rest and 103° to 137° during defecation. Accordingly, the use of changes in the anorectal angle as a diagnostic parameter is difficult not

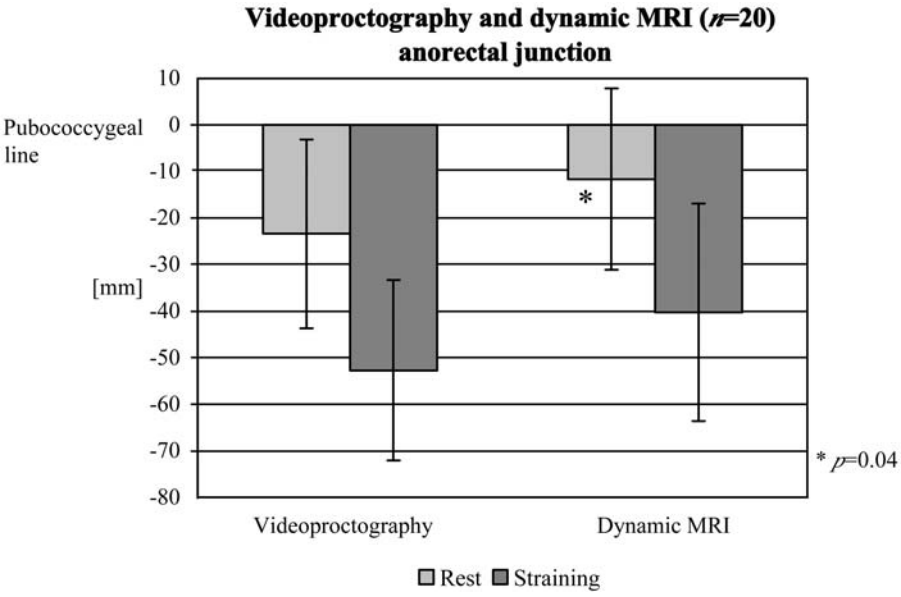

Fig. 10.5. Position of the anorectal junction related to the pubococcygeal line in MRI and videoproctography in 20 patients with complex pelvic floor disorders at rest and at maximal straining during defecation

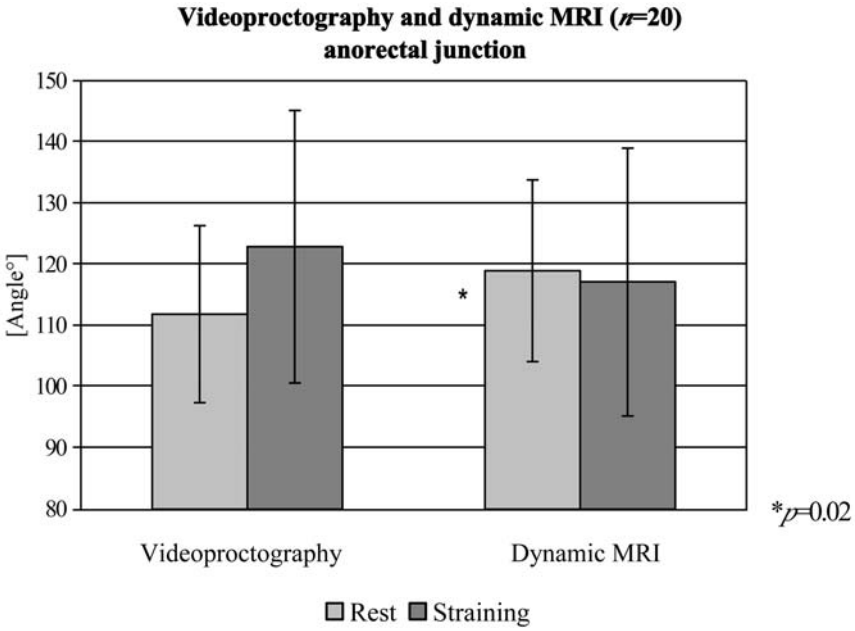

Fig. 10.6. Anorectal angle at rest and during defecation in 20 patients in videoproctography and dynamic MRI

only because data vary significantly, but also because findings of patients and asymptomatic volunteers tend to overlap (Kruyt et al. 1991; Healy et al. 1997a,b; Stoker et al. 2001).

Anterior rectoceles often present with symptoms of incomplete defecation and are often observed along with a descent of the pelvic floor (Schoenenberger et al. 1998). But rectoceles are also found in asymptomatic patients. Therefore, some authors assume that symptoms depend on the size of rectoceles (Lienemann et al. 1997). Because of different approaches in the attempt to measure the expansion of a rectocele, there are still no well-defined normal values available. Delemarre et al. (1994) used videoproctography and MRI to examine 38 patients in the prone position without rectal filling and without defecation. He concluded that videoproctography is superior to MRI in the diagnosis of rectoceles. Lienemann et al. (1997) defined a rectocele as a protrusion of the anterior rectal wall of more than 30 mm according to Yoshioka. He found that, in comparison to clinical examination, MRI was superior to colpocystoproctography in detecting rectoceles. In his study, patients were examined in the supine position (MRI) with rectal filling during maximal straining but without defecation. In contrast, Healy et al. (1997b) rated videoproctography superior to MRI. He defined an expansion of more than 20 mm (according to Yoshioka) as pathological. In addition, he found that a rectocele less than 13 mm measured by videoproctography was missed with the MRI technique. MRI examination again was performed without defecation; the anal canal was marked with a plastic tube.

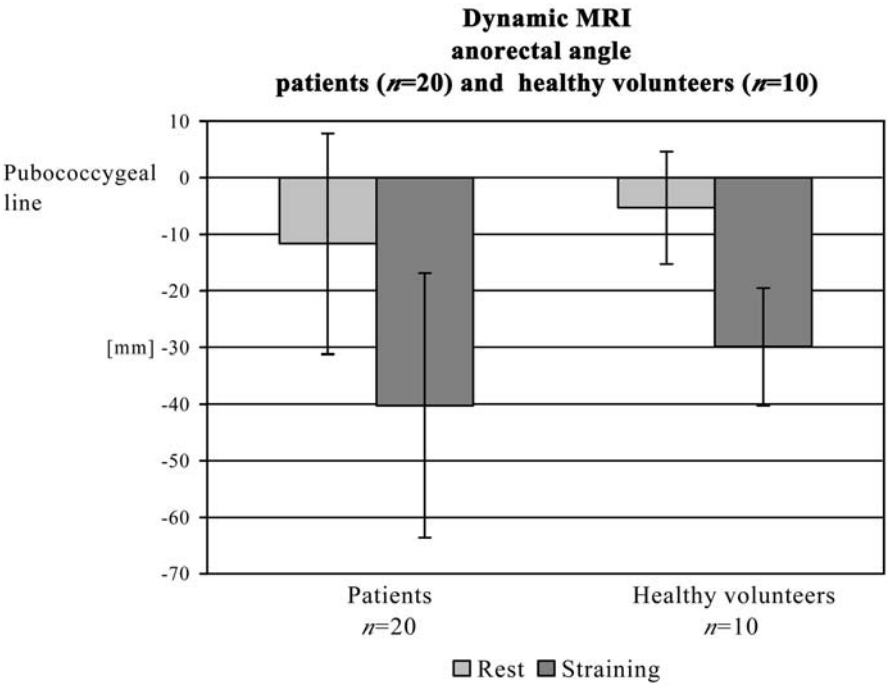

Fig. 10.7. Position of the anorectal junction related to the pubococcygeal line in MRI in patients (n=20) and healthy volunteers (n=10) at rest and at maximal straining during defecation. The difference was not statistically significant, but standard deviation was higher in the patient group

In our own series, sizes of the rectoceles were approximately equal in both procedures: 27 mm (14–59 mm) in videoproctography vs 23 mm (10–40 mm) in MRI. According to our observations, the horizontal position does not seem to be a disadvantage since a rectocele was found in eight out of ten healthy volunteers in MRI, with an average size of 26 mm. This is in part in accordance with data from the literature (Lienemann et al. 1997; Hilfiker et al. 1998), where the incidence of a rectocele in asymptomatic volunteers is about 80%, although these are described as small rectoceles. Our own data show that in standardized conditions videoproctography as well as MRI yield reproducible and comparable data (Figs. 10.7, 10.8).

Incidence and degree of a cystocele and a uterocervical prolapse is usually related to the number of vaginal deliveries, preceding hysterectomy and with chronic constipation leading to increased straining maneuvers (Vanbeckevoort et al. 1999; Fürst et al. 2000). Besides clinical examination, imaging techniques make quantification of findings possible (Lienemann et al. 1997). Yang et al. (1991), Lienemann et al. (1997), Vanbeckevoort et al. (1999) and Healy et al. (1997a) used normal values for the descent of the bladder base and uterocervical junction during straining in relation to the pubococcygeal line. These values were raised partly in healthy volunteers and partly determined at random (Rentsch et al. 2001; Hutzel et al. 2002a,b).

In our routine practice we do not contrast the urinary bladder or the vagina, because of an excellent visualization by natural contrast. The mean values of the descent of the bladder base and uterocervical junction did not differ significantly in patients as compared to healthy volunteers in our own studies (Figs. 10.9, 10.10). In contrast, the maximal values were substantially higher in patients than in healthy females. Interest-

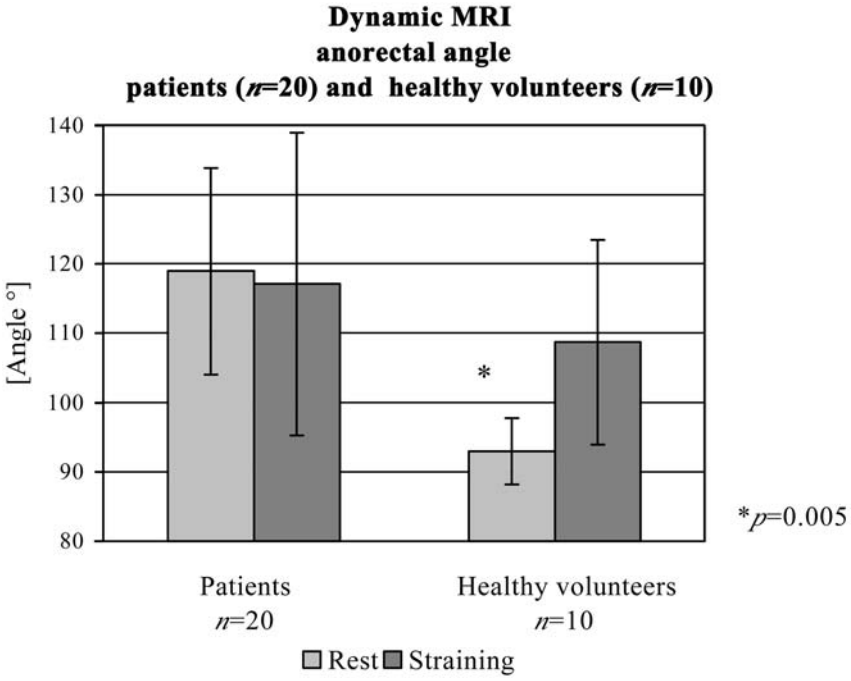

Fig. 10.8. Anorectal angle at rest and at maximal straining during defecation in patients (n=20) and healthy volunteers (n=10) in dynamic MRI

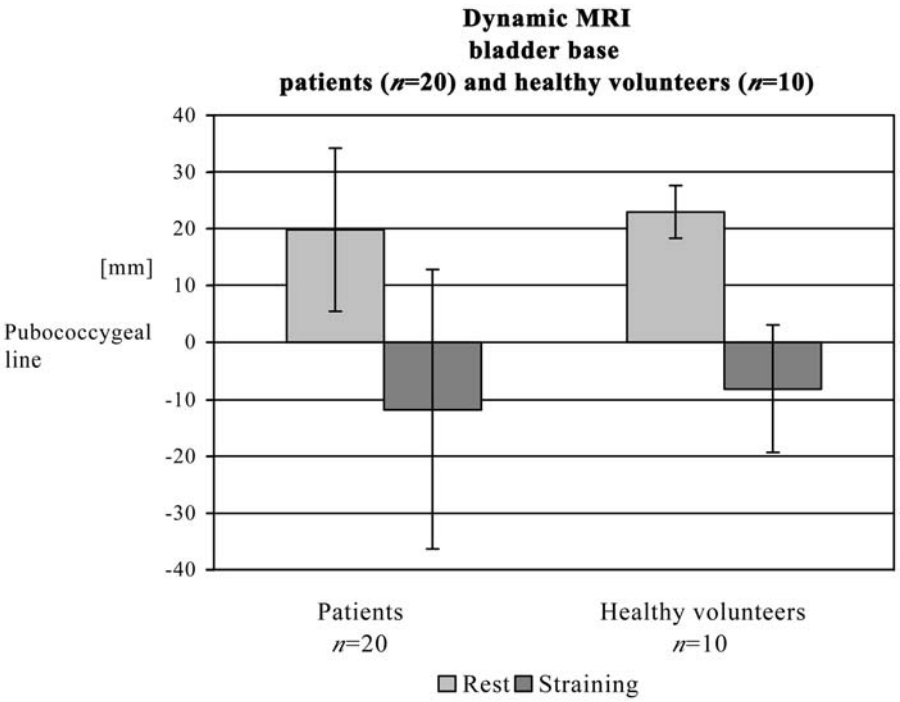

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Fig. 10.9. Position of the bladder base related to the pubococcygeal line in patients (n=20) and healthy volunteers (n=10)

ingly, six out of ten completely asymptomatic healthy female volunteers without a history of previous delivery or surgery were found to have a cystocele, and in three out of ten vaginal prolapse was diagnosed (Fürst et al. 2000; Rentsch et al. 2001; Hutzel et al. 2002a,b) (Table 10.2).

In the studies of Lienemann and Sprenger, 20 and 39 healthy females were examined with dynamic MRI of the pelvic floor including defecation. A cystocele or vaginal prolapse was seen in none of the cases. Since Lienemann's examination and evaluation technique are mainly comparable to our proceedings, the discrepancy of results is hard to explain in this context.

An enterocele is defined as a herniation of peritoneum into the rectovaginal space, which may contain small bowel loops or sigmoid colon. They are often accompanied by severe defecation disorders and a sensation of pressure as well as downward movement of the pelvic floor. The prevalence of enteroceles in women lies between 18%–37%; they often occur after hysterectomy.

Lienemann et al. (2000) examined 55 patients and 11 asymptomatic volunteers with colpocystoproctography and dynamic MRI without administration of contrast medium into the peritoneum or small bowel. The MRI held a clear advantage since the peritoneum and the contents of the enterocele were easily identified. He concluded that MRI may replace colpocystoproctography in the diagnosis of enteroceles. Since contrasting the small bowel or peritoneum is not necessary for the clear identification of pelvic organs and structures, we conclude that MRI is superior to colpocystoproctography in the diagnostics of enteroceles.

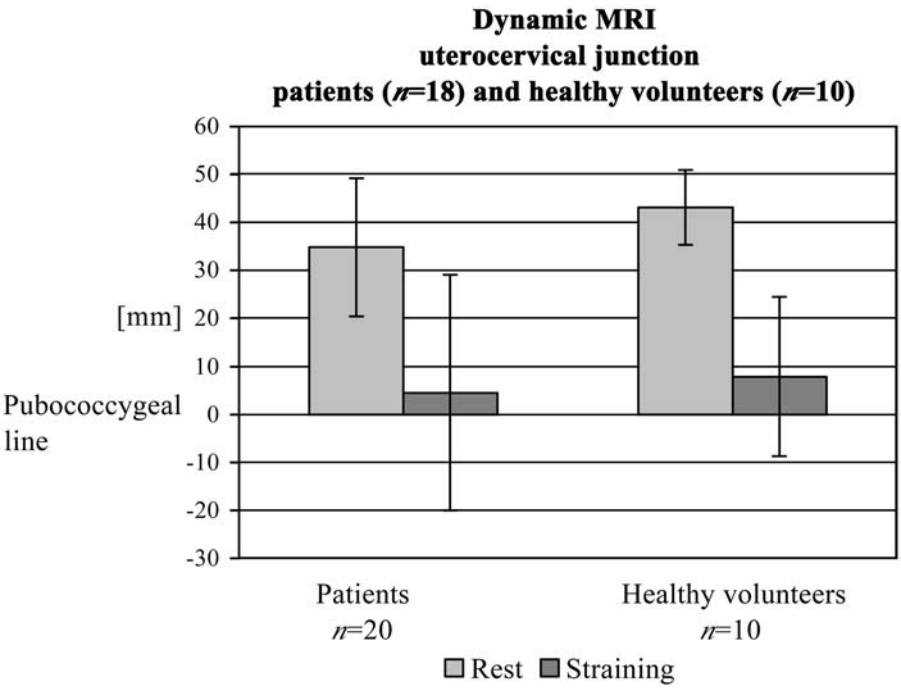

Fig. 10.10. Position of the uterocervical junction or vaginal vault related to the pubococcygeal line in 18 patients and 10 healthy volunteers in dynamic MRI

Table 10.2. Anorectal junction, anorectal angle, bladder base, uterovaginal junction and rectoceles at rest and during straining in patients (n=20) and in healthy individuals (n=10)

	20 patients (18 female) dynamic MRI	10 healthy volunteers dynamic MRI	*P*-value
Anorectal junction (mm)	–11.6 (±19.5) rest	–5.3 (±9.9) rest	NS
	–40.2 (± 23.3) straining	–29.9 (±10.3) straining	NS
Anorectal angle (°)	119.0 (±14.8) rest	93.0 (±4.8) rest	NS
relative movement (°)	117.1 (±21.87) straining	108.7 (±14.7) straining	NS
	–1.9°	+15.7	0.002
Bladder base (mm)	+19.8 (±14.4) rest	+23.0 (±4.6) rest	NS
	–11.7 (±24.4) straining	–8.1 (±11.1) straining	NS
Uterovaginal junction	+34.8 (±18.9) rest	+43.1 (±7.8) rest	NS
(mm)	+4.5 (±26.3) straining	+7.9 (±16.5) straining	NS
Rectoceles (size in mm)	23.0 (±9.2)	26.0 (±6.7)	NS

10.11 Conclusion

Comparing videoproctography and dynamic MRI of the pelvic floor, defecation is essential when performing MRI, because pathological findings may only become evident towards the end of the defecation process. The anorectal junction and the anorectal angle are influenced by the horizontal position of the patients in the MRI. Still, MRI is a valid tool to evaluate the posterior compartment in combined pelvic floor disorders, provided that patient preparation, examination technique and evaluation are standardized. Rectoceles can be easily identified in MRI. In the diagnosis of cystoceles, enteroceles or a uterovaginal prolapse, MRI is superior to conventional defecography despite similar invasiveness. Since the pelvic organs of healthy volunteers show a relatively high mobility, presently suggested normal values for the position of pelvic organs in relation to the pubococcygeal line have to be redefined. It is necessary to evaluate normal values under standardized investigation conditions.

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Chapter 11

Diagnostic Methods to Detect Female Urinary Incontinence

11

Heinz Koelbl, Gert Naumann

Contents

The International Continence Society defines stress incontinence as a symptom, a sign, and a condition (Bates et al. 1979). The symptom is the patient's complaint of involuntary loss of urine with physical exercise. The sign is the observation of urine loss from the urethra immediately upon increasing intraabdominal pressure (e.g., while coughing). The condition, genuine stress incontinence, is the socially unacceptable involuntary loss of urine that occurs when intravesical pressure exceeds maximum urethral pressure in the absence of detrusor activity.

The maintenance of urinary continence involves the interplay of several complex mechanisms. Not only is normal central nervous system function and a normal bladder wall required, but anatomic and functional integrity of the urethra and vesical neck are necessary (Asmussen and Miller 1983). The bladder neck consists of intrinsic and extrinsic elements. The intrinsic component reveals a passive closure due to an interplay between abundant elastic connective tissue and bladder neck smooth muscle. The bladder neck is suspended by ligaments attached to the pubic bone and the levator ani fascia representing the extrinsic component.

The neurologic integrity of the anatomic components maintaining continence is extremely important. Intact innervation of the periurethral striated muscles and pelvic floor musculature by the pelvic efferent nerves and pudendal nerve, respectively, serve to modulate resting tone and reflex increases in urethral pressure with stress. Voluntary increases in urethral pressure by the muscles of the perineal membrane are elicited via upper motor neuron pathways (pyramidal tracts), initiated from the cerebral cortex (Ostergard 1985). Interruption or damage to innervation of these various structures can cause dysfunction at any level.

Various theories on how bladder storage and urethral competence are maintained have been established until now. One theory developed by Enhoerning follows the concept of pressure transmission, which is based on the observations that intraurethral pressure rises simultaneously with intra-abdominal pressure during a cough. Another concept of the urethrovesical competence mechanism, according to Ulmsten and Petros, is that the vagina itself along with other supporting structures, i.e., ligaments, muscles and their connective tissue insertions are responsible for maintaining the pelvic floor aspect of continence. The authors advocate three closure mechanisms. The first is established by a contraction of the anterior pubococcygeus muscle closing the urethra. The second mechanism is the bladder neck closure, by its elongation backwards and downwards against the immobilized proximal urethra. The third mechanism is mediated by a different group of pelvic floor muscles, which are voluntary.

These many facets of possible defects and factors contributing to the closure mechanism of the urethrovesical unit, which may cause the onset of genuine stress incontinence (GSI), warrant a complex investigative approach. Moreover, and as demonstrated in multiple studies the causes for GSI are complex, especially following anti-incontinence surgery. All diagnostic methods complement each other and may not be regarded as conclusive each one alone. Thus a multimodal approach to identifying urinary incontinence and the type of GSI is mandatory. All investigative procedures have brought a new understanding into the onset of GSI caused by a single or multiple defects. However, despite the innovations within the last decades all the procedures have their distinct limits. Thus, all investigative tools form a puzzle and help to confirm GSI primarily based on the patient's symptoms, resulting in a distinct detection of its pathomorphological and/or dysfunctional origin.

The evaluation of the subtype and severity of the urinary incontinence are the main goals in assessing incontinence. All patients should be informed of the spectrum of investigation and treatment options.

11.1 Assessment of Genuine Stress Incontinence

The diagnosis of stress incontinence is based on demonstrating objective loss of urine with physical exertion and ruling out other causes of urinary loss. The differential diagnosis not only includes functional disorders such as detrusor instability and overflow incontinence but anatomic abnormalities such as urogenital fistulae and ectopic ureters.

11.2 Basic Investigations

A thorough evaluation consisting of patient history, neurological and physical examinations, and selected clinical testing will allow an expeditious diagnosis of stress incontinence, while avoiding an incomplete workup (Table 11.1). The history centers on the patient's complaints of urinary loss. Particular attention is directed toward menopausal status, history of previous surgery, and medication intake. Various questionnaires have been introduced into clinical practice. Most of them enable a redundant sequence of questions related to urinary incontinence. However, because of low sensitivity and specificity, scoring systems retrieved from questionnaires with the aim to conclusively assess the type of female urinary incontinence have been omitted in the past.

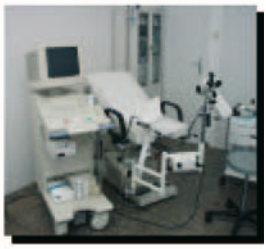
In women whose sole or main symptom is stress incontinence, the likelihood of a diagnosis of GSI approaches 100%, particularly where the physical sign of GSI is also

Table 11.1. Assessment of genuine stress incontinence: basic evaluation

Diagnostic tools in urinary incontinence in female

Basic evaluation

- Medical history
- History of urinary symptoms
- Physical examination
- Clinical evaluation of the pelvis
- Clinical stress test with full bladder
- Measuring postvoid residual urine volume
- Urine for culture/analysis
- Voiding diary



present. In patients with mixed symptoms of stress and urge incontinence, the likelihood of GSI is between 30% and 60% depending on what additional symptoms are present.

A catheterized urine specimen is obtained to rule out the presence of a bacterial urinary tract infection. Neurological examination centers on the functional aspects of anatomic areas innervated by the sacral nerve roots S_2–S_4. Abnormalities should be noted and proper referrals made. The physical examination must comprise a complete gynecological investigation and especially notes the presence of pelvic relaxation, uterine prolapse, cystocele, rectocele, enterocele. The external genitalia should be examined for dermatologic lesions and evidence of irritative or inflammatory conditions. The internal genitalia should be examined for estrogen deficiency, abnormal vaginal secretion or urine, pelvic organ prolapse and abnormal pelvic masses. A pH indicator paper may help to assess estrogen status showing a pH of generally less than 5 in women without infection and good estrogen effect.

Objective tests for the demonstration of urinary loss with physical exertion include the cough stress test and various pad tests. The cough stress test is performed when the patient has a full bladder, most easily after screening cystometry. While standing, one leg is elevated on a stool, and the patient coughs vigorously several times. The patient with stress incontinence will leak in spurts simultaneously with coughing. Care must be taken in this evaluation, for patients with cough-induced detrusor instability may leak several seconds after a cough. A multitude of various pad tests have been described to demonstrate loss of urine. The 1-h pad test, introduced by the International Continence Society, is probably the most accepted standard form (Bates et al. 1979). After 1 h of a battery of physical activities, a preweighed pad is again reweighed for evidence of urinary loss.

When nonsurgical treatment is being considered, the most appropriate would be to rely on clinical assessment. Where surgery is being considered, the role of urodynamic investigation seems to be expanding (Table 11.2).

11.3 Urodynamics

In the patient demonstrating objective urine loss with stress, a normal cystometrogram, and normal neurologic findings, a diagnosis of stress incontinence can easily be made. However, a large number of patients may demonstrate mixed symptoms and clinical findings. These patients require multichannel urodynamic testing to confirm a diagnosis of stress incontinence and rule out other causes of urine loss. Other patients who may require multichannel testing include postmenopausal patients and patients with previous incontinence surgery or those who have planned to undergo anti-incontinence surgery.

11.3.1 Uroflowmetry

Uroflowmetry is a measurement of the rate of flow of urine expelled via the urethra during voiding. It should be carried out in privacy and prior to any urethral instrumentation with residual urine measurement in the initial work-up of any incontinent subject. It gives an assessment of voiding in a simple, noninvasive and relatively inexpensive way. Its role in the assessment of patients with GSI is to establish voiding difficulties, especially prior to surgery, since voiding may be impaired postoperatively.

Table 11.2. Assessment of genuine stress incontinence: advanced evaluation

Diagnostic tools in urinary incontinence in female

Advanced evaluation

- Urodynamics (uroflowmetry, UDP at rest and during stress, cystometry, VLPP)
- Videourodynamics
- Imaging (perineal, introital ultrasound, Urethralultrasound [intraurethral, 3D],X-ray, MRI)
- Endoscopy
- Neurophysiologic testing

11.3.2 Cystometry

Cystometry is the core test of a urodynamic investigation, where the pressure–volume relationship of the bladder is measured to assess detrusor activity, sensation, capacity and compliance of the bladder. Cystometry is of paramount importance to rule out the presence of detrusor instability and to assess efficient storage of urine in incontinent patients and thus is regarded as the gold standard procedure in the diagnosis of GSI.

11.3.3 Urethral Pressure Measurements

Various means to measure the functional integrity of the components that prevent stress incontinence have long been studied and modified. As mentioned earlier, the primary factor leading to the development of stress incontinence is the displacement of the urethra from the intra-abdominal position, leading to impaired pressure transmission during stress. The most accurate measure of urethral function, sphincteric capacity, and support that provides pressure transmission is the urethral pressure profile, which is obtained by using multichannel urodynamic testing (Faysal et al. 1981). The introduction of microtip pressure transducers by Asmussen and Ulmsten has allowed precise and reproducible recordings of these measurements (Asmussen and Ulmsten 1975).

With an understanding of how urodynamics represents the contribution to continence by the internal and external urethral sphincteric mechanisms and the pelvic supporting structures, multichannel testing can also demonstrate how various etiologic factors produce stress incontinence. The resting urethral pressure profile reflects the constant tonus and margin to incontinence provided by the components of the internal urethral sphincteric mechanism and the external urethral sphincter.

Various etiologic factors can predispose to impairment of the internal urethral sphincteric mechanism and external sphincter as they contribute to resting tonus and continence during stress. These same factors also produce low urethral closure pressure. In studying 120 women with urodynamically proven stress incontinence, Hilton found that repeated unsuccessful incontinence operations were associated with the finding of low urethral pressure (Hilton and Stanton 1983a). Previous surgery may result in scar formation around and within the delicate urethral structures. Menopause may also contribute to lower urethral pressure. Hypoestrogenism can result in atrophy of urethral epithelium, urethral smooth muscle, and the submucosal cavernous plexus (Asmussen and Miller 1983; Hilton and Stanton 1983b). Although not the major contributing factor to stress incontinence, resultant low urethral pressure may, in some instances, reduce the margin to incontinence such that only minor anatomic changes can result in loss of urine during stress.

Studies have consistently shown that the resting urethral closure pressure falls with increasing age in women and is lower in groups of GSI women. However, there is a big overlap of values between continent and incontinent females, limiting the discriminatory power of resting profile variables. Variables of the stress urethral pressure profile such as the pressure transmission ratio, maximum urethral closure pressure on stress, and profile area on stress have been found to be the most reliable variables to diagnose GSI, although sensitivity even with these remains poor. It has been shown that patients undergoing unsuccessful surgery for GSI by several different procedures having lower preoperative resting urethral closure pressures and functional urethral length than those treated successfully.

The parameters measured with urodynamic testing allow both a quantitative and a qualitative assessment of the contribution to continence made by the internal and external sphincteric components and the supporting pelvic structures. The urethral closure pressure profile reflects the urethral closure pressure over the entire functional urethral length (length of the urethra over which intraurethral pressure exceeds intravesical pressure). The resting urethral pressure profile primarily reflects intrinsic urethral pressure, termed the urethral closure pressure. This intrinsic pressure maintains continence at rest.

The urethral pressure profile performed during stress maneuvers (e.g., coughing, Valsalva) reflects the positional, mechanical, and dynamic factors contributing to continence. A cough pressure profile is performed by withdrawing the dual microtransducer through the urethra as the patient coughs continuously. The resulting profile can demonstrate the adequacy of pelvic support, represented by pressure transmission, and the possible reflex contraction of pelvic floor musculature, demonstrated by the augmentation of transmitted pressure.

Anatomic descent of the urethra and urethrovesical junction can result from a number of causes. The trauma of childbirth is one of the primary etiologic factors resulting in pelvic floor weakness. Descent of the fetal head distends the genital hiatus and levator muscles along with stretching pubocervical fascia, pubourethral ligaments, and the urogenital diaphragm. This weakening then leads to descent and pos-

terior rotation of the proximal urethra and bladder base. Other causes for pelvic floor weakness include aging and neurologic deficits.

11.3.4 Valsalva Leak Point Pressure

The pressure at which the expulsion of urine from the urethral meatus is observed is the leak point pressure (LPP). The LPP is a direct measurement of the closure function of the entire urethra. Similarly, the intravesical pressure at leakage during abdominal stress (coughing or a Valsalva maneuver) in the absence of a detrusor contraction is called the abdominal leak point pressure. Although higher abdominal pressures are reached on coughing, the Valsalva leak point pressure (VLLP) is better controlled and less variable over time and thus has been established as the standard procedure in GSI patients. VLLP is a promising method of quantifying GSI. However, standardization of methods and conditions, definition and significance of cut-off values for diagnosis and for prediction of GSI is awaited.

11.3.5 Videourodynamics

Videourodynamics combines a routine urodynamic study with X-ray or ultrasound imaging. Urodynamics is used for patients with complicated lower urinary tract disorders mostly due to a neurological condition. It may also offer more accurate diagnosis in patients with GSI or mixed incontinence. It is recommended when the diagnosis remains unclear after simple urodynamic tests or when complicated pathology is expected from the history and symptoms.

In the assessment of GSI, it helps to simultaneously follow pressure measurements of the bladder and the urethra at rest and during stress and to check for descent of the bladder base, hypermobility and leakage in the filling phase. During the voiding phase, the start of voiding, the phase of maximum pressure and flow and the end of voiding, and postvoid residual bladder volume can be investigated. Moreover, anatomic abnormalities of the bladder contour and vesicoureteral reflux can be observed.

11.3.6 Ambulatory Urodynamic Monitoring

Ambulatory urodynamic monitoring (AUM) is most commonly used as a second line test. Signals from a portable state memory unit obtaining abdominal (vaginal) pressure, maximal urethral pressure and intravesical pressure are recorded and downloaded after measurement. Unstable detrusor contractions were found in 89% and 56% of patients undergoing AUM, where urge incontinence and mixed incontinence, respectively, were expected from the medical history, bladder diary, and 24-h pad test. It is a sensitive but not very specific way of detecting urinary leakage, and may be indicated for patients with mixed incontinence symptoms, for those complaining of incontinence without objective evidence of leakage.

11.4 Electromyography

Electromyography (EMG) of the urethral sphincter, the anal sphincter, or the pelvic floor is another method for the diagnosis of lower urinary tract function. It serves to detect normal or abnormal muscle behavior and represents an electrical correlate of muscle pathology. EMG has limited value in routine urodynamic diagnostic work-up. Therapeutic use of surface EMG may be advised in rehabilitation or biofeedback procedures to improve pelvic floor function.

Using single-fiber EMG studies in women with stress incontinence, evidence of chronic denervation was shown, reflecting damage to peripheral branches of the pudendal nerve (Anderson 1984).

Various studies have shown that this reflex contraction and the ability to augment closure pressure are lost with stress incontinence (Faysal et al. 1981). Therefore, the anatomic defect predisposing to poor pressure transmission may place the urethra and its surrounding muscles in a suboptimal position to affect adequate pressure augmentation.

11.5 Ultrasound

Bladder and postvoid residual volumes can be determined transabdominally, although accuracy is not reliable for volumes less than 50 ml (Orgaz et al. 1981). With transabdominal ultrasound, the bladder is scanned in two perpendicular planes (transverse and sagittal) and three diameters (height, width, and depth) are measured. Height corresponds to the greatest superoinferior measurement; depth corresponds to the greatest AP measurement. Both are obtained in sagittal plane scan. The simplest formula used to estimate volume by abdominal ultrasound is bladder vol (ml) = (H × W × D) × (0.7). The correction factor 0.7 is needed because the shape of the bladder is not circular until it is almost completely full.

Transabdominal ultrasound has also proven valuable in the evaluation of the urinary tract in neuromuscular bladder dysfunction and detrusor instability. Brandt and others found that ultrasound of the bladder yielded significantly more diagnostic information than radiography in 27% of their study group. Brandt also demonstrated bladder trabeculation as well as dilated ureters in neuromuscular dysfunction using abdominal sonography (Brandt et al. 1981).

11.5.1 Sonographic Urethrocystography

Numerous studies have demonstrated real-time ultrasonography to be useful in evaluating the anatomic relationship of the bladder, the urethrovesical junction (UVJ), and the proximal urethra. With careful observation, the changes in the shape and position of the vesical neck and the proximal urethra can be determined while the patient is performing a Valsalva maneuver or coughing.

11.5.2 Perineal Ultrasound

Newer applications of sonography place the transducer on the perineum. Avoiding excessive pressure to the perineal region, this scanning technique does not alter anatomic relationships. However, its application in patients with severe genitourinary prolapse is limited.

Ultrasonic urethrocystography by perineal scanning for evaluation of female stress urinary incontinence was suggested by Kohorn and others (1986). The procedure is carried out with the patient in various positions (upright, supine) with legs slightly abducted to allow access of the transducer to the perineum. A linear-array or curved-array transducer scanner is positioned in a sagittal orientation to visualize the bladder, bladder base, urethrovesical junction, and the pubic symphysis. Comparative results between radiologic and perineal sonographic urethrocystography have been reported, giving comparable and reproducible results (Koelbl et al. 1988; Gordon et al. 1989; Schaer et al. 1995). Moreover, changes in bladder neck mobility in nulliparous continent women, during pelvic floor muscle contraction, before and after tension-free vaginal tape (TVT) surgery and Burch colposuspension have been published recently (Schaer et al. 1996a; Peschers et al. 2001; Miller et al. 2001; Atherton and Stanton 2000; Martan et al. 2001).

A standardization of functional sonography was published by the German Association of Urogynecology in 1996, aiming at a common understanding and interpretation of pictures with high quality and reproducibility (Schaer et al. 1996b). Among the various sonographic techniques to perform urethrocystography, perineal and introital ultrasound have been widely used and recommended as the most reliable techniques.

11.5.3 Introital Ultrasound

Regional distortion using vaginal or rectal endosonography, even with small endoprobes, was the reason for development of introital sonography (Koelbl and Bernaschek 1989). The technique involves placing a vaginal sector scanner to the vulva just underneath the external urethral orifice, visualizing the bladder, urethrovesical junction, urethra and symphysis. Modern vaginal probes are thin and give good visualization of the lower urinary tract when placed only a short distance into the vagina. Thus, this technique is devoid of any potential morphological artifact as a result of urethral or bladder neck distortion. Successful colposuspension is found to be associated with a urethrovesical location that is more anterior, although not necessarily more elevated. In addition, overcorrection at anti-incontinence surgery causing postoperative micturition disorders can be visualized by ultrasound. A hypermobile urethra is easily seen on ultrasound and according to this study may help to distinguish different causes for GSI. Movement of the bladder and the urethra during real-time sonography indirectly reflects pelvic floor action during both contraction and relaxation. Pelvic floor defects indirectly can be visualized with both perineal and introital sonography. However, due to the prolapse, the probes may alter lower urinary tract anatomy and give erroneous results. First attempts to identify lesions of the attachments of the lateral vagina to the tendineal arc of the levator ani, termed paravaginal defects, are promising.

11.5.4 Intraurethral Ultrasound

Intraurethral ultrasound (IUUS) is a new endosonographic technique providing high-resolution imaging (20 MHz) of the urethra and the surrounding tissues. This technique is recommended for the diagnosis of diverticula and urinary incontinence, since other imaging methods provide only little information on the urethra and its sphincter. A correlation of urethral anatomy carried out by IUUS with functional urodynamic parameters revealed a decreased rhabdosphincter thickness in patients with GSI and a linear relationship between maximal urethral closure pressure and rhabdosphincter and longitudinal smooth muscle thickness (Heit 2000). The meaning of these findings in relation to urethral pressure measurements merits further evaluation, since it could be helpful in the choice of treatment. Endoluminal ultrasound has also been applied during surgical treatment of urethral diverticula (Chancellor et al. 1995).

11.5.5 Three-Dimensional Ultrasound

The three-dimensional (3D) reconstruction of ultrasound images has become a widespread option in ultrasound equipment since the early 1990s. Three-dimensional ultrasound of the urethra also has become part of scientific interest. Athanasiou et al. (1999) scanned women with urinary symptoms with a 5-MHz three-dimensional perineal ultrasound. All women with urethral sphincter incompetence had a continuous hypoechoic area from the bladder neck to the urethral meatus. Some of the women with severe GSI had breaks in the continuous circle of the rhabdosphincter and it was replaced by hyperechoic areas. The authors think that these observations may indicate damage to the urethral sphincter. Further studies are needed to confirm these observations and to elucidate the clinical implications of 3D ultrasound findings. Moreover, similar results have been obtained with 3D ultrasound of the female urethra comparing transvaginal and transrectal scanning (Umek et al. 2001).

11.6 Conclusion

Urinary incontinence, whether present in the elderly or young female, can have devastating effects on a patient's self-esteem, psychological well-being, and overall physical health. Awareness of the prevalence and scope of stress incontinence is of paramount importance to gynecologists and other primary care physicians.

The primary components that prevent urinary stress incontinence in the female include an internal urethral sphincteric mechanism, an external urethral sphincter, and proper anatomic support of the urethra and urethrovesical junction. Genuine stress incontinence results primarily from a defect in pelvic support of the urethrovesical junction resulting in impaired transmission of intra-abdominal pressure to the proximal urethra and urethrovesical junction. Secondary defects that may contribute to stress incontinence include impaired function of the urethral sphincteric mechanism, which produces low urethral pressures, and dysfunction of reflex contraction of the pelvic floor, resulting in reduced augmentation of transmitted pressure. Individualized therapies directed towards these defects result in correction or improvement of urodynamically measured parameters that correlate with stress incontinence.

Basic investigations are recommended in all patients with symptoms of GSI where conservative therapy is the first choice of treatment. In patients with a complex history, mixed symptoms and previous anti-incontinence surgery must undergo a full urogynecological assessment consisting of urodynamics and imaging analysis. Since GSI may be of multifactorial origin, such as an intrinsic and/or extrinsic defect, only a complex assessment will help to identify its cause and find the appropriate treatment.

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Part IV

Conservative Therapy of Incontinence

IV

Chapter 12

Pharmacological Treatment of Urinary Incontinence

12

Gert Naumann, Heinz Koelbl

Contents

Urinary incontinence is a major clinical problem and a significant cause of disability and dependency in older adults. Prevalence of urinary incontinence is approaching 55%; in healthy nonelderly women residing in the community, it ranges from 11.3% to 62.7%. Stress incontinence is reported to be a predominant type of incontinence, with prevalence rates of 14.7%–52%. Mixed incontinence is also quite common with rates of 3.1%–47.9%. Urge incontinence occurs less often with rates of 2.4%–13.3%.

Overactive bladder is characterized by various symptoms of urgency and frequency with or without urinary urge through involuntary loss of urine. Overactive bladder has a profound affect on decreasing the quality of life with isolation in social activities and depression.

In contrast to the high prevalence and the costs for private help, only 37% of patients report their symptoms to a doctor. The reasons for this are unclear but include suboptimal therapeutic effects, many side effects and ignorance regarding treatment options. Sometimes it is an acceptance of the disorder as a natural part of aging or being unaware that treatment exists. On the other hand, patients are sometimes told by healthcare professionals that urinary incontinence is a normal consequence of aging and that nothing can be done.

In regulation of urine storage and bladder emptying, a complex pattern of efferent and afferent signaling in parasympathetic, sympathetic and somatic nerves is involved.

Overactive bladder can occur as a result of sensitization of afferent nerve terminals in the bladder or outlet region. Disorders of any of these neural structures or changes in the bladder's smooth muscle with denervation, damage to the CNS inhibitory pathways, as can be seen in various neurological disorders such as multiple sclerosis, cerebrovascular disease, Parkinson's disease, brain tumors and spinal cord injury are examples. Overactive bladder may also occur in elderly patients because of changes in the brain or bladder during aging. Normal bladder contraction in humans is mediated mainly through stimulation of muscarinic receptors in the detrusor muscle.

Accurate assessment of the patient is essential in order to optimize treatment. Urinary incontinence is a symptom and not a diagnosis. For starting any kind of treatment it is necessary to have an adequate evaluation of the pelvic floor. The clinical evaluation of the urethrovesical, vulvovaginal and anorectal compartment is the stepping stone for all diagnostic and therapeutic decisions. Investigation of the incontinent patient should start with simple and noninvasive tests. The first step in the diagnosis of incontinence is a detailed history, including any medical conditions and patterns of urination. The history of urinary symptoms should be listed. The physical examination with the pelvic examination helps to evaluate both the structural and functional integrity of the pelvic structures and organs and gives a great deal of information on the external and internal genital region, shows abnormalities or enlargement in the area, pelvic organ prolapse or genital atrophy. One of the important measurements for urinary incontinence is the postvoid residual urine volume. Urinalysis and culture is an essential screening test for the patient with urinary tract symptoms. In order to provide information on urination to the physician, the patient might find it helpful to keep a diary for 3 or 4 days before the office visit.

Recent advantages in diagnosis of urinary tract disorders have resulted in the development of highly complex testing procedures. First the clinician should perform the simplest, least invasive and most informative test. Approximately 20% of patients will require more sophisticated urodynamic testing. Urodynamic studies have become an integral part of the evaluation of female patients with lower urinary tract dysfunction.

Major improvements and technological advances in ultrasonic instrumentation have facilitated the establishment of ultrasound as a diagnostic tool in the management of female patients with urinary incontinence. Ultrasound has also been suggested as an alternative source for imaging the urethrovesical anatomy. As an alternative to the commonly used radiological procedure, the ultrasonographic evaluation of the upper and the distal tract belongs to routine assessment in the pre- and post-therapeutic concept of urogynecology. To exclude pathology in the bladder or urethra, endoscopic techniques such as urethrocystoscopy are very helpful in the diagnostic approach.

For many patients with urinary incontinence, surgical intervention may not represent the optimal approach for management of their incontinence. Just as other medical disorders are controlled pharmacologically, many causes of urinary incontinence respond positively to medical intervention.

12.1 Medical Treatment of Bladder Overactivity

A number of different pharmacological therapies have been studied in the treatment of the hyperactive detrusor (Table 12.1). Most results are based on nonrandomized, controlled clinical trials. Most studies show a high level of placebo effect without great benefit for pharmacological therapies. On the other hand, typical side effects are reported and are responsible for short treatment times (Huggins et al. 2003).

12.2 Anticholinergic Drugs

Anticholinergic drugs are the most active drugs in inhibiting detrusor overactivity through inhibiting the binding of acetylcholine to muscarinic receptors. Of the five types of muscarinic receptors identified (M1–M5), the smooth muscle of the human bladder contains 80% M2 receptors. The remaining receptors are of the M3 type and coordinate contractions of the detrusor muscles. The M3 receptors are also concentrated on the salivary glands. Therefore the systemic anticholinergic drugs specific to the M3 receptor typically induce impaired salivation as well as bladder relaxation.

12.3 Drugs with Mixed Anticholinergic Action

Some drugs used to block bladder overactivity have been shown to have more than one mechanism of action. They all have a more or less pronounced antimuscarinic effect and, in addition, an often poorly defined direct action on bladder muscle.

12.3.1 Oxybutynin

Oxybutynin is one of the more commonly used medications for urinary urgency and urge incontinence and has been the agent of choice in the treatment of overactive bladder (OAB) for three decades. This tertiary amine shows antimuscarinic activity at the M2 and M3 receptors and also local anesthetic and smooth muscle relaxant effects.

Table 12.1. Drugs used in the treatment of detrusor overactivity. Assessment according to the Oxford system (Andersson et al. 2002)

Drug	Level of evidence	Grade of recommendation
Antimuscarinic drugs		
Tolterodine	1	A
Trospium	1	A
Propantheline	2	B
Atropine, hyoscyamine	2	D
(Darifenacin, solifenacin)	Under investigation	
Drugs acting on membrane channels		
Calcium antagonists	Under investigation	
Potassium channel openers	Under investigation	
Drugs with mixed actions		
Oxybutynin	1	A
Propiverine	1	A
Flavoxate	4	D
Alpha-adrenoceptor agonists		
Alfuzosin, doxazosin	4	D
Prazosin, terazosin, tamsulosin	4	D
Beta-adrenoceptor agonists		
Terbutaline, clenbuterol, salbutamol	4	D
Antidepressants		
Imipramine	2	C
Prostaglandin synthesis inhibitors		
Indomethacin, flurbiprofen	4	C
Vasopressin analogues		
Desmopressin	1	A
Other drugs		
Baclofen (intrathecal use)	2	C
Capsaicin	3	C
Resiniferatoxin	Under investigation	

Many studies of noncomparative design have shown that 55%–70% of patients who received the recommended oral dose of the immediate-release form – 2.5–5 mg t.i.d. or q.i.d, for up to 2 years – reported improvement in symptoms of urge incontinence.

Comparing 15 randomized controlled studies of 476 patients treated with oxybutynin, Thuroff et al. (1998) showed a mean decrease in incontinence of 52% and a mean reduction in frequency for 24 h of 33%. Despite the overall subjective improvement rate of 74% (range, 61%–100%), the mean percentage of patients reporting side effects was 70% (range, 17%–93%).

The major problem associated with the clinical use of oxybutynin is its adverse effect profile with side effects in up to 80% of patients due to poor uroselectivity. Mainly these are dry mouth, constipation, blurred vision and tachycardia.

Because oxybutynin passes the blood–brain barrier, in the elderly patient cognitive impairment can occur.

The development of once daily formulations of oxybutynin (oxybutynin ER; Ditropan XL) showed substantial advantages with better compliance, a lower incidence of dry mouth and same efficacy. Clinical trials on oxybutynin ER have compared this drug with immediate-release oxybutynin.

In a multicenter, randomized, double-blind study on 105 patients with urge incontinence, or mixed incontinence with a clinically significant urge component, Anderson et al. (2002) showed a decrease in weekly urge incontinence episodes from 27.4 to 4.8 in the extended-release (ER) group and from 23.4 to 3.1 in the immediate-release (IR) group after therapy, and total incontinence episodes decreased from 29.3 to 6 and from 26.3 to 3.8, respectively. There were decreased dry mouth symptoms (68% in the ER group vs 87% in the IR group), moderate or severe dry mouth symptoms were recorded in 25% and 4%, respectively.

Versi et al. (2000) compared efficacy and safety of oxybutynin ER and IR in 226 patients with urge incontinence and showed a significant reduction in urge urinary incontinence in both groups without significance. In the oxybutynin ER group, there was a significantly lower proportion of moderate to severe dry mouth symptoms.

To minimize side effects through oral intake, other pass forms of oxybutynin have been developed. Rectal administration is one possible way and shows fewer adverse effects than the conventional tablets.

Using an oxybutynin transdermal system in treatment of overactive bladder with eliminating the first-pass effect, there are no significant differences in the incidence of typical side effects compared with placebo. Common side effects of oxybutynin-TDS were pruritus and erythema at the cutaneous application site.

Oxybutynin given intravesically showed clinical improvement in various types of bladder overactivity with only a few side effects. Clinical studies are underway to establish this application form.

In summary, oxybutynin shows good efficacy in the treatment of detrusor overactivity, and is, together with tolterodine, the drug of first choice in patients with this disorder.

12.3.2 Propiverine

Propiverine is a benzylic acid derivate, has a combined antimuscarinic and calcium antagonistic action and leads to improved efficacy and tolerability. Recommended dosage is 15 mg, two to three times a day, not to exceed 60 mg per day.

Clinical advantages were seen in treatment of detrusor overactivity with increasing bladder capacity and decreasing maximum detrusor contractions.

In a review of nine randomized studies on a total of 230 patients, Thuroff et al. (1998) found reduction in frequency (30%) and micturitions per 24 h (17%), a 64 ml increase in bladder capacity, and a 77% (range, 33%–80%) subjective improvement. Side effects were found in 14% (range, 8%–42%). A controlled trial comparing propiverine, oxybutynin and placebo (Madersbacher et al. 1999), has confirmed the efficacy of propiverine and suggested that the drug may have equal efficacy and fewer side effects than oxybutynin.

12.4 Drugs with Antimuscarinic Action

12.4.1 Propantheline

Propantheline bromide is a quaternary ammine that does not have affinity for muscarinic receptor subtypes. The daily dose is 15–30 mg four times; for an optimal effect an individual titration of the dose and often higher dosages is necessary. In comparison of oxybutynin 5 mg × 3, propantheline 15 mg × 3 and placebo in a randomized, double-blind, multicenter trial with 154 patients with idiopathic detrusor instability or detrusor hyperreflexia Thuroff et al. (1991) found no differences between the placebo and propantheline groups.

Newer more specific agents with better dosing schedules and fewer side effects make this older oral antimuscarinic drug less desirable.

12.4.2 Tolterodine

Tolterodine is selective for the bladder rather than the salivary glands and fewer side effects have been reported. Several studies show a significant reduction in incontinence episodes and micturition frequency in case of idiopathic detrusor instability and detrusor hyperreflexia. In a dose of 1–4 mg per day tolterodine is well tolerated.

In a double-blind, randomized study on 1,022 patients with tolterodine 2 mg b.i.d., Chancellor et al. (2000) showed a significant reduction in urge incontinence episodes by 46% v base-line in a comparison with placebo.

The next step to improve patient compliance was the development of a once daily formulation of tolterodine ER. In a study of 1,529 patients, tolterodine extended-release 4 mg once daily and tolterodine immediate-release 2 mg twice daily both significantly reduced the mean number of urge incontinence episodes per week compared with placebo, 71% for tolterodine ER, 60% for tolterodine IR, and 33% for placebo (van Kerrebroeck et al. 2001). The dry mouth side effect (of any severity) was 23% for tolterodine ER, 30% for tolterodine IR, and 8% for placebo.

Tolterodine has become a safe and effective drug with good efficacy and fewer side effects.

12.4.3 Trospium

Trospium chloride is a quaternary ammonium derivate with a high affinity for selective muscarinic receptors but has negligible affinity for nicotinic receptors. Is does not cross the blood–brain barrier and is well tolerated in elderly patients without cognitive impairment. It has no known drug–drug interactions, an advantage for patients taking many medications.

The drug is excreted unchanged in the bladder because of no hepatic metabolism; consequently a large percentage of the drug has direct action on the bladder. Several open studies have indicated that the drug may be useful in the treatment of detrusor overactivity.

In a double-blind, randomized study over 12 months investigating 358 patients with urge symptoms or urge incontinence, Hofner et al. (2000) reported the effects of oxybutynin 5 mg b.i.d. with those of trospium 20 mg b.i.d. When there were identical re-

sults in improving urge symptoms, oxybutynin produced a significantly higher rate of side effects, and the drop-out rate was higher in the oxybutynin group. At the 2003 American Urological Association conference, data from a randomized, double-blind, placebo-controlled phase III trial of 523 patients with urge incontinence was presented. Trospium 20 mg daily was shown to significantly improve frequency, incontinent episodes and bladder capacity. The most common side effects were dry mouth and constipation, occurring in 21.9% and 9.5%, respectively. Trospium was approved by US Food and Drug Administration (FDA) for the indication of overactive bladder in May 2004.

12.4.4 Darifenacin

Looking for antimuscarinic agents with more selectivity for M3 receptors, darifenacin was found at the first selective muscarinic M3 receptor antagonist developed for treatment of bladder overactivity.

In a multicenter, double-blind, placebo-controlled, parallel-group study of 561 patients, Haab et al. (2004) showed a significant improvement of major symptoms of OAB. Incontinence episodes per week were reduced from baseline by 67.7% with darifenacin 7.5 mg and 72.8% with darifenacin 15 mg compared with 55.9% with placebo. The most common adverse events were dry mouth and constipation but very few subjects discontinued the trial because of these side effects.

Darifenacin is currently being evaluated in a phase III global clinical evaluation program for the treatment of bladder overactivity, to identify the optimal dose regimen and to assess its potential clinical benefits. Doses of 7.5 mg and 15 mg once daily seem effective and well tolerated.

12.4.5 Solifenacin

Solifenacin (YM905) is also a selective long-acting muscarinic M3 receptor antagonist. The clinical relevance of these findings is currently being investigated in phase III clinical studies. In a randomized, double-blind placebo- and tolterodine-controlled trial of the once daily agent, solifenacin in patients with symptomatic overactive bladder in 1,033 patients, Chapple et al. (2004) reported a significant improvement in urgency episodes per day (solifenacin 5 mg, –52%; solifenacin 10 mg, –55%; tolterodine 2 mg twice daily, –38%; and placebo, –33%). The same results were found in urge incontinence, a reduction in mean voids per day and an increase in voided volume. Treatment with solifenacin was well tolerated; the rate of adverse events was low and comparable with that of placebo.

12.5 Drugs Acting on Membrane Channels

12.5.1 Calcium Antagonists

Calcium channel blockers decrease bladder contractility and could be helpful as a treatment option to increase bladder capacity and decrease the degree of leakage. Combination of anticholinergics given intravesically and calcium antagonists in the future can give good therapeutic results.

12.5.2 Potassium Channel Openers

Hyperpolarization of the cell membrane through opening of K+ channels leads to relaxation and inhibition of detrusor contraction. Further studies are necessary to find a drug with specific effects without side effects such as hypotension.

12.6 α-Adrenoceptor Antagonists and β-Adrenoceptor Agonists

Relaxation of the bladder neck and proximal urethra through α-adrenergic receptor antagonists and bladder smooth muscle relaxation through β-adrenergic receptor agonists can be effective in selected cases of bladder overactivity. At the moment, no recent studies show safety and effective results in these drugs.

12.7 Antidepressants

Tricyclic antidepressants such as imipramine also work with anticholinergic and α-adrenergic action. There is also an anxiolytic effect of the sympathetic nervous system.

Imipramine is the only drug that has been widely used clinically to treat this disorder. Doses of 10–50 mg three times daily are well tolerated. In contrast to good clinical experience, no randomized trials exist to show evidence in the treatment of detrusor overactivity. Side effects on the cardiovascular system (orthostatic hypotension, ventricular arrhythmias) may be serious for the elderly patient.

12.8 Afferent Nerve Inhibitors

12.8.1 Capsaicin and Resiniferatoxin

The vanilloids capsaicin and resiniferatoxin target the unmyelinated fibers C in afferent nerves. The local anesthetic effect with intravesical administration is of interest. Investigators are hopeful that treatment will consist of bladder instillation of medication, followed by 3–6 months without symptoms.

Typical side effects of intravesical capsaicin are burning sensation at the pubic/urethral level during instillation and general discomfort. Therefore, before application of the drug, an instillation of lidocaine is helpful without interfering with the beneficial effects of capsaicin.

The intravesical application of resiniferatoxin shows a approximately 1,000 times more potent activity than capsaicin. Resiniferatoxin can desensitize bladder sensory fibers. Further studies have to show the advantage of resiniferatoxin as an interesting alternative to capsaicin.

12.8.2 Botulinum toxin A

Botulinum toxin A, first isolated in 1897, acts by inhibiting ACH release at the presynaptic junction. This results in regionally decreased muscle contractility and muscle

atrophy at the site of injection. Because of reversibility of the effect, there is an interval of 3–6 months with improvement of OAB symptoms. Several recent studies show a good benefit in treatment, for example in spinal cord-injured patients with detrusor external sphincter dyssynergia or detrusor hyperreflexia. It is also an alternative in patients with anticholinergic drug-refractory symptoms.

12.9 Drugs Used for Treatment of Stress Incontinence

Goals of treatment in stress urinary incontinence (SUI) are increasing intraurethral pressure by influencing the intrinsic or extrinsic factors. Different types of medications can increase the intraurethral tonus, but only α-AR agonists and estrogens have been used in the past for off-label indications (Table 12.2).

12.9.1 α-Adrenoceptor Antagonists

Stimulation of the α1-adrenergic receptors, located on the bladder neck and proximal urethra, results in contraction of the smooth muscle and an increase in outlet resistance. Pseudoephedrine, midodrine hydrochloride and phenylpropanolamine could improve symptoms of mild stress urinary incontinence in off-label usage.

In 2000, phenylpropanolamine was found to have a 16-fold increase in hemorrhagic stroke in women under 50 years of age. Therefore the US FDA recommended no future using of phenylpropanolamine and other α-agonists in this group.

12.9.2 β-Adrenoceptor Antagonists

β-Adrenergic blocking agents potentiate an α-adrenergic effect with an increase in urethral resistance. There are no randomized controlled trials in the literature, only a bit of information on using propanolol for treatment of SUI. The efficacy is not clearly described.

Table 12.2. Drugs used in the treatment of stress incontinence. Assessment according to the Oxford system (Andersson et al. 2002)

Drug	Level of evidence	Grade of recommendation
Alpha-adrenoceptor agonists		
Ephedrine	3	C
Norephedrine (phenylpropanolamine)	2	Not recommended
Other drugs		
Imipramine	4	C
Clenbuterol	4	C
(Duloxetine)	Under investigation	
Hormones		
Estrogens	2	D

12.9.3 Imipramine

Tricyclic antidepressants such as imipramine show effects on bladder contractility and urethral resistance. Decreasing the contractility of the detrusor muscle and increasing the outlet resistance, symptoms of stress urinary incontinence can be treated. Because of various side effects, this type of drugs is not primary used.

12.9.4 Duloxetine

Duloxetine, a selective noradrenaline and 5-HT re-uptake inhibitor, increases rhabdosphincter contractility via stimulation of pudendal motor neuron a-1 adrenergic and 5-HT-2 serotonergic receptors. It should be the first effective and practicable drug in treatment of stress urinary incontinence, since September 2004 available in Germany as Yentreve. In one of four double-blind, placebo-controlled studies (Dmochowski et al. 2003) with the same results in women with stress incontinence (n=2,188), duloxetine (40 mg twice daily) was shown to cause significant improvements in several efficacy measures (ICS 1-h stress pad test, 24-h pad weight, number of incontinence episodes, quality of life assessment). The drug was well tolerated and there were only a few discontinuations due to side effects (24% for duloxetine, 4% for placebo). Duloxetine is a drug with demonstrated efficacy and safety. The metaanalysis showed only mild side effects, the most common being nausea in up to 23% of patients. The drug is still undergoing clinical trials.

12.10 Hormonal Treatment of Urinary Incontinence

Estrogens have no direct effect on the urethral continence mechanism, but the positive trophic effect on the connective tissue, muscle and vessels are responsible for the improvement of urinary leakage.

Estrogen stimulates connective metabolism and collagen production; in the menopause hormone levels are low, leading to atrophy of the supportive tissues of the bladder and urethra, which unmasks or eventually leads to stress incontinence.

The estrogen-sensitive tissues of the bladder, urethra and pelvic floor all play an important role in the continence mechanism. For a woman to remain continent, the urethral pressure must exceed the intravesical pressure at all times except during micturition. The functional layers of the urethra, which all play a part in the maintenance of a positive urethral pressure, are the epithelium, vasculature, connective tissue and muscle.

While menopause has been recognized by many as a risk factor for incontinence, the precise mechanism is unknown.

Estrogens increase urethral closure pressure and improve abdominal pressure transmission to the proximal urethra.

12.10.1 Estrogens for Stress Incontinence

Several subtypes of estrogens are used in treatment of urogenital atrophy and urinary incontinence in different doses and application forms. This acts on the controversial discussion about the role of estrogen in the treatment of stress incontinence.

With a lack of randomized studies, only two meta-analyses can clarify the situation further. Fantl et al. (1994) reviewed all available literature for estrogen treatment of all causes of incontinence in postmenopausal women between 1969 and 1992. There were only six controlled trials and 17 uncontrolled series in 166 articles published in English. The investigators found a significant subjective improvement for all patients but no significant differences for objective parameters. Loss of urine was not changed and also maximum urethral closure pressure did not increase significantly.

In 1990 Sultana and Walters reviewed eight controlled and 14 uncontrolled prospective trials in women in menopause with all types of estrogen treatment. The results showed good effects on symptoms of urgency and frequency but no significant difference in stress incontinence.

12.10.2 Estrogens for Urge Incontinence

There is clinical evidence that estrogens have a positive influence on postmenopausal urgency and urge incontinence, although this has not been studied in randomized trials.

In a double-blind multicenter study of 64 postmenopausal women with the urge syndrome, Cardozo et al. (1993) showed no differences between oral estriol 3 mg daily and placebo in subjective and objective improvement on bladder disorders.

In the Heart and Estrogen/Progestin Replacement Study 2001, Grady et al. reported a comparison of hormone replacement therapy with 0.625 mg of conjugated estrogens plus 2.5 mg of medroxyprogesterone acetate in one tablet daily (n=768) or placebo (n=757) with follow-up of 4.1 years. Incontinence improved in 26% of the women assigned to placebo compared with 21% assigned to hormones, while 27% of the placebo group worsened compared with 39% of the hormone group (p=0.001).

The results showed a worsening of urinary incontinence symptoms in case of intake of daily oral estrogen plus progestin. A discussion is currently taking place in the literature on the influence of progestin on the negative results on incontinence and cardiovascular events.

12.11 Conclusion

The recent innovative trends in pharmacological treatment of urinary incontinence (Huggins et al. 2003) emphasize that medical therapy is a cornerstone for helping incontinent patients. A modern drug therapy should be effective, improving patient compliance and cost-effective use of resources.

The development of new pharmacological drugs with selective efficacy and only minimal side effects with improvement of quality of life will be the future in the treatment of bladder and urethral disorders.

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Chapter 13

Medical, Behavioural and Minimally Invasive Therapy – A Urologist's View

13

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Contents

13.1 Introduction

It is estimated that whilst more than 200 million people worldwide are affected by incontinence, only a small proportion of these people have received appropriate advice and therapy for their condition. It is equally clearly established that urinary incontinence has a significant impact on the physical, social and mental well-being of individuals, and escalates in prevalence with advancing age. With this in mind a number of initiatives have been instituted by various continence organisations to promote continence awareness and develop appropriate care pathways. A combination of an increasingly elderly population in the Western world and greater health awareness in the community, combined with the development of new pharmacotherapeutic agents, has focused attention in recent years on this disease area. The likely economic consequences of these developments have emphasised the importance of critically evaluating the robustness, cost-effectiveness and cost-benefit of available treatment options for urinary incontinence in both male and female patients.

A major recent development has been the initiation of a worldwide consensus group under the auspices of the WHO and major scientific associations to critically evaluate and develop standardized methodology for research into lower urinary tract function and dysfunction, with particular reference to the classification of incontinence, the standardisation of techniques and the documentation of urodynamic procedures. This has provided a sound platform for the future assessment of the outcomes of both surgical and pharmacological treatment options, which will hopefully facilitate the development of newer and more effective forms of treatment. Certainly review of the existing literature base clearly underlines the limitations of existing knowledge and in particular the paucity of adequately powered studies comprising adequate follow-up data and with sufficiently robust methodology. With these limitations in mind, it is the purpose of this chapter is to discuss the role of medical, behavioural and minimally invasive therapy in the treatment of urinary incontinence in both male and female patients.

13.2 Nervous Control of Micturition

The bladder and urethra comprise a functional unit that is controlled by a complex interplay between the central and peripheral nervous systems and local regulatory factors. Malfunction at various levels may result in micturition disorders, which roughly can be classified as disturbances of storage or of emptying. Failure to store urine may lead to various forms of incontinence (mainly urge and stress incontinence), and failure to empty can lead to urinary retention, which may result in overflow incontinence.

The peripheral nervous mechanisms for urine storage and bladder emptying comprise a complex pattern of efferent and afferent signalling in *parasympathetic*, *sympathetic* and *somatic* nerves (de Groat et al. 1999). During storage (at low levels of vesical afferent activity) spinal reflexes are active, mediating contraction of urethral sphincter mechanisms through somatic (striated muscle) and sympathetic (smooth muscle) nerves. Sympathetic nerves may also mediate detrusor and ganglionic inhibition. During storage, there is no activity in the sacral parasympathetic outflow. Micturition is initiated by distension of the bladder, activating mechanoreceptors in the bladder wall. This triggers a high level of activity in small myelinated afferent nerves (A), and this activity reaches the lumbosacral spinal cord via the dorsal root ganglia. The A affer-

ents connect to a spinobulbospinal reflex consisting of an ascending limb from the lumbosacral spinal cord, integration centres in the rostral brain stem, and a descending limb back to the parasympathetic nucleus in the lumbosacral spinal cord. Afferent information may also be conveyed by small unmyelinated (C-fibre) vesical afferents, which have a high mechanical threshold, but which may be activated by irritation of the bladder mucosa. They may also be active in spinal cord injuries. Efferent micturition reflex pathways reach the bladder through the pelvic nerves.

Normal bladder contraction in humans is mediated mainly through stimulation of muscarinic receptors in the detrusor muscle. Atropine resistance, i.e. contraction of isolated bladder muscle in response to electrical nerve stimulation after pretreatment with atropine, has been demonstrated in most animal species, but seems to be of little importance in normal human bladder muscle. A significant degree of atropine resistance may exist in morphologically and/or functionally changed bladders, and has been reported to occur in hypertrophic bladders, interstitial cystitis, neurogenic bladders, and in the ageing bladder.

Molecular cloning studies have revealed five distinct genes for muscarinic acetylcholine receptors in rats and humans, and it is now generally accepted that five receptor subtypes correspond to these gene products. Detrusor smooth muscle from various species contains muscarinic receptors of the M_2 ($\approx 2/3$) and M_3 ($\approx 1/3$) subtype. There is general agreement that M_3 receptors are mainly responsible for the normal micturition contraction, whereas the role of the M_2 receptors has not been clarified. Muscarinic receptor function in the bladder may be altered in certain disease states, such as outflow obstruction, neurogenic damage, and diabetes and in such circumstances, M_2 receptors may contribute to contraction of the bladder. It is also very clear from the above discussion that higher centres have an important role in the control of lower urinary tract function, and indeed this is the basis for the use of behavioural therapy in the management disorders of bladder storage function.

13.3 Treatment of Incontinence

13.3.1 Life Style Changes

Most of the current literature suggests an association between life style factors and urinary incontinence; however, the small numbers of randomised trials evaluating the role of life style alterations are largely confined to the study of patients with female incontinence; information on male incontinence is mostly derived from generic epidemiological studies.

13.3.1.1 Body Weight

While in men there is no clear association between body weight and lower urinary tract symptoms (LUTS); conversely weight loss is an acceptable form of treatment option for morbidly obese women. Brown et al. (1996) reported an increase in the prevalence of daily incontinence by an odds ratio of 1.6 per 5 body mass index (BMI) units. This compares favourably with the results reported by Subak et al. (2002), where with at least a 5% reduction in body weight they achieved a 50% reduction in the frequency of incontinence episodes in their group of patients.

13.3.1.2 Caffeine

The clinical significance of caffeine intake in urinary incontinence has attracted differing opinions. In patients with detrusor overactivity, caffeine administration has been shown to increase the detrusor pressure measured during bladder filling; whereas in patients with normal bladder function no such increase in detrusor pressure has been observed. Evidence from small clinical trials does suggest that reducing caffeine intake improves incontinence.

13.3.1.3 Fluid Intake

Despite the fact that urine production is significantly related to fluid intake, especially in geriatric patients, there is little evidence to suggest that it influences the outcome of treatment in patients with urinary incontinence, who have a normal fluid intake of 1.5–2 l a day. Thus it is recommended that reduction in fluid intake should be reserved for patients with a particularly high intake of fluid.

13.3.1.4 Constipation

Chronic straining at stool may ultimately lead to a reduction in pelvic floor neural function and this is considered to be a risk factor for both urinary incontinence and pelvic organ prolapse. There are no studies that have longitudinally assessed the consequences of a programme of active management of constipation on the prevalence of urinary incontinence.

13.3.2 Behavioural Therapy

Behavioural interventions include a spectrum of techniques that modify patients' voiding patterns to achieve urinary continence and these include: bladder training/drill, timed voiding, prompted voiding and pelvic floor muscle training (PFMT). Bladder drill was perhaps the earliest intervention used to treat the storage symptoms associated with the symptomatic diagnosis of overactive bladder, namely frequency, urgency with or without urge incontinence.

13.3.2.1 Pelvic Floor Muscle Training

It is believed that a strong contraction of the pelvic floor musculature works in a variety of potential ways: (a) it occludes the urethra, thereby increasing the intraurethral pressure and helping preventing leakage, (b) it compresses the urethra against the pubic symphysis, (c) it acts to prevent urethral descent during any sudden rise in the intra-abdominal pressure, and also (d) it may act via a neural reflex feedback loop (the voluntary urinary inhibition reflex) to inhibit detrusor contraction, which may further contribute to its potential role in treating urge incontinence. Consequently, PFMT has been widely advocated for the treatment of both urge and stress-related incontinence. Since its first description by Arnold Kegel in 1948, PFMT has entered routine clinical

practice and is now routinely used by health care professionals, in particular by physiotherapists, being taught either on an individual or group basis. Inevitably with any such therapy that is intrinsically difficult to clearly define, there is a lack of consistency in the methodology used for PFMT programs, which has made comparison of the results of different studies rather difficult. In this section we will discuss the role of PFMT in treating male and female urinary incontinence.

Post-Prostatectomy Incontinence

Prostatectomy is an important cause of incontinence in men, and certainly incontinence is more common after radical prostatectomy (5%–15%) as compared to transurethral resection of prostate (1%). Non-surgical causes of male incontinence relate principally to abnormalities of detrusor function and include detrusor overactivity, bladder outlet obstruction leading to retention with overflow and poor bladder compliance. Despite conflicting reports in the literature; pelvic floor muscle training (PFMT) is thought to beneficial in the treatment of post-prostatectomy incontinence and it is believed that earlier return of continence may be achieved in patients who additionally receive electrical stimulation (ES), biofeedback or transcutaneous electrical stimulation. In one of the largest randomized control trials conducted to date and including 120 men; van Kampen et al. (2000) studied the effect of PFMT on patients who had undergone radical prostatectomy. They reported that continence was achieved in 88% of the treatment group and 56% of the control group by the end of 3 months and this was sustained out to the end of 1 year in 95% of the treatment group and 81% of the control group. Porru et al. (2001) suggested that patients receiving PFMT continence improved significantly up to 3 weeks after surgery as compared to the control group, but beyond this period the continence rates were similar in both groups. Whilst the initiation of PFMT after prostatectomy remains controversial, as the exercises are easy and simple to perform and teach, it seems likely that initiating PFMT early in the post-operative period is to be recommended.

PFMT in Female Incontinence

The role of PFMT in the management of stress incontinence has been studied in both short- and medium-term studies and has been reported to produce a 65%–75% short-term improvement, but as it is patient led, its long-term efficacy is poorly documented; on the other hand its role in treating urge incontinence remains unclear. Shafik and Shafik (2003) in a recent study reported that PFM contractions may produce their effect by preventing the internal sphincter relaxation produced by the micturition reflex. Failure of the internal sphincter to relax produces a reflex detrusor relaxation, an action possibly mediated through a voluntary urinary inhibition reflex.

It is clear that a therapist skilled in teaching and assessing the pelvic floor muscles is likely to achieve the optimal benefits from PFMT in patients under their care. Whilst it is difficult to define an ideal PFMT program; the two important components of PFMT include effective *strength training* and effective *load training*. For effective strength training it is recommended that co-contraction of other muscle groups should be avoided in order to specifically target the PFM (Bo 1995). Effective load training comprises methods aimed at recruiting the maximum number of motor units to provide bulk to the PFM by hypertrophy. It has been recommended by the WHO

consensus meeting that PFMT protocols should include three sets of 8–12 slow velocity maximal contractions sustained for 6–8 s each, three or four per week for 15–20 weeks. Both subjective (self-reported cure/improvement) and objective parameters (pad test) improve after institution of PFMT irrespective of the type of incontinence (Hay-Smith et al. 2001). Recent randomized control trials comparing PFMT to no treatment or placebo indicate PFMT provides higher cure/improvement rates as compared to no treatment or placebo. The meta-analysis by Hay-Smith showed women getting PFMT were far more likely to show cure/improvement as compared to those receiving no treatment. Comparisons between home-based self-administered programmes and intensive individualized PFMT programmes provide conflicting evidence. Whilst Bo (1995) favoured an intensive approach, others (Wilson and Herbison 1998) reported no significant differences between the two training methods. Biofeedback (BF) techniques have been employed in conjunction with PFMT to improve the outcome of treatment. BF relies on the use of monitoring devices to monitor physiological changes induced by a certain intervention in order to bring this to the patient's consciousness and hence assist PFMT. This is based on the postulate that presenting the physiological response of the treatment to the patient helps motivate them, thereby achieving improved cure rates. Berghmans et al. (1996) reported an advantage during the initial 6 weeks for those patients receiving BF, although in the longer term they did not observe any difference between those receiving BF and those treated with PFMT alone.

Other adjuvant techniques utilized in conjunction with PFMT include electrical stimulation (ES) and weighted vaginal cones. Weighted vaginal cones (VC) are thought to prompt the patient to contract the PFM when there is a sensation of losing the cone, whilst undoubtedly this is a useful adjunct to PFMT; there is at present little objective evidence to support an increased benefit accruing from using a VC in conjunction with PFMT.

The rationale behind using ES is both to improve the efficacy of PFM in preventing stress incontinence and additionally to potentially contribute to inhibition of the detrusor in urge incontinence. It has been widely advocated for use in the treatment of the overactive bladder and stress incontinence and potentially may act by kick starting the pelvic floor and educating the patient on the correct muscles to contract. ES may also improve urinary incontinence by reflexly inhibiting parasympathetic excitatory neurones at the level of the pelvic nerve and by activating sympathetic inhibitory neurones in the hypogastric nerve. There is, however, at present little supportive evidence to show any beneficial effects of combining PFMT with ES and indeed there is insufficient evidence that ES is better than no treatment at all.

Certainly one of the problems are the highly variable treatment protocols which are available. Brubaker (2000) has suggested that given at 10 Hz continually over 20 min daily or twice daily for 20 weeks for overactive bladder, there is good evidence to indicate that it is effective, with an overall 50% improvement/cure rate. Currently there is great interest in utilising patient-specified outcomes, which should make it possible to gauge the level of treatment that may be required and if behavioural treatments fail, involve patients in making the decision as to whether they wish to try medication, or proceed on to surgery.

13.3.2.2 Bladder Retraining

The first report of disciplining the bladder was from Jeffcoate and Francis in 1966; since then it has become a widely used treatment for urge, stress and mixed inconti-

nence. It is believed that bladder retraining improves cortical control over detrusor contraction, thereby inhibiting detrusor overactivity, improving urethral closure and thereby increasing the bladder's storage capacity. By retraining the bladder, it is hoped that there will be a improvement in patients' faulty bladder habits, in the ability to control the symptom of urgency, a prolongation of the voiding interval and these alterations in turn will help to increase patient confidence. Without doubt, in order for bladder retraining to produce positive results it requires motivated staff and for a patient to be motivated and cognitively intact. Visco et al. (1999) in a retrospective study quoted a compliance rate of 55% in women diagnosed with urge incontinence but also acknowledged that 'success in the "real world" may be substantially lower than that described in well-funded labour-intensive clinical trials.'

Like PFMT there are several variations on the theme between various bladder retraining protocols. Whilst the earliest protocols involved patient hospitalisation, the current consensus is on implementing the protocol on an out-patient basis over a period of 6–12 weeks. Such an outpatient bladder retraining program must include an initial voiding interval beginning at 1 h, which is increased by 15–30 min per week until a 2- to 3-h voiding interval is achieved. Other methods to control urgency such as distraction and relaxation techniques and pelvic floor muscle contraction are to be encouraged. If there is no improvement in incontinent episodes after 3 weeks of bladder retraining, the patient should be re-evaluated and other treatment options considered. It has been observed that the benefits accruing from a bladder retraining program start to become apparent after about 2 weeks of treatment. Subjective improvement (patient reported) rates vary from 70% to 90%. Jarvis and Millar (1980) reported that 90% of patients were continent and about 83% were symptom-free and had normal cystometrogram at 6 months follow-up. This finding is further supported by Fantl et al. (1991) who reported 76% of their patients had a reduction in incontinence episodes by 50% or more, over a 6-month period on a bladder retraining program.

A small number of randomized controlled trails (RCT) have investigated the advantages of bladder retraining with various other forms of conservative treatment, contrasting one with another. The limited available evidence does suggest that bladder retraining is as efficient as PFMT and may be as good as anticholinergic therapy in treating women with urge incontinence; however, a combination of simple bladder retraining with PFMT or drug therapy has not shown any particular promise, although the current data in this area is extremely limited. Without doubt this is a fertile ground for further research and such work is essential to allow us to arrive at the most cost-effective treatment plan for patients with incontinence.

13.3.2.2 Timed Voiding

Timed voiding refers to a fixed time interval toileting assistance program which allows for the bladder to remain at a lower volume, thus avoiding involuntary detrusor contractions and thereby preventing urge incontinence. It has been found to be particularly useful for patients who are not capable of independent toileting such as the frail elderly patient with impaired mobility. In a typical program, the patients are asked to void at a fixed interval such as every 2–4 h. There is, however, insufficient evidence at present to clearly define the role of timed voiding as all of the trials to date have used other interventions in addition to timed voiding in the study group. Godec (1984) reported a 79% cure rate in patients with stress incontinence after intervention with a timed voiding schedule.

13.3.2.4 Prompted Voiding

This is particularly useful for the cognitively impaired incontinent patient. It aims to improve bladder control for people with or without dementia by a combination of using verbal prompts and positive reinforcement. It differs from timed voiding in that it is not scheduled in advance. The role of health care professionals is critical in providing an effective program and success with prompted voiding have been reported in up to 60% of patients. A program such as this is more effective for controlling day-time rather than night-time incontinence. As this is a simple and harmless technique, it can be particularly recommended for the treatment of the cognitively impaired elderly patient.

13.3.3 Medical Treatment

The pharmacological treatment of incontinence is aimed at reducing symptoms that can have an affect on all aspects of an individual's quality of life, including social, domestic, psychological, occupational, physical and sexual function. Symptoms of incontinence can be caused by either storage failure (urge and stress incontinence) or voiding failure as in overflow incontinence. The functional unit of the lower urinary tract comprises the muscles of bladder, urethra and the sphincter mechanisms. In order to produce the desired effect pharmacological agents have to act on one or more of the components of the functional unit. With the current focus on providing symptomatic relief to the patient, it is clear that pharmacological therapy can be initiated prior to obtaining cystometric confirmation of detrusor/sphincter function. Costly cystometric investigations should be reserved for those who do not respond to first-line therapy. Indications for cystometry include prior to invasive therapy or where previous medical or surgical therapy has failed, after pelvic surgery or pelvic irradiation, in patients with signs or symptoms suggestive of an emptying disorder, in all those with neurological disorders, or where there is any doubt about the diagnosis.

13.3.3.1 Drugs used for Treatment of Bladder Overactivity

Idiopathic detrusor overactivity may be the result of several different mechanisms, both myogenic and neurological. Most probably, both factors contribute to the genesis of the disease. An abundance of drugs has been used for the treatment of bladder storage disorders as epitomized by the symptom complex of urgency, frequency and urge incontinence otherwise known as the urge syndrome, urgency/frequency syndrome or overactive bladder symptom syndrome.

Antimuscarinic (Anticholinergic) Drugs

Both voluntary and involuntary bladder contractions are mediated mainly by acetylcholine-induced stimulation of muscarinic receptors on bladder smooth muscle. Antimuscarinic drugs will therefore depress both types of contraction, irrespective of how the efferent part of the micturition reflex is activated. In patients with involuntary bladder contractions, the volume to the first contraction is increased, the amplitude of the contraction is decreased, and total bladder capacity is increased.

Atropine and related antimuscarinics are tertiary amines. They are well absorbed from the gastrointestinal tract and pass into the central nervous system (CNS). CNS side effects may therefore limit their use. Quaternary ammonium compounds are not well absorbed, pass into the CNS to a limited extent, and have a lower incidence of CNS side effects. They still produce well-known peripheral antimuscarinic side effects, such as accommodation paralysis, constipation, tachycardia and dryness of mouth. All antimuscarinic drugs are contraindicated in untreated narrow-angle glaucoma.

Antimuscarinics are the most widely used treatment for storage symptoms and urge incontinence. However, currently used drugs lack selectivity for the bladder, and effects on other organ systems may result in side effects that limit their usefulness. One way of avoiding many of the antimuscarinic side effects is to administer the drugs intravesically. However, this is practical only in a limited number of patients. Other routes of administration for drugs such as oxybutynin may reduce side effects due to metabolites by avoiding first-pass metabolism, which underlies the use of transdermal application.

Trospium. Trospium chloride is an antimuscarinic drug with no selectivity for muscarinic receptor subtypes. It is a quaternary ammonium compound with low biological availability (approximately 5%) and is thought not to cross the blood–brain barrier. Trospium is usually given at a dose of 20 mg b.i.d. and is generally well tolerated. Höfner et al. (2000) compared the effects of oxybutynin 5 mg b.i.d. with those of trospium 20 mg b.i.d. in a double-blind, randomized study over 12 months in 358 patients with urge symptoms or urge incontinence. The urodynamic improvements after the two drugs were comparable, but oxybutynin produced a significantly higher rate of side effects, and the drop-out rate was higher in the oxybutynin group. Jünemann and Al-Shukri (2000) compared trospium 20 mg b.i.d with tolterodine 2 mg b.i.d in a placebo-controlled double-blind study on 232 patients with urodynamically proven detrusor overactivity, sensory urge incontinence or mixed incontinence. Trospium reduced the frequency of micturition, which was the primary endpoint, more than tolterodine and placebo, and also reduced the number of incontinence episodes more than the comparators. The rate of dry mouth was comparable in the trospium and tolterodine groups (7% and 9%, respectively).

Tolterodine. Tolterodine is a potent and competitive antagonist at muscarinic receptors, developed for treatment of urinary urgency and urge incontinence . The drug has no selectivity for muscarinic receptor subtypes, but still shows some selectivity for the bladder over the salivary glands in an animal model, and possibly in man. Tolterodine has a major active metabolite with a similar pharmacological profile as the mother compound, and which significantly contributes to its therapeutic effect. Tolterodine is rapidly absorbed and has a half-life of 2–3 h, but the effects on the bladder seem to be more long-lasting than could be expected from the pharmacokinetic data. The main metabolite also has a half-life of 2–3 h. The relatively low lipophilicity of tolterodine implies limited propensity to penetrate into the CNS, which may explain a lower incidence of cognitive side effects .

Several RCTs, both in patients with idiopathic detrusor overactivity and neurogenic detrusor overactivity, have documented a significant reduction in micturition frequency and number of incontinence episodes. Tolterodine's immediate release seems to be well tolerated when used in the dose range of 1–4 mg a day. Abrams et al. (1998) showed comparable efficacy of immediate-release (IR) formulations of tolterodine and oxybutynin but tolterodine was found to have a better efficacy/tolerability profile.

A once-daily formulation of tolterodine has been developed, and a large-scale (1,529 patients) clinical trial compared the effects of this agent to placebo and the twice daily formulation (van Kerrebroeck et al. 2001). Tolterodine extended release (ER) 4 mg once daily and tolterodine immediate release 2 mg twice daily both significantly reduced the mean number of urge incontinence episodes per week compared with placebo. The median reduction in these episodes as a percentage of the baseline values was 71% for tolterodine ER, 60% for tolterodine IR, and 33% for placebo. Treatment with both formulations of tolterodine was also associated with statistically significant improvements in all other micturition diary variables compared with placebo. The rate of dry mouth (of any severity) was 23% for tolterodine ER, 30% for tolterodine IR, and 8% for placebo. The rates of withdrawal were comparable for the two active groups and the placebo group. No safety concerns were noted.

The OPERA study group (Diokno et al. 2003) compared the efficacy and safety profiles of ER formulation of oxybutynin and tolterodine in 790 women; oxybutynin was significantly more effective than tolterodine in reducing micturition frequency, and 23% of women taking oxybutynin reported no episodes of urinary incontinence compared with 16.8% of women taking tolterodine. Both groups had similar rates of adverse events, including those involving the central nervous system; discontinuation rates of treatment were also similar in the two groups.

■ **New Selective Antimuscarinics.** Solifenacin is a long-acting muscarinic receptor antagonist that may have a better functional selectivity for the bladder compared to salivary glands. In animal models, it has been shown to be more bladder-selective than tolterodine, albeit this may not translate to man. It is approximately 17-fold more selective for the M3 receptor. Recently results from phase IIIa trials have become available for 5- and 10-mg does of solifenacin (Chapple et al. 2004); solifenacin was found to produce significant differences in incontinence rates with both 5- and 10-mg doses, whereas tolterodine failed to produce similar results on incontinence, albeit the study was not adequately powered to detect a difference between these agents. The adverse event profile of this agent showed it to be very tolerable. The lowest incidence of dry mouth was reported with the use of 5 mg solifenacin; discontinuation rates with both doses was low and comparable with that of tolterodine.

Darifenacin is a new agent that has up to 50-fold more receptor-subtype selectivity for the M3 over some of the other receptor subtypes. Clinical trial data will shortly be available and are awaited with interest.

Drugs with Mixed Actions

Some drugs used to block bladder overactivity have been shown to have more than one mechanism of action. They all have a more or less pronounced antimuscarinic effect and, in addition, an often poorly defined direct action on bladder muscle. For several of these drugs, the antimuscarinic effects can be demonstrated at much lower drug concentrations than the direct action, which may involve blockade of voltage operated Ca^{2+} channels. Most probably, the clinical effects of these drugs can be explained mainly by their antimuscarinic mechanism of action.

■ **Oxybutynin.** Oxybutynin has several pharmacological effects, some of which seem difficult to relate to its effectiveness in the treatment of detrusor overactivity. It has both an antimuscarinic and a direct muscle relaxant effect, and, in addition, local an-

aesthetic actions. The latter effect may be of importance when the drug is administered intravesically, but probably plays no role when it is given orally. Most probably, when given systemically, oxybutynin acts mainly as an antimuscarinic drug.

Oxybutynin has a high affinity for muscarinic receptors in human bladder tissue. It was shown to have somewhat higher affinity for muscarinic M_1 and M_3 receptors than for M_2 receptors, but the clinical significance of this is unclear.

Oxybutynin is a tertiary amine that is well absorbed, but undergoes an extensive first-pass metabolism (biological availability 6% in healthy volunteers). The plasma half-life of the drug is approximately 2 h, but with wide interindividual variation. Oxybutynin has an active metabolite, N-desethyl oxybutynin, which has pharmacological properties similar to those of the parent compound, but which occurs in much higher concentrations. Considering this, it seems reasonable to assume that the effect of oral oxybutynin to a large extent is exerted by the metabolite. Many controlled studies have shown that oxybutynin is effective in controlling detrusor overactivity, including that due to neurogenic causes. The recommended oral dose of the immediate-release form is 5 mg t.i.d. or q.i.d., even if lower doses have been used. Thüroff et al. (1998) summarized 15 RCTs on a total of 476 patients treated with oxybutynin. The mean decrease in incontinence was recorded as 52% and the mean reduction in frequency for 24 h was 33%. The overall subjective improvement rate was reported as 74% (range, 61%–100%). The mean percentage of patients reporting side effects was 70% (range, 17%–93%).

The therapeutic effect of immediate-release oxybutynin on detrusor overactivity is associated with a high incidence of side effects (up to 80% with oral administration). These are typically antimuscarinic in nature (dry mouth, constipation, drowsiness, blurred vision) and are often dose-limiting. Oxybutynin passes the blood–brain barrier and may have effects on the central nervous system. The drug can cause cognitive impairment, and this side effect may be particularly troublesome in the geriatric population. The effects on the electrocardiogram of oxybutynin were studied in elderly patients with urinary incontinence; no changes were found. It cannot be excluded that the commonly recommended dose 5 mg × 3 is unnecessarily high in some patients, and that a starting dose of 2.5 mg × 2 with following dose-titration would reduce the number of adverse effects.

Once daily formulations of oxybutynin have been developed, the oxybutynin ER (Ditropan XL) uses an osmotic drug delivery system to release the drug at a controlled rate over 24 h. This formulation overcomes the marked peak to trough fluctuations in plasma levels of both drug and the major metabolite, which occurs with immediate-release oxybutynin.

Appell et al. (2001) compared extended-release oxybutynin chloride 10 mg/day and immediate-release tolterodine 2 mg b.i.d in a 12-week randomized, double-blind, parallel-group study in 378 patients with overactive bladder. Extended-release oxybutynin was found to be significantly more effective than immediate-release tolterodine in each of the main outcome measures (number of episodes of urge incontinence, total incontinence, and micturition frequency at 12 weeks) adjusted for baseline, and the rates of dry mouth and other adverse events were similar in both treatment groups. Similar observations can be concluded from a comparison of the two extended-release formulations albeit the clinical significance of the observed differences is of limited significance.

Oxybutynin has a well-documented efficacy in the treatment of detrusor overactivity, and is, together with tolterodine, the drug of first choice in patients with this disorder.

■ **Propiverine.** Propiverine has been shown to have combined anticholinergic and calcium antagonistic actions. The drug is rapidly absorbed, but has a high first-pass metabolism and several active metabolites. It seems most probable that these metabolites contribute to the clinical effects of the drug.

Beneficial effects in patients with detrusor overactivity have been documented in several studies. Thüroff et al. (1998) collected nine randomized studies with a total of 230 patients, and reported reductions in frequency (30%) and micturitions per 24 h (17%), a 64-ml increase in bladder capacity, and a 77% (range, 33%–80%) subjective improvement. Side effects were found in 14% (range, 8%–42%).

In patients with hyperreflexia, controlled clinical trials have demonstrated propiverine's superiority over placebo. Controlled trials comparing propiverine, flavoxate and placebo, and propiverine, oxybutynin and placebo, have confirmed the efficacy of propiverine, and suggested that the drug may have equal efficacy and fewer side effects than oxybutynin.

■ **Flavoxate.** The main mechanism of flavoxate's effect on smooth muscle has not been established – no anticholinergic effect has been found. Comparing the effects of flavoxate with those of placebo in RCTs, investigators have not been able to show any beneficial effect of flavoxate at dosages up to 400 mg three times daily.

■ **Antidepressants.** Several antidepressants have been reported to have beneficial effects in patients with detrusor overactivity. However, imipramine is the only drug that has been widely used clinically to treat this disorder. Imipramine has complex pharmacological effects, including marked systemic anticholinergic actions and blockade of the reuptake of serotonin and noradrenaline, but its mode of action in detrusor overactivity has not been established. It is anecdotally considered by physicians to have mild sedative effects, which can be particularly helpful in the elderly in the treatment of nocturia. On a more worrying note, it is well established that therapeutic doses of tricyclic antidepressants, including imipramine, may cause serious toxic effects on the cardiovascular system (orthostatic hypotension, ventricular arrhythmias). Imipramine prolongs QTc intervals and has an antiarrhythmic (and proarrhythmic) effect similar to that of quinidine. Children and the frail elderly individuals seem particularly sensitive to the cardiotoxic action of tricyclic antidepressants. Very few studies have been performed during the last decade and no good-quality RCTs have documented that the drug is effective in the treatment of detrusor overactivity.

■ **Vasopressin Analogues: Desmopressin.** Desmopressin (1-desamino-8-D-arginine vasopressin; DDAVP) is a synthetic vasopressin analogue with a pronounced antidiuretic effect, but practically lacking vasopressor actions. It is now widely used as a treatment for primary nocturnal enuresis in children, where several RCTs have shown it to be effective. One of the factors that can contribute to nocturnal enuresis in children and probably in adults is lack of a normal nocturnal increase in plasma vasopressin, which results in a high nocturnal urine production. By decreasing the nocturnal production of urine, beneficial effects may be obtained in enuresis and nocturia.

The dose used in most studies has been 20 μg intranasally at bedtime. However, the drug is orally active, even if the bioavailability is low (less than 1% compared to 2%–10% after intranasal administration), and its oral efficacy in primary nocturnal enuresis in children and adolescents has been documented in RCTs; it is used at doses of up 0.4 mg. Positive effects of desmopressin on nocturia in adults have been docu-

mented. Nocturnal frequency and enuresis due to detrusor overactivity responded favourably to intranasal desmopressin therapy even when previous treatment with so-called antispasmodics had been unsuccessful. Also in patients with multiple sclerosis, desmopressin was shown in controlled studies to reduce nocturia, and micturition frequency. Desmopressin is a well-documented therapeutic alternative in paediatric nocturnal enuresis, and seems to be effective also in adults with nocturia of polyuric origin. Even if side effects are uncommon, there is a risk of water retention and hyponatremia during desmopressin treatment, and due consideration should be given to this potential side effect, particularly in elderly patients.

Drugs for Stress Incontinence

At present, failing conservative therapy, the only effective option for the treatment of bothersome stress incontinence is surgical correction. α-Adrenoceptor (αAR) agonists have been naturally employed for treating stress incontinence, as there is substantial evidence supporting the hypothesis that the urethral smooth muscle tone is mediated through the stimulation of αAR in the urethral smooth muscle by release of noradrenaline. A significant limitation is the potential to develop cardiovascular side effects with this group of agents. Radley et al. (2001) demonstrated minimal rises on the mean urethral pressure at which clinically significant changes in blood pressure and heart rate occurred; all their patients developed headache and cold extremities. So the potential availability of an effective and tolerable pharmacological therapy for stress incontinence has been an interesting recent development based on a potential role for serotonin and noradrenaline in modulating urethral smooth muscle tone. Duloxetine, a selective serotonin and noradrenaline reuptake inhibitor (SNRI) that has this potential, is discussed below.

Duloxetine. Venlafaxine is the only SNRI available for clinical use; recently duloxetine has been shown to have a more selective affinity for the serotonin and noradrenaline receptors. In animal models, serotonergic agonists have been found to suppress parasympathetic activity and enhance sympathetic activity in the lower urinary tract. This tends to encourage urine storage by relaxing the detrusor and increasing urethral resistance. Based on animal studies, it has been suggested that the site of action of this drug may be at the level of the sacral motor nucleus of Onufrowitz. Recently results from phase III studies have been published (Dmochowski et al. 2003; Millard et al. 2004). On a 40-mg twice-a-day regimen, duloxetine proved to be useful in up to 60% of the patients. Side effects from treatment were observed in a quarter of patients with nausea, fatigue, headaches and insomnia being the most frequently reported. Both the studies reported a dropout rate of about 25% due to side effects. This appears to be a promising addition to the armamentarium in treating patients with genuine stress incontinence and may bridge the gap between conservative therapy and surgery.

Oestrogens. Epidemiological studies have implicated oestrogen deficiency in the aetiology of the lower urinary tract symptoms that occur after the menopause. It is postulated that oestrogens maintain continence by (a) improving the maturation index of urethral squamous epithelium, (b) increasing the urethral closure pressure and (c) increasing the sensory threshold of the bladder. The role of oestrogens in the treatment of both urge and stress incontinence has been controversial; it is believed that

the benefits of oestrogen therapy are mainly in improving subjective parameters and this could possibly be due to the general feeling of well-being in post-menopausal women being administered oestrogen as well as direct effects resulting from correction of atrophic vaginitis. Oestrogen plays an important role in maintaining the functional and anatomical integrity of the lower urinary tract but its role in the treatment of incontinence has been disappointing. Certainly studies to date when reviewed by meta-analysis support the conclusion that there are observed significant benefits in subjective improvement of stress incontinence but these do not translate well into objective parameters.

13.3.4 Minimally Invasive Therapy in Urinary Incontinence

Bulking agents are an attractive minimally invasive alternative method of treatment for stress incontinence. These agents can be administered either endoscopically in a retrograde manner or antegrade via the transurethral or periurethral routes into the tissue around the bladder neck or the proximal/mid-urethra. The surgical challenge is to get the injectable positioned appropriately with the wall of the urethra. A number of bulking agents have been used in the recent past; an optimal bulking agent should be permanent, nondegradable, biologically inert and should not migrate or change its bulking capability. To date, there is no consensus on the best agent fulfilling these requirements. As bulking agents, Teflon, autologous fat, collagen, silicone particles, detachable micro-balloons and hyaluronic acid with dextranomer and polycarbon particles have all been the object of clinical research. Teflon forms granulomas in the surrounding tissue and tends to migrate and is now considered obsolete. The risk of allergic phenomena complicates collagen use and this agent tends to adsorb over the course of time. Carbon-based material appears to parallel collagen in durability, with the significant advantage of a non-immunogenic response within host tissues. However, injectable bulk agents, although safe and minimally invasive, are not without risk of complications, for instance, the formation of sterile abscess at the injection site requiring surgical intervention.

Autologous fat injection achieves early results effective in 23%–65% of women, similar to those with collagen, but has poor long-term efficacy – being limited by resorption and fibrous replacement as well as the local discomfort associated with harvesting procedures. Whilst excellent short-term results have been reported with collagen and Macroplastique injections, long-term results are poor, with success rates of at best 50% cured or improved at 2-year follow-up. Currently there are no controlled studies comparing bulking agents to conservative therapy or standard incontinence surgical procedures. The data available comes from small prospective studies with short follow-up periods. For this form of treatment to be more acceptable further comparative studies are needed.

13.4 Economics of Conservative Therapy

It is well documented that the cost of incontinence to society is significant, subdivided into the separate domains of direct cost of care and treatment and the indirect economic consequences of incontinence such as loss of productivity. Currently it is estimated that about 200 million people suffer from incontinence worldwide, with a mi-

nority of them seeking professional help and even a smaller proportion commencing treatment. As a consequence, the long-term economic burden to society principally relates to those not seeking any treatment during the early stages of the condition; rather than those who opt for some form of treatment. In the United States for example, annual spending on incontinence is between US $10 and 16 billion; it has been estimated that a woman with urinary incontinence has total lifetime medical costs approximately twice as high as a similar woman without urinary incontinence. It has therefore been suggested that the focus should be on prevention and early instigation of treatment for urinary incontinence.

Patient compliance and good long-term efficacy are central to the cost-effective treatment of incontinence. Treatments with poor compliance rates and poor long-term results are more likely to incur higher costs for the health care system, as this includes costs of providing the failed treatment and subsequently initiating further treatment.

Apart from direct costs of the treatment itself, the overall cost must include the cost of the person providing the treatment. Moore et al. (2003) concluded that the success rates for patients treated by either nurse continence advisors or urogynaecologists were similar at 2 years, but lower costs arose from treatment provided by nurse advisors, because their professional time was less expensive.

Behavioural therapy has limited long-term efficacy possibly due to poor patient compliance, and is extremely labour-intensive. Pharmacological intervention is not bereft of patient compliance problems; this can be largely poor tolerability and efficacy leading to discontinuation of treatment. The recent development of more tolerable drug formulations has been shown to increase patient compliance and thus improve the cost effectiveness of pharmacotherapy. For example it has been estimated that tolterodine ER is as efficacious as its oxybutynin counterpart, with fewer patients reporting significant side effects, thus increasing compliance and having a lower cost per successfully treated patient than its IR formulation or oxybutynin (Chapple et al. 2001).

At present the long-term efficacy of newer bulking agents is not established owing to the limitations of the literature base; currently available data would suggest it to have good short-term benefits but it does have significant failures in the medium term. Further work is required before more definitive conclusions can be reached. In particular, identifying patients who are more likely to benefit from one therapy as opposed to another would be a useful way of the reducing cost of treatment.

Truijen et al. (2001) aimed to find out which factors can predict the outcome of conservative treatment for urinary stress incontinence in women. They found that the presence of a high body mass index, previous pelvic surgery, strong levator muscles and urethral hypermobility appeared to be poor prognostic features. Clearly there is very limited information currently available relating to the efficacy of current therapies for incontinence. Before more definitive conclusions can be reached, there is a pressing need for robust, methodologically validated studies to evaluate which patients will benefit from a particular treatment with particular emphasis on long-term success, retreatment rates and the true costs of treatment These studies should then allow detailed health economic analyses to be performed, to determine the optimal cost-efficacy and hence cost-benefit for any individual treatment, both for the patient and community in general. This will hopefully lead to the development of sound criteria for optimal patient selection for an individual therapy.

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Chapter 14

Medical and Behavioral Treatment of Fecal Incontinence

14

William E. Whitehead

Contents

14.1 Introduction

The treatment algorithm for fecal incontinence involves a progression from medical management and education to behavioral treatment (pelvic floor exercises and/or biofeedback) to surgical repair of the pelvic floor, and if these steps fail, it may end with the management of incontinence with diapers or other containment devices or with a colostomy. Electrical stimulation of sacral nerves is being investigated as an alternative to surgery (Kenefick et al. 2002; Matzel et al. 2003; Rosen et al. 2001). This algorithm is dictated by an effort to try first those treatments that are least costly and have the lowest morbidity. However, there are patient characteristics that help to identify the patients who are most likely to benefit from each type of treatment. These will be discussed in this chapter, along with a description of each treatment and the evidence for its effectiveness.

14.2 Education and Medical Management

A recently published controlled clinical trial (Norton et al. 2003) shows that education about the causes of incontinence and advice about diet can improve bowel control even in patients who have been referred to a tertiary referral center. Norton and colleagues showed that education by a nurse was as effective as biofeedback training and that approximately 80% of patients were improved. The effectiveness of education combined with medical management was confirmed by our laboratory (Heymen et al. 2001a): we found that 35% of patients referred by gastroenterologists for behavioral treatment obtained adequate relief of their fecal incontinence after 4 weeks of medical management.

The educational component of medical management should include

- A description of the anatomy of the pelvic floor and the mechanisms for maintaining continence. If the patient has undergone a diagnostic evaluation, this description can be individualized to include a description specific to the patient, i.e., whether the incontinence is the result of impaired sensation, weak muscles, anatomical defect, etc.
- Education should also include taking a history or having the patient keep a symptom diary to identify precipitants of incontinence that may be unique to the patient and then providing suggestions for how to avoid or minimize the impact of these factors. For example, a patient whose incontinence is precipitated by coughing or lifting may be taught to contract pelvic floor muscles before these events, while a patient with incontinence precipitated by diarrhea may be offered an antidiarrheal medication.
- The educational component should also include dietary advice to improve stool consistency.
- For patients with constipation as a contributing cause of incontinence, education should include habit training, i.e., encouragement to take advantage of the gastrocolic reflex by scheduling bowel movements after the same meal each day (Shepherd et al. 1989; Lowery et al. 1985; Tariy et al. 2003).

Diarrhea (Leigh and Turnberg 1982; Nelson et al. 1998) and constipation (Nelson et al. 1998; Chassagne et al. 1999) are both recognized risk factors for fecal incontinence. Diarrhea increases the risk of incontinence because liquid stools are more difficult to control, especially in the presence of an anatomical defect in the sphincter, and also because forceful peristaltic contraction may overwhelm the sphincter. Constipation contributes to incontinence when a large fecal impaction develops in the rectum and causes reflex dilation of the internal anal sphincter, allowing liquid stool to leak out. Diarrhea or constipation is often not the sole cause of fecal incontinence but interacts with injuries to the pelvic floor or its innervation. In these cases drugs directed at normalizing stool consistency may be combined with behavioral or surgical treatment.

14.2.1 Antidiarrheal Medications

The most common antidiarrheal medications are listed in Table 14.1, together with recommended doses and precautions. These medications include loperamide, which is an opioid analog that does not cross the blood–brain barrier; and diphenoxylate, an opioid analog that acts peripherally to control diarrhea but does cross the blood–brain barrier and cause CNS side effects. Figure 14.1 shows a comparison of loperamide to codeine and diphenoxylate in a randomized cross-over study (Palmer et al. 1980) of patients with diarrhea and fecal incontinence. Loperamide is the preferred drug both because it has fewer side effects and because it is more effective than diphenoxylate. The major precaution with loperamide is that patients may tend to exceed the recommended dose and to develop constipation. Loperamide is sold as a 2-mg tablet, which may not allow titration to the appropriate level because this drug is very potent, but a liquid formulation of loperamide is sold for this purpose.

The tricyclic antidepressant, amitriptyline, has also been found to be an effective antidiarrheal agent that improves fecal incontinence (Santoro et al. 2000). However, amitriptyline has potent CNS effects and should probably be reserved for patients with fecal incontinence associated with irritable bowel syndrome, where its antinociceptive properties are also desirable (Jackson et al. 2000).

Other antidiarrheal agents such as bulking agents and bismuth compounds may also be helpful for milder diarrhea. Fiber supplements have specifically been shown to reduce fecal incontinence in the elderly (Bliss et al. 2001).

Table 14.1. Drugs for diarrhea-related fecal incontinence

Drug	Dose	Comments
Loperamide	2–4 mg average (titrate)	No CNS action; may cause constipation
Diphenoxylate ± atropine	2 × 2.5-mg tablets	Less effective than loperamide, more side effects than loperamide
Amitriptyline	20 mg	Decreases urgency and frequency
Psyllium and gum agar		Milder cases, elderly

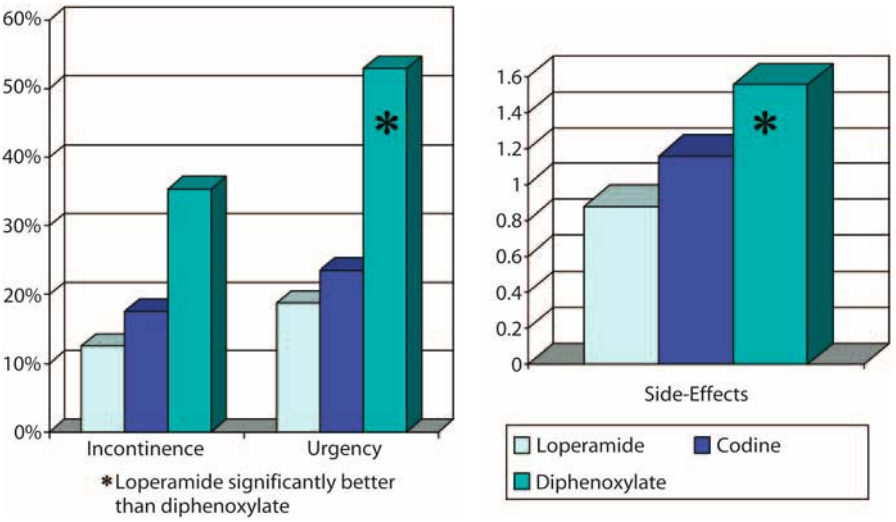

Fig. 14.1. Cross-over study comparing loperamide, codeine, and diphenoxylate. *Loperamide significantly better than diphenoxylate. From Palmer et al. (1980)

14.2.2 Laxatives for Constipation-Related Fecal Incontinence

Constipation is known to be the cause of incontinence in more than 90% of fecally incontinent children (Shepherd et al. 1989; Levine 1975), and it is also associated with fecal incontinence in many elderly people (Chassagne et al. 1999). This type of incontinence is often referred to as overflow incontinence. Its treatment consists of removing the fecal impaction, which is the cause of internal anal sphincter inhibition, and preventing the recurrence of fecal impaction through (a) teaching the patient to attempt defecation at a regular time each day (following a meal) and (b) starting the patient on a daily or frequent laxative regimen (Lowery et al. 1985; Tariy et al. 2003).

Early attempts to treat overflow incontinence in children used enemas; patients were instructed to take an enema if they had no bowel movement for 2 days (Lowery et al. 1985). However, there are two practical problems with enemas: (a) They are poorly tolerated by patients, especially children, and (b) if given daily, they cause tolerance and become less effective. In recent studies, investigators have shown that oral laxatives are as effective as enemas (van der Plas et al. 1996; van Ginkel et al. 2003).

As shown in Table 14.2, there are several classes of laxatives that can be used to treat constipation. The stimulant laxatives based on bisacodyl, cascara, or senna are the best known laxatives, and they are effective if used intermittently, i.e., no more often than three times per week. However, if used daily, patients rapidly become tolerant and require increasing doses.

Osmotic laxatives are those that act primarily by causing secretion of water into the small intestine. The most popular is polyethylene glycol, now marketed as Mirilax. This compound is more effective than placebo at a dose of 8–16 oz daily (Cleveland et al. 2001). Two different formulations of magnesium solutions are also used: magnesium citrate and milk of magnesia. Milk of magnesia is relatively cheap and is effective; it is the most common laxative used in nursing homes in the United States and is also effective when used in children. Sorbitol and lactulose are also used as osmotic

Table 14.2. Drugs for constipation-related fecal incontinence

Drug type	Examples	Comments
Stimulant laxatives	Bisacodyl, senna, cascara	Use no more than every other day to avoid tolerance
Osmotic laxatives	PEG, Mg solutions, lactulose, sorbitol	Good for daily dosing. Some cause electrolyte imbalance
Stool softeners	Docusate sodium	Mild. Require daily dosing
Enemas	Phosphosoda	Alternate day dosing to avoid tolerance. Less effective than other types

laxatives but are poorly tolerated by adults because they produce excessive gas and bloating. The chief advantage of the osmotic laxatives is that they do not result in tolerance, so they can be used daily without losing effectiveness. The only caution is that some of these compounds may cause electrolyte imbalance through absorption of salts or loss of potassium through high-volume secretion.

The overall effectiveness of laxatives for constipation-related fecal incontinence in children is 60%–80% (Lowery et al. 1985; Brazzelli and Griffiths 2001). There are no good studies to estimate effectiveness in adults.

14.2.3 Antegrade Colonic Lavage

Patients with spina bifida frequently have a combination of a denervated sphincter (no voluntary contraction) and constipation (Whitehead et al. 1986). Malone et al. (1990) pioneered a technique for treating this twin deficit by creating an appendicostomy or an artificial conduit to the cecum or proximal colon and having the patient irrigate their colon each morning with large volumes of tap water or a saline enema while sitting on the toilet. Although time consuming, this usually eliminates fecal incontinence for at least a day. In published series, the use of this technique was associated with achieving continence in 77% (Yerkes et al. 2003). Although the Malone procedure has been used mostly in children with spina bifida, it may also be effective in adults with overflow incontinence or in adults with constipation without incontinence (Marshall et al. 2001). Modification of the Malone antegrade colonic enema procedure includes irrigating the descending and sigmoid colon by introducing a tube per rectum, advancing it approximately 25 cm, and pumping water or saline enema solution in by this route. This technique is also reported to substantially reduce constipation and may eliminate constipation-related fecal incontinence (Christensen et al. 2000).

14.3 Biofeedback

14.3.1 Theory of Biofeedback

Biofeedback is a form of motor skills learning in which the individual tries to perform a task and learns from successes and failures how to refine their performance. This is the way we learn to kick a soccer ball. In the case of weak muscles such as a partially

denervated sphincter, however, the intrinsic feedback to know how well we have contracted the muscle may be too weak to support learning. To compensate for this lack of intrinsic sensory feedback, in biofeedback training we measure the sphincter contraction sensitively, amplify it electronically, and feed it back to the patient as a visual display (Whitehead and Thompson 1993).

In clinical biofeedback training, a nurse or other therapist works with the patient and provides verbal instructions on how to contract the sphincter as well as encouragement and praise for successive approximations to the desired response, which may include stronger contractions or responses to weaker distensions of the rectum. The therapist also helps the patient to recognize when (if) they are inappropriately contracting the rectus abdominis muscles when they attempt to contract the sphincter and teaches them to keep these muscles relaxed while practicing sphincter contractions.

Biofeedback for fecal incontinence is usually done with a balloon-tipped catheter, which is used to simulate the sensation of rectal filling, and a pressure sensor in the anal canal which is used to measure voluntary sphincter contraction. The patient is instructed to contract whenever they detect the distention of the balloon. An alternative technique is to use the averaged electromyographic (EMG) activity from the external anal sphincter as the feedback signal. This EMG can be recorded with an acrylic anal plug that has metal plates on its surface to detect the EMG activity. The electrical potentials recorded by these sensors are amplified, filtered to eliminate smooth muscle EMG, averaged, and displayed to the patient. In an intact sphincter muscle, this averaged EMG activity is proportional to the squeeze pressure in the sphincter. However, if there is a significant anatomical defect (sphincter muscle separation), EMG activity may be normal despite ineffective squeeze pressures.

There are no direct comparisons between pressure biofeedback training and EMG to indicate which is more effective. Potential advantages of pressure feedback over EMG include (a) avoiding the confounding effect of anatomical defects in the sphincter on the feedback display and (b) the greater ease of combining sensory training (learning to detect and respond to weaker rectal distensions) with training to improve sphincter strength. However, in a meta-analysis of the literature on biofeedback training, Heymen and colleagues (2001b) found that clinical outcomes reported in studies that used EMG feedback were significantly better than those reported in studies using pressure feedback. Direct comparisons are needed to confirm this.

Biofeedback training requires a median of four training sessions (range, 1–12) carried out at weekly or biweekly intervals. Each session lasts 40–60 min. Training sessions in the clinic are normally combined with daily pelvic floor exercises carried out by the patient at home, and the biofeedback sessions with the therapist are used to teach the patient how to contract appropriately and how to recognize weak sensations of rectal distention. Weekly or less frequent biofeedback sessions with the therapist are preferable to daily sessions because the patient needs time to practice and to benefit from daily pelvic floor exercises.

Biofeedback training is normally carried out by a nurse, physiotherapist, or a psychologist rather than a physician because physician time is more expensive. The cost of biofeedback training varies by provider and setting, and there is no standard cost. In the author's medical center, biofeedback training is provided by a nurse under physician supervision and costs $194 per visit (CPT code 90911).

14.3.2 Patient Selection

The data on which patients respond best to biofeedback training is limited, but the following are general guidelines. Since biofeedback requires a motivated and cooperative patient, it is less likely to succeed in children younger than 7 years old and in adults with dementia, anxiety, or depression (Whitehead et al. 1985, 1986; Heyman et al. 2001). It is also unlikely to benefit patients with a completely denervated sphincter such as those with a spinal cord transaction (Whitehead et al. 1986), and it is less likely to benefit those with substantial impairment in the ability to appreciate rectal distention (Chiarioni et al. 2002). However, patients with partial loss of sensation or with sphincter weakness that is due to partial nerve injury may be the best candidates for biofeedback. On logical grounds, one would expect patients with anatomical defects in the pelvic floor resulting from trauma to be poor candidates for biofeedback training, but studies have so far not confirmed that sphincter morphology predicts the outcome of biofeedback training (Norton et al. 2003).

14.3.3 Diagnostic Evaluation

Because biofeedback is relatively inexpensive compared to surgery and because it involves no morbidity, some advocate trying biofeedback in all patients who have not benefited from medical management rather than performing an expensive diagnostic evaluation to identify the mechanism of incontinence. However, a diagnostic evaluation by anorectal manometry and anal canal ultrasound will influence my expectation of success and direct how the biofeedback training is done, i.e., whether to emphasize strength training or sensory training. For this reason, the author recommends a diagnostic evaluation prior to initiating biofeedback training. Anorectal manometry is used to assess resting and squeeze pressures in the anal canal, thresholds for the perception of rectal distention and urge to defecate, and compliance of the rectum; it is directed towards assessing the innervation of the pelvic floor and rectum. Endoanal ultrasound, on the other hand, tells us nothing about the innervation of the rectum but is the gold standard for assessment of morphological defects. Pudendal nerve motor latencies, which were once advocated to evaluate the innervation of the pelvic floor, has insufficient specificity to be recommended (Diamant et al. 1999).

14.3.3 Efficacy of Biofeedback

Our laboratory conducted a systematic review and meta-analysis of the literature on biofeedback treatment for fecal incontinence up to 2001 (Heymen et al. 2001b), which indicates that the median proportion of patients reporting a significant improvement is 74%. Studies varied in how they defined improvement. The proportion of patients who met a criterion of continence was approximately 50%. Follow-up has been reported for periods up to 1 year and suggests that the benefits of training are well sustained for at least this length of time. We were unable to find adequately controlled studies of biofeedback prior to 2002.

Since publication of this review, a randomized controlled trial was reported form St. Mark's Hospital (Norton et al. 2003), which compared four treatments of increasing complexity and cost: one-fourth of patients were provided education by a nurse with

education about incontinence, a second group received education plus pelvic floor exercises, a third group received biofeedback in addition to education and pelvic floor exercises, and the last group received all these components plus a portable biofeedback device to practice with at home. A total of 171 patients were randomized to these groups (159 were women). The overall results were excellent: 80% of patients described themselves as improved, and there were significant increases in sphincter resting and squeeze pressures, decreases in the frequency of incontinence, improvements in quality of life, and decreases in anxiety and depression. However, there were no differences between the groups on any of these outcome measures: the education-only group achieved improvements comparable to the biofeedback and home practice groups.

The results of the Norton trial (Norton et al. 2003) suggest that biofeedback provides no specific benefit and that the cost associated with it may be unjustified. However, this study contrasts with a large literature suggesting that biofeedback is effective (Heymen et al. 2001b). Additional studies are needed to evaluate the specific benefit of biofeedback after controlling for standard medical management, and such studies are underway.

14.3.4 How Does Biofeedback Work?

There is controversy as to whether biofeedback works primarily by improving the strength of pelvic floor muscles (reflected in increased anal canal squeeze pressures) or whether it works primarily by improving the patient's ability to detect rectal distensions. The earliest publications on biofeedback emphasized the acquisition of muscle strength and paid relatively little attention to sensation (Whitehead et al. 1985; Engel et al. 1974; Cerulli et al. 1979). However, studies by Latimer et al. (1984) and Miner et al. (1990) suggested that sensory discrimination training (i.e., improving the patient's ability to recognize weaker rectal distensions and to respond to them more quickly may be the most important ingredients of successful training. A recent study by Chiarioni and colleagues (2002) provides the most compelling data to date supporting the view that sensory training is the key ingredient of biofeedback training.

Chiarioni and colleagues (2002) recruited 24 patients with severe fecal incontinence (loss of solid stool at least once a week) from a consecutive series of patients and provided biofeedback training to all of them. The biofeedback consisted of coordination training in which they were asked to respond to the sensation of rectal distention by contracting the pelvic floor muscles. Emphasis was placed both on increasing squeeze pressures and on learning to recognize and respond to weaker sensations. At the end of 3 months of biofeedback training, 17 patients were judged to be responders because they showed at least a 75% reduction in the frequency of fecal incontinence, and this group included 12 patients who were completely continent following biofeedback training. The remaining seven patients were labeled non-responders. The investigators then contrasted the responders to the non-responders with respect to both squeeze pressures and sensory thresholds before and after biofeedback training. As shown in Fig. 14.2, all responders had sensory thresholds (threshold for first sensation) of 20 ml or less following training, whereas all but one of the non-responders had sensory thresholds of 50 ml or greater. Moreover, pretreatment sensory thresholds were predictive of which patients would respond to biofeedback training: all responders had baseline sensory thresholds of 50 ml or less, whereas the majority of non-responders had sensory thresholds higher than this range prior to training. Figure 14.3 shows

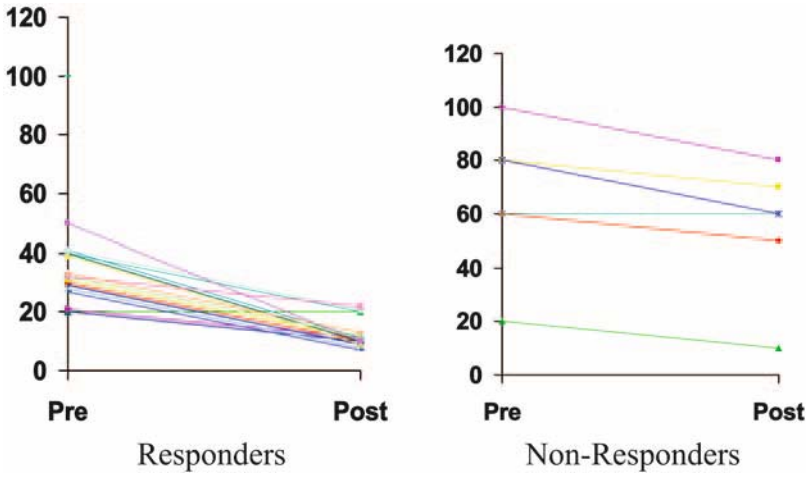

Fig. 14.2. First sensation thresholds (ml) before and after biofeedback training. From Chiarioni (2002)

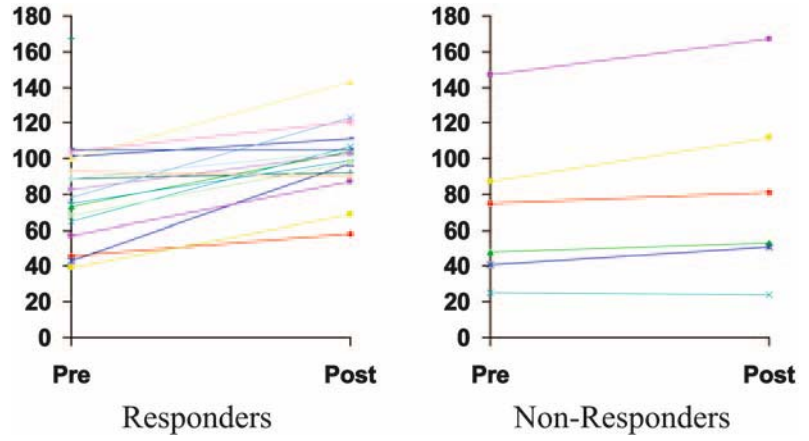

Fig. 14.3. Maximum squeeze pressures (mmHg) before and after biofeedback training. From Chiarioni (2002)

squeeze pressures before and after training and demonstrates that biofeedback did improve the strength of pelvic floor contractions. However, there was an overlap between responders and non-responders to biofeedback and no significant difference between the two groups either in their post-treatment squeeze pressures or their baseline squeeze pressures. These data suggest that sensory discrimination training is the critical component to biofeedback training.

It is possible that the Chiarioni study (Chiarioni et al. 2002) overestimates that importance of sensory retraining and that there are some patients whose primary etiology for fecal incontinence is muscle weakness; these patients would be expected to benefit more from strength training. The author advocates a pretreatment anorectal manometry to assess both sphincter strength and sensory thresholds in order to direct

the biofeedback training to the specific deficits the patient has. Nevertheless, Chiarioni's study suggests that biofeedback training must be able to address sensory retraining as well as strength training in order to achieve optimal results.

14.3.5 Combining Biofeedback with Surgery or Medical Management

Biofeedback operates through a different mechanism than surgery: Biofeedback depends on learning and acts through afferent and efferent nerve pathways to improve continence, whereas surgery corrects morphological abnormalities in the pelvic floor musculature. This raises the possibility that combining biofeedback with surgery (or medical management) may improve outcomes over what can be achieved by either technique alone. This is an emerging area of research.

14.4 Summary and Conclusions

Diarrhea and constipation are recognized risk factors for fecal incontinence, and the first step in conservative medical management is to use antidiarrheal drugs or laxatives to try to normalize stool consistency. Education about the causes of fecal incontinence, including an attempt to identify specific precipitating events (e.g., coughing, eating in public) and to teach ways of coping, should also be incorporated into conservative management. Conservative management with education and drugs to normalize stool consistency are effective in about 60%–90% of patients with constipation-related or diarrhea-related fecal incontinence (Table 14.3). Biofeedback is indicated when patients have failed to respond to conservative management and when they have weakness of the pelvic floor muscles or impaired ability to sense rectal distention as a contributing cause of incontinence. Biofeedback appears to work primarily through improving the ability to detect weak rectal distensions, but improved strength training may be important to improve bowel control in some patients. The overall success of biofeedback training is about 70% (Table 14.3). Biofeedback is often combined with medical management because diarrhea or constipation may interact with sensory–motor defects in the anus and rectum to exacerbate incontinence.

Table 14.3. Treatment options for fecal incontinence

Treatment	Indication	Outcomes
Loperamide	Diarrhea	About 80% decrease
Habit training	Constipation	60% of children
Plus laxative		
Biofeedback	Nerve injury or sensory loss	75% improve 50% cured
Surgery	Muscle injury	68%

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Part V

Operative Therapy of Urinary Incontinence

V

Chapter 15

Innovative and Minimally Invasive Treatment of Stress Urinary Incontinence

15

Christl Reisenauer, Konstantinos Gardanis, Diethelm Wallwiener

Contents

15.1 Introduction

Over the past decades many theories have been proposed to explain why women develop stress urinary incontinence. They have led to different, more or less successful methods of treatment.

Two of these theories are relevant for an innovative and minimally invasive surgical treatment of stress urinary incontinence by using tension-free mid-urethral slings. The latter will be the subject of the following article. A second form of treatment, urethral injectable agents, however, will not be dealt with here as they are described in another chapter of this book.

One of these theories is the Hammock Hypothesis of DeLancey. This theory provides information on the structural support of the urethra and explains how it relates to stress incontinence.

The urethra lies on a supportive layer that is composed of the endopelvic fascia and the anterior vaginal wall. The layer gains structural stability by its lateral attachment to the pelvic sidewall at the arcus tendineus fascia pelvis. The arcus tendineus fascia pelvis is a tense fibrous band between the pubic bone and the ischial spine.

Coughing, for example, increases abdominal pressure and presses the urethra against this hammock-like supportive layer. Consequently the lumen is closed, so that discharge of urine is prevented. The stability of the suburethral layer depends on its connection to the arcus tendineus fascia pelvis being intact. If the supportive layer is unstable it cannot provide resistance against which the urethra can be compressed. This is followed by a loss of urine (DeLancey 1994).

Another theory is the Integral Theory of Petros and Ulmsten. This theory demonstrates that stress urinary incontinence may occur because of a lack of support of the mid-urethra. This is caused by a weakness of the pubourethral ligaments and the anterior vaginal wall (Petros and Ulmsten 1993).

According to both theories, the urethra is not properly closed in stress incontinent women because of dysfunctions or defects in pubourethral ligaments and/or the suburethral vaginal wall. The TVT operation – as a form of a minimally invasive treatment – intends to correct these dysfunctions and defects.

The tension-free vaginal tape (TVT) procedure, as described by Ulmsten, was introduced into clinical practice in 1994–1995 after extensive preclinical research. If conducted by experienced surgeons, it is a simple and effective procedure that can be performed under local anesthesia and requires only a short operative and recovery time.

15.2 Tension-free Vaginal Tape (TVT) – Operation

15.2.1 Surgical Technique

The TVT operation is carried out using a specific two-component instrument comprised of a nondisposable metal handle to which two disposable metal needles are attached. A prolene tape covered by a plastic sheath is fixed to the needles. A catheter guide introduced into a Foley catheter controls the urethra and the bladder at needle insertion (Fig. 15.1).

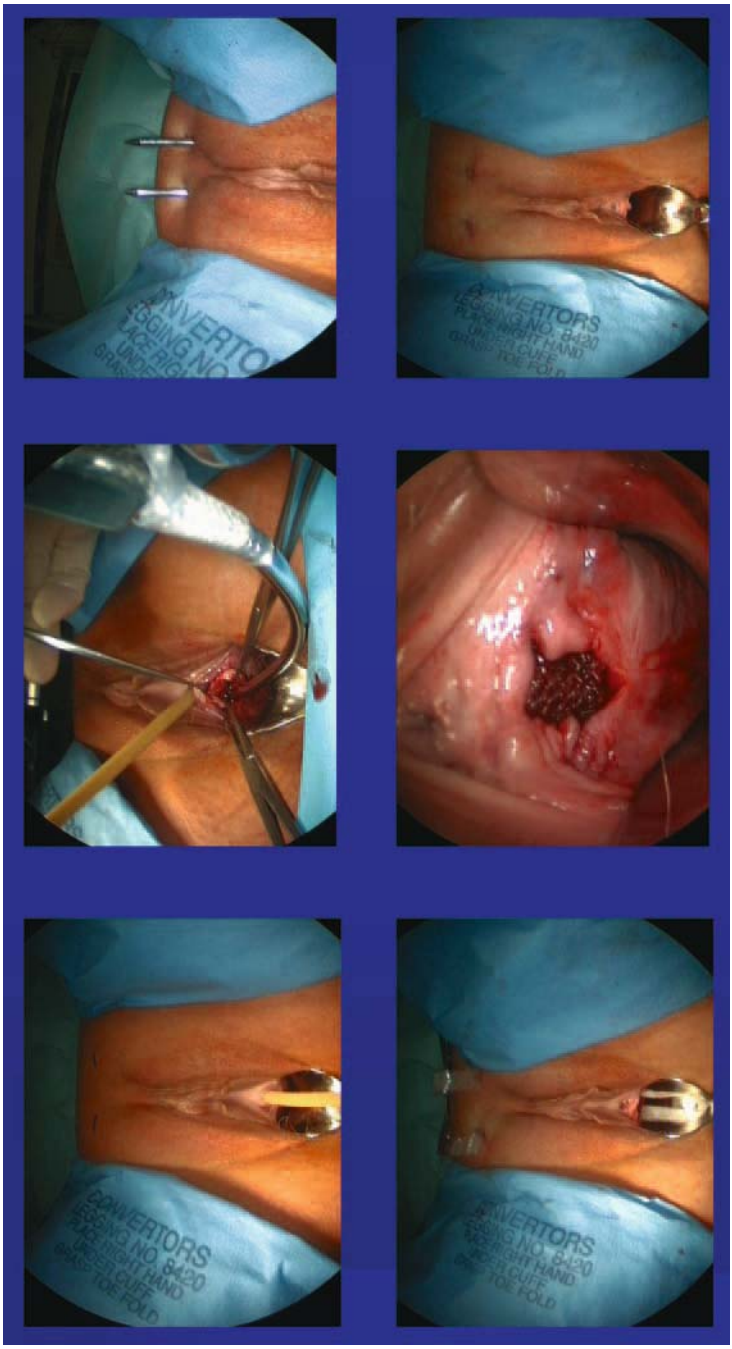


Fig. 15.1. Tension-free vaginal tape operation

After the patient is sedated, a transurethral Foley catheter is introduced and the bladder is emptied. The local anesthesia is given. Two minimal incisions are made in the abdominal skin above the superior edge of the pubic bone, 4 cm apart. Another incision, 1.5 cm long, is made in the suburethral vaginal wall, starting 1 cm from the urethral meatus. Laterally from this incision, a minimal blunt dissection, 0.5–1.0 cm long, is made with scissors to each side of the urethra. With a catheter guide introduced into the Foley catheter, the urethra and the bladder neck are identified. Using the handle with the needle attached, the tape is placed around the mid-urethra as follows: the tip of the needle is inserted into the prepared paraurethral incision on one side of the urethra. The urogenital diaphragm is perforated and, then inside the cavum Retzii, the needle tip is brought up to the abdominal incision in close contact with the back of the pubic bone. As soon as the needle tip has reached the abdominal skin incision, its proximal end is disconnected from the handle. The procedure is then repeated on the other side. At this step of the operation, the patient undergoes cystoscopy to confirm an intact bladder. Still covered by the plastic sheath, the tape is then brought into position by gently pulling the needles upward with the tape attached.

With 300 ml of saline in the bladder, the patient is then asked to cough vigorously, to make sure that continence has been obtained. During coughing, the tape is adjusted so that a few drops of urine are allowed to escape the urethra. When the tape has been placed in an ideal U-shape around the mid-urethra, the plastic sheath is withdrawn. The abdominal ends of the tape are cut with scissors below the skin surface in the subcutaneous tissue. Finally, the vaginal and skin incisions are sutured. The bladder is emptied and no catheter is left in place (Ulmsten 2001).

15.2.2 Indications, Results and Complications

In a prospective long-term multicenter study, Nilsson et al. evaluated 90 patients who had a tension-free vaginal tape operation because of primary stress urinary incontinence. The mean follow-up time was 56 months; 84.7% of the patients were completely cured, another 10.6% significantly improved and 4.7% of the operations were regarded as failures. Only a few complications during or after surgery occurred. In 1.1% of the patients bladder perforation and in 3.3% intraoperative bleeding of more than 200 ml occurred. In 3.3% a retropubic hematoma formed. Postoperative voiding difficulties were experienced by 4.4% of the patients; 5.9% reported de novo urge symptoms and 7.8% experienced urinary tract infections during the first 2 months after operations (Nilsson et al. 2001).

After a 7.6-year mean follow-up time, 81.3% of the women who had been treated with the TVT procedure were cured, 16.3% improved and 1.3% of the operations failed (Nilsson et al. 2003).

The TVT operation can also be recommended for the surgical treatment of female stress urinary incontinence where previous incontinence operations have failed. The operative success seemed not to be diminished by previous surgery (Rezapour et al. 2001). TVT surgery is less successful in stress incontinent women with a very low resting urethral pressure and an immobile urethra (74% of patients were cured and 12% significantly improved after a mean follow-up time of 4 years) (Rezapour et al. 2001).

In the meantime, the tension -free vaginal tape has become one of the most popular surgical procedures for the treatment of stress urinary incontinence. Several re-

ports have confirmed a high curing rate with low morbidity. According to the producer Gynecare, more than 500,000 TVT operations have been carried out so far.

Kuuva et al. evaluated the therapy-associated morbidity of all patients who had undergone a TVT operation in Finland by the end of the year 1999. The incidence of bladder perforation was 3.8%, that of major vessel and nerve injury 0.1% and that of urethral lesion 0.1%. The incidence of minor voiding difficulty was 7.6%, that of urinary tract infection 4.1%, of retropubic hematoma 1.9% and of vaginal defect healing 0.7% (Kuuva and Nilsson 2002). The rate of complications is comparable to the one described by Nilsson (Nilsson et al. 2001).

Problems with bladder voiding occurred when the contractibility of the detrusor was impaired, the bladder outlet obstructed or in the case of a combination of the two.

During recent years, many analyses of results and complications after TVT have been published. In general, intra- and postoperative complications were few and included bladder perforations ranging from 4.9% to 6%, voiding difficulties 4%–12%, de novo urinary urgency 7.4%–12%, urinary infections 3.1%–10.9% and retropubic hematoma 0.4%–1.7% depending on the publication. Both the intraoperative complications as well as the postoperative problems are associated with the individual surgeon's experience (Nilsson et al. 2001; Kuuva and Nilsson 2002; Karram et al. 2003; Bodelsson et al. 2002; Meschia et al. 2001; Moss et al. 2002; Debodinance et al. 2002).

Other rare intraoperative complications include bowel perforation, major vascular injury, obturator nerve injury, urethra penetration and erosion (Vassallo et al. 2003; Fourie and Cohen 2003; Meschia et al. 2002; Shobeiri et al. 2003).

Two prospective randomized studies have been performed to date to compare the efficacy and the complications of TVT with those of Burch colposuspension in the treatment of primary female stress incontinence (Liapis et al. 2002; Ward and Hilton 2002). The results are summarized in Table 15.1 and Table 15.2.

Table 15.1. Results of studies comparing Burch colposuspension and TVT procedure in the treatment of primary female stress incontinence

Prospective, randomized study	Number of patients	Follow-up time	Cure rate Burch-colposuspension	Cure rate TVT
Liapis et al.; Athens/ Greece; Eur Urol 2002	71 patients	24 months	86%	84%
Ward et al.; UK/Ireland; BMJ 2002	344 patients	6 months	57%	66%

Table 15.2. Results of studies comparing Burch colposuspension and TVT in the management of primary stress urinary incontinence

- Six months and 2 years after the TVT procedure the operation proves as effective as the colposuspension for the primary treatment of stress incontinence
- Operative complications are more common with TVT, but length of hospitalization is shorter and the return to normal activity is possible earlier than with colposuspension
- Postoperative complications are more common after colposuspension

15.3 Other Tension-free Suburethral Slings for Treatment of Stress Urinary Incontinence

15.3.1 Materials of Suburethral Slings

A wide range of materials have been used in fashioning a suburethral sling for the treatment of stress urinary incontinence. Biomechanical comparison between autologous, allogenic or xenogenic biomaterials and synthetic materials showed that biomaterials such as dermis have less mechanical strength to support the urethra properly (Choe et al. 2001). Infections such as AIDS, HCV, prions, etc. can make allogenic and xenogenic biomaterials – at least theoretically – dangerous for recipients (Bidmead and Cardozo 2000).

A randomized trial of porcine dermal sling (Pelvicol implant, Bard) vs TVT in the surgical treatment of stress incontinence was conducted by a team from the UK. After a median follow-up time of 12 months, the patient-determined cure rate was 85% in the TVT group and 89% in the Pelvicol implant group. The prevalence of postoperative voiding dysfunction and de novo urge incontinence was 3.4% and 9%, respectively, after TVT and 1.4% and 6%, respectively, after the Pelvicol implant (Arunkalaivanan and Barrington 2003).

In comparison with polypropylene, the material that has been most thoroughly studied, experimental data on collagen-based materials remain scarce.

In a long-term experimental study carried out with rabbits, tensile strength was studied, among other material properties, comparing the different materials such as porcine dermal collagen (Pelvicol, Bard), collagen matrix derived from porcine small intestinal mucosa (SIS, Cook) and Prolene (Johnson & Johnson). Over a 1-year observation period, Prolene proved to have the highest tensile strength. Surgisis was not recognizable after 3 months. During the first half year, Pelvicol was as strong as Prolene, but from the 180th day on, its strength decreased gradually (Claerhout et al. 2003).

The chemical and physical properties of each synthetic material determine how the sling is incorporated into the surrounding tissue and its susceptibility to infection, erosion or rejection. Multifilament fibers may provide a safe harbor for small bacteria and may exclude macrophages and leucocytes. In comparison in the mesh of monofilament fibers, tissue ingrowth and neovascularization is relatively enhanced and cellular access is not inhibited. Thus the risk of infection and erosion is higher when multifilament material is used. The nonwoven polypropylene has a lower grammage and a lower elasticity than woven polypropylene (Fig. 15.2). No material has been as widely accepted worldwide as the TVT (Niknejad et al. 2002; Iglesia et al. 1997; Staskin and Plzak 2002).

Rechberger et al. showed that the clinical efficacy of both TVT (Gynecare) and IVS (Tyco Healthcare) tapes was equally high, the only statistically significant difference between the monofilament and multifilament tape being the higher rate of postoperative urinary retention in the monofilament group, probably caused by the greater elasticity of this tape compared to the multifilament one (Rechberger et al. 2003).

Tables 15.3 and 15.4 show most of the suburethral tapes that are widely used in surgery at present. Unfortunately, only very few of them have been evaluated as to their complications and/ or success rate. Nevertheless we would like to mention the Remeex

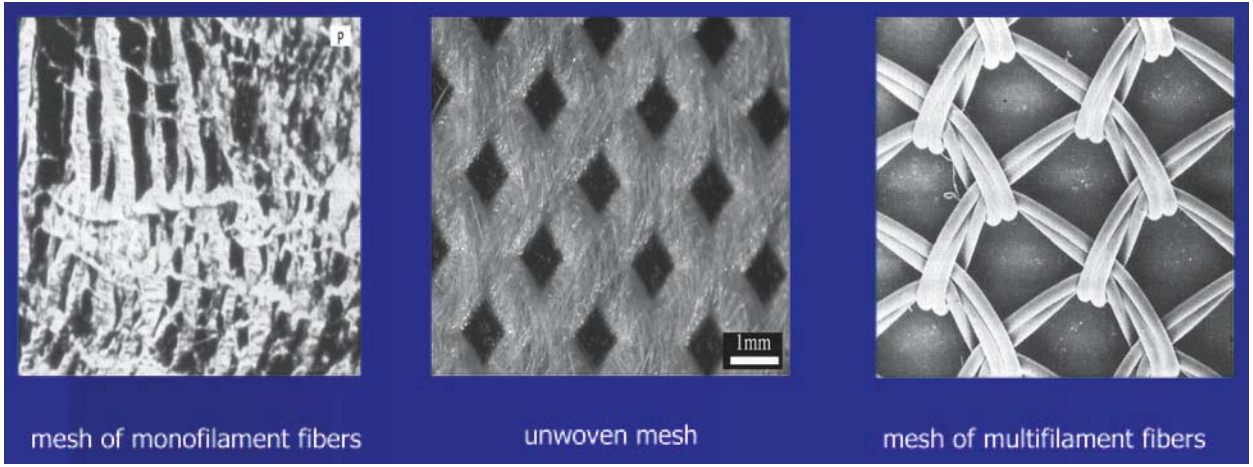


Fig. 15.2. Synthetic material used for the treatment of stress urinary incontinence

Table 15.3. Suburethral slings for treatment of stress urinary incontinence

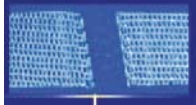
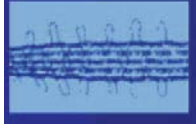
	**T-Sling** **Herniamesh** polypropylene joined by absorbable suture	approach: transobturator suprapubic vaginal		**IVS** **Tyco** multifilament propylene	approach: vaginal
	**Uretex®** **Bard** polypropylene in a teflon sheath	approach: suprapubic vaginal		**Safyre** **Medic Service** pierced poly-propylene between two silicone columns	approach: transobturator vaginal suprapubic
	**Serasis® Serapren®** **Serag Wiesner** polypropylene	approach: vaginal		**Stratasis® TF** **Cook** biomaterial sling small intestinal submucosa	approach: suprapubic vaginal
	**L.I.F.T.®** **Cousin Biotech** polypropylene sling with a suburethral non woven patch	approach: transobturator suprapubic vaginal		**Remeex® System** **Neomedic** readjustable polypropylene sling between two prolene suture	approach: suprapubic/ vaginal
	**Emerald** **Gallini Medical Devices** polypropylene sling woven/ non-woven	approach: transobturator suprapubic			

Table 15.4. Suburethral slings for treatment of stress urinary incontinence

	Suburethral sling	Approach
	TVT Gynecare TVT-O Gynecare monofilament polypropylene	approach: vaginal transobturator prepubic
	SPARC AMS Monarc AMS monofilament polypropylene +resorbable suture	approach: vaginal suprapubic transobturator
	Uratape Porges-Mentor non woven polypropylene +silicone patch Obtape Porges-Mentor non woven polypropylene	approach: transobturator

readjustable sling (Neomedic International). The Remeex system is composed of a suburethral sling with two traction thread sutures connected to a regulation device (varitensor) positioned above the fascia of the abdominal muscles. The polypropylene sling is placed at the urethrovesical angle. This surgical technique allows a postoperative adjustment of the sling tension, especially with patients who have undergone previous incontinence surgical interventions or have intrinsic sphincter deficiency, fixed urethra or urethral hypermobility (Iglesias and Epuna 2003).

15.3.2 Approaches of Suburethral Slings

15.3.2.1 Antegrade Suprapubic Approach

The antegrade suprapubic approach is also used to place other midurethral slings, such as SPARC (suprapubic arc sling systems, AMS), in order to avoid major complications of vascular or bowel injuries. SPARC differs from TVT in how the sling is placed under the urethra. The SPARC needles are passed through two suprapubic incisions, advanced under the pubic rami and enter at the level of the mid-urethra . In addition,

Table 15.5. Approaches of suburethral slings

- Retropubic:
  Vaginal (e.g., TVT)
  Suprapubic (e.g., SPARC)
- Prepubic: (TVT)
- Transobturator:
  Outside-in (Uratape, Obtape, Monarc)
  Inside-Out (TVT-O)

a knotted tensioning suture, which is unique to the SPARC sling, runs longitudinally through the sling. This decreases the stretch on the mesh when plastic sheaths are removed (Tash and Staskin 2003).

The wide use of retropubic tension-free suburethral slings has been associated with various peri- and postoperative complications. To reduce these complications, particularly with high-risk patients such as those who have been operated on before in the lower pelvis, alternative approaches with a prepubic or transobturator passage of the tape have been developed (Table 15.5). Continence rates obtained with these routes have been similar to those obtained after the retropubic route.

15.3.2.2 Prepublic Approach

Prepubic TVT surgery (Fig. 15.3) can be carried out under local anesthesia and the same instrument kit is used as in classic TVT.

As in classic TVT, the operation begins with a small incision under the mid-urethra. Minimal paraurethral dissections are performed. Unlike classic TVT, the dissections, which are needed to receive the preformed canals for the TVT needles, are directed more laterally towards the middle of the ischiopubic bone.

The first needle is introduced straight into the preformed canal. When the ischiocavernosus muscle has been perforated, the needle is angulated straight upwards. Then the needle is passed under the vulva to reach the small skin incision, which had been made near the superior part of the pubic bone at the beginning of the operation. The incision is situated in the middle between the genitofemoral fold and the midline of the symphysis.

The second needle is then introduced at the other side of the urethra. When both needles have reached the abdominal incisions, the ends of the tape are cut. The tape is adjusted at a bladder volume at 300 ml. As the bladder cannot be perforated during the procedure just described, cystoscopy is not necessary. When leakage has been proved minimized during the cough test, the plastic sheaths are removed and the ends of the tape are cut in the subcutaneous layer. Then the abdominal and vaginal incisions are closed.

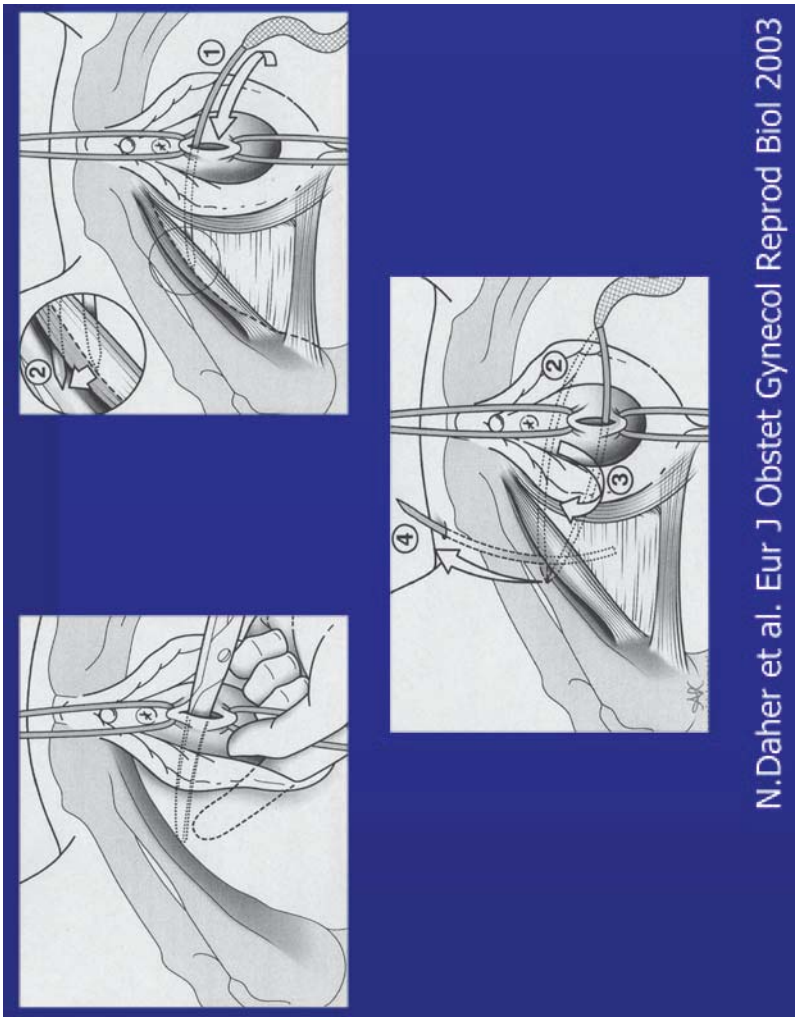


Fig. 15.3. Pre-pubic tension-free vaginal tape

The short-term results with prepubic TVT seem to be similar to those with classic TVT. After a mean postoperative follow-up time of 5 months, Daher et al. showed that 81% of patients were cured and another 13% improved; 6% of the operations failed. Intraoperatively the vaginal wall was perforated when introducing the needle tip laterally to the pubic bone. This was discovered intraoperatively and the needles could be reinserted properly without any postoperative healing problems. Postoperative residual urine of more than 100 ml was recognized in three patients. Some ecchymoses were noted after the procedure (Daher et al. 2003).

15.3.2.3 Transobturator Approach

In the transobturator technique (Uratape, Obtape/Mentor, Porges) as described by Delorme (2001) the tape is inserted through the obturator foramina from outside the vulva to inside the vagina.

Although the transobturator sling's out-in technique is claimed to be a safe procedure, it may cause urethra and bladder injuries.

De Laval (2003) described a novel surgical technique that allows the passage of the tape through the obturator foramina, from inside to outside. This technique avoids damage to the urethra and the bladder and makes cystoscopy unnecessary.

The Monarc transobturator sling (AMS) (Fig. 15.4) is passed from one obturator foramen to the other preserving an intact retropubic space (Pelosi and Pelosi 2003).

After making a small incision along the anterior vaginal wall 0.5 cm below the urethral meatus, the vaginal epithelium is separated from the underlying periurethral fascia using sharp and digital dissection. The internal edge of the obturator foramen is identified. A skin incision is made bilaterally in the genitofemoral fold at the level of the clitoris.

After the skin penetration, the needle passes the superficial perineal fascia and crosses the adductor muscles of the thigh near their pubic bone origin and below the insertion of the adductor longus tendon. Then the needle perforates the obturator membrane, the obturator internus muscle and exits through the vaginal incision. The way through the obturator foramen is in its upper-inner corner at a safe distance to the obturator canal, which is located at the anterolateral upper margin of the obturator foramen. These steps are repeated on the contralateral side.

The polypropylene sling and its plastic sheath are connected to the needle tips at the both sides. Then the needles are retracted through the skin incisions up to the point where they are connected to the sling. After that scissors or tweezers are placed between the urethra and the sling. The plastic sheaths from the slings are removed and then the skin and the vaginal incisions are closed in the usual manner.

So far only short-term results are available, which state an efficacy similar to that of the retropubic tension-free vaginal slings with less risk of overcorrection.

The transobturator vaginal tape inside-out procedure (TVT-O) as described by De Laval (Fig. 15.5) allows the passage of the tape through the obturator foramina from inside to outside by using newly designed specific instruments (De Laval 2003).

The surgical procedure is generally carried out under spinal anesthesia but may also be performed under general or local anesthesia

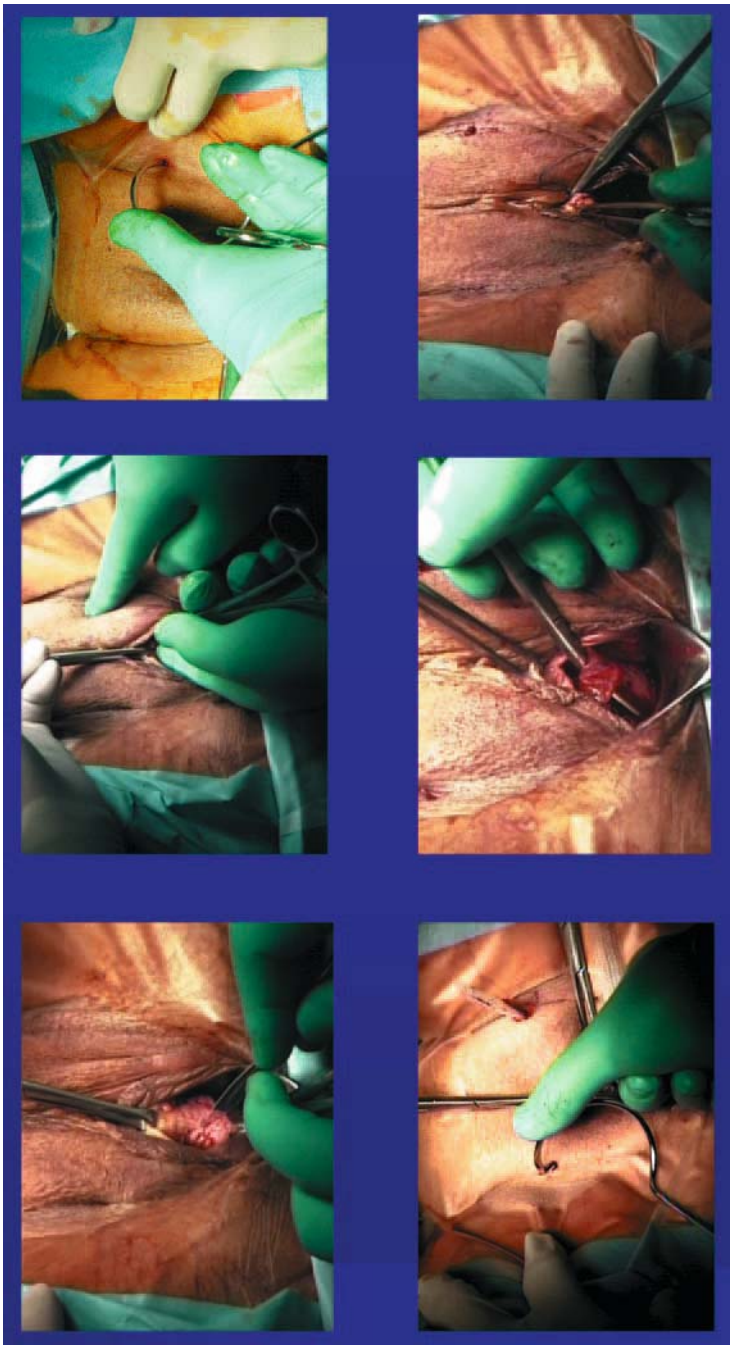


Fig. 15.4. Monarc (AMS) transobturator vaginal tape outside-in

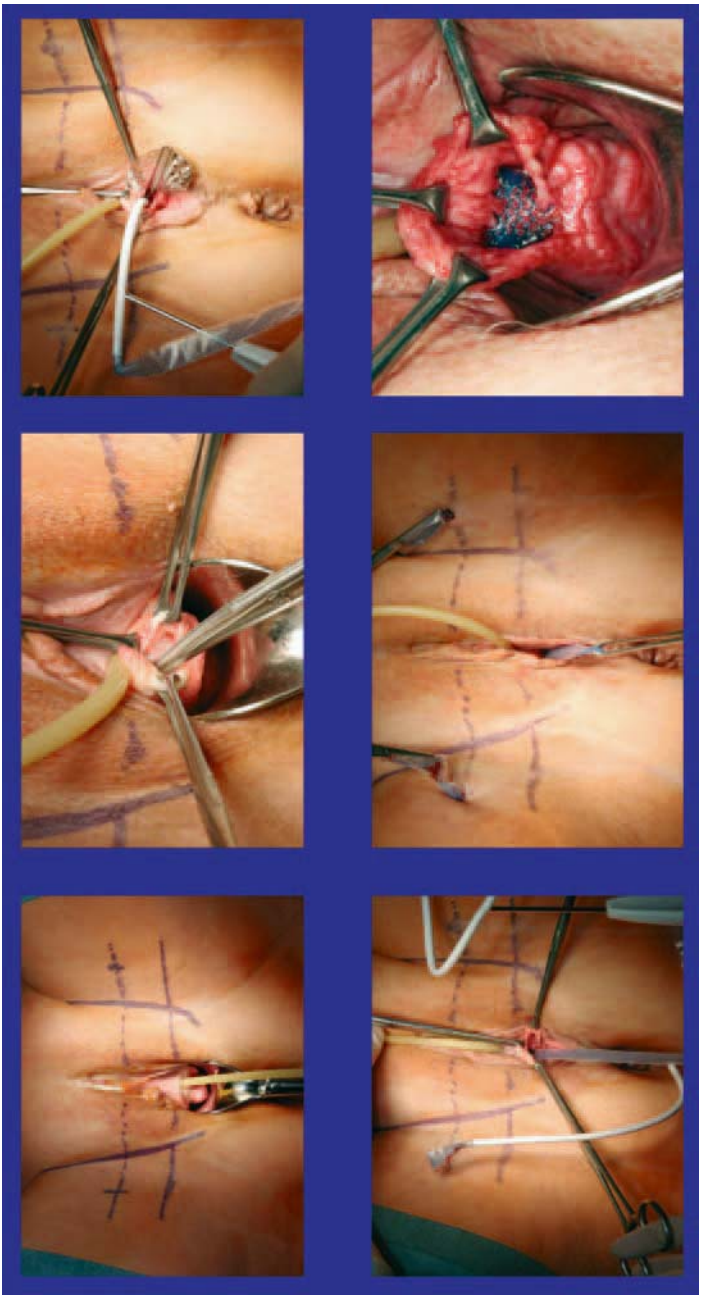


Fig. 15.5. TVT-O (Gynecare) transobturator vaginal tape inside-out

The points where the needles will exit at the skin level are identified by tracing a horizontal line at the level of the urethral meatus. The exit points are located 2 cm above this line and 2 cm outside the thigh folds. Then the anterior vaginal wall is incised at a length of 1 cm and at a distance of 1 cm proximally to the urethral meatus. After that, minimal paraurethral subvaginal dissections are then carried out laterally on either side. This step is followed by introducing fine dissection scissors towards the upper part of the ischiopubic ramus. Once the upper part of the ischiopubic ramus is reached, the obturator membrane is perforated with the tip of the scissors. An introducer is pushed to the preformed dissection canal until it reaches and perforates the obturator membrane. The open side of the introducer's gutter must be facing the operator. The distal end of a tube is mounted onto the spiral segment of a needle and the assembled device is gently slipped along the gutter of the introducer so as to pass through the obturator foramen. After the tube has appeared at the previously incised skin exit point, the tube is pulled from the supporting passer and the latter is retracted until the first centimeters of the tape become externalized. The same technique is applied at the other side. After the ends of the tape have been cut, the tape is aligned under the junction between the mid and distal urethra and the tension of the tape is adjusted by exerting a traction on its two ends and by interposing a pair of scissors between the tape and the urethra so as to create space and avoid any tension of the tape. The plastic sheaths are then removed simultaneously. The tape ends are cut in the subcutaneus layer and the incisions are closed.

De Laval did not observe any intraoperative complications in a study with 107 patients. During a short follow-up time of 1 month, only few postoperative complications were observed. Minor vaginal erosion was noted in one patient. Three patients (2.8%) had complete urine retention; 15.9% of the patients complained about pain or discomfort in the thigh folds for less then 1 week.

15.4 Conclusion

Unfortunately, minimally invasive surgery does not correlate with minimal costs. It is evident that shorter hospitalization reduces the costs but on the other hand instruments and materials for minimally invasive surgery are very expensive.

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Chapter 16

Abdominal, Vaginal or Laparoscopic Approach for Urinary Incontinence?

16

Wolfgang Zubke, Ines Gruber, Diethelm Wallwiener

Contents

Urinary incontinence is extremely widespread. In general more women suffer from urinary incontinence than from diabetes, coronary disease or hypertension. Urinary incontinence is not a disease of recent decades. Throughout human existence, women have suffered from incontinence. There were different attempts to cure these patients conservatively or by surgery. In the oldest medical document in history, the Ebers papyrus, urinary incontinence is already mentioned with the therapeutic approach of vaginal pads. It is unclear whether they were used to raise the urethra or to apply certain medications. Nothing is known about the success of these early attempts. However, all we know is that even 3,500 years ago women suffered from urinary incontinence and were treated with a standardized therapy that was a conservative and not surgical one. Surgical approaches during this time are not yet described.

Which approach did surgeons of more recent times choose to cure urinary incontinence? In 1907 Giordano mobilized part of the musculus gracilis and wrapped it around the urethra. At this time, no further development of this technique took place. However nowadays, we again find similar surgical approaches to cure urinary incontinence.

In 1910 Goebell described the first surgical technique of retropubic suburethral slings. He separated the two parts of the musculus pyramidalis, led them retropubically through the spatium retzii. Then he connected both tips underneath the urethra, in the area of the vesicourethral angle, with the intent of tightening the suburethral tissue and stabilizing the urethra. This approach was later modified by Stoeckel in 1917. The pyramidalis muscle was no longer used because of its insufficient length and was replaced by parts of the aponeurosis, located ventral to the m. pyramidalis and m. rectus abdominis. The Goebell-Stoeckel surgical technique uses an abdominal approach combined with a small vaginal incision. There are no valid studies documenting the success rate of this surgery or long-term results. Nevertheless this technique was fully accepted for decades. However, there was an attempt to look for improvements. For example, one major disadvantage of this method was the dissolution of the tendinous membrane after a certain time and therefore the loss of functional stabilization of the urethra. The effort to improve this method by the concept of a retropubic suburethral sling was one of the early versions of the TVT used today. No long-term results can be found.

16.1 Kelly Plication

In the USA, Kelly introduced a different surgical technique to elevate the urethra. He attached the periurethral tissue at the vesicourethral angel underneath the symphysis by Kelly plication (Kelly and Dumm 1914). In 1937 Kennedy modified this procedure by padding the total length of the urethra. However, in the USA Kelly plication is still used in connection with anterior colporrhaphy and therefore evaluated in most studies as part of the procedure. Early published results were good, but a number of newer studies analyzed the combined Kelly plication/anterior colporrhaphy procedure and showed much lower success rates (see below).

A study was undertaken by Gordon et al. in 1999 to evaluate the efficacy of Kelly plication in preventing postoperative urinary stress incontinence in clinically continent patients undergoing surgery for genitourinary prolapse. Thirty patients with grade-3 genitourinary prolapse were found to have a positive stress test in a preoperative urodynamic setting. In addition to the genitourinary prolapse repair, these patients underwent Kelly plication. Fifty percent of the patients developed postoperative stress in-

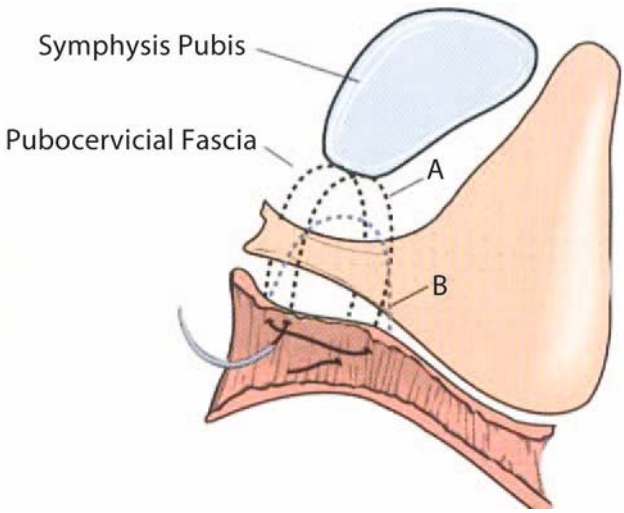


Fig. 16.1.
Kelly plication
(from Benson 2000)

continence subjectively and objectively; 37% developed objective postoperative stress incontinence with no subjective complaints. Therefore Kelly plication does not qualify as a prophylactic procedure in preventing postoperative urinary stress incontinence in clinically continent patients who undergo surgery for genitourinary prolapse.

Eberhard et al. (2003) conclude that periurethral tightening of the tissue is now obsolete for the treatment of incontinence because of extensive tissue damage, which lowers the neutral pressure of the urethra without increasing the pressure transmission over time (Fig. 16.1).

16.2 Anterior Colporrhaphy With and Without Kelly Plication

The theory that a cystocele might be the cause of urinary incontinence has been considered for a long time. This is why the anterior colporrhaphy has been favored as a treatment for urinary incontinence. The idea was to reconstruct the original anatomy and functionality of the pelvic floor. In fact, many retrospective studies showed good postoperative results.

Vahlensiek and Schander (1985), anterior colporrhaphy plus Kelly plication, Beck et al. (1991), anterior colporrhaphy plus Kelly plication, and Tamussino et al. (1999), anterior colporrhaphy without Kelly plication, report continence rates up to 75% after 5 years and longer. Park and Miller (1988), also obtained optimistic result with anterior colporrhaphies with Kelly plications. After 1, 5 and 10 years, 80%, 70% and 66%, respectively, of the patients were cured. Tamussino differentiated his results according to the severity of urinary incontinence. Continence rates after anterior colporrhaphy were 82% among patients with mild stress incontinence but only 49% among those with moderate or severe incontinence.

Bergman and Elia's (1995) purpose was to evaluate the long-term results of anterior colporrhaphy with Kelly plication. The objective success rate after 5 years was only 37%, while after 1 year it reached 63%.

The prospective study of Liapis et al. analyzed the success rate of anterior colporrhaphy with Kelly plication. It revealed a cure rate of 57% within a 3-year postsurgical

evaluation. Harris et al. (1995) also reported a similar cure rate of 46% within a 5-year postsurgical evaluation.

Kammerer-Doak et al. (1999) analyzed objective and subjective success rates of anterior colporrhaphy without Kelly plication in a prospective study. The objective success rate after 1 year was 31%, while the subjective success rate was only 19%. This emphasizes the obvious difference between objectively measured and subjectively evaluated results. De Tayrac et al. (2002) had similar results with anterior colporrhaphy without Kelly plication in terms of the difference between subjective and objective success rates. The objective success rate after 36 months was 53.6%, while the subjective success rate was 57.1%.

In a prospective long term study over a mean follow-up time of 14 years, Colombo et al. (2000) describe an objective success rate of 42% and a subjective success rate of 52% for anterior colporrhaphy without Kelly plication.

It is not clear whether success rates are attributable to the Kelly plication. There have been similar success rates whether Kelly plication was used or not. It seems that older studies show higher success rate than more recent ones. It also appears that success rates were higher when subjectively evaluated than objectively measured. It was shown that the success rate for anterior colporrhaphy depends very much on the severity of preoperative urinary incontinence. It seems that anterior colporrhaphy has a high success rate in short-term cure but the long-term results are nowhere near as good. Taking the above-mentioned limitations into consideration, it is difficult to evaluate a general success rate of anterior colporrhaphy by meta-analysis. However, including the limitations a relative success rate of 62% can be concluded. This result correlates with the meta-analysis by Glazener and Cooper (2003). They report a success rate of 68%. However, this number does not reflect the tendency that more recent studies show less optimistic results. Anterior colporrhaphy did not prove adequate as standard therapy because of its poor long-term results.

Eberhard et al. (2003) designate the diaphragmatic plastic surgery as obsolete for treating urinary incontinence. Because of the stretching of the urethra, the transmission forces are being reduced.

Finally, a study by Weber et al. (2001) has to be mentioned. They compared different techniques of genitourinary prolapse repair. They observed to what extent anterior colporrhaphy might cause urinary stress incontinence. Preoperatively 18% (15/82) of the patients had urinary incontinence, of which 73% (11) were cured after 2 years. Five of the 66 previously continent patients developed de novo urinary stress incontinence. The anterior colporrhaphy obviously can cause urinary stress incontinence.

But anterior colporrhaphy rarely leads to complications. Beck et al. (1991) mention only 1% of relevant complications. They rarely observed complete urinary retention, and de novo urinary incontinence occurred in no more than 8% of patients.

In the above studies, anterior colporrhaphy was proceeded in order to correct cystoceles. The etiology of these defects was not mentioned. It can be presumed that most of them were to the result of central defects. There are in fact other pelvic floor defects leading to a cystocele such as the lateral defect. It is possible that some of theses studies would have shown other results if the etiology of the cystocele had been taken into consideration during surgery. Figure 16.2 illustrates the surgical approach of a combined cystocele with a central and paravaginal defect as performed in our hospital.

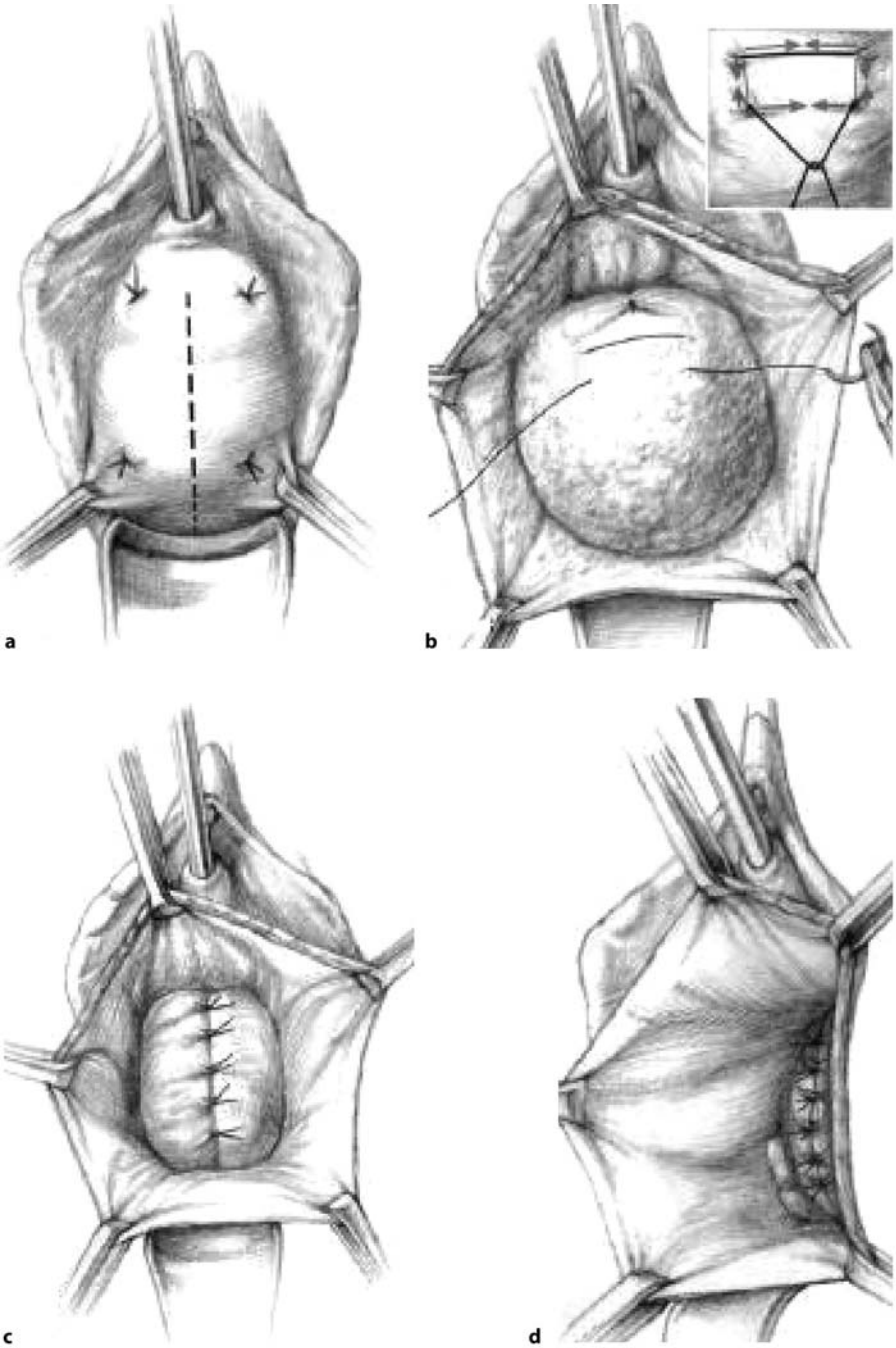
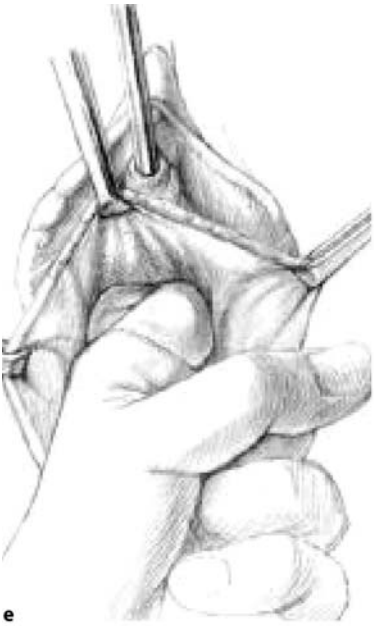


Fig. 16.2a–d.



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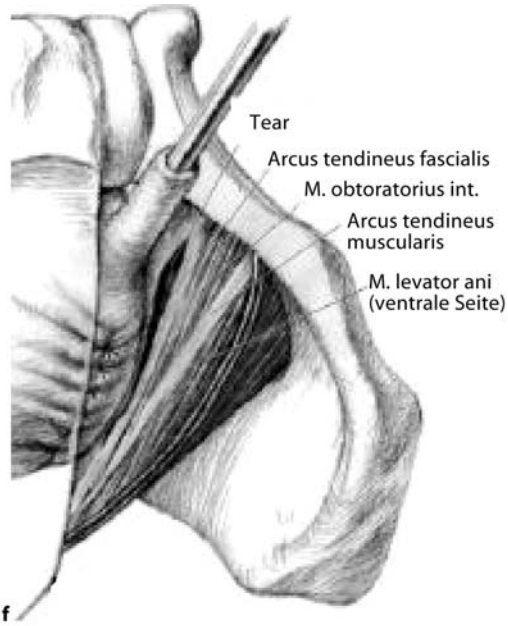
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Arcus tendineus muscularis
M. levator ani (ventrale Seite)

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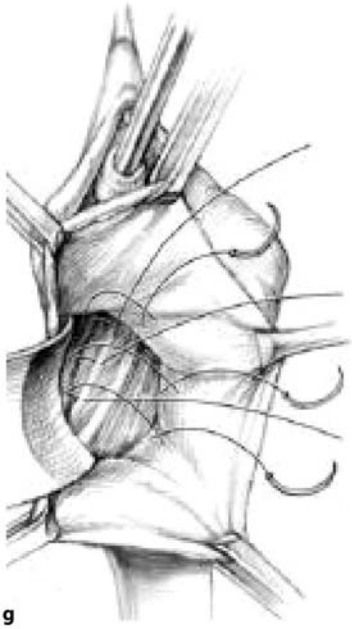

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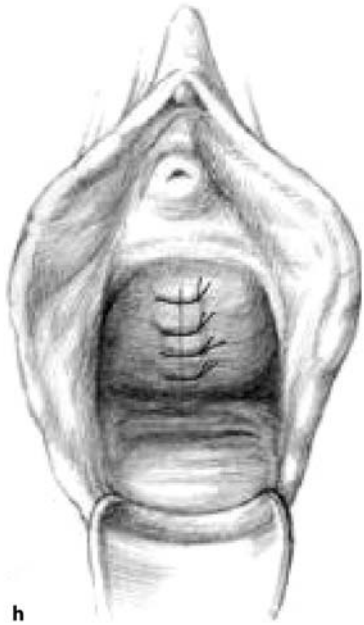

h

Fig. 16.2a–h. Anterior colporrhaphy with central and vaginal/paravaginal repair of a combined cystocele. **a** The combined cystocele with the central and paravaginal defect presents with a prolapse of the anterior vaginal wall; rugae and sulci disappeared as shown. First, the vaginal sulcus is marked on both sides by single knots, then the anterior vaginal wall is dissected medially. **b** The prolapsed cystocele is gathered up by U-sutures. This tightens the fascia pelvina also sagittally to both sides, compare the small picture. **c, d** The central defect is corrected. Superfluous lateral fatty tissue of the Retzius space appears at the site of paravaginal defect. **e** The Retzius space is bluntly opened by the surgeon's fingers. **f** Anatomy in the area of paravaginal defect. **g** Closure of the paravaginal defect; fascia vesicalis, arcus tendineus fascialis and fascia vaginalis are connected in the area of vaginal sulci by nonabsorbable sutures, strength 0. The paravaginal defect is closed by three to five single knots; closure extends from 1 cm ventral to the spina ischiadica up to 1.5 cm paraurethral. **h** Postoperative situs

16.3 Needle Suspension

Needle suspension after Pereyra (1959), Stamey (1973) and Raz (1981) seemed to be very promising for quite a long time. Here again, more recent analyses show less promising results.

In a prospective study Park and Miller (1988) report success rates of 70% after 5 years and 56% after 10 years.

GF Jarvis (1994) calculates an objective cure rate of 70.5% by meta-analysis.

Trockman et al. (1995) report that after 10 years 73% of the patients were satisfied with surgery, 71% of the patients stated improvement in continence but only 20% of the patients showed no symptoms and counted themselves as cured. A total of 22% had to undergo one or more surgeries because of relapse.

Jongen et al. (1999) report a cure rate of 68% after 5 years. However, the investigated number of 25 patients seems to be very small. Moreover, Bergman and Elia (1995) mention a cure rate of 43% after 5 years; the total number of analyzed cases totaled 30 patients. Colombo et al. (1997) report an objective success rate of 57% after 6 years and a subjective success rate of 71% (total number of patients, 21).

Tamussino et al. (1999) could show that 49% of 121 patients who had a needle suspension in combination with anterior colporrhaphy are still continent after 5 years.

Masson and Govier (2000) followed up 135 cases, of which only 14% were still continent after 4 years. The so-called endoscopic approaches in general deliver much better results. That does not imply that the needle suspension is done endoscopically. It means that it is done under cystoscopic control (Fig. 16.3). This method also proved to be disappointing despite of early reported high success rates. Irrespective of methodical differences, all the above mentioned studies summarize a mean long-term success rate of 43%. Here again, more recent studies tend to describe poorer success rates.

Few authors describe complications and side effects. Jarvis (1994) shows with a meta-analysis the complications of needle suspension. Twenty-seven percent of the patients complain about persistent traumatic pain. In 6% of the cases, sutures had to be removed postoperatively and 10.3% had postsurgical voiding difficulties.

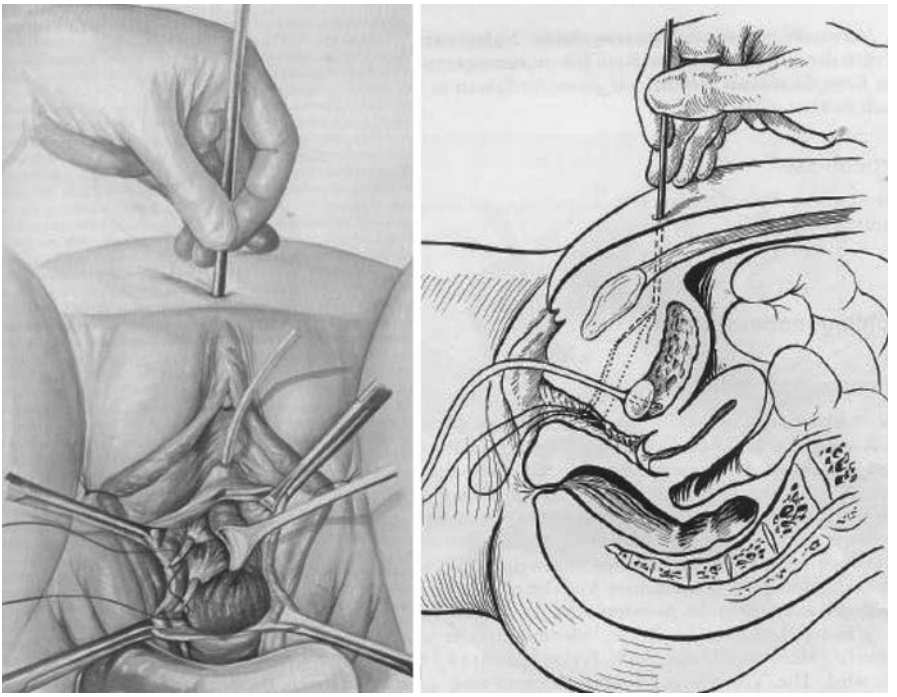

Fig. 16.3. Needle suspension/urethrovesical suspension by Pereyra and Lebherz (from Käser et al. 1983). *Left* Frontal view; right figure: lateral view. After a small suprapubic incision the double needle is guided through paraurethral tissue towards the vesicourethral border. This procedure is repeated on the contralateral side, which results in suspension of the bladder neck by the placed strings

16.4 Different Colposuspension Techniques

In 1949 Marshall, Marchetti and Krantz introduced colposuspension as a treatment for female incontinence. McDuffie et al. presented long-term data already in 1981. The success rate was 90% after 1 year, 86% after 5 years, 72% after 10 years and 75% after 15 years. In the following years, the modification of this technique by Burch (1961) was more and more accepted.

Milani et al. (1985) showed in a retrospective study that cure of incontinence was achieved to a similar extent by both procedures, 71% after the Marshall-Marchetti-Krantz (MMK) procedure and 79% after the Burch operation. Other studies confirmed these results. The surgical technique was modified several times. The Burch operation seems to be the procedure of choice, also because complications involving the periost can be avoided.

Park and Miller (1988) reported a cure-rate of 70% after 5 years and of 75% after 10 years.

Feyereisl et al. (1994) described a cure-rate of 81.6% 5–10 years postoperatively. This was confirmed by other authors: a cure rate of 75% (by Harris et al. 1995) and 82% (by Bergman and Elia 1995), both 5 years retrospectively.

In another retrospective study, Alcalay et al. (1995) reviewed the outcome of Burch colposuspension up to 20 years after surgery (median, 13.8 years). The subjective and objective cure rate amounted 82% after 5 years. However, cure of incontinence following Burch colposuspension seems to be time-dependent with a decline. A plateau of 69% is reached after 10–12 years postoperatively. The authors also described factors which influenced the postoperative outcome negatively. For example, previous bladder neck surgeries, preoperative weight greater than 80 kg and intraoperative blood loss of more than 1,000 ml affected the cure rate adversely. Postoperative complications include de novo detrusor instability (14.7%), long-term complaints of voiding difficulties (22%) and recurrent urinary tract infection (4.6%).

A cure rate of 88% 3 years after surgery was described by Liapis et al. (1996). Tamussino et al. (1999) reported a cure rate of 79% after 5 years, Colombo et al. (2000) talked about an objective cure-rate of 74% after 14 years and a subjective cure-rate of 86%. Aargaard et al. (1994) found a cure rate of 54% after 18years.

Petri (2001) registered within a follow-up period of at least 2 years 2,450 operations and a calculated a cure rate of 81%. Primary surgery showed success in 89% of the cases; operations for relapse in 72% of the cases.

Colposuspension is convincing not only for its very good-long term results but also for its high success rates, consistently published over decades. These data held up in future studies, which benefits colposuspension compared to other techniques. Just analyzing the studies with a follow-up period of 5 years or more, the cure rate amounts to 70%–80%. Colposuspension is the best studied surgical procedure for urinary incontinence and its success is most scientifically proved.

However, complications are also mentioned. Jarvis (1994) combined different studies by a meta-analysis and showed the occurrence of persistent lower gastric pain in 12% and the de novo urge incontinence in 12.5%. Only in 41% or 52%, respectively, a great surgical outcome without any complications could be found.

In a meta-analysis by Vierhout and Mulder (1992), the incidence of de novo urge incontinence was described in 17% of 396 patients.

McDuffie et al. (1981) reported more severe complications in 7.8% of all cases (Fig. 16.4).

16.5 Comparison Between Anterior Colporrhaphy and Colposuspension

In a prospective study, Liapis et al. compared the success rates of anterior colporrhaphy with Burch colposuspension. After postsurgical evaluation of 36 months, 57% of the women with anterior colporrhaphy and 88% of the women with Burch colposuspension were continent.

Bergman and Elia conducted a prospective study with the objective of comparing the long-term results of anterior colporrhaphy, needle suspension and colposuspension. The objective success rate for anterior colporrhaphy was 37%, for needle suspension 43% and for colposuspension 82% after 5 years.

Tamussino et al. (1999) evaluated in a retrospective study the continence rates 5 years after anterior colporrhaphy, anterior colporrhaphy with needle suspension of the bladder neck, and Burch colposuspension. A similar study had been published earlier by Tamussino et al. (1995) and Zivkovic et al. (1995). Five years postoperatively the objective overall continence rates were 61% after anterior repair, 49% after anterior repair with needle suspension, and 79% after Burch colposuspension. Continence

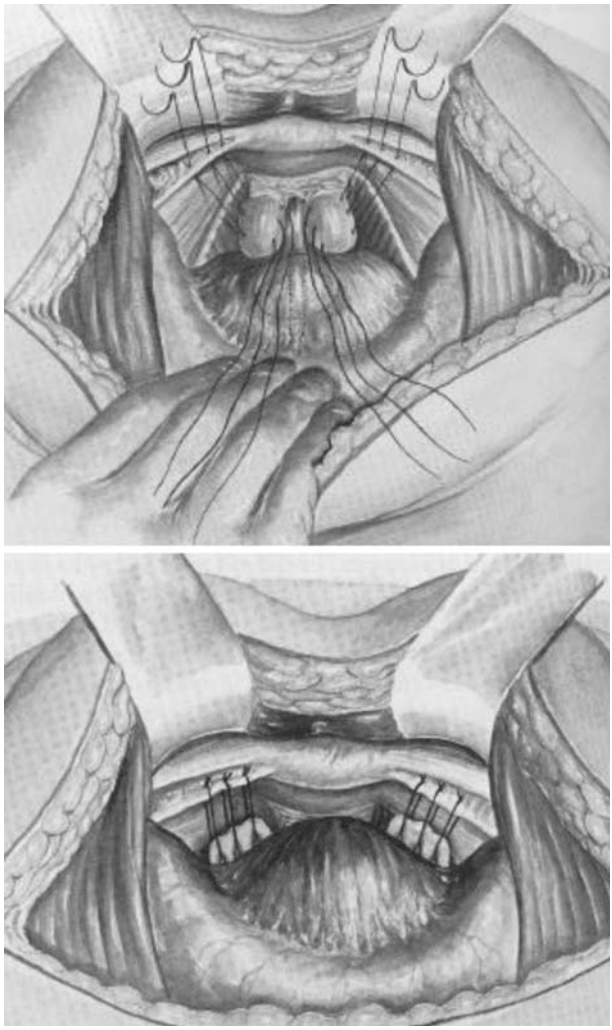

Fig. 16.4.
The Burch colposuspension (from Käser et al. 1983). Suspended sutures attach the fascia pelvina to Cooper's ligament, thereby elevating vaginal fascia more laterally than seen with the original Marshall-Marchetti-Krantz technique

rates after anterior colporrhaphy were 82% among patients with mild stress incontinence.

Hutchings and Black (2001) compared the three mentioned operative procedures in a retrospective nonrandomized multicenter trial. After 1 year they could indicate similar trends, but in general with much lower success rates. The cure rate was 34% for colposuspension, 19% for anterior colporrhaphy and 13% for needle suspension. However, the subjective postoperative evaluation showed better results: 75% of the patients stated improvement of their symptoms after colposuspension, 68% after needle suspension and 55% after colporrhaphy.

Peters and Thornton (1988) retrospectively compared the results of anterior colporrhaphy plus Kelly-Kennedy plication with colposuspension by Marschall-Marchetti-Krantz. Here, they took the grade of anterior genital prolapse and the technique of surgical correction into consideration. The abdominal approach showed higher cure rates than the vaginal approach if anterior prolapse was less prominent (93% vs 40%, 5 years

postoperatively). Both procedures resulted in equal success rates (between 75% and 100%) if genital prolapse was more prominent.

Van Geelen et al. (1988) showed in a prospective study that the transmitted intra-abdominal pressure to the urethra is much more effective after Burch colposuspension than colporrhaphy. This might explain the superiority of colposuspension compared to colporrhaphy as surgery for stress incontinence.

Luna et al. (1999) retrospectively compared the efficacy of both procedures over a time period of 11.3 years. Anterior colporrhaphy had a success rate of 55% and colposuspension a success rate of 58%. The anterior colporrhaphy procedure had more postoperative complications and shorter recurrence intervals (12 months after colporrhaphy vs 58 months after colposuspension). A questionnaire regarding the current status of urinary incontinence was sent to all patients.

Colombo et al. (2000) also demonstrated the superiority of the colposuspension over anterior colporrhaphy. The objective success rate was 74% vs 42%, respectively; the subjective success rate was 86% vs 52%, respectively.

These comparative studies clarify that colposuspension is superior to anterior colporrhaphy by having fewer side effects, except for de novo urge incontinence. Positive results of suburethral sutures and needle suspension cannot be reproduced persistently. These techniques as well as anterior colporrhaphy should be given up as incontinence operation.

16.6 Tension-Free Tape

After a colposuspension, the urethra loses its physiological position. Normally fixed a few centimeters underneath the symphysis, now after colposuspension the urethra is elevated and closely attached to the pubic bone. Despite good success rates for urinary continence, the pelvic floor is weakened by colposuspension. Defects often occur in the posterior compartment, especially if elevation is high and very close to the urethra (Eberhard et al. 2003). This more or less iatrogenically caused descent of the posterior compartment challenged the search for a surgical technique that delivers very good cure rates and does not interfere with stability of the pelvic floor (Fig. 16.5).

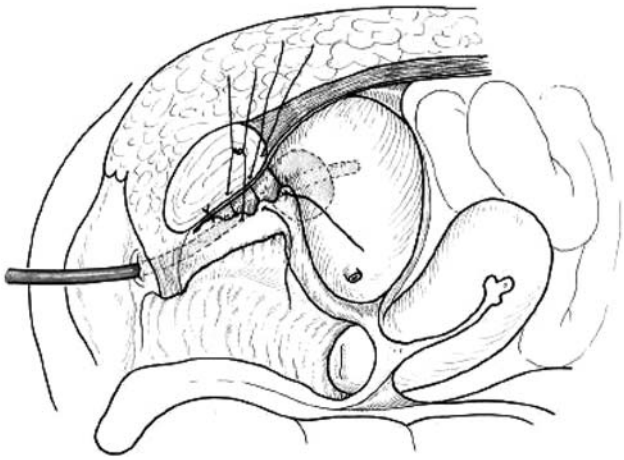

Fig. 16.5.
This figure illustrates the unphysiologic fixation of the urethra after Marschall-Marchetti-Krantz colposuspension. It leads to the development of enteroceles and rectoceles (from Käser et al. 1983)

While colposuspension is an empirically invented surgery for urinary stress incontinence (12 years after its introduction by Marschall et al., the theory of pressure transmission was finally founded by Enhörning (1961), in order to explain the effects of colposuspension), the tension-free vaginal tape (TVT) method was based from the beginning on the integral theory of female stress incontinence, described by Petros and Ulmsten (1990). According to this theory, Ulmsten et al. (1996) developed a retropubic suburethral sling made of alloplastic material. This tape was placed underneath the middle of the urethra in order to stabilize the insufficient pubourethral ligaments. The TVT is put in position by a small incision after local anesthesia. The surgical approach and methods of correction are described by Zubke et al. (2001, 2004a–c).

Excellent surgical outcome and cure rates of at least 90% can be mentioned (Olson and Kroon 1999; Rezapour et al. 2001). Liapis et al. (2001) also report success rates of 90% 44 months after surgery (Fig. 16.6).

Meschia et al. (2001) conducted a prospective multicenter study to evaluate 404 patients during a median follow-up time of 21 months. The subjective and objective cure rates were 92% and 90%, respectively. Intra- and postoperative complications were bladder perforations (6%) and postsurgical bleeding requiring surgery (5%). The authors conclude that the TVT has proved its success, also in combination with other surgical procedures.

Soulie et al. (2001) present a prospective multicenter trail. After a mean follow-up of 15.2 months, 83% of patients were continent. Bladder injuries occurred in 11.5%. No case of de novo urge incontinence was identified.

In a retrospective analysis, Jeffry et al. (2001) assessed the cure rate after 2 years. The objective cure rate was 89.3%, the subjective cure rate was only 66%, 11.6% of patients had bladder injuries, 13% had voiding difficulties and in 25% de novo urge symptoms occurred.

Sevestre et al. (2003) report results of the tension-free vaginal tape (TVT) technique in women with 70 years and older. Of these patients, 67% were cured postoperatively, 13.7% had persistent stress urinary incontinence, 18.4% of patients showed urge symptoms. Overall, 82% of the patients were satisfied with the result of the surgery.

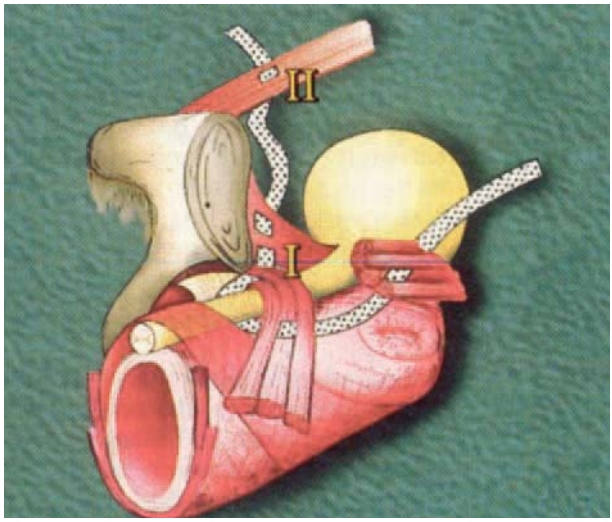

Fig. 16.6.
Tension-free position of the TVT underneath the middle of the urethra; fixation of the Prolene-tape within the pelvic diaphragm and abdominal muscles (from Bettin et al. 2000)

Peschers et al. (2000) calculated an objective cure rate of 87% during a mean follow-up time of 17.5 months. The subjective cure rate was 90% after 1 year. In 5.4% of patients, bladder injuries occurred; 5.1% of patients complained about de novo urge incontinence; erosions of the tape were diagnosed in 9.1%.

A prospective study was undertaken by Levin et al. (2004) to examine the incidence of surgical complications of TVT. Three hundred and thirteen patients were prospectively studied. The mean follow-up period was 21.4 months . In 5.1% of the cases, an intravesical passage of the tape occurred, two of which were diagnosed at 3 and 15 months postoperatively. Five percent of the patients had postoperative voiding difficulties, necessitating catheterization for more than 7 days. However, excision of the tape was required in one case only. Vaginal erosion of the tape was diagnosed in 1.3% of the patients, all of whom were successfully treated by local excision of the eroded tape. De novo urge incontinence developed postoperatively in 8.3% of the patients. The subjective and objective cure rates were approximately 90%. However, most bladder injuries occurred during the surgeons' training-period; afterwards they rarely appeared.

Nilsson et al. (2001) conducted a long-term study over 5 years, with 85% of the patients completely cured. After 7 years the cure rates were 81%, shown by Nilsson et al. (2003).

In order to reduce or avoid side effects of the conventional TVT, new versions of suburethral slings have been introduced, for example, the transobturator tape.

De Leval et al. (2003) evaluated a new, simple surgical technique for the treatment of female stress urinary incontinence. The procedure was carried out in 107 consecutive patients. No perioperative complications were encountered. Of these patients, 2.8% had voiding difficulties that improved after loosening the tape. All patients were continent after operation. This operative procedure was also evaluated by Reisenauer et al. (2004).

Delorme et al. (2004) report their results of their technique of transobturator suburethral tape. Mean follow-up was 17 months with 90.6% of patients cured. One patient (3%) had complete postoperative bladder retention, 6% of patients developed de novo urge incontinence, 15% of patients had voiding disorders indicating bladder outflow obstruction.

A prospective randomized study was undertaken by de Tayrac et al. (2004) to compare the conventional TVT with the transobturator suburethral tape (by Delorme). Mean operating time was shorter with transobturator suburethral tape than with conventional TVT, 15 min vs 27 min. There were fewer cases of complete postoperative bladder retention, 13% vs 26%, and the cure rate after a follow-up time of 1 year was higher: 90% of patients were cured with the transobturator suburethral tape vs 83% with conventional TVT.

16.7 Comparison of Colposuspension and TVT

Although colposuspension and TVT are performed frequently, only a few comparative studies exist. Merlin et al. (2001) did a meta-analysis to compare the IVS, TVT, and Burch colposuspension. They concluded that the TVT procedure appears to be as effective as Burch colposuspension and has shorter recovery times. Colposuspension is associated with a higher risk for blood transfusion than the suburethral sling surgery. In general it was difficult to accurately present the complications with meta-analysis. In the authors' opinion, the complications were clearly "under-reported."

In a prospective randomized study, Koelbl et al. (2002) compared the perioperative results of Burch colposuspension and TVT. The OR time was clearly shorter with TVT than with Burch (27 vs 39 min respectively). Complications such as blood loss, infection, hematoma and urinary tract infections were more frequent with Burch than with TVT. Patients with TVT could be discharged earlier than those treated with Burch (3.3 days vs 8.5 days). Moreover, normal voiding occurred already 3.3 days after TVT, but 7.8 days after Burch colposuspension.

A prospective randomized multicenter study was done by Ward and Hilton (2004) to compare tension-free vaginal tape (TVT) with colposuspension. Of the TVT group, 63% were objectively cured at 2 years, as were 51% of the colposuspension group. The TVT procedure appears to be as effective as colposuspension for the treatment of urodynamic stress incontinence . Colposuspension is significantly more frequently associated with longer recovery times, with the complication of postoperative prolapse and the necessity of re-operation. Moreover, they showed that this re-operation follows colposuspension significantly more often than TVT, which the authors explain by the surgical technique of colposuspension. These findings are also supported by other authors.

In conclusion, compared to conventional colposuspension there is a trend towards TVT.

16.8 Endoscopic Colposuspension

The difference between colposuspension procedures and TVT is the minimally invasive technique, whereas colposuspension requires a small laparotomy. In order to perform colposuspension as a minimally invasive procedure, new laparoscopic approaches had to be developed, especially done by Wallwiener et al. (1994, 1995, 1996). He introduced retziusscopy as an operative approach for colposuspension and proved its surgical practicability in a comparative study. He also showed that the different endoscopic techniques such as laparoscopy and retziusscopy, present equally good results.

First, the question of whether laparoscopic Burch colposuspension produces similarly good results as the classic Burch colposuspension must be answered. Therefore Fatthy et al. (2001) studied 74 patients and compared both procedures. Mean operating times of laparoscopic vs open surgery were 70 vs 53 min, respectively. However, the mean blood loss for laparoscopic Burch was only 42 ml vs 240 ml with colposuspension. The laparoscopic procedure required less postoperative analgesia and a mean hospitalization period of 36 h vs 76 h. Moreover, average time to return to work amounted 8.5 vs 31.5 days with the classic Burch. Success rates were 88% at 18 months in the laparoscopic group, compared with 85% in the open group, demonstrating equal efficacy of both procedures.

Dietz and Wilson (2002) analyzed a longer follow-up time, on average 3.3 years. There was no significant difference between stress incontinence and urge incontinence. However, some endoscopic techniques that are no longer in use seem to show less success: techniques that fix the vaginal fascia at the Cooper ligaments by an interponate (El-Toukhy and Davies 2001) and techniques using tissue glue instead of sutures (review by Weber 2003) (Fig. 16.7).

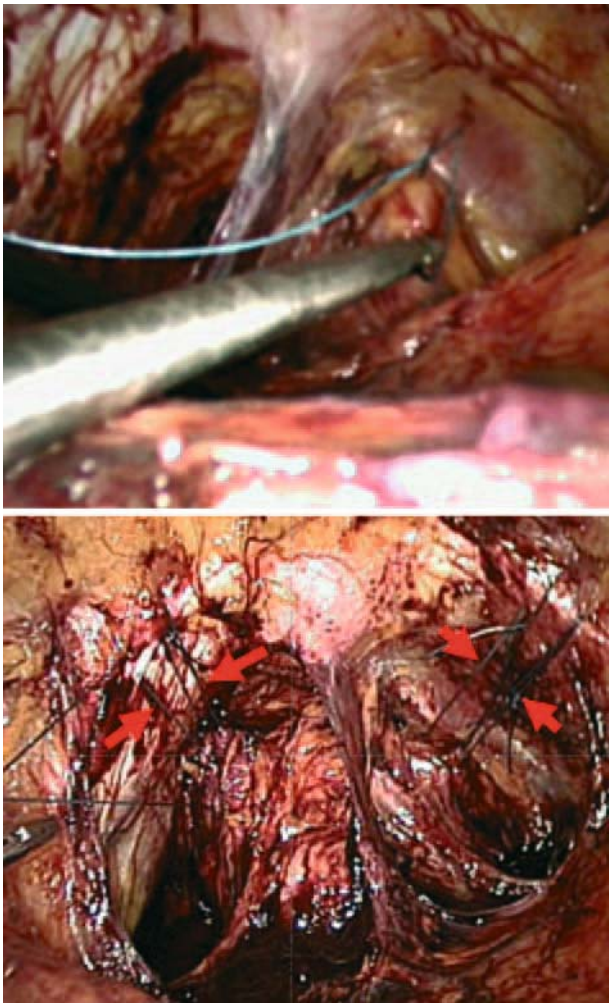

Fig. 16.7.
Laparoscopic Burch. *Top* in correlation with the conventional Burch, the fascia pelvina is elevated vaginally and is fixed with nonabsorbable sutures. *Bottom* postoperative situs; the *red arrows* mark on both sides the sutures of colposuspension. On the *left side*, one suture is still being tied. The fascia between bladder and vagina is elevated in the same manner as modified laparotomy

16.9 Comparison of Endoscopic Burch and TVT

There are two minimally invasive surgical techniques in treating genuine stress urinary incontinence: the tension-free vaginal tape (TVT) and laparoscopic Burch procedures. Practicability, efficacy and side effects of both methods should be analyzed. This was done by Chung and Chung (2002).

Operating time for the laparoscopic Burch procedure is significantly longer. The hospitalization period was very short with both procedures (TVT as an ambulatory intervention; 1.1 days for the laparoscopic Burch). No intraoperative complications have been seen during TVT (91 patients), whereas in the Burch group (51 patients) one bladder rupture and occlusion of the urethra occurred, which were corrected intraoperatively. Postoperatively, one TVT patient suffered from urinary retention that required loosening of the tape 4 months later. After the Burch procedure, six patients still complained of urinary incontinence.

Paraiso et al. (2003) conducted a study to compare Burch colposuspension and the TVT sling procedure at a total of 36 patients. The Burch procedure required clearly more time for surgery than TVT. The hospitalization period was equally long for both procedures. The objective rate of failure measured 3.6% with TVT and 23% with laparoscopic Burch 1 year after surgery. Detrusor overactivity occurred in 13.8% after TVT, but only in 3.9% after Burch colposuspension. Patients with TVT complained about more subjective symptoms than those with Burch. Two ruptures of the bladder occurred during TVT, which made postoperative removal of the sling necessary. In three cases, the endoscopic Burch procedure had to be changed to laparotomy during surgery.

Brenner (2001) showed by a comparative study that the success rate was higher after TVT than laparoscopic Burch colposuspension (93% vs 83%). Accordingly, patients with TVT were more satisfied. One perforation and two hematomas were seen after TVT and three slings had to be cut. The Burch procedure resulted in three bladder perforations. In conclusion, the author favors TVT.

Other authors – Üstün et al. (2003) and Cosson et al. (2002) – have had similar results. We can conclude that TVT as well as the laparoscopic modification of the Burch colposuspension have proved their worth and are equally successful. The cure rates are good after both procedures, but the advantage goes to TVT. Intraoperative complications, which are easily manageable, are seen during both surgeries: 5%–10% laparoscopic Burch interventions had to be converted to laparotomy. The alloplastic material of TVT is substantially more expensive than the Burch sutures. But this is partially

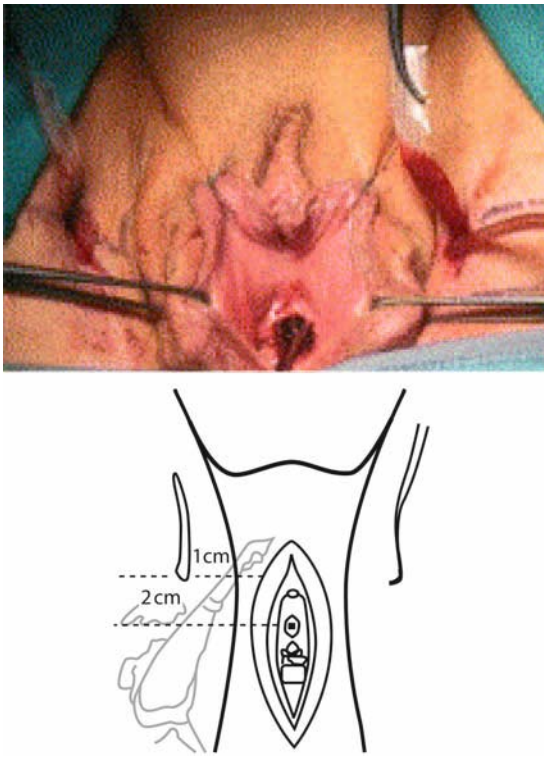

Fig. 16.8.
TVT-O. *Left* situs during surgery. *Right* illustration of the surgery. TVT is placed underneath the middle of the urethra and brought out through the foramen obturatoria on both sides (from de Leval 2003)

made up by a shorter operating time (1 min costs roughly 5–25 euros depending on the specific calculation of the clinic). Moreover, TVT requires shorter hospitalization periods and rarely a change to laparotomy.

Another fact, which was not considered in the comparative studies, is the alteration of the pelvic floor by colposuspension. It leads to weakening of the posterior compartment resulting in complaints and further operations.

Because of all the above-mentioned results, we favor TVT as standard therapy for urinary stress incontinence and have abandoned colposuspension. We use colposuspension only in connection with other abdominal surgeries. Laparoscopic colposuspension has become a procedure for exceptional circumstances. Even in cases of extensive laparoscopic hysterectomies in combination with sacrospinal fixation, we prefer the TVT procedure over laparoscopic Burch.

TVT is currently the standard surgical treatment for urinary stress incontinence. According to recent studies and our own experience (Reisenauer et al. 2004), the transobturator approach seems to result in fewer complications than the conventional TVT method. The TVT variant, TVT-O (Gynecare), is therefore our therapy of choice at present (Fig. 16.8).

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Chapter 17

Diagnostic and Surgical Management of Stress Urinary Incontinence

17

Karl-Dietrich Sievert, Arnulf Stenzl

Contents

17.1 Introduction

The awareness of urinary incontinence has increased during the last decade. Urinary incontinence is no longer taboo. Industry has picked up the incontinence problem and many public advertisements suggest using diapers to treat incontinence. However, the attending urologist and gynecologist are asked to supply a more efficient and effective medical treatment for urinary stress incontinence.

17.2 Types of Urinary Incontinence

There are many types of incontinence. Urinary stress incontinence (49%) accounts for the highest percentage of incontinent patients, while other forms of incontinence such as urge incontinence account for 22% of the patients. Mixed urinary incontinence accounts for 29% (Hampel et al. 2004).

17.3 Female Stress Urinary Incontinence

The cause and mechanism of female stress urinary incontinence is still relatively unknown. Currently, the integral theory of Petros and Ulmsten (1993) seems to be the most accepted theory of the female urinary continence mechanism, although the previous investigations by Hofner and Dorschner (1989) describe the phenomenon even more accurately. Even in the more advanced histological work done by Carlile et al. (1988), as well as the functional and anatomical work of Colleselli et al. (1998) and Stenzl et al. (2000), the mechanism of female urinary continence is still not completely understood.

17.4 Male Urinary Stress Incontinence

Male urinary stress incontinence is better understood and occurs primarily after a transurethral prostate resection or radical prostatectomy. The more repayable continence mechanism of the male seems to depend on the longer functioning urethra.

17.5 Evaluation of Urinary Incontinence

The treatment of incontinence must be initiated with an analysis of the patient's medical history and a full 3-day and night micturition diary. This initial analysis can provide critical information in the treatment approach of incontinence. The analysis must include a test of the actual vesical pressure, urethral closing pressure and urethral mobility in order to choose the best surgical technique. In addition, before incontinence can be successfully treated, a urodynamic evaluation, a urethrocystoscopy and a pad test must first be performed to determine the type of incontinence. Any other co-factors such as prolapse, stool incontinence, etc. need to be considered in the diagnosis.

Depending upon the degree and type of urinary stress incontinence, there are a number of different approaches. Urgency incontinence should be treated first with noninvasive treatments such as drugs (anticholinergics) before a surgical approach is

even considered. With further co-morbidities (e.g., vesical of rectal prolapse), the gynecologist or urologist needs to decide whether a modification or combination of other techniques is required. Other types of urinary incontinence or pelvic pathologies need to be reviewed and the treatment strategy must discussed with the patient.

17.6 Possible Approaches

Using a step-ladder approach (Fig. 17.1), weight reduction is often necessary as a first step. In addition to weight reduction, pelvic floor exercises, supported by biofeedback and/or electrostimulation is recommended (see Chap. 13.

The following varied techniques have been evaluated starting from minimally invasive to those that are invasive. It is important to keep in mind that each patient's case needs to be evaluated and treated individually. The recommended surgical treatment depends upon the patient's requests, their symptoms, the evaluation results and the surgeon's experience.

Before a surgical approach is attempted, a medical drug treatment is one possibility for those with minor symptoms of stress urinary incontinence. Recently, the drug Yentreve twice 40 mg (Millard et al. 2004) has been released. This drug can be tried initially if the female patient does not want a surgical approach (e.g., urethral bulking agents, surgery and artificial sphincter). It should not be underestimated that almost one-third of the patients treated with this drug have experienced nausea (27.9%); how-

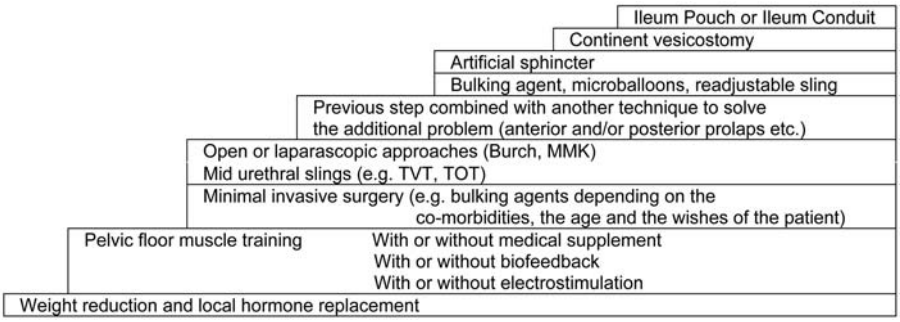


Fig. 17.1. The approach to treat SUI depends on the type of SUI, age, co-morbidities, the conservative approach required, surgical possibilities and patient's wish

Ileum pouch or ileum conduit
Continent vesicostomy
Artificial sphincter
Bulking agent, micro-balloons, readjustable sling
Previous step combined with another technique to solve the additional problem (anterior and/or posterior prolapse, etc.)
Open or laparoscopic approaches (Burch, MMK)
Mid urethral slings (e.g., TVT, TOT)
Minimally invasive surgery (e.g., bulking agents depending on the co-morbidities, age and patient's wishes)
Pelvic floor muscle training
  With or without medical supplement
  With or without biofeedback
  With or without electrostimulation
Weight reduction and local hormone replacement

ever, only 5.3% of them reported severe nausea and therefore stopped the treatment (van Kerrebroeck et al. 2004a).

17.7 Patient History: Analysis and Examination

An analysis of patient's history and voiding habits are essential. It demonstrates the impact of continence and their life quality. Included in the analysis should be questions about the prior medical history of urinary infections and certain illnesses such as diabetes mellitus, Parkinson's disease, multiple sclerosis, and previous surgeries of the pelvis or pelvic floor. Neurogenic bladder dysfunctions or spinal cord or peripheral nerve changes (e.g., disc prolapse, nerve damage after disc surgery, hysterectomy, etc.) should be evaluated. They might be the reason for postoperative, or if not corrected, long-term retention.

17.8 Data Gathering Prior to the Office Examination

One of the best ways to analyze symptoms is the patient's preparation of a micturition and voiding diary over a minimum of 3 full days. This data helps the attending urologist or gynecologist characterize the problem. The diary should contain a significant amount of detail such as actual drink time along with the volume, micturated volume, incontinence (when and how), pad/cloth change, pain, and the whether the patient had the feeling that the bladder was emptied completely. The patient should prepare this diary prior to the first consultation with the doctor. This will help to evaluate the relevance of any urine incontinence and help to determine the impact on the patient's life.

17.9 Office Examination

One of the best ways to evaluate bladder function is video urodynamic evaluation and a transvaginal ultrasound with an improved scanning head. Most likely in the future, 3D or even 4D ultrasound imaging will be used. The 3D imaging seems to ensure the same accuracy and is less invasive, less expansive and less time consuming than dynamic MRT.

If during the examination any sign of urgency incontinence is revealed, those problems need to be treated first. Urgency or urgency incontinence can worsen or appear, which is called de novo urgency if any of the surgical techniques described in the sections below are used. Even in a urodynamic evaluation, bladder overactivity cannot necessarily be seen and therefore it cannot be proven that there is no overactivity. A cystogram should be performed if it is not possible to do a video urodynamic evaluation. A urethrocystoscopy will exclude any pathology such as bladder tumors or urethral strictures. With the stress (Valsalva) test, the leaking can be revealed and prolapse (anterior or posterior) usually appears. After the voiding (urine-flowmetry), the urine residual volume should be determined in order to obtain better knowledge of the bladder function, as any of the surgeries described in the following sections causes an increase in outflow resistance. All these examinations will not only help to predict other kinds of malfunctioning or pathologies, but it is the only objective way to follow up on the outcome of any treatment. Urinary incontinence and prolapse need to be repaired, and if possible, using the same surgical approach.

17.10 Urethral Bulking Agents (Injectables)

17.10.1 Historic Bulking Agents

Because of insufficient external urethral sphincter, bulking agents can be used to raise the mucosa in this location. The submucosal application decreases the diameter of the urethra. The ideal bulking agents should be easily injectable, stay permanently in place and conserve volume over time. They should be hypoallergenic, biocompatible, non-immunogenic, and nonmigratory. Monga et al. demonstrated success of the bulking agent treatment and increased the pressure transmission ratio in the proximal quarter of the urethra. In their opinion, the bulking agents administered in the proximal quarter of the urethra prevents the bladder neck from opening under stress (Monga et al. 1995). However, Khullar argued that placing the bulking agent just below the bladder neck improves the intrinsic sphincter deficiency and creates an outlet obstruction (DSD) (Khullar et al. 1997) (Fig. 17.2).

McGuire et al. defined the indication by a low leak pressure point correlated with a poorly functioning bladder neck and proximal urethra (ISD). The higher leak point pressures correlated to types 1 or 2 hypermobility of the urethra (McGuire et al. 1993).

One of the first bulking agents used was Polytetrafluoroethylene (Teflon). The primary result was cure rates of 55%–61% or an improvement of up to 71% after 17–30 - months. However, in the long-term follow-up, the success rate dropped to below 30% (Herschorn and Glazer 2000; Lopez et al. 1993). Further reports found that the Teflon particles had migrated because of phagocytosis. They were even found as a foreign material in organs such as the lung. In addition to this side effect, Teflon was difficult to use and required very high pressure points to inject.

17.11 Successfully Introduced Bulking with the CE Mark

Several bulking agents are already successfully used in Europe such as silicone (Macroplastique), hyaluronic acid and dextranomer (Deflux/Zuidex) (Table 17.1). Silicone needs to be injected with high pressure as a mixture with a water-based carrier. In follow-up, success rates decreased down to 30% over 3 years (Herschorn 2001). Currently, long-term follow-up data does not exist. Hyaluronic acid was originally used for the vesicoureteral reflux and seems to have no immunological potential. With a special applicator (Zuidex), the material is simultaneously injected in four locations under the urethral submucosa and provides bulking (van Kerrebroeck et al. 2004b; Stenberg et al. 2003) (Fig. 17.3). In addition, Deflux was also introduced as a treatment in male

Table 17.1. The most common bulking agents (material, trade name and the producing/selling company)

Material	Trade name	Company
Silicon	Macroplastique	Innovamed
Collagen	Contigen	BARD
Hyaluronic acid	Deflux, Zuidex	Q-med
CaHA	Coaptite	BioForm

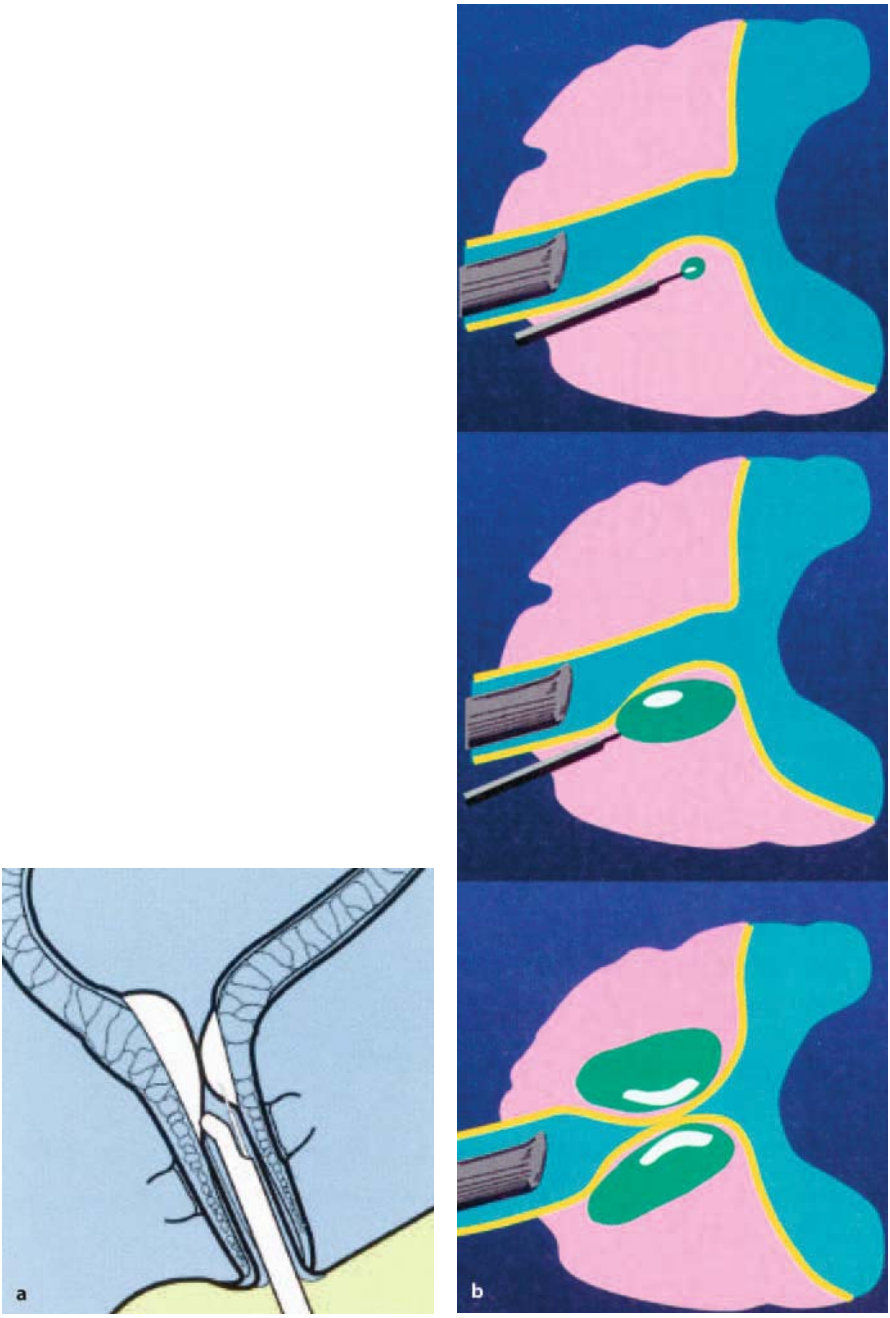


Fig. 17.2a, b. The way to perform the injection using the transurethral (**a**) and paraurethral (**b**) approach is to place a bulking agent. Picture 1: Application of Deflux

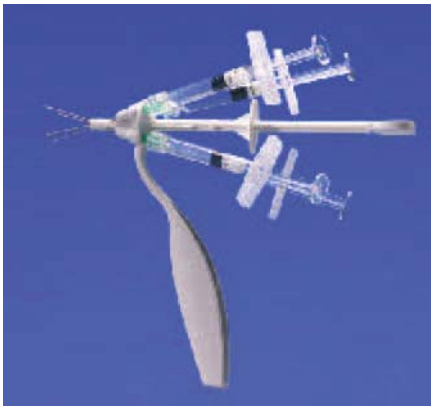


Fig. 17.3.
The Zuidex implacer is composed of four prefilled syringes, each containing 0.7 ml Zuidex gel, syringes each with a 21-G needle. A cannula covers the needles for a smooth introduction into the urethral lumen. Once withdrawn, the cover enables the surgeon to prick into the urethral mucosa in four sites under local anesthesia

stress incontinence after radical prostatectomy. Deflux injected in the area of the insufficient external sphincter appears to improve the continence for those patients after radical prostectomy (Alloussi 2004).

Calcium hydroxylapatite (Coaptite) has been developed to implant teeth in the bone for jaw reconstruction. As a component of the bone, it seems to have no antigenic or inflammatory potential. In the 3-year follow-up study, Mayer et al. (2001) published ten patients' data that showed no complications and demonstrated an improvement or cure rate of 60%.

17.12 FDA-approved Bulking Agents

Another type of bulking agent is collagen. Collagen is widely used around the world for many different applications. It is made from bovine dermis, mainly cross-linked collagen types I and III. After injection, it becomes neovascularized and promotes the invasion of fibroblasts. The advantages are that it is safe and easy to inject. Additionally, it has been proven that it does not migrate and ensures a minimal inflammatory response. Over time, it is replaced by host collagen (Remacle et al. 1990). A disadvantage is that a small group of patients might be allergic, and therefore a skin test is needed. More importantly, long-term follow-up is still required, as the initial results show that the cure rate is low and temporary. One side effect is that de novo urgency and/or persistent incontinence is seen in up to 13% of the patients and 2% of the patients face temporary urinary retention. It appears that collagen's early high success rate of 72%–100% decreases over time without re-injections. With respect to the so-called long-term results, Herschorn and Radomski (1997) have published a cure rate of 72% in the 1st year, which dropped to 57% after 2 years and 45% at 3 years. The continence rate appears to be better with one or two additional treatments, with a mean of 5.6–15 ml collagen administered.

Durapher large particles or pyrolytic carbon-coated zirconium beads appear not to migrate, although this has not been completely proven in the long term (Pannek et al. 2001). Because of the size of the particles, bigger injection needles are needed, with a higher risk of retention in comparison to collagen. With a short follow-up of 12 months, Lightner et al. (2001) looked into the data of 355 women with intrinsic sphincter deficiency (ISD) and found equal effectiveness compared to the bovine collagen; however, less material was used.

17.13 Tissue-engineered Stem Cells for Bulking: Dream or Reality?

Although there are a myriad of materials, none of those discussed in the sections above seems to have the real potential to cure stress incontinence in the majority of patients. Many are easy to inject and improve the patient's quality of life for a specified time. Several of these products are ideal for patients with co-morbidities who should not or who do not want to undergo anesthesia. A disadvantage is that these substances currently need to be repeatedly injected.

Hopefully in the near future there will be more information with regard to autologous agents developed in the field of tissue engineering. Bent et al. published the data of 32 patients after injecting tissue engineered cells. They demonstrated an increase in the leak point pressure to over 90 cm H_2O. Half of the patients were cured and 31% improved in the follow-up after 1 year (Bent et al. 2001). With the application of primary cultured skeletal myoblasts, Yokoyama et al. (2001) hoped that the amount of cells would cause an obstruction in the bladder outlet but no long-term data exists as yet. Strasser et al. (2004) published an improvement in female sphincter function both experimentally and clinically, albeit with short-term results to date. Follow-up data over the next years will demonstrate if this technique will ensure success or if further improvements are needed.

Because it seems that the ideal substance, which is easy to inject without high pressure and decreases the chance of migration or rupture of the tissue, has not yet been found, research will continue to search for an agent that can restitute the insufficient external sphincter in its physiological function.

17.13.1 Mid-Urethral Synthetic Slings

17.13.1.1 Transvaginal Needle Procedures

The history of mid-urethral slings started with the Pareyra procedure in 1959. Over the past years, different modifications to transvaginal needle application were made with a different recognized outcome. However, it appeared that none of these modifications lasted for the long term (Stamey 1973; Wennberg et al. 2003; Kuczyk et al. 1998). The patient's satisfaction was high compared to their presurgical status and in comparison to the invasiveness of the procedure. However, long-lasting results are similar to those of bulking agents. In comparison to other sling procedures, the sutures did not cause tissue irritation or scarring compared with more invasive techniques. One major side effect that is often seen is bladder perforation or the migration of nonresorbable sutures through the bladder wall, thereby causing chronic bladder infections or irritations known as de novo urgency.

17.13.1.2 Vaginal Slings

Because of the long-term outcome of the Stamey procedure, further techniques were developed from the traditional pubovaginal sling first described by Giordano 1907 (Ridley 1985). These vaginal fascia of rectus muscle slings were placed primarily at the level of the bladder neck through an abdominal approach. In a retrospective study, Morgan et al. and Chaiking et al. found in the long-term follow-up that an allografted

Table 17.2. The success rate of the pubovaginal sling is similar, independent of the center performing this study and the percentage of "de novo" urge (5%–7%) and the persisting urge incontinence (23%–41% after more than 10 years of follow-up (Chaikin et al. 1998)

		1 year	2 years	3 years	4 years	5 years	10 years
Morgen et al. (2000)	No. patients		247	178	144	88	
	% cured SUI		93	91	88	85	
Chaikin et al. (1998)	No. patients	250		103		47	20
	% cured SUI	94		94		95	95

fascia sling had a highly satisfactory outcome of 92% and with a cure rate of 85% after 5 years (Morgan et al. 2000) (Table 17.2). When autologous vs allografted slings were compared at the time of a re-operation, Fitzgerald found that the cadaveric sling had disappeared. This was interpreted as a cause of autolysis and a possible reason for failure in the long-term follow-up (Fitzgerald et al. 1999). The cadaveric sling nevertheless seems to be an alternative. Despite the fact that off-the-shelf material operation time has been shortened, patients have to be informed that other procedures are available with a longer follow-up. Brown and Govier (2000) compared autologous and cadaveric fascia data and saw a similar outcome. A minimum of 5 years follow-up is probably needed to give the final recommendation. In order to have a true comparison of the two materials, a random study with the same surgical technique needs to be conducted.

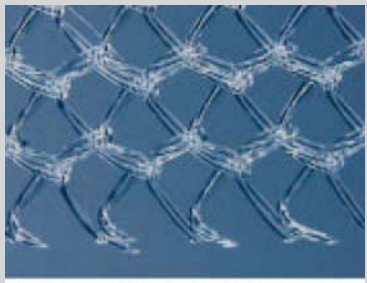
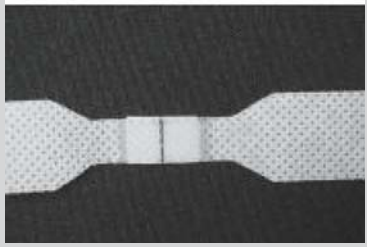
The modification with the bone-anchored sling has a similar outcome that does not justify the more invasive technique; however, this procedure seems to be more preferred by individual surgeons.

17.14 Tension-Free Vaginal Tapes

The first approach of a mid-urethral sling with synthetics was undertaken with Gore-Tex with its well-known failures such as urethral perforations and fistulas. It seemed for a long time that the use of foreign materials would not be used again to treat urinary stress incontinence. Almost a decade ago Petros and Ulmsten (1993) described their integral theory and their use of what is now known as tension-free vaginal tape (TVT). The introduction of new mid-urethral synthetic sling is currently restricted to the following category of patients: obese, elderly, failed prior surgery, low average leak-point pressure or mid-urethral closing pressure with hypermobility and concurrent prolapse repair. An important criterion in placement is that the sling needs to be loosely placed below the urethra. The name "tension free vaginal tape" probably best describes the technique and what all these slings have in common. Other companies have modified their technique with their specified synthetic sling material (Table 17.3). The ideal synthetic material should be an inert material, have a large pore size to minimize the chance of colonization or infection and enhance the vascularization and tissue in-growth.

The overall outcome of slings depends upon the current group of previewed literature. The outcomes that have been published by the developers (Nilsson et al. 2001) are slightly better than the overall outcome of a nationwide analysis (Kuuva and Nilsson

Table 17.3. Comparison of the different materials used as synthetic tapes

Type I	Polypropylene (loosely woven) Complete macro porous net (porous >75 µm) (Prolene, Gynemesh, TVT)	
Type II	Expanded polytetrafluoroethylene (PTFE) Complete microporous net (porous <10 µm) (Gore-Tex, Uratape)	
Type III	Macroporous nets with multi-filament Or microporous components (Parietex, Surgipro, Uretex)	
Type IV	Submicro pores (Not useable as a net)	
Type I	vs Type II and III:	
Type I	less foreign body reaction	
Type I	low infection rate	
Type I	better in-growths	

2002). The long-term 5 year follow-up demonstrates similar overall outcomes to the so called classic procedures (Fritel and Pigne 2002; Maaita et al. 2002; Sander et al. 2002; Olsson and Kroon 1999; Ulmsten 1998 and many others). The longer-term outcome (more than 5 years follow-up) of the prospective sling studies demonstrates a cure rate of about 84%–88% and a significant improvement of 7%–10% with only a failure rate around 5%–8%. The outcome might depend on the mid-urethral closing pressure and many others think the long-term outcome depends on the mobility of the mid-urethra. Fritel et al. pointed out in their study that where urethral mobility is above 60°, the success rate is around 97%. When the mobility decreased to below 30°, the success rate drops to 70%, where the mid-urethral closing pressure is not significant (Fritel et al. 2002).

17.15 Comparison of Two Major Tapes

Additionally, several companies have developed their own system with a shorter follow-up. The SPARC system is one of them with a similar outcome. It has shown similar surgical complications in the 2-year follow-up, but it seems that the tape needs to be surgically placed with a specific tension. In peer-reviewed literature, four studies are available two of which an overall similar or identical outcome (Dietz et al. 2004; Lim et al. 2004). The major difference between Dietz et al. (2004) and Lim et al. (2004) is that with the SPARC system, it was possible to bring in the needles from the abdomen, whereas the TVT system was able to make this approach only recently. The gynecologists seem to be more familiar with placing the needles through the vagina, while urologists using the Stamey procedure seem to prefer the abdominal approach. In addition to the TVT and SPARC systems, other systems have been introduced in the clinic (Table 17.3). While the learning curve is short with most systems, surgeons should usually look for the system they feels best with and stick with it so as to obtain the best results over the long term. An important advantage to consider in selecting the system: a reduction in operating times (approximately 30 min) and a system that can be done under all types of anesthesia. Several departments perform this as an ambulatory procedure with a similar outcome compared to the golden standard techniques for SUI. The successful indication has to be verified with a preoperative urodynamic evaluation. Urethral mobility can be predicted using the Q-tip test. This test is easy to perform and helps to choose the best technique (Bakas et al. 2002). The critical indications to avoid major complications appear to be a mobile urethra and the tape being placed tension free (Table 17.4).

17.16 New Materials: The Resorbable Sling

Recently the modification of the tension-free vaginal tape as a subcutaneous prepubic sling application has been presented. The long-term outcome needs to be demonstrated until it can be decided whether this procedure can be recommended (Daher et al. 2003). Over the past few years, new materials have entered the market. Such products as xenograft acellular porcine dermis (Pelvicol by Bard, West Sussex, UK) and most recently, small intestinal submucosa (SIS, Stratasis by Cook, Ireland) (Table 17.5). With the first short-term follow-up they might be an alternative to the synthetic slings

Table 17.4. Comparison of the nationwide analysis (Kuuva and Nilsson 2002) of complications associated 1455 cases using the TVT procedure in Finland 2001 by Carl Gustaf Nilsson and those of their own clinic (Nilsson et al. 2001)

Complications	% (Kuuva and Nilsson 2002)	% (Nilsson et al. 2001)
Voiding difficulties	7.5	4.4
Urinary retention	2.3	
Urinary tract infection	4.1	7.8
Infection	0.9	1.1
Hematoma	1.9	3.3
Bladder perforation	3.7	1.1

Table 17.5. Acellular materials for urethra slings

	Product	Company	Resorbable	Source
Xenograft	SIS Stratasis Pelvicol	Cook Bard	Yes No	Porcine small intestine Porcine dermis
Allograft	Repliform Alloderm	Lifecell, Boston Scientific	Yes	Human dermis

Table 17.6. Comparison of different slings and their outcome

Authors	Material used	Patients	Cure rate %	Follow-up (months)
Arunkalaivanan and Barrington (2003)	TVT Pelvicol	142	76 74	6–24
Berrington et al. (2002)	Pelvicol	40	85 "sustained"	6–18
Ruter	Porcine SIS with bone anchors	152	93.4	4–48
Colvert et al. (2002)	Stratasis	20 children	70 85% Female 43% Male	9–26

(Arunkalaivanan and Barrington 2003; Rutner et al. 2003; Barrington et al. 2002; Colvert et al. 2002). Those xenograft materials might have a similar reliability as synthetic slings; however, only a short follow-up of approximately 1 year is available (Table 17.6).

17.17 Transobturatoric Tension-Free Tapes

At the EAU 2003 in Madrid, Proget presented the transobturatoric tension-free tapes with the Monarc System. The new approach avoids the retropubic space, theoretically decreases the bladder perforation rate and voiding dysfunctions such as de novo urge. The peer-reviewed data, with a short follow-up of up to 17 months, demonstrates two ways to place the transobturator sling: inside-out and outside-in with an overall similar outcome, shorter operating time and intra- or postoperative complications (Delorme et al. 2003).

17.18 Retropubic Suspensions

The introduction for retropubic urethral suspension by Marshall (1949) and later the modification of Burch (1961), changed the devastating condition of incontinent women in late 1940s. After the first meta-analysis of Jarvis et al. demonstrated for Burch vs Marschall-Manchetti-Kranz (MMK) a cure rate of around 89.8% vs 89.5% (Jarvis 1994), several modifications have been described, but the most frequently quoted for

the Burch method has been Tanagho (1976) and for MMK, the Mayo Clinic (Symmonds 1972). Indications for this procedure are the urethral sphincter incompetence and good vaginal capacity and mobility. The MMK method is only suitable for patients with SUI and a cystocele grade I, whereas the Burch method is a good option for a coexistence grade I–III cystourethrocele (Stanton and Cardozo 1979). This method has not been as historically successful. This is most likely because in the early days, only one suture per side was placed. In laparoscopic surgery, several techniques have been tried such as the Burch procedure (Moehrer et al. 2002). Today the laparoscopic approach is performed with the modification that at least two suture slings per side are placed.

17.19 Artificial Urethral Sphincter

The artificial urethral sphincter is discussed in Chap. (Fig. 17.4) (see Chap. 18, "The Artificial Urinary Sphincter").

17.20 What to Do When All the Efforts Did Not Result in a Continent Patient?

Even if all recommendations in this chapter are followed and the surgery turns out as planned, the long-term success of this approach cannot be predicted. Experts agree

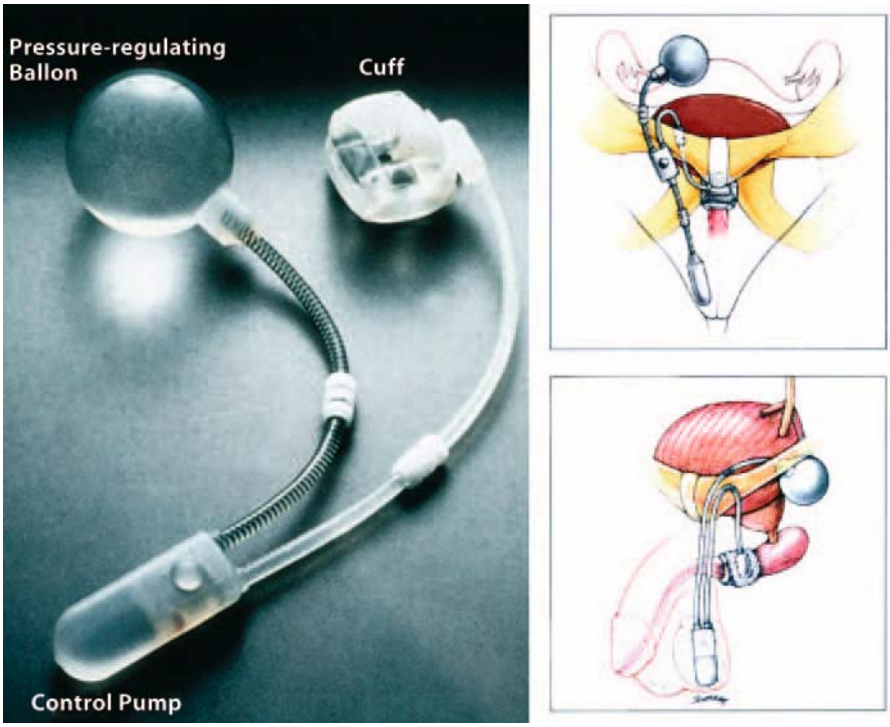


Fig. 17.4. The artificial sphincter implanted in the female and male

that the mobile urethra is the key indication for so-called tension-free vaginal tape. Critical diagnostic tools such as the Q-tip test (Bakas et al. 2002), transvaginal ultrasound, and a lateral cystogram should be performed and if possible, while performing the urodynamic evaluation. In those patients where a fixed urethra is found, a tension-free tape will not cause the needed outflow resistance to make the patient dry. A tape placed with tension might cause long-term erosion or even fistula of the urethra. It appears that the Burch colposuspension does have, in those cases, the best outcome.

No peer-reviewed literature was found in regard to predicting the best surgical choice after the first prior one has failed. Obviously it is preferable to have the highest long-term success rate for the first surgery.

17.21 After a Tension-Free Sling Did Not Bring the Desired Success

For a female patient, after a tension free vaginal tape has been introduced, persistent urinary stress incontinence can be treated with additional bulking agent such as Zuidex (Fig. 17.3) to additionally increase the outflow resistant. Micro-balloons (Fig. 17.5) might be as effective with a lower complication rate compared to the artificial sphincter (picture). The experience of ProACT is still limited and the first multicenter short-term study appears to be very successful (Gilling et al. 2004). This international study group demonstrated in a study with a 2-year follow up that 50% of the patients were cured and the remaining patients had only mild leakage.

17.22 The Sling with Tension

Initial follow-up publications with regard to an adjustable external mechanical regulator (ReMeEx) bladder neck sling are available.(Fig. 17.6) This system, which is used in cases with severe urinary stress incontinence, have a great benefit. The cure rate seems to be between 83% and 96% in 38 patients with a follow-up of approximately 2 years (Sousa-Escandon et al. 2004; Mantovani et al. 2004). With a continued follow-up of additional patients, the outcome will be more accurate. It is also important to ensure that the tension on this sling does not cause fistula or even an obstruction, even though traction is required to close the bladder neck to improve or cure the incontinence.

With severe leakage, an artificial sphincter (Fig. 17.6) is often the surgical choice, although the implant has an almost certain chance of complications. If the urethra and/or sphincter has been damaged by an unsuccessful implant or repair, a vesicostomy will be created with the appendix or an ileum segment using the Mitrofanoff technique. This nipple-pouch or an ileum-conduit might be a suitable alternative and provide the patient with a certain quality of life.

As we have discussed before, the patient needs all available information and the assurance that all questions have been answered in order to determine the pros and cons of the each suggested surgical procedure.

17.23 Urinary Stress Incontinence in Men

The group of male incontinent patients seems to be small, perhaps for two reasons: it is still a taboo subject for the male patient or it does not happen as frequently. Until only recently, the artificial sphincter seems to be an option for the male patient. How-

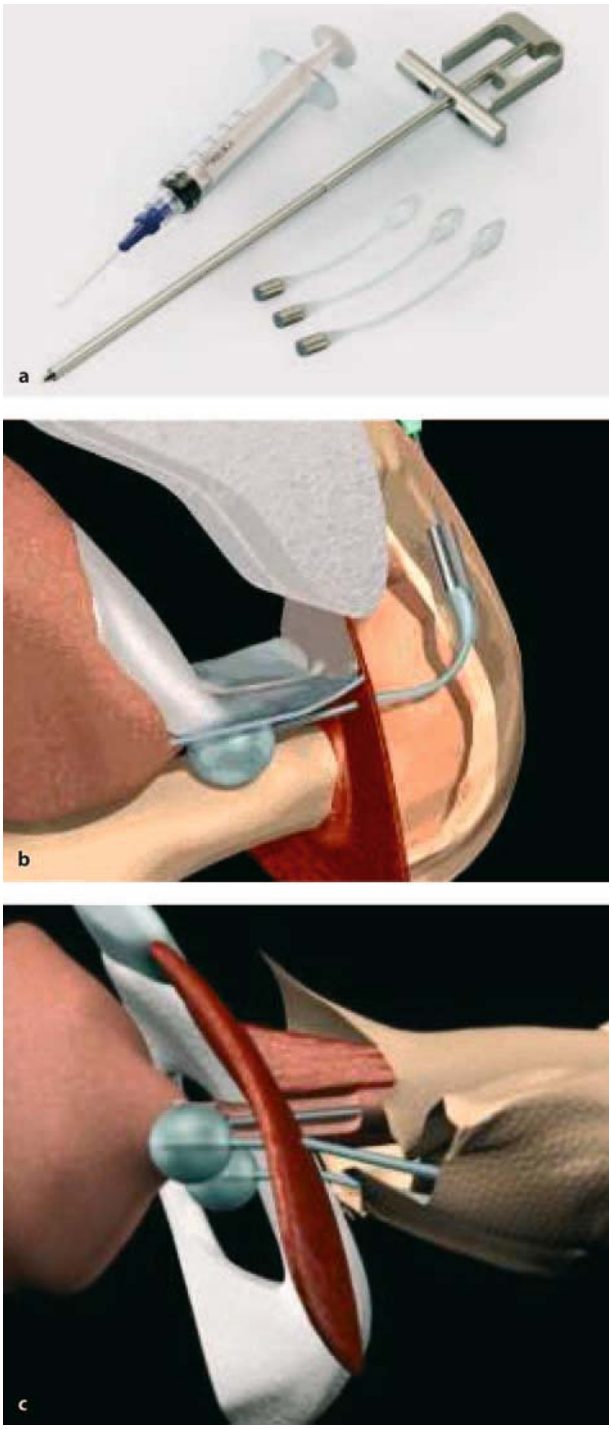


Fig. 17.5a–c.
The micro-balloons (ProACT) and the instruments for implantation (**a**). Implanted ProACT in female (**b**), implanted ProACT in male (**c**)

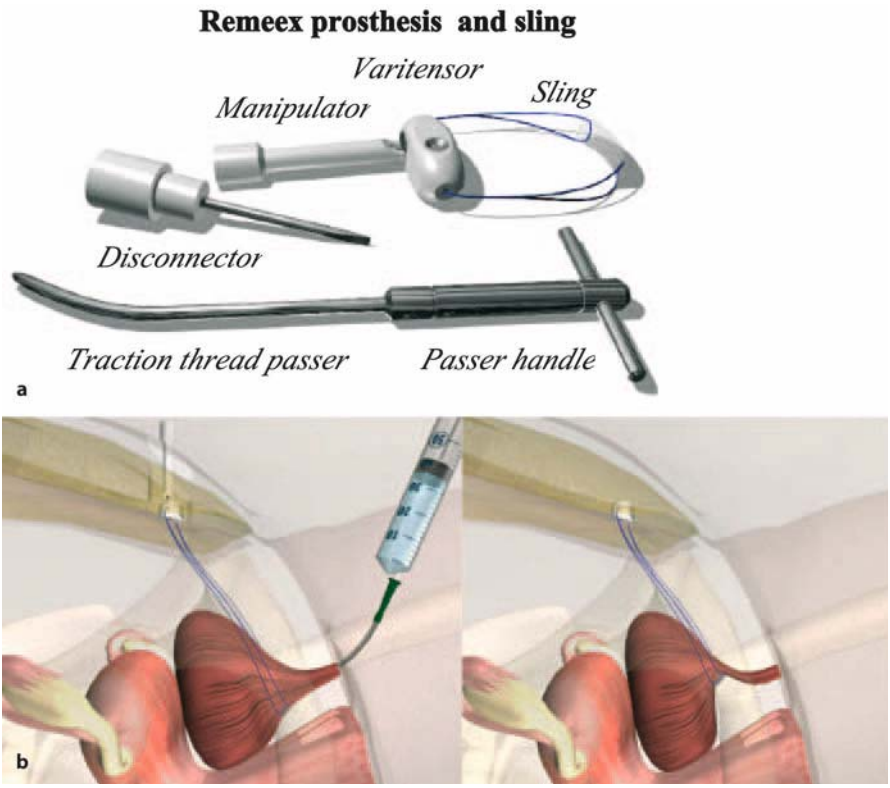


Fig. 17.6a, b. The adjustable external mechanical regulator (ReMeEx) bladder neck sling from Neomedic. **a** The system. **b** Placing the regulator

ever, with the above-mentioned systems there might be another option to treat male urinary stress incontinence. There seems to be no peer-reviewed data available for male urinary stress incontinence with the exception of micro-balloons and the read-just abele sling. During the last years hyaluronic acid, developed for reflux therapy, has been used frequently in male patients after radical prostatectomy to treat urinary stress incontinence. The outcome of this procedure still needs to be substantiated, as well as how many times the patient needs further injections to maintain the result.

The surgical approach, which might be the best, should be evaluated very carefully. It might be difficult to place micro-balloons effectively after radiotherapy or because of scarring. With regards to the other techniques mentioned, no exclusion criteria have been published.

17

17.24 Conclusion

The procedure to choose depends on the findings of the urodynamic evaluation. The best surgical treatment, even with the best urodynamic tools, is hard to choose. The continence mechanism is very complex and not totally understood. Each day, with new information and greater understanding of physiological filling and voiding, the dia-

gram of the mechanism becomes more detailed. In the future, a better understanding of the continence mechanism will be provided by more advanced evaluation tools. These tools will be more precise and help to choose the optimum surgical approach.

Certain uses can help to predict the outcome for the patient.

- Mid-urethral tapes seem to provide excellent results with low morbidity in SUI with urethral hypermobility.
- Type III SUI with a fixed urethra may be best treated with a bladder neck.
- All types of slings can be combined with anterior or posterior prolapse repair.

The patient needs to be informed in detail about the advantages and disadvantages of the varied kinds of SUI treatments. The new slings reduce surgery time but all slings have in common that the patient might have voiding dysfunctions, retention, de novo urge or other side effects until a physiological treatment is discovered and clinically established. New techniques in the near future may include stem cell treatment to restore the functional external urethral sphincter.

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Chapter 18

The Artificial Urinary Sphincter

18

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Contents

18.1 Introduction

Urinary incontinence is a disastrous disease with a severe impact on the social aspects of life. It occurs in all ages but mainly in elderly patients, with an incidence of 17%–55% in females and 11%–34% in males (Thom 2003). The type of incontinence depends on the underlying disease. Of the various causes of urinary incontinence, sphincteric incompetence is one of the most common.

In the male patient, in addition to genuine incontinence, surgical interventions often are responsible for the loss of urine. After radical prostatectomy, urinary incontinence is reported in 0.5%–87% (Hodges 2002; Rudy et al. 1984) of patients. Specialized centers with a high number of interventions report incontinence rates as low as 8%–9% (Walsh et al. 1994). Interestingly, the rates are much higher in nonselected patient groups. Bishoff reported an incontinence rate at 1 year after surgery of 47% after retropubic and of 30% after perineal prostatectomy (Bishoff et al. 1998); the patients were collected based on a cancer registry. Incontinence after transurethral resection of the prostate for benign disease is less common. Stress incontinence is reported to be 2.1%, total incontinence 1% (McConnell 1994). The incidence of stress incontinence following open prostatectomy is 1.9%, total incontinence 0.5% (McConnell 1994). After external beam radiotherapy for localized prostate cancer, an incontinence rate of 1.3% after 5 years was reported (Lee et al. 1996). Other causes for an incompetent sphincter in the male are congenital anomalies such as bladder exstrophy, traumatic rupture of the urethra or neurogenic disturbances.

In the female patient, the yearly incidence of urinary incontinence is approximately 0.6% over the age of 50 (Holtedahl and Hunskaar 1998). The major reason for stress incontinence is genuine. Numerous procedures are available to correct genuine stress incontinence in females, all of which emphasize repositioning of the urethra to allow adequate transmission of intra-abdominal pressures. However, there is a group with recurrent incontinence. Other reasons for an incompetent sphincter in females are, similar to males, congenital anomalies, trauma or neurogenic disturbances.

A number of procedures and devices have been developed for the treatment of total urinary incontinence, one that has been very successful is the artificial urinary sphincter developed by the American Medical Systems, Inc.

18.2 History of the Artificial Sphincter

In 1946, Foley developed a pneumatic artificial sphincter based on the principle of the Cunningham clamp (Foley 1947). An inflatable clamp was placed around the penile urethra connected with a device. In 1972 a new generation of artificial sphincters (AS-721) was introduced by Scott et al. (1973). It consisted of a cuff, a reservoir and two pumps – one for inflating, the other for deflating the device. A set of valves controlled the direction of flow within the system. The cuff was placed around the bladder neck (females, males) and the bulbous urethra (males). This system was used between 1972 and 1974. In the following years, several modifications were made, each model designated with a number (741, 742, 761, 791, 800) (Montague 1981; Scott 1989). One significant change was the use of a balloon rather than valves to control the pressure applied to the urethra, another the implementation of a dip-coated all-silicone rubber cuff instead of a Dacron-reinforced cuff (791 and 800) (Montague 1981; Scott 1989). The disadvantage of all these models was that the bladder neck/urethra was compressed by

the cuff immediately after surgery, increasing the risk for necrosis and erosions (Hald 1986). To avoid these complications, Furlow (1981) propagated a two-staged procedure: only 8–12 weeks after implantation of the device, the tube from the pressure balloon was connected and thereby the sphincter activated. The AS 800, introduced in September 1982 and still the current model, solved these problems (Scott 1985). It consists of an inflatable cuff, a pressure-regulating balloon, a pump and connecting tubes. Initially the cuff was made of Dacron-reinforced rubber; since March 1984 it has been made of specially dip-coated silicone rubber (Scott 1985). It contains a deactivation mechanism. A valve, refill-delay resistor and a deactivation button are incorporated in the pump. The inflatable cuff is available in different lengths.

18.3 Indications and Patient Selection

Urethral sphincter insufficiency with severe (stress) incontinence is the indication for sphincter implantation.

Incontinence should be measured objectively using a *pad test* and should be severe (more than five pads in 24 h) (Perez and Webster 1992). A preoperative *urodynamic investigation* is of utmost importance in order to evaluate the filling and storage phase of the bladder and to exclude detrusor hyperreflexia. A concomitant hyperactive detrusor (urge incontinence) has to be successfully treated prior to sphincter implantation. The maximum urethral closing pressure should be below 30 cm H_2O (Guralnick et al. 2002). Bladder capacity should be sufficient; otherwise bladder augmentation has to be considered. A *voiding cystogram* and a *cystoscopy* exclude infravesical obstruction. There should be no residual urine. In patients with neuropathic lesions, surgery is usually required to decrease outflow resistance and residual urine prior to sphincter implantation. If the patient is willing and able to perform intermittent catheterization, procedures reducing outflow resistance can be avoided.

The upper tract – investigated by *intravenous urography* and/or a *renal function study* should be normal.

Perfusion of the tissue underneath the cuff is important. Any alterations of the blood supply of this tissue such as those caused by irradiation, previous surgery and trauma will increase the risk for erosion. The patient should be mentally and manually able to handle the device.

18.4 Pre- and Postoperative Patient Preparation

Patient preparation is of importance to avoid early infections and should be standardized. The standard used at the AK Harburg follow below:

- Preoperative:
  I. Urine culture should be sterile. Any infection has to be treated.
  II. The day before surgery, the patient starts washing the lower abdomen and genital area with iodine or chlorhexidine solution.
  III. Intravenous antibiotics are given 12 h prior to surgery. Antibiotics with a broad spectrum including Gram-negative bacteria and staphylococcus are preferred.
  IV. Immediately before surgery, the skin is washed with povidone–iodine soap for 15 min. Final skin preparation uses an alcoholic Betadine solution.

- Postoperative:
  I. The sphincter is deactivated.
  II. A small (12F) catheter is inserted at the end of surgery after deactivation but removed within 48 h.
  III. If a drainage had to be inserted it should be removed as soon as possible (best within 24 h).
  IV. Antibiotic treatment is continued until the 5th postoperative day.

18.5 Surgical Technique

For all surgeries, the patient is in a lithotomy position with thighs nearly parallel to the floor so the legs can be moved upward and downward.

Shortly before implantation, all parts of the sphincter (cuff, balloon and pump) are flashed with the last filling solution used. The distal end of the tubes are clamp (bolstered peanut clamps) in order to avoid air bubbles.

18.5.1 Placement of the Cuff

18.5.1.1 Bladder Neck Sphincter

In the female, a vaginal pack is inserted to allow easier identification of the dissection layer for cuff placement. Access is gained to the retropubic space by a low Pfannenstiel incision. The bladder neck and endopelvic fascia are exposed. Palpation of the balloon of the transurethral catheter allows easy identification of the bladder neck. The tissue posterior to the balloon is grasped between the thump and the index finger. If the patient has had no previous vaginal surgery, the plane between the bladder neck and vagina can be created with right-angled scissors. In case of previous surgery, opening the bladder is recommended. Palpation from below and above allows correct identification of the scarred plane and enables dissection without bladder or vaginal perforation. A right-angled clamp is used to pull the cuff sizer through the previously dissected tunnel. Having withdrawn the catheter, the cuff size is determined (normally 6–7 cm). The cuff is easily placed in position underneath the still present cuff sizer.

In males, a transverse lower abdominal incision (Cherney) is preferable to the Pfannenstiel incision as it allows a better exposure of the bladder neck and prostate. After dissection of the bladder neck, the endopelvic fascia is incised lateral to the prostate. Pulling the transurethrally inserted catheter, the exact position of the bladder neck is determined and dissected bluntly below the prostate using the thump and the index finger. The remainder of Denonvilliers fascia is perforated using a right-angled clamp. The sizer is inserted after having enlarged the space, and the exact size of the cuff is determined. The cuff is positioned in the same manner as in females and closed.

18.5.2 Membranous Cuff

A midline perineal incision is made and the bulbocavernosus muscle and the crura of the corpora cavernosa are exposed. The central tendon of the perineal musculature is dissected and the urethra carefully exposed until the muscular layers of the pelvic diaphragm are seen. The diaphragm is split just underneath the bifurcation of the corpora and above the membranous urethra having contact with the pubic bone. Then the urethra is dissected from the pubic bone using a right-angled clamp. After determining the adequate length of the cuff, it is placed around the most proximal part of the urethra, covering the underlying bulbocavernosus muscle. After having sutured the bulbocavernosus muscle to the central tendon, the cuff is located in a position very close to the pelvic diaphragm. This location prevents leakage caused by the patient's sitting on the cuff.

18.5.3 Distal Double Cuff

A perineal midline incision is also made and the bulbocavernosus muscle exposed. Dissection is forwarded in the distal direction. The urethra should be dissected from the corporal bodies over a distance of about 4 cm. Two cuffs, each 4.5 cm in length, are placed around the urethra and closed. Both cuffs have to be positioned close to each other.

18.5.4 Transcorporal Cuff

A distal cuff location is often mandatory in patients after previous erosion or in those requiring revision because of urethral atrophy at the original cuff site. A distal dissection of the urethra increases the risk for urethral injury and erosion. Using a transcorporal dissection, the tunica albuginea is left on the dorsal wall of the urethra, allowing safer mobilization and increasing the size of the tissue being interposed. This technique was described by George D. Webster (Guralnick et al. 2002). The only modification of our technique is the tunica closure of the corpora. In Webster's original technique, the tunica was closed with sutures; in our modification we only cover the corpora defect with a fibrin sponge (Tacho-comb r). A contraindication for this cuff location is normal erectile function.

18.5.5 Placement of the Balloon, Pump and Connection

In patients with a bulbar positioned cuff, an additional small inguinal incision has to be made. The external fascia is incised, the underlying muscle layer split and the peritoneum exposed. Through a small incision, the *balloon* is positioned intraperitoneally. Some surgeons prefer an extraperitoneal paravesical position of the balloon. The dissected layers are closed. The tube leading out from the cuff is threaded subcutaneously from the perineal incision to the inguinal incision and placed over the external inguinal ring. In distal double-cuff patients, both tubes are brought up in the same way.

In patients with a bladder neck sphincter, the balloon is inserted inside the peritoneal cavity, which can be easily accessed by the same incision. Subsequently, the fascia is closed after having placed the cuff and the rectus muscle is readapted. The tubing from the cuff and balloon are brought out separately using a passing tool. The tubing should exit through the full layer of muscles to enter the subcutaneous area.

For implantation of the pump, a subcutaneous space in the inguinal area is dissected free from the underlying fascia. From this point, blunt dissection is carried out down to the scrotum of the male or the labium of the female. The pump should be placed immediately underneath the skin. A long nasal speculum is useful for dissecting an appropriate space and for introducing the pump. The pump is held in position using a Babcock clamp

The balloon is filled with an isotonic mixture of sterile water and radiopaque medium. The hysteresis curve of the pressure-regulating balloon indicates that fairly constant pressure is present with filling volumes of 18–22 ml. Therefore the complicated filling method described by the manufacturer of the AS 800 is not necessary and a simple filling with 22 ml will provide the same device pressure. For a double cuff, 24 ml are used. The tubes are shortened. Connection of the tubes is performed using quick connectors.

18.6 Activation/Deactivation and Function

Deactivation. The artificial sphincter is deactivated immediately after surgery. Therefore the deactivation button on the lateral side of the pump is squeezed. This moves a poppet valve into a locked position so that no fluid is transferred until activation. With the cuff in a bulbar position, the sphincter remains deactivated for 6 weeks. A bladder neck sphincter can be activated earlier when the patient is able to use the pump without pain. Deactivation can be done at any time and is mandatory (with the cuff empty) before any manipulation such as catheterization and urethrocystoscopy (at least in those patients with a bulbar position of the cuff).

Activation. Activation is achieved with a sharp squeeze on the pump, which releases the poppet.

Function. If the system is activated the filled cuff compresses the urethra. Squeezing the pump transfers fluid from the cuff into the balloon. The pressure-regulating balloon begins automatically re-pressurizing, but the resistor of the control assembly delays the refill for approximately 3–5 min and thereby allows bladder emptying.

18.7 Results

The success rate after sphincter implantation ranges between 85% and 95% with a revision rate of 25% over 5–6 years of follow-up.

These results can be achieved in men, women and children. In our opinion, surgery in children should be postponed until after 10 years of life. The defect rate of the artificial sphincter is about 7.6% (Elliot and Barrett 1998). The infection rate for the first implantation is 3%–4%, and for revisions it is higher (9%).

Tissue atrophy underneath the cuff to some degree is unavoidable. In our experience, it is the most common cause of early recurrent incontinence (6–12 months) in

Table 18.1. Review of the literature: women

Author	*N*	Median follow-up (years)	Success	Revisions
Diokno	32	2.5	91%	21%
Mundy	29	?	19%	2%
Webster	25	2.4	92%	0
Norlen	7	5.5	4%	1%
Buzelin[a]	96	2.5	82%	17%
Richard	89	4.2	88%	17%
Schreiter	164	8.7	91%	41%
Total	442		88.8%	24%

[a] Buzelin: implanted and injected material, 1996.

Table 18.2. Review of the literature: men

Author	*N*	Success	Revisions
Barret (1997)	417	88.2%	23.1%
Thomas (1996)	28	86%	28%
Casale (2002)	142	86%	25%
Wilson (2002)	37	66%	
Spiess (2002)	30	83%	40%
Mulcahy (1996)	97	88%	(double cuff)
Schreiter (1999)	369	86%	29%

males (48/321 patients after RRP, 15% in our casuistic) and female patients (22/144 patients, 15.2% of patients).

Despite the introduction of the narrow-backed cuff in 1987, fluid loss due to cuff leakage remained the most frequent late (after more than 5 years) mechanical complication in males (32/321 patients after RRP, 10%) and females (19/144 patients, 13.2%).

Some of the results of the literature are summarized in Tables 18.1 and 18.2.

18.8 Conclusion

The artificial sphincter (AMS 800) is the only model available today. The results achieved are excellent if the indication is correct and perioperative management is careful and adequate. The ideal patient is one with genuine stress urinary incontinence and normal bladder function, although hyper- or hyporeflexia is not an absolute contraindication if treated before or after sphincter implantation. The surgical technique is relatively simple and the only challenge is the choice of the appropriate cuff and reservoir size. Complications include urethral atrophy, erosion, infection and bladder instability. The mechanical failures of the prosthesis have diminished with improved design and manufacturing. Patient satisfaction is high. Currently the only method to treat urinary incontinence in a physiological way is the implantation of the artificial urinary system (AMS 800).

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Part VI

Operative Therapy of Fecal Incontinence

VI

Chapter 19

Sphincteroplasty

Tilman T. Zittel

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Contents

19.1 Introduction

Fecal incontinence constitutes a severe social problem for the person afflicted and reduces quality of life considerably. A rising incidence has been described with increasing age, and it is estimated that about 1%–2% of a Western population suffer from severe fecal incontinence, defined as the involuntary loss of solid stool at least once a week. There is a variety factors that influence continence such as reduced sphincter strength, impaired sphincter integrity, short anal canal length, reduced stool consistency, reduced rectal compliance, reduced anorectal sensation, abnormal rectoanal inhibitory reflex, perineal descent, previous sphincter repair, and mental or congenital disorders. Fecal incontinence can be grouped according to its etiology: traumatic, neuropathic and congenital (Jorge and Wexner 1993). Only patients with a traumatic sphincter defect are candidates for a sphincteroplasty, most of them women after vaginal deliveries, and to a lesser extent patients after accidents or iatrogenic surgical sphincter injuries.

19.2 Diagnostic Evaluation

A careful history should be taken. This includes the symptom duration of fecal incontinence, stool consistency, stool frequency, the estimated time to maximally withhold stool, the frequency of incontinence episodes, whether gas, liquid or solid stool is lost, a careful obstetric history, and whether perianal, anorectal or abdominal surgery has been performed in the past. It might be best to use a structured interview, working up a catalog of standard questions, which might be done by a trained nurse. To quantify fecal incontinence, a grading system according to Parks (0 = perfect continence, 1 = incontinence to gas, 2 = incontinence to liquid stool, 3 = incontinence to solid stool) or a simple scoring system such as the Cleveland Clinic Incontinence Score (0 points = perfect continence, 20 points = total incontinence) should be used. For study purposes, general quality-of-life measures such as the short form 36 (SF-36), and disease-specific quality-of-life measures such as the fecal incontinence quality-of -life scale, which has been endorsed by the American Society of Colon and Rectal Surgeons (ASCRS), might be used (Vaizey et al. 1999; Baxter et al. 2003).

If a reduced stool consistency or frequent diarrhea is reported by the patient, a gastroenterological work-up is necessary, as the treatment of fecal incontinence is frustrating under these preconditions. The patient should be asked for urinary incontinence symptoms as well, as a considerable proportion of patients, estimated as high as 30%–40%, has a combined incontinence problem. In that case, a gynecological or a urological evaluation, and possibly a combined treatment plan is advisable.

The physical examination, best done in lithotomy position on a proctology chair, should include a careful inspection, including the underwear of the patient. Scars, previous episiotomies, a gaping anus or stool soiling might give hints at fecal incontinence. The patients should squeeze and press under visual observation, and the lack of a contractile activity of the sphincter, the use of gluteal muscles during squeezing, the loss of gas or stool, the protrusion of hemorrhoids or rectal mucosa, and an increased pelvic floor descent during straining might be observed. Perianal sensation and the anocutaneous reflex should be assessed, followed by a rectal digital examination to provide information on the resting sphincter tone, the squeeze pressure, or whether a rectocele is present. The puborectalis muscle sling can be palpated dorsally and should

relax during straining. Proctoscopy and rectoscopy allow for inspecting the anal canal and the rectal mucosa visually. In particular, intussusception, which might produce incontinence symptoms such as stool soiling, might be detected during proctoscopy only.

In case of fecal incontinence, we always use endoanal ultrasonography to detect sphincter defects, most being observed ventrally after obstetric injuries (Fig. 19.1). Also, the thickness and the length of the external and internal sphincter muscles can be assessed accurately. Currently, endoanal ultrasonography is the best available tool to define the anatomy of the sphincter apparatus (Cook and McMortensen 1998), and surgery for fecal incontinence should not be considered without it. Unfortunately, the accuracy of endosonography is investigator-dependent, the learning curve being rather flat.

The resting pressure and the squeeze pressure of the sphincter muscles, as well as the length of the anal canal, can be assessed by anorectal manometry. A balloon attached to the tip of the manometry catheter can measure rectal sensation, the compliance of the rectal wall and can detect the rectoanal inhibitory reflex. Although experienced investigators are able to correctly assess sphincter strength by digital examination, a quantification of the sphincter pressures by anorectal manometry is advisable in case surgery for fecal incontinence is contemplated, as it provides proof of reduced sphincter pressures preoperatively. It also provides information for follow-up investigations comparing sphincter pressures before and after conservative or surgical therapy, and manometric squeeze pressure differences have been shown to parallel functional outcome after sphincter repair (Ha et al. 2001).

Defecography, also termed videoproctography or evacuation proctography, can detect internal rectal prolapse (intussusception), which is sometimes difficult to detect on clinical investigation and which might cause stool soiling. Also, the pelvic floor descent during straining can be measured, and rectoceles are easily recognized. The anorectal angle, which contributes to continence and in a way has a valve function, can be measured during rest and straining, and should decrease during squeezing and increase during straining. However, the treatment of fecal incontinence related to sphincter weakness does not necessarily require this investigation (Diamant et al. 1999). We use pudendal nerve terminal motor latency (PNTML) very rarely, as there are very conflicting results regarding the prediction of sphincter repair failure in case

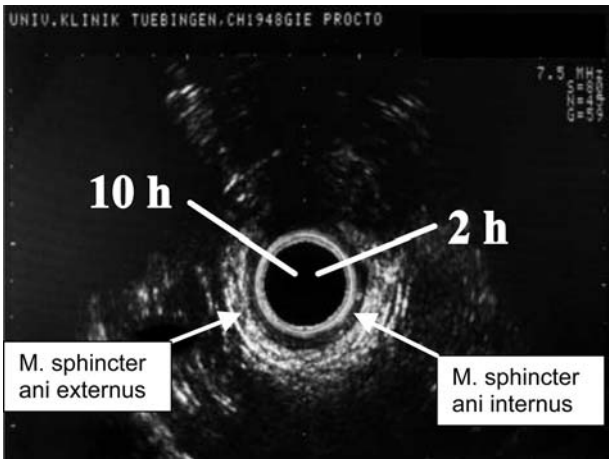

Fig. 19.1.
Endoanal ultrasonography, showing a ventral sphincter defect after obstetric trauma more than 20 years before, extending from 10 h to 2 h in lithotomy position

of a prolonged PNTML (Baig and Wexner 2000), and PNTML has not influenced our decision to perform sphincter repair in the past.

19.3 Operative Technique

A bowel preparation is done with 2 l of polyethyleneglycol (Macrogol), and patients receive low-molecular-weight heparin subcutaneously the evening before surgery. Perioperative antibiotic cover is started with a third-generation cephalosporin and metronidazole when the patient is anesthetized, and continued until the 3rd postoperative day. The patient can be placed in either the lithotomy or prone jack-knife position, the latter of which we prefer. The buttocks are spread to both sides by tapes, and a urethral catheter is inserted and left in place for 3 days. A headlamp might ease the view, although in the jack-knife position, we do not use it routinely. On the operating table, the rectum and the vagina are both flushed with Betadine.

A 180-degree curvilinear incision is made over the defect, most often the perineal body, a flap is raised and the sphincter muscle with its scar is delineated. The skin incision should extend well beyond the sphincter defect. If the sphincter defect results from an obstetric injury, the entire rectovaginal septum is opened. The external sphincter is dissected out best at both sides of the defect first, and no attempt is made to dissect the internal muscle from the external muscle. A division of the sphincter or an excision of the scar is unnecessary (Slade et al. 1977). Direct apposition of the muscle ends is usually performed at the time of injury, while the overlapping sphincteroplasty is the operation of choice in incontinent patients with an isolated sphincter defect detected by endoanal ultrasonography, where the trauma usually occurred years or decades ago (Baig and Wexner 2000; Soffer and Hull 2000). The sphincter is plicated with 4/0 PDS or Prolene sutures, and all sutures are tied once the repair is completed (Fig. 19.2). Overlapping sphincteroplasty is recommended, as direct sphincter apposition has a higher failure rate of about 40% (Blaisdell 1940). In women after an obstetric trauma, both sides of the levator ani muscles are approximated by 4/0 PDS or Prolene sutures once the sphincteroplasty is completed. Bleeding must be controlled meticulously by diathermy, and we inject 2–5 ml of adrenaline 1 : 100.000 at the end of the repair into the operating field. The operating field is cleaned with Betadine before the wound is closed by subcutaneous and skin sutures, both done with 3/0 Vicryl. In case of lost perineum after an obstetric injury, a double Z-plasty can be performed to increase the distance between the anal verge and the introitus vaginae (Keighley 1993). We use one or two 12 Charrière closed suction drains, which are removed on the 2nd or 3rd postoperative day.

The routine use of a covering stoma seems to be unnecessary (Slade et al. 1977; Sitzler and Thomson 1996; Hasegawa et al. 2000), although it might be advisable in redo or technically difficult cases and in patients with a history of perianal sepsis, severe perianal trauma, Crohn's disease or with an increased risk for a wound infection (Scott et al. 1989; Fleshman et al. 1991; Keighley 1993; Baig and Wexner 2000; Soffer and Hull 2000). In that case, a laparoscopic ileostoma might be created first, followed by sphincter repair during the same operation. Injuring the rectal wall during sphincter repair might require a covering stoma as well (Keighley 1993). Postoperatively, the patient is restricted to liquid diet for 3 days, although this might be unnecessary (Nessim et al. 1999). We usually keep the patient in the hospital for 3–5 days postoperatively, although an accelerated stay program for overlapping sphincter repair has been shown to be safe (Rosenberg and Kehlet 1999). We recommend not to bathe for 10 days, but taking

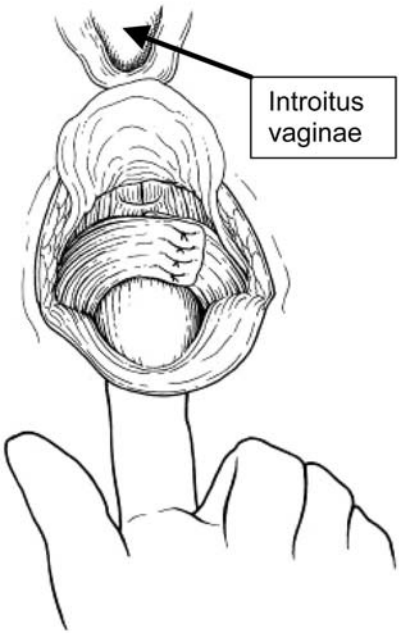

Fig. 19.2. Schematic drawing of overlapping sphincteroplasty. In case of an obstetric trauma underlying a sphincter defect, anterior levatorplasty is performed as well

a shower is allowed. The main threat to a successful outcome is a wound infection, which might render the repair a failure (Keighley 1993). The morbidity is low, usually below 10%, and mortality has been described only rarely in older series (Slade et al. 1977; Fang et al. 1984). Repeat sphincter repairs can be tried if the procedure fails, the previous repair not affecting clinical outcome (Giordano et al. 2002).

19.4 Functional Results

Parks and McPartlin in 1971 first reported their results with overlapping repair (Parks and McPartlin 1971). Usually, satisfactory results are achieved in 70%–80% of patients (Cook and McMortensen 1998; Baig and Wexner 2000). A variety of factors predictive of a treatment failure have been identified, such as age, the duration of incontinence, obesity, a prolonged pudendal nerve latency, an abnormal rectoanal inhibitory reflex, a perineal descent, a previous sphincter repair, a persistent anal sphincter defect, a short anal canal length after sphincteroplasty or an internal anal sphincter defect (Laurberg et al. 1988; Londono-Schimmer et al. 1994; Briel et al. 1998; Cook and McMortensen 1998; Gilliland et al. 1998; Baig and Wexner 2000; Soffer and Hull 2000; Gutierrez et al. 2004). Other studies have refused age, neuropathy and prior incontinence surgery as negative predictive factors (Simmang et al. 1994; Chen et al. 1998; Young et al. 1998; Baig and Wexner 2000; Giordano et al. 2002). As study results are contradictory on the one hand and the presence of a negative predictive factor does not preclude a successful outcome on the other hand (Soffer and Hull 2000), overlapping sphincteroplasty can be offered to most patients with an isolated sphincter defect. The difference in manometric squeeze pressure between pre- and postoperative periods and the increase in anal canal length were both related to postoperative continence (Ha et al. 2001; Hool et al. 1999). Also, the clinical improvement correlated with

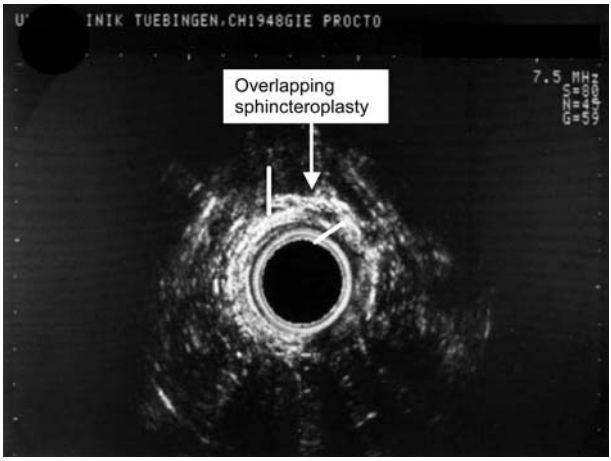

Fig. 19.3.
Endoanal ultrasonography after overlapping sphincteroplasty in the same patient as shown in Fig. 19.1

an improvement in the appearance of endoanal ultrasonography (Fig. 19.3; Pinedo et al. 1999).

Unfortunately, results deteriorate with time (Rothbarth et al. 2000). Beyond 5 years of follow-up, patients are rarely fully continent, and a successful outcome has been observed in 8%–37% only (Malouf et al. 2000; Halverson and Hull 2002; Gutierrez et al. 2004). Nevertheless, 74% of patients remained satisfied with the results of the procedure (Gutierrez et al. 2004), supporting the importance of the patient's view.

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Chapter 20

Dynamic Graciloplasty

20

Cor G.M.I. Baeten, Jarno Melenhorst

Contents

20.1 Introduction

Fecal incontinence is a socially incapacitating condition that generates high treatment costs. It can be treated with numerous therapies. The usual conservative treatments and operations are able to help a high rate of patients, but there are always problems that cannot be solved. Patients who have an absent or a nonfunctional anal sphincter could benefit from a dynamic graciloplasty. Dynamic graciloplasty means a musculus gracilis transposition, which is electrically stimulated.

Almost 60 years ago, Pickrell (Pickrell et al. 1952) described the method to bring a gracilis muscle around the anus in children with anal atresia. With this graciloplasty it was thought that these patients could control their incontinence. In reality it functioned less than was hoped for. The reason for this was that the patients had to contract the gracilis muscle voluntarily. The muscle could sustain this contraction only for a few minutes. Therefore this procedure became obsolete. It took many years before a solution was found.

First physiologists, and later thoracic surgeons (Salmons and Henriksson 1981; Pette and Vrbova 1992; Chachques et al. 1986; Malek and Mark 1989) discovered that a normal skeletal muscle, which consists in the majority of fatigue-prone type II fibers, could change its fiber-pattern by electrical stimulation. This principal applied to the gracilis muscle meant that it was possible to create a nonfatigable neosphincter predominantly consisting of type I fibers. The electrical stimulation also forced the gracilis wrap to contract independent of will. Many surgeons have used this dynamic graciloplasty successfully since 1986 (Baeten et al. 1988, 1991, 1995; Williams et al. 1991; Cavina et al. 1998; Penninckx 2004).

20.2 Indications

Dynamic graciloplasty is indicated for patients with a sphincter defect that cannot be treated by a conventional sphincter repair. This means a defect with such a loss of sphincter muscle that no overlapping Parks repair is possible or in case of a defect in which the muscle remnant is denervated. Also in patients who had anal repair in the past that proved to be non-functional, dynamic graciloplasty can give a solution.

Another indication forms the group of patients with an anatomically intact sphincter but with severe neuropathy. It is possible to treat these patients with sacral nerve stimulation, but when this treatment fails dynamic graciloplasty is an option. Central neurological disorders such as meningomyelocele or cauda equina syndrome also form an indication.

A third group is made up of patients who have no sphincter because of a congenital defect (anal atresia) or an abdominoperineal resection. In these cases one or two gracilis wraps can replace the sphincters and pelvic floor.

20.3 Technique

The technique of dynamic graciloplasty is described by various authors and is in principle almost the same. The patient's skin is prepared at the donor leg, the perineum and the lower abdomen. They receive antibiotic prophylaxis and general anesthesia without muscle relaxants. Epidural anesthesia is also possible.

Then the patients are positioned in lithotomy with the donor leg in a movable stirrup. The draping allows free access to the leg, perineum and lower abdomen.

The gracilis muscle is exposed through an incision in the medial aspect of the upper leg.

At the distal third part of the gracilis, there is overlap of the sartorius muscle, which can act as a reference point. Normally there are one to four peripheral arteries. These are divided and the distal insertion of the gracilis can be freed by blunt dissection under the sartorius below the knee. The tendon can be cut close to its insertion at the tuberositas tibiae. At this stage it can be helpful to make an auxiliary incision below the knee.

The outstretched muscle is then freed of connective tissue, working towards the main artery and nerve. This is invariably found at 8 cm from the origin of the muscle at the frontolateral aspect. Care must be taken not to damage the nerve and vascularization.

Proceeding with the next step in the operation, which is the creation of the tunnel around the anus. Two incisions are made lateral of the anus at approximately 5 cm from the anal verge. Through these incisions one can make the tunnel dorsally from the anus by digital dissection. The reference point of the posterior aspect of the tunnel is the tip of the os coccyx. The frontal tunnel can give problems with blunt dissection. When excessive scar tissue from previous surgery is encountered, an auxiliary incision can be made posterior in the vagina, preventing unintentional perforation of the anorectum.

When the anus is encircled, one has to make a subcutaneous connection between the perineum and the wound in the upper leg. The tunnel created by blunt dissection must be wide enough to allow an unobstructed passage of the biggest part of the gracilis muscle. An entrapment of the muscle is possible, when the passage is too narrow. This will lead to necrosis of the distal part of the gracilis.

To determine which loop configuration will be used; the gracilis muscle must be brought through the tunnels to encircle the anus. When the muscular part is long enough, an epsilon or gamma loop is preferable, in which there is a 360-degree coverage around the anal canal. In case of a short muscular part, one has to settle for an alpha loop (Geerdes et al. 1996).

The distal tendon of the muscle is attached to the contralateral side of the pubic bone if it is a gamma or epsilon loop. An alpha loop is the result of attaching the tendon to the ipsilateral side. Thus, a gamma loop passes the anus first at the frontal, then at the dorsal and again at the frontal side. An epsilon loop goes first dorsally then frontally and again dorsally of the anus, and an alpha loop passes first frontally and then dorsally of the anus.

It is important that the tendon of the gracilis will be attached to the periost of the ramus inferior of the pubic bone, behind the bulk of the muscle and not in front because this would produce an entrapment of the gracilis.

At this stage one has to make a choice whether to proceed with the implant of the electrodes and the implantable stimulator immediately or to delay the implant to a later date. In the latter case, the tendon of the gracilis can be sutured to the periost with a nonresorbable suture and the wounds can be closed.

When the implant is done immediately, it is best to retract the gracilis muscle again into the wound in the upper leg.

Two electrodes, one positive and one negative, are implanted in the outstretched muscle near the side of the entrance of the main pedicle nerve and are connected to a temporary stimulator. The most optimal location of the electrode placement is found

at the location where the muscle contracts firmly with stimulation at a very low voltage. When this spot is found both electrodes can be fixed to the epimysium of the muscle.

Now the gracilis can be brought again in the chosen way around the anus and the tendon is sutured to the periosteum of the ramus inferior of the pubic bone.

The electrodes can now be tunneled to a pocket in the lower abdomen at the same side as where the gracilis was taken. This pocket is made through an incision in the lower abdomen and created underneath the fascia of the musculus rectus abdominis.

Both electrodes can now be connected to an implantable stimulator (IPG) and the stimulator is placed in the pocket, which is closed after irrigating the wound with antibiotics. All skin wounds can now be closed and the operation is completed.

An alternative for the electrode implant is to use one epineural electrode. For this, the nerve leading to the gracilis has to be freed over several centimeters and a quadripolar electrode is sutured over the nerve to the fascia of the underlying muscle.

As mentioned before, the implant can also be done at a later phase. The gracilis muscle then has to be freed again at the spot where the gracilis is plicated in the upper leg. The implant of the electrodes is the same as is described above but now not in the outstretched but in the plicated gracilis. The contractions of the muscle can be seen in the wound or felt around the anus.

During the creation of the tunnel, if an unintentional perforation of the anal canal is made a two-staged operation rather than a single-phase operation should be done.

The risk of infecting foreign material is high after a perforation. This is a serious problem, often requiring re-operations. It must be avoided in all cases.

It is also possible to do this procedure after abdominoperineal resection for patients with rectal cancer. The resection has to be followed immediately by a pull-through of the descending colon to the perineal skin. It is important to do this pull-through in the same operation as the resection because a secondary procedure could lead to many complications. The distal end of the colon (neorectum) can now be encircled by one or two gracilis muscles. Both muscles can be stimulated by implantation of one electrode in each muscle. And both electrodes are connected to one stimulator (Geerdes et al. 1997).

20.4 Stimulation of the Gracilis Muscle

The stimulation period should not be commenced immediately. After the operation it is best to rest the gracilis muscle some for 2–4 weeks and leave the stimulator switched off. After this rest period, the muscle should be trained. The stimulator can be switched on in a frequency of 2.1 Hz. This will give intermittent contractions of the muscle and is felt by the patient as a twinkling but not unpleasant feeling. The voltage can be programmed so that an increase in anal pressure is measured of at least 20 cm Hg. The programming of the implanted stimulator is done telemetrically and can be done in an outpatient department. After the first 2 weeks of stimulation, the frequency is increased to 5.2 Hz and after 2 weeks again to 10 Hz. Every time anal manometry is performed one must be sure that a sufficient pressure increase is found. Over time it is likely that the voltage will have to be increased to provide the desired pressure, while the muscle changes gradually from type 2 into type 1 fibers. The type 1 fibers are non-fatigable but also less forceful than the type 2 fibers and need a higher voltage to result in the same contraction force of the whole muscle. Another reason for the necessity to increase the voltage is the fibrosis formed around the tip of the electrodes, leading to

higher resistance at the side of muscle contact. This demands a higher voltage to give the same effect on the muscle contraction. This increase in voltage will continue over about 6 months and then reaches a plateau that will probably remain for a lifetime (Rongen et al. 2001).

Experience in hundreds of patients has shown that with this training program the muscle really changes into a predominantly type 1 muscle that is able to contract without fatigue. The changes in the muscle can be proven with a simple test: a normal skeletal muscle will show a flat contraction with a stimulation frequency of 25 Hz. A stimulation-changed muscle shows a flat contraction with only 10 Hz. The changes were also proven by biopsies of the muscle, which showed an enormous decrease of type 2 fibers and an increase in type 1 fibers (Baeten et al. 1988). The stimulation of a gracilis muscle changes the fiber pattern into a fiber composition that can give a nonfatigable long-term contraction independent of brain input. In this way, it replaces the function of the original anal sphincters.

The muscle contraction is maintained by the stimulation and results in a closure of the anus. To open the anus the stimulator can be switched off with a handheld programmer by the patient. This results in a relaxation of the gracilis and enables defecation. After passage of stool, the stimulator can be switched on again to close the anal canal.

20.5 Results

It is difficult to compare the results of dynamic graciloplasty since various authors use different criteria for success. Most of them define success as reaching a level of continence of 1 or 2 on the Williams scale. This means normal continence or occasional loss of flatus. Others define success as a more then 50% reduction in incontinence events.

In one fairly large multicenter study (Baeten et al. 2002), in which all the data from different clinics were obtained in a prospective matter, the overall success rate was 62%. The success rates of single-center studies vary from 56% to 74% and are shown in Table 20.1.

Table 20.1. Success rates for dynamic graciloplasty

Author	Year	Number	Success (%)	Infection (%)
1. Baeten et al.	1995	52	73	12
2. Wexner et al.	1996	17	60	–
3. Cavina et al.	1998	31	85	–
4. Mander et al.	1999	64	56	–
5. Rongen et al.	1999	7	71	–
6. Madoff et al.	1999	128	66	32
7. Baeten et al.	2000	123	63	15
8. Rongen et al.	2001	26	72	5
9. Konsten et al.	2001	81	57	15
10. Konsten et al.	2001	200	74	4
11. Penninckx et al.	2004	60	72	15

20.6 Complications

Although the results are good for the majority of the patients, it is obtained at the cost of several problems that had to be solved (Geerdes et al. 1996). One of the most frequently mentioned complications is infection. This is a combination of inflammatory problems at several sites of the operation. There are infections reported at the donor-leg wound. These can be treated in a conservative way, and have no influence on the functional outcome of the dynamic graciloplasty. Infections around the anus are frequently seen and can be treated by drainage and irrigation of the wounds and do not interfere with success unless they are caused by a perforation of the anorectum. Infections at the site of the pocket always require removal of the stimulator, since it is an infected foreign body. This is not the end of the procedure because the IPG and electrodes can be reimplanted again when the infection is healed. A vital muscle normally survives an infection.

No contraction or insufficient contraction of the gracilis can have several causes, grossly divided in two subgroups. The first group consists of patients who are not capable of voluntarily contracting the gracilis muscle. This is a problem of the muscle itself.

One of the causes is a detachment of the distal tendon. Reattaching the tendon to the pubic bone can easily solve this. It can also be caused by fibrosing or necrotizing of the distal end of the gracilis. In this case, this gracilis can no longer be used and the only solutions are a graciloplasty of the other side or an artificial bowel sphincter implant.

The second group consists of patients whose gracilis muscle contracts voluntarily, but this contraction cannot be obtained with stimulation. This must be a problem of the stimulation. One of the reasons for such a problem could be an empty stimulator. Replacement is the solution. Another cause is the dislodgement of the electrode out of the muscle. The electrode should be reimplanted to solve this problem. In a very few cases, the electrode breaks; this can also be solved by renewal of the electrode.

In several patients, incontinence changes into constipation after dynamic graciloplasty at the same rate as we see also after sphincteroplasties or artificial bowel sphincters. The reason for this constipation is almost never a narrowing of the anus, and the cause remains unclear. Dietary modifications and medications together with retrograde colonic irrigation facilitate the passage of stool.

A serious complication is an erosion or perforation through the anorectum. This always causes a serious infection. The best way to proceed in such a case is to give the patient a protective colostomy and to close the defect in the rectum. Care must be taken during preparation and suturing of the tendon. This should not be too tight; otherwise there is a higher risk of perforation due to erosion.

All in all the number of complications is high, but almost all of them are treatable.

20.7 Discussion

Dynamic graciloplasty is a good treatment for patients with incontinence who have no other options. One has to keep in mind that this therapy only restores sphincter function, but has no influence on other reasons for incontinence. For instance, patients with an extreme urge or a nondistending rectum or neorectum or those with nontreatable diarrhea will probably not benefit from a dynamic graciloplasty alone. It can be

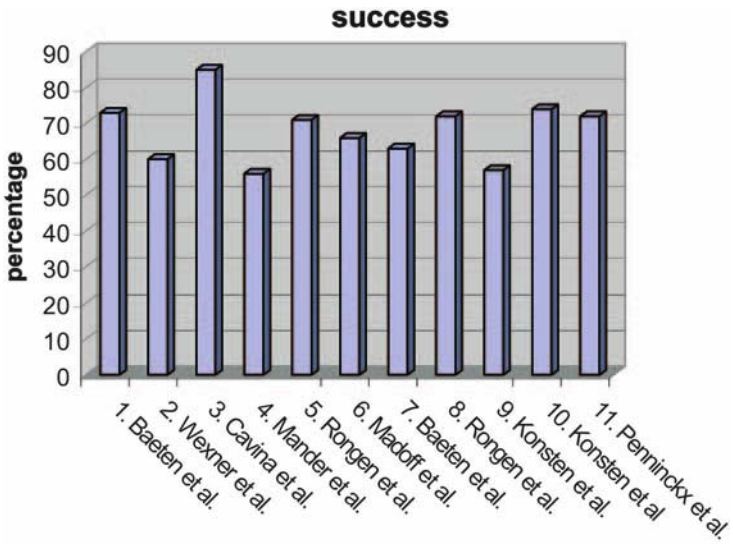

Fig. 20.1. Success rate after dynamic graciloplasty

difficult to evaluate patients with multiple causes for incontinence, and restoring one of the causes will not automatically lead to the solution of the problem of incontinence. Many operations such as anal repair, artificial bowel sphincter and dynamic graciloplasty are considered to be a failure when the patient is not continent, but one has to look for other causes. The function of the sphincter or neosphincter should only be judged after carefully observing all of the problems, before one says that the operation has really failed.

20.8 Conclusion

For the group of patients with severe fecal incontinence due to sphincter malfunction, dynamic graciloplasty forms a good alternative. It is successful in the majority of patients (Table 20.1, Fig. 20.1). Therefore, colostomy is no longer the endpoint of fecal incontinence.

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Chapter 21

The Artificial Bowel Sphincter in the Treatment of Severe Fecal Incontinence in Adults

21

Guillaume Meurette, Paul-Antoine Lehur

Contents

Fecal incontinence is a severe disability that deeply affects the quality of life of the afflicted patients. In the event of ineffective medical treatment and the inability or failure of conventional surgery, the only choice for these patients until recently was to accept their condition or opt for end-colostomy. However, technological progress has opened up the prospect of effective therapy for severe fecal incontinence, both in terms of performance and long-term reliability. Replacement of the sphincter function by an artificial bowel sphincter is one of the options presently available that has shown promising results.

This study aims to provide an overview on the management of fecal incontinence by the means of an artificial sphincter, describing the device and its functioning, the present state of art of the implantation technique and recommendations to follow-up of patients with implants, the most recently published results, and the present indications and contraindications of this treatment.

21.1 Background

Various passive prosthetic methods of anal encirclement have been proposed for the treatment of fecal incontinence since the initial description of Thiersch's wire more than a century ago. The impossibility of achieving an anal opening led to abandoning these methods, which in any event never gave good results. However, these techniques provided the rationale for prosthetic treatment of fecal incontinence, which only proved successful once a mechanism was added to allow anal opening. In the 1970s, urologists developed different models of sphincter devices positioned around the urethra or the bladder neck, which were pressurized and could be opened by a control pump. In 1987, the first use of a urinary artificial sphincter (AMS 800, AUS) in the perianal position was reported from Copenhagen, Denmark (Christiansen and Lorentzen 1987). French experience with anal devices began in 1990 in our center, thanks to the know-how acquired by Prof. J.M. Buzelin, a urologist who had been using the AUS for urinary incontinence since 1985. Our first results with this device were published in 1996 (Lehur et al. 1996).

The development of a device specifically adapted to anal application, the Acticon ABS (artificial bowel sphincter, American Medical Systems, Minneapolis, MN, USA), was the next important step. The first implantation of this new device was performed in Nantes, France, in May 1996. Since this time, experience has been acquired in numerous expert centers worldwide. In the US, FDA approval for the use of the device was obtained in 1999 after completion of a multicenter trial (Wong et al. 2002).

At the same time, Scottish surgeons developed a sphincter device similar in its pressurization concept but of different design, being semicircular and providing an anorectal angulation to restore sphincteric mechanism (Hajivassiliou et al. 1997).

21.2 Description of the Acticon ABS Artificial Bowel Sphincter

The Acticon ABS artificial bowel sphincter is a totally implantable device made of solid silicone rubber. It comprises three parts: a perianal occlusive cuff, a control pump with a septum, and a pressure-regulating balloon (Fig. 21.1). These three components are linked together by subcutaneous kink-resistant tubing.

The occlusive cuff is implanted in the upper part of the anal canal. The closing system incorporated into the cuff uses the initial part of the tubing. The cuff comes in

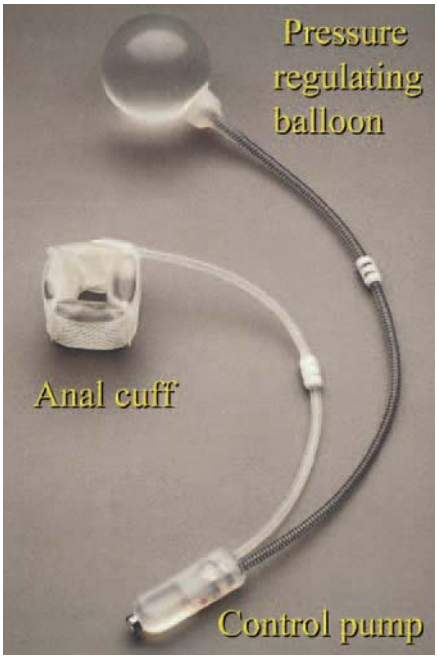

Fig. 21.1.
Overall view of the Acticon ABS artificial bowel sphincter used in the treatment of severe fecal incontinence

different models with respect to length (8–14 cm) and height (two sizes: 2.0 and 2.9 cm) (Table 21.1). The choice of the cuff, an important intraoperative consideration, is determined by measurements made during the implantation procedure.

The pressure-regulating balloon, which is implanted in a pocket created in the subperitoneal space, controls the level of pressure applied on the anal canal by cuff closure. Available pressures range from 80 to 120 cm H_2O, with 10-cm steps (Table 21.1). Thus, the occlusive effect of the cuff depends on its size (length and height), which determines whether it fits more or less tightly around the anal canal, and the pressure level chosen for the balloon.

The control pump is implanted in subcutaneous tissues of the scrotum in men and of the labia majora in women. The hard upper part of the pump contains a resistance regulating the rate of fluid circulation throughout the system and a deactivation button allowing fluid cycling to be stopped by external action. The soft lower part of the

Table 21.1. Comparison of urinary (AUS) and anal (Acticon ABS) artificial sphincters

Components and Function	AUS	Acticon ABS
Cuff height (cm)	2.0	2.0, 2.9
Cuff length (cm)	3–11	9–14
Balloon volume (cc)	20	40
Pressure generated by the balloon (cm water)	40–90	80–120
Septum on the control pump	No	Yes
Reocclusion time lapse (min)	3–4	5–8

Note the changes made in the device to adapt it to restoring anorectal function.

pump is squeezed repeatedly to transfer fluid within the device. A septum placed at the bottom of this soft part is intended for postoperative use in case a small amount of liquid needs to be injected or withdrawn. The principle of this septum is similar to that of an implantable Porta-Cath.

21.3 Functioning of the Acticon ABS Artificial Bowel Sphincter

The function of the Acticon ABS is semi-automatic (Fig. 21.2):

- The cuff ensures anal closure automatically and continuously at low pressures close to physiological values (resting anal pressures). The regulating balloon transmits pressure to the occlusive cuff through the tubing, and the pressure is applied uniformly and nearly circularly to the upper part of the anal canal, restoring a barrier isolating the rectum from the external environment.
- Defecation is initiated by the patient. Anal opening is achieved by transferring the pressurized fluid from the cuff toward the balloon by means of the control pump. The fluid is transferred by 5–15 squeezes on the pump, each evacuating around 0.5 cc from the cuff, thereby lowering anal pressure and opening the anal canal to expel feces. Suitable compliance allows the volume of the pressure-regulating balloon to increase transiently to receive the several cubic centimeters of fluid contained in the cuff.
- Anal closure occurs again automatically in 5–8 min by passive fluid transfer and a progressive return to base pressure in the cuff. The balloon recovers its initial volume during this period, thereby restoring equal pressure throughout the system.

The system can be deactivated temporarily to allow the cuff to be empty and the anal canal continuously open. This arrangement can be used during the postoperative period to avoid manipulation of the cuff and pump during the healing period. Two months of deactivation are desirable after implantation to ensure good integration of the device. The system can then be activated simply by squeezing the pump firmly, a procedure not requiring anesthesia that can be performed during a visit. Deactivation of the cuff in open position is also necessary for transanal endoscopic procedures in order to avoid any erosion or damage to the cuff during the passage of the endoscope. Deactivation is a recent feature, and its absence in earlier models was responsible for some initial failures.

21.4 Implantation Technique – Perioperative Care

Preoperative care includes careful cutaneous and bowel preparation over a 48-h period. Two douches of the operative field are performed daily with an iodinated solution, and complete colonic preparation is done, including X-prep and enemas until fluid becomes clear. Colostomy is not essential if correct bowel preparation can be obtained, except in the case of diarrheic patients who may contaminate the perineal wound by too rapid a resumption of bowel movements. This position has now been adopted by the vast majority of the teams implanting Acticon ABS. Antibiotic prophylaxis based

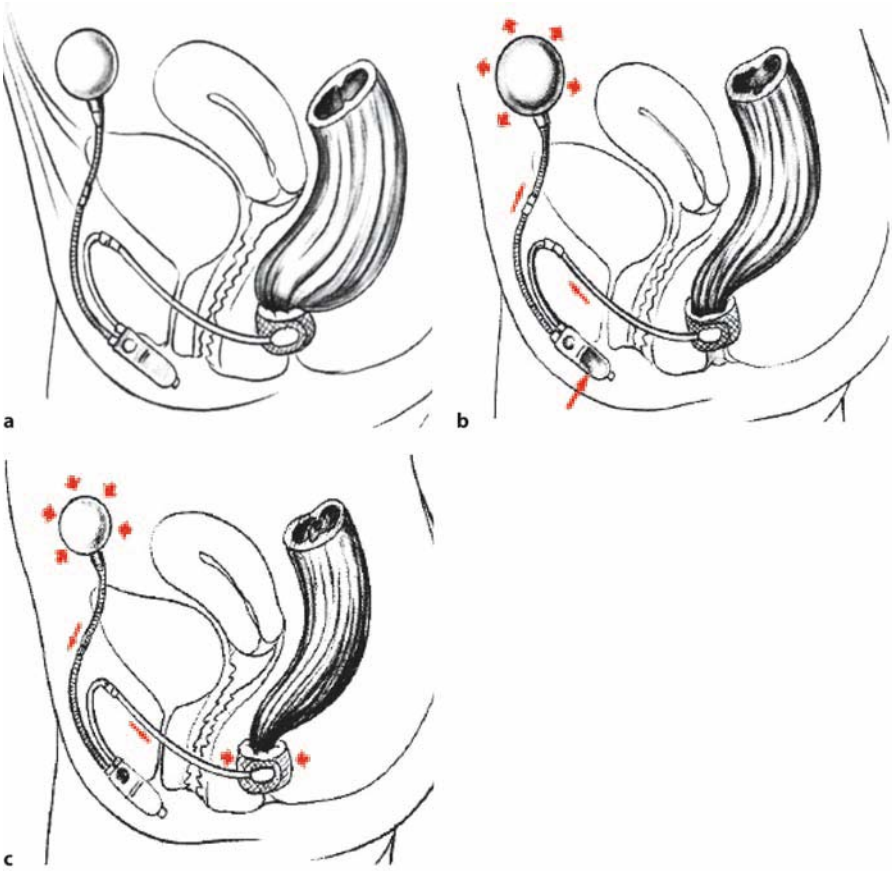

Fig. 21.2a–c. Functioning of the Acticon ABS artificial bowel sphincter. **a** Anal occlusion. Pressure is equilibrated throughout the system, ensuring pressurization of the cuff and thus automatic closure of the anal canal at a predetermined pressure level approximately equal to that of the pressure-regulating balloon selected for implantation. **b** Anal opening, which is controlled by the patient, allows regulated rectal evacuation. The pressure equilibrium in the system is interrupted by the active transfer (manipulation of the control pump) of the fluid from the cuff to the pressure-regulating balloon. **c** Progressive anal closure (*arrows* indicate the direction of fluid transfers within the system after defecation). Automatic return of the fluid (in approximately 7 min) gradually restores cuff inflation and anal closure pressure

on a third-generation cephalosporin and an aminoglycoside is administered in a single dose at the induction of anesthesia.

The operative position of the patient should allow a combined perineal and abdominal approach. The legs should be spread and half-flexed, allowing access to the anus, the scrotum or the vulva, and the subumbilical abdominal level. The first phase of the operation involves the placement of the perianal occlusive cuff. A single preanal incision can be used, allowing rectovaginal or rectourethral separation (5–6 cm high), from which a perianal tunnel can be created around the anal canal by blunt finger dissection. Alternatively, the incision can be made laterally on both sides of the anus, following the example of graciloplasty. A transvaginal approach has also been proposed recently. The length of the occlusive cuff is then determined using a specially designed

sizer. The cuff should not narrow the anal canal, which would hinder defecation. Rectal examination is the best means of determining the caliber obtained. In the event of accidental perforation of the vagina or the rectum at this point in the dissection, implantation of the artificial sphincter should be deferred or possibly abandoned.

Once the perianal tunnel has been made, the preparation of the Acticon ABS device can begin on a sterile table intended for this purpose. Tissues, blood, and any potentially aggressive surgical material are excluded from this area in order to avoid possible alteration of the device. All three components of the system are carefully bled of any air bubbles, which might prevent the cycling of the pressurization fluid. This rather delicate preparation should be entrusted to a nurse trained in the technique. The pressurization fluid is an isotonic solution, since the walls of the artificial sphincter are semipermeable membranes, and radiopaque to allow postoperative control of fluid movements in the system. It is prepared extemporaneously and composed of Telebrix 12 Sodium (53%) and sterile water (47%) in our practice. Other possible solutions are described by American Medical Systems.

The perianal cuff is the first component put in place. Tubing from the cuff is then tunneled subcutaneously to the abdominal incision with a special atraumatic long needle. The rectus abdominis is split to provide access to the subperitoneal space lateral to the bladder. A pocket is created in this space to lodge the pressure-regulating balloon. The cuff is first pressurized with a 55-cc filled balloon connected directly to the cuff. The amount of fluid kept in the cuff after pressurization is carefully measured when emptying the balloon. It is usually between 4 and 8 cc. The balloon is then implanted empty and then filled in its lodge with 40 cc of fluid, a volume at which the pressure delivered to the cuff corresponds to values determined by the manufacturer (usually between 80 and 100 cm of water). The aponeurosis is carefully closed at this step. The control pump is then positioned. As this is the only component that the patient will feel and manipulate, it needs to be perfectly accessible. The occlusive cuff and the pressure-regulating balloon are connected to the pump. The kink-resistant tubes are identified by a color code (black from the balloon and clear from the cuff). Connections are done with special Quick-connectors, preventing any air bubbles from entering the system. After assessing that cycling is correct, the incisions are closed without drainage. The device is deactivated at the end of the procedure by pressing firmly on the deactivation button. In our experience, the entire procedure lasts around 90–120 min.

Immediately after the operation, a fluid diet only is allowed for 3 days to avoid too early a resumption of bowel movements. The anal wound is cleaned regularly. The mean length of hospital stay is 7–10 days if there are no complications. The patient is discharged once defecation has become normal and the incisions are healed. The patient is readmitted 8 weeks later for 1 day during which the artificial sphincter is activated. A firm pressure on the control pump unblocks the deactivation button, allowing the filling of the cuff, which can then play its occlusive role. The patient is given the necessary instructions for opening the sphincter, allowing regular defecation, possibly initiated with small enemas in case of difficulty.

21.5 Recommendations for Follow-up of Patients with Implants

Is it necessary to follow-up patients who have received implants? This is a debatable point since the device is easy to operate and its use rapidly becomes natural for the patient. The patient could be instructed to return in the event of recurrence of inconti-

nence, which would be a good arrangement for persons living far from the implantation center. However, we require regular follow-up for our patients, not only for research purposes but also to check on the proper use of the device, its efficacy in restoring satisfactory anorectal function and the possible occurrence of complications. Postoperative evaluation is based on simple annual examinations (clinical, plain X-rays and anorectal manometry).

Clinical evaluation relative to fecal continence and rectal evacuation is performed best by questionnaires. The efficacy of the device in restoring satisfactory quality of life can also be assessed by specific questionnaires. Such evaluations currently in progress appear to justify the financial investment involved in the use of artificial sphincters (Lehur et al. 2002). The clinical examination checks the proper positioning of the control pump and its accessibility, the efficacy of anal closure (by rectal exam, care being taken not to damage the device), and the quality of anal opening after manipulation of the pump by the patient. The local tolerance of the artificial sphincter is also checked. It is important during the first postoperative months to detect any migration of the cuff. If it is too close to the anal margin, there is risk of skin damage and erosion, leading to contamination of the material and explantation. If detected early enough, this complication can be corrected by reoperation and repositioning of the cuff higher in the pelvic floor. This can be achieved by redoing the perineal incision and simply unbuttoning the deactivated cuff.

Pressurization of the Acticon ABS with a radiopaque fluid allows very simple radiological monitoring. In the immediate postoperative period, deactivation of the device can be easily checked by plain X-rays focused on the pelvis. During activation, a series of X-rays can be used to analyze fluid transfers through the device and thus visualize the sphincter function obtained (Fig. 21.3). These images can also be used for reference purposes in the event of subsequent dysfunction of the device. Endoanal ultrasonography can also be performed during the monitoring procedure. This examination, though not carried out routinely, is considered to be a valid means of assessing the thickness of the tissues encircled by the cuff and detecting any possible atrophy, which would be suggestive of ulceration of the device in the anal canal.

Anal manometry, an important aspect of postimplantation monitoring, precisely and objectively estimates the efficiency of the sphincter(Savoye et al. 2000). We con-

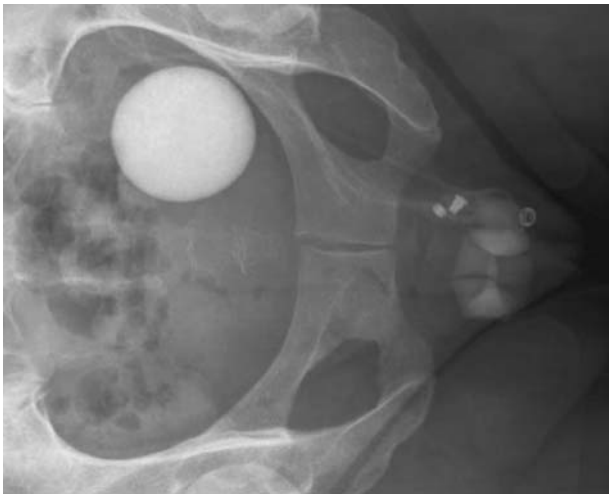

Fig. 21.3.
X-rays of an Acticon ABS artificial bowel sphincter implanted for postoperative fecal incontinence. Filled occlusive cuff with a closed anal canal

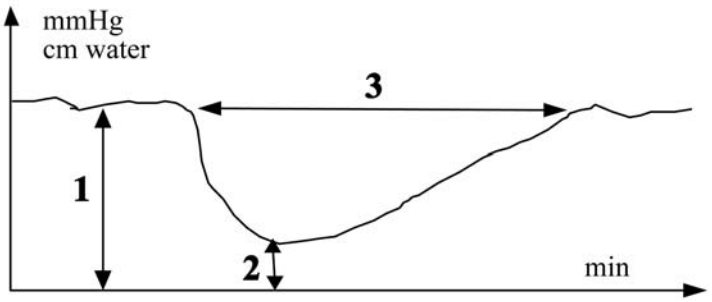

Fig. 21.4. Anal manometry: normal function of an Acticon ABS artificial bowel sphincter Measurements performed during the examination: (*1*) resting anal pressure with the cuff closed (pressurized), (*2*) resting anal pressure with the cuff open (empty), (*3*) time of anal closure

sider that it is important to determine three manometric parameters systematically (Fig. 21.4):

- Basal pressure with the sphincter closed indicates the capacity of the device to create a high-pressure zone in the anal canal. A significant increase as compared to preoperative values contributes to restoring fecal continence.
- Basal pressure with the sphincter opened by the patient represents residual anal pressure. When low, it is indicative of a wide anal opening and easy defecation, whereas a high residual pressure could account for postoperative dyschezia.
- The time required for the sphincter to close again after being opened is also indicative of the quality of rectal evacuation. A sufficient period is needed to obtain complete emptying. Some patients experience a rapid closure quicker than that specified for the Acticon ABS (approximately 7 min normally), which may be also responsible for dyschezia.

Anal manometry can be also used to check whether the patient is manipulating the device correctly. The quality of the pumping, which needs to be slow to be efficient, and of the resulting anal opening can be evaluated on a screen image for the benefit of the patient, as during biofeedback sessions.

21.6 Recently Published Results

The initial results obtained with the urinary type device have been previously reported and discussed. In this review, we have concentrated on the most recent and significant published data. Several centers in Europe, the United States and Australia have adopted the Acticon ABS to treat severe fecal incontinence not amenable to local repair. Reports with larger numbers of cases and longer follow-up have recently appeared, providing a better assessment of this innovative technique and its present place in the treatment strategy of incontinent patients.

21.6.1 Recently Published Results with the Acticon ABS and Personal Series

We have analyzed the most recently published experiences with the Acticon ABS and reviewed our own series of 32 patients (37 implants) in our institution, regarding the main outcome endpoints including infection rate, revisional surgery and explant rate (Table 21.2). The overall incidence of permanent explantation of the Acticon ABS in the published series varies between 17% and 31% with follow-up periods of between 10 and 58 months. Revisional surgery with replacement of part or the entire device has occurred in between 7% and 25% of the patients. The complications leading to explantation include perioperative infection, failure of wound healing, erosion of part of the device through the skin or the anal canal, late infection and mechanical malfunction of the device due to cuff or balloon rupture. As far as function is concerned, successful results were obtained respectively in Spain, Italy, Minneapolis, MN (USA), Rouen (France) and for us, in 15 out of 24 (62.5%), 21 out of 28 (75%), 17 out of 35 (49%), 22 out of 30 (73%) and 23 out of 32 (72%) cases. As others, we have found improvement in quality of life after implantation of Acticon ABS. In a series of 16 patients consecutively receiving implants, with a follow-up of 25 months, a significant improvement in the four separate quality-of-life domains explored in the Fecal Incontinence Quality of Life Scale score was recorded, with a linear correlation between the improvement over time in the quality-of-life index and the evaluation of continence measured by a clinical score (Lehur et al. 2002).

The results from the multicenter cohort study conducted under FDA supervision showed an 85% functional success rate in patients who retained their artificial sphincter (Wong et al. 2002). Of 112 patients included in the trial, 51 (46%) required a revisional operation, primarily because of infection and 41 (37%) required complete explantation. Accordingly, the overall intention-to-treat success rate was finally 53%, but this includes for a majority of the centers their initial experience with the device. Parker and co-workers (2003) reported data from the University of Minnesota, one of the leader groups in the use of the artificial bowel sphincter. They identified two patient groups: those who received implants between 1989 and 1992 (n=10; mean follow-up, 91 months) and those who received implants between 1995 and 2001 (n=37; mean follow-up, 39 months). The overall success rate in the former group was 60% (4/10 explants). The latter group had an overall success of 49%, with a revision and infection rate of 37% and 34%, respectively. Those patients who had successful implant procedures enjoyed a 100% functional success rate at 2 years.

Table 21.2. Results with the Acticon ABS artificial bowel sphincter

	N	Infection rate (%)	Revisional surgery (%)	Explant rate (%)	Mean FU (months)
Wong et al. (2002)	112	25	46	37	18
Ortiz et al. (2002)	22	9	50	32	26
Altomare et al. (2001)	28	18	32	25	19
Parker et al. (2003)	37	34	37	40	39
Michot et al. (2003)	25	7	28	20	34
Our series (unpublished)	32	0	53	31	26

Acticon ABS has also been recently evaluated in a format of randomized control trial (O'Brien et al. 2004). The authors compared a group of 14 patients randomly assigned to Acticon ABS to a similar group entering a program of best supportive care for fecal incontinence. Explant occurred once in the operative group (14%). Improvement at 6 months was significant in the Acticon ABS in terms of continence, and not in the control group. The Cleveland Continence Score was significantly altered in the Acticon ABS group (preoperative value, 19; postoperative value, 5%–75% overall improvement) compared to the control group (preoperative value, 17; postoperative value, 14). Similar changes were observed in quality of life evaluated on different means (SF 36, FIQL, Beck Depression Inventory).

As mentioned, anal manometry is an important part of the postoperative evaluation of the implanted device. The experience of the group from Rouen, France, gave very similar results to our own findings (Table 21.3).

21.6.2 Acticon ABS Reimplantation after Failure

In many series, patients have undergone successful reimplantation after a failure of a previous implantation related to infection, ulceration or mechanical breakdown. In our own series, of 32 patients receiving implants, 10 were explanted but 5 have undergone reimplantation with success. Part of or all the device can be replaced when revision surgery is needed. For Parker et al. (2003), risk of infection following revision was 19%, lower than after primary implantation (34%). Their success rate in this setting was 65% (13/21 cases).

Patients going for Acticon therapy must be aware of the risk of revision surgery. They usually accept redo surgery in case of complications, as they greatly appreciate the benefit obtained with the device.

Table 21.3. Manometric assessment after artificial anal sphincter implantation

	Mean	Range
Closed cuff		
Anal resting pressure (cm H_2O)	108	22
Maximum amplitude of voluntary contractions (cm H_2O)	26	31
Duration of voluntary contractions (s)	18	20
Open cuff		
Total duration of opening phase (s)	113[a]	8
Amplitude of decrease (% of basal pressure)	60	22
Residual pressure (cm H_2O)	40[b]	13
Opening time (s)	14	3

From Savoye et al. 2000.

[a] Total duration of the opening phase in patients with defecation difficulties was significantly shorter (47 s; range, 0–65) than in patients without defecation difficulties (178 s; range, 100–320) (P=.002).

[b] Correlated with the resting pressure recorded before implantation of the artificial sphincter.

21.6.3 New Indications for Acticon ABS

Indications for use of the Acticon ABS are also broadening and have reached the complex field of anorectal reconstruction following abdominoperineal excision. Romano et al. (2003) reported the use of the Acticon ABS in this setting. In a series of eight patients, implantation of Acticon ABS was done at the same time as rectal excision (one case), differed 2 months (five cases), and many years later (two cases). No explantation has been given to date. Among the five patients with an activated device, four are reported to have a good neoanal function. Our personal experience is based on three female patients in whom a Acticon ABS was implanted around a perineal colostomy built after curative rectal excision for T2 cancer (Lehur et al. 2003). Two of them have had preoperative radiotherapy. Implantation was done a mean 3 years after cancer treatment. At a mean 2 years of follow-up, the three patients had an activated and functional Acticon ABS. Tolerance at 2 years was satisfactory. Continence and quality of life significantly improved. The three patients considered to be improved by the implantation even though they were still on retrograde colonic enemas.

In this limited experience, implantation of an artificial sphincter around a perineal colostomy following rectal excision for cancer appeared feasible and safe, even in case of previous radiotherapy.

21.7 Indications and Contraindications

Many factors, both anal and extra-anal, contribute to fecal continence. It is apparent that the achievement of the artificial anal sphincter is to restore a high-pressure zone in the anal canal, in a static manner with no ability to increase pressure in the event of a threat to continence. The artificial anal sphincter corrects the loss of resting anal pressure. It would thus be fallacious to assume that normal continence can be restored by this means, even though the functional results obtained are highly satisfactory.

The best indications for the artificial anal sphincter are lesions of the anal sphincters inaccessible to local repair (Table 21.4). The good results in this context are that the result of other extra-anal sphincter mechanisms being preserved. Thus, the artificial sphincter may be recommended, particularly in young subjects, when the chances for successful local repair are poor.

In cases of incontinence resulting from sequelae of anal agenesis, there is a lower chance of success. The lack of anal sensitivity and a rectal reservoir and the existence of associated colonic motor disorders make all techniques of sphincteric substitution

Table 21.4. Indications and contraindications for the Acticon ABS artificial bowel sphincter

Good indications	Relative indications	Contraindications
Traumatic sphincter disruption	Anal imperforation	Excessive perineal descent
Neurologic incontinence	Severely scarred perineum	Severe constipation
Neurogenic (idiopathic) incontinence	Thin rectovaginal wall Advanced age ?? Diabetes ?? Handling difficulties	Irradiated perineum Perineal sepsis Crohn's disease Anal coitus

more uncertain. There are no available data predictive of the success of the Acticon ABS in this indication, and some patients seem to have obtained better functional results with techniques of anterograde colonic enemas.

In cases of neurogenic or neurologic fecal incontinence, it is essential to take into account possible associated dyschezia and excessive perineal descent. The artificial anal sphincter creates an obstacle to rectal evacuation, which can sometimes cause considerable evacuation difficulties. The restoration of continence should not be achieved to the detriment of evacuation capacities. However, an objective assessment of the state of preoperative transit is not always easy. Patients have often modified their diet to avoid difficulties or have had recourse to antidiarrheic treatments. Rectal prolapse or a history of surgical cure for prolapse should be carefully considered before implantation of an artificial sphincter, insofar as these conditions are indicative of disturbances in the evacuation process.

The contraindications to implantation of an artificial sphincter are more apparent (Table 21.4). Although the role of the artificial anal sphincter in anoperineal reconstructions after amputation of the rectum has not yet been defined, radiation therapy will probably be a limiting factor. The implantation of an Acticon ABS is possible after failure of graciloplasty and has already been reported. Likewise, reimplantation of the device can take place immediately after explantation when all or part of the device has to be replaced because of a mechanical failure, or later, in the event of an infection, after all inflammatory processes have disappeared.

The artificial anal sphincter is suitable for well-motivated, selected patients with fecal incontinence of more than a year's duration, whose condition is regarded as an important personal, familial, and/or social handicap. The technique should be proposed to the patient as an alternative to definitive colostomy. A capability to manipulate the control pump is required as well as sufficient intellectual capacity to understand the functioning of the device and ensure regular rectal evacuation. The success of this innovative technique depends on serious consideration of these selection criteria.

21.8 Conclusion

To conclude, the role of the Acticon ABS artificial sphincter has to be put in perspective regarding the other new minimally invasive approaches of anal incontinence, namely in our experience, sacral nerve stimulation. Although morbidity and the need for revision surgery is high following implantation of the Acticon ABS, outcome in terms of continence and improvement of quality of life is significantly satisfactory. Selection of patients is mandatory to achieve best results. Late mechanical failure is a concern and requires adaptation from the AMS company and continuous evaluation from involved surgeons.

In case of non-response to conservative treatment, local repair or sacral nerve stimulation, the Acticon ABS artificial sphincter is an effective solution for motivated patients and experienced surgeons

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Chapter 22

Innovations in Fecal Incontinence: Sacral Nerve Stimulation

22

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Contents

22.1 Methods and Patient Selection

22.1.1 Technique

The technique for SNS consists of two diagnostic stages, followed by a third therapeutic stage. As it has been well described previously (Schmidt et al. 1990; Matzel et al. 1995a; Hohenfellner et al. 1997), the following will outline the procedure and highlight recent technical developments.

22.1.1.1 Acute Percutaneous Nerve Evaluation

Acute percutaneous nerve evaluation (PNE) aims to determine whether, in the prospective patient, contraction of the striated pelvic floor muscles can be elicited by sacral nerve stimulation (SNS) (thus establishing the integrity of the sacral spinal nerves) and to test the individual relevance of each sacral spinal nerve to anal sphincteric contraction (Matzel 2001) and anal canal closure (thus identifying the optimal site of stimulation). The procedure can be performed under general or local anesthesia.

For acute PNE, needle electrodes (Model 041828 or 041829 Foramen Needles, Medtronic, Minneapolis, MN, USA) are inserted into the dorsal sacral foramina of S2, S3 and S4. This positioning aims for placement close to the site where the sacral spinal nerves enter the pelvic cavity through the ventral opening of the sacral foramen and proximal to the sacral plexus (Matzel et al. 1990).

For correct placement, palpable anatomic landmarks are helpful in identifying the sacral foramina; intermittent stimulation with graduated amplitudes and visual confirmation of the motor response of the pelvic floor and anus will optimize the position of the needle electrode. Although the effect of stimulation on pelvic floor and lower extremity activity may vary among individuals, the following responses are generally typical: S2 stimulation results in a clamp-like contraction of the perineal muscles and an outward rotation of the leg; S3 stimulation leads to contraction of the levator ani and external anal sphincter, resulting in a bellows-like movement, along with plantar flexion of the first and second toes; S4 stimulation produces a strong, bellows-like contraction of the levator ani without movement of leg, foot or toe (Schmidt et al. 1990).

If this acute stimulation successfully elicits contraction of the pelvic floor, subchronic percutaneous stimulation is initiated to evaluate the therapeutic potential of low-frequency stimulation of the identified nerve(s).

22.1.1.2 Subchronic Percutaneous Nerve Evaluation

The sacral spinal nerve(s), found in acute testing to be most effective with regard to muscular contraction and anal canal closure pressure (most commonly, but not consistently, S3), is/are stimulated continuously for a period of time sufficient to demonstrate a potential effect on fecal incontinence. Thus, the observation period depends on the frequency of incontinent episodes: bowel habits, such as frequency and degree of involuntary loss of stool, are documented with standardized bowel diaries.

Two technical options are used for subchronic PNE: a temporary, percutaneously placed, test stimulation lead (or multiple leads) (Model 041830, Temporary Screening Lead, Minneapolis, MN, USA) that will be removed at the end of this phase; or opera-

tive placement of a quadripolar lead, the so-called foramen electrode (Model 3886, Medtronic, Minneapolis, MN, USA). Both types of leads are connected to an external pulse generator for screening (Screener 3625, Medtronic), the latter with a percutaneous extension cable (Janknegt et al. 1996).

Percutaneous placement of temporary test stimulation leads can be done on just one sacral spinal nerve or on multiple spinal nerves to offer the option of testing the effect of stimulation of different sides and levels or of synchronous stimulation of multiple nerves in an awake patient (Stadelmaier et al. 2001). The operative placement of foramen electrodes is usually limited to one site.

With both techniques, the selected sacral spinal nerve is continuously stimulated (pulse width, 210 μs; frequency, 15 Hz), except during voiding and defecation. The amplitude of stimulation may require adjustment, depending on position, tissue reaction or electrode movement, and is adaptable by the patient within a limited range (1–10 V) according to his or her perception of muscle contraction or perianal sensation.

At the end of the screening phase, the percutaneously placed temporary test stimulation lead is removed; the operatively placed foramen electrode is either removed (if unsuccessful) or connected to an implanted pulse generator (so-called two-stage implant; Janknegt et al. 1996), offering the advantage of identical positioning of the electrode during screening and therapeutic stimulation.

22.1.1.3 Chronic Stimulation with a Permanent Implant

Permanent stimulation with a fully implantable device aims to make use of the therapeutic effect achieved by subchronic PNE. Patients with a temporary test stimulation lead undergo simultaneous operative implantation of the quadripolar foramen lead and the pulse generator (Model Itrel II/X-Trel, 7495, Extension kit, Model 3023 INTERSTIM implantable pulse generator, Medtronic, Minneapolis, MN, USA); those with a foramen electrode already in place undergo removal of the percutaneous extension before placement of the pulse generator subcutaneously in the abdomen (Hohenfellner et al. 1997) or gluteal area (Scheepens et al. 2001).

Recently, a less invasive technique that uses a foramen electrode with a modified anchoring device placed through a trocar (Model 3550–18, Medtronic, Minneapolis, MN, USA) has been proposed (Spinelli et al. 2003). This technique can be used either for stage one of the two-stage implant or for electrode placement after successful screening with wire electrodes.

The foramen electrode contains four contact electrodes. The electrode combination most effective with regard to required voltage and the patient's perception of muscle contraction of the perineum and anal sphincter is chosen for permanent stimulation. The parameters used (see subchronic PNE, above) are those found to be clinically effective and to cause no damage to the nerve: pulse width, 210 μs; frequency, 15 Hz; on/off: 5–1 s or continuous stimulation; level of stimulation usually above individual patient's perception of muscular contraction and adjusted if necessary (Schmidt 1988). The pulse generator is activated by telemetry (Model 7432 Console Programmer, Medtronic, Kerkrade, The Netherlands). Patients are instructed to interrupt stimulation with a hand-held programmer (Model 3031, Minneapolis, MN, USA) only for defecation and urinary voiding.

In a different operative approach in patients in whom problems are encountered during foramen electrode placement, the sacral spinal nerves are exposed within the sacral canal by a small dorsal laminectomy of the sacrum, and cuff electrodes (Med-

tronic) with symmetrically arranged contacts are positioned and fixed bilaterally around the sacral spinal nerve (Matzel et al. 2001).

22.2 Patients

Published reports differ with regard to the patient population, representing the evolution of indications.

22.2.1 Indications

As the purpose of SNS is to recruit residual function of the continence organ by electrical stimulation of its peripheral nerve supply, indications were initially confined to patients with deficient striated anal sphincter and levator ani function, but with no gross morphologic defect (determined by ultrasound or MRI) (Matzel et al. 1995b). Thus, the initial patient selection for the SNS protocol was based on the clinical and physiologic finding of reduced or absent voluntary sphincteric function (confirmed by anorectal manometry), but existing reflex activity (confirmed by intact anocutaneous reflex activity or by muscular response to pudendal stimulation with the St. Mark's electrode – the measurement of pudendal nerve terminal motor latency is of no predictive value; Matzel et al. 2004), indicating an intact nerve–muscle connection. In this group of patients the causes varied, covering a spectrum from postoperative sphincteric weakness consequent to anal and rectal procedures to total lack of voluntary sphincteric control as a sequela of cauda syndrome secondary to lumbar spine fracture. The latter suggested the potential use of SNS in neurogenic incontinence (Matzel 2001) (Table 22.1).

With the help of PNE and based on physiologic findings during temporary test stimulation (suggesting that the effect of SNS is not limited to the striated sphincter muscle) (Vaizey et al. 1999), the indications for permanent SNS were expanded to patients suffering from fecal incontinence owing to a deficiency of the smooth-muscle internal anal sphincter, to limited structural defects, and to functional deficits of the external and internal sphincter. Among these patients the causes vary widely (Table 22.1).

Subsequently a more pragmatic approach evolved. Further studies based the indication for test stimulation on the existence of an anal sphincter and residual sphincteric or reflex function – regardless of the underlying physiologic condition. The therapeutic benefit of SNS was subsequently outlined in patients with fecal incontinence owing to reduced striated muscle function from various causes with concomitant urinary incontinence (Leroi et al. 2001) and in a spectrum of neurogenic causes (Rosen et al. 2001) (Table 22.1). Reports focusing on specific etiologies usually represent a well-defined subset of larger patient cohorts (Kenefick et al. 2002c).

22.2.2 Contraindications

Contraindications for the procedure are pathologic conditions of the sacrum that prevent adequate electrode placement (such as spina bifida), skin disease at the area of implantation, anal sphincter damage amenable to direct repair or requiring a sphincter substitute (e.g., artificial bowel sphincter, dynamic graciloplasty), trauma sequelae

Table 22.1. Sacral nerve stimulation for fecal incontinence: patient selection

Report	Etiologic spectrum	Physiologic and morphologic findings
Matzel et al. (1995b, 2001) Matzel (2001)	Post-fistulectomy, sphincter repair	EAS weakness
	Post-Ripstein procedure, rectal resection	
	For prolapse	
	Post-hemorrhoidectomy	
	Cauda syndrome after lumbar spine fracture	
Vaizey et al. (1999)	Scleroderma	IAS weakness
	Primary IAS degeneration	IAS degeneration
	Obstetric trauma	IAS fragmentation + EAS defect
	Idiopathic	IAS + EAS weakness
Leroi et al. (2001)	Post-rectopexy	EAS weakness + Urinary incontinence
	Trauma	EAS gap <30°, Superficial EAS gap <60°
Rosen et al. (2001)	Spinal cord lesion	Neurogenic
	Meningomyelocele	
	Multiple sclerosis	

EAS, *IAS* external, internal anal sphincter.

with micturition disorders or low bladder capacity, pregnancy, bleeding complications, psychological instability, low mental capacity, and the presence of a cardiac pacemaker or implantable defibrillator.

22.2.3 Selection Process

Patients are selected for operative implantation of a permanent neurostimulation device on the basis of clinical improvement during test stimulation. At present no other predictor of functional outcome with chronic stimulation exists. The test stimulation procedure is most commonly considered therapeutically effective if the frequency of episodes of fecal incontinence documented by bowel-habit diary is alleviated by at least 50% (Matzel et al. 1995b, 2004) and if the improvement is reversible after discontinuation of temporary stimulation.

The method of choice for permanent stimulation is the unilateral implantation of a foramen electrode on the spinal nerve site demonstrated to be therapeutically effective during the test stimulation phase. Bilateral foramen electrodes should be considered if unilateral test stimulation is insufficient and bilateral test stimulation reveals acceptable results (Stadelmaier et al. 2001; Matzel et al. 2002). Cuff electrode implantation can be indicated (as stated above) if foramen electrode placement is problematic (Matzel et al. 2001).

Table 22.2. Sacral nerve stimulation for fecal incontinence: clinical results (frequency of episodes of incontinence to solid or liquid stool over a 7-day period)

Report	Patients	Prestimulation	Stimulation		Follow-up (Months)
			Temporary	Permanent[a]	
Single center					
Matzel (2001)	6	9 (2–19)	1.5 (1–5)	0 (0–1)	59 (5–70)
Leroi et al. (2001)	6	2 (1–7)	0 (0–4)	0.5 (0–2)	6 (3–6)
Ganio et al. (2001a)	5	3 (2–14)	0	0	14 (5–37)
Rosen et al. (2001)	16	2 (1–5)	NA	0.7 (0–5)	15 (3–26)
Kenefick et al. (2002b)	15	11 (2–30)	0 (0–7)	0 (0–4)	24 (3–80)
Ripetti et al. (2002)	4	12[b]	NA	2[b, c]	24
Uludag et al. (2002)	27	8.7 (2–38)	0.7 (0–10)	0.5 (0.5–0.7)[c]	6.0†
Altomare et al. (2004)	14	14 (11–14)[d]	NA	0.5 (0–2)[d]	14 (6–48)
Multicenter					
Ganio et al. (2001b)	16	5.5 (1–19)	NA	0 (0–1)	10.5 (3–45)
Matzel et al. (2004)	34	8.3 (1.7–78.7)	NA	0.75 (0–25)	23.9 (1–36)
Cleveland Clinic Continence Score					
Malouf et al. (2000)	5	16 (13–20)	–	2 (0–13)	16
Matzel et al. (2003)	16	16 (12–19)	–	2 (0–7)	32.5(3–99)
Rasmussen and Christiansen (2002)	10	19.5 (14–20)	–	5.5 (0–20)	4.5 (1–12)
Altomare et al. (2004)	14	15 (12.5–17.5)	–	5.7 (2–6)[d]	14 (6–48)

Data presented as median value, unless otherwise indicated.
NA not available.

[a] Data at last follow-up.
[b] Mean value; SD and range not available.
[c] Follow-up value: median of values at published follow-up intervals.
[d] Median values during a 2-week period.

22.3 Results

As with indications, outcome assessment has also evolved. Various tools are applied to measure functional outcome. Initially the most common measures were the number of incontinent episodes or days with incontinence during a set period of time (based on bowel-habit diary) and incontinence score results (Cleveland Clinic Continence Scoring System) (Jorge and Wexner 1993). Subsequently, Quality-of-life instruments such as the SF36 (Ware 1993) and FIQL Score (Rockwood et al. 2000) were added to evaluate the therapeutic effect.

22.3.1 Clinical Results

Since the first report of SNS in the treatment of fecal incontinence, the initial reports from various institutions have been followed by updates, presenting a longer follow-up of existing patients and an extended number of patients (Matzel et al. 1995b, 2001; Matzel 2001; Malouf et al. 2000). The following is limited to the most recent results from these institutions (Matzel et al. 2003; Kenefick et al. 2002b), reporting the longest follow-up and the largest cohort of patients, unless additional information from earlier reports is relevant.

In all studies functional benefit – decreased frequency of involuntary loss of stool or improved Cleveland Clinic Continence Score – was achieved with a permanent implant and remained consistent over the course of follow-up, as long as 99 months (Table 22.2). The results of the test phase were reproduced or even surpassed by chronic stimulation. The majority of patients experienced an improvement of at least 75% (Table 22.3).

Table 22.3. Permanent sacral nerve stimulation for fecal incontinence: clinical results, percentage improvement at last follow-up

Report	*N*	Follow-up (months[a])	100%	75%–99%	50%–74%	<50%
Malouf et al. (2000)	5	16 (3–26)	4	1	–	–
Leroi et al. (2001)	6	2 (1–7)	3	1	1	1
Ganio et al. (2001)	5	14 (5–37)	5	–	–	–
Rosen et al. (2001)	16	15 (3–26)	>3	Average: 67%		
Rasmussen and Christiansen (2002)	10	4.5 (1–12)	4	2	1	3
Uludag et al. (2002)	27	6[b]	Average: 86%			
Kenefick et al. (2002b)	15	24 (3–60)	11	3	1	–
Ripetti et al. (2002)	4	24	NA	NA	NA	NA
Matzel et al. (2003)	16	32.5 (3–99)	12	2	1	1
Altomare et al. (2004)	14	14 (6–48)	NA	NA	NA	NA
Ganio et al. (2001)	16	10.5 (3–45)	12	4	–	–
Matzel et al. (2004)	34	23.9 (1–36)	15	8	7	4

[a] Median.
[b] mean

Sacral nerve stimulation not only decreased the frequency of incontinent episodes or improved the Continence Score, but also was shown to have a beneficial effect on the ability to postpone defecation (Matzel et al. 2004; Vaizey et al. 1999) and to empty the bowel (Matzel et al. 2004).

The rate of complications varied from 0% to 50% (Table 22.4). These comprised pain at the site of the electrode or pulse generator, electrode dislodgement or breakage, infection, loss of effect, or deterioration in bowel symptoms. No chronic central nervous system infectious complications were observed. In only in a limited number of patients did complications (loss of effect [Matzel et al. 2003], deterioration of symptoms [Matzel et al. 2004], pain [Matzel et al. 2003], lead dislocation [Rosen et al. 2001], infection [Matzel et al. 2004]) lead to discontinuation of therapy. No permanent sequelae attributable to the complications occurred. The intention-to-treat analysis revealed therapeutic success in 80%–100% of patients.

Table 22.4. Permanent sacral spinal nerve stimulation for fecal incontinence: complications

Report	*N*	Reported complications[a]	Treatment discontinued	
			Temporarily	Permanently
Ganio et al. (2001)	5	NA	NA	NA
Leroi et al. (2001)	6	Wound dehiscence: 1	NA	NA
		Electrode migration: 1	NA	NA
		Loss of initial clinical effect: 1	NA	NA
Rosen et al. (2001)	16	Infection: 3	3	–
		Lead dislodgement: 1	–	1
Rasmussen and Christiansen (2002)	10	NA	NA	NA
Uludag et al. (2002)	27	Technical problem: 1	1	NA
Kenefick et al. (2002b)	15	Lead dislodgement: 2	2	–
		Pain: 3	–	–
Ripetti et al. (2002)	4	–	–	–
Matzel et al. (2003)	16	IPG dislodgement: 1	1	–
		Loss of effect: 1	–	1
		Pain: 1	–	1
		Urinary retention: 1	–	–
Altomare et al. (2004)	14	Minor wound infection: 1	–	–
		Lead dislodgement: 2	2	–
Ganio et al. (2001)	16	–	–	–
Matzel et al. (2004)	34	Pain: 9	–	–
		Lead breakage: 1	1	–
		Infection: 1	–	1
		Deterioration of bowel symptoms: 3	–	1

NA not available.

[a] Requiring medical or surgical intervention.

22.3.2 Quality of Life

Sacral nerve stimulation clearly improved quality of life (Table 22.5): The SF36 revealed positive changes in multiple subscales, reaching statistical significance in some subscales in single-center trials and in social functioning and mental component summary in a multicenter setting. The disease-specific FIQL showed highly significant improvement in all four categories – lifestyle, coping/behavior, depression/self-perception, embarrassment – in both single-center and multicenter studies.

22.3.3 Anorectal Physiologic Findings

The effect of chronic stimulation on anorectal physiologic testing varies among published reports (Table 22.6). The most common finding was an increase in striated muscle function, expressed as improved squeeze pressure. The duration of voluntary contraction was shown to be increased in one study (Leroi et al. 2001). The effect on resting pressure and rectal perception is inconsistent, although a trend toward decreased sensory and urge thresholds is apparent.

The effect of SNS seems not to be limited to sphincteric function and rectal perception: during 24-h rectal manometry, qualitative changes have been observed in rectal motility: reduction of spontaneous rectal motility complexes (Vaizey et al. 1999; Altomare et al. 2004) and spontaneous anal sphincter relaxation (Leroi et al. 2001). Changes in blood flow recorded by rectal Doppler flowmetry during stimulation give further indication that SNS affects autonomic function of the distal bowel (Kenefick et al. 2003). Improvement in anal sensory function and sensitivity of the perianal and perineal skin during SNS has been reported in one study (Rosen et al. 2001).

22.4 Discussion

Sacral nerve stimulation is a novel treatment in selected patients with fecal incontinence. An increasing body of evidence suggests that the technique is therapeutically effective: not only does it improve continence, but it also has a positive effect on quality of life.

Since the first application of SNS in the treatment of fecal incontinence, the spectrum of indications has been expanded by applying a pragmatic approach to patient selection through test stimulation. The common denominator for suitability for SNS is incontinence owing to weak external or internal anal sphincteric function without a gross morphologic defect amenable to direct repair and an existing, although sometimes residual, neuromuscular connection. As no other predictor for the outcome of SNS exists, selection is based on the functional results achieved during temporary test stimulation. The reproducibility of the clinical results of the temporary stimulation phase with a permanent implant underscores the appropriateness of the test stimulation as a screening method. Additionally, this option of a testing phase with high predictive value gives SNS an advantage over other treatment options.

The technique of foramen electrode implantation carries limited risk. The complication rate is low, and the need for discontinuation is rare. Even if the device must be removed, treatment need not be discontinued permanently, as it can be reimplanted. Recent technical developments further reduce the invasiveness of permanent elec-

Table 22.5. Permanent sacral nerve stimulation for fecal incontinence: clinical results, quality of life

	SF 36			FIQL	
	Categories improved	Lifestyle	Coping/ behavior	Depression/ Self-perception	Embarrassment
Malouf et al. (2000)	SF, RE, MH, RF	NA	NA	NA	NA
Ganio et al. (2001)	NA	NA	NA	NA	NA
Leroi et al. (2001)	NA	NA	NA	NA	NA
Rosen et al. (2001)	NA	Increased*	Increased*	Increased*	Increased*
Rasmussen and Christiansen (2002)	NA	NA	NA	NA	NA
Uludag et al. (2002)	NA	NA	NA	NA	NA
Kenefick et al. (2002b)	All* except HT	NA	NA	NA	NA
Ripetti et al. (2002)	SF*, RE*, PF*	NA	NA	NA	NA
Matzel et al. (2003)	NA	Increased*	Increased*	Increased*	Increased*
Altomare et al. (2004)	NA	Increased*	Increased*	Increased*	Increased*
Ganio et al. (2001)	NA	NA	NA	NA	NA
Matzel et al. (2004)	SF*, MH, RE, RP, BP	Increased*	Increased*	Increased*	Increased*

SF 36: *RE* role-emotional, *GH* general health, *MH* mental health, *BP* bodily pain, *RP* role-physical, *SF* social function, *V* vitality, *HT* health transition, *PF* physical functioning.

NA not available.

* Significant.

Table 22.6. Permanent sacral spinal nerve stimulation for fecal incontinence: anorectal physiologic findings

	Resting pressure	Squeeze pressure	Threshold volume	Urge volume	Maximal tolerable volume
Malouf et al. (2000)	No effect	No consistent change	No effect	No effect	Increased
Matzel (2001)	No effect	Increased*	No effect	No effect	No effect
Ganio et al. (2001)	Increased	Increased	Decreased	Decreased	NA
Leroi et al. (2001)	No effect	No consistent change	NA	NA	Decreased
Rosen et al. (2001)	Increased*	Increased*	Decreased	Decreased	No effect
Rasmussen and Christiansen (2002)	NA	NA	NA	NA	NA
Uludag et al. (2002)	No effect	No effect	NA	NA	NA
Kenefick et al. (2002b)	No effect	Increased*	Decreased*	No effect	Decreased
Ripetti et al. (2002)	Increased	Increased	Decreased	No effect	NA
Matzel et al. (2003)	No effect	Increased*	Decreased	No effect	Increased
Altomare et al. (2004)	No effect	No effect	No effect	Decreased	No effect
Ganio (Uludag et al. 2002)	Increased*	Increased*	Decreased	Decreased*	NA
Matzel et al. (2004)	NA	NA	NA	NA	NA

NA not available.

* Significant.

trode placement (Spinelli et al. 2003). The more invasive technique of open placement of electrodes via a small dorsal laminectomy of the sacrum offers an operative alternative if difficulties are encountered with the temporary wire or foramen electrodes (Matzel et al. 2001). It might also enable one to address anomalies of bony and neural topography.

The physiologic mechanism of action of SNS in the treatment of fecal incontinence is undefined, but deemed to be complex and multifactorial. Experimental work reveals an impact of low-frequency SNS on the transformation of the muscle phenotype towards fatigue resistance (Bazeed et al. 1982). Clinically, SNS can result in contraction of the striated muscle external anal sphincter and levator ani or in facilitation of voluntary contraction in patients with limited or absent function. During chronic stimulation, the effect of SNS is reflected in increased squeeze pressure. In some patients, despite consistent clinical improvement during permanent SNS, the effect on the external anal sphincter has been limited, thus implicating other mechanisms of action. The reduction in rectal sensitivity and contractile activity and anal motility (see "Results") observed during short-term stimulation suggests a modulation of sacral reflex arcs as an underlying physiologic mechanism (Vaizey et al. 1999; Altomare et al. 2004), and changes in rectal blood flow give further support to an effect on autonomic nerve function (Kenefick et al. 2003). The changes in resting pressure, sensory and urge thresholds, and maximal tolerable rectal volume observed during chronic stimulation suggest another potential effect on visceral function.

The fact that a sustained long-term benefit can be achieved with this treatment (Matzel et al. 2001); that patients who experienced a lessening of therapeutic benefit found it to resume after technical problems with the neurostimulator were corrected (Leroi et al. 2001; Malouf et al. 2000); and, lastly, that the clinical effect of SNS was confirmed in a double-blind crossover trial (Vaizey et al. 2000) argue against the likelihood of a placebo effect of this therapy.

Just as one may assume that the clinical effect of SNS is based on multiple physiologic functions, the relative importance of each of these functions and their dependence on pathophysiologic preconditions is unclear.

As the number of studies with a homogenous patient population is limited, and studies with heterogeneous patient populations and limited numbers prevent firm conclusions, it will be important to conduct future trials with patients accurately characterized with regard to morphologic and physiologic causes of incontinence, to define specific indications and exclusion criteria, to correlate clinical function with physiologic findings, and to standardize the evaluation of outcome to elucidate the true therapeutic potential of SNS.

Even though the physiologic effect and the mechanism of action of SNS in the treatment of fecal incontinence are not yet clearly understood, and no single reliably predictive clinical or physiologic indicator exists as yet, satisfying therapeutic results can be achieved if the pragmatic approach of test stimulation is adopted. With the help of the three-stage protocol, patients with a wide variety of causes of fecal incontinence have been identified and treated successfully. Indeed, with this approach, the spectrum of therapeutic uses may be extended to include more areas of colorectal dysfunction (Kenefick et al. 2002a). At present, sacral nerve stimulation represents a valuable addition to the treatment options of fecal incontinence in a patient population in whom conservative treatment has failed and traditional surgical approaches would have limited success.

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Chapter 23

Stoma Surgery

Martin E. Kreis, Ekkehard C. Jehle

23

Contents

23.1 Introduction

Severe fecal incontinence is a debilitating disorder, limiting the patient's social activities to his home environment and locations with a bathroom always available in the vicinity. The patient may be prevented from taking long-distance trips, dining out, and may be completely unable to attend assemblies in any kind of social situation. A large proportion of incontinent patients show symptoms of anxiety and depression (Miner 2004). Contrary to the suffering of the patient, there is almost no perception of this problem in our society, as patients frequently do not report their condition to others, not even to their physician.

Despite a variety of new therapeutic options, fecal incontinence remains a clinical condition that is difficult to treat. Conservative treatment includes regulation of loose stools by diet or constipating agents (Scarlett 2004; Read et al. 1982) and sphincter training by physiotherapy with or without the help of a biofeedback device (Norton 2004). Depending on the leading cause of fecal incontinence, surgery may be undertaken, e.g., to correct rectal intussusception or prolapse (Zittel et al. 2000), sphincter reconstruction either by remnants of the external anal sphincter (Madoff et al. 1999), dynamic graciloplasty (Madoff et al. 1999) or by an artificial device (Lehur et al. 2000). An additional subpopulation of patients may be amenable for a sacral nerve stimulation procedure (Matzel et al. 2004).

Although these procedures to treat fecal incontinence are available, most of them will only improve the situation for the incontinent patient rather than provide a definitive cure. This implies that some patients may still suffer from severe fecal incontinence following attempts to treat their condition either surgically or conservatively or both. If these patients subsequently remain in a debilitating situation as a result of their fecal incontinence, the construction of a stoma may be discussed. The presence of a stoma that is well placed and, therefore, easy to take care of renders the patient almost independent of the requirement of having a bathroom immediately available, allowing an almost normal social life. No reports are available that compare the quality of life of incontinent patients and patients with a stoma. However, it has been shown that quality of life following operations for rectal cancer does not differ between patients who require a permanent colostomy and patients who undergo sphincter-saving resection (Grumann et al. 2001). In the same study, it was further demonstrated that patients with a permanent colostomy have a better quality of life compared to patients who underwent a sphincter-saving procedure with subsequent incontinence. Thus, it is likely that also under different circumstances, the construction of a stoma may substantially improve the quality of life in a severely incontinent patient. Special attention should be paid to the patient's sexual life, as this may be substantially impaired if the partner does not tolerate the other's stoma well. Particularly in the young without an established relationship, this latter aspect certainly is of major importance.

One key question to be considered before stoma placement is whether the stoma is going to be temporary, e.g., for the time of complex reconstructive surgery at the level of the anal sphincter, or whether it will be the definitive solution for the patient's fecal incontinence. We would usually recommend a loop ostomy in patients who are likely to undergo stoma closure in the future. For this kind of stoma, essentially two options are available: a loop ileostomy and a loop colostomy of the transverse or descending colon. Both procedures have advantages and disadvantages. The loop ileostomy has the advantage of a lower incidence of complications such as prolapse (Edwards et al. 2001). The advantage of the loop colostomy is particularly the easier stoma care and

that a transverse colostomy may be placed with minimal operative stress for the patient. If necessary, a transverse loop colostomy may be placed under local anesthesia with an incision just at the stoma site. This type of stoma, therefore, is our preferred option for the debilitated patient with high general operative risk. In patients who require a stoma as a definitive treatment, a Hartmann procedure with an end-descending colostomy is our preferred operation (Fig. 23.1). An end colostomy in the descending colon will usually allow stoma care by irrigation (Fig. 23.2). This procedure of controlled emptying of the bowel every 2–3 days with the potential to dispense with placing stoma bags is frequently perceived as the optimal stoma care in the trained and fit patient (Turnbull 2003). It is of note that all mentioned operations may easily be performed with the laparoscopic approach, if the patient has had no extensive previous abdominal operations (Weiss et al. 1995; Oliveira et al. 1977; Ludwig et al. 1996; Schwandner et al. 1998).

23.2 Preparation

It is almost normal that the patient is somewhat horrified when the possibility of a stoma placement as a cure for severe fecal incontinence is mentioned the first time. Thus, placement of a stoma for fecal incontinence is basically never a one-visit decision. Except for the emergency situation, when stoma placement may be required in patients with an anal sphincter destroyed by perineal injury, this operation should only be undertaken after repeated and extensive discussions with the patient. It is advisable that not only the surgeon explain why a stoma is believed to be advantageous, but also the stoma nurse, who will frequently have more detailed information available on aspects of stoma care and special procedures such as irrigation. According to our expe-

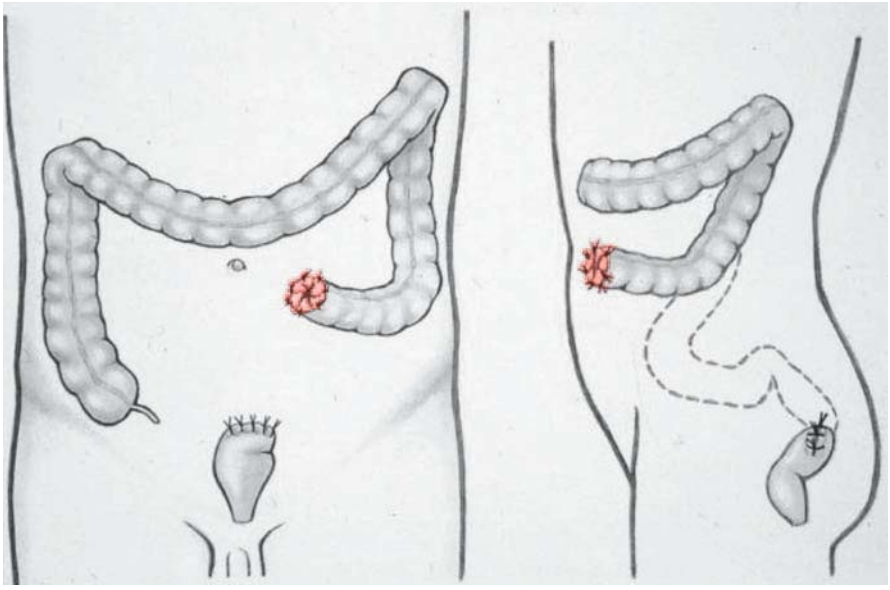

Fig. 23.1. Hartmann situation. This graph displays the situation after a Hartmann operation with a closed rectal stump and an end colostomy at the left colon

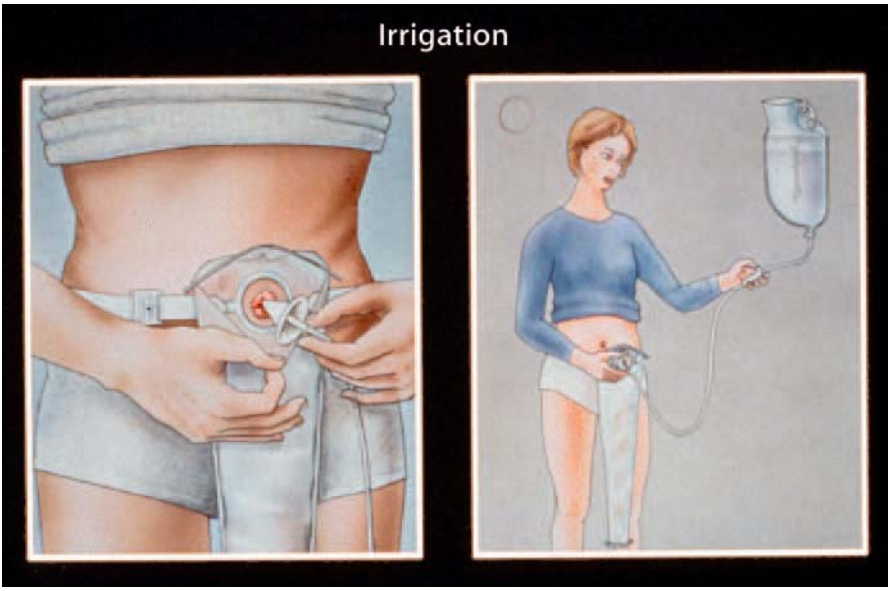

Fig. 23.2. Irrigation. This figure shows the technique of irrigating an end colostomy. With the help of special appliances, a large enema is given into the colostomy, which allows complete emptying of the proximal colon. In suitable patients, this technique prevents evacuations from the colostomy for 2–3 days, which enables patients to dispense with the bag that otherwise covers the stoma for this time period

rience, it is furthermore extremely helpful when the patient who is facing a stoma placement is given the opportunity to talk to somebody who has already undergone this procedure previously since the patient's perspective is certainly different at times compared to the surgeons' or nurses'.

Besides carefully familiarizing the patient with stoma care, the position of the stoma requires optimal planning. The marking should be performed in the supine, upright and sitting positions. Special attention is to be given to skin folds and the level of the pants or belt. It is furthermore mandatory that the patient is able to see the stoma site. This latter aspect is particularly important in the obese patient (Fig. 23.3).

23.3 Technical Aspects of Stoma Surgery

23.3.1 Operative Access

In suitable patients, we prefer the laparoscopic approach, as it allows the patient to profit from the advantages of laparoscopic surgery such as reduced postoperative pain, less frequent postoperative motility disorders and shortened hospital stay (Robinson and Stiegmann 2004). In general, one trocar is placed close to the umbilicus for the camera and one at the site of the future stoma. This arrangement is usually sufficient for a loop ileostomy. If a Hartmann procedure is performed with an end colostomy at the level of the descending colon an additional trocar is required for the dissection and mobilization of the descending colon. If the laparoscopic approach is

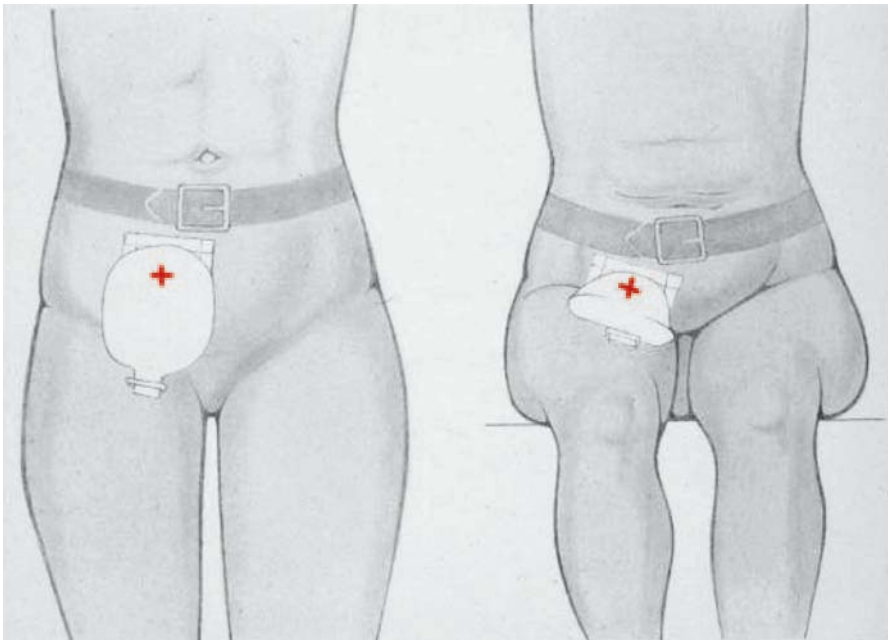

Fig. 23.3. Marking of the stoma site. A good position of the stoma is indispensable for easy stoma care later on and subsequent good quality of life for the patient. The stoma and the stoma bags must not interfere with the patients' belt-line. Furthermore, the patient must see the stoma and it must not be placed in locations where skin folds build up in different body positions

not feasible, a midline laparotomy is performed to avoid any incision at potential future stoma sites, which may be important if the stoma ever has to be replaced subsequent to stoma complications. There are no detailed or conclusive reports on the cost of laparoscopic vs open stoma surgery (Johnsson and Zethraeus 2000). The laparoscopic procedure is likely to be more expensive because of the special materials that are necessary for laparoscopic surgery. However, this is probably balanced by the generally shortened hospital stay following laparoscopic surgery.

23.3.2 Loop Ostomies

We perform a loop ileostomy most frequently (Fig. 23.4; Weiss et al. 1995). The pneumoperitoneum is established following a skin incision below the umbilicus either by use of the Veres needle or a minilaparotomy. Then, a 10-mm trocar is placed and the camera inserted. The skin at the level of the ileostoma is excised with a diameter of approximately 2–3 cm and an additional trocar inserted. In order to have an adequate gap at the level of the fascia, we change the initially placed trocar to a 20-mm trocar, before we grasp the most distal ileal loop that is sufficiently mobile with a Babcock clamp. Alternatively, the fascia may be incised from above after the loop has been grasped. This step is facilitated by having the patient in the Trendelenburg position. The loop is exteriorized and a splint is placed below. Now the position of the proximal and distal part of the loop needs to be confirmed carefully. The abdomen is deflated, the camera port is withdrawn and the fascia and skin are closed below the umbilicus.

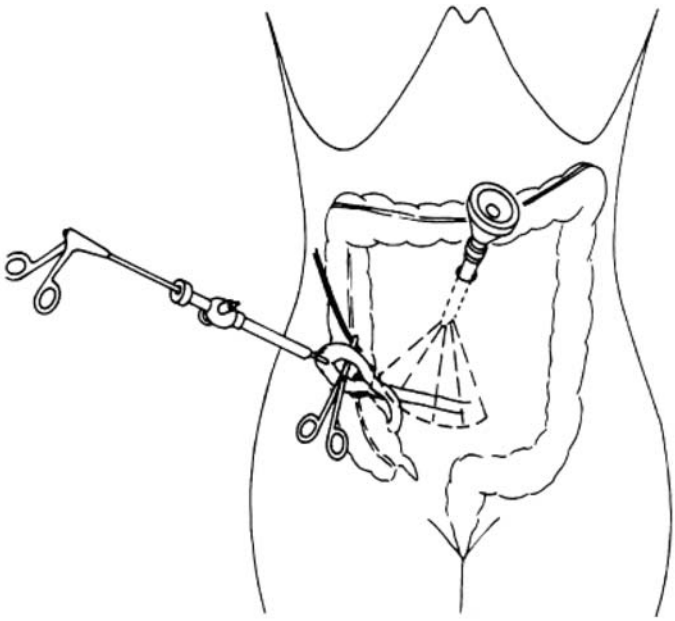

Fig. 23.4. Laparoscopic ileostomy. The technique for the construction of a laparoscopic ileostomy is shown. Note that only two trocars are necessary, one at the umbilicus for the camera and one at the future stoma site

Then the loop is incised at the level of the distal loop such that the proximal loop is fixed to the skin by creating a nipple. The nipple ensures that the stoma appliances can be positioned so that the contents of the small intestine cannot touch the skin. This is crucial in order to avoid later skin problems around the stoma. When the procedure is performed via a midline laparotomy, the fascia is incised at the level of the stoma site just enough to allow the passage of two fingers. In the case of a loop colostomy at the level of the transverse colon, a slightly extended transverse incision is performed to directly pull out a loop of the transverse colon. A nipple is not mandatory when placing a colostomy since the contents of the colon usually do not cause irritations of the skin.

23.3.3 Hartmann Procedure, End Colostomy of the Descending Colon

The sigmoid and the descending colon is mobilized and the colon transected with a stapler at the level of the distal sigmoid colon after division of the mesentery. Identification of the ureter prior to the dissection of the mesentery is advisable since it eliminates the risk of injury. A stapling device that cuts and closes the colon with a stapling line at both ends is most advantageous for this step (e.g., Endostapler, Ethicon, Hamburg, Germany). Caution needs to be used to divide the mesentery away from the part of the colon that will form the colostomy in order to ensure adequate blood supply to the stoma. A disc of about 2–3 cm is excised at the level of the skin and the fascia incised before the end of the descending colon is exteriorized. The colon right below the stoma site should be in a fairly straight position, as a loop or siphon may render intubation of the stoma difficult, potentially precluding a later irrigation procedure. At

times shortening of the colon after it has been pulled through the stoma site may be required. Opening and fixation of the stoma at the skin level following withdrawal of the trocars and closure of the port sites are the final steps of the procedure. In our experience, additional fixation of the stoma at the level of the fascia is unnecessary. The open operation is performed accordingly through a midline laparotomy.

23.4 Postoperative Complications

The most frequently encountered problems following stoma placement are stoma retraction, prolapse, parastomal hernia and skin problems (Shellito 1998). *Stoma retraction* usually is secondary to a technical problem during stoma placement, i.e., tension on the bowel. In most cases, conservative treatment is possible except when the stoma completely slips back into the abdomen causing peritonitis. Then an emergency reoperation is indispensable. For the other cases managed conservatively, time will show whether stenosis or skin problems secondary to difficult stoma care occur with the subsequent need for replacement of the stoma at a different site. *Prolapse* and *parastomal hernia* may also warrant correction either by local excision and shortening of the redundant intestine at the stoma site or by repositioning the stoma to a different position. As some degree of prolapse and parastomal hernia is physiological after some time, surgery should only be undertaken in symptomatic patients or when other problems such as bleeding or obstruction occur. *Skin problems* around the stoma site are basically always a consequence of difficulties in stoma care. In most cases, a stoma therapist will manage to solve these problems by modifications of the stoma care and/or special appliances. If skin irritations are secondary to skin folds at the stoma site, surgical repositioning of the stoma may ultimately be warranted.

23.5 Summary

A diverting stoma is an extremely important option for the treatment of fecal incontinence. It should be considered in patients after unsuccessful conservative or surgical treatment if severe limitations of social activities persist. However, a diverting stoma is not only a last resort but also a reasonable option for patients who seek the most efficacious, simple and quick relief of fecal incontinence. Furthermore, a loop ostomy may be useful during extensive reconstructive surgery of the sphincters. Temporary stomas are usually placed as loop ostomies, while a Hartmann procedure with an end-descending colostomy is our procedure of choice for permanent stoma. Careful marking of future stoma site and extensive advice to the patient preoperatively are indispensable. In the suitable patient, stoma placement may be performed by minimally invasive techniques.

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Part VII

Postoperative Care of Patients After Pelvic Operations

VII

Chapter 24

Postoperative Management After Surgery for Incontinence and Prolapse

24

Ursula M. Peschers, Ralf Tunn

Contents

24.1 Introduction

Incontinence and prolapse surgery is intended to restore anatomy and function. Contrary to oncological surgery, which is carried out to save the patient's life, urogynecological surgery tries to improve the patient's well-being. Therefore postoperative care after surgery for incontinence and prolapse presents specific issues.

24.2 Immediate Postoperative Phase

- Did side effects occur: voiding disorder, residual urine, de novo urge incontinence?

24.2.1 Medium Term

- Incontinence surgery: did symptoms improve?
- Prolapse surgery: is anatomy restored and function preserved?
- How can the result of surgery be preserved?

Unfortunately, to our knowledge there are no evidence-based recommendations because no studies have been published that compare different methods of postoperative care.

24.3 Immediate Postoperative Care

Kidney ultrasound should be performed to exclude hydronephrosis postoperatively.

Proper bladder emptying has to be ensured. Intermittent self catheterization or suprapubic bladder drainage can be used. Patients should void every 2–3 h during the day and at least once during the night. If residual urine is less than 100 cc catheterization can be stopped.

If the patient complains about residual urine and/or de novo urgency a urinary tract infection should be excluded and residual urine checked. Cholinergic drugs help to improve detrusor contraction, alpha-blocking agents additionally decrease the urethral sphincter tonus. Perineal or introital ultrasound can be used to check for bladder neck position after colposuspension and for tape position after tension-free application of a polypropylene tape (Viereck, Kosczsewski). If the patient complains about urgency urinary tract infections have to be excluded. If she does not have significant residual urine anticholinergic drugs can be tried.

Postmenopausal patients should generally receive vaginal estriol, especially after mesh implantation, to avoid erosion of the mesh. Estriol might also be helpful after incontinence surgery when a female patient complains of urgency.

24.3.1 Medium Term:

■ Incontinence surgery: did symptoms improve?

Women should be advised to come for a follow-up appointment if incontinence symptoms persist after 6 weeks. At this time, residual urine has to be checked to exclude overflow incontinence and urinary tract infection. Ultrasound precisely checks for urethral mobility and tape placement. Urodynamics testing should be performed to differentiate between persistent stress urinary incontinence and de novo urge incontinence. Women with urge incontinence should receive anticholinergic therapy if there is no significant residual urine. If residual urine is more than 50 cc the amount has to be closely monitored when the patient is treated with anticholinergic drugs. Residual urine of more that 100 cc in women with symptoms of urgency and urge incontinence mandate treatment by cholinergic or alpha-blocking drugs. If medical treatment is not successful clean intermittent cauterization is required.

If clinical and urodynamic testing confirmed persistent stress urinary incontinence 2 months postoperatively the reasons for failure should be analyzed. If the bladder neck is still hypermobile after colposuspension sutures might have torn out. If the patient still leaks after TVT placement the tape may be too loose. If stress urinary incontinence is mild the patient might be happy to undertake pelvic floor training. However, most women with surgical failure have had trials of unsuccessful physical therapy before. If the new drugs for stress urinary incontinence (duloxetine) are useful, in mild recurrent cases this is still unclear. If the patient opts for surgery therapy must be chosen individually. No general recommendations can be given. There are no data on recurrent TVT operations in patients who had a failed TVT operation before. Generally a different type of surgery (e.g., colposuspension) should be considered if one method has failed. It is absolutely not clear if new transobturatorial tapes will work after TVT has failed. In cases of persistent or recurrent stress urinary incontinence after colposuspension, a second colposuspension is only useful if the bladder neck is still mobile. A suburethral tape such as TVT might be successful.

In unclear cases of postoperative urinary incontinence, a fistula should be kept in mind and excluded if necessary.

■ Prolapse surgery: is anatomy restored and function preserved?

It is very important to keep in mind that the restoration of anatomy does not automatically include that function is restored as well. Patients might develop dyspareunia, anal incontinence and/or urinary incontinence after prolapse surgery. Women should be advised to come back in case of any problems. Dyspareunia might occur after posterior repair or after mesh implantation. New symptoms of anal incontinence require a work-up of the posterior compartment and conservative or surgical treatment.

Masked stress urinary incontinence might become unmasked after prolapse surgery. Minimally invasive surgery such as TVT implantation is mostly the treatment of choice for those patients.

■ How can the result of surgery be preserved?

There are no data that prove that anything can be done to improve long-term results after surgery. However, women should be advised to avoid heavy lifting and straining during defecation. Local estriol might be useful, as explained above. Whether pelvic

floor exercises are useful is unknown. Nevertheless, the patient should perform pelvic floor exercises if they are able to contract the pelvic floor muscles. Physiotherapy is also useful to teach the correct way of lifting to avoid sudden intra-abdominal pressure rises.

Chapter 25

Postoperative Management of Urinary Incontinence After Urologic Surgery

25

Daniela Schultz-Lampel

Contents

25.1 Introduction

Urinary incontinence after urologic surgery is a disappointing experience for both patient and surgeon. However, bladder dysfunction and especially incontinence can occur after pelvic surgery such as radical prostatectomy, transurethral prostatectomy (TUR-P), cystectomy with orthotopic bladder substitution, or even after incontinence surgery. Because of their clinical relevance, this article will focus on two items: incontinence after radical prostatectomy and persisting incontinence after female incontinence surgery. In the early postoperative period, up to 97% of patients are incontinent after radical prostatectomy and also up to 30% of females experience urgency or incontinence after incontinence surgery.

Although continence improves with time in most cases, we should offer patients therapeutic methods to accelerate the regaining of continence and to ameliorate their quality of life.

In addition, accurate preoperative information about the possibility of postoperative bladder dysfunction and incontinence is mandatory as it improves patient's satisfaction rate and quality of life. A thorough preoperative diagnostic work-up and careful surgical techniques are obligate prerequisites to prevent incontinence.

25.2 Incontinence After Radical Prostatectomy

Radical prostatectomy for treatment of localized prostate cancer has become one of the most frequently performed urologic surgeries. Irrespective of a retropubic, perineal or laparoscopic approach and despite improved nerve-sparing and sphincter-preserving techniques, incontinence remains a significant concern for patients and surgeons.

25.2.1 Incidence and Pathophysiology

Estimates of postoperative incontinence rates vary dramatically, ranging from 0.5% to 87%, depending on a number of factors relating to study design, including definition of continence, assessment methods, time since surgery and the patient's vs the surgeon's reporting (Palmer et al. 2000; Alivizatos et al. 2003; Krupski et al. 2003; Young et al. 2003).

The early continence rates directly after removal of the catheter are low and at that time up to 97% of patients lose urine. Retropubic and perineal approaches tend to have better early continence rates than the laparoscopic approach – especially in the early learning phase. However, in the 1 year follow-up, all three approaches have similar continence rates (Wille et al. 2003; Anastaridis et al. 2003; Egawa et al. 2003; Kirschner-Hermann and Jakse 2002) (Table 25.1).

The median time to regain continence ranges somewhere around 3 months depending on the definition of continence and on patient's age and comorbidity (Abbas et al. 2002; Young et al. 2003). Median time to regain continence was 1.4 months in patients younger than 55 years, 3.0 months in patients between 55 and 64 years and 3.3 months in patients older than 64 years. In healthy patients, continence was achieved after 1.4 months, whereas when there were one or two comorbidities or more than two comorbidities, regaining continence took 3.3 months and 3.5 months, respec-

Table 25.1. Comparison of continence rates of retropubic, perineal and laparoscopic radical prostatectomy

Continence rates after surgery	Retropubic	Perineal	Laparoscopic
1 day after catheter removal	21%	40–91%	3%
After 3 months	59%–63%		29%
After 6 months	84%	55%	47%
After 12 months	86%–93%	65%–99%	72%–93%

Wille et al. (2003): retropubic; Anastariadis et al. (2003): laparoscopic; Egawa et al. (2003): retropubic + laparoscopic; HJ Keller, personal communication: perineal; Kirschner-Hermanns and Jakse (2002): perineal.

tively. A further delay in regaining continence was seen after postoperative radiation (Young et al. 2003). Eighty-nine percent of patients achieved final continence status 6 months postoperatively (Fontaine et al. 2000). At the end of the 1st year after surgery, continence rates rose to around 90%, leaving 5%–15% of patients requiring a long-term treatment (Table 25.2).

Intrinsic sphincter deficiency resulting in urinary stress incontinence is the primary cause of incontinence and can be found in 57%–100% of incontinent patients after radical prostatectomy (Comiter et al. 2003). However, in the early postoperative period, up to two-thirds of patients suffer from initial urgency (Fontaine et al. 2000) and detrusor pathologies such as bladder instability or low compliance bladder influence continence in 13% and 25% of cases, respectively, in the long run. A mixed incontinence with bladder and sphincter dysfunction is the cause of incontinence in up to one-third of patients (Oehlschläger et al. 1999; Pfister et al. 2002; Gomha and Boome 2003) (Table 25.3).

Table 25.2. Factors determining time to regain continence after radical prostatectomy

Incontinence after surgery		
• Early incontinence rates		80%–97%
• Time to regain continence		3 months[a]
Age	<55 years	1.4 months
	55–64 years	3.0 months
	>64 years	3.3 months
Comorbity	None	1.4 months
	1–2	3.3 months
	>2	3.5 months
• Overall continence rates >1 year		13%–99%
Incontinence requiring treatment		5%–15%

Wille et al. (2003); Anastariadis et al. (2003); Parekh et al. (2003); Alivizatos et al. (2003).

[a] Young et al. (2003); Smith and Milam (2002); Abbas et al. (2002); Kielbl et al. (2001); Melchior et al. (2000).

Table 25.3. Pathophysiology of incontinence after radical prostatectomy

Pathophysiology of incontinence after surgery	
Intrinsic sphincter deficiency	57%–100%
Bladder instability	4%–13%
Low compliance bladder	11%–25%
Mixed incontinence	28%–31%
Initial urgency	66%

Chao and Mayo (1995); Oehlschläger et al. (1999); Fontaine et al. (2000); Comiter et al. (2003); Gomha and Boone (2003).

25.2.2 Information and Education Before Discharge from the Hospital

Although the patient receives preoperative information about the diagnosis of prostate cancer and possible treatment options and side effects, little is retained of the preoperative education because of the overwhelming nature of the diagnosis. Therefore the early concerns of men in the early weeks after radical prostatectomy are:

- The lack of knowledge on the postoperative recovery period
- The knowledge gaps on catheter care, postoperative pain, incontinence and erectile dysfunction
- The lack of health care professional support

These information deficits severely affect the quality of life and healthy postoperative rehabilitation (Moore and Estey 1999).

Most of the patients are discharged from the hospital only with protective padding and for most of them this is a catastrophe. Only 37% and 61% of men in two studies (Fitch et al. 2000; Palmer et al. 2003, respectively) believe they had received enough information to prepare them to cope with urinary incontinence. Therefore accurate and comprehensive information and instructions on protective aids, diapers, pads, special devices for men, urine drainage sheaths, penile clamps and practical tips and instructions on how to use these devices are mandatory before the patient leaves the hospital (Fig. 25.1). Admission to specialized rehabilitation clinics, continence advisers or continence clinics as well as communication with local chapters of support groups may also help to regain continence more completely.

25.2.3 Diagnostic Work-up

After an appropriate interval to allow for improvement, the patient should undergo a thorough evaluation to assess the contribution of the various causes of incontinence and should be managed using a sequential treatment approach (Wahle 2000). However, there is no consensus on the appropriate interval and the best therapy.

When the patient is not satisfied with his continence status before discharge from the hospital, we directly perform a noninvasive diagnostic work-up taking the his-

Fig. 25.1 Variety of incontinence products: protective aids, diapers, pads, urine drainage sheaths, penile clamps

tory, urine analysis, bladder diary, stress and pad test, physical examination and ultrasound to quantify the urinary loss, and repeat this work-up after 4–6 weeks if there is no improvement. More invasive methods such as cystoscopy, including a video sphincter test or urodynamic studies, are usually not performed before the first 3 months after surgery, but are mandatory when operative interventions are planned (Table 25.4).

Table 25.4.
Diagnostic work-up in post-prostatectomy incontinence

Diagnostic work-up
Before discharge and repeated after 4–6 weeks:
• History: urinary control, number of pads
• Bladder diary
• Stress test
• Pad test
• Urine/urine culture: exclusion of UTI
• Physical examination: PFM contraction
• Ultrasound: residual urine, PFM contraction
After 3 months
• Cystoscopy
• (Video) sphincter test
• Urodynamic studies

UTI urinary tract infection, *PFM* pelvic floor muscles.

Table 25.5.
Questionnaire (modified according to Salomon et al. 2003)

1. Do you leak urine during the day?
   - Never
   - Sometimes (less than once a week
   - Often (at least once a week)
   - All the time
2. Under what circumstances do you leak urine?
   - Never
   - During intense effort (sport, lifting heavy things, etc.)
   - During moderate effort (climbing stairs)
   - During slightest effort (coughing, laughing, etc.)
3. Do you wear pads during the day?
   - Never
   - As a precaution
   - Not more than one pad per day
   - More than one pad per day
4. Do you leak urine during your sleep?
   - Never
   - Sometimes (less than once a week)
   - Often (at least once a week)
   - All night
5. Do you use pads at night?
   - Never
   - As a precaution
   - Not more than one pad per day
   - More than one pad per day

A careful history, favorably completed by a questionnaire (Table 25.4), inquiring about total urinary control, the circumstances of urinary leakage and the number of pads used during the day (Kielb et al. 2001; Salomon et al. 2003), a bladder diary, a stress test and a pad test are prerequisites to quantify urine loss.

A urine analysis is mandatory to exclude a urinary tract infection deteriorating urinary control.

A physical examination should test the capability of pelvic floor muscle contraction.

Ultrasound is necessary to check post-void residual urine and is also able to show if contraction of the pelvic floor can be performed correctly.

Cystoscopy is normally not necessary within the first 3 months, unless obstructive voiding patterns indicate a stricture of the anastomosis. The most important value of cystoscopy is the possibility of sphincter evaluation. A video sphincter test, enabling the patient to watch the procedure of actively contracting his sphincter under cystoscopic view, provides the physician with a quantification of sphincter damage and makes the patient aware of his urethral sphincter and can also be used as a biofeedback mechanism during continence training.

Urodynamic studies are only indicated in small bladder capacity, suspicion of detrusor hyperactivity or low compliance bladder, and are usually not performed in the first 6 months after surgery. The value of urethral pressure profiles and leak-point measurements is controversial (Comiter et al. 2003).

25.2.4 Treatment in the Early Postoperative Period

Because incontinence improves with time after surgery, invasive surgical interventions should be withheld initially. Improvement continues for at least 1 year after surgery, However, if there is still substantial leakage at 6 months postoperatively, few men will regain total urinary control, and investigation and intervention seem warranted (Moorehouse et al. 2001; Smith and Milam 2002). The early treatment relies on behavioral management, including patient education and information, supportive care with continence devices, pharmacotherapy, continence training with pelvic floor muscle exercises and/or biofeedback mechanisms and electrical stimulation (Table 25.6).

25.2.4.1 Incontinence Products and Appliances

Spontaneous recovery of normal urinary control can take more than 1 year. Therefore, in the early period after surgery protective devices should be offered to the patient to improve his quality of life and provide a safe feeling in his social environment.

The most important considerations when selecting incontinence products or devices are that any device used must not leak and must be discreet, easily managed, and must be able to be changed without others noticing it. The volume and frequency of urine leakage, the mobility, the manual dexterity and the patient's preferences determine the choice of the products. Special disposable absorbent products for men may not be suitable or fit in the early postoperative phase but may be an option when continence has improved. Men with a higher degree of incontinence may profit from urinals or urine drainage sheaths. External fixed compression devices such as penile clamps or penile tapes were already presented in 1750 but recently there has been a trend back toward these devices in special cases. However, this form of passive urethral compression should not be applied for longer than 2–3 h/day and is therefore reserved for patients doing sports (Madjar et al. 2001).

Table 25.6.
Treatment options in the early postoperative period after radical prostatectomy

Incontinence after surgery Treatment options in the 1st year
• Watchful waiting • Patient education + support • Protective devices, pads, diapers • Pharmacotherapy (anticholinergic drugs) • Physiotherapy (PFME, BFB) • Electrical stimulation • No invasive surgery before the 1st year after surgery!!!

PFME pelvic floor muscle exercises, *BFB* biofeedback.

25.2.4.2 Pharmacotherapy

Anticholinergic drugs can help to increase the bladder volume after surgery, as 66% of patients have associated urgency in the early postoperative period. Administration of trospium chloride in addition to continence training in the first 3–4 weeks after surgery significantly improved the degree of incontinence, the number of pads, voiding frequency and bladder volume (Otto et al. 2002).

25.2.4.3 Physiotherapy: Pelvic Floor Muscle Exercise, Biofeedback, Electrical Stimulation

Different physiotherapeutic approaches such as pelvic floor muscle exercises (PFME), biofeedback (BFB), electrical stimulation (ES) or a combination of these methods have been used for conservative treatment of incontinence after radical prostatectomy (Fig. 25.2). The reports of the efficacy of these continence training methods are discrepant because trials are often not randomized and controlled. In the Cochrane Review, Moore et al. detected only five randomized studies in a review period from 1980 to 1999. They concluded that it was not possible to reliably identify or rule out a useful effect of these methods and that men's symptoms tended to improve with time irrespective of management of incontinence (Moore et al. 2001). Several studies could not show any significant differences concerning early and late continence rates. Especially in severe incontinence, physiotherapy had limited benefit.

In a recent prospective, randomized study comparing the effect of PFME, ES and BFB on urinary incontinence after radical retropubic prostatectomy, Wille et al. could not see any significant difference in continence rates after 3 and 12 months in any of

Fig. 25.2 Biofeedback and electrical stimulation devices

the three treatment options, concluding that up to €711 can be saved per patient by omitting ES or BFB with preference given to simple PFME (Wille et al. 2003).

There is no conclusion about the optimal timing to start physiotherapy. Starting with PFME or BFB sessions prior to radical prostatectomy resulted in earlier achievement of continence but did not influence the 1-year continence rates (Sueppel et al. 2001; Parekh et al. 2003).

In another study by Bales et al., preoperative biofeedback starting 2–4 weeks prior to surgery did not accelerate the return of urinary control and did not improve the 6-month continence rates (Bales et al. 2000).

Pelvic floor muscle training starting at the 7th postoperative day did not show any differences in early continence rates and continence rates after 1 year compared to no training (König and Pannek 2001).

Starting with physiotherapy using verbal instructions or electromyographic biofeedback immediately after catheter removal did not show differences in effectiveness, as all methods yielded comparable continence rates after 1, 2, 3, and 6 months assessed in the 1 h pad test and the numbers of pads per day. The urine loss decreased from 39 g and 31 g to 3 g and 0 g, respectively after 6 months and the number of pads per day declined from 3.9 and 3.6 to 0.4 and 0.2, respectively (Floratos et al. 2002). However, van Kampen et al. found a quicker recovery of continence in the first 3 months performing biofeedback training with an 88% continence rate compared to a continence rate of only 56% in a control group (van Kampen et al. 2000). After a 3 months training starting the 3rd postoperative day, no significant differences were found in a control group receiving no physiotherapy or when patients underwent either pelvic muscle exercise or electrical stimulation. Similar results were obtained in men after cystectomy and orthotopic bladder substitution using ileum-neobladder (Piechota et al. 1999).

Starting with biofeedback 6 weeks after radical prostatectomy could not improve 6-month continence rates (Franke et al. 2000). Comparing the results after 24 weeks of either verbal instructions, pelvic muscle exercise or additional electrical stimulation, no differences were found in the pad weight test when therapy was initiated 8 weeks postoperatively (Moore et al. 1999).

However, further research is needed to rule out the optimal timing and protocols for physiotherapy and the best practices and training methods. Whether the patient receives the instructions and initial training session from the primary care or home care physician or in a specialized continence center or rehabilitation clinic may be important, because this may have a decisive effect on the correct execution of the exercises and the motivation and compliance of the patient and the outcome as well.

Our Recommendations

We recommend an early onset of physiotherapy with instructions in pelvic floor contractions the day before surgery, repeating this on the 7th postoperative day and then starting with individual training directly after catheter removal. In this early period, it is most important that the patient be able to achieve awareness of his pelvic floor muscles and urethral sphincter in order to correctly execute the exercises. Compared to a simple wait and see strategy, active training has an important psychological aspect for the patient that should not be underestimated. Physiotherapy starting directly after catheter removal allows the patient to actively influence his situation, taking responsibility for the time needed to regain continence and improving his motivation and compliance to do something for his recovery. In our experience, an anticholinergic

medication should also be offered to patients as it has an additional positive effect on urinary control in the first 3–4 weeks.

We also use the benefit of the German health policy: after discharge from the acute clinic, the majority of patients are admitted to specialized rehabilitation centers where they are offered a 3–4 weeks of an intensive training program. Whereas at admission 80% of patients had a second or third degree of incontinence, 33% were completely continent, 39% had a low degree of incontinence and only 28% had a higher degree of incontinence at time of discharge (Hoffmann et al. 2002).

25.2.4.4 Treatment in the Advanced Postoperative Period

Patients who are incontinent 6 months after surgery with no evidence of improvement will probably not become continent on their own or with conservative methods. More than 12 months after surgery, 27% of patients suffer from incontinence that makes protection aids necessary (Augustin et al. 2002).

In these cases, further treatment modalities are required depending on the patient's complaints and distress. The treatment of persistent stress incontinence is mainly based on surgery, as it does not respond to physiotherapy and anticholinergic drugs. While injection therapy with bulking agents is safe and well tolerated, its effect is limited and decreases with time. The best results are achieved by implantation of an artificial sphincter, but with significant complication and revision rates (Table 25.7).

Bulking Agents

After the first injection of Macroplastique, 6 of 50 patients were dry and 28 of 50 were improved. After the second injection, 10 of 40 were dry and 5 additional patients were improved (Kylmälä et al. 2003). However, in the long-term follow-up, the continence rates of all injectables dropped to 8%–48%; consequently we no longer recommend these methods.

Sling Procedures

Sling procedures for male incontinence are attractive as they are easy to perform, inexpensive and nonmechanical. Using autologous or synthetic materials, long-term re-

Table 25.7.
Treatment options in the advanced or late postoperative period after radical prostatectomy

Incontinence after surgery Treatment Options after the 1st year
• Incontinence products or devices • Long-term physiotherapy • Electrical stimulation • Bulking agents (injectables) • Micro-balloons (Pro-Act) • Sling procedures • Artificial sphincter

sults around 50%–70% can be achieved (Schaeffer 2002). However, these techniques do not play an important role in management of postprostatectomy incontinence.

Artificial Urinary Sphincter

Artificial urinary sphincter placement is the current gold standard of treatment for persistent postprostatectomy incontinence. Success rates defined as two pads or fewer per day range from 60% to 80% and patient satisfaction rates go up to 90%. Complete continence is unusual. Only 4% will become completely dry, whereas 60% will further require 0–1 pads, 31% 2–3 pads and 4% 3 or more pads per day (Montagne et al. 2001). Despite its attractiveness, the artificial sphincter is an expensive mechanical device that can fail requiring re-operations ranging from 50% to 60% (Schaeffer 2002). Regarding these reliable continence rates and complication rates, we would not offer an artificial sphincter to a man requiring less than two pads per day unless he significantly suffers from his urinary loss.

Micro-Balloons

A new minimally invasive method is the implantation of two paraurethral balloons at the bladder neck (ProAct) with an adjustable filling status via scrotally implanted tubes (Fig. 25.3). The early results with a follow-up of 3 years are encouraging: 62% of patient will become dry and 29% will be improved. The complication rates are low (Hübner and Schlarp 2003) (Fig. 25.3).

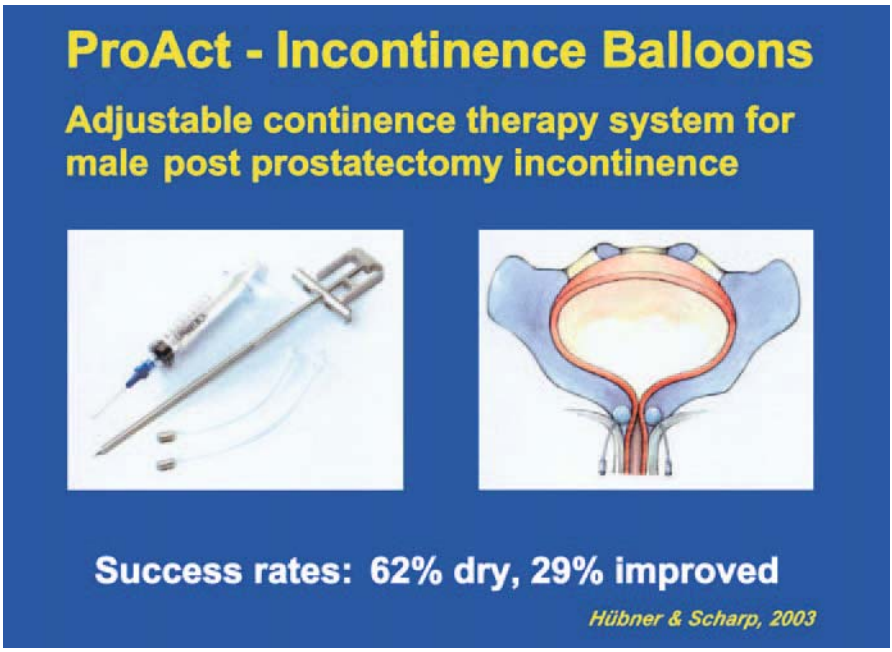

Fig. 25.3 ProAct – Micro-balloons

25.3 Incontinence After Female Incontinence Surgery

25.3.1 Incidence and Pathophysiology

In the long-term follow-up, continence rates for female incontinence surgery range from 70% to 90%. So far colposuspension and fascial sling procedures are still the gold standard of incontinence surgery, but tension-free vaginal tapes have proved to be equally effective in a follow-up of up to 8 years.

In a study exploring the prevalence and outcome of incontinence surgery in females, Diokno et al. conducted interviews in 45,000 households. From the 24,581 women answering the questionnaire, 4% had a history of incontinence surgery. The initial surgical success rate was 74% but the satisfaction rate only 67%, whereas the continence rates after 1–2 years improved to 86% after colposuspension and 91% after a sling procedure. The factors that determined satisfaction were the number of pads, symptoms of stress incontinence and urge symptoms. Interestingly, 53% of patients reported current use of pads or other absorbent devices, indicating a persisting problem with incontinence (Diokno et al. 2003).

Persisting or de novo urgency or urge incontinence is the most severe cause of incontinence after female incontinence surgery. It occurs in up to 26% of patients after colposuspension, sling or tension-free tape procedures as well (Tunn et al. 2001; Volkmer et al. 2003; Rezapour and Ulmsten 2001; Croak et al. 2003).

A de novo urge is often related to a hyperelevation of the bladder neck, false sling or tape position or tape dislocation (Fischer et al. 2002a, b; Nguyen 2002; Scapero and Nitti 2002).

In up to 27% of patients, an additional obstruction occurs after incontinence surgery with incomplete voiding or urinary retention despite attempting a tension-free placement of the tape. In most of these cases, a preoperative detrusor hypocontractility is found. Usually the micturition resolves within the first 10 days after surgery. An obstructive urinary retention making intermittent catheterization necessary occurs in up to 6% of patients (Croak et al. 2002).

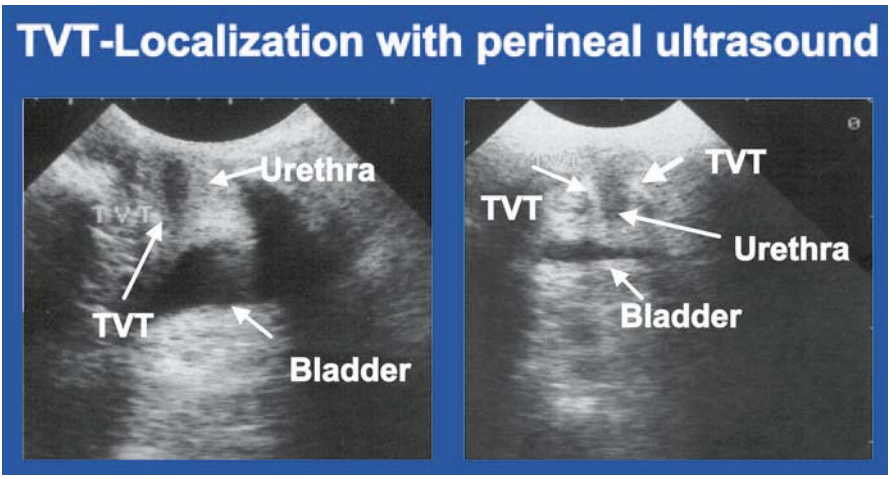

Fig. 25.4 TVT localization with perineal ultrasound

In a study by Sevestre et al., persistent stress incontinence was found in 14% of patients, whereas 18% of failures had urge incontinence and 21% had de novo urgency without incontinence (Sevestre et al. 2003).

However, there are no conclusive data about rates of persisting pure stress incontinence after the various incontinence procedures in females. As in patients with a preoperative hypotonic urethra of less than 10 cm of water in the urethral pressure profile, continence rates after colposuspension and tension-free tapes do not exceed 50%–80%, and other sling procedures will only be slightly better (Rezapour and Ulmsten 2001; McGuire and Lytton 2002). It can be assumed that in this case postoperative persisting stress incontinence will be roughly 20%–30%.

Additionally, urinary tract infections may be responsible for deterioration of continence after incontinence surgery. A urinary tract infection developed in 23% after colposuspension despite antibiotic prophylaxis and 81% of infections occurred after the 7th day (Chilaka and Mayne 1998).

25.3.2 Diagnostic Work-up

As in males suffering from incontinence after radical prostatectomy, the preoperative communication between patient and physician with thorough information on expected outcomes, including dysuric or incomplete voiding and incontinence during the first 4 weeks, may help to decrease dissatisfaction with postoperative results (Croak et al. 2003). Interestingly a longer recovery time was not associated with decreased satisfaction.

A careful history can already distinguish the circumstances of urine loss, whether it is due to stress, urge or mixed incontinence. A bladder diary, stress test and pad test should complete and document these subjective data.

A urine analysis is mandatory to exclude a urinary tract infection deteriorating urinary control.

Physical examination including vaginal examination is performed to test the postoperative healing and the capability of pelvic floor muscle contraction.

Ultrasound of post-void residual urine is necessary to detect obstruction and retention. Perineal or transvaginal ultrasound are excellent tools to identify the localization of a sling or tape and is also an excellent instrument to evaluate the effect of pelvic floor muscle contraction on the urethra and bladder (Fig. 25.4).

Cystoscopy is performed when hyperelevation of the bladder neck and tape erosion or perforation are suspected.

Urodynamic studies are usually indicated when postoperative complaints will be unchanged 4–8 weeks postoperatively and are mandatory before each surgical reintervention (Table 25.8).

25.3.3 Treatment in the Early Postoperative Period

Supplying the patient with incontinence devices adapted to the degree of incontinence is the first step in early postoperative treatment.

Anticholinergic drugs should be tried for at least 4 weeks in case of urgency or urge incontinence.

Pelvic floor muscle exercise, biofeedback and electrical stimulation are further options to improve the continence status.

Table 25.8.
Diagnostic work-up in incontinence after female incontinence-surgery

Diagnostic work-up
• History: urgency, urge or stress incontinence, dysuria
• Bladder diary
• Stress test
• Pad test
• Urine/urine culture
• Physical examination: PFM contraction
• Ultrasound: residual urine
• Perineal or vaginal ultrasound: tape localization
• Cystoscopy: sling perforation or erosion
• Urodynamic studies

PFM pelvic floor muscles.

If urgency and urge incontinence persist 4 weeks after surgery a local infiltration of the anterior vaginal wall with local anesthetic drugs can rule out patients who will improve from a surgical vaginal urethrolysis.

Midline tape lysis or vaginal urethrolysis within the first 4 weeks after placement of the tape succeeded in resolving obstruction in 65%–87% and resolving urgency or urge incontinence in 16%–69%, with a low rate of de novo stress incontinence in 13%–19% (Petrou and Young 2002 Fischer et al. 2002a, b; Carey et al. 2003; Croak et al. 2003; Scapero et al. 2003). From 800 tension-free vaginal tapes, 45 had to be cut, 40% due to retention, 51% due to sensory urge and 9% due to combined pathology. The tape incision was usually performed about 8 weeks postoperatively (Fischer et al. 2002a, b).

25.3.4 Treatment in the Advanced Postoperative Period

In urgency or urge incontinence resistant to pharmacotherapy or not suitable for urethrolysis, a trial of injection of botulinum A toxin in the detrusor muscle or a neuromodulation of the sacral nerves may be justified.

A recurrent incontinence surgery should not be performed earlier than at least 3 months after the preceding operation. Whether classical sling procedures or tension-free vaginal tapes should be preferred in this situation cannot definitively be answered (Wilson et al. 2003). An advantage of the new transobturatory approach may be that this technique will bypass the former region of surgery.

In worst cases, implantation of an artificial urinary sphincter may also be an option in female stress incontinence.

25.4 Conclusion

Urinary incontinence is common after radical prostatectomy and not as rare as could be expected after female incontinence surgery.

As incontinence improves with time, invasive treatment options should be withheld in the early postoperative period.

However, patients should be offered therapeutic methods that improve their quality of life and accelerate the recovery period to regain continence. In this context, phys-

iotherapy is the most important therapeutic approach in the early postoperative period. However, the value of the different methods such as simple pelvic floor muscle exercise, biofeedback training, electrical stimulation or combination therapies remain uncertain.

Accurate preoperative information on possible postoperative bladder dysfunctions or incontinence can improve patient's satisfaction and quality of life.

However, the most important point is to prevent postoperative incontinence with thorough preoperative work-up and careful surgical techniques.

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Chapter 26

Incontinence Treatment after Rectal or Perianal Surgery

26

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Contents

26.1 Introduction

Fecal incontinence is estimated to be present in approximately 4.8% of the healthy adult population, and the incidence of this disorder increases with age, affecting roughly 7% of healthy people over 65. Epidemiological data suggest that approximately 5% of the adult population were unable to control solid stools and up to 20% have problems at least with one type of incontinence (solid or liquid stools, gas) (Giebel et al. 1998).

Anal incontinence can result as a disorder of any mechanism that is normally responsible for undisturbed continence. The condition can be based on a pathologic muscular situation or disorders where the pelvic floor is intact (Table 26.1).

Fecal incontinence after perianal surgery or rectal surgery is usually the result of damage to the anorectal ring; however, varying degrees of impairment for control are seen even after what is considered to be a proper division of a portion of the sphincter muscle. Even anorectal surgery without damage to the sphincter muscle can lead to incontinence under certain conditions. However, treatment will always focus on the main basic underlying condition, i.e., repair or compensation of muscular damage or reparation of a defect in the neuromuscular pathway.

26.2 Etiology

Sphincter injury leading to incontinence is most commonly related to obstetric (denervation of the sphincter) or surgical injury, also accidental anal impalements or injuries after pelvic fractures are seen frequently in centers specialized in incontinence treatment. The main causes of fecal incontinence following surgical procedures are outlined in Table 26.2.

Table 26.1. Disorders leading to incontinence

Sphincter intact
Diarrhea (infection, IBD, Short bowel syndrome, laxatives, sweeteners, radiation)
Overflow (stenosis tumor, impaction)
Neurologic disorders (congenital, i.e., spina bifida, myelomeningocele, multiple sclerosis, dementia, diabetic neuropathy, paraplegia, prolapse)
Sphincter impaired
Congenital anomaly (anal atresia)
Trauma (surgery, obstetric, trauma)
Neurogenically caused atrophy (descensus of the perineum, prolapse, pudendopathy)

IBD inflammatory bowel disease.

Table 26.2. Etiology of fecal incontinence

Colorectal disease
Hemorrhoids, rectal prolapse, inflammatory bowel disease, neoplasms
Gynecology
Obstetric injury, rectovaginal fistula
Surgery
Fistulectomy, hemorrhoidectomy, sphincterotomy, low rectal anastomosis
Urology
Urological neoplasm, prostatectomy
Traumatology
Injury during anal sexual intercourse, war injury, traffic injury
Neurosurgery/neurology
Cerebral (tumor, vascular accident, dementia, trauma)
Spinal (trauma, protrusion, cauda syndrome)
Peripheral (diabetes mellitus, multiple sclerosis, pudendal nerve injury)
Congenital
Spina bifida, meningomyelocele
Miscellaneous
Laxative abuse
Fecal impaction
Encopresis
Diarrhea

26.3 Perianal or Rectal Surgical Procedures Associated with Fecal Incontinence

Several anorectal surgical procedures can lead to incontinence for solid or liquid stool and global figures from the literature report a fecal incontinence rate of around 12% after open sphincterotomy, 30% after fistulotomy, and mild degrees of incontinence can also occur following hemorrhoidectomy (Garcia-Aguilar et al. 1996a,b; Madoff et al. 1992; van Tets and Kuijpers 1994).

Vaginal delivery with or without additional maneuvers is regarded as a potential risk for perineal and/or sphincter injury.

Nevertheless, clinical detection underestimates this problem: only about 2% of women were recognized as having a sphincter defect related to childbirth and only about 1% were identified as having third-degree tears (Sultan et al. 1993).

Contrary to this, based on endoanal ultrasound evidence, Sultan et al. reported that 30% of primigravidae have some persistent defect in the sphincters; however, most of these injuries are incomplete and can be compensated, thus avoiding permanent problems with continence on short-term follow-up.

Furthermore, electrophysiologic studies have shown significantly delayed pudendal nerve latency results in women following vaginal delivery compared to cesarean section. Today some authors assume that pudendal nerve damage during delivery can lead to muscular atrophy and the postmenopausal condition to diffuse weakness of the pelvic floor (so-called idiopathic incontinence).

In order to identify the number of women with continence problems after child birth without sphincter defect, but based on pudendal neuropathy, multicenter long-term studies will be needed.

A portion of patients after anterior rectal resection do experience episodes of incontinence. In the early 1980s, Williams and Johnston reported that 15% of their patients with colorectal anastomosis sited 10 cm or less from the anal verge were incontinent for solid stool occasionally and 10% were incontinent for gas. All patients had increased frequency of bowel action with a mean of 3/24 h at a mean of 40 months postoperatively. These symptoms improved with time (Williams and Johnston 1984).

Since low rectal resection is always associated with a reduction in rectal compliance, an increase in the frequency of bowel movements is a frequent observation in the postoperative period. However, this situation together with a weak sphincter function (either preexistent or following surgery) can lead to severe incontinence problems. Additional radiotherapy (pre- or postoperatively administered) is thought to deteriorate rectal compliance and or sphincter function in some patients as well. Welsh et al. (2003) reported incontinence in more than 50% of their patients with low rectal anastomosis and preoperative radiotherapy.

26.4 Conservative Treatment

26.4.1 Medical Therapy

Medical therapy of fecal incontinence is warranted in conditions with mild degrees of incontinence and often simple measures improve the patient's condition. Dietary measures with high-fiber products and stool bulking supplements will produce soft, formed stool, which is easier to control than liquid stool. Additionally, antidiarrheal agents such as loperamide frequently help when no specific therapy is available for an underlying gut disorder. Finally, irrigation therapy may induce bowel movements and leaves the rectum empty between evacuations.

26.4.2 Biofeedback

In order to improve functional deficits in patients in whom surgery is not clearly indicated, biofeedback therapy is the first therapy of choice. About two-thirds of patients will benefit from biofeedback and a reduction in episodes of incontinence can be achieved in more than 90% of these patients (Madoff et al. 1992). Biofeedback is painless and harmless; however, it is time-consuming and requires a certain compliance of the patient and a dedicated therapist.

26.5 Surgical Treatment of Fecal Incontinence

26.5.1 Traditional Surgical Techniques

Classical surgical treatment includes direct repair of a circumscribed gap in the anal sphincter, the so-called overlapping sphincteroplasty or anal repair, as first described by Parks. Short term, results of this method show improvement of continence in a high portion of patients and may result in restoration of a normal squeeze pressure (Fleshman et al. 1991). In complicated cases, sphincteroplasty can be combined with a levatorplasty or a transposition of one limb of the puborectalis muscle around the anal canal (Miller et al. 1989).

Long-term results of direct sphincter repair have not been published frequently. However, a study by the St. Marks group following patients over 10 years following this operation reports a reduction from 75% to 25% satisfying continence results, which indicates that the mere mechanical restoration of the integrity of the anal canal might not be sufficient for a long-lasting resolution of the problem.

Surgical repair of a diffuse weakness of the pelvic floor using the postanal repair method was first introduced by Parks in 1959. When an anterior levatorplasty and an internal sphincter plication are added (total pelvic floor repair), results might be improved, with complete continence achieved in two-thirds of patients (Chapman et al. 2002; Deen et al. 1993). However, the results of total pelvic floor repair are still discussed controversially in the literature. While the short-term results are frequently satisfying, full continence is rarely achieved in longer follow-up, probably due to muscle atrophy caused by a concomitantly existing pudendopathy.

26.5.2 New Approaches

Patients with larger sphincter defects that are not treatable by direct sphincter repair are candidates for new treatment options such as skeletal muscle transposition or the application of an artificial bowel sphincter, which can improve the situation in up to 75%–80% of patients.

In order to create a new anal sphincter, a variety of methods have been used in the past. Musculoplasty using a free smooth muscle collar initially showed good results; however, the method was often associated with ischemia problems (Hofschneider and Hecker 1981).

Transposed skeletal muscles are most widely used for the creation of a new anal sphincter. Muscles suited for transposition are the sartorius, gluteus maximus and gracilis. Initial promising results with the sartorius muscle in the animal model were not achieved in humans due to devascularization problems. The gluteus maximus was initially used in 1902 and after being abandoned, the method experienced a revival in the 1980s. However, the gluteus muscle is important in daily activities and impairment of its function may pose problems for the patient, and today the method is no longer used.

26.5.3 Muscle Replacement Procedures

26.5.3.1 Dynamic Graciloplasty

The musculus gracilis is the most superficial adductor and has no important function in humans. The superficial position and the proximal neurovascular supply makes this muscle attractive for transposition. First described by Pickrell et al., the method was used for children with congenital anal atresia; it has also been used for patients with rectal prolapse (Atri 1980; Pickrell et al. 1952). Because of poor functional results due to the inability of the muscle to perform tetanic contraction, the method was abandoned.

Newer physiologic findings of muscle fiber transformation by controlled stimulation led to the reintroduction of graciloplasty in a modified form (Pette and Vrbova 1992). Using an implanted pulse generator, the patient can control muscle function by contraction and relaxation; thus the patient achieves the possibility of voluntary defecation (Baeten et al. 1995).

Indications of a dynamic graciloplasty are an external anal sphincter defect that is beyond repair or loss of the anorectum after surgical removal (total anorectal reconstruction, TAR). Contraindications are inflammatory bowel disease, poor motivation or physical or mental incapacity.

In a recently published review of dynamic graciloplasty in the treatment of fecal incontinence reviewing 17 studies on dynamic graciloplasty, Chapman et al. reported a mortality rate of approximately 2%. The morbidity events ranged from 0.14–2.08 per patient; the overall rate across the fourteen primary studies was 1.12. The efficacy for dynamic graciloplasty was between 45% and 85%. The authors conclude that dynamic graciloplasty is associated with a significant risk of reoperation; however, it would be a clearly superior procedure for restoring continence in some patients than maintaining a permanent colostomy (Chapman et al. 2002).

During the period from 1992 to 2002, 82 patients at our institution underwent anal sphincter restoration by dynamic graciloplasty for primary (n=33) or secondary (n=14) total anorectal reconstruction (TAR) following abdominoperineal rectal resection or acquired (n=22) or congenital (n=13) fecal incontinence. Seventy-nine patients were operated on using the single muscle sling with a modified technique for the muscle wrap (split sling) as previously published (Rosen et al. 1998). The first three patients (one patient with APR, two patients following APR because of ulcerative colitis) were operated on using the procedure described by Cavina et al. (1987) (double graciloplasty). Muscle fiber transformation by controlled stimulation was achieved at the beginning of our experience within 8 weeks (38 patients) and now within 4 weeks postoperatively.

At the beginning of the learning curve, rectal injury (n=11) turned out to be the most serious postoperative complication and was observed mainly in patients following TAR. This observation is in accordance with the results of others, describing a direct correlation of the complication rate with the experience with this technically demanding procedure.

As the most prominent functional problem, constipation in patients following TAR impaired the postoperative functional result; however, this was overcome by regular enemas. An improvement in the continence status was observed in 80% of the patients treated for fecal incontinence, and following APR 66% of the patients had acceptable

results without a permanent colostomy, as previously published in an update of 50 patients (Rosen et al. 1999).

Functional results were evaluated according to a modified version of Williams's scale (Williams et al. 1991). All but three continent TAR patients required an irrigation (100–500 ml water/24 h), to overcome defecation problems and to empty the neorectum.

The value of restoring continence with dynamic graciloplasty is still discussed controversially. However, despite the high morbidity and somewhat better than 50/50 chance of a successful outcome, the decline in quality of life subsequent to creation of a stoma makes the graciloplasty an attractive option for some individuals.

26.5.3.2 Artificial Sphincter

In recent years, experience has been gained with the use of artificial neosphincters to treat end-stage anal incontinence in patients who have either failed medical and surgical treatment or who have been deemed unsuitable for conventional therapeutic modalities. These patients are often faced with accepting a permanent stoma as the only alternative to manage their incontinence.

The artificial bowel sphincter was adapted from experience with the artificial urinary sphincter. Christiansen et al. first used the artificial urinary sphincter for fecal incontinence in the late 1980s. This patient had an excellent result with no complications at a follow-up of 3 months.

Since then, several studies have emerged detailing the preliminary experience of various groups with the artificial bowel sphincter. Eventually, several technical modifications were made to the artificial urinary sphincter to make it better adapted for use around the anus. Indications for implantation were very similar to those for dynamic graciloplasty and consisted mainly of neurogenic and traumatic causes. The majority of patients had previous attempts at sphincter repair. The functional outcome was acceptable in about 75% of patients who had achieved a successful implant.

Infection was the most significant complication, with an incidence of roughly 20–25%. Complete explanation of the device was necessary in approximately 20% of patients.

In a recently published multicenter trial from Wong et al. including 112 patients, 37% of their patients had their devices explanted, 6% had a successful reimplantation (Wong et al. 2002). Patients included in the study were evaluated with anal physiology, endoanal ultrasonography, the Rockwood fecal incontinence quality of life scale, overall health evaluation and a fecal incontinence scoring system ranging from 0–120. A score of 88 or higher described severe incontinence for liquid stool one or more times a week, but less than once a day and was the standard inclusion criteria in the study (Rockwood et al. 2000). A successful outcome for 85% of patients with a functioning device was reported.

At 6-month follow-up, the mean fecal incontinence score improved from 105 preimplant to 51 postimplant for 63 patients, and at 12-month follow-up from 105 to 48 for 55 patients; 46% of their patients required a revisional operation for complications. A total of 384 device-related or potential device-related complications were reported; however, the majority of these events (246) required no reoperation.

Devesa reported in a personal series of 53 patients that normal continence was achieved in 65% and continence to solid stool in 98%. Early complications i.e., compli-

cations before activation of the system, included wound separation (15%), infection (13%), hematoma (13%), impaction (9%) diarrhea (8%), urethral fistulas (5.5%) and fever (2%) and were reported in a total of 44% of patients. Late complications after activation of the system were observed in 58% of patients from 6–55 months of follow-up, with constipation described in 22%.

Patients with abnormal rectal sensitivity showed a greater tendency for fecal impaction. Cuff erosion was noted in 10%, but was not statistically associated with preexisting fibrosis, closure of the wound, tension to the wound or soiling or straining at defecation. Other complications were pump erosion (8%), pain (8%), primary infection (6%) pump malfunction (2%) and systemic leaks (2%); none of these reached a statistical relationship with cause of incontinence, gender and age, length of the cuff and number of milliliters sent from the balloon to the cuff (Devesa et al. 2002).

In conclusion, it can be stated from the available literature that dynamic graciloplasty or the artificial bowel sphincter are both procedures comparable in their success rate as well as the possibilities for complications. Both methods are technically demanding and costly procedures, which need sufficient experience to achieve a good outcome.

The response to this kind of therapy is limited by the presence of simultaneously existing neurogenic lesions (e.g., Cauda syndrome). These problems have been addressed by the development of a new method that focuses on the treatment of neurogenic causes of fecal incontinence (by the nerve stimulation approach).

26.6 Sacral Nerve Stimulation

A considerable number of patients with severe fecal incontinence do not show a structural defect of the external or internal anal sphincter on endoanal ultrasonography or magnetic resonance imaging (or will still report as incontinent despite a technically perfect sphincter repair).

In the past, these patients have been considered to have idiopathic incontinence. In this group with primary degeneration and weakness of the pelvic floor muscles (many of them postmenopausal women with one or more vaginal deliveries in their history, sometimes accompanied with obstetrical trauma) as well as in patients with fecal incontinence caused by spinal cord injury or surgery, treatment options have been limited.

Long-term sacral nerve stimulation (SNS) has been proposed for treatment of selected forms of non-neurogenic and neurogenic bladder dysfunction, mainly caused by reduction of the contractility of the detrusor during electrostimulation (Bosch and Groen 1995; Weil et al. 1998). During stimulation, two different reflex arcs are believed to be activated via excitation of S2–S4 afferents. Sympathetic hypogastric activity is increased, and parasympathetic activity of the lower motoneuron of the bladder is reduced. This dual effect is used for the treatment of detrusor hyperactivity.

Based on various studies in the past, SNS is an accepted treatment modality for urge incontinence as well as the pelvic pain syndrome (Thon et al. 1991). Additionally, electrostimulation has been researched extensively for improvement of micturition in patients with spinal cord injuries (Ishigooka et al. 1998).

Anorectal side effects during this treatment for urinary incontinence consisted of increases in anal sphincter pressure as well as colonic motility. Because intramuscular stimulation of an insufficient anal sphincter had been attempted as late as in the 1960s, the application of SNS in patients with incontinence caused by a weak anal sphincter

or of neurologic origin appeared to be an interesting new therapeutic approach (Caldwell 1963).

Since November 1998, 54 patients have been treated for severe fecal incontinence at our institution. The cause of fecal incontinence is summarized in Table 26.3, showing a majority of patients with severe fecal incontinence as a result of spinal cord trauma or surgery.

After temporary (subchronic) external stimulation (PNE, or percutaneous nerve evaluation) over a period of 10–14 days, patients whose continence status improved underwent implantation of a permanent quadripolar lead and a subcutaneously implanted pulse generator. Acute needle testing revealed a positive pelvic floor response in 41 patients who underwent subsequent permanent implantation. The median number of incontinence episodes decreased from six episodes (3–15/21 days) to two (0–5/21 days). The time period of retention of a saline enema test causing an urge until definitive defecation was 2 min (range, 0–5 min) preoperatively and increased to 7.5 min (range, 2–15 min) postoperatively, as previously published (Rosen et al. 2001). Results of preoperative and postoperative (6-month) anal manometry showed a statistically significant increase in maximal resting and squeeze pressures. In 95% (39 patients) who had shown functional improvement during the test stimulation, permanent implantation was a success, in 5% (two patients), the method failed in the later follow-up (one patient was treated with dynamic graciloplasty and one with permanent irrigation). Quality of life domains of lifestyle, coping/behavior, depression/self-perception and embarrassment improved significantly 6 months after sacral nerve stimulation.

Complications were infection in five patients with a reimplantation of the device in three cases, dislocation of the stimulating electrodes in four patients and pain at the generator site requiring operative revision.

SNS has shown promising results in the treatment of fecal incontinence of neurologic etiology as well as that due to idiopathic diffuse weakness (which is regarded a sequela of pudendal nerve damage in many so-called idiopathic patients today).

Very recently this method has shown very promising results in some of our patients with incontinence following radiotherapy and low rectal resection for cancer as well as

Table 26.3. Causes of fecal incontinence in 54 patients treated with sacral nerve stimulation

	N (%)
Neurologic	34 (63)
Spinal cord trauma or surgery	26 (48)
Spina bifida	4 (7)
Multiple sclerosis	1 (2)
Spinal degeneration	1 (2)
Spinal insult	1 (2)
Diabetic neuropathy	1 (2)
Idiopathic	12 (22)
Constipation	3 (5)
Resection of rectum	3 (5)
Anal atresia	2 (4)

with patients with outlet obstruction and constipation. However, in this new group, longer follow-up is mandatory to provide a definitive conclusion.

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Part VIII

Quality of Life and Long-term Results After Incontinence Treatment

VIII

Chapter 27

Quality of Life with Urinary and Fecal Incontinence

27

Todd H. Rockwood

Contents

27.1 Introduction

The assessment of health-related quality of life (HRQoL) has become a more regarded aspect of health research and care. We have realized that curing the disease in whatever way possible regardless of impacts on life is not necessarily desirable. The intent of this material is to present a brief review and critique of what is currently available to assess HRQoL in urinary and fecal incontinence (UI, FI).

Three basic types of instruments that exist for the assessment of HRQoL and condition-specific quality of life (CSQoL) will be presented:

- Type 1 General instruments (MOS-SF36 [Ware and Sherbourne 1992]
- Type 2 Specialized scales (CESD [Radloff 1977]
- Type 3 Condition-specific (CSQoL: FIQL [Rockwood et al. 2000], GIQLI [Eypasch et al. 1995], IQOL [Wagner et al. 1996], KHQ [Kelleher et al. 1997]).

Each of these approaches has relative strengths and weaknesses dependent upon the reason HRQoL data is being collected. As noted by Naughton et al. (2004), type 1 instruments assess generic health status in persons with incontinence and type 3 items are intended to assess the effect of UI/FI on HRQoL. Type 2 instruments are readily available to assess a range of issues and are generally under-utilized in the assessment of HRQoL.

This chapter will review the impact of FI and UI on HRQoL and the value of measuring it in research and in health care delivery. A brief discussion of some of the instruments that are available or have been used for each of the three types will also be presented. This material will include a description of the instrument and its content validity.

27.2 Incontinence and Health-related Quality of Life

In the consideration of the impact of incontinence on life, it is self-evident that there will be an impact. Cultures usually do not have strong mores around the personal elimination of waste, but most have normative expectations and aspects of the issue border on taboos. In addition to the public health considerations, there are numerous personal and social conventions that incontinence can impact. When the focus is limited to HRQoL, rather than on the gestalt of life (well-being), the impact of incontinence is generally most significant in the social, psychological (affective) and functional (behavior) areas of life. The impact of incontinence on areas such as cognition is usually a secondary impact (e.g., a person is not willing to attend university because of incontinence issues). While the secondary impact is no less real, it is not usually an area that is focused on in either the treatment or assessment of incontinence.

Both UI and FI share common impacts in terms of psychological issues (depression, anxiety, efficacy), function (travel, mobility, coping mechanisms), social (isolation, integration) as well as basic issues associated with the reality of everyday life (REL [Berger and Luckmann 1990]). There is a hint of truth in morale building in sayings such as: "Doing a good job around here is like peeing on yourself in a dark suit, it gives you a nice warm feeling but nobody notices" (www.despair.com). In the life of someone with incontinence, the fear that someone will always notice presents challenges to even the simplest activities in life.

Before moving to a discussion of existing instruments that measure HRQoL related to incontinence, it is important to place such measures in the proper context. There is a tendency to equate HRQoL or even CSQoL with overall quality of life. While health contributes to overall quality of life and well being, it is not necessarily the sole determinant of those things. Figure 27.1 presents a simple model, driven primarily by measurement, of the spectrum of life. Historically, well-being instruments have the broadest content found in measures. Instruments such as the General Well-Being Schedule (Fazio 1977) assess a much wider range of issues than the health-related quality of instruments such as the Medical Outcomes Study Short Form (SF36 [Ware and Sherbourne 1992]). Although these instruments assess a much wider range of life, they are not necessarily cast in terms of the relationship between health and life. Generic instruments to assess HRQoL, such as the EuroQoL (Brazier et al. 1993) and the aforementioned SF-36 (Ware and Sherbourne 1992) are instruments that have been developed to assess a much more restricted domain of quality of life primarily within the context of health. It is essential in the use of such measures that we do not assume too much about the relationship between what is being measured and life. HRQoL is not well-being, and though it may contribute significantly to well-being, it is critical that we not make the inference that it is well-being.

An even more restricted group of measures are CSQoL instruments. As Fig. 27.1 illustrates, they represent a small area within well-being. Most instruments for the assessment of QoL in incontinence focus on measuring three areas: function (behavioral), social (isolation, stigma, etc.) and psychological (depression, anxiety, etc.). These measures are either explicitly or implicitly framed within the context of CSQoL: "Due to your incontinence....". As a result, they assess the psychological, social and functional domains that fall within the shaded area of CSQoL Fig. 27.2. In these instances, it becomes even more important to keep in mind what is actually being measured relative to the larger scope of the domains in question (the psychological, social, and functional areas that are outside of the shaded area).

In summary, it is clear that incontinence has an influence on quality of life and that consideration of quality of life should enter into the assessment and treatment of incontinence. Regardless of whether or not that assessment is formal (e.g., a question-

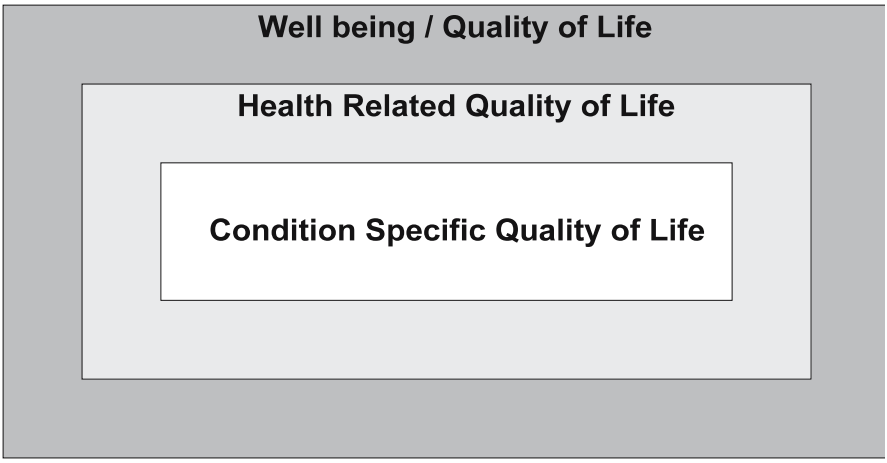

Fig. 27.1. Conceptual framework of quality of life

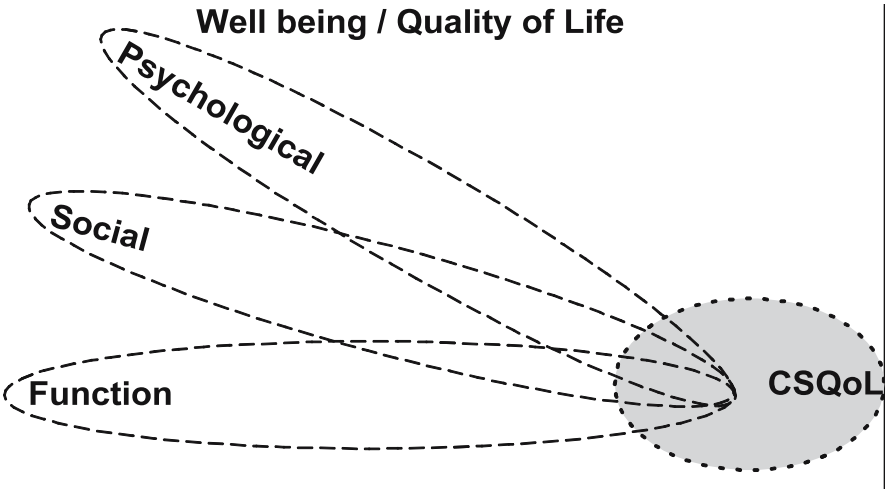

Fig. 27.2. Measurement domain of condition-specific quality of life relative to quality of life

naire) or part of the clinical encounter, it is important that we remain within the boundaries of what is being measured (construct validity) and not allow ourselves to draw inferences that are not founded upon sound measurement (Wainer et al. 1988).

27.3 Instruments

To facilitate the discussion of instruments that exist for the assessment of HRQoL/CSQoL they will be divided into three types: (1) generic health-related quality of life, (2) specialized scales, and finally (3) condition-specific. Table 27.1 presents a brief summary of the scales that will be discussed.

Table 27.1. Summary information for instruments reviewed

Instruments	Items	Scales, domains	Reliability	Validity[a]
Type 1: Generic				
EuroQOL (Brazier et al. 1993)	6	6	×	×
MOS (SF36) (Ware and Sherbourne 1992)	36	8	×	×
Type 2: specialized				
Depressive affect				
Self-Rating Depression Scale (ZUNG) (Zung 1965)	20	1	×	×
Center for Epidemiologic Studies Depression Scale (CESD) (Radloff 1977)	20	1	×	×
Geriatric Depression Scale (Brink et al. 1982)	30	1	×	×
Automatic Thoughts Questionnaire (Hollon and Kendall 1980)	30	1	×	×

Table 27.1. Continued

Instruments	Items	Scales, domains	Reliability	Validity[a]
Social Interaction/Isolation				
Social Avoidance and Distress Scale (SAD) (Watson and Friend 1969)	28	2	×	
Life: Well-being, Mastery and Locus of Control				
General Well-Being Schedule (Fazio 1977)	33		×	×
Purpose in Life Test (Crumbaugh 1968)	20	1	×	×
Adult Nowicki-Strickland Internal-External	40	1	×	×
Control Scale (Nowicki and Duke 1983)				
Mastery Scale (Pearlin et al. 1981)	7	1	×	×
Multidimensional Health Locus of Control Scales (IHLC) (Wallston et al. 1978; Wallston and Wallston 1981)	Varies		×	×
Type 3: Condition-specific: urinary				
Quality of Life in Persons with Urinary Incontinence (I-QoL) (Wagner et al. 1996)	22	1	×	×
King's Health Questionnaire (KHQ) (Kelleher et al. 1997)	21	7	×	×
Incontinence Stress Questionnaire for Patients (ISQ-P) (Yu et al. 1989)	20	3	×	×
Incontinence Impact Questionnaire versions				
IIQ (Schumaker et al. 1994)	30	4	×	×
IIQ-7 (Uebersax et al. 1995)	7		×	×
Urge IIQ (Lubeck et al. 1999)	32	6	×	×
IIQ/II7: Male Adaptation (Fleshner and Herschorn 1996)	Varies		×	×
Type 3: Condition-specific: Fecal				
GIQLI (Eypasch et al. 1995)	36	5	×	×
Adapted KHQ (Bug et al. 2001)	31	10	×	×
Fecal Incontinence Quality of Life (FIQL) (Rockwood et al. 2000)	29	4	×	×
Children				
Child Health Questionnaire (Landgraf et al. 1996)	Varies	10	×	×
Social Avoidance and Distress Scale for Children (SAD) (La Greca et al. 1988)	10	1	×	×
Nowicki-Strickland Internal-External Control Scale for Children (Nowicki and Strickland 1973)	40	1	×	×

[a] It should be noted that the type of validity that has been established is not consistent across all of the different instruments.

Instruments found in the type 1 and type 2 sections apply to both UI and FI, and the discussion of the instruments will differentiate between the type of incontinence. Discussion of the instruments in type 3 will be done for UI and FI separately. The intent of the following material is to summarize the content of these instruments. There are a number of excellent reviews of existing instruments regarding QoL and urinary incontinence in the literature (Corcos et al. 2002; Symonds 2003; Naughton et al. 2004) and fecal incontinence (Rockwood 2004) that provide additional information beyond the scope of this material.

The psychometric properties have been evaluated for all the instruments that are discussed in this chapter. The evaluation of reliability is generally uniform (test/retest, internal) for all the instruments. The validity evaluations are not as uniform. There are multiple methods of establishing validity and each type of validity means different things (Wainer et al. 1988; Nunnally and Bernstein 1994). Within the instruments presented the validity tests include: construct, criterion, discriminating as well as other tests. Space prohibits a discussion of the implication of the type of validity test(s) conducted for each test, but it is important that in the use of the instruments the type of validity test conducted be evaluated relative to the intended use of the instrument.

There is an important issue that is often overlooked when validity is discussed relative to these instruments. It is usually assumed that when an instrument is valid, nonrandom measurement error is minimized. This is not the case: validity assessments rarely evaluate how traditional sources of measurement error in survey methods, question order, response categories, mode of administration, etc. contribute to nonrandom error in measurement (Biemer et al. 1991; Schwarz et al. 1992). It is important when selecting and using 'validated' instruments that one does not assume that measurement error is not present (Rockwood et al. 1999).

The last issue in this area is sensitivity. As with validity, sensitivity encompasses a wide range of meanings: sensitive to clinically relevant change, sensitive to change in the construct, sensitive to life change. All of the instruments are sensitive. Some are well adapted for natural history (dynamics of depressive affect in FI over the life course), others for clinical outcomes (ability to determine if treatment affects life in addition to physiology, etc). In the selection of instruments for research, it is important that sensitivity take on meaning relative to the intent of the research and needs to be evaluated within that context. To say that an instrument is sensitive is not particularly meaningful, they are all sensitive, but they are sensitive to different things.

27.3.1 Type 1: Generic Health-related Quality-of-Life Instruments

Generic HRQoL instruments have been developed for use in the general population. The focus of the measures is directed at assessment of phenomena as it presents in the typical or average population. As a result, these measures are readily applicable to many research settings. From this category, there are two primary instruments that are used to assess HRQoL in incontinence: the EuroQOL (Brazier et al. 1993) and the SF36 (Ware and Sherbourne 1992). (The ordering in the presentation instruments should not be construed to indicate their value for any of the instruments discussed in this chapter.)

The EuroQOL is a six-item survey designed to assess HRQoL in six areas: mobility, self-care, usual activity, pain (discomfort), anxiety/depression, and summary general health rating. A single item assesses each area. The instrument is used much more

widely in Europe and in UI research. The instrument has demonstrated to be an effective tool in assessing HRQoL in incontinent populations.

The SF36 is a 36-item survey with eight multi-item scales and one single item on health transition. The multi-item scales measure the following domains: physical function, role physical, pain, social function, mental health, role emotional, vitality, and general health. Norms have been established for general populations as well as for other specific populations. The instrument is perhaps the most widely used HRQoL tool, and a new version of it has been recently developed (www.qualitymetric.com). As with the EuroQoL, the SF36 has demonstrated that it can be successfully used in the incontinent population.

These two instruments dominate the generic assessment of HRQoL in the incontinence research. Other instruments such as the Sickness Impact Profile, Nottingham Health Profile and Göteborg Quality of Life are also used to assess HRQoL, especially in urinary incontinence. The use of these instruments is not as extensive as the EuroQOL and SF36 (Symonds 2003; Naughton et al. 2004).

The primary advantage to using generic HRQoL instruments is that they allow for comparisons of the study population to the general population or to other populations to which the instruments have been applied. The instruments are intended for use in the general population; therefore they are easy to administer and readily understandable to most respondents. The primary sacrifice in using the generic instruments is the potential for floor effects to emerge, hence affecting ability to detect change.

27.3.2 Type 2: Specialized Instruments

Specialized instruments are dramatically underutilized in the assessment of quality of life in health research in general and in incontinence research in particular. Some of these instruments such as the Self-Rating Depression Scale (ZUNG [Zung 1965]) and the Center for Epidemiologic Studies Depression Scale (CES-D [Radloff 1977]) have been used in research on incontinence. The instruments have proven to be very successful measurement tools. Not all of the instruments presented Table 27.1 have been used in incontinence research or their use has not been reported on, but they represent instruments that could be utilized in incontinence QoL research. Instruments in three primary areas are presented: depression, social interaction/isolation, and mastery/locus of control.

27.3.2.1 Depression

There are numerous short instruments that have been developed to assess depression. Two of the most frequently used instruments are the ZUNG and CES-D. Both instruments have 20 items and generate a single score; ranges for the identification of no depression, mild, moderate, and severe are suggested. These ranges serve as a distinct aid in the interpretation of results. The instruments do not serve a diagnostic function, but are routinely utilized as screening tools. Both of the instruments have been used in FI and UI research. Although the instruments can be used in the geriatric population, the Geriatric Depression Scale (GDS [Brink et al. 1982]) is widely used for this purpose. The GDS is a 30-item instrument that results in a single score with established ranges for determining the severity of depression (there is also a shorter 15-item version [McDowell and Newell 1996]).

In addition to the above instruments, other instruments exist that could be of benefit in the study of the relationship between incontinence and depression, or in the assessment of outcomes. One such instrument is the Automatic Thoughts Questionnaire (Hollon and Kendall 1980). There are two versions of this instrument, one containing 30 items and the other 100 items. The instruments assess automatic negative thoughts associated with depressive affect. The measure provides insight into the dynamic relationship between self-perception and depression and as such can provide useful information for research, or perhaps even clinical work, in the identification and consequences of depression.

27.3.2.2 Social Interaction/Isolation

The measurement of social factors such as integration and isolation is a difficult task. Methods such as network analysis are useful, but difficult to implement and can be overkill for the measurement needed in health research. Alternatives such as the Social Avoidance and Distress scale (SAD [Watson and Friend 1969]) are useful tools. The SAD is a 28-item instrument that assesses avoidance of social interaction and distress/anxiety caused by social interaction. Given the impact that either type of incontinence has on social interaction, instruments such as this could be very useful in specifying the impact not solely in terms of isolation (avoidance), but also produce useful insight into the anxiety associated with social interaction that accompanies incontinence.

27.3.2.3 Life: Well-being, Mastery and Locus of Control

The final area of specialized scales contains instruments from three distinct areas: well-being, meaning in life and locus of control. Looking first at well-being, the General Well-Being Schedule is a 33-item survey, with the first 18 items creating a multi-item scale to assess overall well-being (Fazio 1977). The instrument was initially developed for use by the National Center for Health Statistics, part of the Center for Disease Control in the United States. Instruments such as this can be useful when the scope of research or treatment goes beyond the immediate impact of the disease. A central issue that is borne out in qualitative research on incontinence is that it can impact the basic meaning of life (Rockwood 2004). HRQoL or CSQoL instruments rarely contain items that focus on either changes in the meaning life or even the extent to which an individual feels that life has meaning. The Purpose in Life Test (Crumbaugh 1968) is a short (20 items) instrument that could be used to assess this under studied area.

The health research paradigm is familiar with instruments such as the Multidimensional Health Locus of Control Scales (HLC) (Wallston et al. 1978; Wallston and Wallston 1981). The HLC and similar instruments are useful in health research, but they reflect only the aspect of control. In interviewing individuals with FI, the phrase "my life revolves around my sphincter" is frequently heard; the impact of incontinence is not just on health, it is on life. Dimensions such as mastery, or more generalized control scales, are much more relevant to quality of life than locating control for health. Instruments such as the Mastery Scale (Pearlin et al. 1981) could prove useful in evaluating behavior-based treatments such as biofeedback. The Adult Nowicki-Strickland Internal-External Control Scale (Nowicki and Duke 1983) could be useful tools to assess the

impact that incontinence has on an individual's perception about their ability to control their destiny.

While some of these instruments have been used in the study of incontinence most of them have not, or at least if they have been used, their use has not been reported in the literature. There are several benefits that could come from the increased usage of these types of measures. First, they tend to be much more sensitive to change than generic HRQoL and CSQoL instruments in areas such as depression. Second, going back to Fig. 27.2, they would begin to allow us to assess impact at a more general level: the measurement would allow us to more fully understand and explore the impact of incontinence on social, psychological and functional measures outside of the shaded CSQoL area. These instruments do not have a measurement focus of 'due to incontinence...' and while this removes them from the domain of CSQoL, they are tools that can be used to look at the relationship of specific constructs to incontinence to the larger domain of well-being.

27.3.3 Type 3: Condition-specific Scales: Urinary

Comparatively speaking, a large number of instruments exist to assess CSQoL in UI as compared to FI. This review will focus on four instruments that dominate the assessment of CSQoL for UI. Most of the instruments were initially developed for women, but have either been adapted or found to work well in males. Finally, it is important to note that measures in UI are starting to move beyond just incontinence and are starting to focus on measurements relative to the type of incontinence: urge, stress, mixed, and functional (Symonds 2003).

The first instrument is the Quality of Life in Persons with Urinary Incontinence (I-QOL) (Wagner et al. 1996). The I-QOL has 22 items that are summed and converted to a 100-point scale. The items within the scale assess a range of issues including anxiety (worry about wetting oneself), depression (feel depressed because of incontinence), and behavior/function (sleep, drinking, clothing, etc.). The instrument is used in a large number of studies and demonstrates the ability to detect change.

The King's Health questionnaire (KHQ) is a 21-item instrument that was initially developed to assess CSQoL in females with UI, but has also been utilized in males (Kelleher et al. 1997). The instrument has seven multi-item scales that assess role limitations, physical limitations, social limitations, relationships, affect (emotional problems), vitality (sleep/energy) and severity. The instrument has seen widespread usage and has shown to be a useful instrument to assess CSQoL. It has also been translated into a large number of languages, which makes it a useful instrument for use in diverse populations.

The Incontinence Stress Questionnaire for Patients (ISQ-P) is a 20-item instrument with three multi-item scales: depression, aesthetic/somatic and social (Yu et al. 1989). It should be noted that this instrument is part a group of measures that includes staff observation (ISQ-SOPS) and staff reaction (ISQ-SR). It presents the added strength of a multiple operationalization/multi-method measurement when all three tools are utilized (Campbell and Russo 2001).

The final instrument is actually a group of instruments that derive from the Incontinence Impact Questionnaire (IIQ [Schumaker et al. 1994]). The base IIQ has 30 items with four multi-item scales: physical activity, travel, social function and affect. From this base instrument, a seven-item version has been developed (IIQ-7 [Uebersax et al. 1995]) as well as an instrument to assess QoL relative to urge incontinence (URGE-IIQ

[Lubeck et al. 1999]). The IIQ and IIQ-7, while originally developed for females, have been adapted and are used in the male population (Fleshner and Herschorn 1996). The IIQ family of instruments have been successfully used in trials and outcomes research.

In addition to these instruments, there are other instruments that are used to assess CSQoL. There are several good reviews published that focus solely on CSQoL for UI that contain a discussion of these and other instruments (Corcos et al. 2002; Symonds 2003; Naughton et al. 2004).

27.3.4 Type 3: Condition-specific Scales: Fecal

Three primary instruments have been used to assess CSQoL in FI: the Gastrointestinal Quality of Life Index (GIQLI [Eypasch et al. 1995]), an adaptation of the King's Health Questionnaire for FI (Bug et al. 2001) and the Fecal Incontinence Quality of Life (FIQL [Rockwood et al. 2000]).

The GIQLI assesses five areas:

- 1. Symptom list
- 2. Physical (function as well as perception of functional ability)
- 3. Psychological (primarily affect)
- 4. Social issues
- 5. Disease-specific items (items tied directly to a specific condition, such as bowel urgency for fecal incontinence).

There are 36 items in the instrument. While instruments such as this might not have as much specificity as a traditional CSQoL instruments, they do offer some advantages. The primary advantage is the ability to compare across populations with similar conditions such as other gastrointestinal (GI) conditions. This presents a distinct advantage when comparing the FI population to other populations with GI problems.

The second instrument is an adaptation of KHQ for administration in the FI population (Bug et al. 2001). Wording in the instrument was changed for FI, e.g. "Does your bowel problem. . ." The instrument contains 31 items and has 8 multi-item scales: role limitations, physical limitations, social limitations, relationships, affect, vitality (sleep/energy), coping, general health, plus an assessment of symptom severity. One of the fundamental strengths of the instrument is that it is built upon the established KHQ survey.

The FIQL is composed of four multi-item scales: lifestyle, coping/behavior, depression/self-perception and embarrassment (Rockwood et al. 2000). There are a total of 29 items in the quality-of-life portion of the instrument. (There are additional set of items to assess severity [Rockwood et al. 1999].) The instrument was developed for use in clinical trials and outcomes research in the adult population with FI. The instrument is shown to be responsive to assessing changes in CSQoL in the FI population.

27.3.5 Quality of Life and Children

Measuring HRQoL in children presents a challenge. Constructs such as depression, function, interaction, etc. are relatively stable in adult populations, but can change significantly as a youth moves from childhood to adolescence. This generally requires that multiple versions of the instrument based either on age or development stage be available.

The best instrument currently available for the assessment of HRQoL in children is the Child Health Questionnaire (CHQ [Landgraf et al. 1996]). There are multiple versions of the instruments for different ages as well as self- and proxy-report versions. A common measurement model underlies the different versions of the CHQ, there are ten multi-item scales in the instrument: physical functioning, role social/physical, general health, bodily pain, parental impact-time, parental impact-emotional, role social/emotional/behavioral, self-esteem, mental health and behavior. These ten scales can be used or there are two summary scores that can be calculated: physical health and psychosocial health. Overall, the instrument is the most comprehensive and best-evaluated instrument available to assess HRQoL in children.

While the CHQ is a generic HRQoL measure, there are specialized instruments (type 2 above) that are specifically designed for children. Instruments such as the Locus of Control Scale for Children (Nowicki and Strickland 1973) and the Social Anxiety Scale for Children (La Greca et al. 1988) have been developed specifically for use with children. These instruments are usually not addressed specifically towards HRQoL and especially not CSQoL, but they do represent a tool that is available for assessment of specific issues in children.

27.3.6 Translation

The MAPI Research Institute has an excellent website that contains translation information for many HRQoL and CSQoL instruments discussed in this chapter (www.qolid.org). It is important to note that the list of languages available may not be exhaustive for each instrument. For example, the website identifies there to be English and French versions of the FIQL instrument available, but the instrument has also been translated into Spanish, Italian, and several other languages.

The issue of translation is complex. There is a story often told to graduate students in public health about the first usage of the SF36 in England. While the item "How often do you feel full of pep?" was readily understood in North America, it was not understood in the British population. It seems that in North America "pep" means "energy, vitality" but the British population wondered if it was something that you might drink or eat. While the story may or may not be true, it represents the reality that problems involved in translation are not just about language, but culture as well.

Historically, the standard translation methodology has been translation/back-translation. In health research this methodology still dominates (Sperber 2004). For the past few decades the social science community has been moving towards an alternative method of translation focused on cultural translation (McKay et al. 1996). Cultural translation focuses first on the meaning of the construct being measured across cultures before attempting to linguistically translate the instrument. Establishing that the validity of the construct holds across different cultures is a necessary requirement prior to translating a questionnaire.

The translation issue generally focuses on the instrument but we have found in our work that factors beyond language and culture have to be taken into account. In conducting research in diverse populations living in the U.S. (primarily refugees of the Hmong people and from Somalia) we have found that the method of measurement itself is not understood. Surveys are closely related to multiple-choice tests given to people going through the education system in North America and Europe and, as a result, the form of communication used in survey instruments is generally understood by anyone who grew up in that culture. In other cultures there can be significant barriers posed, not due to the language used in the instrument, but the form of communication that underlies instruments; the question/answer format of communication used in surveys is not understood in some cultures. Finally, for many cultures surveys are understood as a conversation with a purpose, but in working with Hmong and Somali populations we have found that surveys are conceived as more of an interrogation than a conversation.

The desire to conduct surveys in diverse populations is an admirable one, but in conducting this research we need to be sensitive to more than "what does this word translate to in language x." We must take into account whether or not the construct (e.g., depression) retains its validity when an instrument is translated from one language or culture to another. The translation/back-translation process that has traditionally been used for translation focuses our attention on linguistic issues and, while this is important, it is not the only aspect of translation. Translation of instruments must take into account cultural factors as well as issues associated with how questionnaires are constructed and administered.

27.4 Summary

The increased focus on QoL in health research and care is an encouraging one. The conception of health is moving from a model that focused on disease and treatment and is starting to include an assessment of the dynamic relationship between disease, treatment and life. To that end we are seeing a proliferation of HRQoL and CSQoL instruments, which is good. The measurement of HRQoL and CSQoL is still in its infancy, the instruments developed to date are generally adequate, but represent a starting point for the assessment of QoL not an endpoint.

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Chapter 28

Long-term Results After Surgery for Urinary Incontinence

28

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Contents

Over the course of the last few decades, many urinary incontinence operations with modifications and variations of several techniques have been described, and the number is ever increasing; see also Zubke et al. (2004a,b). The task of the surgeon is to select and apply the most suitable procedure for a particular case from the copious supply of techniques on offer. In the past, one proceeded with a static influence and chose the method depending on the institution's school of thought. However, now the present dynamic and globalized science of medicine demands a constant updating of the many methods and theories so that every patient can be optimally treated according to the current level of knowledge. The goal of surgery is to do justice to the patient and to be able to offer her the best operation possible. Essential aids to help the surgeon in the choice of technique for a urinary incontinence operation are the results of clinical studies, using prospective and randomized trials where possible. Using the results from long-term studies, the surgeon must familiarize himself with how the procedure functions over time and ask himself whether the procedure will help in the long term, whether relevant side effects will dominate, and what the risks and benefits are.

The question of whether comparable long-term studies also deliver comparable results is also important. Even in the field of urinary incontinence studies, there are often trends that cannot be immediately comprehended from the method. Several methods (see the following sections) show better results in the studies in the first years after they were introduced than in later years, even with a similar patient collective. The results of the first writer are often not entirely reproducible. Many studies that judge the same operative techniques are not easily comparable, because there are other underlying inclusion requirements or varying evaluation criteria. This naturally makes the validity of the studies relevant as deciding factors for the choice of the study as an operative method. However, despite all these limitations, we have no other objective quality markers for the evaluation of operative interventions for the treatment of urinary incontinence other than these studies, which must be critically analyzed in order to prevent incorrect therapy decisions from being made.

One of the oldest, still practiced operative techniques is the so-called Kelly-Kennedy plication (Kennedy 1937) or the original Kelly plication (Kelly and Dunn 1914). Here, the periurethral tissue in the area of the vesicourethral junction is fixed underneath the symphysis. This method is still widely used in Anglo-American incontinence surgery; it was originally carried out alone, but nowadays, when this method is employed, it is as a rule used in combination with an anterior colporrhaphy. Therefore, few valid long-term studies containing new data and rating only the Kelly plication are available. As a rule, only the combined Kelly plication/colporrhaphy technique has been analyzed. Studies with long-term results of the Kelly plication are discussed with studies of anterior colporrhaphy.

28.1 Anterior Colporrhaphy

Anterior colporrhaphy has long been used as treatment for prolapse. There are many factors involved in the fixation of the cystourethral junction and in its insufficiency: the urogenital diaphragm with its connection, among other things, to the pubourethral ligament and to the Arcus tendineus pelvic fascia. As long as one was not able to estimate the extent of the damage to the individual partial elements, surgery to the neck of the bladder, as described by Richter (1998), had a rather schematic or concise character. Using the presentation that the anatomical form and also the physiological func-

tion define, in a urinary incontinence case one reconstructed the pelvic floor as anatomically as possible with an anterior colporrhaphy, and if necessary, also with a posterior colporrhaphy. As previously mentioned, a Kelly plication would be integrated as a specific operation to restore continence following various schools of thought. The older literature also seems to confirm this procedure.

Park and Miller (1988) compared the long-term results of combined Kelly plication/anterior colporrhaphy with Marshall-Marchetti-Kranz colposuspension and needle suspension according to Pereyra, in a retrospective study (Pereyra 1959). The anterior colporrhaphy with Kelly plication was only carried out on patients with grade 1 stress incontinence, whereas the other two operations were carried out on patients with grade 2 stress incontinence. Therefore, only colposuspension and needle suspension can be compared to each other. The success rate of the operation was measured by means of a questionnaire. Operative success was rated by the patients by indicating no or little leakage of urine.

After the combined Kelly plication/anterior colporrhaphy, 80%, 70% and 66% of patients were cured of their grade 1 stress incontinence after 1, 5 and 10 years, respectively. Perioperative wound infection occurred in 3% of patients, 7.4% required a blood transfusion. Only 2.1% reported cystitis.

Vahlensieck and Schander (1985) reported on over 200 patients who had received an anterior colporrhaphy and Kelly plication as treatment for stress incontinence as an additional operation alongside a vaginal hysterectomy. Of these patients, 62% were cured immediately after surgery, and symptoms were considerably improved in 18%. After 2–8 years, the patients were questioned about their operative results by means of a questionnaire: 47% of them were healed and 25% showed a clear improvement. Consequently, the authors gave a success rate of 70%. Reported serious complications were ligature of a ureter, two wound infections and eight cases of heavy bleeding; 61% of patients with significant bacteriuria were found to have a symptomatic urinary tract infection. Late-onset complications included two patients with dyspareunia due to the introitus being too narrow and one patient was found to have an enterocele as well as adhesions that required treatment.

Beck and co-workers (1991) described their experience of a time period of 25 years with a total of 519 anterior colporrhaphies, 194 of which were carried out as treatment of bladder incontinence. Pre- and postoperative clinical and tonometric control examinations were performed. The follow-up period was between 6 months up to over 5 years. Some collectives were examined and analyzed separately. The treatment of incontinence was carried out with an anterior colporrhaphy and Kelly-Kennedy plication or a modification of this technique in the style of a vaginal retropubic colposuspension. Out of 72 patients treated with the original method, 75% were continent at the time of the control examination; 122 patients were treated with the modified method, and of these, 92% were continent. All in all, it was found that the operative results were clearly more favorable after primary operations (96%) than after relapse operations (after one operation 92% healed, after more operations, 57%). The results for mixed urinary incontinence were unsatisfactory, with a cure rate of only 64%. The following complications were reported: de novo urge incontinence 6%, urethrovaginal fistula 0.4%, need for a blood transfusion 0.5%, and urinary retention 0.5%.

Harris et al. (1995) gave a continence rate of 46% after an average postoperative period of 5.5 years in a telephone-conducted retrospective analysis. Anterior colporrhaphy was also carried out here in combination with Kelly plication. In addition, 93% of patients received a posterior colporrhaphy.

In a prospective comparative study by Bergman and Elia (1995), the long-term results of combined colporrhaphy and Kelly plication were analyzed. After 5 years, only 37% of patients, all primary operative cases, were continent. One year postoperatively, the figure was 63%.

In a prospective study, Kammerer-Doak and co-workers compared objective and subjective success rates. Unfortunately, the study extended only over 12 months; however, it must be stated here that this study was exactly carried out and was objectively measured after the short time period, with only 31% of patients being continent.

Tamussino et al. (1999) evaluated their objectively measured operative success in a retrospective study. The results had already been communicated in another form in 1995 (Tamussino et al. 1995). The authors gave a success rate of 61% after 5 years, and when mild stress incontinence and moderate to severe stress incontinence were differentiated, 82% and 49%, respectively, were cured.

Colombo et al. (2000) observed patients over an average of 13.9 years in a prospective long-term study. Objectively, 42% were cured, subjectively, 52%.

De Tayrac and co-workers (2002) determined subjective and objective operative success after 36 months in a retrospective study. Despite the low time scale of 3 years, this study showed a certain trend in the examination results. After 3 years, 53.6% of patients were objectively cured, and 57.1% subjectively. However, with only 28 patients included, the sample was relatively small, which limits the conclusions of this study.

Putting together the cited long-term results (5 years and longer) in the style of a meta-analysis, we have a long-term success rate for anterior colporrhaphy as a treatment method for stress incontinence of 62%. This correlates well with a meta-analysis by Glazener and Cooper (2003), where the success rate was quoted as being 68% (Table 28.1).

Comparing the studies with and without Kelly plication, a positive use for Kelly plication is not certainly proved.

As further trends show, retrospective studies report better success rates than prospective studies, and the newer studies have shown a certain trend towards lower success rates for anterior colporrhaphy as an operative treatment method for stress incontinence.

28.3 Needle Suspension

For a long time, needle suspension, e.g., according to Pereyra (1959), Stamey (1973) and Raz (1981), was considered an option for the operative treatment for stress incontinence.

In a prospective study, Park and Miller (1988) reported success rates of 70% after 5 years and over 56% after 10 years.

In a retrospective study, Trockman et al. (1995) investigated the subjective therapy success of needle suspension in 135 patients after an average of 9.8 years. Only 20 patients showed a complete treatment success where the incontinence was completely cured, 71% showed an improvement, and a total of 73% were satisfied with the operative results.

Jongen and Brouwer (1999), in a retrospective study, also showed the subjective success of needle suspension. After an average of 64 months, 68% of patients were completely cured and a further 24% were improved. With only 25 subjects, relatively few patients were included in this study, and this limits the conclusions.

Table 28.1. A selection of long-term studies, reporting the urodynamic outcome of anterior colporrhaphy with and without suburethral plication

Author	SP	Study design	Outcome measure	Number of patients	Follow-up (months)	Success rates (%)
Park and Miller (1988)	Yes	Prospective	Subjective	336	1 year 5 years 10 years	80 70 66
Vahlensieck and Schander (1985)	Yes	Retrospective	Subjective	200	24–96	70
Beck et al. (1991)	Yes	Retrospective	Objective	72	6–60+	75
Harris et al. (1995)	Yes	Retrospective	Subjective	50	66	46
Bergman and Elia (1995)	Yes	Prospective	Objective	35 30	12 60	63 37
Kammerer-Doak et al. (1999)	No	Prospective	Objective Subjective	16	12	31 19
Tamussino et al. (1995)	No	Retrospective	Objective	All 107 Mild SI 39 Moderate/severe SI 68	60 60 60	61 82 49
Colombo et al. (2000)	No	Prospective	Objective Subjective	33	13.9 years	42 52
De Tayrac et al. (2002)	No	Retrospective	Objective Subjective	28	36	53,6 57,1
Glazener and Cooper (2003)		Meta-analysis		259 128	5 years >5 years	68 68

SP suburethral plication, *SI* stress incontinence.

Masson and Govier (2000) included 135 patients in their retrospective study and recorded subjective therapy success after 50 months. Only 14% had no involuntary urine loss, 42% had mild urinary incontinence, 38% moderate incontinence and 6% reported severe urinary incontinence.

In the previously cited prospective study from Bergman and Elia (1995), the objective success of needle suspension after 5 years in 30 patients was investigated: 43% were successfully treated.

Colombo et al. (1997) also conducted a prospective study of therapeutic control by needle suspension in urinary incontinence cases. After an average of 6.7 years, 57% of patients were still objectively cured, and 71% reported a subjective cure.

Tamussino and co-workers (1999) combined colporrhaphy with needle suspension in 121 patients. After 5 years, 49% of patients were still healed.

The operative results show a very high variation, from 14% to 70%. Collecting the long-term results in the style of a meta-analysis, we have a continence rate of 43% after 5 years or longer. Jarvis (1994) put together 3,352 cases with an observation period of 1 year in his meta-analysis and found a postoperative continence rate of merely 21.7% (Table 28.2).

28.4 Colposuspension Techniques

In 1949, Marshall, Marchetti and Krantz introduced colposuspension as a treatment for female urinary incontinence. In the following years, the modification of this technique by Burch (1961) was in wider use than the original method. There are also endoscopic techniques described (Wallwiener et al. 1994, 1995, 1996).

Park and Miller (1988) investigated the subjective therapy success of Burch colposuspension after 5 and 10 years in a prospective study of 227 women. The success rates were 70% and 57%, respectively.

In a retrospective study involving 87 women, Feyereisl and co-workers (1994) reported the objective therapy success of Burch colposuspension after 5 and 10 years. 81.6% of women were cured.

Harris and co-workers (1995) in a study of the therapy success of colposuspension (Marshall, Marchetti and Krantz) showed that after 66 months, 75% of the women were continent.

Bergmann and Elia (1995) in a prospective study, showed that 33 patients had a continence rate of 82% after 6 months (Burch 1961).

Tamussino and co-workers (1999) also recorded the objective success of Burch colposuspension in their retrospective study. After 5 years, 79% of women were cured.

Jongen and Brouwer (1999), by means of a retrospective study, reported a subjective success rates of 62.5% (complete cure), and 33.3% (symptom improvement). The validity of this study is limited on the grounds of a small number of subjects (24).

In a prospective study, Colombo and co-workers (2000) showed an objective success rate of 75% after an average of 14.2 years, and a subjective rate of 86%.

Petri (2001) reporting retrospectively on 2450 colposuspensions, with a personal Burch technique modification, showed an average success rate after more than 2 years of 81%. Treated as a primary operation, the cure rate was 89%, and as a relapse operation only 72%.

Alcalay and co-workers (1995) examined their patients after Burch colposuspension over a time period of 10–20 years. Over the first 12 years, there was a definite decline in the cure rate, which leveled out over the years and then reached a plateau of almost

Table 28.2. Selection of long-term studies reporting the urodynamic outcome of needle suspensions

Author	Study design	Measure	*N*	Follow-up (months)	Success rates (%)
Park and Miller (1988)	Prospective	Subjective	97	5 years 10 years	70 56
Trockman et al. (1995)	Retrospective	Subjective	125	9.8 years	No incontinence: 20 Improved: 71 Satisfied: 73
Jongen and Brouwer (1999)	Retrospective	Subjective	25	64	Complete cure: 68 Improved: 24 Failure: 8
Masson and Govier (2000)	Retrospective	Subjective	135	50	No leakage: 14 Mild leakage: 42 moderate incontinence: 38 Severe leakage: 6
Bergman and Elia (1995)	Prospective	Objective	30	60	43
Colombo et al. (1997)	Prospective	Objective Subjective Subjective	Clinical SUI: 21	6.7 years	57 71 100
Tamussino et al. (1995, 1999)	Retrospective	Objective	121 (+AC)	60	49
Jarvis (1994)	Meta-analysis		3,352	1 year	21.7

AR anterior colporrhaphy, *SUI* stress urinary incontinence.

70% after 12 years. These authors were also able to show a difference between primary surgery and surgery for relapses (Table 28.3).

Gathering together our results in a meta-analysis, the cure rate is 70% after 5 years and longer(Fig. 28.1).

28.5 Tension-free Vaginal Tape

Ulmsten et al. (1996) developed a retropubic suburethral sling out of alloplastic material for the operative treatment of female urinary incontinence. The sling is placed under the middle of the urethra in order to stabilize the insufficient pubourethral ligaments, see also Zubke et al. (2001).

Although this new method has circulated relatively quickly, there are currently few long-term results available.

Ulmsten et al. (1999) determined objective therapy success after 3 years in a prospective study of 50 patients. The success rate was 86%.

Olson and Kroon (1999) determined subjective therapy success in a retrospective study of 50 patients: 90% of patients were continent.

Debodinance et al. (2002) observed 15 patients over 3 years in a prospective study and then defined the therapy success. The healing rate was 87%.

Rezapour et al. (2001) checked the objective therapy success in a prospective study of 80 women 4 years after surgery. The success rate was 85%.

Nilsson and Kuuva (2001) showed in a prospective study that just 5 years after surgery, 84.7% of patients were still continent.

Nilsson et al. (2003) reported that 7 years postoperatively, 81.3% of women were objectively and subjectively continent.

From the previous data, the majority of which is from Ulmsten and co-workers, who established the method, we must give the tension-free vaginal tape TVT operation a success rate of between 80% and 85% after 5 years or more (Table 28.4).

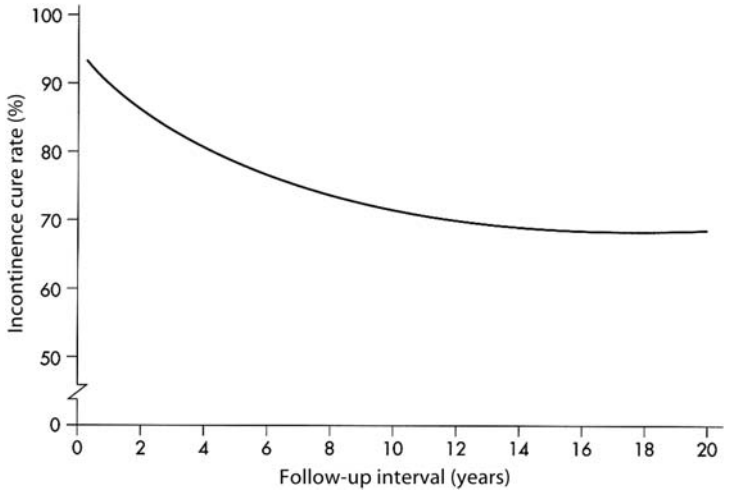

Fig 28.1. Success rated of colposuspension depending on the postoperative interval (Alcalay et al. 1995, from Walters and Karram 1999)

Table 28.3. Selection of long-term studies reporting the urodynamic outcome of colposuspensions

Author	Study design	Outcome measure	Number of patients	Follow-up (months)	Success rates (%)
Park and Miller (1988)	Prospective	Subjective	227	5 years 10 years	70 57
Feyereisl et al. (1994)	Retrospective	Objective	87	5–10 years	81.6
Harris et al. (1995)	Retrospective	Subjective	26	66	75
Bergman and Elia (1995)	Prospective	Objective	33	60	82
Tamussino et al. (1999)	Retrospective	Objective	106	60	79
Jongen and Brouwer (1999)	Retrospective	Subjective	24	63	Complete cure: 62.5 Improved: 33.3
Colombo et al. (2000)	Prospective	Objective Subjective	35	14.2 years	74 86
Petri (2001)	Retrospective		2,450 1st Operation Relapse operation	>24	81 89 72

Table 28.4. Selection of long-term studies reporting the urodynamic outcome of TVT operations

Author	Study design	Outcome measure	Number of patients	Follow-up	Success rates (%)
Ulmsten et al. (1999)	Prospective	Objective	50	3 years	86
Olson and Kroon (1999)	Retrospective	Subjective	51	3 years	90
Debodinance et al. (2002)	Prospective	Subjective	15	3 years	87
Rezapour et al. (2001)	Prospective	Objective	80	4 years	85
Nilsson et al. (2001)	Prospective	Objective	85	56 months	84.7
Nilsson et al. (2003)	Prospective	Objective + subjective	64	7.6 years	81.3

28.6 Discussion

Various difficulties are demonstrated in the comparison of the long-term results of the most important operative techniques for the treatment of female urinary incontinence. The methods themselves are not always comparable, retrospective studies show a favorable trend; the same is valid for subjectively gained results. The objective results are also not always comparable because various tests are cited, the clinical validity of which are clearly variable. Despite all these limitations, some results hold true. The Kelly plication, also in combination with an anterior colporrhaphy, as the method of operative treatment for female urinary incontinence, is less suitable than other methods, if at all. Anterior colporrhaphy is also inferior to other methods in its long-term results. The best investigated method is the colposuspension according to Marshall-Marchetti-Krantz modified by Burch. Colposuspension has proved itself over the last few decades and has been critically rated in worldwide studies. With a cure rate of around 70%, it also shows excellent long-term results. A considerable disadvantage of colposuspension is the artificial displacement of the urethra to a ventral position, through which the development of a central prolapse or rather a prolapse of the posterior compartment is promoted. This disadvantage is not exhibited by Ulmsten's TVT-plasty. The operative procedure is also easier than colposuspension. The available results up to now show even better cure rates after a shorter and longer time. However, they require more independent and further studies by competent centers.

Despite these restrictions, in our clinic we favor treatment of female urinary incontinence with TVT procedure, currently using the de Leval modification (de Leval 2003; Reisenauer et al. 2004). Here, the TVT is placed through the foramen obturatum rather than retropubically, as in the original method. By using this method, we see intra- and immediate postoperative benefits such as less risk of injury and less formation of residual urine in the bladder. But there are no long-term studies available on this modification.

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Chapter 29

Long-term Results of Surgery for Stress Urinary Incontinence – A Urologist's View

29

Prasad Patki, Rizwan Hamid, Julian R. Shah

Contents

29.1 Background

The International Continence Society (ICS) defines urinary incontinence as the complaint of any involuntary leakage of urine, and stress incontinence as a complaint of involuntary leakage on effort or exertion, or on sneezing or coughing (Abrams et al. 2002).

Stress urinary incontinence (SUI) is generally more common in women than men; its presence has great social, physical, economical and psychological impact on these women. A recent European study conducted in four countries showed that overall 35% of women reported incontinence. Stress incontinence was the commonest form (37%), followed by mixed (33%) and urge (20%) (Hunskaar et al. 2004). The true prevalence of stress incontinence is probably higher than this, as actual urodynamic evaluation reveals that mixed incontinence may be overdiagnosed at the expense of SUI (Sandvik et al. 1995).

29.2 Mechanism of Urinary Continence

Continence is achieved by normal interplay of anatomical and physiological properties of the bladder, pelvic floor and urethral sphincter complex. The nervous system also plays a major part by coordinating the activity in all these components.

The role of pelvic floor in providing the support to the bladder and urethra and allowing normal abdominal pressure transmission to proximal urethra is used as a basis in some of the surgical repairs designed for stress incontinence.

29.3 Treatment for Stress Urinary Incontinence

The aim of treatment for stress incontinence is to render the patient continent by the least invasive method with a high cure rate over a long period.

Surgery is the main treatment of stress incontinence. However, conservative measures such as pelvic floor muscle training and biofeedback, electrical and magnetic stimulations and vaginal weighted cones are also used with variable success. Until recently, the role of medical treatment in SUI has remained limited. Various agents have been used off label, including estrogen replacement, alpha-adrenergic agonists, beta-adrenergic antagonists and tricyclic antidepressants. However, none have demonstrated sufficient effect to justify widespread acceptance or approval (Viktrup and Bump 2003). Duloxetine, which is a potent selective serotonin and norepinephrine re-uptake inhibitor (SNRI), has been the focus of much recent attention.

In general, the surgical treatment of SUI has proved to be far more successful than the nonsurgical treatment.

29.3.1 Surgery for Stress Incontinence

Surgical treatments of urodynamic stress incontinence generally aim to improve the support to the urethrovesical junction. They include:

- Retropubic colposuspension such as the Burch, Marshall Marchetti Krantz (MMK) and vaginal obturator shelf (VOS) procedures

- Laparoscopic colposuspension
- Suburethral sling procedure such as the rectus sheath sling
- Tension-free vaginal tape (TVT) and the recently added transobturator tape (TOT)
- Needle suspensions: Stamey, Raz and Pereyra
- Periurethral injectables

In addition to these artificial urinary sphincters, bone anchored slings and four-corner suspensions have been used to treat urodynamic stress incontinence.

The wide variety of treatment options in stress incontinence indicates a lack of clear consensus as to the superiority of one procedure over others. Even though there is a disagreement on the precise mechanism by which continence is achieved, open retropubic colposuspension has been regarded as the gold standard treatment for urinary incontinence.

29.3.1.1 Outcome of Surgery for Stress Incontinence

Since 1949 when Marshall and co-workers described their retropubic vesicourethral suspension, the quest for an ideal procedure has been ongoing. Ideally the best outcome would include a cure from incontinence over the long term with a short, simple procedure associated with the least morbidity and the highest cost effectiveness.

There are over 1,000 publications on the outcome of surgeries for the urodynamic stress incontinence but many of them are not randomized, have poor methodology and provide inadequate data on complications (Black and Downs 1996). Meaningful and clinically useful recommendations can be derived based on a handful of systematic reviews that have integrated the results from high-quality studies.

29.3.2 Open Colposuspension

In 2003 the Cochrane database systematic review studied 33 trials of the open colposuspensions. The overall cure rates were 68.9%–88% with 70% of patients expected to be dry at the end of 5 years (Lapitan et al. 2003). The results with the Burch procedure appear to be durable with longer follow-up, with 69% subjective and objective cure rates at a mean follow-up of 13.8 years (Alcalay et al. 1995). One can expect a decline in the cure rate of only 15%–20% even beyond 5 years with open colposuspensions, which currently is unmatched by other surgical techniques (Lapitan et al. 2003).

Although the medium- and short-term results of the MMK procedure have been good, on longer-term follow up, the subjective cure rate at 17 years is 41% (Clemens et al. 1998). Czaplicki and colleagues noted decreasing continence rates with the MMK procedure from 77% at 1 year to 28% at 10 years (Czaplicki et al. 1998). Hegarty et al. noted a mean continence rate of 61% with follow-up up to 22 years. All failures in this study occurred within the first 2 years (Hegarty et al. 2001). Secondary colposuspensions performed after primary surgical failure also fare well, with 71% subjective and 80% objective cure rates at a mean follow up of 4 years. Although there was an increased incidence in surgery for prolapse, at 5 years 65% were still dry (Thakar et al. 2002). Age, body habitus and complexity of treatment, collagen deterioration, con-

comitant bladder overactivity, surgical skill of the surgeon and associated pelvic abnormalities play a part in the long-term outcome of colposuspensions.

29.3.3 Laparoscopic Colposuspension

Laparoscopic colposuspension was introduced by Vancaillie in 1991 (Vancaillie and Schuessler 1991). The intended benefits included better visualization, shorter hospital stay and lesser morbidity with associated cost effectiveness. Summit et al., in their randomized, prospective study, found short-term success comparable to the open procedure but on longer follow-up laparoscopic retropubic suspensions appears to fail (Summitt et al. 2000). McDougall (1999) noted only 30% cure of SUI at 45 months follow-up (McDougall et al. 1999). Burton (1999) noted significantly more failures at 5 years in the laparoscopic group (Burton 1999).

29.3.4 Endoscopic Bladder Neck Suspensions

Needle suspensions such as Stamey and Gittes have not stood the test of time. Early success rates were replaced by long-term failures with 28% dry at 9 years with the Stamey procedure and 14% dry at 5.3 years with the Gittes procedure (Nigam et al. 2000).

29.3.5 Suburethral Slings

Suburethral slings have been widely used in the treatment of SUI. Culligan et al. reported better results with slings (100% dry) compared to colposuspensions (84.6% dry) at a mean follow-up of 72.6 months (Culligan et al. 2003). However, other than the tension-free vaginal tape (TVT), which utilizes Prolene mesh tape, there is insufficient data to draw meaningful conclusions as to whether alternative slings (e.g., PTFE, rectus fascia,) are as effective as open colposuspension in the management of SUI (Bezerra and Bruschini 2001). It has been reported that the cure rate for TVT is similar to colposuspension at 6 months and 1 year. However, the hospital stay and hence cost for TVT are about 25% lower; comparative data over the long term will show if it is as effective as colposuspension (Bezerra and Bruschini 2001). Complications with TVT such as bladder injury (7.5%–36.3%), significant bleeding (0.9%), nerve injury (0.9%) and urinary tract infection (6.1%) are reported in the literature (Nilsson and Kuuva 2001; Moran et al. 2000). Patients also report having temporary obstruction (12%–49%), dysuria (31.5%), and urge incontinence (6.4%–28.6%) after the TVT procedure (Jeffry et al. 2001; Al Badr et al. 2003). Transobturator tape (TOT) is a novel minimally invasive procedure that is awaiting full evaluation. TOT avoids the perforation of the pelvic floor, thus minimizing the incidence of bladder injury. It can be performed in previously operated patients. The initial results indicate that the technique is efficient, safe and simple to perform (Gunnemann et al. 2004).

29.3.6 Periurethral Injections

Periurethral injections have been used as a minimally invasive method. The randomized trials reported have used collagen, Macroplastique, carbon particles and autolo-

gous fat. A recent review concluded that bulking agents may be used with limited benefit in the short term (1 year), but that results are still inferior to colposuspension (58%–85%) (Pickard et al. 2003). There is no evidence that these agents should be used routinely as the first line of treatment. However, in high-risk patients they may be a useful option for relief of symptoms in the short term, although multiple injections may be required to achieve desired results. Pain, infection, voiding dysfunction, bladder overactivity and migration of particles are some of the longer-term complications noted with periurethral agents.

29.3.7 Artificial Urinary Sphincter

The artificial urinary sphincter has been used in cases refractory to the methods discussed in the preceding sections. The success rate ranges from 91% to 99%, with an erosion rate of between 7% and 29%. It may be concluded that AUS is an acceptable method of managing SUI after the failure of other surgical options (Kowalczyk and Mulcahy 2000). In spite of high cure rates with surgical treatment, there is a postoperative voiding dysfunction rate of 5%–20%, which may be successfully treated with urethrolysis (Dunn et al. 2004).

29.4 Summary

Stress incontinence is the most common type of incontinence seen in women. It has a major impact on their quality of life. Currently conservative treatments such as pelvic floor muscle training have limited success but require high levels of compliance and perseverance. Clearly there is a need to develop effective pharmacological treatment. New medical advances such as duloxetine appear to be promising. At present, surgery remains the most effective option. Although colposuspension is still considered to be the gold standard, minimally invasive procedures such as TVT have the potential to be an effective alternative. None of the procedures to date have significant data on more than 20 years follow-up. Because of the different components to incontinence, a single surgical procedure cannot cure every case. Hence, each case should be considered on its own merit to determine the most appropriate method of treatment. Importantly, as patients become more informed, they should be actively involved in the decision-making process. In the end, only a systematic review of good structured studies over the long term can help make an informed choice easy for our patients.

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Chapter 30

Long-term Results After Fecal Incontinence Surgery

30

Tilman T. Zittel

Contents

30.1 Introduction

Surgery has been a mainstay of incontinence treatment in selected cases since more than 30 years. However, surgery has never been compared directly to conservative treatment forms such as medical treatment, pelvic floor exercises or biofeedback training. Further, most procedures employed have never been compared in a randomized way and with adequate patient numbers. The number of patients treated surgically for fecal incontinence and described retrospectively surpasses 10,000, but only 110 patients have been included in four trials that prospectively randomized surgical treatment. This small number of relevant trials with small sample sizes and other methodological weaknesses made it impossible to identify or refute important differences between different surgical procedures (Malouf et al. 2001; Bachoo et al. 2003).

Several factors might be responsible for this lack of inclusion of patients in randomized trials and the resulting insecurity regarding the best surgical treatment for fecal incontinence. There is a wide variety of underlying etiologies for fecal incontinence, starting with anal atresia in newborns and ending with a slow deterioration of sphincter function or central cognitive functions over the years in elderly persons (Jorge and Wexner 1993). Furthermore, fecal incontinence is highly variable with respect to type (urge, passive or both), clinical severity and its effects on individual patients (Malouf et al. 2001). It is therefore difficult to recruit homogenous patient groups that might be suitable for properly designed trials, and randomized controlled comparisons present formidable ethical and practical problems (Malouf et al. 2001). Prospective multicenter studies have been conducted in recent years to describe the results of newer surgical treatment forms, such as the dynamic graciloplasty or the artificial bowel sphincter (Madoff et al. 1999; Matzel et al. 2001a; Wong et al. 2002). Although this was a step forward, these studies did not compare different treatment forms, and the reproducibility of their results in a general setting is doubtful, since only centers with a high degree of expertise participated. These centers will not be able to treat the large patient numbers that suffer from major fecal incontinence, which was defined as the soiling of stool several times per month and its prevalence being estimated around 2% in the adult population in Western industrialized countries (Nelson et al. 1995; Kalantar et al. 2002; Perry et al. 2002). Regardless of the etiology or the degree of fecal incontinence, there is currently no single standard surgical procedure for fecal incontinence (Malouf et al. 2001). Under these premises, this review will describe the most commonly used surgical treatment forms for fecal incontinence.

30.2 Study Inclusion Criteria

Seven surgical procedures were included (overlapping sphincter repair, postanal repair, preanal repair, total pelvic floor repair, dynamic graciloplasty, artificial bowel sphincter, sacral nerve stimulation), representing the vast majority of patients being described in peer-reviewed journals for surgical fecal incontinence treatment. A Medline search from 1966 to February 2004 was conducted, using the terms of the surgical procedures named above and "anal," "fecal," faecal," "incontinence," and "surgery." A total of 979 abstracts were screened, of which 220 articles were identified that described the results of fecal incontinence treatment with one of the surgical procedures. These articles were copied and read thoroughly. In addition, six standard textbooks of colorectal surgery were screened in order not to miss relevant study results (Keighley and

Williams 1993; Nicholls and Dozois 1997; Corman 1998; Beck and Wexner 1998; Phillips 1998; Pemberton et al. 2002).

A number of criteria had to be fulfilled for a study to be included in this review. These criteria were chosen arbitrarily, and some general study weaknesses, which are discussed in the next section, had to be accepted in order to come to a result at all. The inclusion criteria were as follows:

- A description of the underlying etiology of fecal incontinence
- A defined grading of fecal incontinence before and after surgical treatment
- A mean follow-up of at least 2 years (minimum mean follow-up of 12 months, if only limited data available)
- The availability or the possibility to calculate actual patient numbers with regards to categories of treatment success or treatment failure

30.3 General Study Weaknesses

Virtually all studies on the surgical treatment for fecal incontinence are retrospective, nonrandomized, uncontrolled reports of centers with an assumed degree of excellence, usually all patients being operated by one to three surgeons with a specific interest and experience in the field. In these studies, the surgical procedures are described under the terms generally used, but considerable differences regarding patient mix, preoperative diagnostic work-up, preoperative bowel lavage, the surgical technique used, the perioperative antibiotic regime, the postoperative medical or physical treatment, patient follow-up and the description of the study results exist.

There is a considerable patient mix (see Table 30.1), which limits the possibility to extrapolate study results to a single patient that needs advice regarding the best treatment form. From a scientific point of view, the results of the different studies cannot be

Table 30.1. Surgical treatment of fecal incontinence – general study weaknesses

Patient selection and previous medical or physical treatment failures not described
Low patient numbers (usually below 50 patients per study)
Mix of female and male patients (usually large majority of female patients)
Wide range of patient age (several decades between youngest and oldest patient)
Variety of etiologies for fecal incontinence included in one study
Varying degrees and numbers of birth traumas
Varying duration of fecal incontinence (years to decades)
Patients included with urinary and fecal incontinence
Varying percentage of patients being previously operated for fecal incontinence
Differences in pre-, peri- and postoperative handling
Variation of surgical procedures, varying usage of a temporary diverting stoma
Development of new technologies, varying experience with new technologies
Follow-up of patients varying from telephone interview to intensive diagnostic work-up
Wide range of follow-up time included in the same study (several months to several years)
Wide variety to describe study results (subjective measures, incontinence grading, incontinence scoring, general quality of life, disease-specific quality of life)
Influence of aging on study results unknown
Possibility of the same patients included in several study reports

compared directly. However, to review, analyze and summarize the data available might give an estimate of the success and failure rates of surgical procedures for fecal incontinence, which is important for patients and surgeons to provide a realistic view and to avoid overly optimistic expectations by the treatment options available.

30.4 Presentation of the Study Results

From the literature, there are no generally accepted definitions available regarding the terms "treatment success" or "long-term results" in fecal incontinence treatment, and the determination of success remains an unresolved problem in fecal incontinence surgery (Soffer and Hull 2000; Madoff et al. 2000). Over the years, the description of the study results has improved from subjective and biased terms such as "excellent," "moderate" or "poor" (such studies were excluded in this review), to grading systems (grading in full continence, incontinence for gas, liquid or solid stool and other grading systems [Baig and Wexner 2000; Baxter et al. 2003]), scoring systems (Cleveland Clinic Incontinence Score and other scoring systems [Jorge and Wexner 1993; Baxter et al. 2003]), general quality-of-life measures (SF-36 and other measures [Malouf et al. 2001; Baxter et al. 2003]), and eventually to a disease-specific quality-of-life measure (Fecal Incontinence Quality of Life Scale [Rockwood et al. 2000]). The latter is probably best-suited to describe the impact of a disease or the impact of a treatment on a given person (Hullfish et al. 2002; Baxter et al. 2003), as disease-specific quality of life has been shown to decrease with increasing incontinence (Gutierrez et al. 2004). Although this represents scientific progress and provides better estimates of treatment results, the measurement of fecal incontinence continues to evolve (Baxter et al. 2003). It is therefore impossible to directly compare the results of studies that used different treatment outcome measures.

When judging success of fecal incontinence surgery, it is important to know what the investigators judge as success (Soffer and Hull 2000). In this review, only studies were included that categorized the study results as follows:

- Full continence (continence for gas, liquid and solid stool; rare gas leakage possible, usually less than once per month)
- Success (continence for liquid and solid stool; rare stool leakage or soiling possible, usually less than once per month)
- Improvement (continence for solid stool, if preoperative not possible; soiling and wearing of pads possible)
- Failure (no improvement, incontinence for solid stool or reoperation)

In the tables, the patient numbers in the categories "full continence," "success" and "improvement" were added up, meaning that the category "success" includes the patients with "full continence" and the category "improvement" the patients from the categories "full continence" and "success." The difference between the category "improvement" and the total number of patients represents the failure rate. Subtracting the number of patients of the category "full continence" from the number of patients of the category "success" gives the actual number of patients of the latter category, and subtracting the number of patients of the categories "full continence" and "success" from the number of patients of the category "improvement" also gives the actual number of patients of the latter category.

30.5 Overlapping Sphincteroplasty

Parks and McPartlin in 1971 first reported their results with overlapping repair (Parks and McPartlin 1971). A 180-degree curvilinear incision is made over the defect, most often the perineal body, a flap is raised and the muscle with its scar is delineated. No attempt is made to dissect the internal muscle from the external muscle. The ends of the muscle are dissected (although this is not mandatory [Slade and McPartlin 1977]), and the muscle is sewn in place in an overlapping fashion (Soffer and Hull 2000). Although it is not finally proven that direct apposition of the muscle ends provides worse results, this is usually performed at the time of injury, while the overlapping sphincteroplasty is the operation of choice in incontinent patients with an isolated sphincter defect operated years after the injury (Baig and Wexner 2000). A diverting stoma is unnecessary in most cases, but might be advisable in redo cases or technically difficult cases (Baig and Wexner 2000; Soffer and Hull 2000). The morbidity is low, usually below 10%, and mortality has been described rarely in older series (Slade et al. 1977; Fang et al. 1984).

Details on the patient populations and the long-term results are given in the Tables 30.2 and 30.3. Factors predictive of a treatment failure, such as age, the duration of incontinence, obesity, a prolonged pudendal nerve latency, a perineal descent, a previous sphincter repair, a persistent anal sphincter defect, a short anal canal length after sphincteroplasty or an internal anal sphincter defect have been identified (Laurberg et al. 1988; Londono-Schimmer et al. 1994; Briel et al. 1998; Cook 1998; Gilliland et al. 1998; Hool 1999; Baig and Wexner 2000; Soffer and Hull 2000; Gutierrez et al. 2004), but other studies have refused age, neuropathy and prior incontinence surgery as negative predictive factors (Simmang et al. 1994; Chen et al. 1998; Young et al. 1998; Giordano et al. 2002). As study results are contradictory on the one hand and the presence of a negative predictive factor does not preclude a successful outcome on the other hand (Soffer and Hull 2000), overlapping sphincteroplasty can be offered to most patients with an isolated sphincter defect.

In the short term, a significant improvement of fecal incontinence can be achieved in approximately 60%–90% of patients (Cook 1998; Baig and Wexner 2000; Soffer and Hull 2000). However, results deteriorate with time (Rothbarth et al. 2000), and beyond 5 years of follow-up, patients are rarely fully continent. In three true long-term studies, a successful outcome has been observed in 8%, 22% and 37% only (Malouf et al. 2000a; Gutierrez et al. 2004; Halverson and Hull 2002).

30.6 Postanal Repair

The postanal repair devised by Parks offers the possibility of increasing the anal canal length by plicating the iliococcygeus, the pubococcygeus, the puborectalis and the sphincter ani externus muscles at the dorsal aspect of the anal canal (Parks 1975). The procedure has been mainly reserved for patients with idiopathic or neuropathic etiology of incontinence, where medical and physical incontinence treatment failed. The morbidity is usually low (between 5% and 20% [Henry and Simson 1985; Yoshioka and Keighley 1989; Matsuoka et al. 2000]), and mortality has been reported only rarely (Yoshioka and Keighley 1989).

Details on the patient populations and the long-term results are given in the Tables 30.4 and 30.5. A variety of factors potentially predictive of a treatment failure have

Table 30.2. Long-term results of overlapping sphincteroplasty (mean follow-up, 2–5 years)

Author	Year	*N*	F	Mean age	Etiology (o/s/t)	Previous surgery	Follow-up (mean)	Follow-up (range)	Full continence	Success	Improvement
Fang et al.	1984	76	62	43/27/7	20/76		35	2–62	44/76	68/76	73/76
Christiansen and Lorentzen	1987	23	14	34	5/10/8		26	6–96		15/23	22/23
Yoshioka and Keighley	1989	27	14	34	9/11/4	5/27	48	16–108	7/27	20/27	
Engel	1994	28	25	41	15/11/2	4/28	50	15–116	16/28	21/28	22/28
Sangalli	1994	36	36	37	36	4/36	34	3–121	21/36	29/36	35/36
Nikitas	1996	42	37	45	26/11	3/42	38	12–66	16/42	25/42	32/42
Oliveira	1996	55	55	48	55	30/55	29	3–61	13/55	39/55	44/55
Briel	1998	55	55	45	55	7/55	24		36/55		
Chen et al.	1998	12	12	45	12		50	20–72		8/12	10/12
Gilliland et al.	1998	77	77	47	53/16/2	30/77	24	2–96	20/77	42/77	48/77
Karoui et al.	2000	74	68	56	61	0/74	40	9–98	21/74	38/74	56/74
Rothbarth et al.	2000	39	39	51	39		39	12–114		24/39	
Buie	2001	158	158	36	143	28/158	**43**	6–120	36/158	97/158	139/158
Cumulative		702							230/628	426/647	481/581
									37%	66%	83%

Previous surgery, previous surgery for fecal incontinence.
Follow-up is given in months.
See text for the definition of "success" and "improvement".
F female, etiology: *o* obstetric, *s* surgical, *t* trauma.

Table 30.3. Long-term results of overlapping sphincteroplasty (mean follow-up, 5 years and more)

Author	Year	*N*	F	Mean age	Etiology (o/s/t)	Previous surgery	Follow-up (mean)	Follow-up (range)	Full continence	Success	Improvement
Scott	1989	6	5		Crohn disease		94	18–192	5/6	5/6	5/6
Londono-Schimmer et al.	1994	94		43			59	12–98	13/94	47/94	71/94
Malouf et al.	2000	47	47	43	47		77	60–96	0/47	4/47	27/47
Halverson and Hull	2002	49	47	39	31/7/3	2/49	69	48–141	6/49	18/49	24/49
Gutierrez et al.	2004	130		47			120	84–192	8/130	29/130	62/130
Cumulative		196							32/326	104/326	189/326
									10%	32%	58%

Previous surgery, previous surgery for fecal incontinence.
Follow-up is given in months.
See text for the definition of "success" and "improvement".
F female, etiology: *o* obstetric, *s* surgical, *t* trauma.

Table 30.4. Long-term results of postanal repair (mean follow-up, 2–5 years)

Author	Year	*N*	F	mean age	Etiology	Previous surgery	Follow-up (mean)	Follow-up (range)	Full continence	Success	Improvement
Womack	1988	16	14	59	Mixed		26	15–48	6/16	14/16	14/16
Pinho et al.	1992	47					31		2/47	8/47	29/47
Deen et al.	1993	12	12	51	Neuropathic		24	22–28		4/12	5/12
Le Blanc	1993	22	22	58	Idiopathic		34		2/22	12/22	19/22
Engel	1994	38	34	57	Idiopathic		43	15–126		8/38	17/38
Jameson et al.	1994	36	33	57	Idiopathic		25	6–72		10/36	19/36
Athanasiadis	1995	31	30	66	Idiopathic	20/31	**50**	24–90	2/31	10/31	16/31
Van Tets et al.	1998	11	20	55	Neuropathic		42	18–60	0/11	3/11	5/11
Matsuoka et al.	2000	20	20	68	Mixed	10/20	36	12–90		7/20	9/20
Cumulative		233							12/127	76/233	133/233
									9%	33%	57%

Previous surgery, previous surgery for fecal incontinence.
Follow-up is given in months.
See text for the definition of "success" and "improvement".
F female, etiology.

Table 30.5. Long-term results of postanal repair (mean follow-up 5 years and more)

Author	Year	*N*	F	Mean age	Etiology	Previous surgery	Follow-up (mean)	Follow-up (range)	Full continence	Success	Improvement
Yoshioka and Keighley	1989	116		59	Mixed	39/116	60	12–120			94/116
Setti-Carraro	1994	34	34	64	Neuropathic		73	61–95		9/34	28/34
Buttafuoco and Keighley	2000	47		51	Mixed		114			13/47	13/47
Cumulative		197							?	22/81	135/197
									?	27%	69%

Previous surgery, previous surgery for fecal incontinence.
Follow-up is given in months.
See text for the definition of "success" and "improvement".
F female.

been tested such as age, the duration of incontinence, a prolonged pudendal nerve latency, a previous sphincter repair, and the results of anorectal manometry, but none has shown a correlation with treatment outcome (Matsuoka et al. 2000).

In Parks' study, postanal repair improved continence in 81% of patients (Parks 1975), but a successful outcome might vary between 26% and 85% of patients (Athanasiadis 1996; Matsuoka et al. 2000). The results seem to deteriorate with time. Jameson reported improvement of incontinence in 83% of patients after 6 months, which was maintained in only 53% after 25 months (Jameson et al. 1994). Two to 5 years postoperatively, around 10% of patients are fully continent, about 30% can control liquid and solid stool, and around 60% report an improvement. These results do not seem to further deteriorate beyond 5 years of follow-up (Yoshioka and Keighley 1989; Setti-Carraro 1994; Buttafuoco and Keighley 2000).

30.7 Preanal Repair (Anterior Levatorplasty and Sphincteroplasty)

Preanal repair consists of an anterior levatorplasty in combination with an anterior plication of the external sphincter, which is done via a curved anterior perineal incision and a dissection of the rectovaginal septum (Athanasiadis 1996). The procedure has been used for incontinence of idiopathic, neuropathic and traumatic origin as well as for patients after an unsatisfactory result of postanal repair (Miller et al. 1989; Deen et al. 1993; Österberg et al. 1996). There is a limited number of study reports, but the morbidity seems to be low (5%–10%) with no mortality reported (Deen et al. 1993; Österberg et al. 1996, 2000).

Details on the patient populations and the long-term results are given in Table 30.6. There are only limited data available, suggesting that the usage of this procedure is not widely distributed. Accordingly, the results must be taken with care. The procedure may achieve results similar to those of overlapping sphincteroplasty (Österberg et al. 2000), but a small randomized trial (n=12 per arm) indicated that total pelvic floor repair achieved better results (Deen et al. 1993).

The results seem to deteriorate with time, as the only true long-term study with a mean follow-up of 8.5 years reported continence for liquid and solid stool in only 38% of patients and improvement in 64% of patients (Österberg et al. 1996).

30.8 Total Pelvic Floor Repair

The procedure combines postanal and preanal repair as described above. It has been described for neuropathic incontinence and as a staged pelvic floor repair after failed postanal repair (Pinho et al. 1992; Deen et al. 1993). There is a limited number of study reports, but the morbidity seems to be very low (<5%), with no mortality reported (Pinho et al. 1992; Deen et al. 1993, 1995; van Tets and Kuijpers 1998). Details on the patient populations and the long-term results are given in Table 30.7. Obesity, a history of straining at stool and perineal descent were associated with a poor outcome (Körsgen et al. 1997). Total pelvic floor repair was superior to preanal or postanal repair in one randomized trial (Deen et al. 1993), but was equal to postanal repair in another (van Tets and Kuijpers 1998). Total pelvic floor repair was more cost-effective than postanal repair due to an increased reoperation rate and an increased postoperative number of visits after postanal repair (Buttafuoco and Keighley 2000). There are no true long-term reports that provide detailed incontinence outcomes following this procedure.

Table 30.6. Long-term results of preanal repair (mean follow-up at least 1 year)

Author	Year	*N*	F	Mean age	Etiology	Previous surgery	Follow-up (mean)	Follow-up (range)	Full continence	Success	Improvement
Deen et al.	1993	12	12	51	Neuropathic		24	22–28		4/12	6/12
Athanasiadis	1994	18	18	62	Idiopathic	6/18	22	6–39	3/18	13/18	15/18
Österberg et al.	1996	85	85	45	Mixed		102	18–216		32/85	54/85
Österberg et al.	2000	31	31	68	Idiopathic		12	12–12		18/31	27/31
Cumulative		146							3/18	67/146	102/146
									17%	46%	71%

Previous surgery, previous surgery for fecal incontinence.
Follow-up is given in months.
See text for the definition of "success" and "improvement".
F female.

Table 30.7. Long-term results of total pelvic floor repair (mean follow-up at least 1 year)

Author	Year	*N*	F	Mean age	Etiology	Previous surgery	Follow-up (mean)	Follow-up (range)	Full continence	Success	Improvement
Pinho et al.	1992	36	36	51	Mixed	14/36	15	3–18	11/36	18/36	34/36
Deen et al.	1993	12	12	51	Neuropathic		24	22–28		8/12	10/12
Deen et al.	1995	18	18	57	Neuropathic		16			6/18	15/18
Körsgen et al.	1997	63	63	57	Neuropathic		36	18–78		8/63	27/63
van Tets and Kuijpers	1998	9	9	55	Neuropathic		42	18–60	0/9	2/9	3/9
Buttafuoco and Keighley	2000	32		51	Mixed		79			17/32	30/32
Cumulative		170							11/45	43/170	119/170
									24%	25%	70%

Previous surgery, previous surgery for fecal incontinence.
Follow-up is given in months.
See text for the definition of "success" and "improvement".
F female.

30.9 Dynamic Graciloplasty

Graciloplasty was first described by Pickrell in 1952 for fecal incontinence treatment in children, and Baeten was the first to describe the continuous stimulation of the transposed gracilis muscle in an adult (Pickrell et al. 1952; Baeten et al. 1988). The stimulated, so-called dynamic graciloplasty, is more effective than the unstimulated graciloplasty and the standard graciloplasty today. Stimulation by a given frequency and voltage is increased stepwise over weeks, allowing the muscle fibers to adapt to a continuous contraction by changing from fast-twitch, fatigable type II muscle fibers into slow-twitch, fatigue-resistant type I muscle fibers (Chapman et al. 2002). Intramuscular stimulation seems to achieve better results than direct nerve stimulation (Mavrantonis and Wexner 1999; Konsten et al. 2001). The stimulator is implanted subcutaneously under the belly or in the buttock and can be turned off by an external magnet to allow defecation. The procedure is complex with a high morbidity rate (average of more than one complication per patient) and a mortality of about 1% (Chapman et al. 2002). In a prospective multicenter study, morbidity was 77%, the device correction or removal rate 19%, and the reoperation rate for complications 38% (Matzel et al. 2001). The stimulator and the electrodes cost around 1,000 euros (Ortiz et al. 2003), and the battery of the stimulator has to be changed after a median of 7–8 years (Rongen et al. 2003). However, compared to the costs of colostomy, the procedure seems to be cost-effective (Adang et al. 1998).

Details on the patient populations and the long-term results are given in Table 30.8. It was very difficult to extract the actual patient numbers or to categorize the postoperative incontinence improvement from some of the studies cited. Study results of dynamic graciloplasty differ with respect to etiology, anal atresia being more difficult to treat (see Tables 30.9). Studies describing graciloplasty after abdominoperineal resection for rectal cancer (total anorectal reconstruction) were not included, as double graciloplasty is mostly used, patients are often irradiated and tumor recurrence occurs. Study results do not seem to deteriorate in the long run, once the procedure has been completed successfully (Wexner et al. 2002; Rongen et al. 2003), but true long-term studies are not available yet.

30.10 Artificial Bowel Sphincter

Christiansen 1987 first described the implantation of an artificial bowel sphincter (ABS) for fecal incontinence with a prosthesis originally designed to treat urinary incontinence (Christiansen and Lorentzen 1987). This device, called AMS 800, was later modified to better fit the anatomical structures of the lower rectum and the anal canal. This new device was named Acticon Neosphincter, and is the device now used by many colorectal surgery centers. The procedure is complex and in a prospective multicenter study, a morbidity of 86% was observed, revisional operations became necessary in 46%, and in 37% of patients, the device had to be explanted, resulting in a success rate of 53% on an intention-to-treat analysis (Wong et al. 2002). On the other hand, no mortality was reported from this and other studies. The ABS costs around 10,000 euros, but the hospital costs assessed by diagnosis-related groups and the price of the devices were similar at around 11,000 euros for dynamic graciloplasty and ABS (Ortiz et al. 2003). In an institution employing both the dynamic graciloplasty and the ABS, the ABS was judged more convenient for institutions treating small numbers of patients,

Table 30.8. Long-term results of dynamic graciloplasty (mean follow-up at least 1 year)

Author	Year	*N*	F	Mean age	Etiology	Previous surgery	Follow-up (mean)	Follow-up (range)	Full continence	Success	Improvement
Sonnino	1991	7	4	13	Anal atresia		53	6–150	4/7	7/7	
Baeten	1991	10	7	38	Mixed	10/10	13	6–60		6/10	8/10
Williams	1991	32	23	49	Mixed	20/32	16	3–38	0/32	14/32	19/32
Baeten	1994	9	3	28	Anal atresia		>24	4–78		5/9	
Baeten et al.	1995	52	37	44	Mixed	39/52	25	3–88	12/52	38/52	40/52
Geerdes	1996	67	48	44	Mixed		32	4–104		52/67	
Christiansen	1998	13	10	48	Mixed	13/13		7–27	3/13	6/13	11/13
Rosen	1998	10			Mixed	8/10	19	3–53	3/10	9/10	9/10
Madoff et al.	1999	104	72	50	Mixed	65/104	24			69/104	
Sielezneff	1999	16	11	42	Mixed	14/16	20	6–37	10/16	10/16	13/16
Baeten	2000	123	98	50	Mixed	76/123	>18	18–18		47/81	
Wexner et al.	2002	115	92	50	Mixed	86/115	24	24–24	12/83	42/83	40/83
Rongen et al.	2003	200	153	48	Mixed	130/200	45			144/200	
Cumulative		746							40/206	446/684	147/223
									19%	66%	66%

Previous surgery, previous surgery for fecal incontinence.

Follow-up is given in months.

See text for the definition of "success" and "improvement".

F female.

patients with dynamic graciloplasty for incontinence after rectal cancer treatment were extracted (except for Williams 1991, n=7).

Table 30.9. Long-term results of dynamic graciloplasty with respect to etiology

Congenital incontinence (anal atresia)							
Author	**Year**	***N***	**F**	**mean age**	**Follow-up (mean)**	**Follow-up (range)**	**Success**
Sonnino	1991	7	4	13	53	6–150	4/7
Baeten	1994	9	3	28	>24	4–78	5/9
Baeten et al.	1995	12	4	27	25	3–88	6/12
Geerdes	1996	13			32	4–104	7/13
Rosen	1998	6			19	3–53	6/6
Madoff et al.	1999	18	10	26	24		9/18
Baeten	2000	16	8	32	12	12–12	8/13
Rongen et al.	2003	28			45		15/28
Cumulative		109					60/109
							55%
Acquired incontinence (trauma, obstetric)							
Author	**Year**	***N***	**F**	**mean age**	**Follow-up (mean)**	**Follow-up (range)**	**Success**
Williams	1991	20			16	3–38	12/20
Baeten et al.	1995	24	20	48	25	3–88	22/24
Geerdes	1996	34			32	4–104	31/34
Rosen	1998	4			19	3–53	3/4
Madoff et al.	1999	85	62	50	24		60/85
Baeten	2000	107	78	53	12	12–12	45/83
Rongen et al.	2003	98			45		80/98
Cumulative		372					253/348
							73%

See text for the definition of "success" and "improvement".

but it was stated that both technical failures and complication rates were very high in both types of treatment (Ortiz et al. 2003).

Details on the patient populations and the long-term results are given in the Tables 30.10 and 30.11. All studies included a mixture of incontinence etiologies. Long-term results with a median follow-up of 5 years or more are only available for the ABS type AMS 800 (Wong et al. 1996; Christiansen et al. 1999; Parker et al. 2003), a device that is no longer used. These three studies reported a cumulative success rate of 48% (19/39), which was slightly worse than studies reporting results of the ABS Acticon Neosphincter with a shorter mean follow-up of 19–30 months (see Table 30.11, cumulative success rate 55%, 143/246). There are no long-term results regarding the ABS Acticon Neosphincter beyond 28 months, the success rate with a follow-up around 2 years being about 58%. Study results do not seem to deteriorate in the long run, once the procedure has been completed successfully (Wexner et al. 2002; Rongen et al. 2003), but true long-term studies are not available yet.

Table 30.10. Long-term results of artificial bowel sphincter, type AMS 800 (mean follow-up at least 1 year)

Author	Year	*N*	F	Mean age	Etiology	Previous surgery	Follow-up (mean)	Follow-up (range)	Full continence	Success	Improvement
Christiansen and Sparso	1992	12	9		Neuropathic	3/12	19	6–34		5/12	10/12
Lehur et al.	1996	13	9	44	Mixed		20	4–60	5/13	9/13	9/13
Wong et al.	1996	12	5	33	Mixed		58	30–76	3/12	9/12	9/12
Christiansen et al.	1999	17	11	46	Neuropathic	6/17	84	60–120	1/17	4/17	8/17
Parker et al.	2003	10		47	Mixed		91	29–143		6/10	6/10
Cumulative		64							9/42	33/64	42/64
									21%	52%	66%

Previous surgery, previous surgery for fecal incontinence.
Follow-up is given in months.
See text for the definition of "success" and "improvement".
F female.

Table 30.11. Long-term results of artificial bowel sphincter, type Acticon Neosphincter (mean follow-up at least 1 year)

Author		Year	*N*	F	Mean age	Etiology	Previous surgery	Follow-up (mean)	Follow-up (range)	Full continence	Success	Improvement
Lehur	1998	13	9	40	mixed		30		5–76		8/13	11/13
Lehur	2000	24	17	44	mixed		20		10–35		18/24	18/24
Malouf et al.	2000	18					26		2–39		6/18	6/18
Altomare	2001	28	28	58	mixed	15/28	19		7–41		14/28	21/28
Ortiz	2002	22	17	47	mixed	17/22	28		6–48	4/22	9/22	14/22
Devesa et al.	2002	53	35	46	mixed		27		7–55	29/53	37/53	43/53
Lehur et al.	2002	16	14	43	mixed		25		7–49	6/16	10/16	11/16
Parker et al.	2003	35		47	mixed				6–24		21/35	21/35
Michot[a]	2003	37	22	52	mixed	6/37	42			12/37	20/37	20/37
Cumulative		246								51/128	143/246	165/246
										40%	58%	67%

Previous surgery, previous surgery for fecal incontinence.

Follow-up is given in months.

See text for the definition of "success" and "improvement".

F female.

Some patients with type AMS 800 included.

30.11 Sacral Nerve Stimulation

Sacral nerve stimulation, first used by urologists to treat urinary incontinence, was introduced by Matzel et al. to treat fecal incontinence (Matzel et al. 1995). Sacral nerve stimulation may be tested in incontinent patients with a morphologically intact anal sphincter. In a prone position, sheathed needles are inserted into the sacral foramen of S2, S3 and S4, and current is applied. The most efficient sacral nerve to stimulate the anal sphincter, most often S3, is chosen for short-term chronic stimulation with an impulse generator. If percutaneous nerve stimulation for 6–10 days improves incontinence significantly and symptoms relapse upon ceasing temporary stimulation, a permanent impulse generator is implanted subcutaneously in the lower abdominal wall or below the superficial fascia in the buttock.

The morbidity of this approach seems to be low, but technical problems such as electrode migration occur and device removal due to intractable pain has been described (Ganio et al. 2001; Leroi et al. 2001; Matzel et al. 2001). In patients with fecal and urinary incontinence, both can be improved by sacral nerve stimulation (Ganio et al. 2001; Leroi et al. 2001).

Details on the patient populations and the long-term results are given in Table 30.12. There is a limited number of studies, with no study describing more than 16 patients, and most studies including a mixture of incontinence etiologies. Since there is a test phase, which prohibits the permanent implantation of the impulse generator in nonresponding patients, there is a high success rate, with almost all patients receiving a permanent stimulator having a significant improvement of fecal incontinence. The longest mean follow-up is around 3 years, and these studies reported a significant improvement of fecal incontinence in 23 of 26 patients (88% [Matzel et al. 2001, 2003; Kenefick et al. 2002a]). There seems to be no deterioration of the initial improvement of sphincter function up to 99 months after the implantation of the impulse generator (Matzel et al. 2003).

30.12 Quality of Life

Today, it is generally accepted that measuring the quality of life and taking the patient's perspective into account are indispensable for judging the outcome of surgical treatments. However, adequate tools to measure quality of life have been developed in recent years only, and it has become evident that unspecific quality-of-life measures do not adequately reflect the influence of specific diseases on the quality of life. Therefore, disease-specific quality-of-life measures had to be validated. For fecal incontinence, Rockwood developed a Fecal Incontinence Severity Index (FISI [Rockwood et al. 1999]) and a Fecal Incontinence Quality of Life Scale (FIQL [Rockwood et al. 2000]), which have both been endorsed by the American Society of Colon and Rectal Surgeons (ASCRS).

Suitable tools to measure quality of life after fecal incontinence surgery have become available only recently; accordingly, there are no quality-of-life data available regarding treatment outcomes after pelvic floor repairs. Limited data on quality of life are available after anterior sphincteroplasty, which has been shown to improve the FISI. Patient-rated and surgeon-rated FISI scores were identical and correlated with the FIQL (Halverson and Hull 2002), and the degree of fecal incontinence correlated negatively with the FIQL. Interestingly, incontinence to gas only did not decrease the

Table 30.12. Long-term results of permanent sacral nerve stimulation (mean follow-up at least 1 year)

Author	Year	*N*	F	Mean age	Etiology	Previous surgery	Follow-up (mean)	Follow-up (range)	Full continence	Success	Improvement
Malouf et al.	2000	5	5	59	mixed	1/5	16	3–26		4/5	5/5
Ganio et al.	2001	5	4	62			19	5–37		5/5	5/5
Ganio et al.	2001	16	12	51	mixed	6/16	16	3–45		12/16	16/16
Matzel et al.	2001	6	5	50	mixed	5/6	37	5–66		3/6	5/6
Rosen et al.	2001	16		50	neurologic 11	2/16	15	3–26		16/16	16/16
Kenefick et al.	2002	15	14	60	mixed	7/15	24	3–60	11/15	14/15	15/15
Kenefick et al.	2002	4	4	61	scleroderma 4		32	6–60	4/4	4/4	
Matzel et al.	2003	16	14	54	mixed	8/16	33	3–99	11/16	12/16	14/16
Cumulative		83							22/31	70/83	80/83
									71%	84%	96%

Previous surgery, previous surgery for fecal incontinence.

Follow-up is given in months.

See text for the definition of "success" and "improvement".

F female.

quality of life compared to patients who were fully continent (Gutierrez et al. 2004). It is also remarkable that although the rate of continent patients who underwent anterior sphincteroplasty a median of 10 years before decreased over time, only 6% of those being fully continent at 10 years, 74% of patients remained satisfied with the results of the procedure (Gutierrez et al. 2004), supporting the importance of the patient's view of surgery.

Dynamic graciloplasty has been shown to improve the quality of life significantly. The State-Trait Anxiety Inventory questionnaire and the Nottingham Health Profile, although not disease-specific, both improved 1 year after a successful dynamic graciloplasty, with good correlation between the clinical results scored by the physician and the patient (Baeten et al. 1995; Adang et al. 1998). In a prospective multicenter trial, the SF-36 was improved in three of eight categories, and the Fecal Incontinence Type Specification in all ten categories, and the patients' self-rating of bowel control significantly improved after 1 year (Baeten 2000; Wexner et al. 2002). Of the SF-36, the category "social functioning" correlated with continence (Wexner et al. 2002).

There are six reports describing an improved quality of life after the implantation of an artificial bowel sphincter (ABS). In general, treatment-related quality-of-life changes only refer to patients with a successful ABS implantation. Vaizey et al. investigated six women preoperatively and 3 months after an ABS implantation by the SF-36, and found a significant improvement in two out of eight subscales (role emotional and social function) (Vaizey et al. 1998). O'Brien et al. used a quality-of-life questionnaire with 39 questions specifically constructed for patients with anal incontinence by American Medical Systems (Vaizey et al. 1999). In ten patients with a successfully implanted device, the score significantly improved after device activation (O'Brien and Skinner 2000). Sixteen patients were studied with the FIQL 6–12 months after ABS implantation, and the quality of life largely improved in all four domains explored (Lehur et al. 2002). Devesa et al. retrospectively assessed 25 patients with the FIQL and observed significant improvements in all four domains as well. In addition, the postoperative increase of the anal resting pressure correlated with the coping/behavior subscale (Devesa et al. 2002). In a multicenter study, 59 patients completed the FIQL 12 months after device activation. A variety of incontinence symptoms impairing the quality of life were improved postoperatively, but the scores of the four domains were not given. In 44 patients, the health status questionnaire (HSQ) was completed 12 months after activation, and the HSQ significantly improved (Wong et al. 2002). Finally, Parker et al. reported a significantly improved FIQL 12 months after device activation in all four domains in 14 patients. However, of 35 devices implanted successfully in this study, only 17 were functional at 12 months, of which 14 were evaluated regarding quality of life (Parker et al. 2003). No quality-of-life data were reported for those patients who had a failed ABS implantation in this study as well as in all the other studies cited, indicating that only patients with successful device implantation were evaluated, which reflects a selection bias. Formally, quality-of-life data should be evaluated on an intention-to-treat basis, and these data are not available yet.

Limited data on quality of life are available after sacral nerve stimulation (SNS). Rosen et al. reported a significant improvement in all four domains of the FIQL in 12 patients 6 months after permanent implantation (Rosen et al. 2001). Matzel et al. found an improvement of borderline significance in all four domains of the FIQL a median of 18 months after device activation in four patients (Matzel et al. 2003). In five patients with permanent SNS and a median follow-up of 16 months, all patients showed an overall improvement of the SF-36, but no statistical analysis was provided (Malouf et al. 2000). In four patients with multiple sclerosis, the different subscales of the SF-36

showed a variable improvement, physical and social function being the most consistent. However, no actual data with statistical analysis were provided (Kenefick et al. 2002). In 14 patients with a median follow-up of 24 months, two domains of the SF-36 (role physical and social function) were significantly improved (Kenefick et al. 2002). Taken together, the available quality-of-life data stem from a very limited number of patients. As reported for the artificial bowel sphincter, no quality-of-life data were reported for those patients that had a failed SNS implantation, again reflecting selection bias. Although the study results are promising, further data collected on an intention-to-treat basis are needed.

30.13 Conclusion

The armamentarium of surgical procedures to treat fecal incontinence has increased over the past decades. The interest in pelvic floor repairs seems to be fading, as the functional results remain unsatisfactory. There are a few continuing publications on anterior sphincteroplasty, and although the repaired sphincter and the functional results seem to deteriorate in the long term, it has to be kept in mind that around 75% of patients were still satisfied with the result of the procedure after a median follow-up of 10 years (Gutierrez et al. 2004). Considering the low morbidity of the procedure, anterior sphincteroplasty remains an option in patients with an isolated sphincter defect.

Dynamic graciloplasty and the artificial bowel sphincter are complex and expensive procedures with a high morbidity and failure rate. Therefore, they should be reserved for carefully selected patients, and patients should be referred to specialized centers. Both remain treatment options for younger, motivated patients with severe fecal incontinence. Sacral nerve stimulation might be the most thrilling advance in recent years, originally used for patients with severe fecal incontinence and no detectable anatomical sphincter defect, but now also being successfully tried in patients with an anatomical sphincter defect or after an unsuccessful sphincter repair. The morbidity of the procedure is low, and the test phase of sacral nerve stimulation is a big advantage, as patients improving their continence during test stimulation have a more than 90% chance of improving their continence with permanent stimulation. Follow-up of successful sacral nerve stimulation is available for up to 10 years now, with no decrease in efficacy surfacing thus far (Matzel et al. 2003). The stimulating device is expensive, currently prohibiting its use on a large scale. However, as physicians' and the society's awareness of the detrimental effects of fecal incontinence rises, and considering that cardiac pacing or cardiac defibrillators are now standard care in selected patients, its costs may no longer be allowed as an argument to deny this treatment to a patient in need, and the situation might change in the future, allowing more patients to receive a costly treatment on the one hand, but dramatically increasing their quality of life on the other.

Finally, there is a need for surgeons specializing in fecal incontinence treatment to be able to offer the surgical treatment options named above. With aging societies, increasing awareness of incontinence problems and better-informed patients, the number of patients that seek treatment for fecal incontinence will rise. This chapter might serve as an overview to give these patients a realistic judgment of the long-term result that can be expected after surgical treatment for fecal incontinence.

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Chapter 31

Quality of Life with a Permanent Colostomy

31

Brigitte Holzer, Harald R. Rosen

Contents

31.1 Introduction

Since the introduction of abdominal perineal excision (APR) by Ernest Miles in 1908 and the concurrent demand for radical resection of the tumor-bearing rectum, nearly 43 years elapsed before Goligher first expressed concern regarding the sequel of surgical problems in the course of tumor resection affecting patient's quality of life (QoL) (Goligher 1951; Miles 1971).

Today it is widely accepted that most patients with rectal cancers or disorders that will require surgical therapy can be treated with sphincter preservation by standardized surgical techniques (Renner et al. 1999). However, although the lowest rates of APR and consequent permanent stoma formation have been reported to be between 9% and 10% in specialized units, observation of multicenter studies have shown significantly higher numbers of patients who undergo APR (37%–68%) (Allun et al. 1994).

A permanent colostomy may be constructed for patients with low rectal cancer, anorectal inflammatory bowel disease, persistent incontinence despite attempted surgical correction, neurological disorders or anorectal agenesis.

In the past, many publications have dealt with the sequel of APR and the presence of a permanent colostomy, and it is widely accepted that this procedure involves a heavy price for affected patients (Camilleri-Brennan and Steele 1998; Grumann et al. 2001; Koller et al. 1996; Sprangers et al. 1995; Williams and Johnston 1983).

31.1.1 Social Well-Being

Social life may deteriorate after surgery for rectal cancer, although results are contradictory. A colostomy may bring a fear of being a nuisance to other people, mainly because of odor, and there may be embarrassment about the presence of a stoma.

Wiring et al. in 1975 examined a group of 214 patients who had a permanent colostomy and a group of 110 who had restorative surgery. There was significantly reduced social contact in the colostomy group. Similarly, MacDonald and Anderson in 1985 noted that those with a colostomy tended to participate less in social activities than those without a stoma; their interests in outdoor pursuits were significantly less.

In 1984 MacDonald and Anderson found a statistically significant worsening partner relationship in 29% of patients with a colostomy compared with 14% of those who had a sphincter-saving resection.

31.1.2 Psychological Well-Being

There are some studies showing a high prevalence of psychological problems in patients operated for rectal carcinoma, even though the instruments used in most cases may not be psychometrically reliable. Patients with colostomies tend to suffer most.

Devlin et al. in 1971 found that 23% of 83 patients suffered from a severe form of psychological disturbance after APR, compared with one of 37 patients who had a sphincter-saving operation.

Williams and Johnston in 1983 reported a 32% prevalence of depression following an APR, compared with a 10% prevalence after anterior resection.

In 1975 Writing et al. used the Heidelberg Colostomy Questionnaire in a study that covered mainly social and psychological function in patients with a stoma. They concluded that the colostomy was associated with a significant degree of depression, hopelessness, loneliness and suicidal thoughts.

The patients after APR studied by MacDonald and Anderson in 1984 were found to have a statistically significantly higher incidence of low self-esteem and feelings of stigma than those who had undergone a sphincter-saving resection.

Interestingly, there has been some controversy among surgeons about the real impact of a permanent colostomy on patient quality of life (QoL), and although most of them consider a permanent colostomy being associated with a marked deterioration in patient QoL, there are some data that show that a permanent colostomy may even be more beneficial for patient QoL than a very low sphincter-preserving anterior resection (Grumann et al. 2001).

Despite such observations, it is evident that the consequences of rectal surgery have an important bearing on a patient's quality of life. Although differences in definition exist, quality of life may be regarded as representing one individual's ability to carry out daily activities, as well as satisfaction with personal performance and with the balance between disease control and adverse effects of treatment (Gotay et al. 1992; Olschewski et al. 1994). However, our own experiences as well as the observations of others indicate that QoL following the therapy of a certain disorder is influenced by various other factors than by the treated disease alone.

31.2 Preoperative Expectations

Patient's expectations in regard of the disease and the proposed operation appear to be of major importance for his or her subjective perception of the outcome of treatment. What does the patient expect from the operation? Apart from the primary desire to achieve cure from the disease, other expectations on the part of the patient can only be surmised.

In a prospective study we evaluated the patient's preoperative expectations as objectively as possible and to describe the patient's priorities in relation to age, gender and socioeconomic status.

In the period from 1998 to 2001, 167 patients were given a questionnaire consisting of 15 questions prior to surgery for colorectal cancer. The questionnaire included various aspects that were thought to influence the patient's quality of life. Moreover, the patients had the opportunity to rate the questions they considered most important.

The following five items were considered most important by the total group of patients: complete cure of the disease was rated most important (98%) followed by the avoidance of a stoma (93%), undisturbed continence (90%), less pain (54%), normal digestion (42%) and good control over bowel evacuation (41%).

In contrast, the following aspects were considered less important by the patients: the ability to eat as desired (43%), to use public transport (29%) or to attend public events (27%). Avoidance of adjuvant chemotherapy or radiotherapy was considered important by 26%, being able to travel by 17%, being able to resume work as soon as possible by 16%, and an undisturbed sexual life by 11%. The appearance of the scar was given the least priority (8%).

31.2.1 Influence of Age

Cure from the disease – rated most important by the total group – was given significantly less priority by patients older than 80 years of age compared to those younger than 79 years of age (p=0.0065).

Having an operation without a stoma was significantly less important for patients aged 28–50 years compared to those older than 51 years (p=0.0144).

31.2.2 Influence of Education

An evaluation of the data in relation to the education level revealed that patients who had attended school for more than 12 years gave less importance to the question of a colostomy (p=0.061). These patients considered it very important to avoid adjuvant treatment (p=0.0087) and also gave more importance to the ability to resume work early (p=0.0061).

In summary, our patients gave the highest priority preoperatively to the question of the cure of disease, as anticipated, followed by the problems of colostomy and continence. However, we believe that factors apart from those we investigated (age, gender, education) should be taken into account when evaluating these results.

Solomon et al. described that patients' preferences do not always accord with those of clinicians. Unless patients' preferences are explicitly sought and incorporated into clinical decision making, patients may not receive the treatment that is best for them. In a prospective study, patients undergoing curative surgery for colorectal cancer were interviewed postoperatively to elicit their preferences compared with those expressed by clinicians. There were significant differences between patients and clinicians. Clinicians were more willing than patients to trade survival to avoid a permanent colostomy in favor of chemoradiotherapy. Patients' strongest preference was to avoid chemotherapy, more than to avoid a permanent colostomy (Salomon et al. 2003).

Furlani and Ceolim in Brazil described that their nurses should assume their roles as patient educators in the whole preoperative process in order to facilitate improvement of quality of life for the stoma patient (Furlani and Ceolim 2002).

31.3 QoL Instruments

Controversial results of the impact of a permanent colostomy on the patient's QoL can be partly explained by the different quality of life-instruments that were used, partly by differences in patient populations (Audisio et al. 1997; Grumann et al. 2001) (Ta-

Table 31.1. QoL questionnaires used in patients with rectal disorders

Nottingham Health Profile	General QoL questionnaire
QLQ-C30	QoL in pts with cancer (EORTC)
SF-36	General QoL questionnaire
QLQ-CR 38	QoL in pts with colorectal cancer
ASCRS FI questionnaire	QoL in pts with fecal incontinence
DDQ-15	Digestive disease QoL questionnaire

ble 31.1). An instrument should be of proven validity, that is it must measure the intended variable and not another. It must be reliable, measuring the variables accurately, and also sensitive, measuring any changes present.

Generic questionnaires such as the Nottingham Health Profile are useful and allow the researcher to compare QoL across whole patient populations. However, they may not be sensitive enough to measure changes in QoL that may be brought about by different types of surgery or adjuvant treatment.

On the other hand, differences in global QoL associated with different operations may truly not exist, the benefit of surgery resulting solely from the removal of the tumor, irrespective of the surgical technique used. Questionnaires that have been designed for use in patients with cancer, such as the Rotterdam Symptom Checklist and the European Organization for Research and Treatment of Cancer (EORTC) QLQ-C 30 core questionnaire, may be more suitable. In addition, further questionnaires specific to colorectal cancer are necessary. For example, the EORTC group developed a colorectal cancer questionnaire or module (QLQ-CR 38), which has been validated in the Netherlands and is being tested in a number of international phase III trials.

In a recent multicentric trial focusing on QoL aspects in patients with a permanent colostomy, we have modified a validated instrument for QoL measurement in patients suffering from fecal incontinence. For this purpose, the QoL questionnaire for fecal incontinence introduced by Rockwood and co-workers for the American Society of Colorectal Surgeons (ASCRS) was adapted by simply replacing the term "incontinence" by "colostomy". A pilot study confirming the applicability of this instrument was conducted at different institutions and the questionnaire proved to be easily understandable. However, it must be admitted that there is still a lack of a validation process for the specific use in patients with a stoma.

31.4 Individual Factors Influencing QoL in Patients with a Stoma

31.4.1 Age and Gender

Nugent et al. (1999) described in their study that some patients cope extremely well with their stoma and others find them both distressing and disruptive to their lifestyles. A possible reason for this may be related to age or the patients' previous condition. Patients with an ileostomy most frequently have inflammatory bowel disease as their underlying pathology (90% in a series of 16,470 stoma patients) and are generally unwell before stoma formation (Fleshman and Lewis 1991). This contrasts with patients with colostomy, who are generally older, have cancer, and may be asymptomatic.

Contrary to this finding, a study be Stryker et al. examined 675 patients with ileostomies. The group of patients aged 60 years old or older fared as well or better than the younger group (Stryker et al. 1985).

Furthermore, it must be taken into account that sexual and urological problems arising as a complication after pelvic floor surgery (and not directly related to the formation of a colostomy) will affect patients' QoL as well.

In the largest study of 16,470 American stoma patients, 59% of patients with colostomy and 25% with ileostomy had problems with their sex lives (Fleshman and Lewis 1991).

The study by Awad et al. confirmed that 25% of patients with ileostomy had moderate or severe problems with their sex lives (Awad et al. 1993).

An in-depth study looked at sexual concerns in 50 patients with ileostomy and found that 24% of male patients were unable to obtain or sustain an erection; 32% said sex was physically difficult; and 46% found sex psychologically difficult (Rolstad et al. 1983).

Devlin et al. reported in 1971 that 51% of patients over 65 years old who had a colostomy felt socially isolated, in contrast to 19% of younger patients with a stoma. In this study, women felt more socially isolated than men.

31.4.2 Counseling

In a study of Karadag and co-workers, a profoundly negative impact of a colostomy or ileostomy on QoL was shown and they suggested that specialized counseling of these patients by a dedicated team could improve QoL significantly (Karadag et al. 2003). With two QoL questionnaires, 43 stoma patients before and after stoma therapy were interviewed. The results were analyzed regarding the stoma-related problems in the subgroups of patients with irrigating colostomies (n=16), nonirrigating colostomies (n=15), and ileostomies (n=12). After stoma therapy, the irrigating colostomy patients had a significantly higher score than the nonirrigating colostomy and ileostomy patients. Cumulatively, all of the items improved significantly after stoma therapy, for example, getting dressed, bathing and participating in sports.

Nugent et al. also described an inadequate preoperative counseling in their study. Operating before appropriate counseling can be given is occasionally avoided, but even in emergency situations it is desirable that a stoma therapist should visit the patient before the operation to discuss sitting and consequences of a stoma. A significant proportion of patients felt that additional support would be helpful (Nugent et al. 1999).

However, it must still be emphasized that even in countries with a high quality of surgical skills in coloproctology disorders, specialized stoma therapy groups are still under-represented in comparison of the total number of patients.

A possible reason may also be the low intake of stoma support groups and other patient associations. This is in agreement with a large national survey of stoma patients in France, where only one-third of patients with a stoma were members of a stoma group (Baumel et al. 1994).

31.4.3 Time of QoL Evaluation

In some studies, the scores of many quality-of-life dimensions were lower than baseline in the early postoperative period. Surgery also restricted the social life of these patients for the first few months. After 3–6 months, most scores had returned to preoperative values. The scores of most dimensions then remained similar to baseline.

However, although improved emotional function, mental health and future perspective reflect a positive and optimistic attitude despite disfiguring surgery, the score of perception of body image was worse than baseline for the whole year after operation. This may have resulted from the difficulty in accepting a stoma or abdominal scars (Camilleri-Brennan and Steele 2001; White and Hunt 1997).

In accordance with these observations, we recommend including patients in QoL studies only after rectal surgery (colostomy or sphincter preservation), with a minimal history of 1 year following definitive surgery (closure of a protective stoma or formation of a permanent colostomy or ileostomy, respectively)

31.4.4 Social Factors (Education, Religion)

We felt that the patient's social and cultural situation might strongly effect the QoL outcome after the formation of a permanent colostomy. Therefore, we tried to evaluate possible social and geographic factors that could have an impact on QoL of patients following APR. In an international trial, patients operated on for low rectal cancer by APR were evaluated using a QoL questionnaire mentioned above. The results for the four domains of QoL (lifestyle, coping behavior, embarrassment, depression), as well as for subjective general health were evaluated with regard to age, gender, education and geographic origin in a univariate and multivariate analysis (Table 31.2).

Thirteen institutions in 11 countries included data from 257 patients. While the analysis of results of general health did not reveal any significant differences, the analysis of the four domains of QOL showed a significant influence of the geographic origin (Fig. 31.1). The presence of a permanent colostomy showed a consistently negative impact on patients in southern Europe as well as in patients of Arab (Islamic) origin. On the other hand, age, gender and educational status did not reveal a statistically significant influence.

There are many reasons for these statistically consistent findings in our study.

Since the worst QoL results in all domains were found in patients of Islamic religion, we assume that religious factors may play a very important role. This issue has been addressed in a recent paper by one of our study participants (M.A.K.) who described a significantly poorer outcome in patients following APR compared to patients with sphincter-preserving surgery (Kuzu et al. 2002). In the APR group, a significantly greater number of patients stopped praying daily and fasting during Ramadan. This resulted in significantly higher social isolation and affected QoL even more negatively.

Table 31.2. International study of QoL after stoma formation

Total	257 patients (%)
Male	149 (58%)
Female	108 (42%)
Age (median, min, max)	63.5 (17–91) years
Educational status	
No high school	97 (37%)
High school	65 (25%)
College or university	71 (28%)
Missing data	24 (10%)
Geographic origin	
Northern Europe (Copenhagen, Aarhus, Goeteborg)	81 (32%)
Middle Europe (Erlangen, Luebeck, Krakow, Nantes, Geneva, Vienna)	113 (44%)
Southern Europe (Barcelona, Padua, Ankara)	25 (10%)
Arab or Asian origin (Alexandria)	29 (12%)
Missing data	9 (2%)

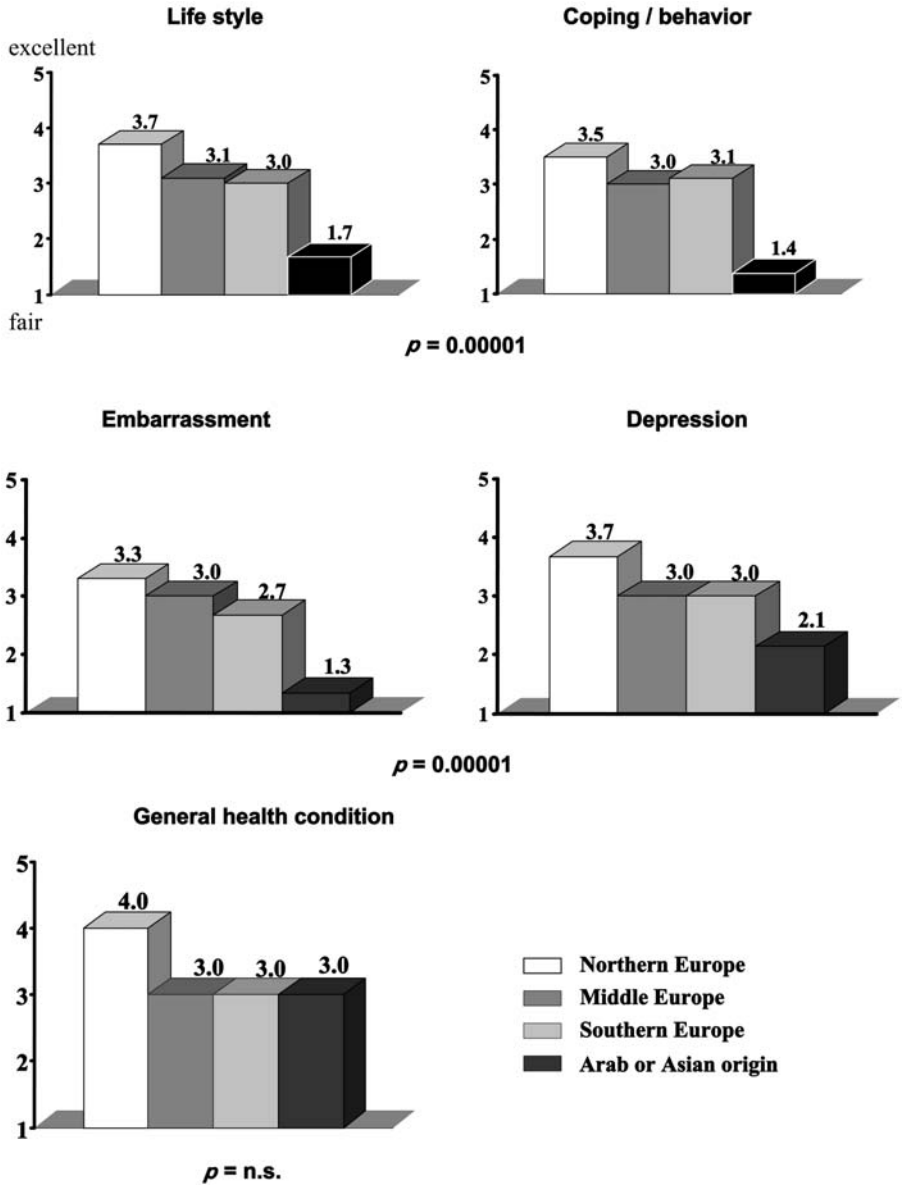

Fig. 31.1. Results of quality of life according to geographic origin

Another aspect of the explanation for our findings may be attributed to the fact that postsurgical stoma care varies widely throughout Europe. It is obvious that patients who have standardized support available in hospital and (even more) at home, and who receive repeated counseling by qualified specialists in stoma care, will overcome daily problems arising from their colostomy much more easily than patients who are left alone in this situation. Furthermore, the presence of well-trained stoma therapists

might also result in a higher percentage of patients using more sophisticated instruments such as stoma irrigation, which leads to further improvement in QoL.

Another possible factor for our observation might be a very simple climatic reason. It is possible that in countries that have warm weather for most of the year, the effect of a colostomy might be more pronounced since the patient will have not more than one layer of clothing covering the stoma bag. Patients in northern countries, however, will be able to hide their colostomy much more easily.

Furthermore, the constant and statistically significant observation of the geographic influence in the various domains of quality of life proves that the situation after formation of a permanent colostomy is dependent on individual factors influenced by the social context and the patient's community. We feel that this observation should be taken into account when patients are given preoperative counseling. Furthermore, evaluations of QoL studies should also consider important aspects of the patient's life such as social background, culture and religion.

31.5 Conclusion

Assessment of QoL gives valuable information of consequences created by different procedures. QoL studies in patient's with the necessity to receive a permanent stoma have increased our knowledge about possible sequel to various factors in patient's well being. Preoperative expectations as well as postoperative QoL results are influenced by individual factors and it must be accepted that statements about the impact of various procedures to QoL should never be generalized.

However, the availability of already existing information may help the surgeon when obtaining informed consent from patients before major surgery for rectal cancer as well as for individual counseling.

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Part IX

How Can We Improve the Treatment of Incontinence?

IX

Chapter 32

Is Urinary or Fecal Incontinence a Preventable Event?

32

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Contents

32.1 General Consideration

Increasing attention has focused on maternal morbidity and the long-term sequelae of childbirth, since both perinatal and maternal mortality rates have fortunately decreased in the last few decades. Urinary and fecal incontinence are debilitating conditions not only leading to medical problems and costs, but also to embarrassment, isolation and loss of independence.

The pelvic floor is a dynamic system of interconnected muscles, nerves, ligaments, and viscera controlling continence and reproduction. The exact mechanism by which childbirth may lead to incontinence is unclear. Common mechanisms proposed to be responsible for childbirth-associated urinary incontinence include denervation injury and mechanical trauma. Other less commonly blamed mechanisms of damage include hormonal variation, abnormal vascular pulsations of the periurethral plexus, and decreased functional urethral length. Three phases of damage and repair regarding the effect of childbirth on the pelvic floor can be recognized. The first phase concerns the injury that occurs during pregnancy and delivery. The next is the repair phase, when the body heals this injury as best it can. The last is the maintenance phase. Factors such as age and disease influence the healed injury and may alter the body's ability to compensate for it. There may also be recovery after an acute injury and there may be a gradual decline in function, especially with age, as has been shown for urethral function (Perucchini et al. 2002). This deterioration may be accelerated following vaginal delivery. Even though the continence mechanism is repeatedly damaged, women are able to remain continent and compensate for the damage. But also without pregnancy and delivery, a significant number of older nulliparous women complain of stress urinary incontinence (Buchsbaum et al. 2002).

Care is needed to put the findings of studies of childbirth injury in proper context. The gold standard for evidence-based medicine is the randomized clinical trial. Randomized controlled trials (RCT) are rare in the area of childbirth and incontinence. The ability to conduct RCTs is hampered by the long follow-up needed to truly understand the impact of childbirth on incontinence. On the one hand, what may seem like a major injury during the 1st months after delivery may heal entirely with time and be of no long-term importance. On the other hand, what may at first seem to be a minor injury can become clinically important years later, after age and disease have taken their toll.

Three grades of prevention can be distinguished: primary prevention aims to remove the causes of a disease, secondary prevention aims to detect asymptomatic dysfunction and treat it early to stop progression, and tertiary prevention aims to treat existing symptoms to prevent progression of disease. When doing studies on prevention of incontinence, it may be very difficult to screen all potential trial participants to see if a disease process (i.e., incontinence) is absent altogether, or present but asymptomatic. In addition, there are many factors that contribute to incontinence (denervation, poor muscle function, fascial defects). It is therefore difficult to distinguish between primary and secondary prevention when talking about incontinence.

32.2 Incidence of Urinary and Fecal Incontinence

Incidence of urinary and fecal incontinence is discussed separately. Prevalence studies of double incontinence are rare and show extremely varying results, ranging between 5% and 69%.

32.2.1 Incidence of Urinary Incontinence

32.2.1.1 Incidence of Urinary Incontinence Before First Pregnancy

The prevalence of urinary incontinence in fertile women varies depending on the target population, the definition and the design used. Few studies have focused on urinary incontinence before the first pregnancy. Most often data on the prevalence of incontinence are taken from studies that focus on incontinence after or during pregnancy. The prevalence found most often varies between 4% and 12%, and little information is available on the severity of the symptoms. Furthermore, symptoms may vary in intensity and depend on a women's activity, and it has been reported that nulliparous women complain less regarding symptoms than parous women. Francis found that 40% of primigravid women had a history of occasional incontinence before becoming pregnant (Francis 1960). If such a history was present, then incontinence invariably became worse during pregnancy. Wilson et al. (2002) found that 84% of the women with onset of incontinence before pregnancy were still incontinent 5–7 years later, compared with only 31.8% of women who were dry before pregnancy.

32.2.1.2 Incidence of Urinary Incontinence During Pregnancy

Urinary incontinence is a common occurrence during pregnancy, affecting 4%–82% of women (Baessler and Schüssler 2003). Often it is a transient condition. Incontinence during pregnancy is attributed to the enlarged uterus, fluctuating hormone levels, increased glomerular filtration rate, temporary changes in the urethrovesical angle and other changes of normal pregnancy. There are some data on the severity of incontinence. In a recent study by Chaliha, 43.7% of 549 nulliparous women were found to have incontinence during pregnancy, 9.3% claiming daily leakage and 24.9% reporting incontinence less than once a week. Incontinence symptoms seem to increase during pregnancy. At 16 weeks of pregnancy, Hojberg et al. (1999) found 3.9% of nulliparous women with incontinence (but only 0.5% reporting incontinence at least once a week). Two older studies report on incontinence in early pregnancy at a rate of 6%–15% in nulliparous women. According to most studies, incontinence is more frequent in multiparous than in nulliparous women throughout the whole pregnancy. Incontinence during early pregnancy is reported by 15%–26% of multiparous women.

32.2.1.3 Incidence of Urinary Incontinence After Childbirth

It has been suggested that that vaginal delivery is the main contributing factor for incontinence, possibly because of damage to important muscle tissue or nerves. According to several studies after childbirth, incontinence is a common problem, with a reported incidence of 20%–38% in the first 3 months after delivery (Wilson et al. 1996; Chaliha et al. 2003; Farell et al. 2001; Viktrup 1992). About 3% report daily or more frequent leakage.

Stress urinary incontinence (SUI) may persist 1 year postpartum in 24%–75% of primiparous women (Viktrup et al. 1992; Baessler and Schuessler 2003). De novo SUI has been reported to develop in 4%–19% of women who gave birth vaginally (Meyer et al. 2001). Women with stress incontinence 3 months after first delivery carry a partic-

ular risk of 92% of having stress incontinence symptoms 5 years later; without any symptoms after the first delivery, the incidence of stress incontinence was 19% (Viktrup and Lose 2001). According to the same authors, subsequent deliveries seem not to play an important role in the development of long-lasting stress incontinence.

32.2.2 Incidence of Fecal Incontinence

Fecal incontinence, defined as the involuntary loss of flatus or feces, is reported in 4%–38% of women after vaginal delivery (Thacker and Banta 1983; MacArthur and Bick 1997; Hall et al. 2003). Obviously, these discrepancies in the observed prevalence of fecal incontinence depends on the population studied, the definition of incontinence used and on how the data were collected. Furthermore, the prevalence of (fecal) incontinence is probably underestimated, as few affected women voice their symptoms (Johanson and Lafferty 1996). Fecal incontinence reduces the quality of life of affected women and has substantial direct and indirect long-term costs (Mellgren and Jensen 1999; Rockwood and Church 2000).

32.3 Factors That Might Influence Continence During Pregnancy and Delivery

The contribution of obstetric factors to the development of SUI is controversial. Historically, it was assumed that perineal trauma should be prevented. According to a Cochrane database review of the literature on episiotomy by Carroli, the traditional routine use of episiotomy in general and midline episiotomy in particular cannot be justified. An increased risk of anterior perineal trauma but not of incontinence was found. Viktrup et al. (1992) found a higher rate of SUI after mediolateral episiotomy 5 years after childbirth.

In some studies, the duration of the second stage of labor and birth weight was associated with a higher incidence of stress incontinence. Other investigators found no significant correlation between stress incontinence and fetal head circumference, the second stage of labor, or birth weight (Baessler and Schüssler 2003; Reilly et al. 2002). Viktrup et al. (1992) showed that all statistically significant associations between obstetrical risk factors and the incidence of SUI immediately after delivery had vanished 3 months later! No significant obstetrical risk factor was correlated to incontinence 5–7 years after delivery in a study by Wilson et al. (2002). Leighton and Halpern (2002) performed a systematic review on the effect of epidural analgesia on urinary incontinence and found urinary incontinence to be only more frequent in the immediate postpartum period. No positive or negative effects of epidural analgesia on continence were found by Meyer et al. (2002).

Obesity has been associated with a higher risk of urinary incontinence during pregnancy and postpartum (Burgio et al. 2003; Baessler and Schüssler 2003; Reilly et al. 2002). Wilson et al. (1996) examined maternal risk factors for postpartum UI. In addition to vaginal delivery and multiparity, they also found obesity to be associated with the development of incontinence 3 months after childbirth. The same author found the prevalence of incontinence similar in women having three or more Caesarean sections (38.9%) to those delivered vaginally (37.7%). Markers of collagen weakness, including striae, varicose veins, hemorrhoids, and joint hypermobility, which previously had been implicated in the pathogenesis of incontinence, did not predict

postpartum urinary or fecal incontinence in a later study. Changes in collagen may result in greater mobility of the bladder neck, resulting in stress incontinence. This was suggested by King and Freeman (1998), who used perineal ultrasonography in 128 primigravidae antenatally and then again 10–14 weeks after delivery. They found an increase in bladder neck mobility antenatally in those women who subsequently developed postpartum stress incontinence.

Risk factors for anal sphincter injury and postpartum fecal incontinence include vaginal delivery, primiparity, instrumental delivery, especially if forceps are used, episiotomy, delivering a large baby, a baby in occipitoposterior presentation, maternal position during delivery (squatting), maternal age, oxytocin augmentation, prolonged second stage of labor, and delivering at night (Handa et al. 1996; Jander and Lyrenas 2001). Interventions to reduce the exposure of mothers to these risk factors are progressively being evaluated. Most of these risk factors of urinary and fecal incontinence are actually correlated, and intervention that could ease overall the process of childbirth will act on several of these factors.

32.4 Primary Prevention of Urinary and Fecal Incontinence

32.4.1 Before Pregnancy

Wilson et al. examined maternal risk factors for postpartum UI. In addition to vaginal delivery and multiparity, they found obesity to be associated with the development of incontinence 3 months after childbirth (Wilson et al. 1996). The impact of weight loss in association with pregnancy on the long-term incidence of urinary incontinence has not been studied. Chaliha evaluated the role of antenatal history and physical markers suggestive of collagen weakness, and their role in predicting postpartum incontinence. Postnatal urinary incontinence and anal incontinence was not related to race, antenatal body mass index, the presence of striae, hernia, varicose veins, piles or a family history of incontinence, prolapse or collagen weakness. Higher joint mobility scores were associated with incontinence of flatus but not fecal urgency or urinary symptoms (Chaliha et al. 1999). In a recent prospective cohort study in nulliparous women, Tincinello also found a significant association between elbow hyperextension and stress urinary incontinence but no association between joint mobility scoring and postpartum stress incontinence. Although collagen weakness has been implicated in the pathogenesis of incontinence, generally accepted physical markers of collagen weakness are not established. Perhaps the studied markers were not representative of collagen weakness, or a larger study with a longer follow-up is required.

It is only by identification of meaningful predisposing factors that place an individual patient at risk that we will be able to make meaningful progress toward effective primary prevention. At the same time, we should establish strategies for secondary prevention by identifying alterable promoting factors that over a women's lifetime can contribute to the progression from damage but compensated pelvic floor to a decompensated and symptomatic pelvic floor disorder.

Elective caesarean section could be discussed if there were clear markers for postpartum urinary incontinence. However, there are many unanswered questions regarding the protective effect of elective caesarean section (see "During Pregnancy" below).

Risk factors for fecal incontinence are present before pregnancy. Several authors have pointed out that fecal incontinence is present before pregnancy in a substantial

proportion of women and is a predictor of incontinence after delivery. Some constitutional characteristics will increase the risk of pelvic floor damage during delivery. A narrow subpubic arch angle (below 90°) has been found to be associated with prolonged labor and postpartum fecal incontinence (Frudinger et al. 2002). Interestingly, perineal and anal sphincter trauma, assessed by ultrasound, was found not to account for the higher rate of postpartum anal incontinence in these women. Women with irritable bowel syndrome are more likely to experience subjective alteration of fecal continence postpartum compared with the healthy primigravid population, but they are not at increased risk of anal sphincter injury (Donnelly and O'Herlihy 1998). Currently, there is no intervention that could influence the outcome of delivery in these women with a higher risk of postpartum incontinence.

32.4.2 During Pregnancy

Perineal massage involves massaging the vaginal introitus and the perineum 10 min a day from the 34th week of pregnancy until delivery and is believed to reduce perineal trauma by increasing tissue elasticity. Several randomized trials have evaluated this intervention. In a large multicentric study on perineal massage conducted in Canada, among participants without a previous vaginal birth, 24.3% from the perineal massage group and 15.1% from the control group were delivered vaginally with an intact perineum, for a 9.2% absolute difference (95% confidence interval, 3.8%–14.6%) (Labrecque and Eason 1999). However, the intervention did not reduce the risk of severe perineal laceration and there were no differences with respect to perineal pain, dyspareunia, sexual satisfaction, and incontinence of urine, gas, or stool 3 months postpartum (Labrecque and Eason 2000). In another trial, perineal massage was found to reduce the risk of anal sphincter tears from 3.6% to 1.7%, p=0.04, but did not reduce the risk of pain, dyspareunia, or urinary and fecal problems (Stamp and Kruzins 2001).

Since birthweight is a risk factor for a difficult delivery and anal sphincter tear, reducing the weight of the baby could be beneficial. The strategy for this outcome would be identifying large babies before delivery and offering early labor induction to the mother. This involves several difficulties but has been evaluated in a randomized trial.

32.4.3 At Delivery

32.4.3.1 Episiotomy

The debate around the practice of episiotomy to expedite vaginal delivery and reduce the severity of perineal pain has produced numerous articles (Thacker and Banta 1983; Woolley 1995). A systematic review from the Cochrane library has summarized the current knowledge on the topic (Carroli and Belizan 2001). This review was restricted to randomized trials of acceptable quality, the best strategy to reduce bias. The authors found that the restrictive use of episiotomy was associated with fewer posterior perineal traumas (relative risk [RR], 0.88; 95% confidence interval [CI], 0.84–0.92), need for suturing perineal trauma (RR, 0.74; 95% CI, 0.71–0.77), and healing complications at 7 days (RR, 0.69; 95% CI, 0.56–0.85). No difference was shown in the incidence of major outcomes such as severe vaginal or perineal trauma nor in pain, dyspareunia or urinary incontinence. The fact that fecal incontinence was not considered a relevant is-

sue in this review points to the insufficient attention focused on this morbidity. Although there has been no randomized trial comparing restrictive episiotomy to routine episiotomy for instrumental delivery, textbooks and authoritative reviews seem to encourage the use of mediolateral episiotomy for instrumental delivery (ACOG 2001; Cleary-Goldman and Robinson 2003). In a large population-based study of risk factors for third-degree perineal tears, mediolateral episiotomy appeared to protect substantially against damage to the anal sphincter complex during delivery (OR, 0.21; 95% CI, 0.20–0.23) (de Leeuw and Struijk 2001).

32.4.3.2 Instrumental Delivery

Instrumental delivery is considered as one of the major risk factor for anal sphincter laceration during vaginal birth (de Leeuw and Struijk 2001; Christianson et al. 2003). The preferred instrument, forceps or vacuum, for helping vaginal delivery varies between countries, centers, and individuals. Several randomized trials have been conducted comparing forceps to vacuum delivery, which were reviewed in a Cochrane systematic review (Johanson and Menon 2000). These authors found that the vacuum extractor (as demonstrated by the intention-to-delivery analysis) is significantly less likely to cause serious maternal injury than are forceps. Therefore, avoiding instrumental delivery would potentially prevent urinary and fecal incontinence. Various techniques may help to achieve lower rates of instrumental deliveries, such as companionship in labor, active management of the second stage of labor with oxytocin, upright posture with use of the birth cushion or undertaking fetal scalp blood sampling rather than expedited delivery when fetal heart rate decelerations occur (Johanson and Menon 2000). When epidural analgesia is used, allowing time for the analgesic effect to wear off, or having a more liberal approach to the length of the second stage would also reduce the need for assisted delivery (Johanson and Menon 2000). However, in a randomized trial, delayed pushing prolonged labor by 1 h but did not result in significantly higher rates of altered continence or anal sphincter injury, when compared with immediate pushing (Fitzpatrick and Harkin 2002).

32.5 Secondary Prevention of Urinary and Fecal Incontinence

32.5.1 Urinary Incontinence

32.5.1.1 Pelvic Floor Muscle Exercise During Pregnancy

Kegel speculated in 1948 that pelvic floor muscle training (PFMT) done before delivery could strengthen the pelvic floor and mitigate against subsequent damage from childbirth. A Cochrane review (Hay-Smith and Herbison 2002) concluded that there is insufficient evidence to determine whether physical therapies can prevent incontinence in childbearing women. Only one of seven studies had excluded women with prior urinary incontinence symptoms.

In a recent prospective randomized controlled trial, Mørkved et al. (2003) assessed whether intensive muscle training during pregnancy could prevent urinary incontinence. The training group attended a 12-week intensive pelvic floor muscle exercise (iPFME) program during pregnancy (n=148), supervised by physical therapists. They

trained with a physical therapist for 60 min a week for a period of 12 weeks between 20 and 36 pregnancy weeks. The control group received customary information (n=153). At 20 weeks, 31% of the women in the intervention group and 30% of the women in the control group reported urinary incontinence at least once a week within the last month and were categorized as incontinent. Women in the iPFME program were 33% less likely report urinary incontinence at 36 weeks' pregnancy and 39% less likely to report urinary incontinence at 3 months post partum relative to the control group. They calculated that iPFME during pregnancy prevented urinary incontinence in about one in six women during pregnancy and one in eight women after delivery. Subgroup analysis for women classified as incontinent at 20 weeks and before pregnancy were consistent with the overall result. This study is the largest of only three published random controlled trials addressing the effect of iPFME during pregnancy. Reilly et al. (2002) conducted a similar study but focused on a group of women presumably at risk for developing postnatal stress incontinence because of increased bladder neck mobility. Their findings also suggest that antenatal pelvic floor muscle exercises are effective in reducing the risk of postpartum stress incontinence in primigravidae with bladder neck mobility. Reilly reported a 40% reduction in the likelihood of urinary incontinence in the intervention group. Only Reilly et al. conducted a trial that excluded women with prior incontinence symptoms. Their study provides the best evidence to date of primary/secondary prevention after supervised and intensive pelvic floor muscle training. However, there is still insufficient knowledge about whether pelvic floor muscle exercise during pregnancy can prevent urinary incontinence in later life. In a study by Sampselle, the positive effect of pelvic floor exercise on incontinence seen during pregnancy and 6 weeks and 6 months after delivery disappeared 12 months after delivery (Sampselle et al. 1998). The authors of the study speculate that this is due to normal tissue repair.

32.5.1.2 Pelvic Floor Muscle Exercise After Pregnancy and Delivery

In a recent study, Chiarelli and Cockburn reported of a prospective randomized trial to test physical therapy-delivered postpartum intervention tailored to mothers at risk for developing incontinence after delivery. Mothers who had an instrumental vaginal delivery and had delivered a baby 4,000 g or over were included. Women were not blinded to whether they were in the intervention or the control group. The women randomized to the intervention group were seen by a physical therapist once during their stay in hospital and again for a single visit with the same physical therapist 8 weeks after delivery. Both visits were completed in 50 min. There was a significant benefit in the intervention group who had a prevalence of urinary incontinence of 31% at 3 -months postpartum when compared with the usual care group who reported urinary incontinence in 38%. Glazener et al. assessed the effect of nurse assessment with reinforcement of pelvic floor muscle training exercises and bladder training compared with standard management among women with persistent incontinence 3 months postnatally in a randomized controlled trial with 9 months of follow up. Women in the intervention group had significantly less urinary incontinence (59.9% vs 69.0%) and also fecal incontinence was also less common (4.4% vs 10.5%). They concluded that conservative management provided by nurses seems to reduce the likelihood of urinary and coexisting fecal incontinence persisting 12 months postpartum (Glazener et al. 2001).

Meyer et al. recruited primiparae during pregnancy, randomized them to receive intervention (12 sessions of biofeedback and electrostimulation with experienced physical therapists) or control groups at 2 months after delivery. Outcome was evaluated at 10 months postpartum. At this time 20 of 26 women in the intervention group no longer had stress incontinence symptoms vs one of nine in the control group. Overall Meyer et al. did not show that there was any difference in prevalence of urinary incontinence between the intervention group and the control group (Meyer et al. 2001). In another of the few trials that included postpartum women, Sleep and Grant found no reduction 3 months after delivery for women in whom the use of postnatal pelvic floor exercises was reinforced (daily visits by midwives while in hospital to reinforce pelvic floor muscle exercise) compared with standard management given to all women who had recently given birth (Sleep and Grant 1987).

32.5.2 Fecal Incontinence: Diagnosing and Treating Anal Sphincter Tears After Childbirth

Tears of the anal sphincter are underdiagnosed after vaginal delivery. Tears of the anal sphincter are diagnosed clinically in as many as 5% of women at the time of delivery and are associated with subsequent anal incontinence (Thacker and Banta 1983). Postpartum sonographic studies of the anal sphincter have shown that clinically occult anal sphincter tears are even more frequent, with an actual prevalence of sphincter defects of between 35% and 41% (Burnett et al. 1991; Sultan and Kamm 1993; Campbell and Behan 1996; Rieger and Schloithe 1997; Sandridge and Thorp 1997; Zetterstrom and Mellgren 1999). Clinically undiagnosed tears are associated with subsequent anal incontinence in up to 50% of affected women.

32.5.2.1 Improving the Recognition of Anal Sphincter Tears

Clinical diagnosis. The knowledge of perineal anatomy is insufficient among obstetricians (Chaliha and Sultan 2000). Teaching in the recognition of anal sphincter tear and their management is needed, especially for junior doctors and midwives, who are the ones on duty at night and during weekends and finally perform most sutures of perineal tears after childbirth. In a cohort study evaluating the effect of teaching and of a second independent assessment of the perineum, the proportion of anal sphincter tear diagnosis increased from 2.5% to 14.9% (Groom and Paterson-Brown 2002).

Ultrasound. Since anal endosonography has revealed anal sphincter tears undetected at the time of delivery, a cohort study was undertaken to evaluate its feasibility in the delivery room, immediately after delivery (Faltin et al. 2000). Anal endosonography immediately after vaginal delivery allowed diagnosis of clinically undetected anal sphincter tears that were associated with subsequent fecal incontinence. A recent randomized trial involving 752 primiparous women without clinical anal sphincter tear evaluated the addition of ultrasound to clinical examination of the perineum and showed a reduction in severe fecal incontinence from 8.7% to 3.3%, a benefit that was still found 1 year after the delivery (Faltin and Boulvain 2004).

32.5.2.2 Repair of Anal Sphincter Tears

The principles and repair of anal sphincter tears have been recently reviewed (Sultan and Thakar 2002). Although most interventions are nor evidence-based, several points were mentioned to describe good clinical practice.

■ **Setting.** The repair should be done as soon as possible, as delayed repair could be associated with edema and infection. However, waiting for an experienced obstetrician could be advantageous. The surgery should also be performed in sterile conditions, under good lighting, with adequate surgical tools and assistant help, all conditions that require use of an operating theatre.

■ **End-to-end or Overlapping Repair.** Secondary repair of the anal sphincter is generally believed to have better outcome when performed with an overlapping technique. However, a systematic review from the Cochrane library on surgery for fecal incontinence reveals that the small number of relevant trials identified together with their small sample sizes and other methodological weaknesses severely limit the usefulness of the review for guiding practice and made it impossible to identify or refute clinically important differences between the alternative surgical procedures (Bachoo et al. 2003). For primary repair, some reports suggest that the repair should be performed end-to-end (Sultan and Monga 1999). However, the technique has been evaluated in a randomized trial and was not superior to conventional approximation of the torn ends of the sphincter (Fitzpatrick and Behan 2000).

■ **Prevention.** Repair of the perineum.

■ **Immediate Postoperative Care.** A recent randomized trial has compared laxative use after primary suture of an anal sphincter tear to a constipating regiment with codeine. There was no difference in the symptomatic or functional outcome of repair between the two regimens, but patients in the laxative group had a significantly earlier and less painful bowel motion and earlier postnatal discharge.

32.5.2.3 Pelvic Floor Training

Some authors recommend pelvic floor exercises after an anal sphincter tear, although there is little evidence that this is beneficial (Sultan and Thakar 2002; Glazener et al. 2001).

32.5.2.4 The Role of Subsequent Deliveries

A prior third-degree or fourth-degree perineal tear has been found to be associated with a 3.4-fold increased risk of a recurrent severe obstetrical laceration (Payne et al. 1999). However, only women who had sustained a complete anal sphincter tear extending to the mucosa (4° tear) were at higher risk of incontinence 12 years later if they had delivered again (Sangalli and Floris 2000). Women who had a less severe tear had no extra risk of fecal incontinence if they delivered vaginally again.

There is no evidence available on the management of subsequent deliveries in women with a previous anal sphincter tear. Since the risk of recurrence of the tear is relatively high, some authors have suggested to offer a cesarean section to women with mild or severe fecal incontinence (Sultan and Thakar 2002). For asymptomatic women, there is some evidence that those with an important anal sphincter defect on endosonography have an increased risk of deteriorating function if they deliver vaginally (Fynes and Donnelly 1999; Faltin et al. 2001).

For the delivery itself, there is no evidence favoring any intervention. However, factors associated with an increased risk of sphincter or pelvic floor damage (instrumental delivery, especially if expected difficult, heavy baby, occipitoposterior presentation, long second stage of labor) should be detected and if possible, a cesarean section offered.

32.6 Tertiary Prevention of Urinary Fecal Incontinence

Urinary and especially fecal incontinence are unvoiced symptoms (Johanson and Lafferty 1996). Therefore, it should be systematically sought in all women as a routine screening. All women with symptoms of urinary incontinence should be asked about symptoms of fecal incontinence and similarly, all patients complaining of anal incontinence should be asked about urinary incontinence symptoms. If bothersome symptoms are found, effective treatments exist (Hay-Smith and Herbison 2002; Bachoo et al. 2003).

32.7 The Role of Cesarean Section

Despite the increase in caesarean sections over the last 25 years, the incidence of urinary incontinence does not appear to have decreased. Increasing media coverage on urinary incontinence could have changed the awareness of incontinence symptoms in the population and influenced the threshold for diagnosis and surgery. In the US, the rate of caesarean delivery reached an all-time high of 26.1% in 2002! Undeniably, some women would avoid serious pelvic floor damage such as urinary incontinence if delivering via caesarean. However, there are many unanswered questions regarding elective caesarean section (and caesarean section on demand). Although it is tempting to attribute all pelvic floor disorders to childbirth practices, the truth is more complex and just beginning to be sorted out. One of the difficulties in assessing the role of pregnancy and childbirth in the development of urogenital prolapse and incontinence is that symptoms may develop years after the index pregnancy. Furthermore, symptoms may vary in intensity and depend on a women's activity. Women may have symptoms many years before seeking help.

In a recent large population-based study of 15,307 women, Rortveit et al. investigated the association between childbirth, caesarean section and urinary incontinence in women who were either nulliparous or had undergone only caesarean or only vaginal deliveries. They found that only stress and mixed incontinence were associated with the mode of delivery, not symptoms of urge incontinence. Stress urinary incontinence was most prevalent in women who had a vaginal birth (12.2%), followed by mothers delivered by caesarean (6.9%), and lastly the nulliparas (4.7%). However, only 5.6% of mothers had a caesarean. The individual woman's risk of moderate to severe inconti-

nence would be decreased from about 10% to about 5% if she delivered all of her children by caesarean section. This decrease would apply only until 50 years of age, since there was no association of incontinence with mode of delivery in older age groups. One of the limitations of this study is that there was no stratification of data for women who had caesarean deliveries before the onset of labor. The result of three other recent studies suggest that caesarean delivery performed before the onset of labor is more protective (Farell et al. 2001; Hannah et al. 2002; Groutz et al. 2004).

32.7.1 Should Women with or Without Risk Factors for Incontinence Be Allowed to Choose a Planned Cesarean Section?

Editorials in the 1980s argued that such requests should be denied. There is agreement that today more women than ever are requesting delivery by elective cesarean section without an accepted medical indication, and physicians are uncertain how to respond. Recent studies indicating that a planned caesarean delivery is as safe for the mother as vaginal delivery, coupled with an increasing demand for the surgery, prompted the American College of Obstetricians and Gynecologists (ACOG) to publish a committee opinion in November 2003. It supports "the permissibility of elective caesarean delivery in a normal pregnancy, after adequate informed consent." The more permissive attitude toward elective caesareans also runs counter to the recommendations of The International Federation of Gynecology and Obstetrics guidelines: "Because hard evidence of net benefit does not exist, performing caesarean sections for non-medical reasons is ethically not justified." Similarly, the World Health Organization states that a caesarean section rate of over 15% indicates inappropriate usage.

However, if a woman without an accepted medical indication requests delivery by elective caesarean section and, after a thorough discussion about the risks and benefits, continues to perceive that the benefits to her and her child of a planned elective caesarean outweigh the risks, then most likely the overall health and welfare of the woman will be promoted by supporting her request. Whether women should be informed explicitly about the risk of incontinence problems postpartum remains a question not answered.

32.7.2 Will the Urinary or Fecal Incontinence Rate Decrease as the Cesarean Section Rate Increases?

Rortveit et al. have shown that a threefold increase in their study population's caesarean delivery rate of 5.6% would only reduce the population's attributable risk of any urinary incontinence from 33% to 29%. In addition, the Breech term Study (Hannah et al. 2002) gives further evidence of the limited value of caesarean section. Calculations based on that study indicate that a caesarean section rate of 100% would result in a 26% reduction in postnatal urinary incontinence. Thus the attempt to reduce urinary incontinence by performing a caesarean would have limited effects. According to a further study of Rortveit et al., after the age of 65 years the association between urinary incontinence and mode of delivery or parity leveled off, suggesting that other factors, such as age, must have gained prominence.

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Chapter 33

Concept of the Pelvic Floor as a Unit: the Case for Multidisciplinary Pelvic Floor Centers

33

G. Willy Davila

Contents

33.1 Introduction

The concept of the pelvic floor as a single functional entity is gaining increasing degrees of acceptance among the subspecialists who address the problems associated with dysfunction of any or all of its components. As such, arbitrary walls that had previously been assigned between the anterior, middle and posterior compartments of the pelvic floor are being appropriately disregarded. However, the verticalized organization of clinical care along organ systems, traditionally determined by postgraduate training program organization, has not significantly changed over the recent past (Fig. 33.1). It is becoming more clearly understood that dysfunction in any of the pelvic floor components typically results in some degree of associated dysfunction elsewhere in the pelvic floor. Practice patterns and residency training program content are not adapting to these more commonly accepted and understood multiorgan dysfunction syndromes. Thus, patient care may not be optimized until clinical practice formally adapts to the concept of the pelvic floor as a horizontal unit (Davila and Ghoniem 2003). At Cleveland Clinic Florida, the clinicians involved in the care of all pelvic floor problems are located in a single clinical facility. We believe that our patients benefit greatly from this physical proximity and the ability to see multiple clinicians during a single visit.

33.2 Background

Recent surveys of affected populations have revealed that the majority of women with colorectal dysfunction who undergo surgical therapy also suffer from urogynecologic problems. Compared to the general control population, in whom a 30% incidence of urinary incontinence or genital prolapse is expected, those surgically treated for fecal incontinence have a 53% incidence of urinary incontinence and 18% incidence of genital prolapse (Gonzalez-Argente et al. 2001). Of those who underwent surgery for rectal prolapse, 65.5% reported urinary incontinence and 34% genital prolapse. Not only does this data confirm the high incidence of concomitant multicompartment pelvic floor dysfunction, but it suggests that within the spectrum of severity of pelvic floor disease, rectal prolapse may represent a more severe degree of dysfunction.

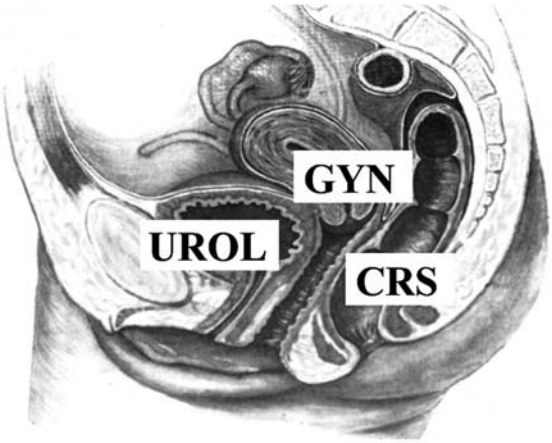

Fig. 33.1.
Traditional vertical view of the pelvic floor

Similar surveys regarding the incidence of fecal incontinence among women with urinary incontinence and pelvic organ prolapse have revealed a high coincidence (Jackson et al. 1997). Despite the convincing nature of this data, most centers have not instituted a multidisciplinary approach to the pelvic floor. A survey of the participants at the 12th Annual Cleveland Clinic Colorectal Symposium revealed that although 96% of colorectal surgeons inquire about urinary incontinence while evaluating women with fecal incontinence or rectal prolapse, only approximately 50% worked with a urologist or urogynecologist in treating those affected. Only 44% had performed simultaneous operations for urinary, genital, and/or colorectal dysfunction (Kapoor et al. 2001).

Interesting interdisciplinary differences are found when addressing identical clinical situations. Evaluation and treatment of the symptomatic rectocele represents a unique area of philosophical and clinical differences between colorectal surgeons and gynecologists. In the above-mentioned symposium survey, of the colorectal surgeons who treat anterior rectoceles, 80% routinely use defecography during the evaluation, and they use this information when deciding on whom to operate. In a survey of International Urogynecologic Association (IUGA) members regarding clinical practice patterns, only 6.5% of members (primarily Urogynecologists) use defecography as an evaluation tool (Davila et al. 2001). It is only through scientific scrutiny, and dialogue, that such marked differences in practice patterns can be evaluated for value and cost-effectiveness.

Combining urologic, gynecologic and colorectal reconstructive procedures can safely be undertaken during one surgical session. In fact, this may be preferable in women with significant degrees of pelvic floor dysfunction. Our previous experience has demonstrated that morbidity is not increased, success rates may be enhanced, and recovery time shortened when all pelvic floor dysfunctions are sequentially treated during the same operative session (Sun et al. 1999). This can be beneficial to a patient who will thus avoid separate surgical procedures with associated morbidities, neurologic damage, and prolonged recovery phases. Unfortunately, coordination of patient evaluation procedures as well as surgical procedures, which may involve multiple surgeons, can be increasingly challenging. We have found that practicing in a single center, with shared clerical and nursing personnel, can minimize many potential obstacles.

33.3 Anatomic and Functional Correlates

The pelvic floor is composed of the visceral and neurofibromuscular structures found within the pelvic bony cavity. Among colorectal surgeons, the notion of the pelvic floor being composed of the structures posterior to the rectovaginal septum has been erroneously popularized. However, this view excludes the genital and urinary tracts and should be discarded. The principal components of the pelvic floor include the lower urinary tract (the anterior compartment) the female lower reproductive tract (the middle compartment), and the lower gastrointestinal tract (the posterior compartment). All compartments function as a unit and are interdependent. As such, dysfunction in one compartment is typically associated with dysfunction in an adjacent compartment. The turf barriers that have been instituted in clinical practice are merely the result of tradition and training, rather than actual common sense. A clinician who cares for women with pelvic floor dysfunction should be comfortable in eliciting symptoms of dysfunction in all compartments and be a member of a team that is capable of addressing all pelvic floor dysfunctions concomitantly.

Functional relationships of the bladder/urethra unit and the rectum/anus units are analogous in the storage and disposal of body waste products. Dysfunction in either the anterior or posterior compartments can result in urgency/frequency syndromes (overactive bladder and irritable bowel syndrome), obstructive outflow symptoms (detrusor sphincter dyssynergia and anismus/paradoxical puborectalis contractions), and sphincteric incompetence (urinary and fecal incontinence). These conditions have a tendency to coexist in women with pelvic floor dysfunction. Unfortunately, symptoms of dysfunction in one compartment are typically not elicited by a clinician caring for dysfunction in another compartment. In addition, sexual dysfunction due to middle compartment abnormalities is even less understood and carries with it a potential greater degree of complexity.

33.4 Anatomic Defects

Structural support of the components of the pelvic floor is quite complex. Support structures include ligamentous entities as well as endopelvic fascia, and neuromuscular structures. The levator musculature provides support to all of the components of the pelvic floor. Any degree of neuromuscular dysfunction can thus affect all supported structures and result in symptomatic incontinence or prolapse. It is uncommon to have an isolated anatomic defect. As such, there is frequent coexistence of anterior compartment support defects (cystocele) along with posterior compartment anatomic defects (rectocele). With worsening degrees of pelvic floor dysfunction, prolapse of severity can increase and result in exteriorization of vaginal contents and/or rectal prolapse.

We have observed a number of patients who demonstrated progressive pelvic floor dysfunction – whether operated on or not – and have noted the progression of symptoms from urinary or fecal incontinence to genital prolapse and eventually rectal prolapse. Whether this progression signifies a greater degree of disease severity is yet to be objectively demonstrated.

33.5 Obstetrical Correlates

In women, the common denominator to pelvic floor dysfunction is related to the vaginal birth process and its associated neuromuscular damage to the pelvic floor support structures (Snooks et al. 1984). Pudendal nerve damage is a universal occurrence following a vaginal delivery. Although it may not initially be symptomatic, in time, most women will express some degree of pelvic floor dysfunction symptomatology. As our understanding of the impact of vaginal birth on the pelvic floor support structures increases, prophylactic measures such as antepartum pelvic floor exercises and selective use of elective cesarean delivery may increase in clinical usage. We frequently see young women with fecal incontinence due to a broken-down fourth-degree laceration as well as significant urinary incontinence following a difficult vaginal delivery. Risk assessment strategies need to be developed to provide information regarding risks to an individual patient, allowing the proper decision-making process to occur in preparation for the birth process (Davila 2001).

33.6 The Pelvic Floor Team

In order to comprehensively address pelvic floor dysfunction, clinicians adept at management of bladder, genital, colorectal, sexual and neuromuscular problems are required. It has become accepted that one clinician cannot be adept at managing all pelvic floor dysfunctions. As such, a team approach is crucial in providing appropriate pelvic floor care. Although the components of the team may vary depending on expertise and training, all compartments should be adequately represented. Concomitant therapy for pelvic floor dysfunction may include rehabilitative therapy such as biofeedback and functional electrical stimulation, and/or performance of concomitant pelvic reconstructive surgical procedures. At Cleveland Clinic Florida, the members of the Pelvic Floor Team are found within a single institution, as outlined below:

- Urogynecology/reconstructive pelvic surgery
- Urology/female urology
- Colorectal surgery
- Gastroenterology
- Biofeedback/physiotherapy
- Sexual dysfunction therapist
- Mental health specialist
- Nursing personnel
- Outcomes/research coordinators
- Clinical and research fellows

33.7 Patient Flow

Patient intake and flow patterns may be determined in a number of different ways. Intake through individual clinician referral patterns is most commonly used. However, a centralized intake center, with a triage clinician/nurse is likely the most time-efficient means of introducing a new patient into a multidisciplinary center. We have adhered to the traditional system of introduction through individual clinicians, primarily so as not to disrupt previously existent referral lines. Once a patient is seen, the clinician makes every effort to identify symptomatic dysfunction of the adjacent compartments. This is typically done during data collection at the initial entry visit. Our data collection forms include questions regarding urinary, fecal, genital and sexual function and potential dysfunction symptoms (Fig. 33.2). It is crucial for subspecialists to be aware of symptoms typical of dysfunction in other compartments in order to promptly involve other clinicians. Although we are not currently using a uniform database system, each subspecialty collects comprehensive data, and follow-up appointments are made such that evaluation and testing is scheduled in an organized fashion. For example, if a patient is initially seen by the urogynecology service and rectal prolapse is identified, she is scheduled to see the colorectal consultant on the day she returns for urodynamic testing. Final consultations are coordinated such that treatment recommendations can be made based on all identified problems. Thus, sequential sur-

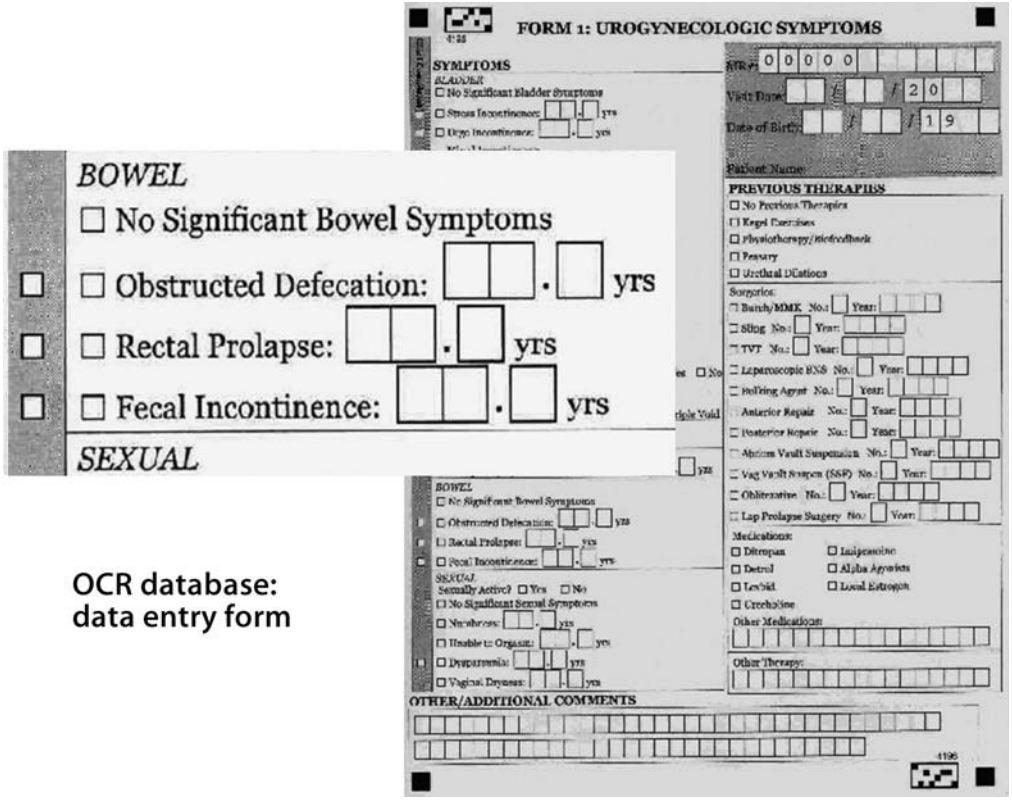

Fig. 33.2. Data collection should be interdisciplinary

Table 33.1. Combined surgical procedures are beneficial to patients

	Amenability
Sphincteroplasty	
ASCP/PVDR/Burch	+++
AR/sling/SSF	+++
PR	+
Abdominal rectopexy	
ASCP	+/–
PVDR/Burch	+++
AR/PR/sling/SSF	+++
Perineal resection	
ASCP/PVDR/Burch	+++
AR/sling	+++
PR/SSF	++
Colpocleisis	+/–

ASCP abdominal sacrocolpopexy, *PVDR* paravaginal defect repair, *AR* anterior repair, *SSF* sacrospinous fixation, *PR* posterior repair.

geries can be avoided. If biofeedback is recommended, severity of all identified problems can be monitored.

Combining surgical procedures for coexistent pelvic floor problems can be safely accomplished. There are procedures that can be performed more efficiently than others (Table. 33.1). Vaginal, perineal and abdominal procedures should be coordinated with careful planning. Areas where conflicts can develop include abdominal fecal soilage, maintaining the integrity of the rectovaginal septum, disrupting the uterosacral ligaments, and sharing of the sacral promontory. In an ideal situation, we schedule operating rooms simultaneously so that one team can be operating on one patient while another team operates on another, switching when each procedure is done. Careful planning typically avoids significant delays for either team, and we have not found morbidity to be increased by this approach. Recovery time is not prolonged, and return of normal function is not delayed.

Careful preoperative planning and cooperative surgical teams are key to being able to institute a coordinated pelvic floor surgical program.

33.8 Educational Programs

There are enormous educational opportunities for both clinicians and patients within the confines of a pelvic floor center. We have a number of organized conferences designed to improve education and patient care. These include:

- Pelvic floor conference. A monthly interdisciplinary conference involving all clinicians involved in the care of Pelvic Floor Center patients. Complex cases are presented, and treatment plans are discussed. Results of previous evaluations are presented including urodynamics, cystoscopy, anal manometry, endoanal ultra-

sound and defecography results. Follow-up on previously discussed cases is given. Particular attention is given to surgical patients in whom preoperative planning is crucial. Participation of all staff, postgraduate fellows and residents is expected.

- Pelvic floor dysfunctions symposium. An annual postgraduate symposium with lecturers representing all components of the pelvic floor. Participants in the audience represent all subspecialties involved in the care of women with pelvic floor dysfunction. Non-Cleveland Clinic lecturers are invited. Live surgeries are shown during the 4th day of the conference. Case scenarios are presented and discussed with the audience.
- Core lecture series. The education of residents, clinical and research fellows in each of the subspecialty components of the Pelvic Floor Center is a key mission of Cleveland Clinic Florida. Each department thus has a core lecture series for its residents and fellows. Each lecture series includes detailed discussions of dysfunction of all of the compartments of the pelvic floor, as well as physiotherapy, anatomy, pathology and statistics.

Many of the barriers to the creation of a pelvic floor center are based on resistance to change and politically pervasive practice patterns (Wall and DeLancey 1991). Based on our experience over the past few years, there is no doubt that both patients and clinicians benefit greatly from a team approach to the pelvic floor.

33.9 Summary

The development of a multidisciplinary Pelvic Floor Center is a natural progression of our increasing knowledge regarding the complexity and multiorgan involvement of pelvic floor dysfunction. One clinician cannot manage all of the potential dysfunctions in symptomatic women. Quality of life can be negatively impacted in a number of ways in patients suffering from symptomatic dysfunction, thus emphasizing the importance of identifying and treating all pelvic floor problems in a simultaneous fashion. In addition, care of one compartment can result in dysfunction in an adjacent compartment. Comprehensive care by a team of clinicians can optimize outcomes and improvement in quality of life. Our current model at Cleveland Clinic Florida is evolving as our knowledge regarding pelvic floor problems increases. Modifications of the above-described Pelvic Floor Center model are applicable to most clinical institutions providing care to symptomatic women.

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Part X

On Asymmetry in Sphincters

X

Chapter 34

Functional Asymmetry of Pelvic Floor Innervation and Its Potential Role in the Pathogenesis of Fecal and Urinary Incontinence – Report from the EU-sponsored Research Project OASIS (On Asymmetry In Sphincters)

34

Paul Enck, Fernando Azpiroz, Roberto Merletti

Contents

34.1 Assessment of Pelvic Floor Innervation by Conventional Neurophysiological Techniques

34.1.1 Neurophysiology of the Pelvic Floor

Incontinence to urine and/or stool can derive from a variety of clinical conditions, some of which are primary events where incontinence is an unavoidable consequence of the disease such as bladder and/or anal/rectal cancer or inflammation of the respective storage organs. In many systemic disorders, incontinence occurs as the consequence of direct involvement of neural pathways to and from the bladder and anorectum such as in multiple sclerosis, diabetes mellitus, and other diseases. Finally, if injury of the continence organs occurs with surgery (e.g., episiotomy) or trauma (e.g., delivery), incontinence may be the consequence (Hinninghofen and Enck 2003). In many cases, however, incontinence appears to be idiopathic, that is without an immediate preceding event, and is usually attributed to age-related degeneration of the neuromuscular apparatus maintaining continence or to traumatic events in the past (e.g., childbirth). As neurophysiological diagnostic testing has revealed pathological findings in many of these patients, idiopathic incontinence is frequently also labeled neurogenic (Kiff and Swash 1984).

Except for the determination of the terminal motor latency of the pudendal nerve (PNTML) by a less invasive technique (Kiff and Swash 1984), where a glove-mounted surface electrode is used to stimulate the pudendal nerve through the rectal wall, and evoked responses are recorded from the anal sphincter by another pair of electrodes at the finger base, the neurophysiology of pelvic floor functions (Vodusek 2004) has never been a clinical routine tool used by many investigators and in many patients. This is because needle EMG is an invasive and painful procedure for the patient and requires a great deal of experience on the side of the clinician.

Besides PNTML recording, surface EMG has only been used for assessment of the latencies of corticoanal afferent and efferent pathways – for the whole pathway as well as for fractions thereof – via recordings of somatosensory and motor evoked potentials (Enck et al. 1992), and mainly for research purposes only.

Consequently, very little is known about the normal neurophysiology of pelvic floor innervation in healthy volunteers, and contribution of its neuropathology to the pathogenesis of fecal and or urinary incontinence. This is especially true for the question of whether innervation of the pelvic floor sphincters is symmetrical or asymmetrical in nature even in healthy volunteers, and whether this can be a contributing factor to the occurrence of incontinence symptoms.

34.1.2 Unilateral Pudendal Neuropathy – Fact or Fiction?

Routine clinical experience with recording of PNTML (Kiff and Swash 1984) will occasionally result in differences in potential amplitudes and latencies, which have been attributed by some authors to unilateral pudendal neuropathy but were assumed to be due to technical difficulties to achieve a good electrode-to-pudendal nerve contact on both sides during rectal digital examination by others.

Of all patients with pelvic floor problems undergoing PNTML in a study by Sangwan et al. (1996), 8% had no response on both sides and 14% responses from one side only. In the remaining patients, 61% had normal and 39% had abnormal PNTML; of all

patients with abnormal PNTML, 28% were delayed on both sides, and 71% on one side only. In total, one-quarter of patients had what the authors called unilateral pudendal neuropathy. In a similar but larger report from another group (Lubowski et al. 1988), 15% of PNTML investigations showed delayed or missing response on one side only.

However, another explanation for this phenomenon would be that despite its anatomical symmetry, pudendal nerve *function* may also be asymmetrical in some subjects, as is the case with other bilaterally innervated organs (e.g., the esophagus) (Hamdy et al. 1997). If this holds true, is may carry significant clinical implications specifically in those subjects with asymmetry of innervation, e.g., in case of unilateral trauma (Enck et al. 1996). A research hypothesis based on this assumption is illustrated in Fig. 34.1 and was the basis of subsequently conducted research.

34.1.3 Evidence for Functional Asymmetry of Pelvic Floor Innervation

Three approaches have been taken to evaluate functional asymmetry of pelvic floor innervation in healthy subjects and in patients.

34.1.3.1 Intraoperative Monitoring of Pudendal Sensory and Motor Pathways

Deletis et al. (1992) investigated children in whom individual dorsal root action potentials from the S1–S3 roots were recorded intraoperatively after electrical stimulation of the dorsal penile or clitoral nerves, in preparation for surgery within the cauda equina. In most patients, pudendal afferent activity was present in S2 and S3 bilaterally; in some, the afferent activity was confined to a single root bilaterally, and in one, to a single root on one side. No lesion of the roots or rootlets carrying significant afferent activity was created during the rhizotomy, and no dysfunction in micturition resulted. In a replication study by the same groups (Huang et al. 1997), the pudendal afferent distribution was often confined to a single level in 18% of the patients or even to a single root in 7.6%. None of the patients thus mapped developed long-term bowel or bladder complications when the dominant root was saved from rhizotomy. Recently, Deletis and co-workers (Krzan et al. 1999) compared the radicular distribution of anal and pe-

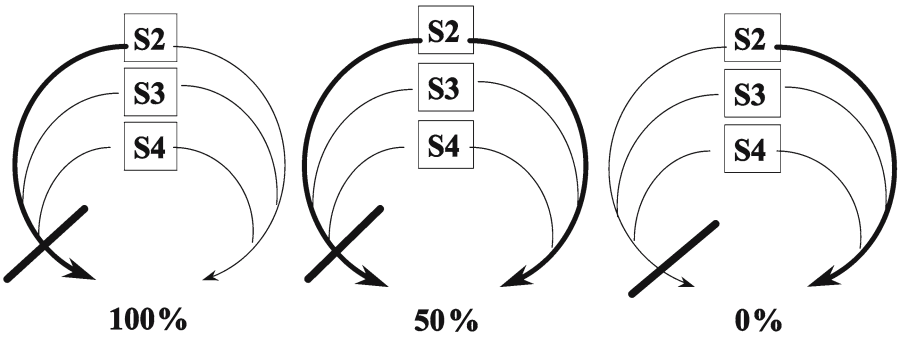

Fig. 34.1. A research hypothesis of the clinical relevance of functional pudendal nerve asymmetry in case of unilateral trauma, i.e., the same trauma can have entirely different consequences

nile/clitoral afferents in 22 of these children and found that in more than half of the patients, the main carrier was identical, while in 41% the main carrier of anal afferents was caudal to that of penile/clitoral afferents. In 9% the main and only carrier of anal afferents was a single root. Dissociation of fecal and urinary incontinence could be explained by different primary sacral carrier roots for anal and penile/clitoral afferents.

Sacral spinal root pacemaker implantation is a new technique in treatment of fecal incontinence but requires intraoperative decision as to which two of the six potentially functional sacral spinal nerves should carry the electrodes. Matzel et al. (1999) investigated incontinent patients undergoing evaluation for chronic sacral spinal nerve stimulation and continent patients undergoing testing for treatment of neurogenic bladder. Both in continent as well as in incontinent patients, the dominant level was often not symmetrical, and in many cases, the highest responses obtained from left- and right-side root stimulation were not on the same level.

34.1.3.2 Central (Cortical) Representation of Motor and Sensory Functions of the Pelvic Floor

Topographic cortical mapping of both cerebral hemispheres was performed by Turnbull et al. (1999) in healthy subjects by applying suprathreshold transcranial magnetic stimulation (TMS) to individual points on a scalp grid centered over the vertex and then recording the electromyographic responses from the external anal sphincter, rectum, and tibialis anterior muscles. Cortical mapping showed that the anal responses were bilaterally represented on the superior motor cortex of both cerebral hemispheres; a similar topography was found for the rectal responses. A similar study by another group that was undertaken (Witscher et al. 1998) in healthy volunteers showed latencies and motor thresholds to be similar between the dominant and the nondominant hemisphere, but the area over the nondominant hemisphere was significantly larger compared to the dominant one. In two out of ten cases, the intraindividual left : right area of activation was asymmetric (>30% difference), in one case each the left or the right side was dominant. This distribution was not related to handedness.

To compare cortical responses following electrical stimulation of the human anal canal to responses after stimulation of median and tibial nerves, Stottrop et al. (1998) employed magnetoencephalography (MEG). Electrical stimuli were applied to the anal canal, and to median and tibial nerves at different repetition rates, using below-pain-threshold intensities. Magnetic brain responses were averaged time-locked to the stimuli. Magnetic responses to stimulation of the anal canal were explained by unilateral (five subjects) or bilateral (two subjects) sources; at least in a subgroup of volunteers this representation is asymmetrical.

34.1.3.3 Peripheral Nerve Stimulation and Recording

As outlined above, individual differences between the left and right pudendal nerve terminal motor latency (PNTML) can occasionally be found in healthy humans. This was first described as normal in healthy subjects by Hamdy et al. (1998). When they investigated healthy subjects following transcranial magnetic stimulation (TMS) conditioning of the motor pathway before applying PNTML stimuli, right or left pudendal nerve stimulation evoked anal responses of similar latencies but with significant asymmetric amplitudes in six of eight subjects (Hamdy et al. 1999).

To explore whether muscular function of the external anal sphincter (EAS) is symmetrical or asymmetrical in healthy volunteers, healthy volunteers were investigated by needle EMG of the anal sphincter muscle (Middelsdorf et al. 1998), and significant intraindividual asymmetries of EMAP amplitudes were found in approximately one-third of cases. None of the differences found were directly related to gender and age of the subjects.

In summary, there is sufficient empirical evidence to assume that the left-to-right ratio of pelvic floor functions is asymmetrical in a subgroup of volunteers and/or patients; based on the preliminary data cited above, this fraction may be about 20%, while in the remaining, the function may be symmetrical. It is currently open to discussion whether this asymmetry is cortical in nature, or whether any cortical sign of asymmetry only reflects peripheral dominance of pudendal pathway utilization. This needs to be studied in more detail in the future.

34.1.4 Clinical Relevance of Asymmetry in Patients with Incontinence

Left and right side anal surface EMG (S-EMG) recordings by means of a modified anal plug electrode and a conventional S-EMG system was used to assess the innervation of the external anal sphincter at both sides in the anal canal separately in Wietek et al. (2002). Three cohorts were studied: nulliparous women in the third trimester (Study 1), primiparae within 6 months after nontraumatic vaginal delivery (Study 2), and women after childbirth-related third- or fourth-degree perineal tear 6–12 months postpartum (Study 3). Approximately 40% of nulliparous women reported signs of mild fecal incontinence; however, relative asymmetry was neither correlated to symptom severity nor to manometric measures (Study 1). In Study 2, 40% of women had an episiotomy performed, of which one-third developed severe incontinence. The association between asymmetry and incontinence did not reach significance level; however, comparison of pre and postpartum measures of S-EMG showed high reproducibility within subjects. In study 3, approximately 40% of women reported moderate to severe incontinence. Asymmetry and symptom severity were significantly correlated. Manometry revealed a significant negative correlation between relative asymmetry and squeeze pressure but not with resting pressure. It was concluded that functional asymmetry of anal sphincter innervation is associated with incontinence symptoms, but only after childbirth-related injuries (trauma) (Wietek et al. 2002).

With the same technique, a large series of consecutive patients with fecal incontinence were investigated during routine diagnostic work-up of an incontinence outpatient clinic (Hinninghofen et al. 2003) to assess the functional innervation of the left- and right-side external anal sphincter (EAS). Besides being investigated by mass surface EMG, all patients underwent conventional clinical diagnostic work-up including anorectal manometry, endoanal ultrasound, defecography, and other routines. A symmetry index was computed (SI=mean(left-right)/max(left,right) of the EMG amplitude), defining the relative S-EMG amplitude symmetry between 0=symmetric and 1=asymmetric. A subgroup of 30% of the patients were regarded as asymmetric. More women than men were identified as asymmetric, and the association between female gender and asymmetry status was significant. Among the (female) patients with asymmetric innervation, two out of three had a history of deliveries. The symmetry status (SI) between women with childbirth was significantly higher than in those without, but the degree of asymmetry was not related to the number of childbirths.

Asymmetry degree was also correlated with the results of diagnostic work-up to identify major determinants and consequences of relative asymmetry, but without the clinical investigators knowing the results of symmetry assessment. In both men and women, a significant and negative correlation of SI to the EAS squeeze pressure was found, and a positive association with sphincter defects detected during endosonography. Association with EAS squeeze pressure was stronger in men than in women, but in men, the SI was also correlated positively to resting pressure.

The symmetry status (SI) also correlated with the degree of incontinence, as assessed by the Wexner Score: patients with severe incontinence were significantly more frequently asymmetric than those with mild incontinence.

Functional asymmetry of EAS innervation appears to vary from physiological to pathophysiological grades, and in the latter case, results in decreased squeeze pressures of the EAS. However, overall moderate to weak correlations indicate other important factors contributing to symptom development and severity on the one hand and asymmetry of sphincter innervation on the other.

34.2 The Project OASIS

34.2.1 Multiple-Electrode Array Surface EMG to Study Sphincter Innervation

While the above-cited literature gives preliminary evidence to the clinical relevance of functional asymmetry of sphincter innervation, important questions remain, which can only be resolved with a new technology that allows screening of pelvic floor innervation in large patient and volunteer cohorts. This in itself excludes conventional neurophysiological techniques based on needle EMG from this task. On the other hand, surface EMG has so far only been used to evaluate within-subject changes of pelvic floor function with therapy, e.g., after biofeedback training (Enck 1993), or latencies of somatosensory and somatomotor responses following central, spinal, or peripheral stimulation of the pathways (Kiff and Swash 1984; Sangwan et al. 1996; Swash 2002; Vodusek 2004). It is not regarded as an appropriate technique to diagnose pelvic floor innervation and its dysfunctions (Pullman et al. 2000).

A recently described new technology using multielectrode arrays (MEA) to study individual motor unit action potentials (MUAP) from large muscles in the body's periphery (Merletti et al. 1999a, b) was the starting point of a European Community-sponsored research project whose first results were reported recently (Hinninghofen et al. 2002; Liu et al. 2002; Merletti et al. 2004). It was named OASIS (On Asymmetry in Sphincters – The role of functional asymmetry in sphincter innervation for incontinence, QLRT-2001-00218) and included four clinical partners (from gastroenterology, surgery, gynecology, and urology), a technical partner for biomedical engineering, and two small industrial partners. It started working in January 2002 for a total of 3 years.

34.2.2 Background of Surface EMG Technology

Although the detection of surface EMG signals is relatively easy, the interpretation of the signal features for understanding physiological mechanisms and monitoring pathological conditions is a complex task (Farina et al. 2004c). Surface EMG signals are in-

deed affected by many factors whose effect on the variables extracted from the signal is often not intuitive. As an example, it has been only recently recognized that EMG signals detected at different locations over the same muscle may have significantly different amplitudes (Roy et al. 1986; Jensen et al. 1993), which implies that electrode location is of primary importance for comparing results (Hermes and Freriks 1997). The difficulties in interpreting results has led, in some cases, to rather strong critiques of this noninvasive technique (Haig et al. 1996; Pullman et al. 2000).

The most frequently used montage for surface EMG signal detection is the bipolar configuration, which consists in recording the difference between signals detected by two electrodes placed over the same muscle at a certain distance from each other. This detection modality has been used in many studies on the assessment of the external anal sphincter (EAS) functions (e.g., Kiesswetter 1976; Nielsen et al. 1985; O'Donnell et al. 1988; Binnie et al. 1991) with a variety of electrode shapes, sizes, and locations. Signals recorded by the bipolar configuration are affected by anatomical, geometrical, physical and detection system parameters (Farina et al. 2002). Among these factors, the most relevant are the thickness of the layers interposed between the electrodes and the muscle, the tissue in-homogeneities, the length of the fibers, the interelectrode distance, the shape and size of the electrodes and the relative location and orientation of the electrodes with respect to the muscle fibers. The relevance of these factors for the interpretation of results depends on the specific muscle architecture.

In recent years, efforts have overcome the limitations of the classic bipolar EMG recording technique (Zwarts and Stegeman 2003). The followed approach has been based on increasing the number of electrodes placed over the muscle in order to obtain a map of the potential distribution over the skin rather than a single local observation. The use of multichannel surface EMG makes it possible to concomitantly detect bipolar EMG derivations from a number of locations over the muscle. The availability of more than one detection point may be useful for the selection of the optimal locations to reliably extract the descriptive variables of the signal. Moreover, it provides an insight into the mechanisms of generation of the signals, which may help in understanding and reducing the sources of artifact in the detection.

In the research field, multichannel surface EMG is being recorded from muscles of rather simple architecture. In the case of the EAS, the placement of many detection systems over the muscle presents important technological limitations. Recently, these limitations have been overcome, and systems for surface EMG detection from this muscle with up to 48 electrodes have been presented (Merletti et al. 2002, 2004; Enck et al. 2004a).

34.2.3 Muscle Anatomy and Concepts Behind the Array Detection

Muscles are composed of nearly parallel fibers that constitute the contractile structural units. A motoneuron innervates a group of muscle fibers, which thus constitutes the smallest functional unit of the muscle. The motoneuron and the fibers it innervates are called a motor unit (MU). Muscle fibers of a MU are randomly distributed in the muscle (MU territory) and each axon reaches the fibers by the neuromuscular junctions. The pool of neuromuscular junctions of the fibers belonging to a MU is distributed in a territory, termed innervation zone.

The electric impulse that propagates along the motoneuron and reaches the neuromuscular junction determines the excitation of the muscle fiber membranes and the generation of propagating action potentials. A transmembrane current distribution

(depolarization zone) corresponds to this potential distribution. The depolarization zones propagate without attenuation along the muscle fibers from the neuromuscular junctions to the two tendon endings (Fig. 34.2). The velocity with which the action potential propagates depends on the fiber diameter and type and is termed muscle fiber conduction velocity (CV). The intracellular action potentials generate and extinguish at the neuromuscular junctions and tendons, respectively. The summation of the action potentials generated by fibers innervated by a single motoneuron determines the MU action potential.

Each depolarization zone can be seen as a moving source of electric field at some depth below the skin. If the source moves along the fiber, the surface potential distribution will move with it. An electrode system placed on the skin will detect an interference signal due to the contributions of the action potential trains of all the active MUs. Increasing contraction force results in activation (recruitment) of an increasing number of progressively larger MUs and in an increase in the frequency of activation (firing rate) of those already active (Henneman's principle). The set of activation instants of a MU is termed firing pattern.

Figure 34.1a shows the characteristics of EMG signals detected at different locations along the biceps brachii muscle. The detection is performed by a number of equally spaced bipolar recordings, located along a line. This multichannel system is also known as linear electrode array (Masuda et al. 1998; Merletti et al. 1999a, 2003). The array detects signals with similar shape, which propagate in two opposite directions starting from the innervation zone. The basic idea is to locate electrodes along the muscle fiber orientation covering the entire muscle length.

34.2.4 An Anal Probe with Multiple Electrode Arrays

Following the concepts behind the design of a linear array, in the case of the EAS it is necessary to locate electrodes around circumferences in order to follow the main muscle fiber orientation. As in the case of electrodes displaced longitudinally along rectilinear fibers (Fig. 34.2), the displacement of electrodes along a circumference allows the detection of the MU action potentials from their generation at the innervation zone to their extinction at the tendon endings. For this purpose, a specific probe was designed (Merletti et al. 2003, 2004; Enck et al. 2004b).

The anal probe (Fig. 34.2) is composed of a rounded-tip plastic cylinder, 150 mm in length and 14 mm in diameter, holding a circumferential array of 16 equally spaced silver bar electrodes, located at a distance of 20 mm from the probe tip and aligned with the probe axis. A flexible, multiwire cable encapsulated in silicone rubber is provided at the bottom of the probe, and is used to connect the circular array to a multichannel EMG amplifier.

A small plastic marking, encapsulated in the probe tip, indicates electrode 1 and the direction of numbering. A plastic fin at the end of the probe, also aligned with electrode 1, helps the operator in checking the orientation of the probe with respect to a fixed reference during and after insertion.

The probe is manufactured using a purposely designed machine, which injects melted biocompatible plastic (polystyrene) at a temperature of 250°C into a metallic mold, with a pressure of 120 atm and a variable injection speed. The probe can be sterilized chemically and is autoclavable.

By means of a multichannel electromyograph for surface EMG signals to which the probe is connected, each bipolar signal is amplified, band-pass filtered and acquired

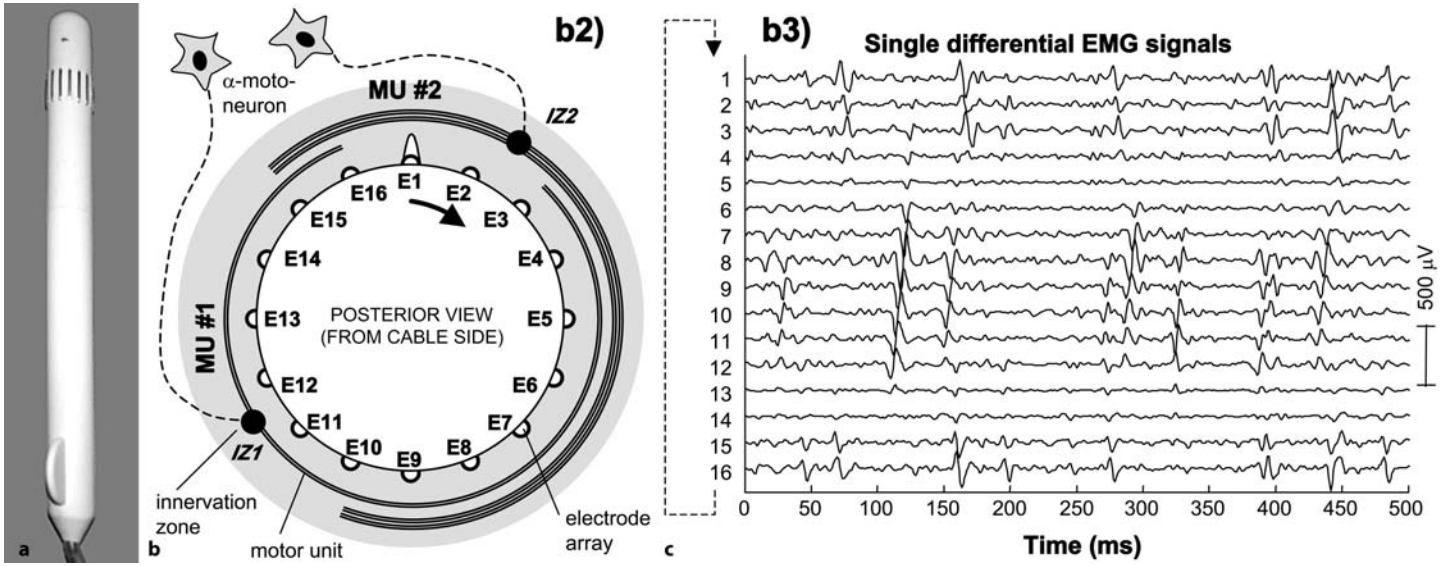

Fig. 34.2a–c. Principles of multichannel surface EMG detection with circular arrays from anal sphincter muscles (**a**–c). **a** 16-channel anal probe. **b** Schematic representation of anal probe position with respect to the external anal sphincter muscle; two motor units (*MU#1* and *MU#2*), characterized by different lengths, number of fibers and innervation zone positions (*IZ1* and *IZ2*) are depicted as an example. **c** Sample epoch, 500 ms long, of multichannel single differential EMG signals, detected with the probe shown in B1 on external anal sphincter muscle at maximum contraction level. Some MUs seem to be innervated at one extremity

by a PC equipped with an analog-to-digital (A/D) conversion board and with a purposely designed acquisition and display software. Galvanic insulation through optical coupling is present between the probe and the acquisition system, providing a high degree of safety to the patient and protection from electrical shocks.

Figure 34.2 also shows example signals detected with the system described above. Similar signal features as in the case of other muscles can be recognized. In particular, the action potentials propagating from the innervation zone and terminating at the fiber endings can be detected from the multichannel recordings.

A similar probe carrying 3×12 electrodes was developed for recording of MUAP from the urethral sphincter; however, due to technical difficulties and challenges (limited size, hygiene requirements, etc.) during development we are not able to report systematic data at this point.

34.2.5 Signal Interpretation and Development of Sphincter Models

The multichannel recordings are the summation of the action potentials of the active MUs. The decomposition of surface EMG signals is the procedure for the detection and extraction of the contributions of the single MUs. The ability to track the activity of single MUs allows the study of central and peripheral properties of the neuromuscular system such as motor control strategies and MU anatomical and physiological properties. For the purpose of the decomposition, double differential signals (obtained by subtraction of two consecutive bipolar recordings) are often used to enhance the selectivity of the detection.

A software tool for the analysis of single MU properties developed by Gazzoni et al. (2004) was applied to signals detected from the EAS using the probe described in the previous section. The method is automatic, without interaction with the operator, and involves a segmentation phase and a classification procedure (to detect action potentials and identify the MUs to which they belong), which adapts to slow changes of the MU action potential shapes.

Surface EMG signals detected with electrode arrays provide more information with respect to each signal considered independently. The partial redundancy (i.e., the observation of the same phenomena from different detection points) of the information provided by multichannel detection can be advantageously used by the decomposition technique for MU action potential identification, making it possible to identify discriminative information for the classification. At this moment, the method is not able to resolve superpositions of MU action potentials; for this reason, the detection of almost all the activation instants of the MUs significantly contributing to the signal is possible only in specific cases. In general, an incomplete firing pattern is extracted.

34.2.5.1 Models

A model is a set of equations describing a physical system which predicts, to a certain extent, the changes in the system as a consequence of modifications in the parameters. One of the greatest problems when studying a mathematical model of a physiological system is biological complexity, which requires using substantial approximations in the model. It is of fundamental importance to tackle the difficulties with a gradual approach, testing the hypothesis, fitting simulations with experiments, critically analyz-

ing the improvements in the prediction and interpretation capabilities of the models. Indeed, the detailed geometry and parameters are usually unknown, so that a precise model is usually not available. Furthermore, the parameters change among subjects, so that a set of parameters properly selected for a subject may be useless when studying another individual. Besides these limitations, modeling has an important role in the interpretation of experimental results since it provides (a) indications on the sensitivity of signal features to the physiological mechanisms under study and (b) an estimation of system parameters that cannot be measured directly. For example, starting from a simple mathematical model of a sphincter as a perfect cylindrical muscle (Farina et al. 2004a,b), as shown in Fig. 34.3, numerical experiments can be performed to generate the surface EMG detected in different conditions, varying anatomical or physiological parameters such as fiber length or position. Such simulations can be useful to compare detection system performance in different conditions, to improve their design or select the best way to use them. Moreover, comparing experimental data with the simulations, it is possible to infer the value of unknown parameters or of the actual geometrical configuration.

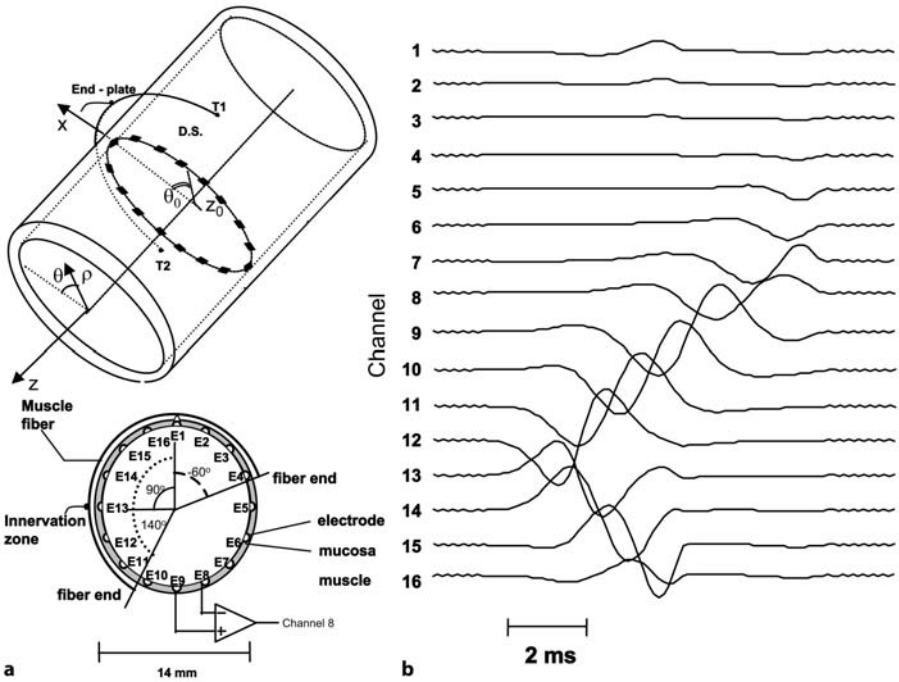

Fig. 34.3. a Geometry of a mathematical model of a sphincter as a circular cylinder (Farina et al. 2004b). **b** Example of simulation of single differential surface EMG signals detected with 16 channels. The muscle fiber is 1 mm deep within the muscle. The innervation zone is at –90°, the tendons at –140°, 60° (0° corresponding to the dorsal side and to electrode E1). The relative short duration of the simulated action potential is due to the generation of a single fiber potential, to the small fiber depth, and to the specific selection of geometry and conductivity of the muscle tissues

34.3 First Results of the OASIS Technique to Study Healthy, Continent Subjects

In the following we will present representative applications of the multichannel surface EMG detection system and processing techniques presented in the previous sections, applied to signals from the anal sphincter in healthy, continent subjects.

34.3.1 EMG Signal Amplitude

Surface EMG amplitude may be indicative of the exerted force (Bigland-Ritchie 1981); thus it has been used for this purpose in many clinical studies. However, amplitude indicators (such as the average rectified or the root mean square value) are very sensitive to factors other than the relative degree of muscle activation. The detection of signals in many points over the muscle makes it possible to analyze the sensitivity of signal features to electrode location. Figure 34.4 shows signals detected by the anal probe described above. The 16 signals obtained by the bipolar systems show significantly different amplitudes. As expected and demonstrated elsewhere (Roy et al. 1986), the signals detected in proximity of the innervation zones or tendon endings have a lower amplitude than the others. Different electrode configurations provide signals with different amplitude and spectral characteristics. As an example, Fig. 34.4 reports the signals detected by three bipolar systems with electrodes symmetrically placed. The figure also shows how the orientation of the electrode may affect the signal amplitude.

The variability of amplitude measurements is significantly reduced if the proper electrode location is selected specifically in each recording condition. A possible criterion is to estimate signal amplitude from bipolar arrangements located between the innervation zone and the tendon endings. In this case, the maximum amplitude is obtained. A multichannel measurement is required to identify the optimal position.

34.3.2 Noninvasive Assessment of Muscle Anatomical Properties

Multichannel EMG signals can obtain important information about anatomical properties of the muscle under study (Masuda et al. 1983, 1985; Roy et al. 1986; Merletti et al. 1999b, 2003; Roeleveld and Stegeman 2002; Rainoldi et al. 2004). According to the concepts described in "The Project OASIS" (see also Fig. 34.2), visual analysis of the multichannel recordings estimates the length of the muscle fibers, the location of the innervation zones and the tendon regions. Figure 34.5 shows signals detected from the EAS with the visual identification of the MU anatomical features (innervation zones and fiber length). The MUs are innervated at different locations. The potentials propagate from the innervation zone, towards the fiber endings, with a specific CV.

34.3.3 Detection of Single Motor Unit Activities

The application of the decomposition technique to signals acquired from the sphincter muscle showed that it is possible to noninvasively identify MUs at low and high contraction levels (Merletti et al. 2004). In many cases it was possible to detect the

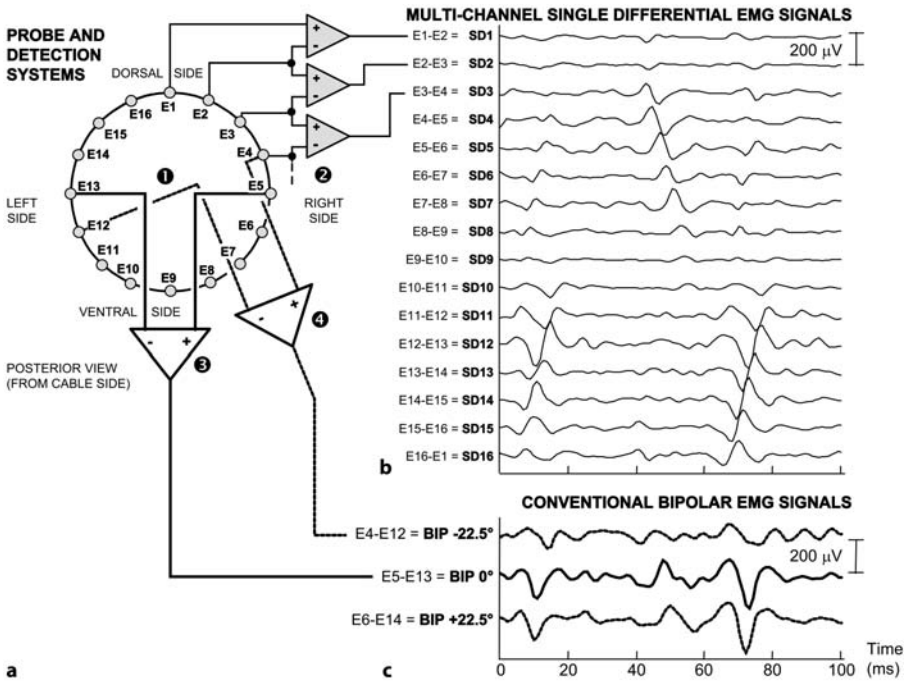

Fig. 34.4A, B. Examples of surface EMG detection from the anal sphincter muscle using different detection systems. **A** Schematic representation of the rectal probe (*circles*), shown from cable side (see also Fig. 34.2A and corresponding caption). Multichannel EMG detection is obtained with a series of differential amplifiers (❶). Conventional bipolar EMG recording is instead obtained detecting a single signal as the difference between two opposite electrodes (❷), from which only amplitude-based information can be extracted (❸). Effect of rotation of a bipolar probe by a one-electrode step (22.5 degrees) in counter-clockwise direction. **B** Sample epoch, 100 ms long, of multichannel single differential EMG signals detected from external anal sphincter muscle during maximal contraction, using the probe shown in Fig. 34.2A, B1, and the detection method schematized in (❹). **C** Sample epoch of conventional bipolar EMG signals, calculated from opposite electrodes on the same signal shown in **B**, in three different probe orientations: electrodes aligned to left-right direction (BIP 0°, *solid line*), rotated by 22.5 degrees counter-clockwise (BIP –22.5°), and clockwise (BIP +22.5°). In this specific case, a slight (–22.5 degrees) rotation of the probe in counter-clockwise direction would not produce a significant effect, while a rotation in the other direction would greatly affect both the amplitude (by roughly a twofold factor) and shape of the potentials

same MUs at different contraction levels as well as the progressive and the recruitment of new ones with increasing effort.

Figure 34.6 shows an example of decomposition of two signals recorded at 100% and 50% MVC from an incontinent subject. At 100% MVC four MUs are detected. By decreasing the contraction level to 50% MVC, two MUs are de-recruited. The same two MUs are active at both contraction levels. The firing pattern of MU 2 is rather well reconstructed for both contraction levels. Since the symptomatic subject was not able to maintain the 50% MVC contraction, the activity gradually decreased from $t = 2$ s and stopped at $t = 7$ s. This behavior is well described in the de-recruitment pattern shown in the right column diagrams of Fig. 34.6.

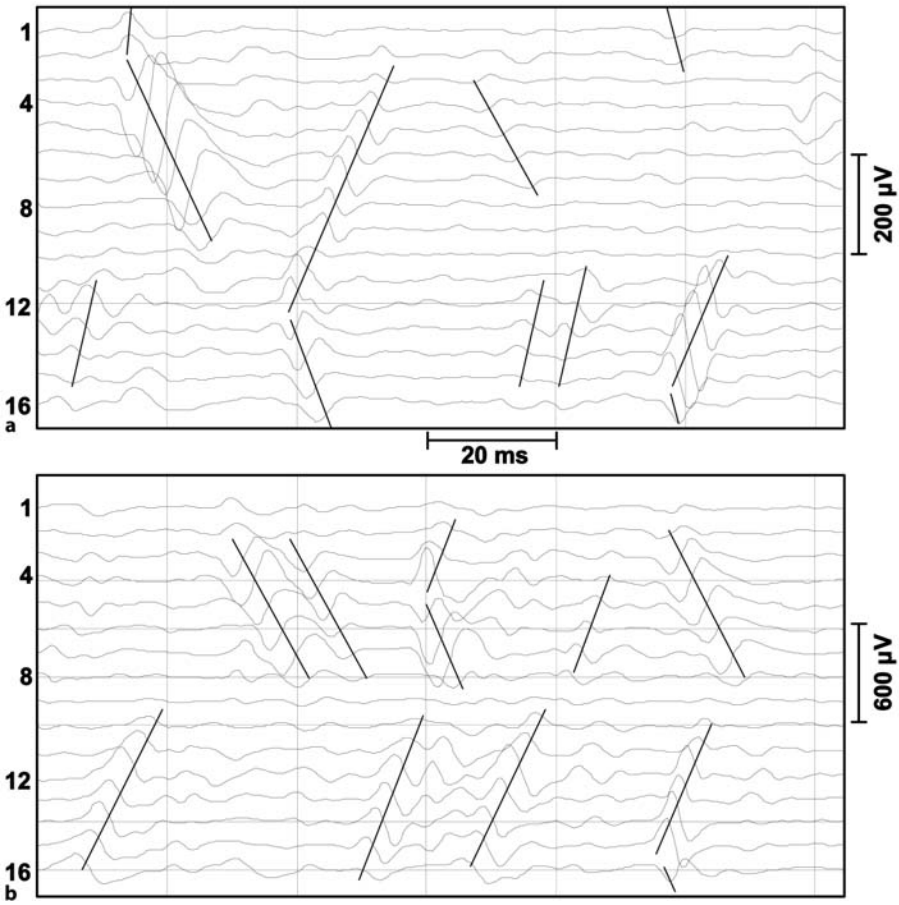

Fig. 34.5a, b. Examples of multichannel EMG signals detected from the external anal sphincter muscle of a female subject. Signals were acquired from 1-cm depth in the anal canal. **a** Relaxed condition, **b** maximal voluntary contraction. Note the different vertical scales in **a** and **b**

34.3.4 Estimation of Muscle Fiber Conduction Velocity

Muscle fiber CV is an important physiological parameter since it reflects muscle fiber type and contractile properties (Andreassen and Arendt-Nielsen 1987). Conduction velocity can be estimated from multichannel surface EMG signals by computing the delay of propagation between signals detected by systems placed along the fiber direction (Farina and Merletti 2004). In case of sphincter muscles, the specific geometry of the muscle makes the estimation of CV critical. Indeed, the observed delay of propagation depends not only on the velocity of propagation, but also on the location of the muscle fibers within the muscle (Fig. 34.7). Methods for estimating CV from these muscles should be based on the concomitant estimation of the source depth and of the propagation delay. Results from limb muscles indicate that this goal is feasible from two-dimensional surface EMG recordings (Roeleveld et al. 1997, 1998).

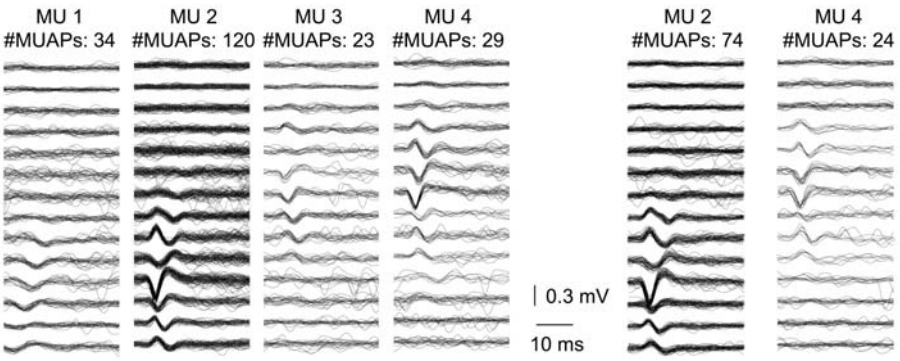

Fig. 34.6. Example of the decomposition of signals recorded during 10-s-long contractions at the contraction levels 100% MVC (on the *left*) and 50% MVC (on the *right*). Superposition of the MU action potentials belonging to each of the four MUs. Note that the same MUs (*#2* and *#4*) are identified at the two contraction levels and new MUs (*#1* and *#3*) are recruited at 100% MVC. In particular, MU #2 firing pattern is quite well reconstructed

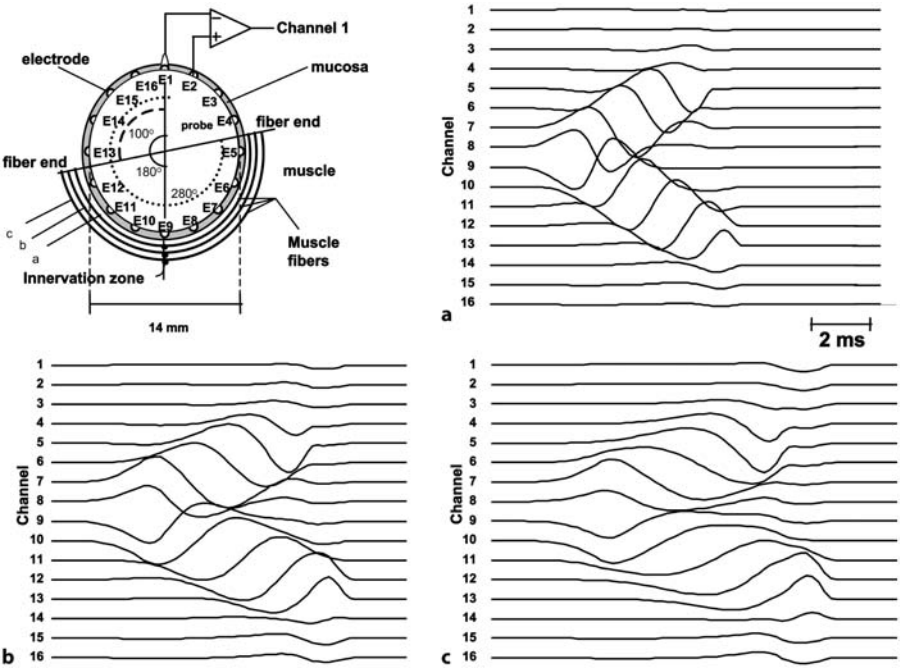

Fig. 34.7a–c. Simulation of EMG signals generated by three fibers at different depths within the muscle. The model is a two-layer circular cylinder (Farina et al. 2004b) with muscle and mucosa (1 mm thick). The innervation zone is at 0°, the fiber ends at –100°, 80° (0° corresponding to the dorsal side and to electrode E1). The fibers are 1 mm, 2.5 mm and 4 mm deep within the muscle. The set of signals reported in **a**, **b** and **c** are normalized with respect to the maximum amplitude

34.3.5 Differences in Sphincter Innervation Between Men and Women

Fifty-two healthy subjects with no history of neurological or pelvic floor problems (37 nulliparous females and 15 males, 20–55 years old) were recruited in three centers (Dept. of General Surgery, University Hospitals Tübingen, Germany; Dept. of Gynecology, Vivantes Klinikum Neukölln Berlin, Germany; Division of Digestive Disease, University Hospital Val d'Hebron, Barcelona, Spain) and investigated as described above (Enck et al. 2004a).

The left column of Fig. 34.8 shows the histograms of the innervation zone (IZ) distributions at the three depths in the 15 male subjects. At all three levels the IZs are rather scattered, showing a large interindividual variability. If the three histograms are added, the plot of Fig. 34.9 is obtained. An apparent predominance of right-left innervation with respect to ventral-dorsal innervation can be detected.

The right column of Fig. 34.8 shows the histograms of the IZ distributions at the three depths in the 37 nulliparous female subjects. An innervation pattern similar to that observed in males appears only at the 1 cm level. At the 2 cm level, the distribution of IZs is more uniform around the circle and at the 3 cm level IZs are mostly in the dorsal and ventral regions with predominance on the ventral side.

A considerable amount of information can be extracted from the S-EMG of the EAS. This study deals only with the location of the IZs detectable at 1-cm, 2-cm and 3-cm depth levels in the anal canal during maximal voluntary contractions. Except for our recently reported work showing that it is possible to identify MUAPs of the EAS and that there is large interindividual variability (Liu et al. 2002; Merletti et al. 2004), no previous experience on this topic has been reported. Although IZ can be identified from a single MUAP, at least ten MUAPs starting at the same location and showing bidirectional propagation were required in this study to identify such location as an IZ. The MUAPs generated in this location could belong to different MUs. This criterion is rather arbitrary and has the purpose of guaranteeing a positive identification of an IZ. Relaxing it would increase the number of IZs by including those where fewer MUAPs are generated, but would also increase the risk of erroneous detection due to artifacts; this may be appropriate once more experience with this technique has been gathered. This criterion therefore underestimates the total number of innervation zones observed in the EAS with the electrode array. Two additional limitations should be considered: (a) the IZs of MUs that are far enough from the electrodes, so that their MUAPs are near the noise level, are not detected, and (b) the MUAPs showing unidirectional propagation are not considered. For the reasons indicated above, these results should be considered preliminary. More solid evidence will come with the development of automatic procedures for detecting IZs and with a larger number of subjects.

These data may make it possible to close a missing link between different clinical findings with respect to the pelvic floor. First, the incidence and prevalence of urinary and fecal incontinence is known to be significantly higher in women than men, especially at higher age (Nelson 2004); this is usually attributed to specific risks for pelvic floor trauma women undergo with pregnancy and childbirth.

The pathophysiology of incontinence recognized these gender-specific risk factors (Snooks et al. 1986), as has the investigation of the role of asymmetry in incontinence (Wietek et al. 2002). It is conceivable that the different probabilities of innervation of the ventral region at different depths – as found in our study – may be a developmen-

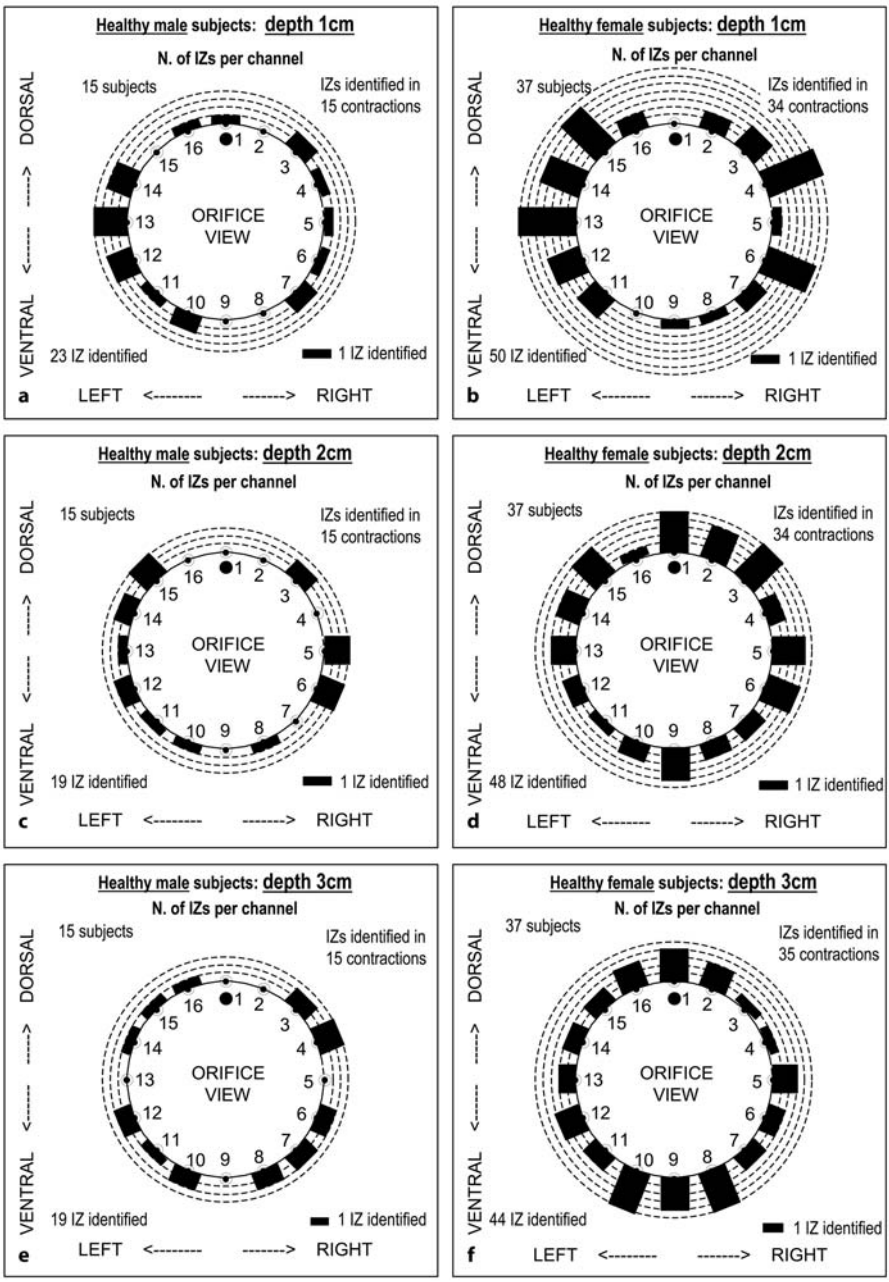

Fig. 34.8a–f. Histograms of the number of innervation zones (IZ) found under each channel in 15 males (left column) and 37 females (right column) at the depth levels of 1 cm, 2 cm and 3 cm

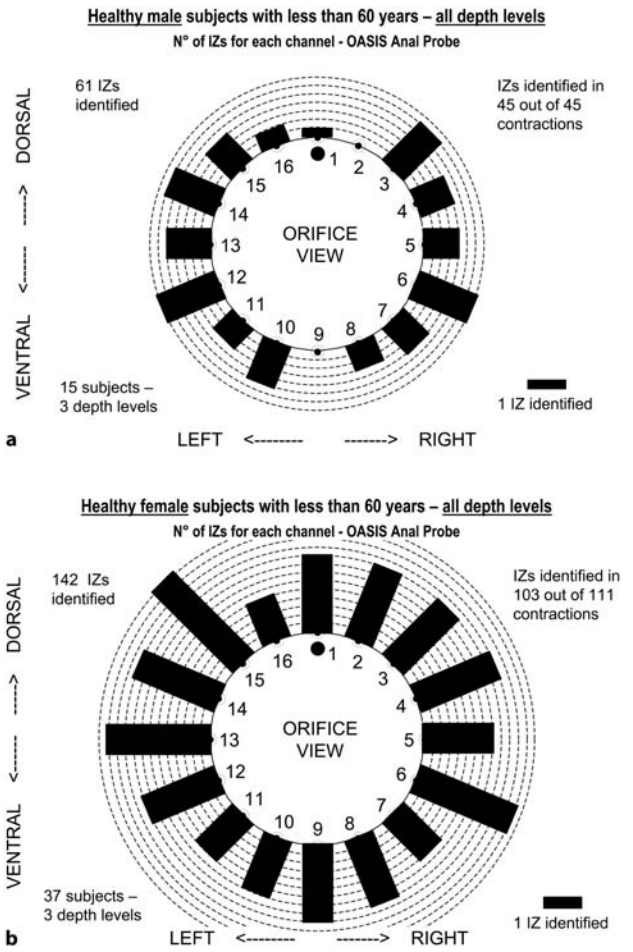

Fig. 34.9. Cumulative histogram of the number of innervation zones (IZ) found under each channel in 15 males and 37 females. The IZs at different depth levels are pooled together

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tal consequence of higher risks for birth trauma in this region of the pelvic floor, and is "aimed" at preventing or reducing the risk of incontinence in such case.

Second, pelvic anatomy has also shown significant differences between men and women, especially since new imaging technologies (endoanal ultrasound, MRI) have been applied to the study of pelvic floor anatomy (Schäfer et al. 1994; Eckardt et al. 2002).

Three anatomical concepts of the external anal sphincter and its innervation are currently represented in the published literature: (a) a traditional concept claiming that the EAS consists of three bundles of striated muscle fibers that are all three circular in nature, but with varying attachment, also varying between the genders. This concept has frequently been replicated in the anatomical textbooks and is the most widely used concept of sphincter anatomy (Cook and Mortensen 2002). Electrophysiologically, only two of the three parts of the EAS could be distinguished, a subcutaneous part and a deep part (Podnar and Vodusek 1999). (b) A more recently developed con-

cept (Bogduk 1996) described the EAS as a series of three loops to account for a great variability in patients of different ages and genders. In this concept, only in the basal loop muscle fibers run circumferentially, while the fibers of the other two loops decussate anteriorly in the perineal body. This is in agreement with data from endoanal ultrasound showing deficiency of the EAS muscles in the anterior upper anal canal, especially in women. (c) A final concept has been proposed by Fritsch et al. (2002) and is based on both plastificated anatomical preparation (to maintain the relationship in size between adjacent structures) as well as pelvic floor imaging by ultrasound and magnetic resonance techniques. According to this concept, the EAS consist of two parts: a subcutaneous part with circumferentially running muscle fibers, and a deep loop that opens in the midline ventrally, but demonstrates thickened muscle bundles ventrolaterally, especially in women.

"Little is, however, known about asymmetries of anatomy; interestingly, anatomical studies frequently dissect specimens only unilaterally, so intersubject variability is noticed, but intrasubject variability (asymmetry) not" (Vodusek 2004).

With regards to somatic innervation on the EAS, the pudendal nerve is traditionally described as deriving from the S2–S4 ventral roots. All the branches form one major trunk – the pudendal nerve – that leaves the pelvis via the great sciatic foramen to enter the gluteal region. In the posterior part of the canal, it gives off the inferior rectal nerve; then it branches into the perineal nerve, and the dorsal nerve of the penis/clitoris. One of its branches innervates the anterior part of EAS, regularly and equally on both sides. "Normal variability of human neuroanatomy is often mentioned; there may also be some sex differences . . . How much variability and asymmetry there is in this EAS innervation has not been explored" (Vodusek 2004).

To our knowledge, only one study has addressed the issue of symmetry of innervation more directly: Wunderlich and Swash showed that unilateral experimental damage of the pudendal branch innervating the EAS in Rhesus monkeys resulted in bilateral denervation changes and bilateral reinnervation signs (Wunderlich and Swash 1993), which was attributed to interdigitation of muscle fibers across the midline of the circular muscle. This at least opens the possibility that the distribution of innervation zones (motor unit endplates) may be unequal between both sides of the anal canal in individuals.

In light of the increased risk of the ventral and superficial part of the anal sphincter for damage during childbirth, increased ventral innervation in the deep part and increased lateral innervation in the superficial part may be nature's mechanisms to reduce the consequences of trauma.

Among the many findings, one important fact is that at deeper muscle layers of the EAS, the muscle body becomes thinner and less distinguishable from the surrounding connective tissue, especially in ventral region (Williams et al. 2001), and especially in women . Interestingly, this is the same area in which the data from this study showed a higher likelihood of innervation (i.e., more frequent IZs).

Finally, measurement of pelvic floor functions such as anorectal manometry has long been noted to show significant differences between the genders: women exhibit lower resting pressures (a function of the internal anal sphincter) and squeeze pressures (attributed to the EAS) than men, irrespective of age, but the ultimate reasons for this have never been disclosed. Usually, this is discussed with respect to a different muscle composition (e.g., the ratio of type-1 to type-2 fibers) in women, but solid data are missing. With the data from the study presented here, it becomes conceivable that an altered innervation pattern in women – a less homogenous innervation in the circumference – may change the function of the sphincter apparatus during contractions

as measured by the pressure inside the anal canal. Final proof of the hypothesis will, however, require further studies.

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