MEDICAL RADIOLOGY

Diagnostic Imaging

A. L. Baert
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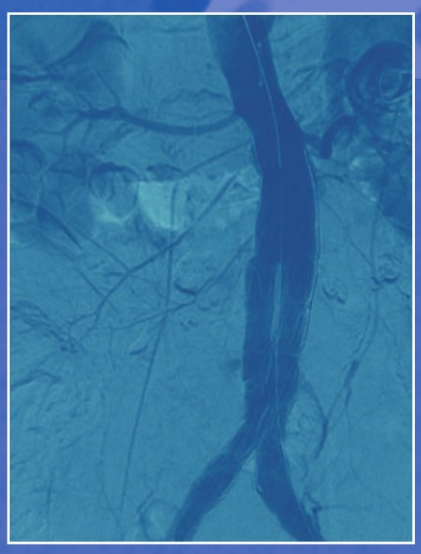
Vascular Interventional Radiology

Current Evidence in Endovascular Surgery

M. G. Cowling
Editor



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MEDICAL RADIOLOGY
Diagnostic Imaging

Mark G. Cowling (Ed.)

Vascular Interventional Radiology

Angioplasty, Stenting, Thrombolysis and Thrombectomy

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Foreword by
A. L. Baert

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For

Lynn, Thomas and *Oliver*

Foreword

Endovascular therapy is now largely recognized as a major advance in modern medicine.

Seldinger's revolutionary non-invasive percutaneous approach to the vascular system opened up a totally new medical field. Innumerable new technical methods, newly designed catheters, sophisticated new endovascular devices and novel materials have been developed during the past decades. Radiologists have played a major role in laboratory research as well as in the application of endovascular therapy in the clinical environment. Interventional radiology has thus contributed enormously to strengthening the position of the radiologist as a member of the clinical team responsible for the management of patients in our modern hospitals. A volume presenting the current knowledge in this expanding field was therefore sorely needed in the Medical Radiology series.

The editor, M.G. Cowling, is a leading expert in vascular interventional therapy with long personal experience. He was able to obtain the collaboration of many other internationally renowned vascular radiologists. I would like to thank him for his relentless efforts to coordinate the different contributions and to finalize this volume on schedule.

The editor and the authors are to be congratulated for this well-written and exhaustive volume offering the latest insights and evidence on vascular interventional therapy.

This outstanding volume will certainly meet with keen interest from interventional radiologists and vascular surgeons. They and their patients will greatly benefit from its contents. Referring physicians may also find this book very useful for learning more about the indications, possibilities and limitations of non-invasive vascular treatment. I am confident that it will encounter the same success with readers as the previous volumes published in this series.

Leuven

Albert L. Baert

Preface

Vascular Interventional Radiology, or endovascular therapy as it is becoming increasingly known, continues to develop rapidly. As our patients survive longer because of advances in treatment in other areas, such as coronary artery disease, peripheral vascular disease is becoming an increasingly common problem. In addition, those requiring treatment are increasingly likely to be elderly. They are less able to tolerate open surgical procedures, and will therefore often benefit immensely from minimally invasive vascular procedures.

Although in some countries the prevalence of smoking appears to be reducing in response to public health measures, other risk factors such as hypertension and hyperlipidaemia remain common. In addition, the incidence of diabetes is actually increasing, probably in association with obesity. Therefore, for the foreseeable future, peripheral vascular disease will remain an important phenomenon.

Increasingly it is possible to diagnose peripheral vascular problems non-invasively using Doppler ultrasound, Computerised Tomographic angiography and Magnetic Resonance angiography. These techniques serve to further lower the risk involved in managing these patients, as well as potentially reducing cost.

There are also significant advances in management of venous disorders, such as endovenous laser therapy for varicose veins, showing that Interventional Radiologists have skills that can be applied ever more widely to assist in the management of important clinical problems. This volume aims to provide up to date evidence on both established and developing techniques. It is only with such information that practitioners can encourage their more widespread use.

I would like to thank all of the authors who have contributed to this volume. In addition, my secretary Mrs Sue Dudley who has provided immense support. Springer-Verlag, and in particular Ms Ursula Davis, have provided all necessary support, and I would also like to thank Prof Baert for entrusting me with this project.

Staffordshire

Mark G. Cowling

Contents

1 The Aetiology of Vascular Disease

R. David Wells and Mark G. Cowling

CONTENTS

1.1 Introduction

The vast majority of vascular disease that concerns interventional radiologists in the western world involves atherosclerosis, aneurysmal disease and fibromuscular dysplasia and as such this chapter concentrates mainly on these processes. Before discussing these pathological processes, the normal arterial structure will be briefly described. Other vascular disorders such as vasculitis, popliteal entrapment, cystic adventitial disease and Raynaud's phenomenon are currently not amenable to treatment with interventional radiological techniques, and are therefore omitted from this chapter.

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1.2 Normal Arterial

The arterial system consists of three basic types of vessel:

1. The large elastic vessels, in the thoracic, abdominal aorta and the iliac arteries. With their elasticity they aid the maintenance of the diastolic blood pressure.
2. Medium sized muscular arteries, including the superficial femoral and brachial arteries as well as visceral branches, which distribute blood to the capillary beds.
3. The smaller arterioles that modulate vascular tone and themselves have a large role in the regulation of systemic blood pressure and the delivery of oxygen and nutrients to the tissues.

Arterial anatomy is well described and consists of three basic layers; the tunica intima, tunica media and tunica adventitia. The intima is the internal layer of the artery and is formed from a single layer of mesenchymal endothelial cells, basement membrane and internal elastic lamina loosely attached to the media by supportive connective tissue. Endothelial cells have a complex role in the homeostasis of the vascular tree and adjacent flowing blood secreting enzymes, growth factors, immunoglobulins and anticoagulants depending on the vascular bed they serve.

The media is the thickest layer of the arterial wall and consists mainly of elastic fibres and smooth muscle cells containing actin and myocin filaments which contract to varying degrees; hence the ability to modulate the arterial vascular tone. Pathologically the smooth muscle element of the media has a large role to play in the development of the atherosclerotic plaque.

The adventitia comprises of loose connective tissue, lymphatics and its own nutrient arterial supply known as the vasa vasorum.

The arterial system can also be conveniently classified into the particular vascular territories they

supply, e.g. cerebrovascular, coronary, renovascular, and peripheral vascular beds.

1.3 The Aetiology and Pathophysiology of Atherosclerosis

The pathophysiology of atherosclerosis in the peripheral artery tree is complex, involving a disturbance of the normal homeostatic mechanisms including endothelial dysfunction (Anderson 1999), platelet activation, lipid metabolism, inflammatory response, oxidative stress, smooth muscle activation and thrombosis (Libby 2002).

Cigarette smoking incurs the greatest risk in the initiation and development of atherosclerosis, with smokers up to five times more likely to develop the disease. The mechanisms are multifactorial involving endothelial dysfunction, increased oxidised LDL and a hypercoagulable state increasing the propensity for thrombosis.

Diabetes mellitus is an important risk factor for hyperlipidemia and atherosclerosis; it is also commonly associated with hypertension, abnormalities of coagulation, platelet adhesion and aggregation and increased oxidative stress. Diabetics with poor glycaemic control are up to four times more likely to develop plaques (Fowkes et al. 1992; Kannel and McGee 1985). Stopping smoking along with good glycaemic control, however, also offers the greatest benefit in long term survival and limb salvage (Quick and Cotton 1982).

Hypertension is a risk factor for the development of atherosclerosis. Hypertension is associated with morphologic alterations of the arterial intima and functional alterations of the endothelium that are similar to the changes observed in hypercholesterolemia and established atherosclerosis. Endothelial dysfunction is a feature of hypertension. Hyperlipidemia is an established risk factor for atherosclerosis. Oxidised LDL is a key feature in the development of plaques and there is convincing evidence that lowering serum cholesterol reduces the risk of subsequent coronary heart disease events and overall mortality (Gaziano 1996; Haffner et al. 1999).

Atherosclerotic lesions do not occur in a random fashion, and haemodynamic factors are also important. Fluid shear stresses generated by blood flow activate the endothelium and influence the phenotype of the endothelial cells by modulation of gene expression. Atherosclerotic plaques characteristically occur in regions of branching and marked curvature at areas of geometric irregularity and where blood undergoes sudden changes in velocity and direction of flow. Decreased shear stress and turbulence may promote atherogenesis at these levels (Topper and Gimbrone 1999).

1.3.1 The Development of the Atherosclerotic Plaque

1.3.1.1 The Endothelium and Endothelial Dysfunction

A thin layer of vascular endothelium separates the circulating blood volume from the subendothelial matrix and the media of the blood vessels and is the key centre for vascular homeostasis (Furchgott and Zawadzki 1980), controlling the balance between vasodilatation and constriction, coagulation and anticoagulation and the modulation of the inflammatory response.

These mechanisms are maintained by vascular autocrine and paracrine feedback loops involving prostaglandins, nitrous oxide (Ludmer et al. 1986) and angiotensin II. Endothelial dysfunction caused by the risk factors described above potentiates the development and progression of atherosclerosis(Loscalzo 2001).

The endothelium also supports the recruitment and adhesion of macrophages and their diapyesis through the endothelium into the subendothelial matrix with the production and secretion of local cytokines (Rosenfeld 1996), these take up the oxidised LDL forming the basis of the atherosclerotic plaque (Libby 2000).

1.3.1.2 Inflammatory Response

Circulating LDL is absorbed into the subendothelial matrix and becomes oxidised (Hansson 2001). The inflammatory response is initiated via the secretion of selectins and cytokines which attract macrophages from the blood and via diapyesis migrate into the matrix (Hansson 2001). These scavenger white cells then imbibe the oxidised LDL becoming 'foam cells' due to their lipid laden content. Cytokines have a secondary effect of stimulating smooth muscle cell (SMC) mitosis and migration into the subendothelial layer through the internal elastic

lamina (Schonbeck and Libby 2001) thus forming the lipid laden plaque.

1.3.1.3 Role of Smooth Muscle Cells

Smooth muscle cells change their character once stimulated by injury, growth factor or cytokines becoming migratory, secretary cells capable of proliferation via the process of mitosis and secretion of matrix proteins and enzymes that become the dominant component of plaque growth (Rivard and Andres 2000). The extracellular matrix of the plaque secreted by the SMCs contain products such as proteoglycans, collagen, elastin and fibronectin (Raines 2000). SMCs control the homeostasis of collagen metabolism and when stimulated in the process of atherosclerosis, favours the deposition of collagen and through maturation and shortening of the collagen fibres resulting in fibrosis and luminal stenosis (Rekhter 1999).

1.3.1.4 Compensatory Vascular Remodelling

To compensate for the enlarging atherosclerotic plaque and subsequent luminal narrowing the vessel enlarges to maintain luminal patency, a process known as geometric remodelling (Glagov et al. 1987; Pastercamp et al. 2000). However, once the plaque has reached a critical size (> 40% of the cross sectional area) the artery can no longer enlarge and the lumen narrows as the plaque grows. The injury also initiates vasoconstriction further narrowing the lumen.

1.3.1.5 Unstable Plaques

Plaques susceptible to rupture have been shown to have a lipid laden core with a thin fibrous cap and inflammatory macrophages at the cap surface (Davis et al. 1993). Enzymes secreted by the macrophages breakdown the thin cap eventually leading to plaque rupture (Galis and Khatri 2002), and exposure of the vulnerable tissue to thrombosis that can critically stenose or occlude the lumen causing acute symptoms (Makin et al. 2002). This is of great importance in the aetiology of coronary thrombosis, and also has a role in carotid artery disease.

1.3.1.6 Thrombosis

During plaque rupture the underlying 'naked' lipid core and collagen base are exposed to the circulating blood. Platelets aggregate in the exposed tissue and via the cascade pathways (Rauch et al. 2001) form a platelet thrombus to cover the breach. However, the fragile thrombus may cause distal embolisation or acute occlusion of the vessel.

1.3.1.7 Summary of Stages of Development of the Atherosclerotic Plaque

1. LDL absorbed into the subendothelial layer.
2. LDL is oxidised.
3. Macrophages are attracted into the subendothelial matrix and imbibe the oxidised LDL.
4. SMCs are attracted into the matrix, proliferate and secrete glycoproteins.
5. Plaque enlarges and fibroses.
6. Vascular remodelling compensation.
7. Loss of remodelling compensation, propensity for stenosis and occlusion.
8. Unstable plaques may rupture and thrombose, leading either to vessel occlusion or distal embolisation.

1.4 The Aetiology of Arterial Aneurysms

The incidence of abdominal aortic aneurysms (AAAs) in post mortem studies from Sweden found AAAs in 4.7% of men and 1.7% of women aged 56–74 years old (Bengtsson et al. 1992). This was correlated in a prospective screening study of more than 125,000 patients aged 50–79 years old with the definition of an aneurysm given as an aortic diameter of greater than 3 cm (Brady et al. 2001).

The tensile strength of the artery is determined mainly by the structure of the media and the elastin and collagen fibres within it. In aneurysmal disease the homeostatic balance between the elastase proteolytic enzyme and alpha 1 antitrypsin (elastase inhibitor) is disrupted for example by an environmental factor such as cigarette smoking resulting in a generalised increase in elastase (Campa et al. 1987; Cohen et al. 1991; Tilson 1988).

Abdominal aortic aneurysms have been attributed to a weakening of the arterial wall as a result of atherosclerotic vascular disease caused by the atheromatous lesions. Recent evidence supports a multifactorial process in which atherosclerosis is involved. Other aetiological factors include changes in the matrix of the aortic wall with age, proteolysis, metalloproteinase changes, inflammation, infectious agents (e.g. syphilis, mycotic infections), and a genetic predisposition (e.g. Marfan syndrome, Ehlers-Danlos syndrome).

The development of atherosclerotic plaques within the aorta and the inherent repair mechanism that surrounds this initial insult renders the media subject to neutrophil infiltration and as such the potential for elastase and collagenase secretion. This, combined with an increase in diastolic blood pressure, weakens the tensile strength of the aorta and it gradually dilates. Environmental and genetic factors have a large role in aneurysm development and make it difficult to predict who may be prone to the disease (Rehm et al. 1998).

True aneurysms involve dilation of all three layers of the vessel wall, whereas false aneurysms are caused by the disruption of one or more layers of the vessel wall and are usually either iatrogenic or post traumatic. Elastin and collagen are the primary structural elements of the aortic wall. The distribution of elastin and collagen fibres are lowest in the infrarenal aorta and hence, with their proteolytic destruction, dilatation of the aorta ensues until inevitable rupture, unless there is early surgical or interventional management. Once an aneurysm diameter is more than 6 cm there is a 25% annual rupture risk. The risk of cardiac related mortality has also been shown to be proportional to aneurysm size.

Increased concentrations of several proteases capable of degrading collagen and/or elastin have been found in the walls of AAAs and in aortic occlusive disease; both are manifestations of atherosclerosis.

An immunologic component to atherosclerotic vascular disease has been recognized and is characterized by infiltration of the aortic wall by macrophages, T lymphocytes, and B lymphocytes; these are known to activate proteolytic activity. The nature of this response has led researchers to investigate autoimmunity in the pathogenesis of AAA. Recent reports describe *Chlamydia pneumoniae* antigens, in contrast to active infection, in the walls of AAA. After the infectious agent is cleared, an antigenic stimulus remains, stimulating proteolytic activity with weakening of the vessel wall and aneurysm formation. Inflammatory aneurysms, once believed to be distinct entities, are currently considered one extreme in the spectrum of atherosclerotic aneurysms; these account for 3%–10% of all AAAs (Rasmussen and Hallett 1997).

The familial pattern of AAA has long been recognized with a 15%–19% incidence among first-degree relatives (Salo et al. 1999). This observation suggests that one or more genes are related to AAA and atherosclerosis. The identification of these genes may ultimately enable the early detection and prevention of AAA in high-risk patients (Hirose et al. 1998).

1.5 Fibromuscular Dysplasia

1.5.1 Background

Fibromuscular dysplasia (FMD) is a non-atherosclerotic, non-inflammatory vascular disease that was first reported by Leadbetter and Burkland in 1938, and described originally as a disease of the renal arteries. However, it has subsequently been shown that it can affect virtually any vascular arterial bed.

FMD is an angiopathy that affects medium-sized arteries predominantly in young women of childbearing age. FMD most commonly affects the renal arteries and is a cause of refractory renovascular hypertension. Of patients with identified FMD, renal involvement occurs in 60%–75%, cerebrovascular involvement occurs in 25%–30%, visceral involvement occurs in 9%, and arteries of the limbs are affected in about 5% (Luscher et al. 1987; Gray et al. 1996).

In patients with identified cephalic FMD, 95% have internal carotid artery involvement and 12%–43% have vertebral artery involvement. Although FMD can affect arteries of any size (Hill and Antonius 1965), involvement of smaller ones, including intracranial vessels, is rare.

1.5.2 Types

These are related to the three-layer structure of the artery:

- Intimal fibroplasias: <1% – Long, smooth narrowing which appears radiologically similar to vasculitis (Harrison and McCormack 1971).

- Medial fibroplasias: Commonest – 'String of beads' in middle section of the artery (Begelman and Olin 2000).
- Adventitial fibroplasias: Rarest – Peri-arterial hyperplasia, a collar of elastic tissue causing short, tight stenosis (McCormack et al. 1966).

The aetiology of FMD is not known; however, a variety of genetic, mechanical and hormonal factors have been proposed. The strongest link is genetic as the disease is more common in first degree relatives of patients with FMD of renal origin (Pannier-Moreau et al. 1997).

1.5.3 Aetiology

Although the aetiology of FMD is unknown, several other associated vascular pathologies have been identified, including aneurysms (7.3%) (Cloft et al. 1998) and arterial dissection. For example, it is a predisposing factor in 15% of spontaneous cervical carotid dissections (Arunodaya et al. 1997; Eachempati et al. 1998).

The increased incidence of FMD in women as compared with men suggests a possible hormonal or genetic influence. Some authors have proposed the sex difference to be related to immune system functioning, but overt inflammation, as is observed in most classic autoimmune diseases, is histologically lacking.

The Ehlers-Danlos syndrome (type IV) has been associated with medial fibroplasia. This syndrome should be suspected in patients with multiple aneurysms in addition to the typical angiographic findings of fibromuscular dysplasia (Schievink and Limburg 1989).

In case reports, FMD has been associated with mutations in collagen (Tromp et al. 1993), and with alpha 1-antitrypsin deficiency (Schievink et al. 1998). Associations with neurofibromatosis, Alport syndrome and phaeochromocytoma have also been suggested (Gray et al. 1996).

1.6 Conclusion

The most common vascular diseases encountered by interventional radiologists are atherosclerosis and aneurysmal disease. Although with public health measures such as a reduction in smoking, the incidence of atherosclerosis may decline in the future, it currently represents a significant public health issue. In addition, the increasing prevalence of diabetes within the population would suggest that atherosclerosis will not disappear altogether. Endovascular techniques will therefore remain at the forefront of the management of peripheral vascular disease for the foreseeable future.

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2 Assessment of Peripheral Vascular Disease

Mark G. Cowling

CONTENTS

2.1 Introduction

As radiologists we are very familiar with the use of sometimes very expensive investigations to solve clinical problems. However, it is important that, as interventionalists, we recognise the need for a thorough clinical assessment of our patients before recourse to expensive and possibly unnecessary investigations. Lower limb ischaemia is much more common than in the upper limb. It may be acute or chronic, with the latter manifesting itself either as intermittent claudication or critical limb ischaemia.

Thus, it is crucial to take a thorough history and examination. After this, investigations may be required to assess the severity and location of the arterial disease. It is also necessary to assess the general health of the patient, for example by identifying risk factors. This will not be covered in detail in this chapter.

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2.2 History

The definitions of many of the terms used in the description of vascular disease are symptom based, meaning that the history is all important. Thus, acute limb ischaemia is defined as "any sudden decrease or worsening in limb perfusion causing a potential threat to extremity viability" (TASC 2000). Intermittent claudication describes leg pain that is brought on by exercise, is of sufficient severity to cause the patient to stop and is relieved by rest. Finally, critical limb ischaemia is usually readily identified clinically, but defies precise definition. Nonetheless, these patients have a chronic history featuring rest pain, possibly associated with ulceration or gangrene.

2.3 Examination

On examination the limb may appear normal in claudication, may be pale and cold in acute limb ischaemia or may show hair loss, atrophy of the subcutaneous tissues, ulceration or gangrene in critical limb ischaemia. It is attractive and logical to think that palpation of the limb pulses may indicate the likely site of the vascular stenosis or occlusion responsible for the symptoms. However, the presence or absence of peripheral pulses is, in fact, an unreliable guide (Criqui et al. 1985). For example, assessment of the strength of the femoral pulse is an unreliable indicator of the presence of aortoiliac disease (Campbell et al. 1984), although the presence of a bruit on the symptomatic side is of value. Similarly the popli-

teal artery can be very difficult to detect even when normal, and assessment of the dorsalis pedis artery can be difficult because of variable anatomy.

2.4 Investigations

There are two issues which need to be addressed in the further assessment of peripheral vascular disease. The first is the severity of the ischaemia and the second is the location of the arterial disease causing it.

2.4.1 Severity of Ischaemia

The mainstay for assessment of the severity of ischaemia is the measurement of Doppler ankle pressures. Exercise testing can be a useful supplement to this. Other investigations such as plethysmography and transcutaneous oximetry are used less commonly.

2.4.1.1 Doppler Ankle Pressures

A continuous wave (CW) probe is used to detect flow in impalpable arteries. A sphygmomanometer cuff is then used to measure the systolic blood pressure. The cuff is placed around the ankle, inflated to greater than systolic pressure, then slowly deflated. The pressure at which the return of blood flow detected by Doppler occurs is the systolic blood pressure. The brachial systolic pressure is also measured. The ratio of the ankle pressure to the brachial pressure is then calculated to give the ankle brachial index (ABI). Use of ABIs allows patients to be compared, and also change within individual patients to be detected. Thus, a normal ABI is 1.0, and claudicants usually have an ABI of less than 0.9. A European Consensus Document has defined critical limb ischaemia (CLI) as persistent rest pain for more than 2 weeks, with or without ulceration or gangrene, with an ankle systolic pressure of less than 50 mmHg (EWGCLI 1992).

Ankle pressures can become quite inaccurate in the presence of vascular calcification, the classic example being in peripheral vascular disease secondary to diabetes. The vessels become relatively incompressible leading to falsely elevated pressure readings. Toe arteries rarely calcify, so the measurement of toe pressures is often recommended in these patients (Ubbink et al. 1997)

2.4.1.2 Exercise Testing

Exercise testing is generally performed using a treadmill, and is of value in patients who have a convincing history of claudication with normal Doppler ankle pressures at rest. Conventionally the speed is set at 3.5 kph at a gradient of 10°. The duration of exercise may be standardised to 1 min (Laing and Greenhalgh 1980) or may be continued until the patient experiences pain. The increase in muscle blood flow brought about by exercise will cause a fall in ankle pressures if there is significant arterial disease (Berglund and Eklund 1980).

2.4.1.3 Plethysmography

Plethysmography, sometimes called pulse volume recording (PVR), describes the measurement of limb volume. Short term alterations in limb volume can largely be ascribed to changes in the amount of blood contained within it (Brodie and Russell 1905). Completely accurate limb volume measurements require the use of very cumbersome equipment. Simpler equipment employing cuffs over segments of the limb allows volume changes to be measured using a pulse volume recorder. Other available measurements include limb diameter using a mercury strain gauge, blood skin volume measured by infrared photoplethysmography or skin blood flux by laser Doppler.

The difficulty with all of these measurements is that they are more complex and expensive than Doppler ankle pressures. Their main role is therefore in the assessment of venous disease and as research tools (Ruckly 1988). The role of plethysmography in clinical practice may change with the advent of digital photoplethysmographic sphygmomanometers, which are cheaper and require less expertise than Doppler pressures.

2.4.1.4 Other Techniques

Transcutaneous oximetry is time consuming, requires the skin to be heated and produces inac-

curate results if the skin is hyperkeratotic. Isotope blood flow measurements are very sensitive in detecting arterial disease, but the information is of little practical value. These, and other techniques such as photoplethysmography, laser Doppler, thermography and isotope clearance have not found their way into routine clinical use.

2.4.2 Location of Arterial Disease

In order to plan therapy, be it via endoluminal or open surgical means, it is crucial to have a clear idea of the location of the vascular disease. The levels of disease are divided into aortoiliac, femoropopliteal and distal segments. An assessment also needs to be made of the severity of disease in each segment if it is multilevel. In general proximal stenoses or occlusions are treated first, both because better results would be expected, and the effectiveness of more distal treatment is limited by poor inflow.

Clinical examination may be misleading. For example, palpation of the femoral pulse is proven to be unreliable in detecting mild or moderate aortoiliac disease that may be haemodynamically significant (Green and Greenhalgh 1986). The presence of a femoral bruit on the symptomatic side, however, can be very helpful in the detection of a haemodynamically significant aortoiliac lesion. In addition, it is obvious that in the presence of femoropopliteal disease palpation of the pedal pulses, or even the measurement of Doppler ankle pressures, will be of no value in determining patency or otherwise of the distal calf arteries.

2.4.2.1 Segmental Arterial Pressures

If there is not ready access to non-invasive imaging such as duplex Doppler, then it is possible to gain information about the level of arterial disease by performing segmental arterial pressures (SAP). The principle is simple, in that four cuffs are applied to the lower limb at the upper thigh, above the knee, below the knee and above the ankle. Each cuff is inflated, and the pressure at which the return of the signal detected by a Doppler probe at the ankle is measured. A gradient of greater than 20–30 mmHg between cuffs indicates the presence of haemodynamically significant occlusive arterial disease. In addition, the difference between the same sites on opposite legs should not be greater than 20 mmHg (Walker et al. 1986). Potential problems with the technique include the fact that detection of flow occurs remotely from the cuff which may produce falsely low pressure readings if there is occlusive disease below the it, and the size of the high thigh cuff may produce a falsely elevated pressure reading.

Pulse volume recordings can also be obtained using the same arrangement of cuffs. Differences in the amplitude of the pulse volume at various levels gives an indication of the location of occlusive disease. Although these techniques are shown to be accurate compared to angiography, with a concordance of up to 95% if both techniques are combined (Rutherford et al. 1979), certainly in Europe these techniques are not widely used. However, they provide an alternative in localising vascular disease in the vascular laboratory setting if duplex ultrasound is not readily available.

2.4.2.2 Duplex Ultrasound

Duplex ultrasonography uses a combination of B-mode and pulsed Doppler ultrasound. B-mode ultrasound produces a grey scale image of the vessel to be examined allowing assessment of features such as size, wall thickness and plaque morphology. If a plaque is readily visible, it is also possible to obtain a measurement of the luminal narrowing caused by it. This is not always as easy as might be imagined, because the presence of calcification within the vessel wall, which is very common, can degrade the images due to acoustic shadowing.

The Doppler principle allows velocity measurements to be made. Sound reflected from the moving blood cells undergoes a frequency shift dependent on both the velocity of the cells and their direction of flow. Conventional pulsed Doppler (duplex) ultrasound allows the operator to interrogate a specific part of a vessel to produce a Doppler wave, which provides measurements of systolic and diastolic velocities as well as information about the shape and type of Doppler spectrum produced (Fig. 2.1).

As well as producing a spectrum, the Doppler information may be represented in colour, overlying the grey scale image. Blood flowing in the vessel is represented as either blue or red, depending on the direction of flow. The colour intensity changes according to velocity, with increased velocities producing brighter colours. This feature allows the

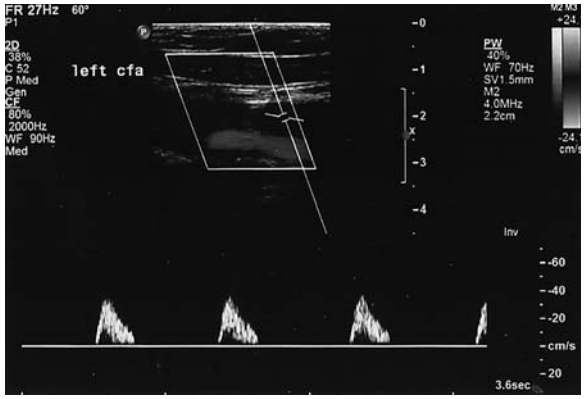

Fig. 2.1. Doppler ultrasound of the left common femoral artery. In particular note the monophasic waveform, indicating the presence of a significant stenosis, or possibly occlusion, proximal to that segment

operator to perform a fairly rapid survey of the vessel, selecting areas of high velocity turbulent flow for more detailed interrogation using Duplex ultrasound. Stenoses cause an increase in systolic velocity and also spectral broadening. A significant stenosis (50% or greater diameter reduction) will cause a doubling of peak systolic velocity (PSV). This is the most commonly used criterion when identifying a haemodynamically significant stenosis (Sensier et al. 1996).

There are a number of other features which may also be of value, though some have pitfalls. If the waveform is monophasic, rather than the normal triphasic pattern, this is a reliable sign that proximally there is a significant stenosis. Severe stenoses and total occlusions may be difficult to differentiate form one another. However, a marked reduction in the PSV may occur immediately proximal to a total occlusion, though clearly if there is a large collateral vessel present this will not occur. In the aortoiliac segment the severity of stenoses may be underestimated in up to 25% of cases (Legemate et al. 1991).

Despite these limitations, Duplex ultrasound is non-invasive and therefore totally safe. It is also undertaken by technicians in many institutions, making it relatively inexpensive compared to other modalities such as conventional angiography, CT angiography (CTA) or magnetic resonance angiography (MRA). Duplex ultrasound may be used to pre-plan endovascular treatment, meaning that when a patient attends for angiography there can be fairly high confidence that treatment can be undertaken at the same session (Elsman et al. 1996). It is also of value in pre-operative vein mapping prior to bypass grafting, graft surveillance and in assessing patency of tibial vessels prior to femorodistal bypass where angiography has not shown the tibial vessels adequately distal to an occlusion.

2.4.2.3 Conventional Arteriography

Conventional arteriography is an invasive technique which involves percutaneous catheterisation of a vessel, delivery of contrast and acquisition of the resulting X-ray image. Sites of arterial access are covered elsewhere in this volume. The catheters used for angiography are now very small (3, 4 or 5 F), and as a result bleeding complications are generally very low.

The use of digital subtraction arteriography (DSA) is now standard. The image is obtained via an image intensifier, with, on newer equipment, a CCD attached. This produces a digital image which is recorded by a computer system. The first one or two images are acquired before the introduction of X-ray contrast. When the contrast is introduced the first (mask) image is subtracted from the contrast images. Thus, the only data which appears on the subtracted images is the intravascular contrast. Although there may be some artefacts caused by misregistration of the mask and contrast images caused by patient movement or bowel gas, these can often be overcome by post processing. Many systems now also allow longitudinal table movement during image acquisition, so that it is possible to follow the contrast bolus. All of these features combined allow less contrast to be used than was previously required for non-subtracted arteriography.

The advent of DSA meant that it became possible to perform intravenous studies (IVDSA), whereby a catheter is placed in the right atrium, usually from a vein in the arm, and contrast injected. After passing through the pulmonary circulation and the heart, the contrast bolus enters the systemic circulation and can be imaged. Although the principle is attractive, and this technique was popular for a while, it is beset with problems. The contrast doses required are high, and if the patient has poor cardiac function, which is a common problem in patients with peripheral vascular disease, imaging may be very difficult. In the author's experience the results from IVDSA were commonly disappointing, and with the advent of CTA and MRA there is no longer any need to resort to this technique.

High quality angiographic technique is important in order to avoid missing lesions. Oblique views may be required to adequately examine the iliac arteries and the origin of the profunda femoris. One must also avoid making the contrast overly dense, which can mask significant lesions seen "en face".

Severe complications of diagnostic angiography are now relatively infrequent. The most likely is bleeding which may require prolonged compression; haematomas are uncommon and false aneurysm formation is rare. Dissection of an iliac artery is rarely significant from retrograde passage of a guidewire, but if flow is limited a stent will be required. Distal embolisation is usually easily treated by percutaneous aspiration thrombectomy. Cholesterol embolisation may occur in the presence of a severely atheromatous aorta. Thankfully this is a very rare occurrence, as it may be fatal.

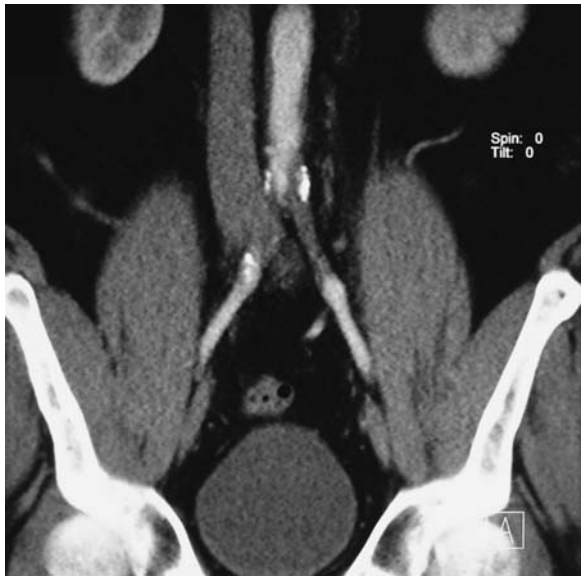

Fig. 2.2. Coronal CTA multiplanar reconstruction of the aortic bifurcation in a 45-year-old man with bilateral short distance claudication. Note bilateral common iliac artery occlusions

2.4.2.4 Computed Tomographic Angiography

Computed tomographic angiography (CTA) first became possible with the advent of spiral CT scanners. Contrast is injected through a peripheral vein using a pump. After it has reached the systemic arterial circulation the CT data is acquired. As the X-ray tube and detector array rotates, the patient is moved through the CT gantry so that a volume of data is acquired. The data can then be viewed axially as well as being reconstructed into 3D images. With older, single slice spiral scanners, the volume that could be scanned was limited both by the patient's capacity to hold their breath, and by the heat capacity of the X-ray tube. Thus it would typically only be possible to scan one area such as the iliac arteries. In addition, slice thicknesses of 2–3 mm had to be used, which limited the spatial resolution of the images.

The advent of multislice scanning has brought about a revolution in CT in general, with great benefits for CTA in particular. Scanners producing 16 slices are now commonplace, though up to 64 slice machines are available. Sixteen slice machines allow section thicknesses of as little as 0.75 mm to be employed, producing very high quality reconstructions (Fig. 2.2). CTA is of particular value in imaging aortic and iliac aneurysms, both prior to open repair, and in assessment for potential endovascular repair. It is also possible to image the aortic arch, carotid arteries and lower limb vessels with ease. Whilst CTA may not be the first choice for these applications, it can be very useful where MRA is limited in its availability or where it is contraindicated.

2.4.2.5 Magnetic Resonance Angiography

Magnetic resonance angiography (MRA) has been developed over the last few years to become a very powerful tool for imaging vascular disease. It has the advantages of being non-invasive and not requiring the use of ionising radiation. MRA images can be acquired using a variety of techniques with or without intravenous gadolinium as a contrast agent. Although non-contrast techniques, such as time of flight, are cheaper because they do not require the use of gadolinium, they suffer from more artefacts than contrast enhanced MRA.

Several studies have shown that peripheral MRA is an accurate technique, and with the advent of stepping table technology it is now possible to image the entire lower limb vasculature in one session (Fig. 2.3).

Unfortunately, MRA is not yet universally readily available, and it is time consuming as well as being relatively expensive. MRA is also not suitable for all patients, either due to claustrophobia or contraindications such as cardiac pacemakers.

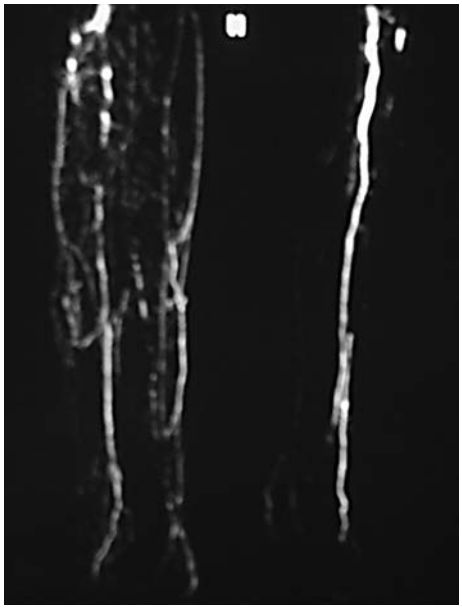

Fig. 2.3. Contrast enhanced MRA of the tibial vessels in a diabetic patient with foot ulcers. Note the severe vascular disease on the right, with no single continuous run-off vessel, and the single patent peroneal artery on the left

2.5 Conclusion

Once the patient has been assessed clinically, there is a wide array of investigations that can be used to further assess lower limb ischaemia. All patients should have their ABIs measured as a baseline assessment of the severity of ischaemia. Further measurements on follow-up allow the degree of deterioration, or improvement after treatment to be measured objectively. Exercise testing is of value where there is doubt about the diagnosis of intermittent claudication. It also provides an objective measure of walking distance prior to the decision to intervene.

Non-invasive laboratory based tests provide further information regarding severity of ischaemia and location of vascular lesions. The techniques chosen will depend largely on local expertise and availability. Thus in Europe, duplex ultrasound is a very commonly used technique, whereas plethysmography and SAPs are more frequently used in the USA. These techniques are suitable for use in assessment of intermittent claudication. If, once the patient has been assessed, angioplasty is thought to be appropriate, it is now possible to proceed directly to this without performing prior angiography on a separate occasion.

If a patient presents with critical limb ischaemia, they will usually proceed directly to angiography, both because of the relative urgency of the situation, and because if open surgery is to be undertaken a map will be required for planning purposes. Clearly, at the time of angiography, it is possible to undertake appropriate endovascular treatment as well. The situation is similar in patients presenting with acute limb ischaemia.

CTA and MRA offer the prospect of being able to provide a map for planning of open surgery without recourse to invasive angiography. However, their place in management is evolving and they have yet to gain universal acceptance.

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3 Equipment and Environment

Vikramaditya Prabhudesai

CONTENTS

3.1 Introduction

There have been tremendous advances in techniques and technology since the first arteriogram by Dos Santos et al. in 1929. The role of an angiographer has evolved from diagnosing arterial and venous diseases to offering definitive treatment.

With this new level of complexity and skill comes a need to design an angiography suite capable of meeting this demand (Bakal 2003). The same room may also be used for non-vascular intervention. The requirements for such a suite are different from that of a cardiac catheter laboratory or a neuroradiology suite.

3.2 Angiography Suite

Ideally, all diagnostic and therapeutic vascular procedures should be performed in a hospital based dedicated angiography/interventional suite (Cardella et al. 2003).

An ideal angiography suite must have adequate space for the radiological equipment, monitoring and emergency care equipment as well as enough space for patient care and recovery (Fig. 3.1). An ideal examination room would be 65 m^2. Large lead lined doors are needed which are wide enough to admit beds with ancillary equipment. The ceiling should be 3.5–4 m high with additional space above that to allow mechanical access. In addition, the following features are needed:

1. The fluoroscopy unit
2. Enough electrical points for ancillary equipment that may be needed
3. A scrub sink with hot and cold water and hand wash solution which is outside of the examination room
4. A dirty utility room, with a sluice, adjoining the suite
5. Piped anaesthesia gases, suction machine and physiological monitoring equipment
6. Surgical ceiling mounted lights and ceiling lights that can be dimmed
7. Storage space, apron rack and shelves for all the equipment
8. Ultrasound machine, with an additional monitor next to the fluoroscopy monitor
9. Manometry equipment for measurement of arterial (pulmonary or peripheral artery) and venous pressures

Fig. 3.1. An ideal angiography suite

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If the room is to be used for endovascular stent grafting for aortic aneurysms, then operating room standards must also be met. A management plan in case of complications or emergencies should be in place.

The control room is separate, and lead lined glass allows visualisation of the suite. An intercom is useful, whilst the use of blinds may be necessary in certain cases. The control room should have a computer which can access the patient records and all laboratory investigations in addition to monitors and X-ray viewers that will allow review of previous imaging.

An air conditioned room for the power equipment, transformer and other electrical equipment is needed with an additional room for storage of consumables.

A recovery room with patient bays, each with the necessary monitoring equipment is essential. Patients may be kept here and monitored till transport to appropriate wards or day care centres. Additional support space for staff, patients and relatives may be shared with the general radiology department or be dedicated to the angiography suite.

3.3 Fluoroscopy Equipment

The fluoroscopy unit (Pooley et al. 2001) must be a 'C' or a 'U' arm unit which can rotate around the patient in the axial and the sagittal planes. The unit is motor driven with the angles displayed on the monitor/control unit. It should be possible to vary the source detector distance. Combination of fluoroscopy arm and table movement should make imaging of the whole body possible. Manual override and locking should be possible. Modern equipment also has built-in systems to prevent collision and patient injury or damage to equipment.

The table should have a floating top and be able to support at least a 140-kg patient. As CO_2 angiography is being used more frequently the table should also have lateral tilting capabilities, in addition to head up and head down positions. There should be an extra set of controls on the table for use by the angiographer. It should be possible to move the C-arm away or move the table out from under the arm in case of emergencies.

The image intensifier should have a large field of view with at least two or three field sizes. Digital subtraction and acquisition (DSA) is standard on all present-day fluoroscopy units. There are many modern systems on the market, with most or all of the following:

1. Pulsed fluoroscopy for dose reduction
2. Variety of frame rates (1–15 frames/s)
3. Various collimators
4. Dose free display of filter and collimation position
5. Filters to reduce skin dose
6. Image overlay
7. Road mapping and land-marking
8. Last image hold and frame-grab
9. Automatic table movement/stepping allowing imaging of a limb with a single contrast injection

Excellent image quality is a must and is provided by a large matrix, usually 1024×1024, and some modern systems provide a higher resolution of 2048×2048. Some newer systems have flat panel detectors. Other requirements for image processing, display and archiving include:

1. Frame averaging to form and change masks
2. Post acquisition image enhancement
3. Pixel shifting
4. Annotation
5. Cine display
6. Histogram creations
7. Windowing and contrast/brightness changes
8. Flow measurements
9. Region of interest (ROI) and distance measurements
10. Stenosis quantification
11. Maximum opacification (view trace) and a variety of other image manipulations

Newer units have increased functionality including fluoroscopy storage and rotational scanning/imaging. The latter allows three-dimensional imaging of complex vascular structures in multiple projections with just one contrast injection. Although the most common use of such equipment is in the neuroangiography setting, it can be of value for imaging of iliac arteries and renal transplant arteries.

A system for the angiographer to review all the images should be incorporated on the unit. Having two monitors helps in case of complex procedures where multiple series need to be reviewed and a reference image is required; failing this, it should be possible to split the main screen. Ceiling suspended monitors should be positioned so that they can be viewed from either side of the table.

Power injectors capable of varying the rate of contrast injection are needed. Additionally a CO_2

injector may be needed, although it is possible to fill a syringe from a CO_2 cylinder and perform a hand injection. The injector should have visual and audible malfunction signals. It should display the parameters such as volume, rate and pressure of each bolus injection.

3.4 Environment and Patient Care

All procedures are performed in strict aseptic conditions. Sterile gowns and gloves in addition to masks and caps are worn by the operators and their assistants. Eye protection is advisable to avoid splashes and sterile coverings are used for any equipment that may contaminate the field. All staff must follow full aseptic techniques in the preparation of the carts and for handing over equipment, instruments and consumables. The handling of all 'sharps' must be in accordance with occupational health regulations. Universal precautions need to be followed when handling patients and any body fluids.

Resuscitation equipment and the expertise for its use must be available to deal with the complications that may occur during interventional procedures. The interventional suite must be equipped with a standard hospital approved 'arrest trolley'. This must have the full complement of drugs, defibrillator, breathing masks/bags and intubation kit.

The vast majority of cases are performed under local anaesthesia. Conscious sedation is used in some cases (see Chap. 5). In rare cases general anaesthesia is used, hence suitable facilities and equipment must be available for such occasions. During the procedure all vital signs need to be recorded. Cardiac monitoring is performed routinely, whereby it is more important for pulmonary angiography. Intravenous access is mandatory in all cases for fluids, sedation and any medication as may be needed. An appropriately qualified nurse monitors the patient throughout the procedure, keeping a record of all medication given.

The patient needs continuous monitoring following the procedure. This is done in an appropriate setting of a recovery room, or a similar unit. Bedrest is mandatory, the duration depending upon the type of procedure. The vital signs are recorded and the puncture site is inspected. In case of any complications the nursing staff has to inform the physician in charge immediately. A written record of the procedure is made, along with appropriate findings and immediate complications if any. It is important to communicate with the referring physician in case of the latter. The duration of stay in hospital following a diagnostic or therapeutic procedure will depend on hospital and department policy. Many procedures are being performed on an out-patient basis. Some complicated cases, however, still require at least overnight admission, not least for pain control. Strict discharge criteria need to be formulated, which must be met before the patient can go home.

The patient is usually followed by the referring physician. Multi-disciplinary meetings are useful for feedback and also to formulate treatment plans.

3.5 Consumables

A basic sterile tray is needed in each case. This may be disposable or reusable after appropriate sterilization. The components of this tray include basins for the antiseptic solution, saline flush, soaking of wires and catheters; sterile instruments, and the necessary needles, wires and catheters.

There is a wide variety of needles, guidewires and catheters available for use by an interventional radiologist. Available needles should include micropuncture kits, single-wall and double-wall puncture needles in 18G or 19G sizes.

Most guidewires are made of stainless steel coil wrapped tightly around an inner mandrill that tapers to the working end. There is a central filament which prevents separation if the wire breaks. Wires are available in a variety of sizes (from 0.010 to 0.038 in. in diameter) and lengths (50–300 cm). Other characteristics include a variety of tip configuration (straight, angled, 'J' shaped, tapered, floppy and tip-deflecting), torquability, stiffness and outer coating (hydrophilic wires). Teflon coating reduces friction. Some wires are impregnated with heparin to reduce thrombogenicity. In addition to steel, nitinol, platinum and gold are used in wire construction. To increase the useful life, wires should be wiped with saline soaked gauze each time the wire is removed or catheter exchanged. If possible the wire should be stored in a saline bowl, as build-up of thrombus or dried contrast may make the wire useless.

Angiographic catheters are made of Teflon, polyurethane, polyethylene or nylon and are designed for safe and efficient vascular cannulation. A large variety of catheters are commercially available. Hydrophilic coating on catheters improves trackabilty

and wire braiding improves torquability. Catheters vary in size, length and number of side holes and shapes. Catheters should be kept wet and flushed prior to use. Intermittent flushing improves the life and reduces the incidence of clot formation at the tip of the catheter. A range of sheaths are also available which help with reducing oozing from the site of vascular access. In addition they prevent vessel wall injury when multiple catheters are exchanged and when angioplasty, thrombolysis or embolisation is planned.

A wide variety of balloon and covered and non-covered stents are available. These are available in different sizes and lengths. Infusion catheters for thrombolysis, atherectomy devices, Fogarty catheters for clot retrieval and a variety of snares and vascular biopsy and foreign body retrieval instruments are commercially available. In addition there is a huge armamentarium of embolic agents at the disposal of the vascular radiologist. More details are beyond the scope of this chapter. However, it should be emphasised that before embarking on any procedure the interventional radiologist should ensure that he has the full range of equipment likely to be required to complete any given procedure. In addition, equipment and drugs required to treat any complications that may occur should also be available. Examples would include stent grafts for the treatment of vessel rupture and aspiration catheters and thrombolytic agents for the management of peripheral emboli.

3.6 Conclusion

In the last two decades interventional radiology has advanced hugely. Treatment may be highly complex with significant potential complications. It is therefore essential that good imaging equipment is available in a clean, preferably theatre standard, and spacious environment. A sufficiently wide variety of equipment in the form of guidewires, catheters and so forth should be available to allow procedures to be completed safely. In particular, there should be equipment available for the management of complications.

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4 Consent

Michael R. E. Dean

CONTENTS

4.1 Introduction

The last 20 years have seen a considerable increase in the number of patients who resort to legal action when their medical or surgical treatment fails to live up to their often overoptimistic expectations. Over the same period of time there has been a marked increase in the amount of damages awarded to the patient when the court finds that the doctor or hospital has been negligent. It is therefore of great importance that, when consent is obtained, the patient is given a realistic description of the intended treatment or operation and this must include details of its limitations and possible complications. Giving an overoptimistic description of the likely efficacy of the proposed treatment will lead to disillusionment and a consequent mistrust of both the treatment and of the doctor delivering it. It is essential therefore that the vascular radiologist is confident that the chosen procedure is preferable to the alternatives, be it surgery or conservative management. One must not be influenced by a desire to try out a new procedure or a new endovascular device unless it is in the patient's best interest. Equally one must not be influenced by pressure from clinicians who do not necessarily appreciate the limitations of procedures.

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Interventional radiological vascular procedures are quite correctly referred to as minimally invasive. This term may lead the patient to believe that they can be performed without risk, whereas in reality the complications of some procedures can result in serious morbidity or even death. For this reason the possible complications must be carefully outlined when obtaining the consent of the patient before the procedure. The process of obtaining consent, however, should not be regarded as a means of defence against possible litigation but as an essential part of the whole clinical process. The discussions involved in obtaining consent are an important part of establishing effective communication and trust between the doctor and the patient.

4.2 Consent for Routine Procedures

Every patient who attends the radiology department for routine angiography or for simple or complex endovascular procedures must have given proper consent. For consent to be valid it must have been obtained voluntarily and without undue pressure from any source, and the patients must fully understand the procedure and its implications. Consent for routine procedures should be obtained before the patient's admission to hospital if at all possible. It is not acceptable to obtain consent outside the radiology suite on the day of the procedure as this would be seen as putting undue pressure on the patient to accept the proposed treatment, and even obtaining consent after admission to hospital may be regarded as coercive. There has been some reluctance from radiologists to devote proper time to discussion with the patient. Radiologists historically have not been involved with the delivery of treatment but with investigation and diagnosis. The development of interventional techniques has altered this situation over the last 20 years and radiologists must take their clinical responsibili-

ties seriously. The ideal time to obtain consent from the patient is in an outpatient clinic a few days before the procedure since this allows the patient time for thought and time to discuss the information with relatives or friends if they so wish. It is well known that a patient's recall of information provided at the time of obtaining consent is at best patchy and may be very poor. The provision of information sheets which describe the procedure, its limitations and its possible complications can overcome some of these problems of recall. To be effective, however, the information sheets must be very clearly and simply written so that they can be easily understood by a lay person. When the patient is admitted to hospital the radiologist who is to perform the procedure should be available to answer any further questions which may have arisen after time for thought or discussions with friends or relatives.

When obtaining consent the radiologist should explain to the patient in simple terms why the intended procedure is considered to be in their best interest and why the alternatives, such as surgery or conservative management have been rejected. It goes without saying that the patient still has the right to reject the advice and to opt for alternative therapies. In such circumstances it is quite acceptable to outline the possible risks of not accepting the proffered advice but it is not acceptable to pressure the patient to agree to the proposed procedure.

The radiologist should then describe the procedure in plain and simple terms. Drawings or other visual material can be invaluable in helping the patient to understand the details. The likely success rates of the procedure and the possibility of recurrence should then be discussed. The success rates should be, as far as possible, based on the doctors own experience and not on figures quoted in the radiological literature which are often optimistic. Finally the patient should be informed of the possible complications. There is still some discussion as to which complications should be mentioned. Clearly common complications must be mentioned, and as a rule complications which occur in 1% or more of procedures would be regarded as in this category. In England it is likely that a court would rule that serious or significant complications, however rare, should be mentioned if they might affect a reasonable patient's judgement as to their acceptance of the procedure. There is a very delicate balance to be struck between providing the patient with full information and deterring them from accepting a procedure which is clearly in their best interests. At the end of the process of consent it is usual for the patients to sign a form to indicate their agreement to the procedure. The signature alone is not proof of proper consent if the procedure and its complications have not been fully described. In England the standard consent form asks the doctor obtaining consent to outline the reasons for the procedure and to list the possible complications that were described to the patient. Where such a form is not used the outline of the discussion with the patient should be recorded in the patient's notes and in particular the possible complications which were mentioned should be listed.

Should the patient decline to accept the intended course of treatment their decision, however illogical or perverse it may seem, must be accepted unless there is reason to believe that the patient lacks the capacity to make a reasonable decision. In this situation the doctor should discuss the proposed treatment with the patient's relatives or with other members of the health care team, but no relative or any other person may give consent on the behalf of the patient. If the procedure is considered to be in the patient's best interests and if they lack the capacity to consent then it is possible to continue but the reasons for doing this must be clearly recorded in the patient's notes. Where there is doubt or opposing views then it will be necessary to obtain legal advice and in some cases it will be necessary to obtain a ruling from the court.

There will be a small number of patients who refuse to be given full information about the procedure and its possible complications preferring instead to trust in the doctor's judgement that this is the correct course of action. In these circumstances this refusal should be recorded in the patient's notes together with the reasons why the treatment is considered appropriate.

4.3 Who Should Obtain Consent?

Ideally the doctor who is going to perform or supervise the intended procedure should personally be responsible for obtaining the consent of the patient. When this is not possible the task can be delegated to a junior doctor or, in certain circumstances, to a nurse, if the doctor in charge of the patient is satisfied that the person obtaining consent has been properly trained to fully understand the procedure, its indications, its limitations and its possible com-

plications. The person obtaining consent must be able to answer any question about the procedure that the patient wishes to ask; if they are unable to do this fully then the task has been improperly delegated. The doctor in charge of the patient ultimately is responsible for ensuring proper delegation and ultimately is responsible for ensuring that valid consent has been obtained.

4.4 Consent for Emergency Procedures

In an emergency consent clearly cannot be obtained in the same manner as for a routine procedure as time is at a premium. Where possible the patient should be given a brief account of the need for the procedure and its possible complications. If the patient is unconscious, heavily sedated or otherwise unable to give consent then such treatment as is necessary to preserve life or to deal with the immediate emergency should be given. Any further procedures required that are not immediately necessary should be postponed until they can be properly discussed with the patient.

4.5 Consent for the Use of New Medical Devices and New Procedures

Since 1998 the regulations for the use of new medical devices have been standardised across the Member States of the European Community under the European Medical Devices Directive. This allows free movement of medical devices across the Community and under the directive all new devices must have obtained a CE mark before they can be sold. This CE mark indicates that the device satisfies the stated essential requirements intended to ensure the following:

1. A device does not compromise the clinical condition of the patient, the users, or, if applicable, any third party.
2. A device achieves its intended purpose as designated by the manufacturer.
3. Any risks associated with the device are judged by informed clinical opinion to be acceptable when they are weighed against the benefits to the patient and when they are compatible with a high level of protection of health and safety.

Member States of the European Community each have a competent authority which is responsible for ensuring that the Directive is properly implemented. A CE mark can only be obtained when the manufacturer has proven to the competent authority that the device satisfies the essential requirements for safety and performance. This proof may be based on extracts from the existing scientific literature or it may be based on the outcome of a specifically designed trial which has been previously approved by the competent authority. A manufacturer wishing to carry out a trial of a new device must give written notice of this to the competent authority. This must be accompanied by a full description of the investigation and a letter indicating the approval of the research ethical committee of each hospital which is to participate in the trial. Devices without a CE mark may thus only be used as part of a specific trial which has received the approval of the competent authority and the local research ethical committee. When obtaining consent prior to use of the device the patient must be given a careful explanation of the possible advantages of the new device and that there is little information as to the short term or long term outcomes. They must be given the right to decline the use of the device if they so wish, and be reassured that the best alternative form of treatment will still be available.

When a truly innovative form of new procedure is to be tried then there must be prior approval for the procedure from the local research ethical committee. In the United Kingdom, in addition, the National Institute for Clinical Excellence (NICE) has a New Procedures Committee which is responsible for the evaluation of new procedures and any new procedure should be registered with NICE. The local research ethical committee will require a standardised consent form to be used to ensure that the patient is fully aware of the experimental nature of the new procedure but the doctor obtaining consent must be sure that the patient fully understands the implications spelt out in the consent form.

4.6 After the Procedure

After the procedure the radiologist should always write a detailed account of the whole procedure in the patient's notes. This should start with the name of the procedure performed, the name of the operator and the names of any staff that have assisted.

Practical details of the procedure should be fully described and this should include the types of catheters, arterial guide wires and other equipment which was employed. All drugs administered before, during and immediately after the procedure should be listed. This detailed account is not just required for medico-legal reasons, should a later complaint arise, but if a repeat procedure became necessary this account might be invaluable in selecting the catheters and guidewires which were successful on the earlier occasion. Finally the radiologist must ensure that clear written instructions for the patient's aftercare are sent to the ward staff together with the patient's notes.

In the event of a complication during the procedure details of the circumstances and details of the remedial action taken must be clearly recorded in the notes. If it becomes necessary to obtain help from a clinical colleague then the name of the colleague and the action taken should be described. Every vascular radiologist will inevitably encounter a complication and it is important to be completely honest with the patient about the facts of the situation. Nothing will provoke the suspicion and distrust of the patient more than evasive answers. A clear and honest explanation of the events may well avert subsequent legal action. If the complication is potentially serious then it is sensible to make a photocopy of the patient's notes both as a back up should the original notes be mislaid and as a ready source of reference should questions about the procedure subsequently require an answer. Changes should never be made to a patient's notes once written. If a later correction is required or additional facts need recording then this must be done as a new paragraph which is clearly dated and signed. Alterations to the notes can suggest that there was an attempt to conceal the true facts of the complication. Clearly written notes are vital. It is virtually impossible to defend an accusation of negligence with inadequate medical records.

4.7 Conclusion

An accusation of negligence is a distressing experience for any doctor. Maintaining high standards of practice, being sure that any procedure is in the patient's best interest, being careful and considerate when obtaining consent and providing an honest account of events should a complication occur will go a long way to avoid such an accusation. When a radiologist is unfortunate enough to be accused of negligence meticulous records of each case will be invaluable since the accusation is usually made long after memories of the case have faded.

5 Sites of Arterial Access and the Role of Closure Devices in Percutaneous Arterial Intervention

Nicholas Chalmers

CONTENTS

5.1 Introduction

Percutaneous access to the arterial tree is a prerequisite to undertaking diagnostic arteriography or endovascular intervention. Although the transfemoral route of access is the most commonly used, there are many other choices available to the radiologist. At times the alternatives can be invaluable in facilitating procedures that would not otherwise be possible. The use of closure devices reduces the need for groin compression. However this appears to be at the expense of an increased risl of complications. Whilst closure devices are undoubtedly useful in selected cases, the current evidence does not support their routine use.

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5.2 Femoral Access

5.2.1 Retrograde

Retrograde puncture of the common femoral artery has been the gold standard for arterial access since Seldinger's landmark innovation in 1953 (Seldinger 1953). The common femoral artery has the advantages of being a relatively large and superficial artery which lies anterior to the hard bone surface of the femoral head. The large calibre ensures that large sheath sizes will be tolerated without causing intimal injury, spasm or occlusion of blood flow. The superficial location facilitates needle puncture. The hard surface posteriorly makes the artery easy to palpate and to apply pressure afterwards to achieve haemostasis.

Retrograde puncture of the common femoral artery is therefore a relatively safe approach associated with a complication rate of about 1%. Apart from haematoma, which is to some extent inevitable, the commonest puncture site complication is false aneurysm. This is frequently associated with a low puncture, below the femoral head and frequently at the common femoral bifurcation or lower. The risk of a low puncture is greater in obese patients, because the femoral head is covered by the abdominal apron and palpation of the femoral head is difficult. Some operators use the groin skin crease as a marker for arterial puncture. This practice is to be deplored. The groin skin crease varies considerably in its relation to the femoral head depending mainly on obesity. If there is doubt as to the correct level, fluoroscopic screening of the femoral head is recommended to determine the correct puncture site.

Retrograde puncture of an impalpable common femoral artery is often required for iliac intervention. The impalpable artery can be located in various ways. Fluoroscopy will show the anticipated path of the artery and ideal puncture site. It may also show arterial wall calcification to guide needle

puncture. The opposite common femoral artery may have already been catheterised, if a bilateral approach is used. In this situation, an angiographic roadmap of the common femoral on the impalpable side can be used to guide the needle. Ultrasound can be used to locate the artery and guide needle puncture. Ultrasound will also show the bright arcuate shadow of the femoral head which will enable puncture at the correct level. Ultrasound localisation has been shown to reduce the number of needle passes required to access the artery (Zealley and Chakraverty 2005).

5.2.2 Antegrade

Antegrade puncture of the common femoral artery is required for many infrainguinal procedures. Antegrade puncture is frequently more difficult than retrograde, particularly in the obese. The location of the arterial puncture is ideally the same as for retrograde, namely mid-common femoral artery. The oblique passage of the needle through the soft tissues therefore necessitates a skin puncture on the lower anterior abdominal wall. In obese patients it is often necessary to push the abdominal apron out of the way. An assistant may be required for this. If an antegrade puncture is too low, the needle will almost always enter the profunda femoris artery in preference to the superficial femoral. If the common femoral is punctured within 1 cm of the bifurcation, the guidewire will generally enter the profunda. In this situation, a catheter with a short angulated tip should be introduced into the profunda. By careful withdrawal of the catheter under oblique fluoroscopy it is usually possible to steer a guidewire into the SFA. Alternatively a guidewire with a 15-mm J tip may be helpful: the gently angled tip may deflect off the posterior wall of the common femoral and selectively enter the superficial femoral in preference to profunda.

Antegrade puncture of the common femoral carries the risk of puncture above the inguinal ligament. On fluoroscopy the puncture site will be seen to be anterior to the upper third of the femoral head or the acetabulum. This is associated with an increased risk of retroperitoneal haemorrhage and false aneurysm. The risk can be reduced by avoiding placement of large sheaths if high puncture is suspected. The clinical presentation of retroperitoneal bleeding can be insidious and requires a high index of suspicion. The bleeding may not be visible and there may be only an ill-defined fullness in the iliac fossa associated with only minor discomfort. There is usually moderate tachycardia, but blood pressure is frequently maintained for several hours and the initial presentation may be with sudden drop in blood pressure in the middle of the following night. Clinical suspicion of a high puncture and vague symptoms post-procedure should therefore prompt a switch from a day-case to an overnight stay.

5.3 Upper Limb Access

When femoral access is not available for diagnostic angiography due to iliac occlusion, historically alternative access sites have been used, initially the translumbar route and more recently the brachial route. The translumbar approach was popular for many years and associated with a low complication rate. The development of small diameter steerable catheters led to a preference for the brachial approach although it is generally acknowledged that the risks were higher (Watkinson and Hartnell 1991; Lienemann et al. 1993). In recent years, non-invasive imaging modalities such as CT have rendered the need for arterial catheterisation for diagnostic purposes redundant in many centres. Arterial access via the upper limb is sometimes useful for renal artery or superior mesenteric artery procedures due to the downward slope of these vessels.

5.3.1 Axillary

Historically axillary (or, more likely, high brachial) puncture was favoured because of its larger diameter compared with the brachial artery at the elbow or the radial artery.

The axillary (high brachial) artery can be palpated with the arm externally rotated and abducted. The humeral head lies posteriorly, so some degree of compression can be achieved at the end of the procedure. This vessel segment has two major disadvantages compared with the common femoral: its smaller diameter and its proximity to the brachial plexus and nerves of the upper limb, which can give rise to temporary or permanent neurological sequelae. The axillary artery and the nerves of the upper limb traverse the axilla within a fascial sheath. Thus even a small haematoma within the

sheath may exert pressure on the adjacent nerves resulting in debilitating neuropraxia.

5.3.2 Brachial

The brachial artery is easily palpated at the elbow. It can be rather mobile, but is otherwise easily punctured and good compression is possible, post-procedure, against the distal humerus. The main disadvantages of the brachial approach are the adjacent median nerve and the fact that, being an unpaired vessel of relatively small calibre, local dissection at the puncture site may have serious consequences. The median nerve is usually medial to the artery at the elbow, but the relationship is inconstant. The median nerve is frequently numbed by the local anaesthetic, or touched by the puncture needle resulting in electric shock sensations. Persistent nerve damage occurs occasionally.

The risk of permanent neurological damage following brachial or axillary puncture is small, but given its severity, an alternative non-invasive imaging modality such as CT angiography should be considered for diagnostic purposes when the femoral pulses are impalpable.

5.3.3 Radial

The radial artery at the wrist is increasingly the approach of choice for diagnostic and interventional cardiology (Archbold et al. 2004). The radial approach has much to recommend it, assuming the ulnar artery supply to the hand is adequate. This is assessed by Allen's test during which the fist is clenched during compression of both ulnar and radial arteries. The fist is then opened and the ulnar artery is released. If patent, colour returns to the hand within 10 s. Allen's test demonstrates satisfactory ulnar collaterals in 94% of patients. Pulse oximetry and plethysmography are more sensitive and will demonstrate adequate collaterals in all but 1.5% of candidates for radial approach (Barbeau et al. 2004). The radial artery can safely accommodate catheter sizes up to 6 F with a low complication rate. Sheaths of 7 F are tolerated by 70% of males and 45% of females (Saito et al. 1999). Temporary occlusion occurs in about 5%, and permanent occlusion in fewer. In most cases the artery can be repunctured in the future if necessary.

There is little literature on radial access for non-cardiological procedures. Apart from isolated case reports, the literature appears to be limited to three series of (mainly) lower limb diagnostic angiography (Al-Kutoubi et al. 1996; Cowling et al. 1997; Michel 2004) and one of renal artery stenting (Kessel et al. 2003). Disadvantages include the need for long catheters for visceral and iliac intervention, with consequently reduced torque control. There is also the small stroke risk associated with emboli from any upper limb access. Use of this route for non-cardiological intervention warrants further investigation.

5.4 Distal Lower Limb Access

5.4.1 Popliteal

The popliteal artery can be approached with the patient prone on the X-ray table (Tønnesen et al. 1988). The artery can be opacified with contrast (if a catheter has already been deployed in the common femoral). Alternatively, ultrasound guidance can be used (Heenan et al. 1994). The artery lies deep to the vein at this level, so a route that avoids transfixing the vein may be desirable. The popliteal approach is sometimes useful after a failed attempt at antegrade recanalisation of a femoral artery occlusion. The retrograde approach may be successful. Other indications for a popliteal approach include recanalisation of flush SFA origin occlusions and angioplasty of tandem lesions in the iliac and femoral segments from a single puncture (Saha et al. 2001). The popliteal line is more direct than the contralateral approach. Disadvantages of the popliteal are the discomfort to the patient of the prone position and the inability to achieve good manual pressure on the puncture site deep in the popliteal fossa. Despite that, haemorrhagic complications appear to be rare although numbers are limited (Yilmaz 2002).

5.4.2 Calf Vessels

Spinosa et al. (2005) have reported experience with catheterisation of the dorsalis pedis or anterior tibial or posterior tibial arteries at the ankle to permit combined antegrade and retrograde sub-

intimal recanalisation of occlusion where distal re-entry cannot be achieved following antegrade approach alone, or where there is only a limited length of distal patent vessel. Distal vessel puncture is achieved using a micropuncture kit (Cook) with ultrasound or fluoroscopic guidance - arterial calcification or contrast medium injected through the antegrade catheter delineate the vessel. Limb salvage rates at 6 months are promising.

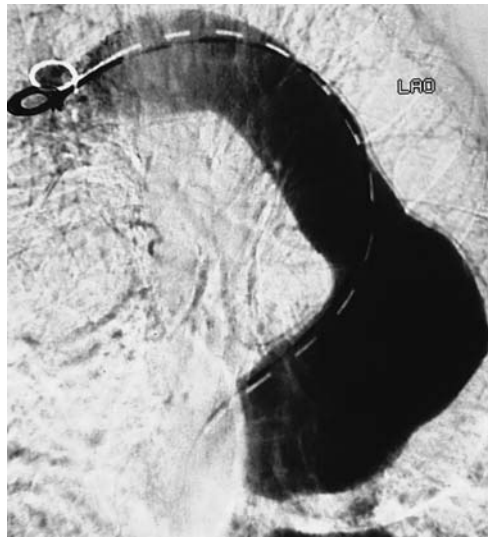
5.5 Alternative Approaches

5.5.1 Translumbar

Prior to the days of high quality preformed shaped catheters and modern non-invasive imaging modalities, the translumbar route was for many years the favoured access for peripheral and renal angiography and many angiographers in the over-50 age group have experience of hundreds of these. More recently the translumbar approach has been described in isolated case reports for coronary intervention (Henry et al. 1999). The indications for this approach today would seem to be vanishingly rare.

5.5.2 Carotid

The standard approach for diagnostic angiography of the cerebral vessels prior to the days of good quality pre-formed diagnostic catheters was by direct needle puncture of the carotid and vertebral arteries. New developments in catheters and in non-invasive imaging has rendered this obsolete However, recently there has been some interest in



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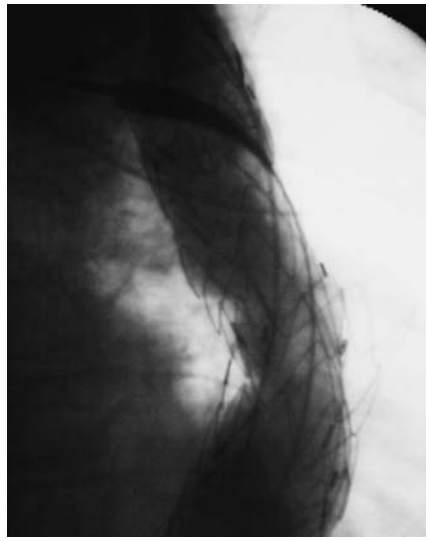

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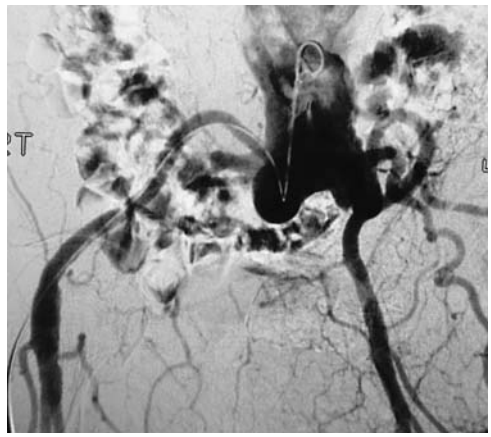

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Fig. 5.1a–c. Endoluminal repair of a thoracic aortic aneurysm via right common carotid approach. **a** Large aneurysm of the descending thoracic aorta. **b** Marked tortuosity of the common iliac arteries precludes standard femoral access. **c** Three overlapping stent graft devices have been deployed in the thoracic aneurysm via a right common carotid approach

the carotid approach for abdominal (May et al. 2000; Estes et al. 2001) and thoracic (Fig. 5.1) stent graft placement, when infradiaphragmatic access is impossible. The common carotid artery has the advantages of relatively large calibre (8–10 mm) and relatively superficial location. Furthermore, most patients will have adequate collateral supply and will therefore tolerate temporary occlusion of the vessel. With surgical exposure, and control of the internal and external carotid arteries, the risks of dissection and air or particulate embolus can be minimised.

5.6 Closure Devices

Use of closure devices to rapidly seal the arterial puncture site and eliminate the need for manual compression found ready acceptance when the devices started to be introduced some years ago. They were perceived as permitting faster mobilisation and enabling more rapid throughput of patients particularly in cardiac catheter labs.

5.6.1 Technologies

Various ingenious technological approaches have been developed. The Perclose device deploys a suture in the arterial wall to achieve haemostasis. The Angioseal consists of an external collagen plug as well as an absorbable polymer footplate which is deployed within the artery and held in place by a thread and a tensioning device. The Vasoseal and the Duett devices consist of a collagen plug which is deployed on the external surface of the arterial wall at the puncture site.

Each type of closure device has its own specific strengths and drawbacks, so familiarity with more than one type is advisable. Common femoral artery disease is a contraindication to the use of the Perclose suture device and the Angioseal device which relies on the intravascular footplate. Misplacement of the footplate may occur if the arterial puncture is too low – at the common femoral bifurcation or below (Fig. 5.1). Thus a common femoral angiogram is recommended prior to deployment of these devices. On the other hand, common femoral artery disease is not a contraindication to the use of the Vasoseal or Duett devices.

The Perclose suture device is the only one which is completely independent of clotting factors, haemostasis being dependent only on the adequacy of the suture. Therefore this has the advantage in patients with severe coagulopathy and those who have received substantial doses of anti-coagulant, anti-platelet or thrombolytic agents.

Repuncture at the same site is possible at any time after the use of the Perclose device. Immediate repuncture is not possible after use of the Angioseal because of the intravascular footplate. Repuncture after an interval of 3 weeks is permitted.

The Perclose and Angioseal devices are contraindicated in the presence of arterial disease at the puncture site. This limits their applicability in much interventional radiology practice.

Success rates in deployment of the closure devices are generally high, although there is a definite learning curve with the Perclose in particular and a failure of proper deployment in a small percentage. Almost immediate haemostasis can be achieved in the great majority without the need for manual compression of the artery. This is popular with patients and staff.

5.6.2 Complications

Puncture site infection has been documented as a complication of all the devices, but not of manual compression, presumably the suture thread or collagen plug acting as a conduit for bacterial infection from the skin surface (Carey et al. 2001).

Ischaemic sequelae are described with both the Perclose and Angioseal devices. The mechanism may be due to physical obstruction of the artery by the Angioseal footplate, or to late neointimal hyperplasia. Flow limiting dissection has been observed following Perclose deployment, with or without thrombosis and distal embolisation (Wagner et al. 2003). Arterial narrowing, probably due to some of the collagen plug entering the arterial lumen has been described after use of the Vasoseal device (Foran et al. 1993).

Misplacement of the Angioseal footplate is reported and may be associated with a low puncture (Fig. 5.2). Common femoral angiography is recommended prior to deployment to ensure that the arterial puncture is at an appropriate level in a disease-free artery. Late migration of the footplate has also been observed.

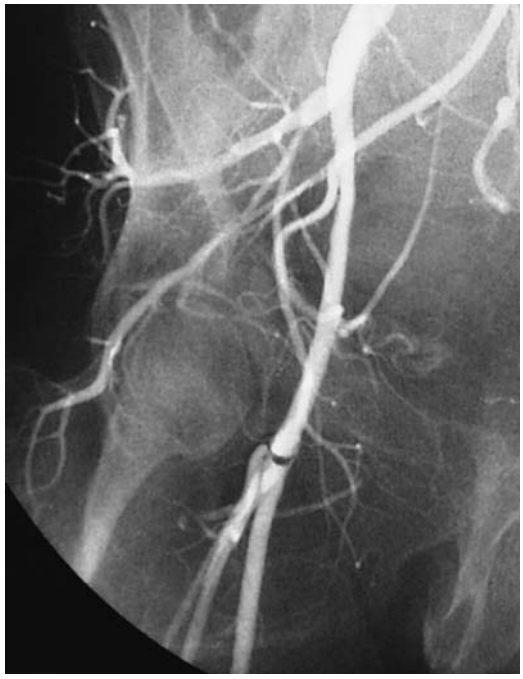

Fig. 5.2. Misplaced Angioseal footplate. The misplaced footplate is clearly seen as a well defined filling defect in the distal common femoral artery. The initial puncture was too low, probably in proximal superficial femoral or profunda. Hence the footplate has deployed across the common femoral bifurcation

5.6.3 Comparison with Manual Compression

There are numerous substantial series in the literature describing the use of closure devices. These are usually non-randomised and inhomogeneous, involving various regimens of anticoagulation and antiplatelet agents. None has shown any advantage over manual compression in terms of complication rates.

Two meta-analyses have recently been published, with aggregate data on all comparative studies. In the first of these (Koreny et al. 2004), when all randomised trials totalling 4000 patients are included, there was no difference in outcome in terms of haematoma or false aneurysm. The time to haemostasis was reduced in the closure-device cohort by 17 min. However, when analysis is restricted to a sub-group of high quality studies (those with allocation concealment, blinded outcome analysis and intention to treat analysis) a different outcome was observed; there was a significantly higher risk of both haematoma [relative risk (RR) 1.9] and false aneurysm (RR 5.4) in the closure device group.

The second meta-analysis (Nikolsky et al. 2004) included all randomised, case control and cohort studies for a total of 37,066 patients. The three main types of closure device were compared with manual compression. Individually there was no difference between the closure devices and manual compression in terms of complications. Collectively, there was an increased risk of complications associated with closure devices (odds ratio 1.34, 95% CI 1.10–1.79).

Two case-controlled study comparing suture-mediated closure with manual compression have suggested a significantly higher rate of complications, some serious, associated with the use of the closure devices. (Carey et al. 2001; Wagner et al. 2003). A review of the surgery required to deal with complications associated with arterial access (Boston et al. 2003) concludes that the complications associated with closure devices (infection, ischaemia,) are more complex and difficult to deal with than those associated with manual compression (haematoma, false aneurysm).

5.6.4 Current Indications

Some workers use closure devices routinely for procedures such as uterine fibroid embolisation in the belief that this permits safer same-day discharge. This is a subgroup with typically healthy femoral arteries. Recently the occurrence of some serious ischaemic and infective complications in the lower limb has led many to question the justification for their use and a moderation in enthusiasm for their use in routine cases. On the other hand, some centres continue to report good results with no serious complications (Chrisman et al. 2005).

There remains a subgroup of patients in whom closure devices are undoubtedly helpful. This includes patients with severe coagulopathy, or those who require continuous treatment with high does anticoagulation, antiplatelet or thrombolytic therapy. In these patients closure devices produce rapid haemostasis which would otherwise not be achievable. Other valid indications for their use include patients at increased risk of recurrent bleeding due to restlessness, confusion, inability to lie flat etc. Closure devices have been used with success following antegrade femoral puncture (Duda et al. 1999). There are also reports of their successful use to close subclavian artery punctures following inadvertent arterial catheterisation during attempted subcla-

vian central venous catheter placement (Nicholson et al. 2004).

Endoluminal repair of aortic aneurysm is usually performed following surgical exposure of the common femoral artery. This is because the delivery systems of the stent-grafts measure up to 8 mm diameter (24 F). An ingenious modification of the Perclose device has been developed to permit its use in percutaneous punctures of much greater diameter that it was originally designed for enabling these procedures to be done percutaneously. This modification, dubbed "Preclose," involves initial deployment of two Perclose sutures in the arterial wall, at an angle to each other. The sutures are not tightened at this stage. The puncture site is then dilated progressively to enable the stent graft delivery system to be introduced. At the end of the procedure, the delivery system is withdrawn and the suture knots are tightened. A reasonable success rate has been reported, with satisfactory completion of the procedure in about 75% of cases, the remainder requiring some sort of surgical repair of the arteriotomy (Rachel et al. 2002).

5.6.5 Evidence for Early Mobilisation

Much of the literature supporting the use of closure devices cites the reduced time to mobilisation following their use compared with manual compression. This, however, simply reflects the pre-determined protocols used in the various trials: those patients allocated manual compression follow a protocol which specifies a longer period of bed rest than those randomised to closure devices. Thus it is a foregone conclusion that use of a closure device will be associated with reduced time to mobilisation.

There is little evidence to underpin the bed-rest regimes that most centres follow. A meta-analysis of the controlled trials comparing longer versus shorter periods of bed-rest found that shorter periods of bed-rest were not associated with greater risk of complications (Allen et al. 1999). Indeed, side effects (mainly back pain) were increased by longer duration of bed-rest. All available evidence therefore suggests that even with manual compression, the shorter the duration of bed-rest the better. This fact was not unknown to the patriarch of interventional radiology, Charles Dotter, who wrote in 1960, when diagnostic catheter sizes were considerably larger than today's, "…..patients are kept under observation until they are able to walk freely without causing bleeding, usually 10 to 15 minutes after application of the dressing" (Dotter 1960).

Our own experience of day case interventional procedures using sheaths of up to 7 F suggests that same day discharge is safe in the great majority of patients, using manual compression alone. All puncture site complications in our series were apparent within 4 h of the procedure (Butterfield et al. 2000).

In summary, the routine use of closure devices definitely reduces the time to achieve haemostasis following arterial puncture. This appears to be at the cost of an increased risk of complications, sometimes serious. Furthermore, the evidence that patients can be mobilised earlier is poor. Judging by the activity of many internet discussion forums and American lawyers' websites, we can expect a flurry of litigation in respect of such complications. The routine use of closure devices is therefore questionable. There remain selected subgroups in whom closure devices are of undoubted benefit and in whom their use should be encouraged.

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6 Aortoiliac Intervention

Anthony A. Nicholson

CONTENTS

6.1 Introduction

The first peripheral angioplasties performed by Charles Dotter in 1964 were carried out in the superficial femoral artery. However, following the introduction of balloon angioplasty it is probably true to say that aortoiliac angioplasty and stenting has come to define peripheral vascular intervention. This is largely because these segments were the first areas in which early evidence suggested comparable outcomes with surgery but with reduced morbidity and mortality. In the US more people undergo aortoiliac stent placements than undergo aortofemoral bypass surgery (Murphy 2000).

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6.2 The Evidence for Aortoiliac Intervention

When considering the accumulated evidence for any therapeutic intervention, consideration should be given to whether randomised controlled trials (RCTs) and observational studies are mutually exclusive. To evaluate this requires some knowledge of why interventional radiologists and vascular surgeons turned so rapidly to percutaneous iliac intervention and why iliac stenting had such an impact from 1990 onwards. Both have been used to evaluate the question such different techniques pose. There are those who would dismiss observational studies on the basis that RCTs are seen as more reliable estimators of how well a treatment works. There is however evidence that observational studies do not over-estimate the size of treatment effect when compared with their randomised counterparts (Benson and Hartz 2000; Concato et al. 2000). In many instances concordance is in fact better between RCTs and observational studies than that observed when meta-analysis of small randomised trials are compared to the results of large randomised trials (Lau et al. 1998). This is probably because concordance is not perfect within these studies and also because variability previously seen as a nuisance factor may in fact simply mean that where randomised trials are studying diverse patient populations, observational studies are amalgamating larger populations to reach average population wide effects with less variability but more uncertainty about which sub group is likely to benefit.

For interventions that show very large harmful effects in observational studies, randomised trials may be justifiably discouraged and never performed. Similarly for interventions that have already shown large beneficial treatment effects in observational trials the ethics of randomisation may also be questioned. Conversely, interventions with mode postulated effects should be subject to randomised trials although it would be wrong not to give observational studies comparable credit

and to discard such evidence. Clearly there are also interventions with such small postulated effects that adequately powered randomised trials would not be possible to perform because of the required ample size. Here, only observational evidence may be generated (Ioannidis et al. 2001).

Where does aortoiliac evidence fit into this pattern? There would appear to be two aspects to the evidence; the choice between endovascular versus open surgical reconstruction and angioplasty versus stent.

6.2.1 Open or Endovascular Surgery for Symptomatic Aortoiliac Disease?

There are a great many observational studies in the literature which suggest that both surgery and endovascular treatment are safe and efficacious in the aortoiliac segments. However, the clinical differences shown are not great. Therefore RCTs should be the standard by which we decide which is best. There is only one RCT that has compared open surgery to angioplasty in symptomatic iliac disease (Wolf et al. 1993). In this study 263 men with iliac disease contributing to either rest pain or lifestyle limiting claudication were randomised to either surgery or angioplasty. Of these patients 126 underwent bypass surgery and 129 patients underwent angioplasty. There were 3 deaths in the group that underwent surgery and none in the angioplasty group. Primary success favoured open surgery but limb salvage favoured angioplasty, though these differences were not statistically significant. Patients in both groups had prompt and sustained increase in haemodynamics and quality of life and no significant difference in outcome in a median follow up of 4 years. This study clearly favours angioplasty as outcomes between the two treatments are no different but the morbidity and mortality is higher in the open surgical group. It is a study of one particular sub-group. There were no women in the study and traditionally they have smaller arteries which are more difficult to treat. However, this is true for both surgery and for endovascular treatment. In addition there are numerous compounding variables which the study has not taken into account. In a randomised study of this size it is impossible to perform sub-group analysis on those with comorbid conditions such as diabetes, heart disease, hypertension, renal failure or those with more proximal or more distal disease.

In a second, non-randomised comparative study the complication rate, primary patency and cost of stent deployment were compared with direct surgical reconstruction for the treatment of severe aortoiliac occlusive disease (Ballard et al. 1998). A total of 65 patients underwent stent deployment and 54 patients had surgical reconstruction. Statistical analysis found no significant difference between the groups in terms of clinical, demographic or presentational features and there were no significant differences in late complications. However, the cumulative primary patency rate for bypass grafts was significantly better than for iliac stents at 18 months (93% vs 73%), 30 months (93% vs 68%) and 42 months (93% vs 68%). Multi-variate analysis suggested that females, anyone with ipsilateral superficial femoral artery occlusion and anyone who had procedure related vascular complications and hypercholesterolemia were more likely to thrombose their bypass graft or stent. Costs did not differ significantly.

So here we have two studies with very different conclusions. The first is a randomised and the second an observational study. It is difficult to determine which of the many variables in the observational study affected which group, and it is of course possible that patients who were less fit for open surgery were treated by endovascular means.

So what should we tell our patients? The fact is that the literature regarding surgery or iliac intervention remains controversial. For this reason a Transatlantic Intersociety Consensus (TASC) working group looked at all the available evidence (TASC Working Group 2000). The TASC group graded evidence and made recommendations according to the US Agency for Healthcare Policy and Research Guidance for identifying levels of evidence. The document deals separately with the recognised vascular segments but also with intermittent claudication, chronic limb ischaemia and acute limb ischaemia. It points out that intermittent claudication is by and large a benign condition with fewer than 2% of patients ever requiring an amputation. The evidence suggests that the best predictor of this is an ankle brachial index at presentation of less than 0.5. Intervention for intermittent claudication should therefore be confined to patients with severe lifestyle limiting disease particularly affecting ability to work.

The acute and critical limb ischaemia situation is clearly different and where aortoiliac disease contributes to the condition it needs to be treated. The TASC document then goes on to classify disease at different segments. In recommendation 32, aortoiliac disease is classified into four types, A–D (Fig. 6.1). The TASC document considers that the available evidence is consistent with endovascular treatment

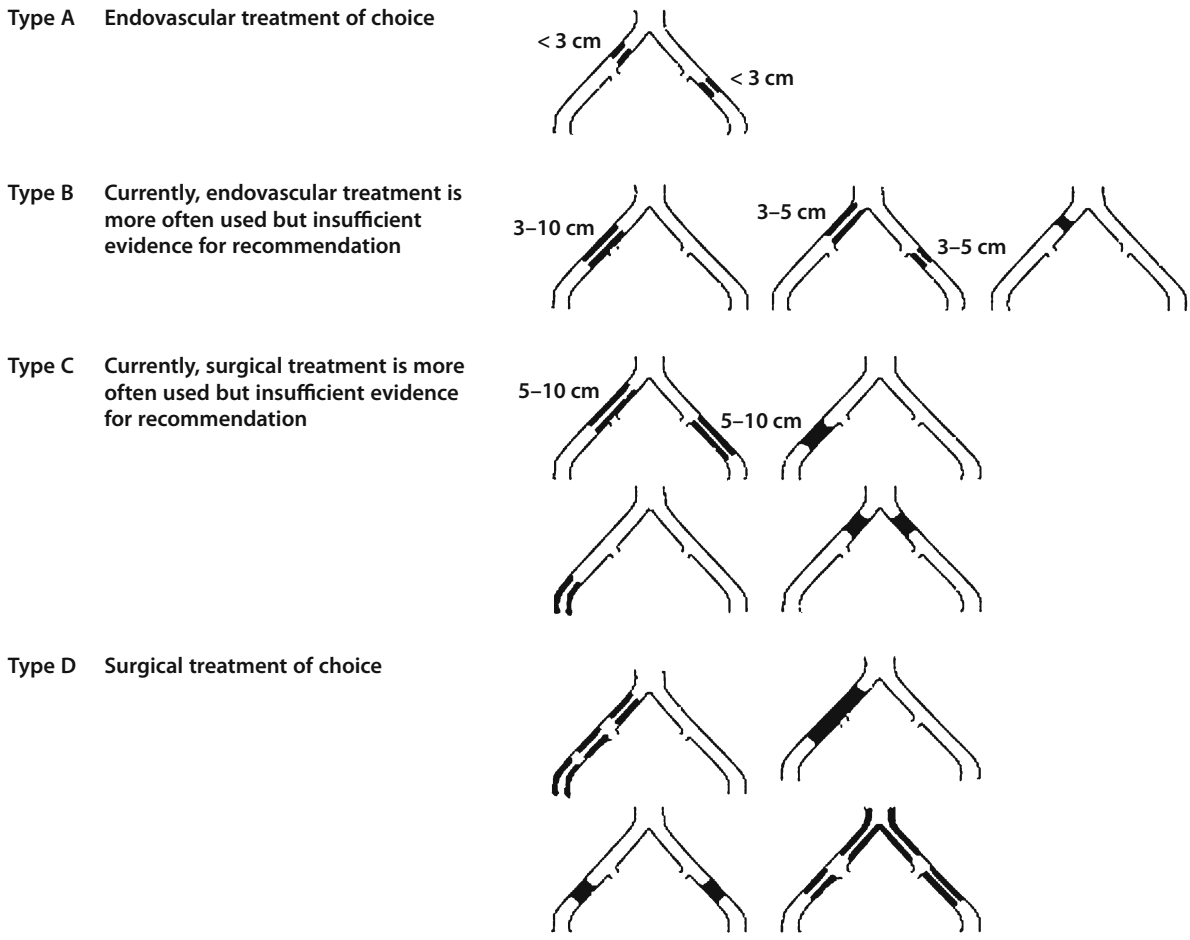


Fig. 6.1. TASC recommendations in the treatment of aortoiliac disease (TASC Working Group 2000)

for type A lesions and open surgical treatment for type D lesions. TASC considers that the evidence for the efficacy of one treatment instead of another is not sufficient for types B and C lesions. Of note is a recent survey among vascular surgeons in which it was stated that for all types of aortoiliac lesion the TASC document is generally ignored and endovascular treatment is performed where possible (Charing Cross International Meeting, March 2005).

Before looking at the evidence for angioplasty or stent, it is important to decide which lesions we should be treating.

6.2.2 When Is a Lesion Significant?

Aortoiliac intervention should only take place in the clinical scenario above and where there is a lesion likely to compromise blood flow thereby contributing to the patient's clinical symptoms. A number of imaging modalities will provide detailed and precise information about the morphology of the aortoiliac segment, and have been described in detail in Chap. 2. With regard to angiography the haemodynamic significance is usually measured by assessing the degree of narrowing it produces. Secondary signs such as asymmetric flow on the side in question, extensive collaterals and flow defects can give further information. However, there is intra- and inter-observer variability in the estimation of the degree of stenosis present when that estimation is based on the degree of a stenosis. In one trial measurements based on angiography alone were found to be only 45% sensitive and 63% specific (Kaufman et al. 1982). Intravascular ultrasound could give better measurements of cross sectional area of stenoses but it is expensive and not widely available. The measurement of a pressure gradient across a stenosis at the time of angiography should in theory give pre-

cise information about the significance of stenotic disease. However, there is no consensus in the literature regarding what constitutes a significant gradient (Nemeceka and Bhave 2000). Kamphius et al. (1999) found that by using all the suggestions from the available interventional literature on the significance of gradients they would have stented anything between 4% and 87% of their patients, emphasising the overall lack of consensus. They suggested that a mean gradient of 10 at rest or after vasodilation should be used as a marker of significance and this is generally accepted, though there is no evidence at all for this. Because some stenoses become more significant at higher flow rates and attenuate the higher frequency components of pressure waveforms many believe that the systolic pressure is the most sensitive measure of a significant stenosis. Others argue that peripheral resistance is far more important and that a mean pressure gradient is more closely related to this than a systolic gradient and is therefore more physiologic. Peripheral resistance can of course be decreased in order to mimic limb exercise with the use of vasodilators but there is no consensus on which vasodilator or dose, nor at what time a gradient should be measured. There are in addition many technical factors that can cause false readings. These include bubbles in the transducer, the diameter of the catheter in comparison to the diameter of the stenosis and whether the catheter has end holes or side holes. In addition simultaneous pressure measurements allow direct comparison of pressure waveforms proximal and distal to a stenosis while pull back pressure offer the advantage of a single transducer and unilateral vascular access. In reality most practitioners assess the pulses and the anatomical information provided by the angiogram. Pressures are often reserved to check post intervention gradients but when performed pre intervention a mean gradient of over 5 mm Hg is accepted if all the other features point to significance.

6.2.3 Angioplasty or Stent?

There is little data and therefore much uncertainty about the role of stents compared with angioplasty alone, particularly for patients with focal aortoiliac stenoses. However, early aortoiliac angioplasty had a high rate of embolic complications, particularly when dealing with occlusive rather than stenotic disease. Indeed many vascular radiologists felt that iliac occlusions should not be dealt with percutaneously because of an embolic complication rate of up to 47% (Ring 1982). The introduction of aortoiliac stenting was a response to this, patency improvement being a secondary consideration. It could therefore be argued that the RCT is unethical in aortoiliac occlusive disease. Nevertheless RCTs have been performed, though usually on a mixture of occlusive and stenotic disease with very dubious methodology. One such study demonstrated 4-year patency rates of 91.6% for stents and 74.3% for angioplasty alone (Richter 1989).

There is only one peer reviewed published randomized clinical trial that compares primary stent placement with PTA followed by stent placement if needed in the iliac arteries. The Dutch Iliac Stent Trial (DIST) (Tetteroo et al. 1998) enrolled 279 patients with lifestyle-limiting intermittent claudication caused by iliac artery stenosis or occlusion, and randomized them into two similar groups. Subjects assigned to group I received primary Palmaz (Cordis Corp, Miami, FL) stent placement for iliac disease; those in group II were treated with angioplasty, with stents reserved for patients with suboptimal angioplasty results as judged by a residual pressure gradient in excess of 10 mm Hg. Patients were to be assessed with interviews, treadmill studies, and sonography 3,12 and 24 months after treatment. The authors reported that 43% of patients who were randomized to angioplasty received iliac stents and that 2-year cumulative patency rates for the two groups were similar at 71% versus 70%. The authors concluded that because angioplasty followed by selective stent placement is less expensive than primary stent placement, the former should be the treatment of choice for lifestyle-limiting intermittent claudication caused by iliac artery occlusive disease.

However, only 29 iliac artery occlusions were treated among 279 patients, and by study design, patients with occlusions more than 5 cm in length were ineligible for enrollment. Even with that strict length threshold for eligibility, 10 of the 12 subjects (83%) with occlusions failed angioplasty alone. Although stents seem to offer special benefits in the treatment of longer segment and occlusive lesions (Vorwerk et al. 1995), little guidance about such patients (who might constitute 35%–40% of those with aortoiliac insufficiency in one's practice) is therefore provided by this trial.

Furthermore, most patients in the DIST study had mild clinical symptoms, and only 22% of patients in each group were classified as having Society for Vascular Surgery/International Society for Cardiovascular Surgery (SVS/ISCVS) grades 3–5 ischemia.

Only 10% of patients had diabetes, and only 10% had simultaneous iliac artery disease and occlusion of the ipsilateral superficial femoral artery. The mean pretreatment, resting ankle brachial index in both groups was 0.77. As a consequence, the milder pattern of atherosclerotic disease observed in the DIST study differed from that encountered in many interventional practices.

In addition the study was designed to have a 90% likelihood of detecting a 10% difference in post treatment arterial patency after 12 months between the two groups (power = 90%). Unfortunately, because of inadequate recruitment and funding, the trial was terminated after less than 80% of the intended sample had been enrolled. Outcome information after as little as 1 year is available in the published report for about 60% of subjects who ultimately enrolled, a fraction that actually represents less than 45% of the intended patient sample. Thus, even though the authors did not observe "substantial differences" in clinical outcomes between their experimental groups, the DIST study was more likely to miss than to detect the same potential 10% improvement in 12-month patency rates that was used to configure the trial as the actual power was less than 50%.

Because of under-recruitment, the authors attempted to amplify their sample by reporting the number of lesions treated, rather than the number of subjects actually involved. For example, a patient with simultaneous common and external iliac stenoses or occlusions was classified as two treated lesions, rather than as a single person. As a result, little information about crucial patient subgroups (e.g., occlusions vs. stenoses, common iliac vs. external iliac lesions) can be gleaned from this report.

There is a recently completed second RCT of stent versus angioplasty in aortoiliac disease (The STAG Trial). This is not yet published but a personal communication from the authors suggests that there are significantly fewer major complications following stent compared to PTA but that stents confer no benefit in terms of patency (P. Gaines, personal communication). If so then we are brought full circle to the original premise that stenting infers benefits in terms of reduced complications rather that improved patency. Though this author is not in a position to comment until the publication of this study, much will depend on the power of the study and the case mix and sub-group analyses within it. If these are inadequate then little of true value will be available from STAG.

As previously stated, it would be very wrong to ignore observational data when considering the evidence. A meta-analysis of such studies has been performed (Bosch and Hunink 1997). This found a better technical success rate for stenting (97%) rather than angioplasty (91%) $p<0.05$. It also found a better overall 4-year primary patency for iliac stents in critical limb ischaemia (67% vs. 35%), though this not the case for claudicants (77% vs. 65%). This emphasises the need for significant sub-group analysis in any study. A cost effectiveness analysis (Bosch 1998) of aortoiliac stenotic disease suggested that PTA and selective stent insertion for suboptimal results is the most cost effective option but did not deal specifically with technically more difficult and potentially complicated occlusive disease.

6.2.4 What Conclusions Can We Draw from the Evidence?

As shown there is conflicting and confusing evidence available. Conclusions are difficult to draw but a bottom line is probably the following:

- We should defer to the TASC recommendations most of the time.
- However, consideration should be given to the clinical state of the patient when considering open or endovascular surgery.
- Aortoiliac stenoses should be angioplastied, reserving stents for residual gradients greater than 10 mm Hg after vasodilators.
- Aortoiliac occlusions are best stented to reduce complication rates.

6.3 Technical Aspects

The femoral pulse is often weak or absent in aortoiliac disease. The quickest and simplest way of accessing a femoral artery under these circumstances is by direct palpation in thin patients (bearing in mind anatomical landmarks) or visualisation of common femoral calcification under fluoroscopy and direct puncture. Ultrasound is also useful but lengthens the time taken to puncture and can be difficult in obese patients. Where disease and symptoms are unilateral it is often better to perform angiography from the normal side where the femoral pulse is good, as iliac stenoses and many iliac occlusions can be accessed and crossed with a wire from the contralateral side. Guidewire access across an aortoiliac stenosis is

successful in the overwhelming majority of patients especially if torquable curved hydrophilic wires are used. Occlusions can often be crossed ipsilaterally but if this is not possible a subintimal channel can often be made which facilitates access from the contralateral side using a sidewinder type catheter.

6.3.1 Aortoiliac Stenotic Disease

As indicated above, the evidence suggests that angioplasty alone should be the procedure of choice in stenotic disease. A balloon should be used which is suitable to the diameter and length of the lesion. Oversizing is not recommended, as it leads to pain and possible rupture. Indeed, it is advisable not to have patients heavily sedated during the balloon inflation, and it is important to titrate balloon inflation according to the patient's tolerance. Pain is indicative of adventitial stretching and may herald arterial rupture. If severe pain is experienced, it is usually prudent to discontinue balloon inflation or to switch to a balloon with a smaller diameter. 3000–5000 IU of heparin is mandatory.

The end point for aortoiliac revascularization procedures is determined by intra-arterial haemodynamic measurements, which are readily obtained in this arterial segment. Ideally, simultaneous wave forms obtained above and below the treated segment should overlap, with no mean or systolic gradient. Generally, most patients have some separation of the wave forms at peak systole, with a slightly more rounded peak observed distally. The systolic gradient usually measures between 1 and 3 mm Hg, but the mean gradient may still be zero. Because of the variability in blood pressure over even short intervals of time, repositioning a single catheter across a lesion and measuring pressures at different times is an unreliable way to obtain pressure measurements.

Often, ideal haemodynamic results are not achieved because of recoil or patient intolerance to balloon inflation to a calibre consistent with elimination of the gradient. This situation may demand a stent of suitable diameter and length. Balloon mounted stents are normally preferred in this situation, though self-expanding stents may be desirable if the problem is intolerance.

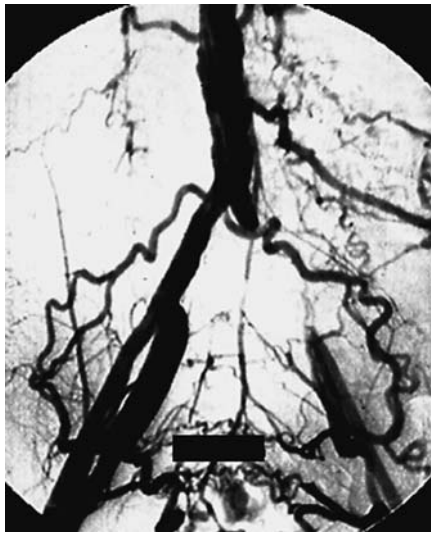
It should however be understood that in critical limb ischaemia there may be favourable outcomes even when borderline pressure gradients remain after intervention, because almost any haemodynamic improvement may provide benefits in favour of wound healing or symptomatic relief. In these patients, such a result is preferred over a prolonged procedure with increased risk of complications. An emergency surgical procedure should clearly be avoided. Conversely, patients who complain of intermittent claudication often have mild residual symptoms if a trans-stenotic gradient of more than a few millimetres of mercury persists. Injection of vasodilators to assess results of an intervention can be informative when the results are borderline in patients with intermittent claudication. A gradient of less than 8–10 mm Hg mean after intra-arterial injection of 0.2 ml of nitro-glycerine is considered a satisfactory result (Kaufman et al. 1982).

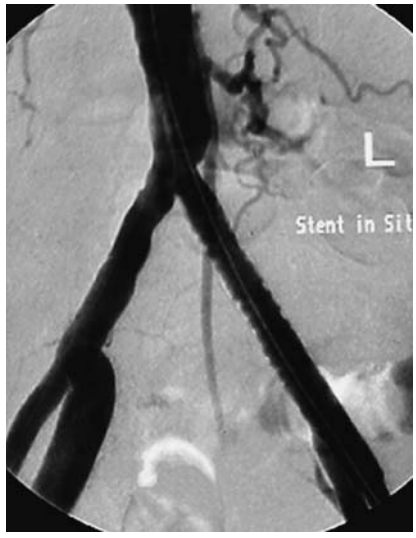
Isolated aortic stenosis should be treated with a balloon of appropriate diameter as the kissing balloon technique requires bilateral punctures and the end result is invariably inadequate because of the figure eight shape of the dilatation.

6.3.2 Chronic Iliac Occlusions

As stated above, the chronic iliac occlusion can be crossed from the ipsilateral or contralateral side. To avoid embolic complications such occlusions should, in the author's opinion, be stented, though some would disagree. This requires the insertion of a stent prior to angioplasty (Fig. 6.2). Self-expanding stents are indicated and in the author's experience they will always traverse the chronic occlusion over the wire. Again heparin is mandatory. Once a stent of appropriate diameter and length has been deployed it can then be inflated with a suitable sized balloon. If there is a suitable iliac stump at the ostium, a uni-iliac stent will work well. If however the occluded iliac artery does not have a stump and the aortic lumen tapers smoothly to the occlusion then "kissing" iliac stents may have to be used, even when the contralateral iliac artery does not have a significant stenosis (Dyet et al. 1993). This should be avoided if at all possible, as although the early results are good (Dyet et al. 1997), especially in small arteries, the long term patency is inferior to uni-iliac stenting. The external iliac artery is slightly more prone to rupture than the common iliac but responds as well to stenting.

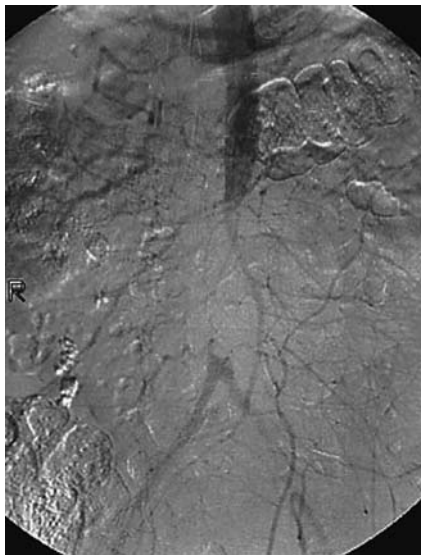
Thrombolytic therapy for chronic iliac occlusions adds cost, requires prolonged immobilization and hospital stay and carries the risk of bleeding complications. It should be reserved for acute aortoiliac occlusions (Fig. 6.3).


a



b

Fig. 6.2a,b. Chronic common iliac occlusion in a patient with lifestyle limiting intermittent claudication. There is a short segment of patent artery at the ostium allowing insertion of a uni-iliac stent with a good final result



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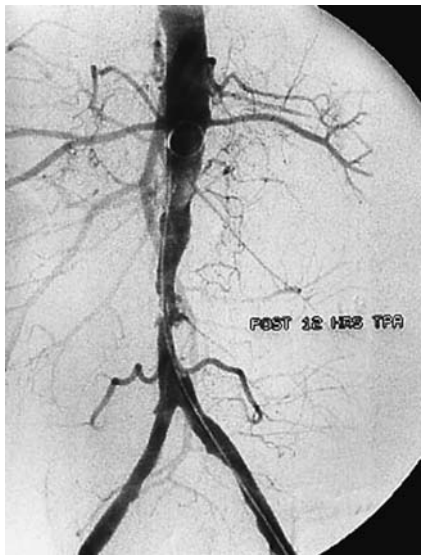

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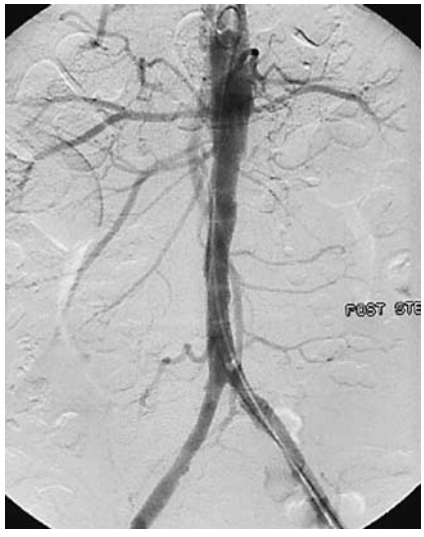

c

Fig. 6.3a–c. IVDSA (**a**) demonstrates aortic occlusion in a 76-year-old patient causing acute limb ischaemia. The patient was in sinus rhythm and had no previous cardiac history. An echocardiogram was normal. It was assumed that the occlusion occurred secondary to aortic plaque rupture. Following 12 h of thrombolysis the aorta was patent though clearly diseased (**b**). The segment was then treated successfully by stent insertion (**c**)

6.4 Complications of Iliac Angioplasty and Stenting

Complications and deaths do happen during aortoiliac interventions (Fig. 6.4). The British Iliac Angioplasty Study (BIAS) (British Society of Interventional Radiology 2001) followed 1135 patients for 12 months. The complication rate was 20.4%, though no treatment was required in 15.2% of these which were mainly small groin haematomas. Of these patients 2.8% required surgery or a transfusion and 2.6% required further endovascular treatment. Importantly arterial perforation occurred in four patients. Two of these had covered stents inserted and survived. The other two did not and died giving an overall mortality of 0.17%. The complication rates reported in BIAS confirm the early literature (Belli et al. 1990).

6.4.1 Puncture Site Complications

Haemorrhage and/or haematoma formation is not only the most common bleeding complication but is also generally the most easily recognized. However, it is important to remember that blood may dissect

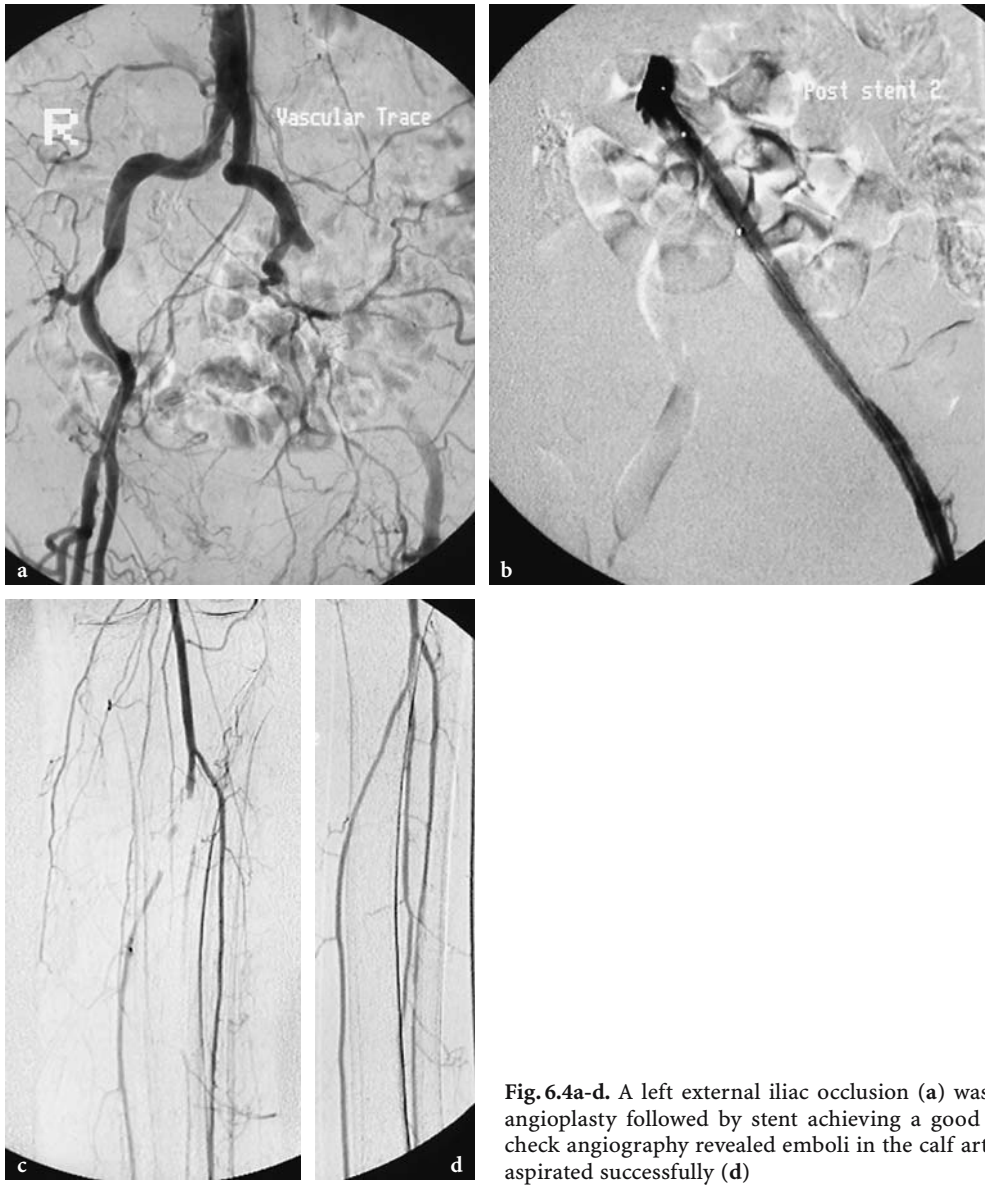

Fig. 6.4a-d. A left external iliac occlusion (**a**) was treated by primary angioplasty followed by stent achieving a good result (**b**). However, check angiography revealed emboli in the calf arteries (**c**) which were aspirated successfully (**d**)

away from the site immediately over the arteriotomy and, in the case of retroperitoneal extension, massive blood loss can occur without apparent local abnormality. Because of the lack of visible manifestations, failure to monitor pulse and blood pressure may allow critical and potentially fatal blood loss to go unchecked. A pulsatile mass at the puncture site may herald a contained leak or pseudoaneurysm, with the main concern being the potential for rupture and haemorrhage. For small lesions, careful observation may be best because many of these lesions will spontaneously close. Ultrasound-guided compression can be used in many cases because it is non-invasive and uses readily available equipment. However, success depends significantly on anticoagulant therapy. In those patients who are anticoagulated, the success rate decreases to 62% from 73%. In addition, this technique is sometimes limited by the inability to apply adequate compression because of patient discomfort or because of the wide neck of the pseudoaneurysm. Stent-grafts have been used but are costly and not without their own complications. Perhaps a safer therapy for pseudoaneurysms that cannot be treated with compression is percutaneous thrombin injection (see Chap. 15).

6.4.2 Arterial Rupture

One of the most dramatic and (fortunately) infrequent complications of angioplasty and stenting is arterial rupture. It is most often an immediate event with dramatic symptoms and angiographic findings. However, subacute and chronic presentations are also possible. There are several risk factors for arterial rupture. Steroid therapy is a commonly recognized risk factor. Other conditions that weaken the arterial wall include the presence of fibromuscular dysplasia, adjacent inflammatory arterial changes, or infection of the arterial wall. Mechanical factors also contribute. Overdistention of the artery by the use of too large a balloon is a commonly stated concern. However, in most reported cases of rupture, the authors had thought that the balloon was appropriately sized. Rupture of the angioplasty balloon may also contribute to the arterial rupture. This is caused by a sudden delivery of a high-pressure jet at a focal point from the hole in the balloon. In some cases, surgeons operating to repair a rupture have identified large, sharp or densely calcified atherosclerotic plaques that probably sliced through the arterial wall during balloon inflation. Prior mechanical trauma, such as laser recanalization or balloon thrombectomy, may predispose to arterial rupture either by actual perforation or by weakening of the arterial wall.

The most important first step to managing an arterial rupture is recognition of the problem. This allows rapid response and control of the situation before excessive haemorrhaging occurs. Often, when rupture occurs during angioplasty, the patient experiences severe pain. Interestingly, the pain may relate not to the rupture itself but to the pressure caused by blood leaking out of the artery. Reinflation of the angioplasty balloon to tamponade the leak often leads to immediate relief of the pain. In some cases pain also causes immediate systemic symptoms, such as bradycardia, diaphoresis, and decreased level of consciousness. Unfortunately, one cannot rely on such dramatic symptoms to herald a rupture. Cases of rupture have occurred with the patient having no pain or other symptoms. Thus, it is very important always to perform an arteriogram immediately after angioplasty. Gross extravasation of contrast is generally seen in cases of frank rupture. A secondary fluoroscopic sign is medial displacement and effacement of a contrast-filled bladder secondary to mass effect from the retroperitoneal haemorrhage.

Once an arterial rupture is recognized, rapid action is required to prevent death. Maintaining a wire across an angioplasty site until the result has been assessed is vital. Having a wire past the disruption will allow one to gain immediate control of the situation. Tamponade of the leak can usually be easily achieved by inflating a balloon across the area of rupture, most often the same balloon that was used for angioplasty. However, one should not assume that this same-size balloon will suffice. Thus, arteriography should be performed both proximally and distally to the rupture to ensure tamponade. Because patients may have hypotension or bradycardia, the operator must also attend to resuscitation with intravenous fluids and/or atropine as needed.

Once the haemorrhage is controlled and the patient has been resuscitated, attention can be turned to definitive therapy. In the past ruptures were managed surgically with either patching of the vessel or with ligation and bypass. However, balloon tamponade described above may also provide definitive treatment, though with the risk of thrombus formation and embolisation. In the modern era of endovascular therapy, the most elegant potential solution to arterial rupture is endovascular stent grafting. Obviously, for this to be a viable option, one must have an endovascular graft readily available. An alternative to stent grafting is the deployment of

a bare metallic stent. This probably works by compressing the arterial wall layers against each other thus sealing the leak. One must remember, however, that several cases of arterial rupture have reportedly occurred during primary stent deployment. Having graft material as an impermeable barrier to cover the arterial defect would certainly seem to be preferable to the use of a bare metal stent. Although arterial rupture would seem to be a catastrophic event, almost all of the reported cases have been successfully managed without loss of life or limb.

6.4.3 Embolization

Embolization occurs more frequently than we think. A Doppler probe placed on a common femoral artery during iliac intervention will confirm this. However, significant embolic events occur in 3%–7% of patients (Dyet et al. 1997). Emboli can consist of atherosclerotic plaque, thrombus or cholesterol. The nature of the emboli determines the success of the different therapeutic options. Local thrombolytic infusion, which is a mainstay of treating distal emboli, works poorly if the embolus is solid material like plaque. Percutaneous aspiration thrombectomy is a good technique for either thrombus or plaque. It requires a non-tapered catheter with a large end hole. Occasionally large emboli have to be surgically removed.

Lesion type is a risk factor with significant embolic events occurring in iliac occlusions more frequently than with stenoses (Ring 1982). In one series embolization occurred in 9% (6 of 66) of patients with iliac occlusion but in only 0.9% (2 of 223) of patients with stenoses (Strecker et al. 1996). Some authors think that the risk of embolization relates to how the stent procedure is performed. This author's published experience (Dyet et al. 1997) was of five episodes of embolization out of 72 iliac occlusions (6.9%) that were treated with stenting. All occurred during balloon dilatation before stent deployment. Based on this experience, secondary dilatation after deployment of a self-expanding stent is the technique of choice. However, primary stent deployment does not completely eliminate the risk of embolization.

6.4.4 Stent Related Complications

Device related problems such as failure to deploy or misplacement are increasingly rare and beyond the scope of this chapter. Stent infection is an extremely serious complication that carries a significant risk of morbidity and mortality, and is rare. However, infection does occur sporadically. It has been speculated that the incidence of stent infection is probably significantly underreported because few clinicians suspect that arterial stents can become infected.

Although the cause for stent infection is sometimes obscure, a number of factors have been implicated. Multiple catheterizations of the same groin site has been implicated as have increased procedural time and local haematoma formation. Temporally remote events that lead to bacteraemia can also lead to stent infection.

The presentation of stent infection is variable. Acute stent infection can be seen as quickly as 2 days after implantation, whereas some patients with remote or secondary stent infection have presented years after the initial procedure. Pain, fever and white blood cell count elevation are common, though some patients have presented both without fever and with normal white blood cell count. A pulsatile mass can herald formation of a pseudoaneurysm. Another manifestation of an infected stent is septic emboli to the leg. This may appear as a rash or painful petechiae in the leg or hypogastric region.

Once a patient is suspected of having an infected stent, management should be aggressive. Antibiotics should be administered as soon as blood cultures have been obtained. *Staphylococcus aureus* is the most common offending organism and antibiotic therapy should tailored to this bacterium. However, antibiotics alone are probably not sufficient. The most common therapeutic strategy has been resection of the infected segment and surgical bypass. Fatalities and limb amputations have occurred but given the large number of stents that have been placed without infectious sequelae, it is unclear if antibiotics should be used routinely at the time of implantation.

6.5 Conclusion

There is a large body of evidence supporting the safety and efficacy of the endovascular treatment of iliac arterial lesions under the appropriate clinical circumstances. Although debate continues, it seems a reasonable strategy to perform angioplasty for iliac stenosis, employing stents where angioplasty alone has failed. Iliac occlusions, however, should

be managed by primary stent insertion to avoid the high risk of distal embolisation. The results of iliac artery angioplasty or stenting are comparable to those of surgery, and despite the TASC recommendations, a majority of surgeons and interventional radiologists seem to favour the endovascular option wherever possible. Serious complications are relatively uncommon, but procedures should always be performed with very careful technique, including maintaining the guidewire positioned across the lesion until a satisfactory result has been confirmed. This allows the management of any complication endovascularly, meaning that it should only rarely be necessary to resort to surgery.

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7 Femoropopliteal Arterial Intervention

Gunnar Tepe

CONTENTS

7.1 Introduction

With the rise and development of new endovascular techniques during the past two decades, the treatment of peripheral arterial disease (PAD) has undergone dramatic change. In January 2000, the Trans-Atlantic Inter-Society Consensus document was published in order to create standardized guidelines for the management of PAD (TASC 2000). Since January 2000, a new generation of nitinol self-expanding stents and stent-grafts has become available. In addition, new techniques such as brachytherapy, cryotherapy, and cutting balloons are being used for prevention of restenosis. These newer devices and techniques were not included in the TASC 2000 literature summary and recommendations. With the evolution of such devices there are new opportunities for endovascular intervention in the SFA. The purpose of this review is to summarize different new approaches, their limitations, current important clinical trials and future developments which may change treatment paradigms. The basic techniques of intervention in the SFA are well described in many other texts, and will not be dealt with.

The superficial femoral artery (SFA) and popliteal artery are frequently affected by atherosclerotic disease. In the past, revascularization has been by means of surgical femoropopliteal or femorodistal bypass (TASC 2000; Cheng et al. 2001). However, open surgery is more invasive, requires longer hospitalization, is less successful where distal run-off is limited and anticoagulation may be required where there is an anastomosis below the knee.

7.2 The History of Interventional Treatment in the SFA

Non-surgical revascularization began in earnest more than 20 years ago with percutaneous angioplasty (PTA). One major limitation of PTA is the restenosis rate due to early vessel recoil and neointimal proliferation. Unlike other vascular beds, the incidence of restenosis in the SFA is very high (Fig. 7.1) with restenosis rates of 20%–70% being reported (Duda et al. 2003, 2005). This compares with 6-month restenosis rates (defined as stenosis greater than 50%) of 20%–35% in the coronary arteries, 15%–20% in the renal artery and 2%–5% in the carotid artery after angioplasty alone. In the SFA, the technical success and durability strongly correlate with the lesion morphology, with generally poorer results after treatment of longer stenoses and/or occlusions (TASC 2000). Metallic stents have been highly successful in reducing restenosis rates in territories such as the coronary and renal arteries. However, no such benefits were initially demonstrated in the SFA. Patency rates 12 months after the placement of Wallstents (Boston Scientific, Natick, Maryland) and Palmaz stents (Cordis, Miami, Florida) in mostly short SFA lesions have been reported to range between 22% and 61% (TASC 2000).

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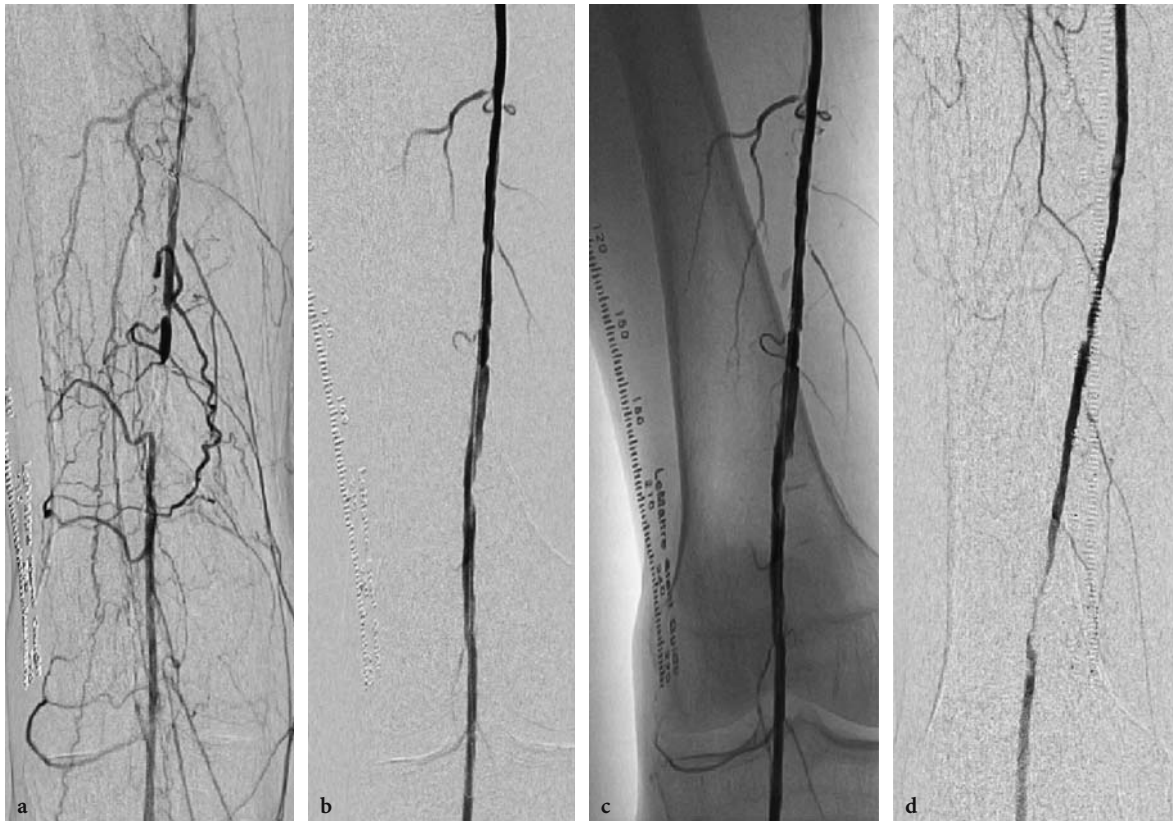

Fig. 7.1. a Digital subtraction angiogram of the superficial femoral artery of a patient with claudication. The short occlusion was successfully dilated (**b**,**c**). However, after 6 months, restenosis occurred (**d**) which correlated with recurrent limitation of walking distance

7.3 Equipment and Technique

The SFA can be approached either contralaterally or ipsilaterally. The contralateral approach involves crossing the aortic bifurcation, making it more complex. A long sheath placed over the bifurcation may be of value, and certainly the technique may be helpful in treating proximal lesions. The ipsilateral approach is in many ways simpler. An antegrade puncture of the common femoral artery is performed below the inguinal ligament. It has the advantages that standard length guidewires and balloons may be used, and any complications that may occur can be managed relatively easily.

Angioplasty can be carried out using 5-F vascular sheaths, but if stents are to be used 6-F sheaths will be required. Having placed a sheath in the vessel the lesion must be crossed. In the case of stenotic disease this is usually relatively easy. However, occlusions may be more difficult to cross, especially if they are calcified. Here, hydrophilic guidewires, such as the Terumo (Terumo Corp., Japan) are of immense value. In the case of occlusive disease, the passage of the guidewire will often be subintimal, and some workers set out deliberately to form a subintimal channel, claiming superior results.

7.4 Nitinol Self-Expanding Stents

Nitinol stents have been proposed as a potential solution for treatment of complex SFA lesions. Modern nitinol stents exert a constant radial force on the arterial wall and are more flexible than their predecessors, including balloon expandable stents such as the Palmaz. Currently, there are several nitinol stents available on the market including the Luminex (Bard, Murray Hill, NJ) and Zilver stents (Cook, Bloomington, IN). However, most of the available data relates to the SMART stent (Cordis, Miami, Florida). The clinical results of the various stent designs may

not be the same, as there are important differences between their designs and surfaces.

Due to their poor flexibility, balloon expandable stents can only be used to treat short lesions. In addition, because of the high restenosis rates, they were only used to treat the complications of balloon angioplasty such as elastic recoil or flow limiting dissection. Several studies suggest that the patency rates are higher with nitinol stents than with PTA or stainless-steel stents (v.i.), and in the future such devices may therefore be more widely used in the SFA.

7.4.1 Self-Expanding Stents for Prevention of Restenosis

In a retrospective analysis of primary stenting of 92 limbs in 82 patients with chronic limb ischemia, Mewissen (2004) implanted 189 SMART stents (2/limb, lesion length 4–24 cm). The lesion characteristic according the TASC classification was "A" in 10, "B" in 49, and "C" in 33 patients. Post dilation was performed only within the stent, avoiding angioplasty of the vessel at either end (Mewissen 2004). The immediate technical success rate was 98%, and patients were followed for a mean of 263 days. At 12 months, the restenosis rate (stenosis greater than 50%) was 22%, and at 24 months 44%. Interestingly, the TASC grade, stent length, gender, or level of ischemia did not predict in-stent restenosis. These high patency rates after SMART stent implantation are in line with observations of others. Vogel (1994) described primary patency rates of 95%, 84%, and 84% after 6 months, 1, and 2 years in a total of 41 patients. The longest follow-up of nitinol stents in the SFA is available from the SIROCCO 1 and 2 databases. Duda et al. (2002, 2005) reported their results of 46 patients who had chronic limb ischemia and SFA occlusion (57%) or stenosis (average lesion length, 81.4 ± 51.7 mm) who received bare SMART stents. The restenosis rate in the stent at 6 months was 11.6%. The improvements in ankle brachial indices and symptoms of claudication were maintained over 24 months. An example of an excellent long-term result of a SMART stent is given in Fig. 7.2.

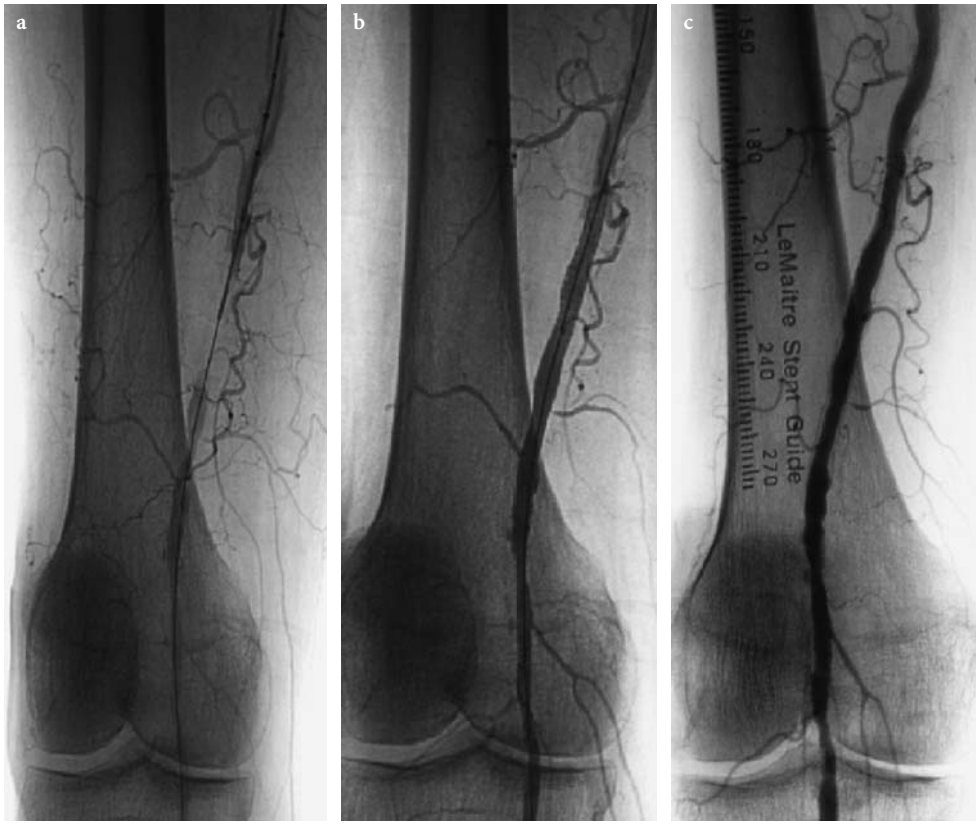

Fig. 7.2. a Digital subtraction angiogram of the superficial femoral artery of a patient with claudication. The occluded artery was successfully crossed with a guidewire and one Nitinol stent was placed (**b**). The follow-up angiogram after 6 months (**c**) showed no recurrent restenosis. The patient had unlimited walking distance

7.4.2 Drug Eluting Stents in the SFA

Drug eluting stents have been revolutionary in the field of coronary intervention. Due to the dramatic reduction of restenosis, both with sirolimus (rapamycin) and taxol (paclitaxel) coated stents, increasing numbers of patients receive those stents as first line treatment for prevention of restenosis after coronary intervention. To date, one trial has been published which examines the potential role of drug eluting stents in preventing restenosis in the SFA, the SIROCCO study. In SIROCCO I, 36 patients with symptomatic peripheral artery disease were treated in a multicentre, prospective, randomized study comparing sirolimus-eluting SMART stents with uncoated SMART stents.

Sirolimus has a unique dual action mechanism involving both anti-inflammatory and cytostatic antiproliferative effects resulting from inhibition of a signal transduction kinase, the mammalian target of rapamycin (mTOR) (Duda et al. 2003; Tepe et al. 2005; Toutouzas 2002). All patients had de novo or restenotic lesions with a diameter stenosis > 70% over a length that ranged from 7 to 20 cm or occlusions that ranged from 4 to 20 cm. The primary endpoint of this study was the in-stent mean percent diameter stenosis by quantitative angiography at 6 months. In addition, all patients received clinical follow-up and Doppler ultrasound for 2 years. The results at 6 months demonstrated inhibition of in-stent neointimal proliferation, reflecting a trend toward a reduction in late loss. The rate of binary restenosis (defined as stenosis greater than 50%) was 0% in the sirolimus-eluting stent group and 23.5% in the uncoated stent group. Interestingly, the restenosis rate for the uncoated stents was much lower than had been expected from results published in the literature with Wallstents and Palmaz stents. The SIROCCO I study also compared two different types of drug eluting stent, and found that the results of slow-eluting stents were superior to fast-eluting stents. Therefore, the SIROCCO II study was undertaken to compare the slow-eluting stents with bare stents (Duda et al. 2005). The 6-month analysis supports the good results of the drug eluting stents of SIROCCO I. Although not published yet, the 2-year data have been recently reported. At this time, there is no significant difference between the drug eluting and bare stents. It seems, therefore, that the benefit of the drug elution may be lost after 2 years.

7.4.3 Mechanical Limitations of Self-Expanding Stents in the SFA

Until recently, fractures of nitinol stent struts have only been reported in single cases after stent implantation across flexion points. However, during systematic angiographic follow-up after long segment femoral artery stenting with conventional and sirolimus-eluting nitinol stents, performed in the SIROCCO I study, stent fractures were observed in 18.2% after 6 months and in 24% after 2 years of the cases (Duda et al. 2003, 2005). In SIROCCO I, the number of stents to be used was limited to three whereas in SIROCCO II a maximum of only two stents was allowed. In SIROCCO II there was fracture rate of 11.6% at 6 months with only an additional two stent fractures at 24 months. No correlation between the fracture rate and the incidence of restenosis has been reported. However, there was one re-hospitalization associated with a stent fracture. This patient, although asymptomatic, underwent prophylactic placement of a stent-graft for vessel ulceration at the site of a strut fracture. Scheinert et al. (2005) have undertaken a systematic X-ray follow-up evaluation of all patients treated in their institution with self-expanding nitinol stents in the SFA. Fractures were detected in 37.2% of the stents. The incidence of fractures was higher after long-segment femoral artery stenting versus short-segment stenting. The fracture rates differed between the varying available stents with lower rates reported for the SMART and the SelfX (Abbott Vascular, Beringen, Switzerland) stent and higher rates for the Luminex stent (BARD, Murray Hill, NJ). Even though these findings raised concerns, their clinical significance remains unclear.

7.5 Stent Grafts

Stent grafts have been used in the SFA in the hope of preventing acute closure as a result of elastic recoil, and inhibition of vascular smooth muscle cell proliferation, with consequent restenosis, inside the lumen. Early results and short-term follow-up data with Dacron-covered stent-grafts were promising (Ahmadi et al. 2002). However, significant clinical problems were encountered, including post-implantation syndrome with fever and persistent pain in approximately 50% of the patients, an early rethrom-

bosis rate of 17% and a primary 2-year patency rate below 50%. Therefore, Dacron-covered stent-grafts have not been further evaluated. Unlike Dacron, the ePTFE (expanded polytetrafluoroethylene) coated stent-graft (Hemobahn endoprosthesis, W.L. Gore & Associates, Flagstaff, CA), showed much improved results. The largest study to date is the International Feasibility Study. This study of 80 patients with SFA occlusive disease showed excellent clinical results with 79% primary and 93% secondary patency rates at 1 year (Bray et al. 2003). Even in long-term follow-up, Saxon et al. (2003) demonstrated primary patency rate of 87% at 2 years follow-up, though this was a single-centre trial which enrolled only 15 patients (Saxon et al. 2003). The only negative results with this prosthesis were published by Deutschman et al. (2001). The 49% patency rate might be attributable to an edge effect due to both oversizing of the stent and post-dilation of the stent edges beyond the stented area.

A different PTFE covered prosthesis was evaluated in the COVENT study and recently presented by Wiesinger et al. (2005). In total, 130 stents were placed in 98 patients. Primary patency rates were 92% at 6 months and 90% at 1 year. Secondary patency rates were 98% and 96%, respectively. Limitations of stent grafts are the larger sheath sizes required and the higher cost compared to uncovered stents.

7.6 Cryoplasty

The PolarCath peripheral balloon catheter (Boston Scientific) is a novel angioplasty system that simultaneously dilates and cools the plaque and the vessel wall in the treated area. Cooling is achieved by inflating the balloon with nitrous oxide rather than the usual saline/contrast mixture. The surface of the balloon rapidly cools from 37°C to –10°C. It is believed that cooling induces an acute phase change that triggers apoptosis in smooth muscle cells (Grassl and Bischof 2005). The drop in temperature causes interstitial fluid in the arterial wall to freeze. Ice crystals form, generating high radial, longitudinal, and circumferential forces. This non-inflammatory form of cell death can potentially produce several beneficial effects, including reduced elastic recoil and constrictive remodeling, as well as reduced neointimal hyperplasia.

Despite FDA approval in late 2002 and availability on the European market since the beginning of 2005, clinical data on cryoplasty are limited. Fava et al. (2004) reported 15 patients with femoropopliteal arterial lesions which were treated with cryoplasty. Cryoplasty was performed at 6 atm of pressure and delivered at –10°C for 60 s. Technical success was achieved in 93%, and after 6 months there was 0% binary restenosis. Late angiographic follow-up at 14 ± 4 months demonstrated primary patency of 83.3%. In a multicentre registry, 102 patients were enrolled at 15 sites in the US and Germany. Stand-alone success of the PolarCath was achieved in 87%. In an interim analysis of 45 patients, the 9-month clinical patency was 85% (Grassl and Bischof 2005; Fava et al. 2004).

7.7 Cutting Balloons

Cutting balloons are relatively new devices which were originally designed for the percutaneous treatment of recurrent stenosis due to neointimal hyperplasia within coronary artery stents. The catheters have three to four microsurgical blades mounted longitudinally on the balloon. They are designed to cut directly into the stenotic lesion during the initial balloon inflation (Ansel et al. 2004; Cejna 2005). The blades disrupt the ring of neointimal hyperplasia, theoretically preventing elastic recoil, and dilate rigid stenosis that respond poorly to PTA alone. Additionally, microincisions produce a directed neointimal disruption and less wall tension than the diffuse hoop stress produced by conventional PTA, thereby minimising intimal trauma. The data with cutting balloons in the peripheral vasculature are limited. Engelke et al. (2002) reported 15 consecutive patients who were treated with the cutting balloon for 16 anastomotic stenoses after infrainguinal bypass surgery. The technical success was 94% with cumulative patency rates of 84% and 67% at 6- and 12- to 18-month follow-up, respectively.

7.8 Brachytherapy

Only a small number of trials have investigated the effectiveness of endoluminal irradiation in femoropopliteal arteries. The first clinical data in peripheral arteries were obtained in a non-random-

ized study on recurrent stenoses initiated in 1990. Long-term results of up to 7.5 years after treatment demonstrated a patency rate of 84% (Böttcher et al. 1994; Liermann et al. 1994, 1997). The study was limited, however, by the small number of patients, its non-randomized nature, as well as follow-up with angiography being obtained in only a limited number of patients.

In the Vienna-2 study, a total of 113 patients with long-segment lesions of the superficial femoropoliteal artery were randomized either to receive PTA alone or brachytherapy with an iridium-192 source (Pokrajac et al. 2000). The restenosis rate at 6 months was 54% in the PTA arm versus 28% in the PTA plus brachytherapy arm. Limitations of this study were that it was non-blinded and the device for radiation delivery was not centred within the vessel lumen. Subsequently, brachytherapy was investigated in further prospective blinded trials using a centred iridium-192 source (Vienna-3 up to Vienna-5) (Pokjrajac et al. 2005; Wolfram et al. 2005a,b). Although endovascular brachytherapy with gamma radiation proved to significantly reduce the restenosis rate after femoropopliteal angioplasty of recurrent lesions, it was of no benefit in de novo lesions. The Vienna-5 study was carried out to evaluate the effectiveness of endovascular brachytherapy in the prevention of restenosis after femoropopliteal stent implantation. Brachytherapy together with stenting did not improve 6-month patency because of a high incidence of early and late thrombotic occlusions.

The recently reported final results of the Peripheral Artery Radiation Investigational Study (PARIS), a randomised trial of peripheral brachytherapy performed in the USA, showed no difference between the treatment and the control group with respect to clinical and angiographic end points. Despite the difficulties with patient recruitment and follow-up in PARIS, these negative results had the consequence of abolishing peripheral endovascular irradiation by most interventionalists in the US (Waksman et al. 2001). In summary, more data exist which support the theory of endovascular therapy being effective in reducing the restenosis rate in peripheral arteries. Nevertheless, in particular the logistical problems posed by the need for different departments (interventionalist, radiation specialists) to be available at the same time, safety issues addressing the problem of the use of radiation in a benign disease, and the availability of alternative treatment modalities result in very limited use of this technology.

7.9 Conclusion and Future Considerations

Since the publication of the TASC document in 2000, several new devices have been developed which may improve the outcome of endovascular therapy in the SFA increasing the success rate and especially reducing the incidence of restenosis. Therefore, the use of endovascular treatment in TASC A and B lesions may become the norm. Brachytherapy seems to reduce the restenosis rate in restenotic lesions but, compared to other approaches, afterloading therapy is very time-consuming and complicated. The literature on cutting balloons and cryoplasty is very limited, so that a final conclusion can not be drawn. Self-expanding nitinol stents clearly showed improved patency rates compared to balloon angioplasty. The clinical relevance of stent fractures is currently unclear, but may yet limit the role of stents in the SFA. In early/mid 2006 a revised TASC document will be published. It will generally be more in favour of interventional treatment over the surgical approach. The document will take into account the new data which are summarized in this chapter.

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8 Crural Arterial Interventions

J. A. Reekers

CONTENTS

8.1 Introduction

Crural artery disease can be seen in combination with more central peripheral arterial disease (PAD), but it may also be seen predominantly in isolation below the knee. Age- and sex-adjusted odds ratios for current smoking status and plasminogen levels are significantly associated with atherosclerotic disease in the aortoiliac and femoropopliteal segments, whereas with diabetes mellitus the association is found to be in the crural and femoropopliteal segments. There seems to be no association for lipid profiles and fibrinogen (Haltmayer et al. 2001). Also other risk factors for PAD, such as elevated erythrocyte mean corpuscular volume, which has been shown to be an independent predictor of severe atherosclerosis in the iliac and the femoropopliteal segment, have no relation to crural vessel disease (Mueller et al. 2002). Thus, there is a clear relation between atherosclerotic crural artery disease and diabetes. As diabetes has more or less reached endemic proportions with an annual yearly growth of 2.5%, it is to be expected that management crural vessel disease will become an increasingly important part of our endovascular practice. Even more so due to the negative impact of crural disease and subsequent critical ischaemia, on the quality of life and the poor prognosis with regard to limb salvage and survival. The combination of diabetes, crural vessel disease and critical limb ischaemia is an important public health issue.

8.2 Epidemiology

The term critical limb ischaemia refers to a condition characterized by chronic ischaemic rest pain, ulcers, or gangrene in one or both legs attributable to objectively proven arterial occlusive disease. Critical limb ischaemia implies chronicity and is to be distinguished from acute limb ischaemia. Its incidence is approximately 500–1,000 per million year (people, population), with the highest rates among older subjects, smokers and diabetics. Furthermore, patients with critical limb ischaemia have an elevated risk of future myocardial infarction, stroke and vascular death, three-fold higher than patients with intermittent claudication. Critical ischaemia should therefore not been seen and treated as a stand-alone manifestation of PAD and management of associated risk factors is very important to favourably influence the risk profile in each patient suffering from PAD.

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8.3 Treatment Options

Surgical options including amputation and bypass surgery have dominated treatment for decades. Despite this, the first percutaneous transluminal angioplasty (PTA) ever performed, by Dotter in 1964, was for critical ischaemia. Patency rates after infrapopliteal bypass surgery are influenced by many factors: inflow state, type of conduit, number of calf vessels, presence of uninterrupted flow to the foot, and patency of pedal vessels (Aune et al. 1996; Bertele et al. 1999; Panayiotopoulos et al. 1997). Published success rates are highly variable; this is probably accounted for by patient selection (Roder et al. 1997; Panneton et al. 2000; Cavillon et al. 1998).

Primary patency rates after distal venous bypass can be up to 58% at 1 year and 37% at 5 years. For prosthetic grafts, patency rates are much lower (Horvarth et al. 1990). Balloon angioplasty was for some time considered a second best treatment. However, with the publication of excellent results for angioplasty, including the use of subintimal techniques, in the early 1990s, this changed (Horvarth et al. 1990; Flueckiger et al. 1992; Hauser et al. 1996; Schwarten and Cutcliff 1988). Percutaneous treatment is now seen by many as the first option for treatment of critical ischaemia due to crural vessel disease.

8.3.1 Indications for Treatment

The primary indication for crural intervention is limb salvage. However, with the known low complications rate from PTA, Fontaine IIb is also seen by some authors as an indication to treat stenosis (Horvarth et al. 1990; Flueckiger et al. 1992; Hauser et al. 1996; Schwarten and Cutcliff 1988). For occlusions, however, claudication is not considered an appropriate indication, as there is a high potential complication rate.

In the literature, the rate of primary amputation for critical lower leg ischaemia ranges from 10% to 40%. It is performed when no distal vessels suitable for grafting are present, or in neurologically impaired or non-ambulatory patients. So, patients with chronic leg ischaemia (CLI) face a gloomy future. Long-term survival with CLI is significantly lower than that of a matched population (Bertle et al. 1999). Although patients receiving revascularization have a better chance of recovering from CLI after surgery, there is no improvement in survival or limb salvage compared to those in whom surgery was deemed unnecessary (Panayiotopoulos et al. 1997). Moreover, there is a high mortality in this heterogeneous group of patients with CLI, reaching up to 30% at 1 year. Limb salvage is, however, of more importance to these patients, and this is known to exceed patency. The most plausible explanation for this is that healing of ulcers and/or infection will reduce the oxygen demand. From this perspective, any peripheral bypass for CLI is a supportive "temporary" bypass. Although bypass surgery is performed frequently, there is still limited evidence for its effectiveness (Leng et al. 2000).

Infrapopliteal bypass surgery is a demanding procedure requiring high surgical skill and experience in a patient group with poor long-term survival. A less or minimally invasive therapy like subintimal PTA with equivalent results could, therefore, be a desirable alternative. Furthermore, even after a failed PTA, all surgical options remain open.

8.3.2 Equipment

The important items of equipment to be considered are sheaths, guidewires, angioplasty balloons and stents. Although the latter are not used routinely, they are occasionally required to treat complications.

- Sheaths: Most procedures can be performed through a 5-F sheath, though if placing a stent, a 6-F sheath is required. Sheaths with a marker-tip have advantages, but the most important quality is kink resistance for antegrade use.
- Guidewires: Both 0.035", 0.018 or 0.014" may be used. Hydrophilic guidewires can be invaluable for crossing difficult stenoses.
- Angioplasty balloons: Standard 5-F balloons can be used, though 3-F systems are also available. In the author's experience the most commonly used balloon diameter is 3 mm. Coronary cutting balloons may also be helpful in treating rigid stenosis.
- Stents: The Sorin carbon coated stent is specifically designed for the crural vessels, but coronary stents provide a viable alternative.
- Closure: Closure devices are used more and more, as they may help to prevent retroperitoneal bleeding, which is a well-known complication from an antegrade puncture. However, this is not currently supported by the literature (see Chap. 5).

8.3.3 Techniques

Crural artery recanalisation is best performed through an antegrade puncture of the common femoral artery. Approaching crural vessels contralaterally is very cumbersome, requires PTA balloons with long shafts, and makes the management of any complications considerably more difficult.

8.3.3.1 Transluminal Recanalisation

Transluminal recanalisation of crural vessels is the preferred technique for treatment of stenotic lesions or very short occlusions (<1 cm). It is a standard angioplasty technique which can be performed using a standard 0.035" wire and 5-F balloon platform. However, many like to use the more sophisticated 0.018" or 0.014" guidewires and small French size balloons, or even a mono-rail system. There are no data in the literature to support either, however, and the small size platform is much more expensive. The only advantages of the smaller sizes might be the preservation of flow and the ability to perform angiography during the procedure. This will certainly reduce procedure time. However, we advocate reducing procedure time by using the " hit and run" method, which employs standard 0.035" guidewires and balloons. The lesion is crossed with a guidewire on a roadmap image. After short balloon dilatation the balloon and the wire are immediately removed and the lesion is only re-crossed if completion angiography shows an unsatisfactory result (Fig. 8.1). This approach is based on the premise that we are aiming to achieve a temporary increase in flow rather than produce an anatomically perfect result.

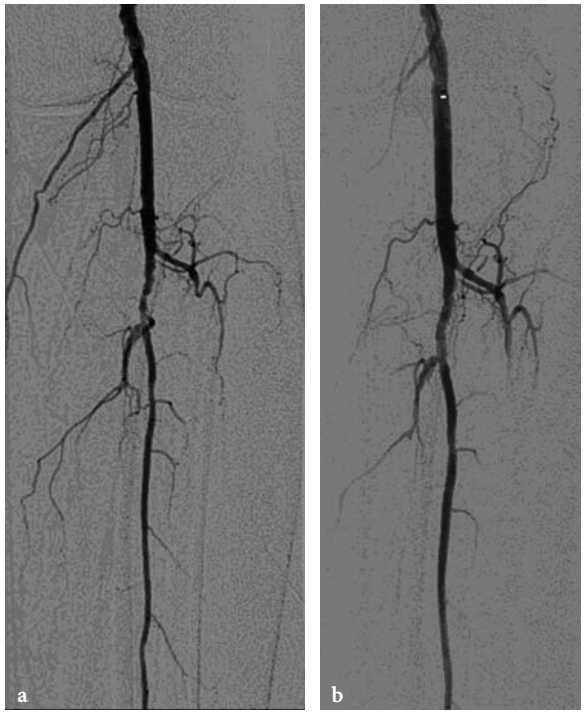

Fig. 8.1. a A severe stenosis in the tibioperoneal trunk. **b** After transluminal PTA with a short 3-mm balloon

8.3.3.2 Technical Factors

Spasm can be a problem with crural PTA. This can be treated by using spasmolytics such as nitrates. However, prevention is always better than treatment. Spasm is often caused by the movement of the guidewire, especially into muscular side-branches. Since guidewire movement is most likely to happen during catheter exchange, this is highly unlikely to occur with the " hit and run" method, and in our practice spasm is very rare. If catheter exchanges are to be performed it is better to administer spasmolytics prophylactically and to observe the guidewire tip continuously under fluoroscopy when exchanging catheters, avoiding inadvertent movement.

When angioplasty is to be performed such that the balloon will cover the origin of a major side branch, some advocate placing a safety wire within it. In general this will cause more problems than benefits, because origin occlusion of a previously patent vessel is rare. It may, however, be of benefit if the origin of the branch is already significantly stenosed.

The final important question is how extensively to treat lesions in the crural vessels. Can one perform a PTA of the distal crural vessel, or of the plantar arch, or should we restrict this technique to the proximal vessels?

Also here there are no data to guide us, and we therefore have to be pragmatic. So, if a distal stenosis at the ankle in a solitary crural vessel is present, this should be treated for limb salvage. However, if there is also a more severe proximal stenosis, one can treat this first and await the clinical result. Such decisions have to be made on the basis of experience, bearing in mind that complications from crural PTA are rare, but if they happen, they can be grave.

8.3.3.3 Results

Primary technical success for crural stenosis is in excess of 90%. The cumulative limb salvage rate at 2 years is also very high, and can exceed 80% in some studies. Complications are rare and include spasm , thrombosis and peripheral embolisation (Horvath et al. 1990; Flueckiger et al. 1992; Hauser et al. 1996; Schwarten and Cutfcliff 1988). There is a relationship between the length of the treated segment and patency. Longer or multiple lesions have a worse outcome, and stenoses fare better than occlusions (Schwarten and Cutfcliff 1988).

8.4 The Concept of a Temporary Bypass

Subintimal angioplasty or percutaneous intentional extraluminal recanalisation (PIER) was first described in 1990 (Bolia et al. 1990). We published our results in 1994 (Reekers et al. 1994), and since then there have been several publications from other institutions confirming the value of the PIER technique (London et al. 1994; Heenan et al. 1995; Green et al. 1998; Balas et al. 2000; Vraux et al. 2000; McCarthy et al. 2000; Yilmaz et al. 2001). The technique is widely accepted for superficial femoral artery lesions, and is now becoming progressively more accepted for treatment of occlusive disease in the crural vessels (Bolia et al. 1994; Ingle et al. 2002). In our view only those patients in whom PIER fails should undergo surgery.

8.4.1 Subintimal Angioplasty

Subintimal PTA for long crural vessel occlusions is an extension of the technique, which is described elsewhere (Reekers and Bolia 1998). The essentials of the technique are shown in Fig. 8.2.

The two main advantages of the PIER technique are: ability to cross long chronic lesions and the option for revascularization of more than one crural vessel (Fig. 8.3).

Although it is helpful if there is a patent vessel beyond an occlusion, our experience has shown that even a blind exploration may be succesful (Fig. 8.4). Although the technique is generally quite successful, the presence of heavy calcification may cause failure; however, we will usually still make the attempt. Crural vessels are also more vulnerable to perforation. This is most often seen during subitimal passage of the guidewire, but also sometimes occurs after balloon dilatation. If the wire can be passed along the perforation, low pressure dilatation for a few minutes will often seal it. If the perforation does not seal and extravasation becomes a problem, the re-opened vessel has to be reoccluded again with a proximal coil. To prevent spasm we give local spasmolytics . It is only after passage and re-entry that we give heparin (5000 iu), minimising the risk of potential bleeding secondary to guidwire perforation. Although the term “perforation” sounds very troubling, it is in general a minor problem. Indeed, if one can find a new route for passage again, the procedure can sometimes still be finished successfully.

8.4.2 Materials and Methods

As indicated above, we always use 5-F balloons and 00.35” wires, because they give better push and stability. Passage of a chronic occlusion sometimes needs a lot of force and smaller wires will kink. To create a subintimal channel we use an angled Terumo guidewire (Terumo Corp, Japan), whose floppy tip is formed into a distal loop. By shortening or increasing the loop length, a softer or more rigid section of the guidewire can be used for creating the subinitmal channel. Movement of the guidewire and catheter combination can become very difficult or even impossible, because of friction in the subintimal space. To overcome this problem we always recanalize with a combination of looped Terumo wire and a balloon catheter (see Fig. 8.2). If distal movement is difficult we perform a dilation to make some space and advance the balloon catheter a little further. Balloon dilation is repeated as the catheter is advanced. In this way the balloon catheter effectively makes a “tunnel” distally. We generally use long length balloons (3 mm×8 cm) but others use 3 mm×2 cm balloons for this combination technique.

Using the balloon in the manner described makes creation of the subintimal passage possible. However, re-entry into the true lumen must still be achieved to complete the procedure. After re-entry

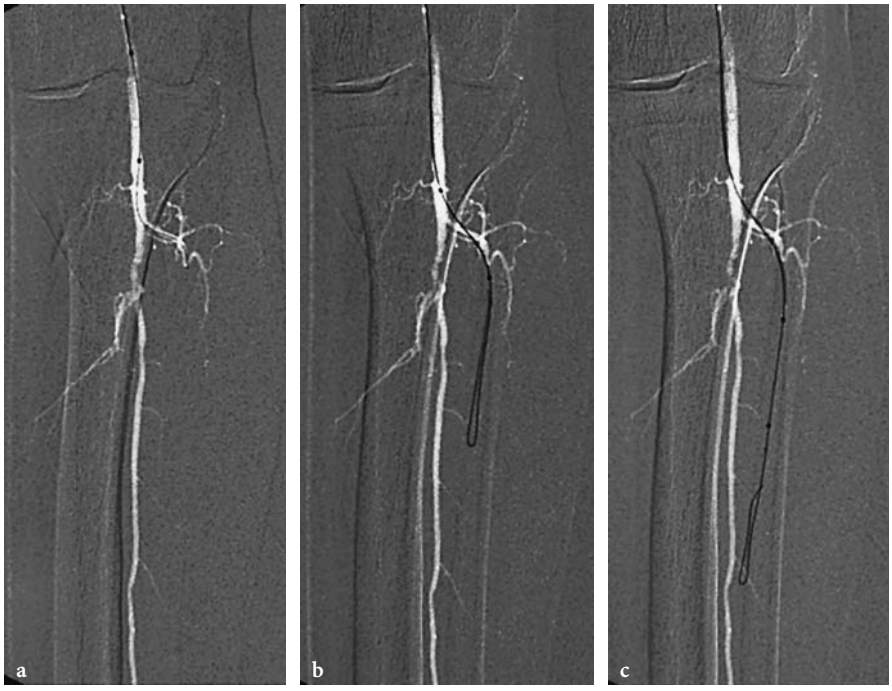

Fig. 8.2. a Total occlusion of the anterior tibial artery. With a combination of a short 3-mm balloon and an angled Terumo wire the lesion is crossed with the loop-technique. **b** The loop in the anterior tibial artery position. **c** When the loop is advanced the wire is supported with the balloon catheter. When distal movement of this combination is prevented by friction, the balloon can be inflated briefly to allow advancement. This is repeated until distal re-entry is obtained

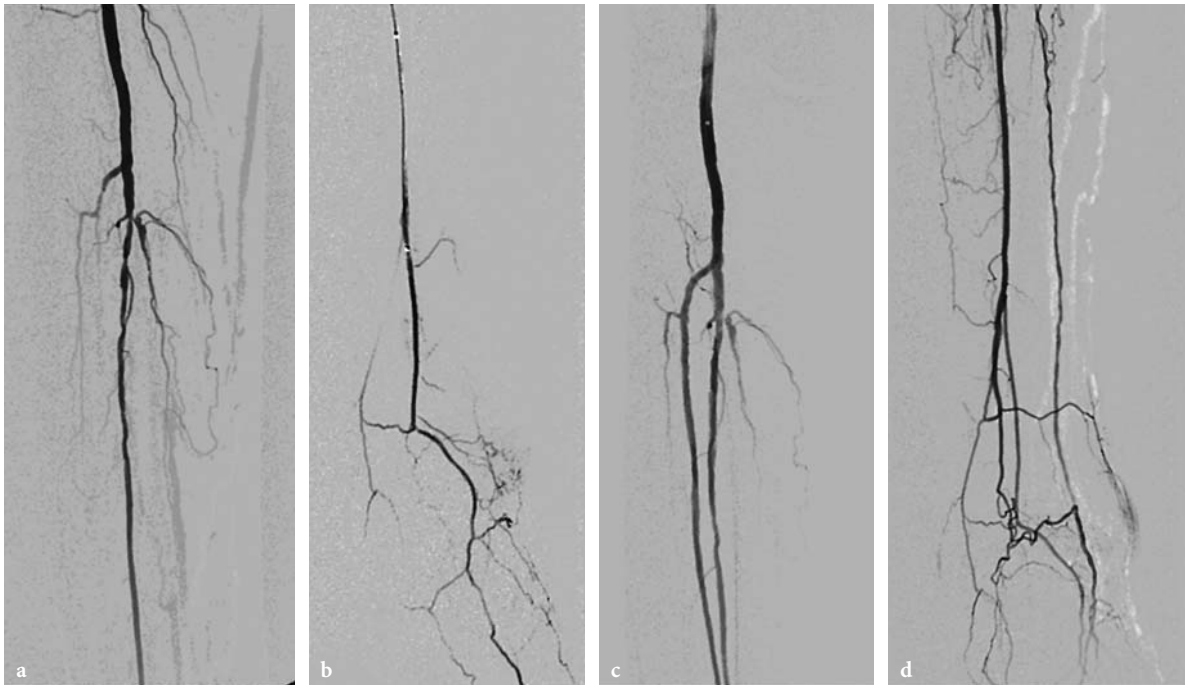

Fig. 8.3a–d. PIER for chronic crural occlusion. **a** Angiography shows only a patent peroneal artery with multiple proximal stenoses. **b** After PTA of the peroneal artery there is still relatively poor outflow to the foot. **c,d** After subintimal recanalization of the anterior tibial artery there is a marked improvement in outflow to the foot

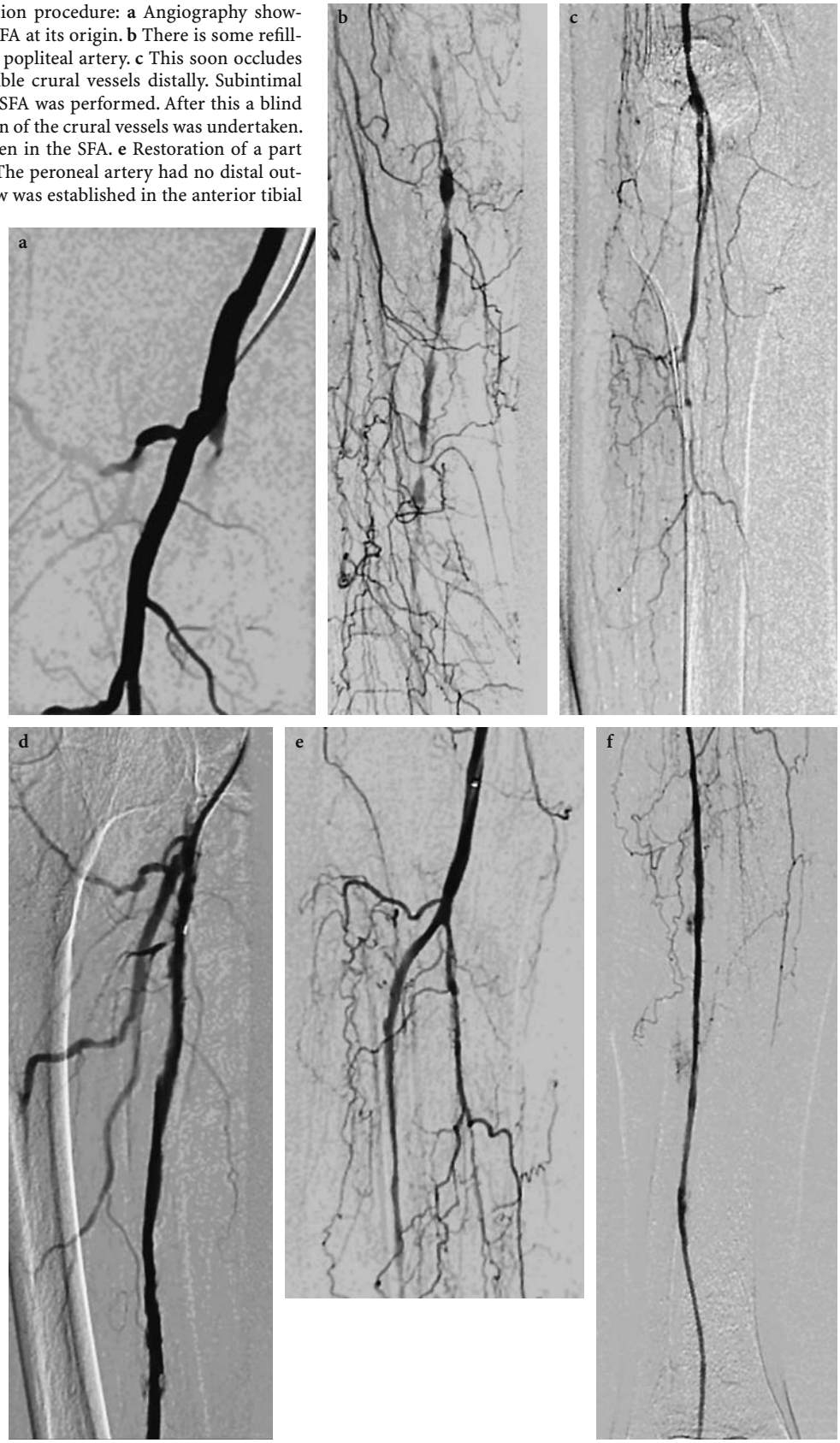

Fig. 8.4a–f. Combination procedure: **a** Angiography showing occlusion of the SFA at its origin. **b** There is some refilling at the level of the popliteal artery. **c** This soon occludes and there are no visible crural vessels distally. Subintimal recanalization of the SFA was performed. After this a blind subintimal exploration of the crural vessels was undertaken. **d** Subintimal neolumen in the SFA. **e** Restoration of a part of the trifurcation. **f** The peroneal artery had no distal outflow, but distal outflow was established in the anterior tibial artery

the whole segment is dilated with the balloon using short overlapping inflations.

After dilatation of the complete crural vessel segment we remove both the balloon catheter and the guidewire to perform angiography. It is, in our experience, always possible to re-cross the subintimal segment for re-dilatation in the event of an inadequate result. Such inadequate results can be improved by prolonged dilatation (2–3 min). In our experience larger balloons offer no advantage and have a higher risk of perforation. We therefore always dilate crural vessels with a 3-mm diameter balloon. If the result is still not satisfactory dilations can be repeated, though this is only required occasionally. If the flow is good and uninterrupted the procedure is finished regardless of the anatomical appearance. In our opinion there is no indication for routine stent placement in the crural vessels.

8.4.3 Results

A cumulative limb salvage rate of 94% at 36 months after a technical success of 86% has been reported (Ingle et al. 2002). To understand these results, you also have to adopt the concept of "temporary percutaneous bypass" (Reekers 2002); in other words ignore primary patency and look instead at limb salvage alone.

There seems to be no difference between long or short subintimal lesions regarding clinical outcome. In addition, and perhaps surprisingly, patients with diabetes have as good outcomes compared to non-diabetics.

8.4.4 Medication

All patients for PTA of the crural vessels, both transluminal and subintimal, receive 5000 iu heparin after passage of the guidewire through the lesion. To prevent spasm we also routinely give a 5-mg bolus of Tolazoline directly into the target vessel. This can be repeated if neccesary. Alternatively boluses of 10–20 μg of nitroglycerin can be given.

All patients should be on aspirin before the procedure. Clopidogrel is sometimes given after the procedure for 6–12 weeks, but there is no evidence for this.

8.5 Additional Procedures

8.5.1 SAFARI Technique

This is an extension of the PIER technique, whereby using subintimal arterial flossing with antegrade-retrograde intervention (SAFARI) the vessel is recanalized. A distal crural vessel is punctured and a wire is snared through an antegrade approach in the femoral artery. This technique can be used in the event of failure to re-enter the distal true lumen or when there is a limited segment of patent distal target artery available for re-entry (Spinosa et al. 2005).

8.5.2 Outback Catheter

A catheter which can be used to facilitate difficult re-entry after subintimal passage. The current experience with this catheter is anecdotal in the crural vessels.

8.5.3 Stents

There has been increasing interest in the use of stents in the crural vessels to treat suboptimal results or as a bail-out procedure. Coronary stents have been used, but the carbon coated stent (Inperia, Sorin Biomedical, Italy) has proved to have very good patency rates in a small RCT (Rand T, personal communication). There is at this moment no evidence that stents should be used as a first option.

8.5.4 Covered Stents

Covered stents are only used infrequently, such as after traumatic vessel perforation or pseudo-aneurysm formation. In our limited experience the long-term follow-up seems to be good, but there is no evidence from the literature regarding these devices.

8.5.5 Cutting Balloons

Cutting balloons are available in diameters suitable for the crural arteries. They are used mainly to treat

stenosis at the anastomoses of crural bypass grafts (Engelke et al. 2002). They are sometimes used to treat rigid stenoses in which standard angioplasty balloons have failed. Although these balloons seem to increase technical success, there are no data as to whether they also increase patency.

8.5.6 Other Devices

There is currently a revival of interest in the use of atherectomy and laser recanalisation devices. There is no data regarding their use, but given the already high technical success rates for the PIER technique, it seems unlikely that they will provide any advantage in terms of recanalisation. Until data regarding limb salvage rates becomes available we should exercise caution in employing these techniques.

8.6 Conclusion

Endovascular treatment of crural artery disease can be very valuable in the management of critical limb ischaemia. Although primary patency rates can at first seem disappointing, these should be ignored in favour of limb salvage rates, which are much more impressive. The PIER technique makes it possible to recanalise long, and often chronic, vessel occlusions to provide a temporary bypass. This allows resolution of the manifestations of critical limb ischaemia, such as ulceration, which will usually not recur, even if the vessel occludes.

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9 Thrombolysis, Mechanical Thrombectomy and Percutaneous Aspiration Therapy

Graham Munneke, Robert Morgan and Anna-Maria Belli

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9.1 Introduction

Over the past 20 years there have been many developments in the percutaneous, minimally invasive dissolution and removal of thrombus from the vasculature. Available methods include lysis by drugs, which enhance the body's native thrombolytic system, and those which involve physical maceration and/or removal of clot. This chapter will focus in particular on the use of these techniques in acute arterial ischaemia. Surgical options in this condition include balloon embolectomy, bypass grafting and primary amputation. This cohort of patients frequently has many co-morbidities and percutaneous methods offer a potentially less invasive option.

9.2 Pharmacological Thrombolysis

Thrombolytic agents have now been part of routine clinical practice for more than two decades. In that time they have found application in the peripheral and in particular cardiac vasculature. The first thrombolytic agent was Streptokinase, named after the haemolytic streptococci which produce it. Its first intra-arterial use was reported by Dotter et al. (1974) in a patient with acute leg ischaemia. Streptokinase provokes antibody formation, and repeated administration may result in allergic reactions or lack of efficacy. Newer fibrin selective agents such as Alteplase (TPA) (Actilyse; Boehringer Ingelheim, Bracknell, Berks) and Reteplase (RPA) (Rapilysin; Roche, Welwyn Garden City, Herts) have replaced streptokinase for peripheral applications. Reteplase has a half life of 14 min, almost five times that of Alteplase, and so for some indications may be given as a bolus rather than continuous infusion. However, a systematic review of large cardiac trials in 2003 showed that outcome was independent of choice of thrombolytic agent (Dunbar et al. 2003).

9.2.1 Indications

9.2.1.1 Arterial

Peripheral thrombolysis is indicated in acute myocardial infarction, massive pulmonary embolus causing cardiovascular embarrassment and selected cases of ischaemic stroke. There is no evidence that catheter directed administration is of additional benefit and these indications will not be covered further in this chapter.

Acute limb threatening ischaemia is the most common indication for catheter directed thrombolysis. It may result from in situ thrombosis in vessels with pre-existing atheroma, embolism to previously normal lower limb vessels or bypass graft thrombosis. In situ thrombosis of previously diseased vessels is more likely if there is a previous history of intermittent claudication. In cases of peripheral embolisation there will be no antecedent history of claudication but there may have been a recent myocardial infarction or history of atrial fibrillation as a source of emboli. Thrombosis of lower limb bypass grafts, both prosthetic and autogenous vein, may also be treated with thrombolysis, although success with vein grafts is unlikely following more than 72 h of thrombosis (Belkin et al. 1990). Due to the severity of possible complications treatment should be limited to patients with threatened but viable limbs (Rutherford grades IIA and IIB) (Kessel et al. 2004).

Special mention must be made of thrombosed popliteal aneurysms. Thrombolysis of these may lead to massive distal embolisation. Thrombolysis does, however, have a role when the run-off vessels are thrombosed. A catheter is advanced distal to the aneurysm allowing thrombolysis of the runoff prior to surgical bypass of the aneurysm. Acute upper limb ischaemia as well as thrombosis of mesenteric (Pillari et al. 1983) and renal arteries (Rudy et al. 1982) are treatable with thrombolysis.

9.2.1.2 Venous

The use of thrombolysis in deep venous thrombosis (DVT) is aimed at restoring venous patency and preserving valvular competence and thus reducing the incidence of post-thrombotic venous insufficiency (Kessel and Patel 2005). This indication is currently controversial given the potential side effects of thrombolysis. A review of 12 randomised trials comparing thrombolysis with anticoagulation for DVT found that thrombolysis significantly reduced post-thrombotic syndrome and improved venous function at follow-up. This was, however, at the expense of increased bleeding complications and two strokes out of 668 patients (Watson and Armon 2004).

One clear indication for venous thrombolysis is phlegmasia caerulea dolens. In this rare condition there is extensive venous thrombosis resulting in arterial compromise and limb loss if not treated promptly (Centeno et al. 1999). Thrombolysis is administered by both arterial and venous catheters in this situation.

Spontaneous or effort related thrombosis of the subclavian vein, the Paget-Schroetter syndrome, results from hypertrophy of the subclavius and scalenus anterior muscles. Treatment of the condition is by a combination of thrombolysis followed by venoplasty and resection of the first rib (Divi et al. 2005) (see Chap. 17). Thrombolysis of dialysis access fistulae is used as an alternative to open or percutaneous thrombectomy (see Chap. 16).

9.2.2 Contraindications to Thrombolysis

Absolute:
- Cerebrovascular event within the last 2 months
- Active bleeding diathesis
- Recent gastrointestinal bleeding (within 10 days)
- Neurosurgery/intracranial trauma within the last 3 months

Relative:
- Major surgery/trauma/cardiopulmonary resuscitation (within 10 days)
- Uncontrolled hypertension (systolic > 180 mmHg, diastolic > 110 mmHg)
- Puncture of non-compressible vessel
- Recent eye surgery
- Diabetic retinopathy
- Hepatic failure
- Pregnancy
- Bacterial endocarditis

9.2.3 Technique of Intra-arterial Thrombolysis

A recent Cochrane review (Kessel et al. 2004) of peripheral thrombolysis concluded that systemic

intravenous thrombolysis should not be used as it is associated with poor clinical outcomes and a higher bleeding rate than local infusion. Local catheter directed thrombolysis aims to deliver the maximum concentration of lytic agent into the thrombus with the minimum systemic side effects. Pre-thrombolysis imaging should ideally be non-invasive (duplex/computed tomography/magnetic resonance angiography), thus avoiding unnecessary arterial punctures. However, if conventional angiography is required the radial artery approach has been shown to be safe prior to lysis (Cowling et al. 1997). If thrombus is present at or above the level of the common femoral bifurcation definitive access from the contralateral side and a crossover technique is employed. For more distal disease antegrade access provides the most straight forward route. If it is possible to pass a guidewire through the length of the thrombus this is thought to predict a favourable response to thrombolysis (Working Party on Thrombolysis in the Management of Limb Ischaemia 2003). The catheter should then be embedded within the thrombus for drug delivery. Thrombolysis may be given as a continuous low dose infusion, for example tPA 0.5–1.0 mg/h. Alternatively an accelerated technique may be employed. Up to three initial boluses of 5 mg tPA are given at 10-min intervals over 30 min, followed by an infusion of 3.5 mg/h for 4 h, then 0.5 mg/h (Braithwaite et al. 1997). The accelerated method does significantly decrease the time required to restore flow, so may be indicated in patients with severe ischaemia and neurosensory deficit, whose limbs will not remain viable if perfusion is not restored rapidly. A combination of the two methods may be employed, with an initial bolus of 5 mg TPA followed by a low dose infusion. Finally the pulsed spray technique uses a pump to periodically inject small volumes of thrombolytic through a multiple side hole catheter, thus combining chemical and mechanical disruption of thrombus (Buckenham 1992). The available data suggests, however, that vessel patency and limb salvage rates are independent of the individual technique or thrombolytic agent used (Thomas and Gaines 1999; Kessel et al. 2004; Kessel and Patel 2005). Angiography should be performed at regular intervals to asses clot dissolution and allow the catheter to be repositioned within the thrombus as required. The infusion should be terminated when flow is restored, if there is clinical deterioration in the limb in the absence of evidence of continued lysis or if there has been no progress in lysis since the last angiogram. Following successful lysis, underlying stenotic lesions should be sought and treated (Fig. 9.1). If no

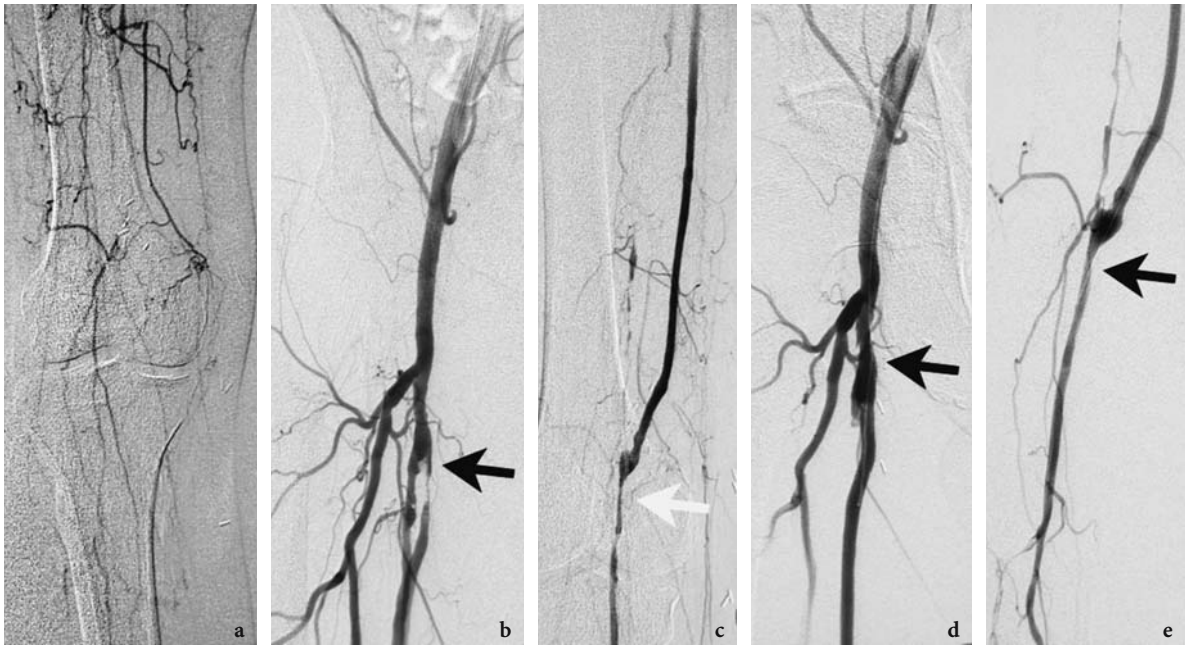

Fig. 9.1a–e. Graft Thrombolysis. **a** Angiogram in a patient with a 2-day-old occlusion of a femoropopliteal vein graft. The graft is completely occluded. **b,c** Post 22 h of thrombolysis via the contralateral femoral artery flow has been restored within the graft. Proximal (*black arrow*) and distal (*white arrow*) anastomotic strictures have been unmasked. **d,e** Post angioplasty the strictures have been abolished (*arrows*)

causative factor is found, long-term anticoagulation should be considered as otherwise patency rates are extremely poor (Hall et al. 2001).

Thrombolytic agents only act on fibrin. They have no action on prevention of new thrombus formation. For this reason heparin or anti-platelet agents may be given in combination with thrombolysis. There is no firm data on the relative risks and benefits of heparin during thrombolysis (Working Party on Thrombolysis in the Management of Limb Ischaemia 2003), but many practitioners use it in the hope of reducing access site and peri-catheter thrombosis. Coronary trials have demonstrated the safety and efficacy of the glycoprotein IIb/IIIa receptor inhibitor Abciximab. However, as yet there are no studies of significant power to support its use in the peripheral circulation (Kessel et al. 2004).

9.2.4 The Results of Thrombolysis in Peripheral Arteries

There have been three large scale randomized trials comparing thrombolysis with surgery. In the first, Ouriel et al. (1994) randomized 114 patients with severe ischaemia (Rutherford grade IIb) of mean duration 2 days to either surgery or thrombolysis. The limb salvage rate was identical for both groups (82% at 12 months). However, the cumulative survival rate was significantly better in the thrombolysis group (84% vs 58%). The authors found that the difference in survival related to an increased cardiovascular mortality in the surgical arm within 30 days.

The Surgery or Thrombolysis for Ischemic Lower extremity (STILE) trial (The STILE Investigators 1994) prospectively randomized 393 patients with non-embolic arterial or graft related lower limb ischaemia to lysis or surgery. The trial was halted because although amputation free survival was similar at 6 months (82.3% surgery vs 82.9% thrombolysis), patients treated with thrombolysis had significantly higher levels of continued or recurrent ischaemia. The trial has been subsequently criticized due to the high level of failure of catheter placement in the thrombolysis group; these were categorised as treatment failure. This has led commentators to suggest that some of the radiologists involved with the study were not familiar with the technique. The study also included many patients with ischaemia of more than 2 weeks duration. When stratified for duration of ischaemia patients with symptoms for between 0 and 14 days had lower amputation and mortality rates with thrombolysis. Patients with symptoms of greater than 14 days' duration fared better with surgery. In thrombolysis patients who subsequently required surgery, 58% had a reduction in the complexity of procedure.

The Thrombolysis or Peripheral Arterial Surgery (TOPAS) trial (Ouriel et al. 1998) randomised 544 patients with acute embolic or thrombotic occlusions of the lower limb to thrombolysis or surgery as their initial management. Amputation free survival was not significantly different for surgery or thrombolysis at 1 year follow up (69.9% and 65%, respectively). Although there was no difference in the mortality figures there was an excess of bleeding complications in the lysis group (12.5% vs 5.5% for surgery). In the subsequent 6 months patients in the surgical arm required an additional 551 open surgical procedures compared with only 315 in the lysis group. In the same time period 31.5% of the thrombolysis patients were alive without amputation having only had a percutaneous procedure.

The National Audit of Thrombolysis for Acute Leg Ischaemia (NATALI) includes consecutive data from 11 centres in the UK (Earnshaw et al. 2004). It includes more patients (albeit non-randomised) than all the previous trials combined. They recently published outcome figures at 30 days for patients treated from 1990 to 2000. Amputation free survival was 75.2%, although this had increased to 80% in the later years of the registry. Amputation and death rates were both 12.4%. Factors leading to decreased amputation free survival included increasing age, diabetes, longer duration and greater severity ischaemia. Major haemorrhage requiring transfusion or therapy occurred in 7.8% of cases, with minor haemorrhage in 6.3%. There were only five deaths from haemorrhage out of 1133 patients. Stroke occurred in 2.3% of patients. Half were thrombotic rather than haemorrhagic and most occurred during anticoagulation after thrombolysis.

There is a general belief that the use of thrombolysis for arterial ischaemia is declining. This was confirmed by a survey sent to members of the thrombolysis study group (Richards et al. 2003). Of the twenty-two centres who responded 19 reported a reduction of its use. Reasons given for this included concerns with regard to efficacy and complications. Given the advancing age of the population, thrombolysis will pose a higher stroke risk in a greater proportion of patients. In addition thrombolysis is time consuming, with patients revisiting the intervention suite on several occasions. The decline in need for graft lysis may be explained by more aggressive surveillance, leading to intervention to prevent

rather than treat thrombosis, and also perhaps by an increased use of vein as a conduit for bypass surgery.

It is clear that neither surgery nor thrombolysis is applicable to every patient. The data suggest at least equal efficacy but increased bleeding complications with thrombolysis. However, although overall clinical outcomes and mortality are comparable, it must be remembered that surgery is also associated with complications. Careful selection of patients likely to benefit from each technique is essential to achieve optimal results.

9.3 Percutaneous Thrombectomy

Percutaneous thrombectomy is an alternative non surgical method by which thrombus is removed from the vascular system. There are now a number of devices on the market that aim to remove thrombus by mechanical rather than pharmacological means and thus avoid the associated side effects. Thrombectomy techniques range from simple catheter aspiration to mechanical devices which fragment the thrombus through to those which fragment and remove the thrombus. Percutaneous aspiration thrombectomy (PAT) uses catheters and guidewires available in any interventional department, whereas mechanical thrombectomy requires investment in specific equipment. Percutaneous thrombectomy may be performed as a stand alone procedure. However adjuvant balloon angioplasty or thrombolysis may be required if there is an underlying stenotic lesion or considerable residual thrombus, respectively.

9.3.1 Indications

9.3.1.1 The Arterial System

Indications include the removal of spontaneous emboli from the peripheral vascular system, as a rescue procedure when there is distal embolisation during angioplasty or stenting and the evacuation of thrombus from native vessel and bypass graft occlusions. Thrombectomy is most successful when the age of the thrombus is less than 2 weeks (Morgan and Belli 2002). Thrombectomy may be preferred over thrombolysis when the limb is threatened and rapid revascularisation is required. Although the majority of experience of arterial thrombectomy is in the lower limbs it also has potential application in the upper limb, visceral and renal arteries.

9.3.1.2 Venous System

Indications in the venous system include clearance of thrombus in the lower limbs, central veins and inferior vena cava and the fragmentation of large pulmonary embolus in cardiovascularly compromised patients. As with thrombolysis there is no clear evidence for the use of thrombectomy in deep venous thrombosis but it may be used in selected cases to rapidly reduce clot burden (Frisoli and Sze 2003). It may have particular application in phlegmasia caerulea dolens, where rapid removal of thrombus and restoration of venous flow is required to avoid venous gangrene.

9.3.1.3 Dialysis Fistulae and Grafts

So far this has been the major use for thrombectomy devices. Thrombosis of dialysis access is usually diagnosed early and so treatment is initiated while the thrombus is fresh and soft. Embolisation during recanalisation has less severe sequelae in the venous system than the arterial, and prosthetic dialysis grafts in particular are resistant to damage from the thrombectomy device (see Chap. 16).

9.4 Percutaneous Aspiration Thrombectomy

9.4.1 Equipment

Aspiration of thrombus via a wide lumen catheter was first described by Greenfield et al. (1969) and later applied to the arterial system by Symes et al. (1984) and Starck et al.(1985). Thin walled guiding catheters such as the Brite Tip (Cordis, Berkshire, UK) are most suitable as they provide the maximum lumen diameter. Straight catheters usually suffice but they are available with a variety of shaped tips if required. They should be used with a sheath with a removable hub (William Cook, Bjaeverstock, Denmark). This allows removal of thrombus from the haemostatic

valve. A 6- to 8-F catheter should be used in the femoropopliteal segments and a 4- to 6-F catheter in the infra-popliteal circulation. Percutaneous aspiration thrombectomy is mainly used for acute arterial and graft occlusions below the inguinal ligament, and it may also be used as an adjunct to pharmacological thrombolysis (Fig 9.2). It may be used for iliac occlusions but this carries the risk of embolising distally into the lower limb. It is most effective at clearing short occlusions. When it is applied to longer occlusions additional thrombolysis is often required (Wagner and Starck 1992). The most common indication for PAT is as a salvage procedure when there is distal embolisation following angioplasty.

9.4.2 Technique

Due to the need to minimize the size of access sheath the largest catheter size that we use in the infra-inguinal circulation is 8 F. In practice a 6-F catheter will usually suffice, with the 8-F catheter held in reserve for large clot burdens. The tibial artery origins will usually accommodate a 6-F catheter but standard 4- or 5-F end hole angiographic catheters (e.g., Cobra) should be used for distal tibial thrombi.

Access is gained with a removable hub sheath. The catheter is advanced over a guidewire until its tip is lodged distally in the thrombus. A 50-ml Luer lock syringe is then attached and suction is applied by an assistant. The catheter is moved slowly back and forth through the thrombus until blood flow stops indicating that thrombus is lodged in the catheter. Suction is maintained and the catheter removed. The sheath hub is removed with the catheter, flushed to ensure it is free of thrombus and replaced onto the sheath. The contents of the syringe and catheter are then injected into a bowl draped with gauze to retain any thrombus. Progress should be monitored via angiograms through the sheath. The procedure may be repeated several times although note should be made of how much blood is aspirated. Frequent 150-µg aliquots of Glyceryl Trinitrate should be administered intra-arterially, as passage of the catheter is a potent source of spasm in the infra-popliteal arteries.

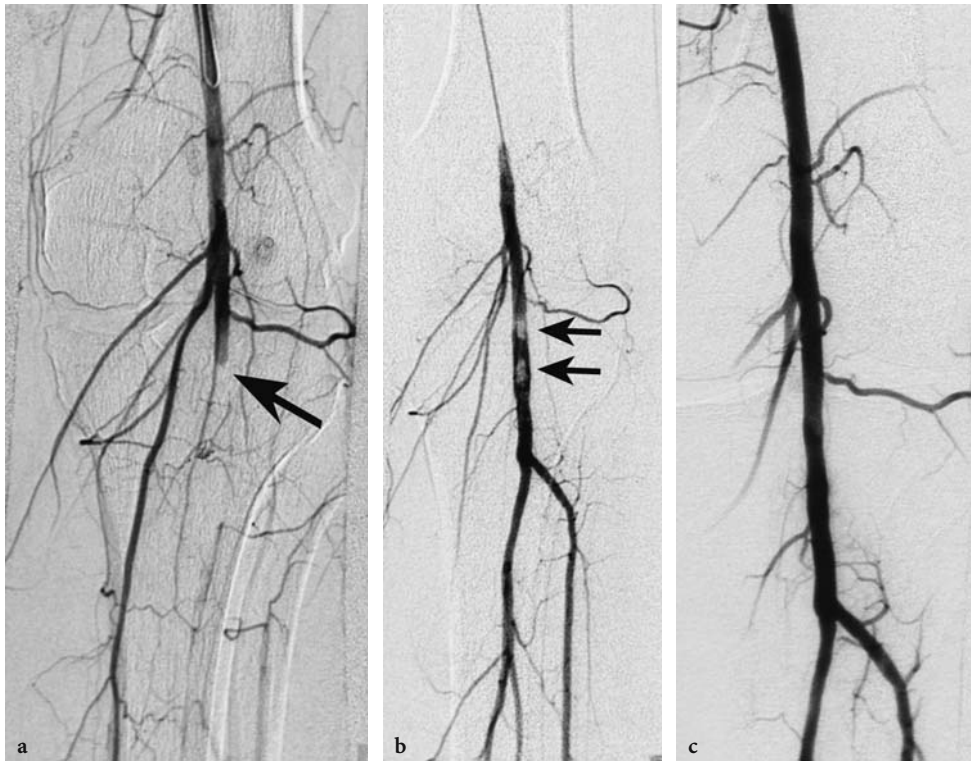

Fig. 9.2a–c. Thrombolysis and percutaneous aspiration therapy. **a** Antegrade femoral angiogram in a patient who presented with acute ischaemia of the left leg. There is acute embolic occlusion of the below knee popliteal artery (*arrow*). **b** Appearance post 24 h of catheter directed thrombolysis. There is restoration of flow to the tibial vessels. However, there are still filling defects consistent with residual embolic material (*arrows*). **c** Following suction thrombectomy with a 6-F guiding catheter there is clearance of all the emboli

9.4.3 Results of PAT

There is little available data for the use of PAT as sole therapy. Zehnder et al. (2000) reported on their series of 93 infra-inguinal occlusions. They achieved a 90% primary technical success with 78% limb salvage at 12 months follow-up. However, PAT was the sole therapy in only 31% of their patients, with 22% requiring additional thrombolysis and 60% PTA. Wagner and Starck treated 102 patients with acute de novo embolic occlusions (Wagner and Starck 1992; Wagner et al. 1994). Their results of 86% technical success rate giving a 88% limb salvage rate at 1 year compare well with published results for surgical embolectomy (Dregelid et al. 1987). Their suggestion that PAT be used in preference to Fogarty embolectomy is supported by a 30-day mortality of less than 4% verses up to 26% for surgery. However, once again, 60% of their patients required adjunctive therapy, either thrombolysis or mechanical fragmentation. PAT is more likely to be sufficient as sole therapy in cases of intra-procedural embolisation. Cleveland et al. (1994) achieved 87% technical success in 15 patients with embolisation following PTA.

9.4.4 Complications of PAT

Major complications are uncommon. Attempted aspiration may lead to embolic material being forced distally. This is still amenable to further more distal aspiration. Passage of the catheter to and fro in the vessel lumen risks causing dissection. This is less of a risk when there is acute embolisation of a non-diseased vessel. If the dissection is flow limiting it should be treated with prolonged balloon inflation. Although the procedure may be repeated care should be taken to monitor the amount of blood aspirated. If repeated aspiration produces only syringes filled with blood the procedure should be stopped.

9.5 Mechanical Thrombectomy

The following is not an exhaustive list of devices, but provides examples of those commercially available and the results obtainable.

9.5.1 Thrombus Fragmentation Devices

9.5.1.1 Amplatz Thrombectomy Device (ATD)

The ATD (Microvena technologies, White Bear Lake, Minn.) consists of a 7-F, 75-cm or 120-cm long catheter with a metal capsule at its distal end which houses an impeller blade. The impeller blade is rotated at up to 150,000 revolutions/min by a turbine driven by compressed air. The revolving impeller creates a recirculating vortex which draws thrombus into the capsule. The thrombus is macerated by the impeller blades and emitted from the capsule via three side holes. There is no extraction capability with the ATD and it disperses fragments into the bloodstream. Experimental studies have shown that 98.2% of particles are less than 13 μm in size (Yasui et al. 1993). However, emboli of up to 1000 μm in diameter were found. Hydrodynamic devices such as the angiojet and oasis (v.i.) have been shown to perform better in this respect (Muller-Hulsbeck et al. 2002). There is a channel within the device which allows injection contrast or thrombolytic agents, but the guidewire must be removed before activation. As such it must be deployed through a guiding catheter and lacks the manoeuvrability of other wire devices. In addition the ATD is prone to mechanical failure from drive shaft fracture when used around acute angles.

9.5.1.2 The Arrow-Trerotola Device

The Arrow-Trerotola device (Arrow International, Reading, PA) consists of a 5-F, or 7-F over the wire shaft with a distal nitinol basket. The basket is rotated at 3000 revolutions per minute by a motor incorporated in the handle. The rotating basket cleaves thrombus into fragments of 1–3 mm in size (Trerotola et al. 1996). These may then be aspirated from the delivery sheath. Vesely et al. (2000) found the device produced excellent clearance of haemodialysis grafts. It is simple to use and with its in-built drive mechanism does not require the purchase of additional equipment. However, animal studies have demonstrated complete endothelial denudation following its use (Lajvardi et al. 1995). This, in combination with its propensity to produce distal embolisation, make it unsuitable for arterial use. Current indications are therefore limited to

thrombectomy in dialysis grafts and native AV fistulae (Rocek et al. 2000).

9.5.2 Devices Which Both Fragment and Extract Thrombus

9.5.2.1 Angiojet

The Angiojet rheolytic thrombectomy catheter (Possis Medical, Minneapolis, Minn.), in common with the Oasis and Hydrolyser devices (v.i.), works by generating a Venturi or Bernoulli effect (negative pressure induced by fast flowing saline jets) at the tip of the catheter. The 5-F catheter is dual lumen and is introduced over an 0.018" guidewire. Saline is pumped down the intake lumen under high pressure by the dedicated Angiojet drive unit. At the tip, the saline jet is directed in a retrograde direction into the exhaust lumen. This creates a low pressure zone which draws thrombus toward the tip and into the exhaust lumen. The sophisticated pumping mechanism provides almost iso-volumetric operation and has safeguards to detect occlusion of either the intake or exhaust lumens, thus preventing rapid intravasular overload or phlebotomy (Stainken 2003). The Angiojet has been shown to remove thrombus from vessels much larger than its own (2 mm) diameter (Drasler et al. 1992) and results in much less endothelial damage than surgical embolectomy with a Fogarty balloon catheter (Sharafuddin et al. 1997). The particles produced by the Angiojet are small, with 99.83% being less than 100 μm in diameter (Kasirajan et al. 2001), making it safe for use in arteries, veins and dialysis fistulae. The safety of the Angiojet has also been demonstrated in the coronary circulation (Kuntz et al. 2002). The main disadvantage of the system is the initial cost of purchasing the dedicated pump unit.

9.5.2.2 Oasis

The oasis thrombectomy system (Boston Scientific, Galway, Ireland) is a triple lumen catheter available in 6-, 8- and 10-F sizes. One lumen accepts a 0.018-in. guidewire, the other two lumens being for intake and exhaust. Heparinised saline is pumped by a conventional angiographic injector down the intake lumen. The jet is directed back into the exhaust lumen by a shaped catheter tip. This creates a Venturi effect, which fragments thrombus and directs it into the exhaust lumen for evacuation. An in vitro study looking at hydrodynamic thrombectomy devices found that the Hydrolyser and Angiojet work iso-volumetrically. However, the Oasis withdraws a greater volume of fluid than it injects giving the potential for procedure related anaemia (Muller-Hulsbeck et al. 1999).

9.5.2.3 Hydrolyser

The Hydrolyser (Cordis, Johnson and Johnson, Miami, Fla.) is a 6- or 7-F double lumen catheter. Heparinised saline is injected at 3 ml/s by a conventional angiographic pump. The saline is directed by a hairpin loop at the distal end towards a 6-mm side hole. This creates a localized Venturi effect that disrupts thrombus and sucks it into the exhaust lumen (Fig. 9.3). In vitro studies have shown that the eccentrically placed exhaust lumen creates a non-uniform vortex which may lead to tenting of the vessel wall toward the catheter, producing endothelial damage (Bucker et al. 1996). The catheter can be used over a 0.025 guidewire; however, this partially obstructs the outflow lumen resulting in a reduction in thrombus extraction (Kasirajan et al. 2001). A comparative in vitro study of the Hydrolyser and Angiojet devices in arterial and venous models found that both had acceptably low levels of distal embolisation (4.8% and 1.8%, respectively). It also found although both systems removed a substantial amount of thrombus their performance was significantly enhanced by the use of a guiding catheter (Bucker et al. 1996).

9.5.3 Peripheral Arterial Technique

The method of mechanical thrombectomy is similar for most of the devices. Antegrade arterial access should be obtained if possible. The Angiojet and Hydrolyser devices are flexible enough to be used over the aortic bifurcation through a Balkin sheath (Cook, Europe, Denmark). The Amplatz thrombectomy device is prone to drive shaft fracture when used around corners and so cannot be introduced from the contralateral side. The three Venturi effect

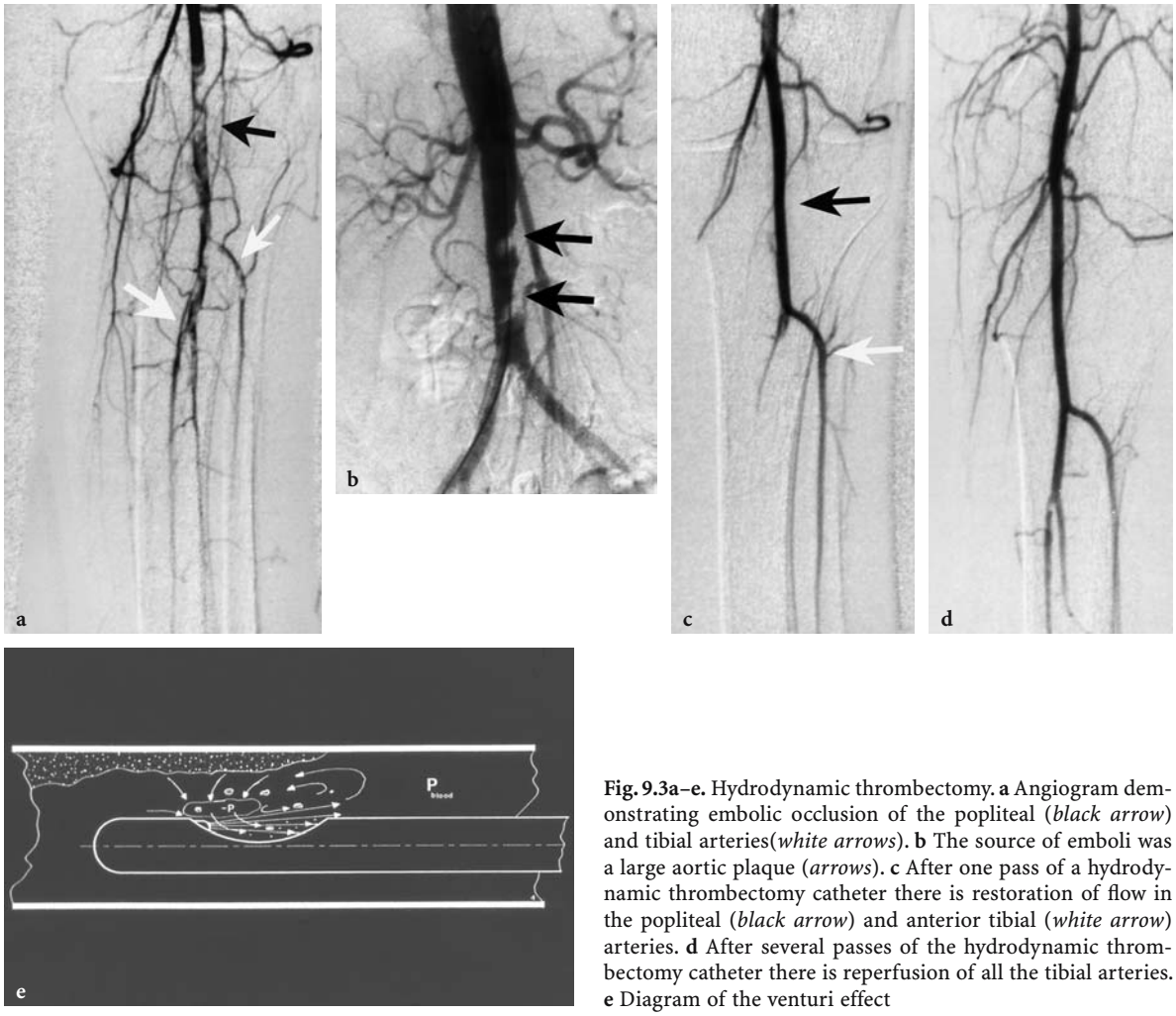

Fig. 9.3a–e. Hydrodynamic thrombectomy. **a** Angiogram demonstrating embolic occlusion of the popliteal (*black arrow*) and tibial arteries(*white arrows*). **b** The source of emboli was a large aortic plaque (*arrows*). **c** After one pass of a hydrodynamic thrombectomy catheter there is restoration of flow in the popliteal (*black arrow*) and anterior tibial (*white arrow*) arteries. **d** After several passes of the hydrodynamic thrombectomy catheter there is reperfusion of all the tibial arteries. **e** Diagram of the venturi effect

catheters (Angiojet, Oasis, Hydrolyser) can be used over a guidewire such as the V-18 Control wire (Boston Scientific, Galway, Ireland) to aid manipulation. The Amplatz thrombectomy device can not be activated with a guidewire in place and should be used with a guiding catheter. The catheter should be advanced until it lies distally within the thrombus before activation. This minimizes the risk of the catheter or arterial pressure pushing the thrombus distally. Once activated the catheter is passed slowly retrograde and antegrade through the thrombus. Activation time for devices driven by angiographic pumps is limited by the volume of the pump reservoir. Control angiograms should be performed through the sheath to monitor progress. When treating crural vessels frequent doses of vasodilator should be given. If there is incomplete clearance of thrombus, adjuvant PAT or thrombolysis may be performed.

9.5.4 Complications of Mechanical Thrombectomy

Vessel dissection due to passage of the catheter is usually self limiting and is less common with over the wire devices. In vitro studies have shown that although hydro-dynamic thrombectomy provokes neointimal hyperplasia (van Ommen et al. 1996) and endothelial denudation (Sharafuddin et al. 1997), it is less than occurs with Fogarty balloon embolectomy. Clinically significant embolisation is less common with the hydrodynamic devices (Angiojet, Oasis, Hydrolyser), which evacuate thrombus and produce smaller particles. Particulate embolisation of up to 12% of initial clot volume occurs with the Angiojet (Sharafuddin et al. 1997), with 99.8% being smaller than 100 μm. Larger emboli are usually readily removed by further thrombectomy, PAT or thrombolysis. There is potential for fluid overload

with the hydrodynamic devices. The Angiojet functions essentially iso-volumetrically but fluid balance should be observed with the other two devices. All mechanical thrombectomy devices cause haemolysis, the degree of which is related to activation time (Nazarian et al. 1994). Frank haemoglobinuria may occur with prolonged use of the Angiojet. Clinical sequelae are rare, but care should be taken in patients with renal insufficiency. In addition, intracellular potassium is released and bradycardia and heart block have been reported with central venous use (Haskal 2002).

9.5.5 Results of Mechanical Thrombectomy

In a literature review of all the major mechanical thrombectomy trials Kasirajan et al. (2001) found that mechanical thrombectomy alone was technically successful in between 11.8% and 95%. The study quoting 11.8% was by Hopfner et al. (1999) using the oasis, and the next lowest complete clearance with mechanical thrombectomy was 52%. In all series adjuvant therapy with thrombolysis, PAT or angioplasty was performed where there had been partial success. Primary patency rates ranged between 43% and 69% at 6 months to 1 year, with amputation rates of between 0% and 17.7%. In a retrospective multicentre registry of rheolytic thrombectomy, patients with acute native vessel or graft occlusion had complete thrombus removal in 71% and partial removal in 22%. Additional thrombolysis was required in 37%, and underlying lesions were treated with angioplasty or stenting as appropriate. Mortality and amputation rates were 7% and 4% at 30 days (Ansel et al. 2002). There are no prospective randomized trials comparing mechanical thrombectomy with surgery. Differences in the definitions of technical success (ranging from complete thrombus removal to > 50% removal) also make comparison of different devices difficult. Muller-Hulsbeck and Jahnke (2003) compared their results in 112 patients with acutely occluded native arteries or bypass grafts treated with the Angiojet with data from the TOPAS trial. The Angiojet seemingly performed better with only 10% mortality and 80% amputation free survival at 1 year. However, as the authors comment, the results may not be directly comparable due to differences in study design and patient selection.

Firm data on mechanical thrombectomy in peripheral veins is not available. As sole therapy it is unlikely to provide complete clot clearance. However, when combined with thrombolysis it can reduce lysis time and dose (Frisoli and Sze 2003).

Mechanical thrombectomy in dialysis fistulae provide results similar to thrombolysis (Barth et al. 2000) and surgery (Vesely 2003). However, continued patency rates are low for all techniques and dependent on identification and treatment of underlying stenotic lesions.

9.6 Conclusion

Percutaneous therapy has an established role as an alternative to surgery in the treatment of intravascular thrombus. Thrombolysis and mechanical thrombectomy may be used on their own or in combination to achieve the best result. Patients with thrombus of less than 14 days in age who have co-morbidities making them high risk for surgery should be treated by percutaneous means. If available, mechanical thrombectomy should be used to restore blood flow, with thrombolysis reserved for cases of incomplete thrombus clearance. It is wrong to say that either surgery or percutaneous therapy is best for all patients. For example, where there is distal disease and no run-off, balloon embolectomy is unlikely to be successful. Lysis may open up the run-off vessels and so avoid amputation. Use of clinical judgment and team working is required in choosing the correct treatment modality for each patient.

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10 Upper Limb Arterial Intervention

Douglas R. Turner and Steven M. Thomas

CONTENTS

10.1 Introduction

Arterial intervention in the upper limb is undertaken far less frequently than in the lower limb. Symptomatic ischaemic disease has a much lower incidence than in the leg, is more likely to be of acute onset secondary to embolisation, and a greater proportion of the chronic cases are attributable to small vessel occlusive disease, rather than large vessel atherosclerotic disease. Traumatic arterial injuries are relatively common, and the nature of the local anatomy has particular implications for diagnosis, imaging and treatment.

The relative infrequency of symptomatic upper limb arterial disease means that comparatively sparse data is available, particularly with respect to endovascular treatment, and especially when considering the vasculature distal to the axillary artery. Although endovascular techniques have become commonplace, the transition from established surgical practice has not been based on conclusive scientific evidence. Instead, the driving force has been the attraction of minimally invasive techniques, which appear to have lower mortality and morbidity, and a shorter recuperation period.

10.2 Upper Limb Ischaemia

Symptomatic upper limb ischaemia is rare compared to the lower limb accounting for less than 5% of all vascular therapeutic procedures. The causes of upper limb ischaemia are more commonly acute in onset, and are less frequently associated with generalised atheromatous disease. A lack of symptoms probably, at least partly, reflects the smaller muscle mass and reduced haemodynamic requirements of the upper limb during exercise.

10.2.1 Chronic Upper Limb Ischaemia

Chronic ischaemia in the upper limb can be divided into large and small vessel causes (Table 10.1). The

Table 10.1. Causes of chronic upper limb ischaemia

Small vessel (hand)	Large vessel (arch to wrist)
• Raynaud's syndrome	• Atherosclerosis
• Atherosclerosis	• Trauma
• Connective tissue disease	• Chronic thromboembolism
• Vibration injury	• Thoracic outlet syndrome
• Diabetes mellitus	• Vasculitis
• Chronic renal failure	• Fibro-muscular dysplasia
• Buerger's disease	
• Frostbite	

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commonest cause of symptomatic upper limb ischaemia is Raynaud's syndrome, a small vessel vasospastic condition, but as endovascular techniques play no part in its management it will not be discussed further here.

10.2.1.1 Atherosclerotic Occlusive Disease

Atherosclerotic occlusive disease is the commonest cause of symptomatic chronic large vessel upper limb ischaemia, occurring most frequently in the subclavian and innominate arteries. The left subclavian is affected 3–4 times more frequently than the right (Schillinger et al. 2001), possibly as a result of different haemodynamic stresses. Atheromatous plaque causes symptoms via a flow-limiting stenosis or occlusion, or by acting as a source of atheroembolic material producing 'blue digit' syndrome or vertebrobasilar ischaemia.

The effects of flow-limiting lesions are determined by their position, as both the intracranial circulation and the rich collateral networks, particularly around the shoulder and upper chest, may compensate satisfactorily for a chronic occlusive lesion. Such compensation around a prevertebral subclavian lesion may lead to flow reversal in the ipsilateral vertebral artery, known as a steal phenomenon. This type of compensation depends on adequacy of the circle of Willis and of the other brachiocephalic arteries. The increased haemodynamic demands of the arm musculature during exercise in the context of inadequate collateral supply can lead to vertebrobasilar insufficiency and the classical description of subclavian steal syndrome (Miller-Fischer 1961).

Subclavian artery stenosis or occlusion may be important when the internal thoracic artery is used as a conduit for coronary artery bypass graft (CABG) procedures. The proximal subclavian artery is stenosed in some 0.5%–2.0% of cases (Diethrich and Cozacov 1995), and may result in a coronary-subclavian steal that can precipitate cardiac ischaemia. Some authors have recommended subclavian angiography (Harjola and Valle 1974) and percutaneous transluminal angioplasty (PTA) of a significant stenosis, prior to CABG, with surveillance subsequent to CABG to identify and treat (re)stenosis (Westerband et al. 2003).

Despite the above, subclavian artery stenotic disease usually has a benign natural history (Ackermann et al. 1988), and most cases of even severe innominate and subclavian artery stenosis are asymptomatic. Symptoms of chronic arm ischaemia, when they occur, are similar to those found in the lower limb. Intermittent claudication, rest pain, gangrene, and ulceration are all well recognised.

10.2.1.1.1 Investigation

Duplex ultrasound is very sensitive for upper limb stenotic disease as most of the arteries are superficial. However, the intrathoracic innominate and proximal left subclavian arteries cannot generally be directly imaged with ultrasound, but stenoses/occlusions can be inferred from a damped downstream duplex waveform, and reversal of flow in the ipsilateral vertebral artery. Computed tomographic angiography (CTA) is very useful for proximal disease assessment. Magnetic resonance angiography (MRA) has been extensively utilised for imaging of the arch vessels, can provide some dynamic information, and can image the distal vasculature.

Angiography has long been considered the 'gold standard' for evaluation of the upper limb arteries, allowing dynamic imaging and assessment of pressure gradients across stenoses. However, as a first line, less invasive techniques are often used, with angiography reserved for cases where other imaging is inconclusive or when proceeding to endovascular intervention.

10.2.1.1.2 Treatment

Surgery using transthoracic and extrathoracic approaches has been utilised to enable anatomic and extra-anatomic reconstruction, with excellent reported success and patency rates. These are of the order of 86%–100% in the short term, with long term patency remaining above 80% at 5 years (Cinar et al. 2004; Farina et al. 1989; Law et al. 1995), unless autologous vein grafts are used, which have lower long-term patencies (Law et al. 1995; Ziomek et al. 1986). However, associated morbidity and mortality is not inconsequential. Reported mortality following transthoracic procedures may be as high as 6%–22% (Berguer et al. 1998; Kandarpa et al. 2001). Extrathoracic techniques have a much better safety profile, but reported mortality still reaches up to 3%, with significant complications in as many as 10%–19% (Kandarpa et al. 2001; Wittwer et al. 1998).

PTA of the subclavian artery was first reported by Mathias et al. (1980). Since then, PTA with or

without stenting has become the first line treatment, mainly because of the lower morbidity and mortality of this approach (Kandarpa et al. 2001).

In a review of 423 treated arteries, Becker et al. (1989) reported an overall complication rate of 5%, with 1% relating to the central nervous system. Similar results were noted by de Vries et al. (2005) with a major stroke and death rate of 0.9%, minor stroke/amaurosis fugax 2.7% and local complications 4.5%. Technical success in stenotic disease is reported in 90%–100% of cases (de Vries et al. 2005; Henry et al. 1999; Motarjeme 1996). However, although some authors quote similar rates of technical success when dealing with occlusions (Martinez et al. 1997; Sadato et al. 2004), a number of other studies report immediate technical success rates as low as 46%–65%, due to failure to cross the lesion (de Vries et al. 2005; Hebrang et al. 1991; Henry et al. 1999; Motarjeme 1996). Schillinger et al. (2001) found that predictors of procedural failure were occlusions and long stenoses (≥ 2 cm).

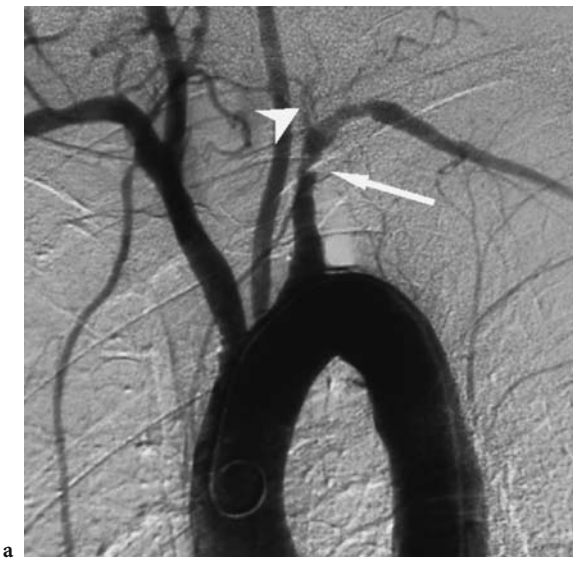
It is important to consider the approach when dealing with these lesions and this may affect the chances of technical success. Percutaneous upper limb arterial intervention can be performed transfemorally or transbrachially (rarely transaxillary). Transfemoral access is useful as devices (e.g. stents) can be used with less chance of access site damage. However, prolonged catheterisation in the aortic arch risks potentially catastrophic cerebral embolisation. Furthermore, ostial disease of the arch branches, and occlusions, may be more difficult to deal with via the groin. Transbrachial access is generally more useful in these circumstances, as the relative proximity of the lesion to the access site gives better catheter and wire control. In practice it is often best to have both transbrachial and transfemoral access, with brachial access obtained using ultrasound. This allows the use of a 'wire-loop' technique, with the upper limb lesion crossed via a brachial approach using a 4- or 5-F system. The wire can then be snared from below, and the device (e.g. a stent requiring a larger sheath size) deployed across the lesion from a femoral approach.

During the procedure, particularly when treating prevertebral and perivertebral subclavian lesions, there is a risk of embolisation to the posterior intracranial circulation, causing stroke. However, in the presence of subclavian steal, Ringelstein and Zeumer (1984) showed that retrograde flow in the ipsilateral vertebral artery takes between 20 s and 20 min to reverse following treatment, thereby providing protection. Vitek (1989) found pre- and postvertebral stenoses could be safely treated with PTA balloons placed across the vertebral artery origin, whatever the direction of initial vertebral flow, as long as the perivertebral subclavian artery was disease free. Perivertebral lesions appear to be most likely to generate vertebral emboli during PTA, and there is also a risk that the vertebral origin will become occluded by atheromatous material during angioplasty. It is then usually best to use vertebral protection, utilising a 'kissing balloon' technique (with a second balloon inflated simultaneously in the proximal vertebral artery), or at least to place a wire into the vertebral artery so that its origin can be angioplastied if necessary (Fig. 10.1).

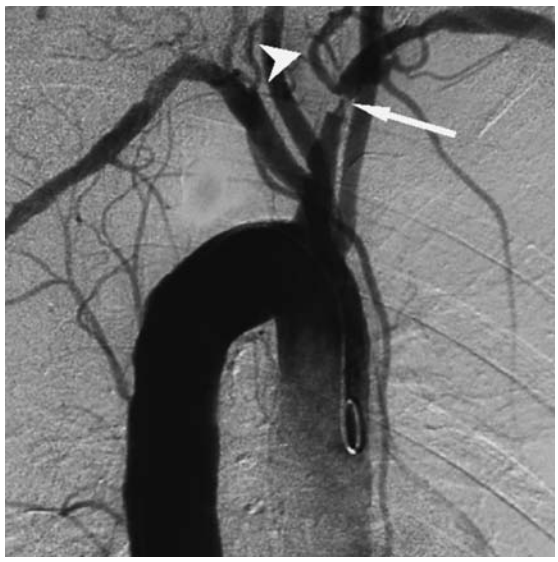
The size of stent or PTA balloon used should be appropriate to the size of adjacent non-diseased artery. We find that balloon sizes of 7 mm or 8 mm are most commonly used. Whichever the route of access, good endovascular technique and judicious use of heparin is mandatory to minimise the risk of embolic complications.

Long term results for PTA of subclavian and innominate artery stenotic disease have shown primary patency of 70%–93% at 1–3 years (Farina et al. 1989; Henry et al. 1999; Rodriguez-Lopez et al. 1999; Schillinger et al. 2001), although longer term figures demonstrate a wider variability of 54%–90% at 5 years (de Vries et al. 2005; Farina et al. 1989; Schillinger et al. 2001).

If a stent is to be used, consideration has to be given as to whether to utilise a self-expanding or balloon mounted device. The choice of stent type depends primarily on the location of the lesion, and generally balloon mounted stents are used where accurate placement is required, e.g. for ostial disease (Fig. 10.2). Self-expanding stents treat elastic recoil but may lack the radial force to remain expanded in a fibrotic lesion. Some operators reserve stenting for cases where there is suboptimal result from angioplasty due to stenosis recoil or flow-limiting dissection, but others use primary stenting of all significant subclavian and innominate lesions (Brountzos et al. 2004; Henry et al. 1999). In theory, primary stenting reduces the risk of flow-limiting dissection and distal embolisation, although there is little evidence to support this. Post-procedural luminal diameter following stenting is better than with PTA alone, but some data suggest longer term outcome might be less advantageous than PTA alone, with reported primary patency of 73% and 60% at 1 and 4 years, respectively (Rodriguez-Lopez et al. 1999; Schillinger et al. 2001). Secondary patency results are more satisfactory at



a



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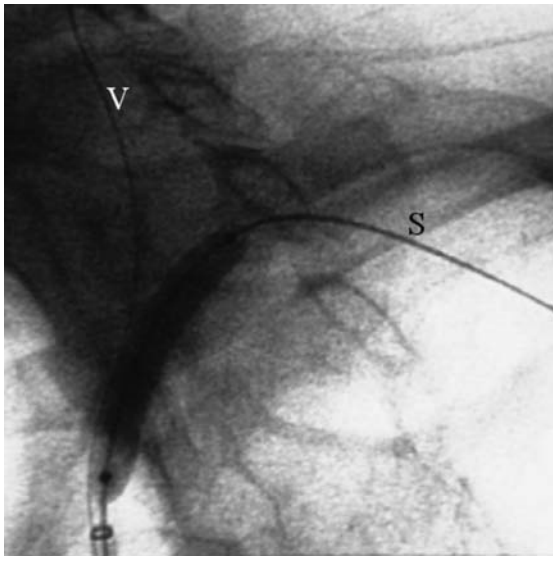
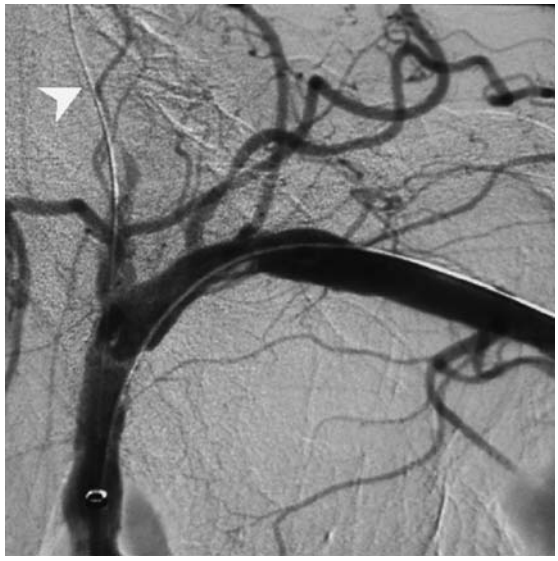
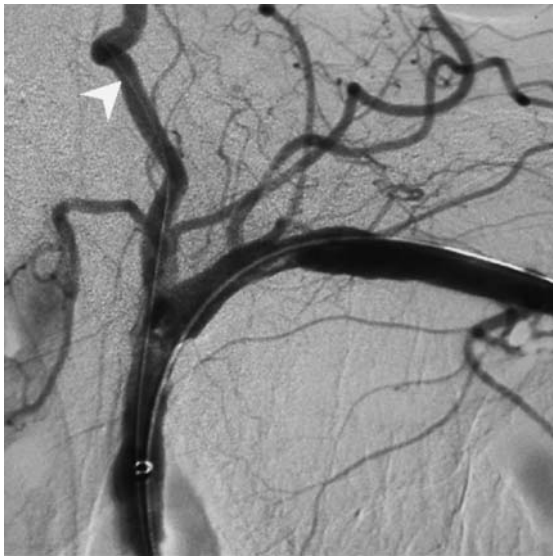


c



d



e

Fig. 10.1a–e. a,b Left subclavian artery stenosis (*arrows*). Note the proximity of the origin of the vertebral artery (*arrowhead*). **c** Balloon angioplasty of the stenosis with a supporting guidewire in the subclavian and axillary artery (*S*) and a protection guidewire in the vertebral artery (*V*). **d** Following angioplasty, the stenosis has improved, but there is now absent flow in the vertebral artery (*arrowhead*), which is rectified (**e**) by subsequent angioplasty of the vertebral artery origin

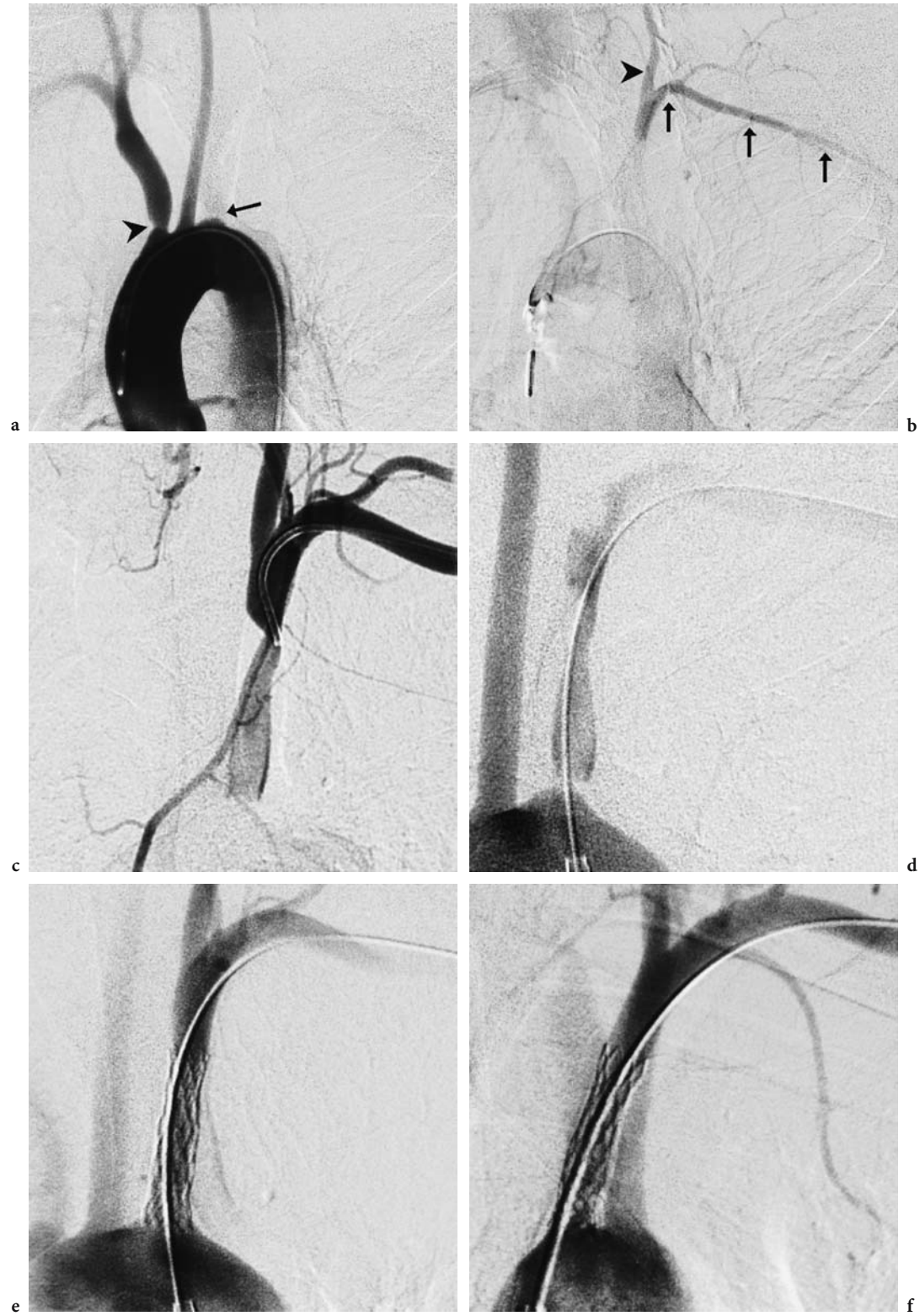


Fig. 10.2a–f. a Arch aortography demonstrates occluded left subclavian artery origin (*arrow*) and incidental minor innominate artery stenosis (*arrowhead*). **b** Distal subclavian and axillary artery (*arrows*) fill via retrograde vertebral artery flow (*arrowhead*). **c** The occlusion was crossed with a wire from the brachial approach, which was snared from below to allow transfemoral stenting via a long 8-F sheath (**d,e,f**).

90%–94% (Henry et al. 1999; Rodriguez-Lopez et al. 1999). Further concern relates to the long-term structural integrity of stents in the distal subclavian artery, where compression between the first rib and clavicle, and flexion forces on arm movement can lead to strut fracture and recurrent stenosis/occlusion. It was hoped that self-expanding stents might solve this problem, with their ability to conform to these compressive forces, but this does not appear to prevent breakage (Phipp et al. 1999). Fortunately, most subclavian atheromatous lesions are prevertebral, and here, stent disruption is much less likely.

For occlusions, there is some evidence that primary stenting may be superior to PTA alone. Duber et al. (1992) reported a poor patency rate of 43% at 16 months following PTA in a small cohort of patients with subclavian artery occlusion. By comparison, Martinez et al. (1997) found an 81% cumulative patency rate at 6 months following stenting of occlusions, similar to the 86% patency at 1 year noted by Sadato and colleagues (2004). However, long-term data of stent performance in proximal upper limb occlusions is lacking.

10.2.1.2 Other Diagnoses

Atherosclerosis is the major cause of chronic large vessel occlusive disease in the upper limb, but other diseases have a relatively larger role than in the lower limb.

The inflammatory arteritides such as Takayasu's disease and giant cell arteritis cause stenotic and occlusive lesions by mural inflammation and fibrosis. Medical therapy to suppress active inflammation remains the cornerstone of treatment.

Surgery or endovascular treatment is usually reserved for the treatment of severely symptomatic stenoses in the chronic 'burnt out' phase of the disease, although endovascular intervention has been reported during active disease. Results are generally inferior to those reported for atheromatous disease (Joseph et al. 1994; Kerr et al. 1994), probably due to the transmural nature and greater extent of involvement in inflammatory arteritis (Maškovi et al. 1999). However, acceptable results have been demonstrated in a number of small series, including some cases of active disease where adjuvant systemic therapy was given to reduce the risk of early restenosis (Sharma et al. 2000; Tyagi et al. 1998). Furthermore, recurrent stenoses can be safely treated with further endovascular intervention (Tyagi et al. 1998).

Previous radiotherapy, particularly in the axilla for nodal metastases from breast carcinoma, or over the lung apex for bronchogenic lesions, can cause large artery steno-occlusion, often over a long segment. Surgical bypass can provide good results (Jindal and Wolfe 2005; Law et al. 1995; Ziomek et al. 1986). However, surgery to previously irradiated tissue may be fraught with difficulties. Endovascular techniques offer a potential solution to some of the problems with surgery. Only small case series exist: short-term results are good, but long-term are blighted by recurrent steno-occlusion (Liu et al. 1998; McBride et al. 1994).

10.2.2 Acute Upper Limb Ischaemia

Symptomatic acute ischaemia of the upper limb is more common than its chronic counterpart, and may lead to severe ischaemia, occasionally necessitating amputation. Eyers and Earnshaw (1998) found that 17% of all cases of acute limb ischaemia occur in the arm, and is usually due to macroembolic disease, with 90% of cardiogenic origin. Other causes of acute upper limb ischaemia are listed in Table 10.2. The most common landing site (60%) of upper limb emboli is the brachial artery (Hernandez-Richter et al. 2001; Kaufman 2004). In general, embolic occlusion of the brachial artery

Table 10.2. Causes of acute upper limb ischaemia

- Embolus
  - Cardiogenic
  - Proximal atheroma
  - Aneurysm
  - Fibromuscular dysplasia
  - Vascular injury
- Trauma
- Thrombosis
  - Brachial/radial artery cannulation
    - Iatrogenic
    - Inadvertent in intravenous drug use
  - Occupational
  - Vasculitis
  - Spontaneous
  - Hypercoagulation syndrome
- 'Steal' from haemodialysis fistula formation
- Aortic dissection
- Compartment syndrome

is not usually limb threatening because of collateral flow. Conservative therapy with anticoagulation is often appropriate, particularly in elderly patients, as there is a high incidence of co-morbidities which contribute to significant mortality rates of between 5.6%–19% at 30 days (Hernandez-Richter et al. 2001; Sultan et al. 2001) and 63% at 5 years (Licht et al. 2004). However, severe ischaemia requires urgent treatment; diagnosis is frequently clinically apparent and the majority of cases are best and most easily treated surgically, with or without angiographic confirmation. Technical success following surgical thrombectomy is achieved in 65%–94%, limb salvage rates are between 82% and 100% and residual symptom rates are reasonably low. Local and general complications occur in up to 28% (Eyers and Earnshaw 1998; Hernandez-Richter et al. 2001; Licht et al. 2004). If the limb is not immediately threatened, endovascular therapy may be considered, usually with catheter directed thrombolysis. In the largest published series of 55 patients, of whom 40 were deemed suitable for intra-arterial thrombolysis, the overall rate of complete recanalisation was 55%. All patients had some clinical improvement. Those with successful thrombolysis required no further intervention, and those in whom thrombolysis failed were treated medically (56%) or by embolectomy (44%). All limbs were saved, with only mild residual symptoms in 1.8% of the original 55 patients (Cejna et al. 2001). These results are supported by Coulon et al. (1994) who reported a complete recanalisation rate of only 63%, but limb salvage in all 13 of their patients, 15% of whom had mild residual symptoms. Patients with limited surgical options for severe ischaemia because of very poor distal run-off resulting from thromboembolism, may also benefit from fibrinolytic therapy (Johnson et al. 1999).

However, despite their reasonable results, these series are small, there is no data that gives a true comparison with surgical thromboembolectomy or conservative treatment, and generally there is sparse evidence to guide endovascular treatment in the acutely ischaemic upper limb.

Micro-embolism can present with vertebrobasilar symptoms, or with the classical 'blue digit syndrome', caused by digital micro-infarcts and splinter haemorrhages. Showers of micro-emboli from ulcerated proximal atheromatous plaque frequently lead to intermittent symptoms. Treatment involves aggressive anti-platelet medication and PTA to treat the offending plaque, leading to remodelling and stabilisation (Gaines et al. 1999).

10.3 Trauma

Vascular injuries of the upper extremity occur more commonly than in the legs. A significant proportion of upper limb vascular trauma is iatrogenic, secondary to arterial catheterisation or misplaced venous line insertion. Conservative measures are usually appropriate for minor trauma, and imaging is not required unless there are 'hard' signs of vascular damage.

Severe trauma can result in arterial transection or branch avulsion leading to life-threatening haemorrhage. Surgical intervention traditionally provides the mainstay of therapy, but use of endovascular techniques has been reported in small numbers of patients. The potential benefits of avoiding a 'hostile' surgical environment with its inherent risks favour minimally invasive therapy, though logistics often mean that surgery is the first consideration. Endovascular intervention is unlikely to be successful in the severely disrupted artery because of the difficulties crossing the traumatised vessel with a guidewire, but bleeding branch vessels may be embolised using coils. If a guidewire can be placed across a damaged segment of artery, an inflated balloon catheter of appropriate size will tamponade the lesion (Lin et al. 2000). This allows time for consideration of other therapeutic options, or may indeed treat small arterial wall deficits. Stent-grafts have been used to repair actively bleeding axillary artery injuries (Dinkel et al. 2002), post-traumatic occlusion (Strauss et al. 2001), and exclude arteriovenous fistulae and false aneurysms (Broadbent et al. 2003; Hilfiker et al. 2000). Long-term outcome is uncertain but emergency stent-graft placement for arterial damage may provide a valuable short-term solution, allowing other, potentially more serious, injuries to be stabilised before surgical repair.

Inadvertent arterial puncture during central venous catheterisation can be treated by external pressure if the injury is compressible, but if this is not possible, or unsuccessful, endovascular treatment can be performed using angioplasty balloon tamponade, stent-grafting (Schoder et al. 2003) or use of commercially available closure devices (Nicholson et al. 2004).

10.4 Thoracic Outlet Syndrome

Thoracic outlet syndrome (TOS) describes a number of different symptoms related to compression of subclavian vessels and the brachial plexus exiting the

thoracic outlet, typically occurring when the arm is abducted. There are a variety of recognised causes including cervical ribs and fibrous bands, but many cases occur in the presence of 'normal' anatomy. Neurogenic symptoms are commonest (90%), and arterial TOS is unusual accounting for only 1%–2% of cases (Davidovic et al. 2003; Kaufman 2004). Symptoms include positional ischaemia, a palpable pulsatile mass and sequelae of distal embolisation. Diagnosis can be established on duplex ultrasound, and angiography, where classically there is compression of the distal subclavian artery upon provocative hyperabduction of the arm. However, this is also seen in 30% of 'normal' individuals. More sensitive indicators to pathological involvement include persistent stenosis and vessel irregularity in the neutral position, occlusion and distal subclavian artery dilatation or aneurysm formation. MRI or CT may be helpful in identifying abnormal soft-tissue structures.

Endovascular options for treatment include thrombolysis of in-situ thrombus, stenting for stenoses, and stent-grafts for aneurysm exclusion. However, because of the underlying mechanism, stent/stent-graft devices are placed in a position of high compressive stress, and mid- to long-term results have been disappointing, with restenosis, occlusion and device disruption (Phipp et al. 1999). Their use is generally not recommended unless combined with surgical decompression (Kaufman 2004). Surgical decompression and repair/bypass probably remains the treatment of choice at this time (Rigberg and Freischlag 2004). However, it should be noted that 20% of patients show no improvement following surgery.

10.5 Aneurysmal Disease

Aneurysms of the upper limb arteries are rare, accounting for less than 2% of all peripheral aneurysms. The position of the aneurysm may give some clue as to its aetiology. Proximal subclavian and innominate artery lesions are most likely to be degenerative, whereas distal subclavian and proximal axillary artery aneurysms are usually secondary to the rare arterial TOS. More distal aneurysms are highly likely to be secondary to trauma. Mycotic lesions and connective tissue disorders should always be considered. Aberrant right subclavian arteries often have a patulous origin, and are associated with proximal aneurysmal dilatation, which may lead to oesophageal compression (dysphagia lusoria) and a high risk of rupture (Lacroix et al. 2003).

Aneurysmal disease can thus lead to rupture, thrombosis, distal embolisation or, particularly if intrathoracic, compressive symptoms. Imaging is best performed with CTA/MRA if proximal, and ultrasound if peripheral.

The rarity of upper-limb aneurysms means no firm recommendations regarding treatment are available. Surgical repair or bypass is well established, and may also treat the underlying cause (e.g. decompression in TOS). However, subclavian artery aneurysm repair can result in a complication rate as high as 46% (Salo et al. 1990), particularly if transthoracic techniques are required. Endovascular repair using stent grafts has been described in a number of small series, both as an elective and emergency procedure (Lacroix et al. 2003; Schoder et al. 2003). However, there remains no long-term data on stent-graft durability and performance.

10.6 Conclusion

The circulation of the upper limb can be affected by a broad variety of disorders. However, upper limb arterial disease is markedly less common than that seen in the lower limb. As a result, firm evidence regarding how specific lesions and disorders should be treated is often lacking. It would appear, however, that use of endovascular techniques in the management of upper limb arterial stenoses and occlusions is associated with fewer complications than open surgery, with acceptable clinical rates. Endovascular therapy is however not suitable for the treatment of TOS, because some form of surgical decompression is required.

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11 Management of Renal and Visceral Arterial Stenoses

Mark G. Cowling

CONTENTS

11.1 Introduction

The two main aetiologies for renal artery stenosis (RAS) are fibromuscular dysplasia (FMD), a cause of secondary hypertension in younger patients, and atheroma. Other aetiologies such as neurofibromatosis and middle aortic syndrome are much more rare. With increased longevity and improved survival after events such as myocardial infarction and stroke, atheromatous renal artery stenosis (ARAS) is becoming a more prevalent disorder. The availability of non-invasive imaging techniques also means that it is being diagnosed more frequently. Visceral artery stenoses causing symptomatic gut ischaemia are fairly uncommon, but endovascular therapy can play an important role in their management.

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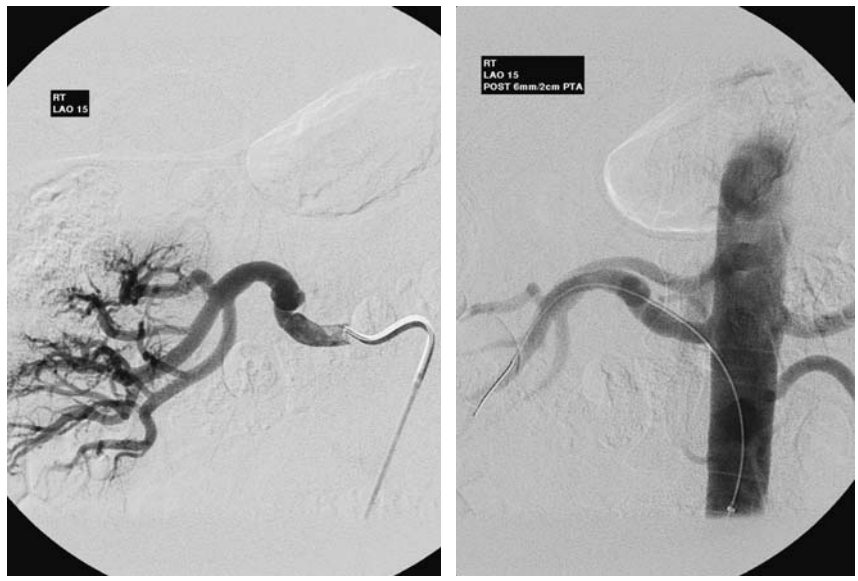
11.2 Renal Artery Stenosis

The two main aetiologies of RAS are quite distinct in their clinical manifestations and tend to present at different times of life. FMD is rare, but its importance lies in the fact that with suitable treatment it represents a potentially curable cause of hypertension in young patients. FMD causes web like stenoses which narrow the renal artery lumen (Fig. 11.1). The consequent reduction in renal perfusion activates the angiotensin system, causing hypertension which may be very difficult to control pharmacologically. Although it may progress, it rarely causes renal artery occlusion or renal dysfunction. The nature of the pathology makes it eminently suitable for treatment by angioplasty, with good and sustained long term clinical results (Surowiec et al. 2003).

Atheromatous renal artery stenosis is rather more complex. ARAS occurs in an older patient group than FMD, and as such its role in causing hypertension is much less clear cut. Most of these patients will have essential hypertension, which may even be a contributory cause of the atheroma which has lead to RAS. Despite this, however, it is clear that there is a group of patients in whom there is a renovascular component to their hypertension. This is usually apparent where blood pressure has become impossible to control adequately with drug therapy. Although cure of hypertension will not be possible, renal revascularisation may make pharmacological control easier.

Renal impairment may also be associated with ARAS, and in the author's experience this is the most common reason for consideration of renal revascularisation. The most straightforward patient group are those who present with a rise in serum creatinine after commencing an angiotensin converting enzyme inhibitor (ACEI). If the patient requires treatment with this class of drug, and most with cardiovascular disease will benefit from such treatment, there is a strong case to perform renal revascularisation. Impaired renal function alone is not necessarily an indication for treatment. The trend in renal function is very



a b

Fig. 11.1. a Selective right renal arteriogram showing classical features of FMD in a 32-year-old patient with hypertension not being controlled by multiple agents. **b** Flush aortography performed via long sheath. This image demonstrates that appearances in the treated artery have improved considerably, but have not been abolished completely. Nonetheless there was an excellent clinical response. Note also a smaller upper pole artery which is unaffected by FMD

important in this setting. Patients with a stable serum creatinine may well be best left untreated, as that situation could persist for many years without progression to dialysis. In that setting, the risk of renal revascularisation is considered by most workers not to be justified. However, in the case of deteriorating renal function, there is a strong case for revascularisation, as without it the likely outcome is end stage renal failure and dialysis. This is especially true in cases of bilateral renal artery stenosis, or where there is a single kidney. It is probably not worth treating where the serum creatinine has risen above 300–350 μmol/l. Similarly, patients who are already receiving dialysis therapy are unlikely to benefit from renal revascularisation. The exception in both of these cases is where there has been a very rapid deterioration in renal function. In this instance long chronic renal damage may not yet have occurred, and if revascularisation can be performed within a few hours or days the results can be striking.

Finally so-called flash pulmonary oedema represents an infrequent but strong indication for intervention. The pathophysiology of this condition is not well understood, but it tends to occur in patients with coronary artery disease and either bilateral ARAS or ARAS affecting a single functioning kidney.

11.3 Investigation of RAS

Having identified a patient who is clinically suspected of having RAS, it then becomes necessary to investigate them. Several imaging techniques are available including conventional angiography, CT angiography (CTA), MR angiography (MRA) and finally captopril renal scintigraphy.

Conventional angiography is regarded by many as the "gold standard" technique. It has the disadvantages of being invasive, with the attendant complications, as well as requiring iodinated contrast media and ionising radiation. However, in the case of FMD, it is the only one of the techniques named above that has the spatial resolution sufficient to confidently exclude the diagnosis.

CTA also has the disadvantages of using ionising radiation and requiring iodinated contrast. The latter is a particular disadvantage in patients with diabetes and/or renal impairment, who are at higher risk of contrast induced nephropathy. For this reason CTA has become our second line for the non-invasive investigation of RAS. Nonetheless, particularly with the advent of multislice technology, CTA is capable of producing very high quality renal arteriograms. It provides a useful second line where MRA is not possible, for example in patients with cardiac pacemakers. CTA has a high sensitivity and specificity (90%–98%), and being a cross sectional technique provides information about the best projection angles to use when planning renal artery intervention (Fleischmann 2003). CTA is also of value in the assessment of restenosis within renal artery stents (Raza et al. 2004).

MRA is non-invasive and does not involve the use of iodinated contrast media. Non-contrast enhanced renal MRA using time-of-flight or phase contrast

techniques has significant limitations. These are largely overcome by using Gadolinium enhanced renal MRA. Many series are available, and the sensitivity and specificity of Gadolinium enhanced MRA in the detection of renal artery stenosis have been reported as 88%–100% and 70%–100%, respectively (Zhang and Prince 2004). Like CTA, MRA also allows the renal artery anatomy to be examined prior to intervention to facilitate planning which obliques should be used. This not only shortens the procedure, but also reduces the dose of iodinated contrast required.

Captopril renal scintigraphy relies on the principle that administration of the ACE inhibitor procedures a significant reduction in renal blood flow in a kidney affected by RAS. The technique is rather cumbersome and expensive, and has largely fallen out of use.

Thus, once the decision has been made to investigate a patient for RAS, it is now possible to non-invasively establish the diagnosis. Our first line investigation, in common with many, if not most, other centres, is renal MRA. If this reveals a significant stenosis which is considered suitable for intervention, the patient will then undergo renal revascularisation. In our practice there are two main exceptions to this, where we would elect to proceed directly to conventional angiography. The first is in the presence of accelerated hypertension in a young patient, in whom FMD is suspected, as in our view this is the only way to totally exclude FMD. The second is in patients presenting with rapidly deteriorating renal function with or without pulmonary oedema, in whom renal artery stenosis is strongly suspected. In this setting we would proceed directly to intervention if a stenosis is found.

11.4 Technique of Renal Revascularisation

Before commencing the procedure, fully informed consent is vital. The patients must understand the reasons why the procedure is being undertaken, be it for uncontrolled hypertension, renal impairment or flash pulmonary oedema. In the case of hypertension it should be clear that the only realistic aim is improved control rather than cure. With regard to renal impairment, they should understand that the aim is to halt a decline in renal function rather then reverse it. Similarly, renal function may be worsened in a significant proportion of patients. The risk of losing a kidney altogether is probably around 1%. Patients with a single kidney must be aware that in this event they may require dialysis which would most likely be lifelong, as transplantation is unlikely.

11.4.1 Renal Angioplasty

The procedure is most commonly performed through a femoral artery approach, and this will described in detail. However, if required by the patient's anatomy, for example the presence of iliac artery occlusions or a very steeply angled renal artery, the brachial approach can be used. A 6-F sheath is inserted into the femoral artery. The author favours the used of a long (typically 35-cm) sheath, though some others use guiding catheters. A preshaped catheter is then used to access the renal artery. One of the simplest to use is the Sos Omni (AngioDynamics, Queensbury, NY), which is a very similar shape to the Simmons catheter, but has a soft tip which can be reformed in the abdominal aorta, avoiding the need to reform it in the aortic arch. If the Sos Omni is unsuccessful, which is rare, the author will generally use a Cobra 2 catheter. The catheter is used in combination with a guidewire to cross the lesion. A hydrophilic guidewire such as a Terumo can be very helpful, especially in lesions that are difficult to cross, though many would also use the soft tipped Bentson guidewire. Having crossed the lesion, heparin and an antispasmodic drug are administered. The author uses 3000 units of heparin and 300 μg of isosorbide dinitrate, respectively.

With the catheter across the stenosis, the guidewire is changed to a specialist guidewire such as the Jindo (Cordis, Miami, FL). This has a short tapered floppy tip (4 cm long, 0.022" diameter). The wire then increases rapidly in diameter along its length to reach 0.035". The guidewire itself is very stiff, providing good support for the angioplasty balloon. The atraumatic nature of the tip is very important, as it can be placed in a cortical branch without significant danger of causing spasm. An angioplasty balloon is then introduced over the guidewire and angioplasty performed. Balloons are not oversized, but should instead be the same diameter as the artery distal to the stenosis. The exception to this is in the case significant post stenotic dilatation, where it is necessary to undersize slightly. Typical balloon diameters will vary between 5 mm and 7 mm, with females generally requiring smaller balloons. Loin pain with balloon inflation is common, but should not be severe. In the event of the latter, vessel rup-

ture may occur, and dilation should be stopped and a smaller balloon used. After dilation the balloon is removed and the guidewire left in place, and a check angiogram performed through the long sheath or guiding catheter. If there has been a complication or further dilation is required, access has thus been maintained to allow additional intervention. The presence of stenoses at vessel bifurcations, which are more common in FMD, may require the use of "kissing balloons", or additional guidewires to protect side branches. Such lesions are relatively unusual with atherosclerosis, but are seen, especially where there is an early bifurcation of the renal artery.

11.4.2 Renal Stenting

In many respects insertion of renal artery stents is performed in a similar way to renal angioplasty. However, stents are normally inserted at the ostium of the renal artery because they are used for the treatment of atheromatous disease. It is therefore essential to have a clear idea of the exact location of the ostium to facilitate accurate stent placement. Whilst it is possible to perform flush aortography in a number of projections to achieve this, it does potentially involve a significant contrast load even before commencement of the stent procedure. In our institution, almost all of the patients requiring renal arterial intervention for ARAS have had cross sectional imaging, either CTA or MRA for diagnosis. It is therefore our practice to refer to the cross sectional imaging to determine the obliquity required to optimally image the ostium of the target vessel. A single flush aortogram is then performed at that angulation for confirmation.

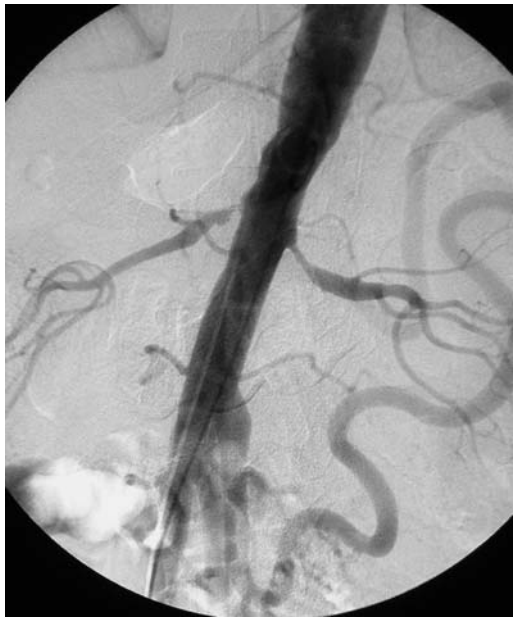
Prior to stent insertion it is of value to predilate the stenosis with a 4-mm balloon to ease the passage of the stent across the stenosis (Fig. 11.2). Although many recommend the use of a guiding catheter, modern long sheaths also perform very well. Use of either allows angiograms to be performed whilst finally positioning the stent prior to deployment.

There are no reported adverse consequences associated with leaving the stent projecting 2 mm or so into the aorta. Positioning the stent in this manner ensures that the entire lesion is stented.

Many systems have been reduced in diameter and now allow the use of 6-F sheaths. It may occasionally prove necessary to perform renal arterial intervention from a brachial approach, for example when femoral access is not possible or if the renal arteries are sharply angulated inferiorly (Fig. 11.3).

11.4.3 Intervention in Renal Transplants

Although technically similar in many ways to angioplasty or stenting in native kidneys, the management of transplant renal artery stenosis involves some important differences. Cadaveric transplants are generally anastomosed to the recipient external iliac artery, because it is possible to obtain the full length of



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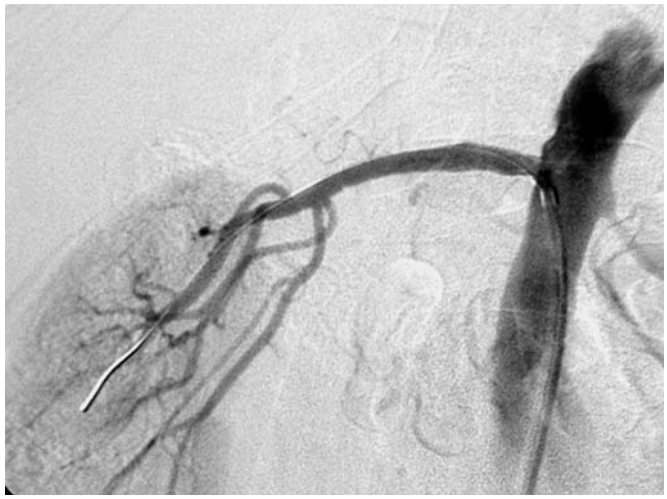


b

Fig. 11.2a,b. a Flush aortography in a patient experiencing episodes of flash pulmonary oedema. There is bilateral ostial renal artery stenosis. **b** Flush aortography after stent deployment on the right, showing the stent ideally postioned 2mm into the aortic lumen.

the renal artery as well as a patch of donor aorta. Live related transplants have a shorter artery, and as such are usually anastomosed to the recipient internal iliac artery. Thus as a general rule, it is usual to approach a cadaveric transplant ipsilaterally, whereas treatment of a live related transplant will normally involve a contralateral approach, crossing the aortic bifurcation to access the origin of the internal iliac artery.

11.5 Results

The results of percutaneous treatment for renal artery stenosis can be looked at in terms of the pathology being treated, and subdivided into technical success and clinical outcome. The latter is clearly very important, as however successful a procedure is

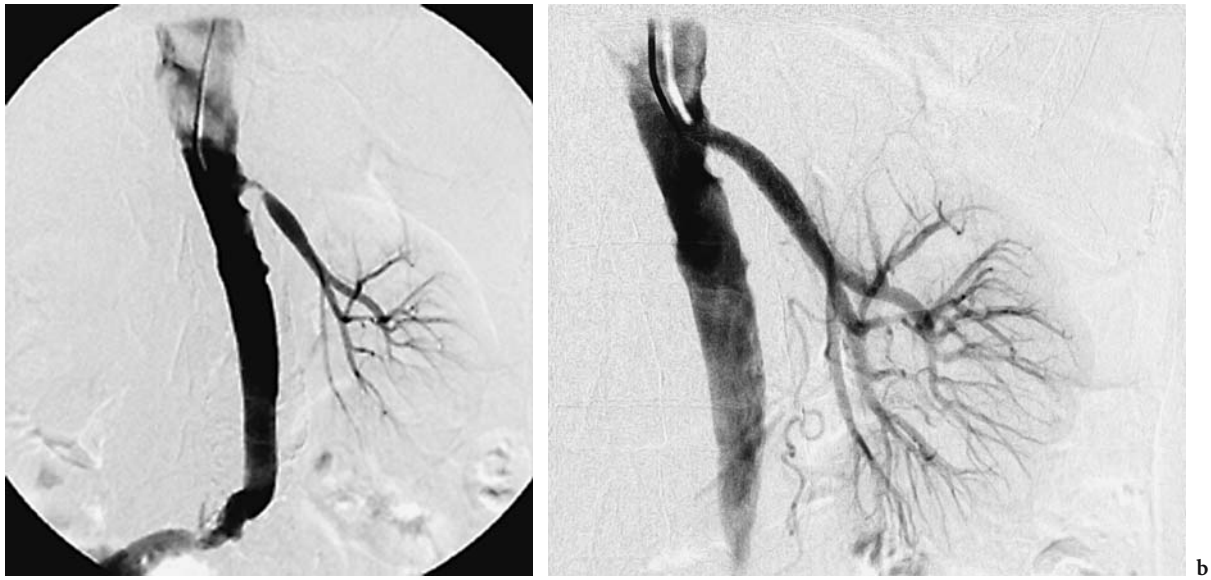


Fig. 11.3. a In this patient with a severe stenosis affecting a single left kidney, a femoral approach was not possible because the right external iliac and left common iliac arteries were occluded. A 90-cm long 6-F sheath was positioned in the upper abdominal aorta, and a Headhunter catheter used to select the left renal artery. **b** There was a good technical result after stent insertion, and the patient's episodes of flash pulmonary oedema resolved. Unfortunately, she developed a false aneurysm of the brachial artery, but this was successfully managed by thrombin injection

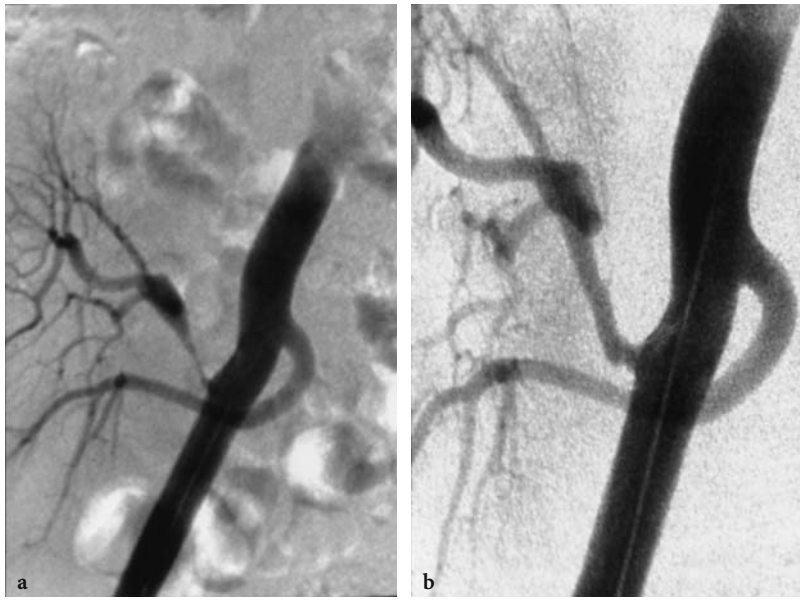


Fig. 11.4. a Transfemoral arteriogram of a cadaveric renal transplant in the right iliac fossa. Note a diffuse 90% stenosis of the proximal transplant artery. **b** This was treated by angioplasty for graft dysfunction, with a good technical and clinical result

technically, if there is no associated clinical benefit the entire procedure is rendered pointless.

11.5.1 Fibromuscular Dysplasia

The technical success for angioplasty in FMD has been reported as 91% in a review of ten series involving 90 patients (Flechner 1984). The technical results also appear to be durable, with a predicted 10-year patency rate of 87% being reported (Tegtmeyer et al. 1991). More recent, though admittedly smaller, studies have demonstrated similar results (Birrer et al. 2002; Surowiec et al. 2003). Clinical success is also excellent, with a cure rate of 25%–85% for hypertension reported. In a further 13%–60%, improvement in hypertension control is to be expected (Tegtmeyer et al. 1996). The published data therefore indicates that percutaneous angioplasty is the best treatment for renal artery stenosis caused by FMD. In addition, should a stenosis recur, it is usually straightforward to perform a further dilation.

11.5.2 Atheromatous Renal Artery Stenosis

Technical success of angioplasty for ARAS is generally held to be disappointing. The majority of atheromatous renal artery lesions are ostial, and early reports suggested technical failure rates as high as 80% (Cicuto et al. 1981; Sos et al. 1983). This figure contrasts with success rates of 75%–100% for truncal lesions. Although more recent reports give better results for technical success (Hoffman et al. 1998), they are still poor. The immediate technical results of renal artery stenting are, in contrast, excellent, with success rates in excess of 90% reported (Dorros et al. 1995; van de Ven et al. 1995). Such promising data led van de Ven and colleagues (1999) to undertake a randomised trial of renal artery angioplasty versus stenting. They randomised 84 patients (42 to angioplasty and 43 to stenting), and followed them for 6 months. Primary success was 57% for angioplasty and 88% for stenting. Primary patency at 6 months was 29% for angioplasty and 75% for stenting. Restenosis after a successful primary procedure occurred in 48% of the angioplasty group and 14% of the stent group. Twelve of the angioplasty group underwent stent insertion due either to primary or late failure of angioplasty. An intention to treat analysis showed no difference in the clinical results of the two groups. A cost effectiveness analysis was also performed, and the authors conclude that although the clinical outcomes of angioplasty followed by rescue stenting are similar to those of primary stenting, primary stenting is more cost effective.

Although in technical terms the choice between angioplasty and stenting now seems clear, data regarding the clinical outcomes of treatment of ARAS are far less certain. A great deal of effort has been put into trying to establish whether treatment of ARAS is beneficial in the management of hypertension. In truth it is unrealistic to expect much effect on hypertension in elderly patients with atheromatous, noncompliant vessels. In addition, up to 32% of patients receiving best medical therapy have been reported to show spontaneous improvement in their hypertension (Brawn and Ramsey 1987). It is generally acknowledged that modern hypertensive agents are even more efficacious than at the time of that study, and it may therefore be the case that hypertension is now more easily managed. It is therefore not justified to treat every hypertensive patient who has ARAS with renal artery stenting. However, there probably is a place for treating patients who have uncontrollable hypertension requiring maximal doses of multiple agents. The logic behind this is that even if the outcome is to improve control despite needing the same number of agents, this is a worthwhile gain clinically. The problem is that one does not know the outcome of the procedure until after it has been performed.

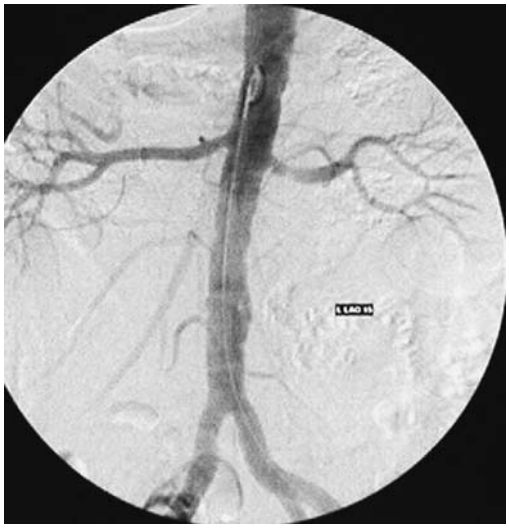
With regard to renal function, the picture is far from clear. The simplistic view that renal impairment in ARAS is due to impaired blood flow, and should therefore be treatable by revascularisation, is clearly untrue. The situation is far more complex, with other factors being involved, not least progressive and irreversible renal damage occurring over a period of time prior to diagnosis and treatment. There is some evidence that renal stenting may be of value in a proportion of patients with impaired renal function and ARAS. Improved renal function is generally taken as representing a greater than 20% reduction in serum creatinine, stable function a less than 20% increase or decrease and worsened renal function a greater than 20% increase. There is not, however, a linear relationship between serum creatinine and glomerular filtration rate (GFR). It has therefore been advocated that reciprocal creatinine plots should be used instead (Harden et al. 1997). These authors showed that the mean rate of decline in renal function was significantly reduced by stenting. Thus, although renal function continued to deteriorate in some patients, the rate was

slower, potentially delaying the onset of dialysis. A study looking at outcomes after renal angioplasty (Harden et al. 1997) showed that serum creatinine improves in 25%–43%, remains stable in around 33% and deteriorates in 10%–35%. Despite the anatomically superior results of stenting, there is seemingly little difference with regard to the effect on function, as most recently shown by the Dutch group (van de Ven 1999) in their randomised study.

11.6 Complications

There is no agreed reporting standard for complications in renal revascularisation. Moss and Hamilton (2000) undertook an analysis of a total of 24 studies of both renal angioplasty and stenting. They divided complications into major (renal insufficiency, renal artery occlusion, renal artery damage including rupture etc.) and minor (temporary renal insufficiency, retroperitoneal haematoma, groin complications etc.). They found that major complications occurred in 7.8% and minor complications occurred in 7.0%. The complication rates were similar between the stent and the angioplasty group, with the only exception being the 6.4% rate of stent misplacement. There is relatively little difference in complication rates between the angioplasty and stenting groups.

With modern equipment and endovascular techniques, it is often possible to successfully treat complications. Thus, for example, should renal arterial rupture occur, it can be managed by inserting a balloon expandable stent graft. If arterial thrombosis occurs, often this can be managed by thrombolysis. If the artery is occluded by dissection (Fig. 11.5) because it has been difficult to cross, it may still



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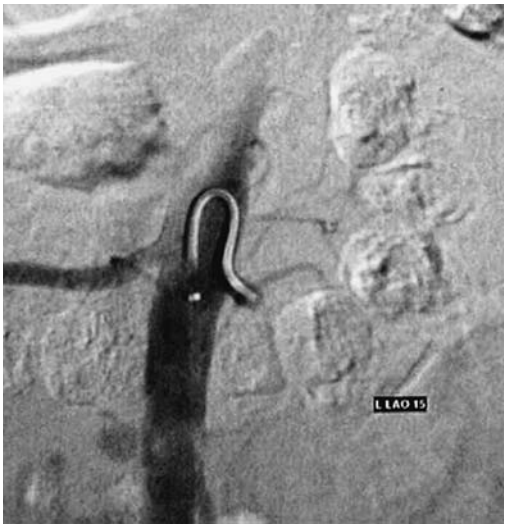

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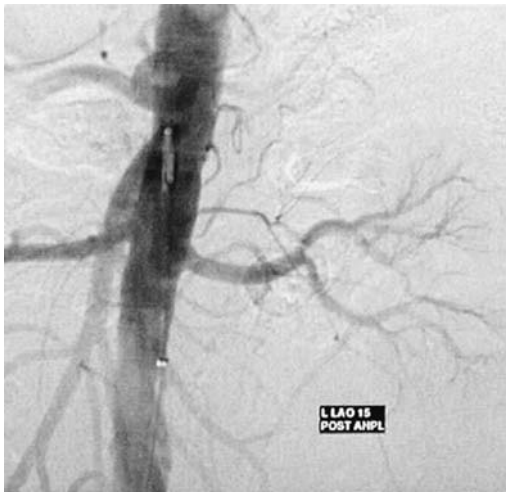

c

Fig. 11.5. a Pre-treatment arteriogram in a patient with an ulcerated plaque causing a 70% stenosis of the left renal artery. Treatment was being undertaken because of a rise in serum creatinine after administration of an ACE inhibitor. **b** Despite careful guidewire manipulation, vessel dissection occurred, causing complete obstruction of the vessel. **c** Using an angled Terumo guidewire it proved possible to cross the occluded segment and perform an angioplasty to reopen the vessel. The post-angioplasty appearance was so good that a stent was not used

however, prove necessary to undertake emergency surgical repair to effect reperfusion.

The most common complication, reduction or loss of renal function, can be multifactorial. Contrast induced nephropathy will often recover over a week to 10 days, though in patients with pre-existing renal impairment, serum creatinine may not return to its pre-treatment level. Cholesterol embolisation may also occur; this is generally not reversible, and if severe may be fatal.

Restenosis is the most important late complication. Where it occurs in patients who have had angioplasty for FMD it is almost always possible to manage with further angioplasty. Restenosis after angioplasty for ostial ARAS is so frequent that primary stenting is justified on cost effectiveness grounds (van de Ven 1999), and so strictly should be a thing of the past. However, there is an incidence of in stent restenosis of 6%–12%. This can be managed either by angioplasty or placement of a further stent. Neither strategy is perfect, and there is currently no evidence to support one over the other.

11.7 Management of Visceral Artery Stenoses

Mesenteric ischaemia is a relatively rare entity. It may be acute or chronic, but it is the latter that generally comes to the attention of interventional radiologists. The rarity of mesenteric ischaemia is explained by the presence of three arteries supplying the gut combined with a rich collateral supply. Thus it is generally accepted that at least two of the vessels need to be affected before symptoms occur. In the author's experience, this has generally involved occlusion of two vessels with a stenosis of the third. There is usually evidence of vascular disease elsewhere, and there is often quite severe aortic involvement.

The diagnosis is generally made quite late, with the patient having undergone multiple investigations for weight loss and, frequently post prandial, abdominal pain. They may also experience diarrhoea, nausea and vomiting. Latterly we have found CTA to be an invaluable tool in establishing the diagnosis. Although MRA may be equally useful in identifying stenotic or occlusive disease, CTA gives a much clearer depiction of vessel wall calcification. This gives an indication of how good the response to endovascular therapy may be, and also allows decisions regarding which vessel to treat to be made beforehand.

11.8 Indications for Treatment

If the patient has classical symptoms with vessel involvement as described above, a good response to treatment is highly likely. Other patients whose symptoms are less typical may eventually be treated because there seems to be no other option. However, treatment results in this group are often disappointing. Endovascular treatment is only indicated for intrinsic disease of the mesenteric vessels, which for practical purposes is always due to atheroma, even though FMD is a theoretical possibility. Extrinsic compression does not respond to angioplasty, and at present there is no evidence as to whether stents will fair any better in this setting.

11.9 Technique

The author uses essentially an identical technique to that employed for renal revascularisation. Although a brachial approach has certain potential advantages, because of the caudal angulation of the visceral vessels, with modern guidewires, long sheaths and guiding catheters the femoral approach is often feasible. It is probably most often a matter of operator preference (Fig. 11.6).

There are no randomised data on whether angioplasty or stenting are most suitable for this indication. Several studies have suggested no difference when angioplasty is used for treatment of ostial or non-ostial lesions of visceral vessels (Allen et al. 1996; Matsumoto et al. 1995). However, the numbers of cases published in the literature are inevitably small. Since there is no likelihood of randomised data ever becoming available on this matter, it would seem reasonable to look at the renal arterial data. Ostial stenoses of the visceral vessels are caused by aortic atheroma, in a very similar way to ostial stenoses of the renal arteries. Thus, based on the Dutch randomised trial (van de Ven 1999) the response to angioplasty might be expected to be less than that for stenting. Although some workers suggest that the pathology is different and that angioplasty with selective stenting is a better policy, we shall never know for sure. Pragmatically, therefore, the author has adopted the policy of primary stenting for ostial visceral artery stenosis. Non-ostial lesions are still treated by angioplasty, with stent insertion reserved for angioplasty failures such as elastic recoil or flow limiting dissection.

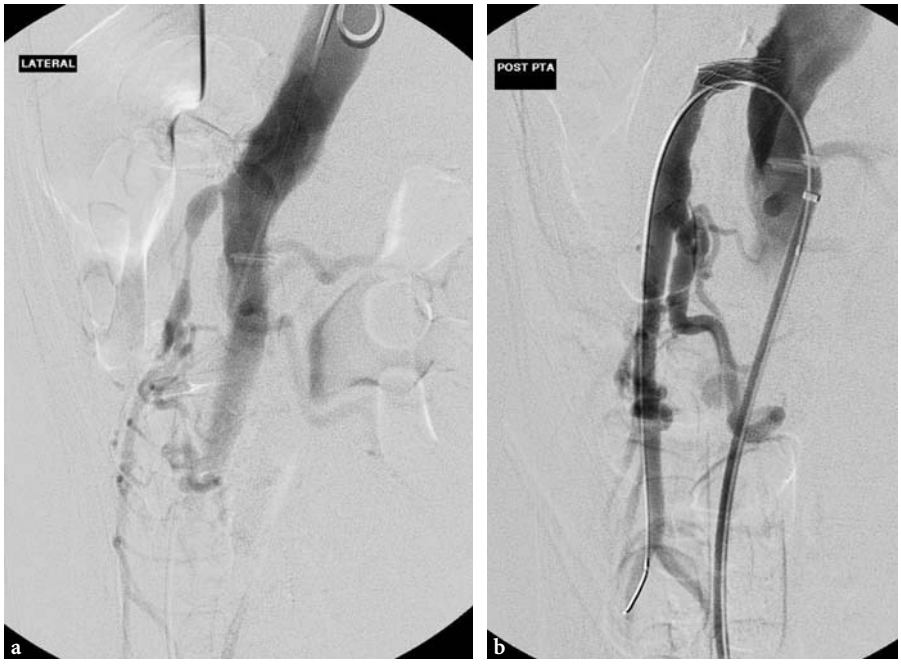

Fig. 11.6. a Flush aortography in a 58-year-old lady with a 1-year history of abdominal pain after meals and 25-kg weight loss. It confirms the findings of a previous CTA, which had shown occlusion of the coeliac axis and IMA, with a severe stenosis at the origin of the SMA, and a further stenosis within the SMA itself. **b** Despite the angulation of the vessel, it proved possible to predilate the origin with a 4-mm angioplasty balloon and insert a 6-mm diameter balloon expandable stent. The stenosis within the SMA itself was successfully treated by angioplasty.

11.10 Results

The number of series published on this subject is growing. However, all of the publications concern series of 10–25 patients, and are not randomised. Earlier series from the late 1980s to mid 1990s reported technical success rates for angioplasty of between 79% and 95% (Odurney et al. 1988; Simonetti et al. 1992; Matsumoto et al. 1995; Allen et al. 1996). More recent series (Sharafuddin et al. 2003; AbuRahma et al. 2003; Chahid et al. 2004; Resch et al. 2005) have technical success rates of between 94% and 100%. These series, which include a mixture of angioplasty and stenting, therefore show a trend towards slightly better technical results. It is difficult to speculate as to the reasons for this, but it may in part be due to improvements in the equipment available, and also the availability of stents. Despite the improvements in technical outcomes, however, the immediate technical success remains broadly similar, with figure of anything between 80% and 100% being reported. Recurrent symptoms due to restenosis remain a problem, with between 21% and 39% requiring reintervention.

Although the long term results are inferior to those of surgery, they do illustrate that endovascular techniques offer a reasonable alternative in patients with intestinal ischaemia who are unfit for open revascularisation. An increasing number of patients fall into this category as our population ages.

11.11 Complications

It is difficult to be certain about complication rates in this situation. All of the series are relatively small, and there is almost certainly a degree of under reporting. Perioperative mortality of up to 5.8% has been reported, but this represents a single patient in only one of the series cited (Resch et al. 2005). Vessel dissection is clearly a worrying possibility, but in most cases successful management by stenting should be expected. Although embolisation to the gut is a theoretical possibility, reports would suggest that it rarely causes any clinically important problems.

11.12 Conclusion

Percutaneous renal revascularisation has become an accepted procedure for certain clinical indications. These include uncontrolled hypertension, especially when caused by FMD, flash pulmonary oedema and deteriorating renal function. There is evidence from one trial that it is more cost effective to treat ARAS by primary stenting. However, with easier access to non-invasive imaging, it is becoming clear that RAS is a common problem in our aging population. It is far from clear at present which of these patients

should be treated to avoid renal artery occlusion and the consequent need for dialysis. The results of two randomised trials are awaited.

Stenosis of visceral arteries causing clinical symptoms is rare, but can be managed by percutaneous techniques. It is unlikely that there will ever be definitive data available concerning whether angioplasty or stenting are superior. However, based on data from the renal arteries the author generally chooses to stent ostial visceral artery stenoses and angioplasty truncal lesions.

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12 Endovascular Abdominal Aortic Aneurysm Repair

Richard G. McWilliams and M. Murphy

CONTENTS

12.1 Introduction

Endovascular repair (EVAR) of an abdominal aortic aneurysm was first reported by Parodi et al. (1991). This was met with great enthusiasm by radiologists and vascular surgeons and, throughout the 1990s there was an explosion of interest in EVAR. The initial endovascular devices were crude and often made in the operating theatre just before deployment. The initial interest from the medical community resulted in the rapid development of improved devices and sophisticated means of endovascular deployment. The commercialisation of endovascular grafts made these widely available and throughout the 1990s there was a burgeoning population of patients treated with EVAR. Initial anecdotal cases were a prelude to the progression through the levels of scientific evidence. There are now over 755 publications relating to EVAR in peer-reviewed journals and the progression has been from case reports, single centre series, multicentre registry data, comparative studies with contemporaneous controls having open repair, to national randomised control trials. Two major national randomised controlled trials have now been published (EVAR 1 Trial 2005; EVAR 2 Trial 2005; Greenhalgh et al. 2004; Blankensteijn et al. 2005; Prinssen et al. 2004). The largest of these is the UK EVAR 1 trial which randomised patients suitable for both endovascular and open repair to either EVAR or open surgery. The 30-day mortality data from this study were published in 2004 and the 4-year durability data were published in June 2005. These results and their consequences will be considered later in this chapter.

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12.2 Assessment/Indications

The indications for EVAR vary from centre to centre and country to country depending upon the level of funding for EVAR and the enthusiasm and experience of the vascular team. UK practice for most of this millennium has been governed by the EVAR randomised trials.

Most aneurysms are initially diagnosed on ultrasound, however, cross-sectional imaging is necessary for further evaluation of the aneurysm morphology when considering EVAR. Contrast-enhanced CT is considered the modality of choice in most centres. The CT should include the entire abdominal aorta from the level of the diaphragm down to the common femoral arteries. Spiral and especially multidetector row scanners allow accurate measurement and three-dimensional reconstruction. Workstation review of the cross-sectional imaging is essential for full assessment of aneurysm morphology and graft planning. Conventional angiography is rarely needed nowadays prior to surgery due to the quality of cross-sectional images. Occasionally angiography is used for further assessment where the iliac arteries are tortuous and calcified to gauge if it is possible to pass a catheter and stiff guidewire. Magnetic resonance imaging (MRI) is also used in certain centres for aneurysm assess-

ment (Anbarasu et al. 2002; Thurnher et al. 1997) Gadolinium-enhanced angiography is the mainstay of MRI assessment but it is important that T1- and T2-weighted images are obtained and reviewed as these give additional information on the aneurysm sac and thrombus.

Anatomical criteria to determine suitability for EVAR must be fulfilled and this starts with the aneurysm diameter. This is generally taken from CT data and involves measurement of the largest diameter which may be an AP, transverse or oblique axis. Asymptomatic aneurysms are generally not treated unless the diameter is greater than 5.5 cm. This is based on the data from The UK Small Aneurysm Trial which showed that surgical intervention was not justified for aneurysms less than 5.5 cm (The UK Small Aneurysm Trial 1998). The diameter in The UK Small Aneurysm Trial was based on the AP diameter recorded at US. Diameters measured at CT can be greater if oblique diameters are taken, particularly if the axial CT slice is not tangential to the centre lumen axis of the aneurysm. There is an argument for measuring the aneurysm diameter on reconstructed slices that are tangential to the centre lumen of the aneurysm which is our current practice.

The landing zones in the infra-renal aorta and iliac arteries with EVAR are the equivalent of the surgical anastomoses with a bifurcated surgical prosthesis. However, unlike the sutured surgical anastomosis, endovascular "anastomoses" are not currently sutured. They rely on the radial force of the sealing stent, the first fabric-coated stent, to achieve a seal and prevent migration. To achieve this the infra-renal neck must be parallel and relatively thrombus free for 15 mm below the renal arteries. The neck must not be very angulated and ideally the angle of the neck in relation to the supra-renal aorta should be less than 60°. The iliac landing zone, typically in the common iliac artery, must also be reasonably parallel and thrombus free. If the common iliac is unsuitable as a landing zone because of its shape or diameter then extension into the external iliac artery is often performed with endovascular occlusion of the proximal internal iliac with coils to prevent retrograde flow into the aneurysm sac after EVAR.

The delivery system for endovascular devices is large and ranges from 16 F to 24 F. The iliac arteries must be of a size that can accommodate these large devices with a 24-F device requiring an external iliac artery diameter of at least 8 mm. Iliac tortuosity can be a problem for device delivery, but if these vessels are not heavily calcified then the angles usually straighten upon the introduction of a stiff guidewire. The worst combination is a small, tortuous, calcified external iliac artery which will contraindicate a transfemoral approach to endovascular aneurysm repair.

12.3 Devices

The endovascular "stent-graft" comprises a metal stent which is covered with fabric, either polytetrafluoroethylene or polyester (Fig. 12.1). There are three types of stent-grafts available for treating abdominal aortic aneurysms: tube, bifurcated and aorto-uni-iliac grafts. Straight aortic tube grafts where the proximal and distal attachment sites are in the aorta have been used previously but were associated with a high incidence of distal endoleak and are rarely used nowadays.

Bifurcated devices are used in approximately 90% of cases (EVAR 1 Trial 2005). These are of two varieties, modular grafts which comprise two or three separate components that are assembled in vivo and

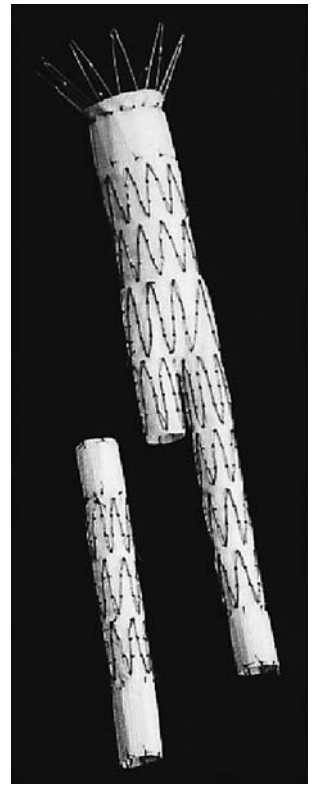

Fig. 12.1. A two-piece modular bifurcated stent-graft (Zenith, Cook, Bloomington, USA) that incorporates a bare supra-renal stent with barbs for increased fixation

single-piece bifurcated grafts. Modular devices tend to be more versatile and offer the potential to treat more aneurysms than single-piece devices.

The aorto-uni-ilaic device is a graduated tube stent-graft which is deployed from the supra-aneurysmal aorta to one iliac artery only. The opposite iliac artery is then occluded with an endovascular occlusion device in order to prevent retrograde blood flow into the aneurysm sac and a femoro-femoral crossover graft maintains blood flow into the opposite limb. This device is used in approximately 10% of cases and offers potential advantages when there is a poor landing zone in one iliac artery or alternatively can be used when there is pre-existing iliac occlusion.

The metal in the stents is generally stainless steel or nitinol. The nitinol stent is less radio-opaque but is associated with significantly lower MRI artifact which offers the potential to follow up this group of patients with MRI, thus avoiding the radiation risk associated with repeated CT examinations (van der Laan et al. 2004). Small radio-opaque gold or platinum markers are placed on the stent-graft to improve visibility and aid orientation during deployment.

The stent-graft relies on the radial force of the top and bottom sealing stents to exclude the aneurysm and maintain graft position. Many devices also have barbs to engage the vessel wall or supra-renal uncovered stents to add additional stability and help reduce the incidence of late migration, which would lead to device failure and potential rupture of the aneurysm.

12.4 Planning the Procedure

Stent grafts are planned at the CT workstation, where accurate vessel diameters may be calculated on axial images reconstructed at right angles to the attachment zones and where centre-lumen lengths may be calculated on multiplanar or 3D-reconstructed images.

The sealing stents of the endograft are oversized by approximately 15%–20% to the external diameter of the aorta and iliac landing zones. One of the aims of the endovascular procedure is to cover the entire aorto-iliac segment from below the renals to the common iliac bifurcation. The length measurements are thus important and endografts are planned to be of adequate length with sufficient overlap of modular components.

Occasionally a small lower pole accessory renal artery may be sacrificed if there is only a short segment of aortic neck below this and a longer segment above the accessory vessel but below the main renal arteries. The decision to sacrifice a renal vessel depends on the amount of cortex supplied by this branch and the patient's renal function.

If the common iliac artery is aneurysmal then a decision may be taken to extend the endograft limb into the external iliac artery. It may be necessary to embolise an internal iliac artery to prevent backfilling of the aneurysm sac. Alternatively, branched iliac grafts allow preservation of flow to the internal iliac. Whichever strategy is employed, every effort is made to preserve at least one internal iliac artery. Bilateral internal iliac artery occlusion is associated with a risk of pelvic ischaemia and neurological sequelae (Kritpracha et al. 2003; Engelke et al. 2002; Kwok et al. 2001).

12.5 Technique

In the UK, EVAR is typically performed by an endovascular team that includes a vascular surgeon and interventional radiologist. Procedures are performed in either an endovascular suite, which should provide theatre-grade sterility, or an operating theatre using a mobile image intensifier and carbon-fibre table. Facilities for open surgery must be available and may rarely be required if arterial rupture occurs upon attempted device delivery or if there is a need for conversion to open surgery. The incidence of primary conversion to open surgery, however, is now very low.

Procedures may be performed under local, regional or general anaesthesia. Surgical exposure and control of the common femoral arteries is the most common means of delivering the device; however, percutaneous suturing devices are now available that allow for an entirely percutaneous procedure. Intravenous heparinsation is necessary and ideally the activated clotting time (ACT) should be monitored throughout the procedure.

Most devices are modular comprising two or three components. The main component is the body of the graft which is inserted transfemorally over a stiff guidewire. This is deployed so that the fabric at the top of the graft is close to but does not cover the lowest renal artery (Fig. 12.2). Before the device is released, angiography is performed to determine

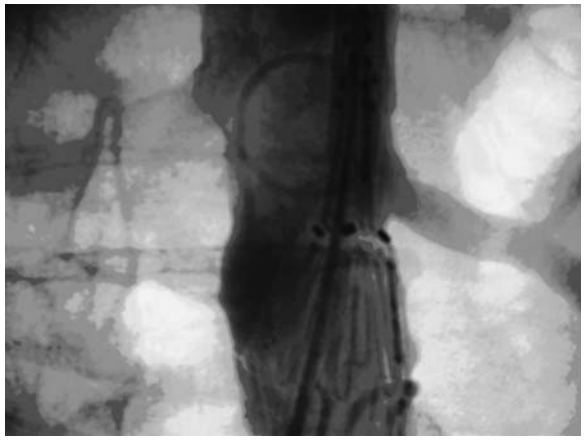

Fig. 12.2. Angiogram before final graft deployment shows the radio-opaque fabric markers just below the lowest renal artery, left renal in this case

the level of the renal arteries and the X-ray tube is angled craniocaudally, if required, to avoid foreshortening the aortic neck, which may occur with anterior angulation just below the renal arteries. Oblique angulation, typically left anterior oblique, is used to profile the ostium of the lowest renal artery, which is positioned in the centre of the image to avoid parallax errors.

Typically iodinated contrast medium is used for angiography; however, where available, carbon dioxide has proved to be a viable alternative, providing protection for the kidneys from contrast nephrotoxicity (Bush et al. 2002). Intravascular ultrasound (IVUS) is used in a few centres both to help with the final decisions about graft sizing and for identification of the aortic anatomy at deployment (White et al. 1997; Zanchetta et al. 2003). The expense of IVUS probes limits this to a few centres only.

Once the main body is released there is the need to extend on both sides into the common iliac arteries. This is straightforward on the side of the main component as there is already a guidewire through the device and it is a simple manoeuvre to overlap into this a leg extension piece from the bifurcation of the body into the lower common iliac on the ipsilateral side. The contralateral limb is more difficult as this requires cannulation of the short leg or 'stump' of the main body of the device prior to introduction of the contralateral limb. This can be challenging particularly in large aneurysms when the 12-mm opening of the short leg must be cannulated within a large space of several centimetres. If there is no mural thrombus and a large aneurysm then this can be difficult.

Once the device is assembled in vivo then completion angiography is performed to exclude the presence of endoleak and ensure that the visceral and iliac arteries remain patent. Every effort is made to treat endovascularly any graft-related endoleak. There is anecdotal evidence to suggest that an unresolved proximal type I endoleak may increase rather than decrease the risk of rupture of an aneurysm. Type II or sidebranch endoleaks are often seen on completion angiograms and no further intervention is necessary at this stage.

12.6 Monitoring of Stent Grafts

Patients treated with EVAR may develop problems specific to the technique and it is mandatory that all patients are entered into a structured surveillance programme. The most important specific complications are endoleak, stent-graft migration and stent wireform fracture. All of these may lead to device failure with continued enlargement of the aneurysm sac due to inadequate exclusion and risk of aneurysm rupture. The surveillance strategy must incorporate imaging that allows for the detection of these specific problems. Most surveillance protocols currently rely on CT scanning. However, the combination of US and plain radiography is a viable alternative (Murphy et al. 2003; McWilliams et al. 1999). MRI is not suitable for stainless steel grafts but has been reported as an alternative for grafts with nitinol endoskeletons (van der Laan et al. 2004).

Endoleak was first defined by White et al. (1996) as persistent blood flow outside the graft and within the aneurysm sac. Endoleak has been classified according to the source of perigraft flow into four groups (White et al. 1998a,b):

Type I Proximal or distal graft attachment site leaks
Type II Retrograde flow into the aneurysm sac from aortic sidebranches such as lumbar arteries or the inferior mesenteric artery
Type III Caused by a defect in the graft either due to fabric disruption or disconnection of a modular overlap
Type IV Graft wall porosity

The most serious endoleaks are type I and III which are associated with aneurysm enlargement and rupture (Fig. 12.3). Secondary intervention

to correct these endoleaks is almost always necessary. Whilst rupture has been reported with type II endoleaks these are considered to have a more benign course and a conservative approach to management is taken unless there is evidence of continuing sac enlargement.

Stent-grafts are subjected to distraction forces in vivo due to the pulsatile blood flow. These distraction forces act longitudinally and challenge the graft fixation and overlap zones. The stent-graft resists these forces due to its fixation mechanisms which include the radial force of the sealing stent and the barbs which engage the aortic wall. The distraction force is dependent on the patient's blood pressure and the cross-sectional area reduction between the proximal/aortic and distal/iliac sealing stents (Sutalo et al. 2005). Failure of fixation will lead to migration (Fig. 12.4) or modular disconnection with late type I or type III endoleak and risk of aortic rupture. Graft limb distortion with subsequent thrombosis can also occur secondary to migration. The detection of migration during post-operative surveillance is important as it usually leads to pre-emptive intervention to prevent graft failure.

Wireform fractures have been reported in most stent-grafts. The fracture may lead to diminished stent strength and loss of radial force which can result in migration. Additionally the jagged ends of the fractured metal may cause tears in the fabric and subsequent endoleak. These fractures are best seen on plain abdominal radiographs.

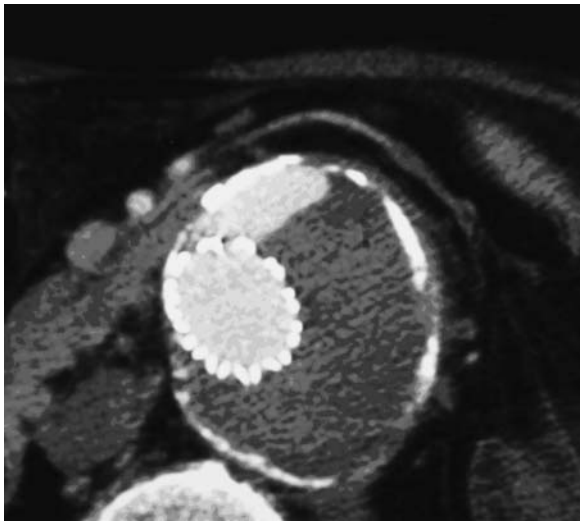

Fig. 12.3. Axial contrast-enhanced CT image after EVAR showing contrast medium outside the stent-graft within the aneurysm sac. This is due to a proximal type 1 endoleak

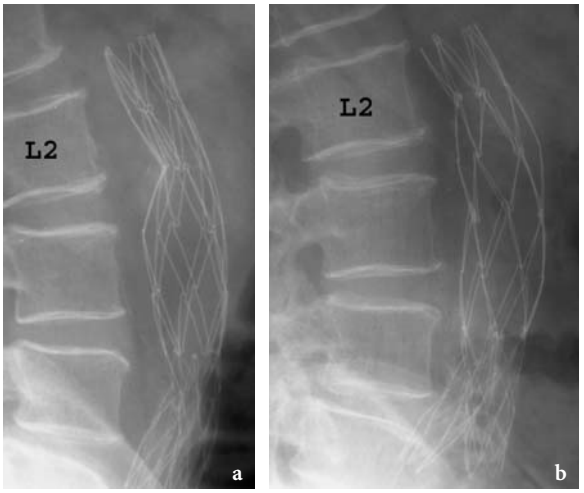

Fig. 12.4a,b. Plain abdominal radiographs during annual follow-up performed to a standardised protocol to minimise projectional variation in position. There has been downward movement of the proximal stent-graft with reference to bony landmarks

12.7 Evidence

The most important sources of evidence concerning EVAR to date are the UK EVAR trials – EVAR 1 and EVAR 2 (EVAR 1 Trial 2005; Greenhalgh et al. 2004; EVAR 2 Trial 2005). These two multi-centre randomised trials began in September 1999. The EVAR 1 trial randomised patients with infra-renal abdominal aortic aneurysms of at least 5.5 cm to either endovascular or open aneurysm repair. All patients were aged 60 years or older, deemed fit for open repair and anatomically suitable for endovascular repair. Between September 1999 and December 2003, 1082 patients were randomised. The 30-day mortality data showed a significant advantage in favour of EVAR – 1.7% in the EVAR group and 4.7% in the open repair group. The 4-year data from EVAR 1 show a persisting, significant 3% reduction in aneurysm-related mortality in the EVAR group (EVAR 4%, open 7%); however, there was no significant difference in overall 4-year mortality between the two groups. EVAR was found to be more expensive and is attended with a higher rate of reintervention.

The EVAR 2 trial was designed to investigate the role of EVAR in patients unfit for open surgery which was perceived to be the original role of EVAR. The EVAR 2 trial recruited 338 patients, aged 60 years or older, with aneurysms of at least 5.5 cm and anatomically suitable for EVAR but deemed unfit for open

aneurysm repair. These patients were randomised to EVAR with best medical therapy or best medical therapy alone. The 30-day operative mortality in the EVAR group was 9%. The 4-year data from this trial show an overall mortality of 64% with no significant difference in mortality rates either for aneurysm-related deaths or all-cause mortality between the two groups. In this study EVAR did not demonstrate a survival benefit in patients unfit for open repair and additional costs were incurred in comparison to the non-intervention group. The conclusion from the EVAR 2 study is that funding is better utilised in the optimisation of medical care for this cohort of patients rather than early endovascular aneurysm repair. Patients in both of the UK EVAR trials will be followed until 2010 to further assess the durability of EVAR.

Similar results to EVAR 1 have been published by the Dutch Randomised Endovascular Aneurysm Management (DREAM) Trialgroup (Blankensteijn et al. 2005; Prinssen et al. 2004). This multicentre, randomised trial compared open repair with EVAR in 351 patients with aneurysms of at least 5 cm who were suitable for both techniques. There was a 3.4% difference in 30-day mortality rates (1.2% EVAR, 4.6% open). As per the UK EVAR trials, there is a persisting reduction in aneurysm-related death in the EVAR group; however, no overall survival difference was observed.

The medical community is currently reflecting on these results to determine the future role of endovascular aneurysm repair. Given the equivalence of EVAR and open repair at 4-year analysis it is likely that EVAR will be funded by health care providers and patients are likely to have either option available where the anatomy is suitable for endovascular repair. The EVAR 2 results are surprising and inform us that, despite our best intentions, unfit patients with asymptomatic aneurysms are best served by treatment of their underlying cardiorespiratory diseases rather than endovascular aneurysm repair.

There have been no randomised trials of the use of EVAR in the management of ruptured abdominal aortic aneurysms. The first published case report of EVAR for a ruptured aneurysm was in 1994 (Yusuf et al. 1994). Since then there have been a number of single centre series published that have reported widely varying mortality rates, ranging from 0% to 45% (Greenberg et al. 2000; van Sambeek et al. 2002; Larzon et al. 2005; Lachat et al. 2002; Hechelhammer et al. 2005; Hinchliffe et al. 2003). These differences are likely to reflect selection bias, as the mortality for symptomatic aneurysms is very likely to differ from unstable ruptures. It should be remembered that the mortality for open repair of ruptured aneurysms is close to 50% and it is likely that emergency EVAR can improve on this. Randomised trials have not started and there remains debate as to the possibility that these will ever be conducted for this group of patients.

12.8 Future Developments

Migration of the currently available endovascular stent-grafts is a problem that requires a solution. Unfortunately, endografts are not well incorporated into the aortic wall and thus the risk of migration continues with time. Experimental work is underway to try and coat the attachment areas of stent grafts with growth factors which will promote the ingrowth of endothelial tissue (van der Bas et al. 2002, 2004).

The combination of metal and currently available fabrics has resulted in cases of fabric degeneration with resulting endoleaks. In the future, either the fabrics used will have improved durability or we will move away from stent-grafts composed of metal/fabric combinations.

The main anatomical feature that limits the role of currently available devices is the quality and length of the infra-renal neck. This is because the fabric cannot be placed above the renal arteries without occluding them. The aorta at the level of the renal arteries is much less prone to aneurysmal degeneration and this is an attractive site to place the sealing stent of an endograft. Renal blood flow may be retained by manufacturing holes or fenestrations in the fabric of the sealing stent. Fenestrated grafts are now available commercially and several hundred grafts have been implanted. The location of the fenestrations is carefully planned from thin section CT data and these pre-planned fenestrations are manufactured to be at the correct height and correct position on the circumference of the graft. The endovascular procedure then involves releasing the stent-graft correctly in vivo and then catheterising the targeted vessels transfemorally from within the stent-graft. Stents are then placed in the ostia of the renal arteries (Fig. 12.5). Experience has taught us that renal artery occlusion may occur with un-stented fenestrations due to partial shuttering of the vessel ostia by the fabric of the stent-graft.

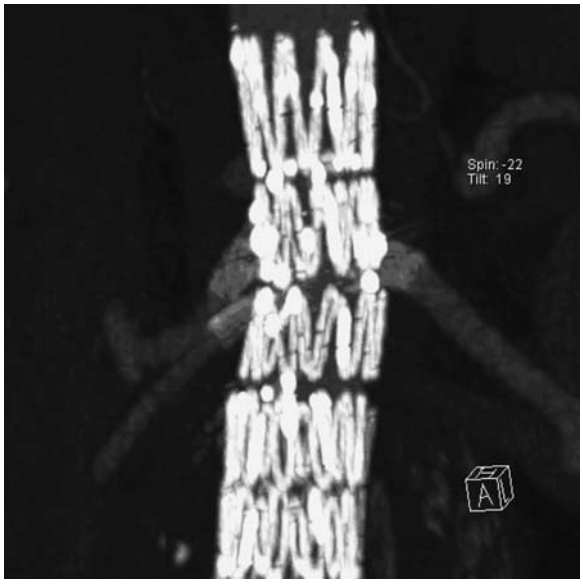

Fig. 12.5. Coronal reconstructed image from contrast-enhanced CT after EVAR with a fenestrated graft. Stents can be seen in two right renal arteries and one left renal artery

Single centre series have been published on the use of fenestrated endovascular grafts in the management of juxta-renal aneurysms. The initial results have been encouraging with high rates of primary technical success with almost all of the targeted vessels patent at the end of the procedure (Anderson et al. 2001; Greenberg et al. 2004; Verhoeven et al. 2004). The endoleak rate has been very low. There have been a small number of late occlusions of renal arteries. This is a risk with all vascular stents due to the development of neo-intimal hyperplasia. Fenestrated grafts are expensive, typically three times the cost of standard devices and higher levels of evidence and durability data are required before such devices will be easily funded.

Experimental work on fenestrating grafts after deployment has been reported (McWilliams et al. 2003). The concept is that the graft is deployed across a vessel ostium and then the fabric punctured either from within the graft into the target vessel or from within the target vessel into the lumen of the graft. This initial hole would then be enlarged with a standard angioplasty balloon or a cutting angioplasty balloon and then a stent would be deployed. Successful "in situ" fenestration to open the left subclavian artery during an endovascular case has been reported (McWilliams et al. 2004).

Fenestrated grafts are not well suited for the treatment of thoraco-abdominal aneurysms where the fabric of the stent-graft will not abut the wall of the aorta at the level of the visceral arteries. If the aorta is aneurysmal at the level of the visceral arteries then branched endografts have been used to successfully exclude the aneurysm (Fig. 12.6) (Chuter et al. 2001; Tse et al. 2004). Branched endografts have also been used in the treatment of aortic arch aneurysms to preserve the great vessels and in common iliac arteries to preserve the internal iliac artery (Abraham et al. 2003). Covered stents are used to join the branches of the aortic or iliac stent-graft to the target vessels. The available evidence is currently limited to individual case reports and small case series. There is an increased number of modular connections in these grafts and this raises concerns regarding junctional leaks. We also have concerns about the long-term patency of covered stents in normal branch vessels and the possibility that the branches may occlude due to kinking if the aneurysm shrinks. This has led some investigators to seek ways of injecting polymers into aneurysm sacs so that they do not shrink and potentially avoid some of the stresses on endovascular grafts due to changing anatomy as the aneurysm shrinks after successful exclusion. This remains experimental.

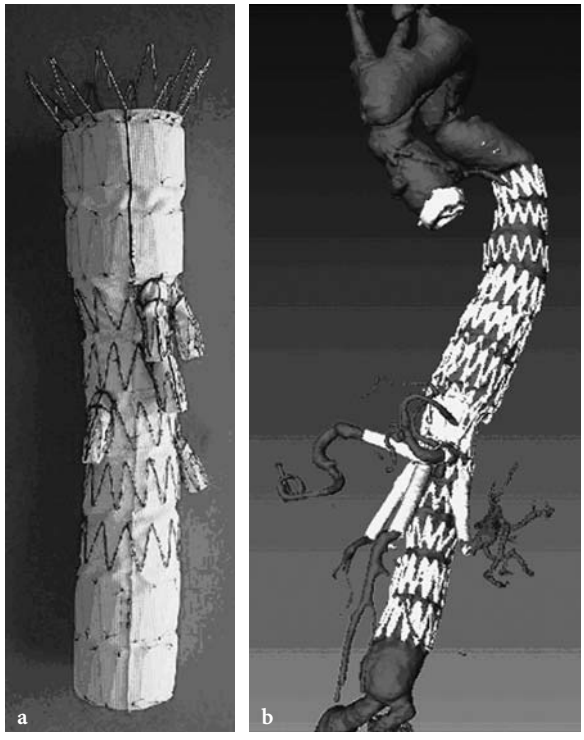

Fig. 12.6a,b. Complex multi-branched stent-graft (**a**) for repair of an aneurysm involving all the visceral arteries. **b** A reconstructed image from follow-up CT scanning showing patency of all the branch vessels

12.9 Conclusion

There has been marked progress since Parodi and colleagues' first case report in 1991 and the initial early use of home-made devices. Endovascular repair of infra-renal abdominal aortic aneurysms can now be justifiably considered an established technique. Randomised controlled trial evidence shows equivalence with open surgery at 4-year analysis. Continued progress can be expected both to improve the durability of currently available devices and to extend the role of endovascular repair to more complex aneurysms. All phases of this treatment – (case selection, graft planning, graft deployment and surveillance) – are heavily dependent on imaging. There is therefore a need for both general and interventional vascular radiologists to have an understanding of endovascular aneurysm repair.

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13 Endovascular Repair of Thoracic Aortic Aneurysms

H. Rousseau, J. P. Bolduc, C. Dambrin, B. Marcheix, G. Canevet, V. Lannareix, C. Cron, A. Mugniot, P. Otal, and F. Joffre

CONTENTS

13.1 Introduction

Annually, thoracic aortic aneurysms (TAA) affect approximately 6 out of 100,000 persons and the descending thoracic aorta is involved in about 40% of those cases (Bickerstaff et al. 1982). Thoracic aortic aneurysms typically occur in elderly heavy smokers with hypertension, coronary artery and obstructive pulmonary diseases. Untreated patients with large thoracic aortic aneurysms have a 2-year mortality rate of over 70%, most deaths due to aneurysm rupture (Crawford and De Natale 1986).

Although refinements in the surgical treatment of thoracic aortic aneurysms have reduced the death and complication rates over the past two decades (Kouchoukos and Dougenis 1997; Safi et al. 1998; Lawrence et al. 1999), they are still between 1.5% and 26%, even in high-volume centers with experienced staff (Lawrie et al. 1994; Coselli et al. 1996; Kouchoukos and Dougenis 1997).

During the last few years, new endovascular methods of treatment for descending thoracic aneurysms have gone through explosive technological developments. The procedure uses a stent graft to serve as a blood flow conduit through the aneurysm sac, thus excluding the aneurysm from the circulation. The stent graft is anchored at the proximal and distal ends of the aneurysm on disease free portions of the aorta, excluding the aneurysm, therefore preventing aneurysm expansion and rupture. This technique has certain potential advantages; first the peripheral arterial access eliminates complications of thoracotomy; secondly aortic cross-clamping is not necessary, decreasing cardiac and spinal cord complications; thirdly blood loss is significantly reduced and hospital stays, especially within the intensive care unit, are considerably shortened thereby reducing total costs.

13.2 Indications for Treatment

The indications for stent graft placement are generally the same as those of surgical treatment (Kouchoukos and Dougenis 1997). In poor surgical candidates, stent graft placement is usually indicated as an elective or urgent procedure for a wide spectrum of pathological and iatrogenic conditions. In good surgical candidates, there is controversy regarding which patients should undergo stent graft placement and which should be subjected to surgery, mainly because the long-term results of endovascular treatment are still unknown. In addition to physical condition, anatomical, device-specific and technical matters must be addressed before considering transluminal stent graft placement. The major anatomical factors to be taken into account include the localization and morphology of the disease, the quality of the disease-free proximal and distal aortic

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necks, the distal vascular access and the limited tortuosity of the abdominal and thoracic aorta.

In the following pages, we will review the current treatments of true and false thoracic aneurysms, acute and chronic type B dissections, intramural hematoma (IMH) and penetrating aortic ulcers (PAU). The role of endoluminal stent grafting will be evaluated within the context of each of these subgroups.

13.3 Technical Aspects

13.3.1 Devices

A variety of devices are available in Europe (Table 13.1). All stent grafts are self-expanding and constrained in a sleeve or sheath. They are made of a metallic Nitinol skeleton (except for the stainless steel Cook device), and covered by a membrane of either polytetrafluoroethylene (Gore and Endofit devices) or polyester (Medtronic, Bolton, Jotec and Cook devices). Proximal or distal ends of the graft can be fully covered or not. Usually, Medtronic, Endofit, Bolton and Jotec devices have bare stents at the ends to provide better anchorage to the aortic wall. The Gore and Cook devices are fully covered but in addition Cook's possesses metallic barbs for better fixation. A variety of sizes are available, meaning that it is generally possible to treat patients with an "off the shelf" device (Table 13.2). Finally new grafts with fenestration or branches are being evaluated.

Table 13.1. Device types available in Europe

Companies	Device	Metal	Covering
Medtronic	Talent	Nitinol	Polyester
Gore	TAG	Nitinol	e PTFE
Cook	Zenith	Stainless steel	Polyester
Endofit	Endofit	Nitinol	e PTFE
Jotec	E Vita	Nitinol	Polyester
Bolton Medical	Relay	Nitinol	Polyester

All but one of the stent grafts are deployed by holding the central pusher stationary whilst withdrawing the delivery sheath. The exception to this is the TAG device from Gore, which is deployed by pulling a string. As a result the device first expands in the middle of the graft, increasing the risk of distal migration when implanted in a large aneurysm with significant angulation and a short neck. Most commercially available thoracic stent grafts do not significantly shorten during or after deployment.

13.3.2 Pre-procedural Planning

Pre-treatment imaging is crucial to evaluate patient eligibility to endovascular treatment, select the appropriate stent graft and plan the procedure. Multi–detector computed tomography (MDCT) with 3D reconstructions is probably the best method for evaluating the anatomy of the aorta as well as the iliac and femoral arteries with regard to diameter, calcifications and tortuosity. Magnetic resonance (MR) imaging is also a good alternative, especially when slow flow conditions are suspected (dissection, endoleaks) or in patients with renal failure. However, due to the lower spatial resolution, its inability to show calcification, poor availability and incompatibility with life support and monitoring equipment of MR, MDCT is generally preferred. Angiography using a calibrated catheter is less useful than MDCT, but can help to estimate the lesion length and aortic angulations in some complex cases.

Stent graft diameter is based on MDCT or MR measurements, oversized by 10%–15% to provide good apposition to the aortic wall. As for length, at least 1.5 cm of normal aorta at each end of the graft are required to prevent migration. Whenever possible, greater proximal and distal coverage should

Table 13.2. Device sizes

Device	Diameter (mm)	Length (mm)	Modular	Size of the delivery device	Sheath
Talent	26–46	150–200	Yes	22–25	No
TAG	26–40	100–200	No	20–24	Yes
Zenith	22–42	100–220	Yes	18–22	No
Endofit	30–42	140–240	No	22–24	Yes
E Vita	24–40	130–230	Yes	24–27	Yes
Relay	28–44	95–200	Yes	22–25	No

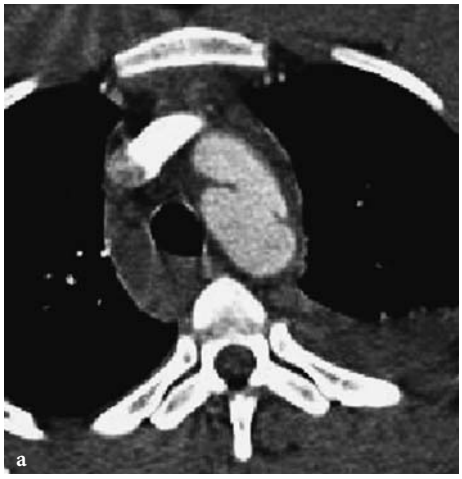
be employed to prevent late stent graft migration and endoleaks due to aortic disease progression. Proximal or distal stent graft extensions should be available during the stent graft implantation in case of suboptimal stent graft deployment. If two stent grafts are necessary, an overlap of at least 5 cm should be used.

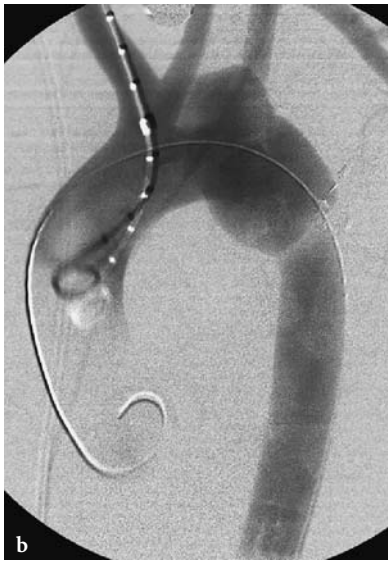
13.3.3 Stent Graft Insertion

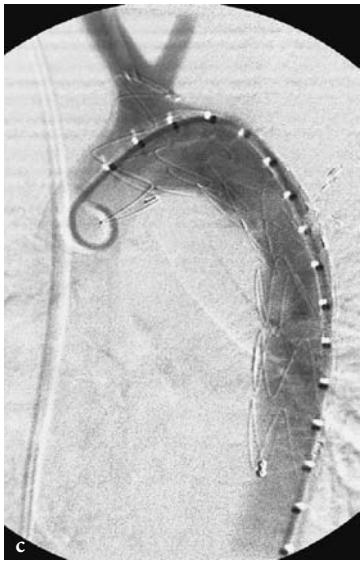
Endovascular stent placement procedures are performed via the femoral or external iliac approach under local or general anesthesia. When the iliac arteries are too tortuous or too small, vascular access may be achieved through the common iliac artery or the infrarenal aorta using a temporary conduit to provide vascular access.

Ideally, the vascular procedure must be done in an angiography suite equipped to operating theatre standard (see Chap. 3). All the procedures should be performed under digital subtraction angiography and, if available, transesophageal echocardiography (TEE). TEE can provide additional information, such as the position of intimal tears in aortic dissections. Furthermore, TEE may also provide useful information after stent graft insertion such as the presence of kinking, perigraft leakage and heart status.

A 5-F, 30-cm long sheath with a distal radio opaque marker (Cordis; Johnson & Johnson) is placed via the left brachial artery to identify the ostium of the left subclavian artery and allow angiography during the procedure. This marker is crucial for optimal stent placement in an aneurysm with a short proximal neck. In more distal lesions, a guidewire may be placed by femoral approach to mark the origin of the celiac trunk or mesenteric artery (Fig. 13.1).







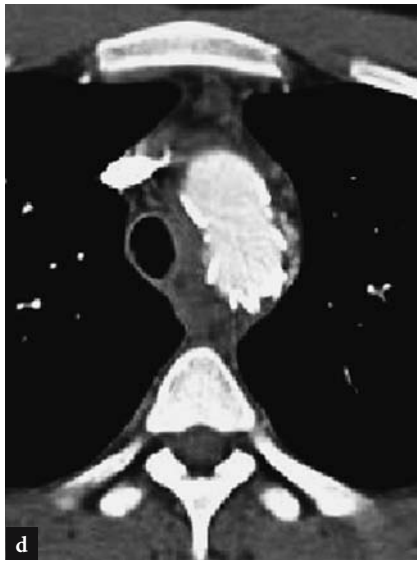


Fig. 13.1a–d. a,b Axial CT scan and digital subtraction arteriogram showing the typical features of aortic transection. **c** Post-stent graft arteriography demonstrates exclusion of the false aneurysm, deliberate occlusion of the left subclavian artery, and placement of the bare stent of a Talent device across the common origin of the left common carotid and brachiocephalic arteries. Note the pigtail catheter placed from the right side, which was used as a landmark during the procedure. **d** A follow-up CT scan confirms exclusion of the false aneurysm

After administration of a 5000 IU bolus of heparin, the delivery system is inserted over a 260- to 300-cm long guidewire (Back-Up Meier/Boston Scientific; Amplatz/Boston Scientific or Lunderquist/Cook) through the transverse arteriotomy of the common femoral artery and advanced under fluoroscopy. Iliac or aortic tortuousities may impede stent graft insertion, even when the stent graft is positioned over a very stiff guidewire. In such cases, to facilitate the progression of the stent graft, the "pull & through technique" can be used. A guidewire is pushed into the descending aorta through a long sheath placed via a right brachial approach. The end of the wire is grabbed using an intravascular snare and pulled out from the femoral artery, thus providing a firm pathway for the stent graft progression. In this situation the guidewire should be covered with a long sheath up to the level of the aorta to avoid tearing of the brachiocephalic trunk.

Just before the device is released, vasodilators (such as sodium nitroprusside) are intravenously administered to decrease the systolic pressure to about 70 mm Hg. Adenosine-induced cardiac standstill has been proposed to ensure precise Stent graft positioning but is not often used (Dorros and Cohn 1996). After correct positioning, the device is deployed. A latex balloon is then inflated to mould the stent graft at both ends and obtain complete expansion. To avoid aortic dissection, the balloon inflation must be performed only inside the graft. An aortogram is obtained to verify proper stent graft positioning and complete aneurysm exclusion. Finally, the delivery sheath is removed and the arteriotomy is sutured.

For follow-up, MDCT is performed at the time of discharge and thereafter at 3, 6, and 12 months then annually. Chest radiographs are obtained at the same time intervals. For young patients, MRI follow-up is recommended (Figs. 13.2, 13.3).

The normal aorta above the aneurysm must be at least 15 mm long on the inner arch side otherwise the probability of an incomplete seal is high. If the neck is too short, a left carotid-subclavian artery bypass may be created beforehand. However, many authors have reported no complications after intentional LSA occlusion by stent grafts without surgical transposition (Hausegger et al. 2001; Rehders et al. 2004). If symptoms develop (steal syndrome or left arm ischaemia), surgical revascularization can be performed electively on a subsequent occasion. Before occluding the LSA, contralateral vertebral artery perfusion and collateral pathways should be

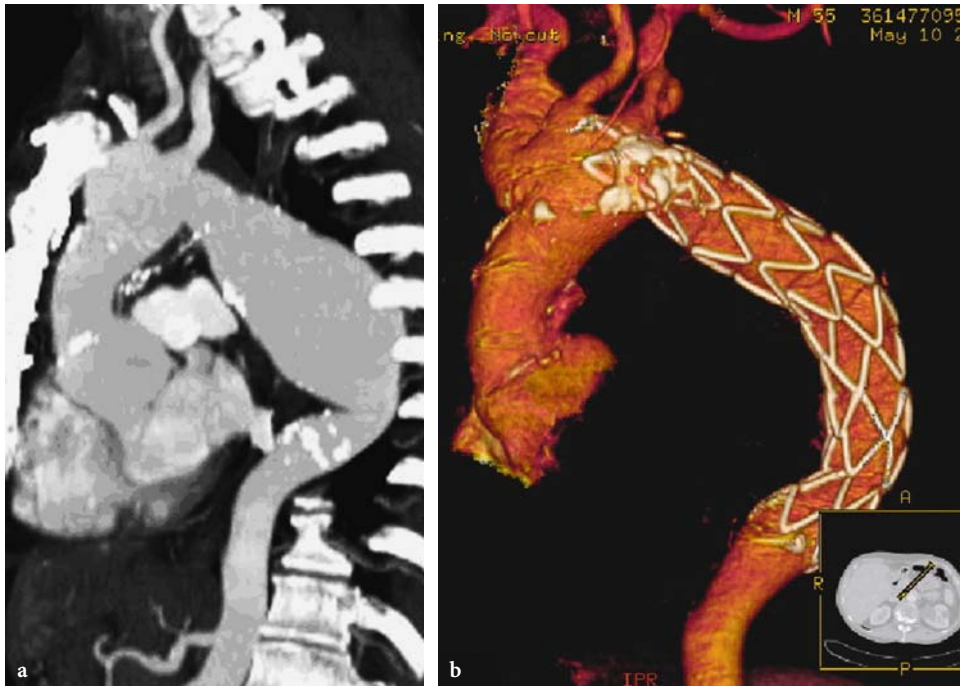


Fig. 13.2a,b. a A 54-year-old man with a history of previous surgery to the aortic arch, developed a large thoracic aneurysm of the descending aorta, as shown on the multiplanar CT reconstruction. **b** This was treated with a single stent graft placed just beyond the left subclavian artery

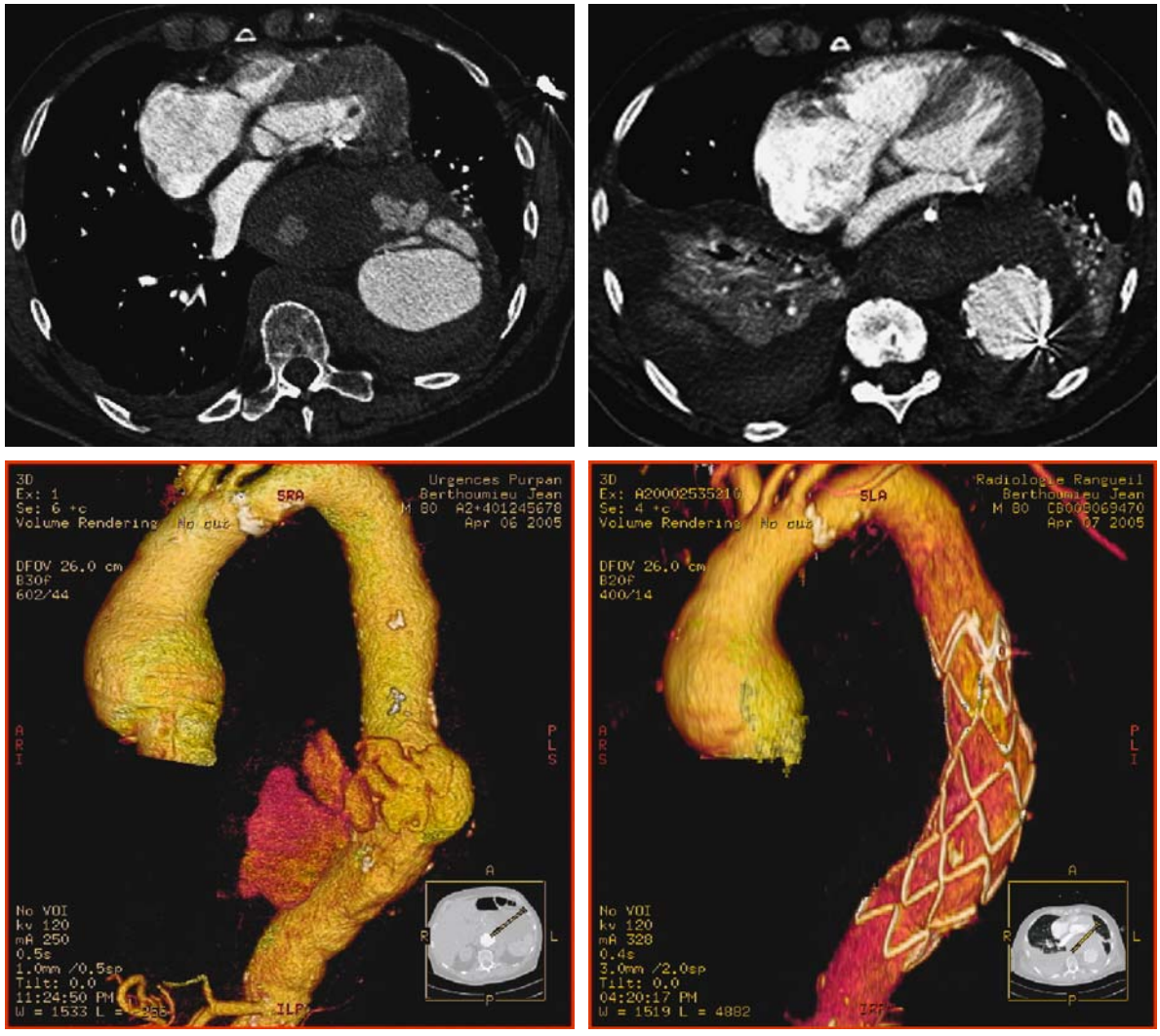


Fig. 13.3a–d. **a** Axial CT scan and (**b**) 3D reconstruction of a ruptured thoracic aneurysm in an 84-year-old man. **c** Axial CT scan and (**d**) 3D reconstruction showing successful treatment of the rupture with a single Jotec endoprostheses. Satisfactory exclusion of the rupture has been maintained during the follow-up

assessed to avoid major neurological complication. In the study of Rehders et al. (2004) 22 patients had intentional stent graft occlusion of the LSA. On follow-up, systolic blood pressure differential was observed between the arms (138+/–14.0 vs. 101+/–21.0 mmHg; p=0.05), but 68.2% patients remained asymptomatic without functional deficit or temperature differential. Seven (30%) patients reported mild subclavian steal syndrome symptoms but no patient required secondary surgical intervention (Rehders et al. 2004). When the aneurysm involves the aortic arch, proximal placement of the stent graft necessitates some form of bypass to the left common carotid artery usually from a branch of the brachiocephalic artery.

13.4 Results

In their review article, Dake (2001) state that technical endovascular thoracic aneurysm repair can be attained in 98%–100% of cases. There are very few reported long-term results of stent graft placement. However, so far, the reported morbidity and mortality rates of stent graft treatment compare favourably with those of surgery, despite the fact that many patients are referred because of their high surgical risk. A metaanalysis was done by the Haute Autorité de Santé (HAS) French National Authority for Health in 2005. A summary of these results is given in Tables 13.3–13.5 (Dake et al. 1998, 1999;

Resch et al. 1999; Gravereaux et al. 2001; Fujikawa et al. 2001; Criado et al. 2002; Thompson et al. 2002a,b; Orend et al. 2002, 2003; Palma et al. 2002; Czermak et al. 2002; Ellozy et al. 2003; Sunder-Plassmann et al. 2003; Melnitchouket al. 2004; Orford et al. 2003; Daenen et al. 2003; Marty-Ané et al. 2003; Scheinert et al. 2004; Amabile et al. 2004; Rousseau et al. 2005).

Adverse events occur in a minority of cases, and many of these complications can be diagnosed and managed with minimally invasive techniques. Complications such as endoleaks, stent graft migration, infection, fracture, erosion or aortic rupture can be observed during the procedure itself or following it.

Table 13.3. Meta-analysis of procedural outcomes using the Medline, Embase and Pascal database of all published series, on thoracic aortic aneurysms including more than 20 patients. Between January 1995 and April 2005, 31 studies published from the English-language literature, involving a total of 1890 patients were included

Technical success	94.6%
Surgical conversions	1.4%
Hospital stay	6.6 days
Intensive care unit stay	2.9 days
Mortality (total)	11.7%
Mortality at 30 days	
• Elective	• 5.9%
• Emergency	• 16%
Neurologic complications	
• Paraplegia	• 2.1%
• Stroke	• 4.5%
Renal insufficiency	5.2%
Respiratory complications	9.8%

13.4.1 Peri-procedural Complications

In our experience of 150 stent grafts, we were able to introduce the stent graft via the common femoral or external iliac artery in 100% of cases. In contrast Dake et al. (1998) report that only 58% of their patients could be treated via the transfemoral route. The aortic approach was needed in up to 30% of cases. Access problems (i.e., dissection or iliac rupture) were encountered in 3% of cases and were treated with stents or stent grafts. Access problems are more frequent in young patients in whom arterial spasm is more likely, or those with severely atherosclerotic arteries.

Stent graft migration is reported in 2%–20% (Resch et al. 1999; Palma et al. 2002). Migration is caused by the "wind sock" effect of ventricular ejection, particularly when proximal fixation is at or near the aortic arch. To avoid this serious technical problem, we lower the blood pressure with vasodilator or beta-blocker drugs. In cases of insufficient lesion coverage resulting from stent graft migration, a stent graft extension (not a cuff, which would provide insufficient length) should be used to correct the problem.

Accidental occlusion of branch vessels is more difficult to manage. Distal displacement of the graft can be attempted by pulling the stent with a balloon

Table 13.4. Meta-analysis of stent graft related complications

Stent graft complications	
Vascular access complications	5.9%
Stent graft fracture	5.3%
Stent graft migration	2%
All endoleaks	10.5%
Early endoleaks	
• Type 1	• 13.4%
• Type 2	• 76%
• Type 3	• 20%
• Type 4	• 4%
Late endoleaks	
• Type 1	• 12.6%
• Type 2	• 61.8%
• Type 3	• 23.5%
• Type 4	• 14.7%

Table 13.5. Results for Dissections

Technical success	98.5%
Surgical conversions	2.3%
Major complications	11.2%
Minor complications	2.4%
Procedure related complications	6.8%
Retrograde type A dissections	1.9%
Neurologic complications	2.9%
• Paraplegia	• 0.8%
• Stroke	• 1.9%
False lumen thrombosis	75.5%
Late surgical conversions	2.5%
Late secondary additional stent graft	4.6%

inflated within the section of graft in the aneurysm sac, thus avoiding friction from the aortic wall. Another option is to place a stent inside the compromised vessel, protruding into the aortic lumen, thus displacing the stent graft membrane and restoring blood flow.

Aortic perforation may occur during stent graft insertion and is easily recognized as a rapidly enlarging hematoma or hemothorax. Immediate coverage of the perforation with a stent graft is the first treatment option. Aortic perforation may also occur due to erosion of the aortic wall by stent graft struts. These perforations may be either asymptomatic or lead to aortic rupture or fistula formation. In curved landing zones, stent grafts without proximal or distal uncovered elements may be more appropriate to avoid such aortic erosions.

In our series, we did not convert any endovascular procedure to open surgery which is a major improvement compared to the 4% conversion rate reported by Dake (2001). Greenberg et al. (2000) converted 3 (12%) of 25 cases to correct inadvertent coverage of the celiac trunk, control bleeding or rectify a massively kinked descending aorta so that the stent graft could be inserted.

13.4.2 Post-Procedural Complications

The incidence of transient post-implantation syndrome (fever, leukocytosis and elevated C-reactive protein) is well recognised and is seen in 20%–60% of cases. The syndrome is thought to be a nonspecific systemic inflammatory reaction. Patients usually recover with conservative treatment in 2–10 days.

Pleural effusion occurs frequently; the cause uncertain, but it may be a foreign body reaction in the adjacent pleura. It usually resolves spontaneously within 3 months after the intervention.

Mortality is the most important criterion in appraising the results of TAA treatment. In their largest series, Dake (2001) reported a perioperative mortality of 9%. The likely reason for this lower mortality rate compared to conventional surgery is the minimally invasive nature of endovascular therapy. Perhaps the most important feature is avoiding the haemodynamic stress of aortic clamping. The actuarial survival rates were 81% after 1 year and 73% after 2 years.

Paraplegia is crucially influenced by the duration of aortic clamping in the open thoracic aortic surgery. Despite many improvements in the technique, the rates of paralysis in conventional open surgery range from 1.5% to 19% in high-volume centers (Lawrie et al. 1994; Coselli et al. 1996; Kouchoukos and Dougenis 1997). Although the endovascular repair of thoracic aortic aneurysm shows a promising reduction in operative morbidity, there is a persistent risk of spinal cord ischaemia, albeit lower than with open repair (Gravereaux et al. 2001). According to the review published in 2001 by Dake, paralysis occurred in up to 1.6% of the 3000 patients treated worldwide. This low complication rate compared to surgery can be explained by the shorter procedural time, the persistent blood circulation throughout the procedure and the absence of aortic cross clamping. Furthermore, there is less postoperative respiratory failure and less prolonged hypotension, further lowering the risks of delayed paraplegia. Concomitant or previous abdominal aortic aneurysm repair and long-segment thoracic aortic exclusion appear to be important risk factors of spinal cord ischemia (Mitchell et al. 1999; Gravereaux et al. 2001). Greenberg et al. (2000) showed a correlation between the length of stent graft coverage and spinal cord ischemia complications which they observed in 12% of their patients. The use of short stents (i.e., those < 15 cm) and a stepped approach if long segments need to be covered reduces paraplegic complications (Erbel et al. 2001).

Spinal cord protective measures such as cerebrospinal fluid drainage, steroids and prevention of hypotension should be used in patients with the aforementioned risk factors.

Successful treatment of stent graft induced paralysis by cerebrospinal fluid drainage has been reported by Tiesenhausen et al. (2000) and Ortiz-Gomez and co-workers (2001). Reichart et al. (2001) also reported a case of post-endograft paraparesis that was successfully treated by surgical reimplantation of intercostal arteries. As a whole, because delays in the onset of the neurologic deficit have been encountered after endovascular TAA repair, careful follow-up with neurologic examination and institution of cerebrospinal fluid drainage upon the first signs of deficit may be beneficial.

Strokes may be caused by the manipulation of wires and catheters in an atherosclerotic aortic arch. The incidence of this complication is lower with the new grafts than the 7%±3% rate reported by Dake et al. (1998). To minimise the embolic risk, the tip of the delivery system should be as short and flexible as possible, no manipulation on artificial aortic valves should be performed as thrombi may be present

and good anticoagulation is mandatory. Finally, it is imperative to flush the delivery device completely to avoid gas emboli.

13.4.3 Late Complications

Endoleak, defined as blood flow within the aneurysm sac, is a serious sequela that may lead to secondary rupture of the aorta. The classification of thoracic endoleaks is similar to the one currently used at the abdominal level (Fig. 13.4). Type 1 endoleaks, proximal or distal, show flow that originates from the stent graft attachment sites. Type 2 endoleaks are related to retrograde aortic filling from branch vessels, especially the left subclavian, intercostal or bronchial arteries. Type 3 endoleaks occur when there is a stent graft structural failure, including defects in the fabric, fractures or junctional separations of two devices. These endoleaks often result from stent graft disconnection, which is more likely to occur when multiple stent grafts with short overlapping areas are used. Type 4 endoleaks are caused by stent graft porosity. Finally, type 5 endoleaks or endotension are also described. Primary endoleak rates are similar to those encountered in the infrarenal aorta (4.2%–53%) (Dake 2001). However, in contrast to infrarenal aneurysms, the majority of endoleaks are successfully treated with a new graft as they are Type I or III. Type II endoleaks in the thoracic aorta have been mainly described arising from the subclavian artery, with retrograde filling by intercostal arteries seen rarely. Coil embolization or surgical exclusion of the left subclavian artery is sometimes useful to treat persistent endoleaks.

Secondary endoleaks due to migration or dislocation of modular junctions may result from inadequate grip or seal, but also from the inability of the relatively inflexible device to conform to distortion of the aorta that may occur after successful exclusion.

Finally, atherosclerotic aneurysms of the descending thoracic aorta typically occur in elderly patients with a diffusely diseased tortuous aorta. These aneurysms may progress so that the proximal or distal landing zones may dilate over time, allowing stent graft migration causing endoleaks. In order to prevent these complications, stent graft landing zones should be as long as possible and if two or more devices are used, stent graft overlap should be at least 5 cm to avoid late disconnection.

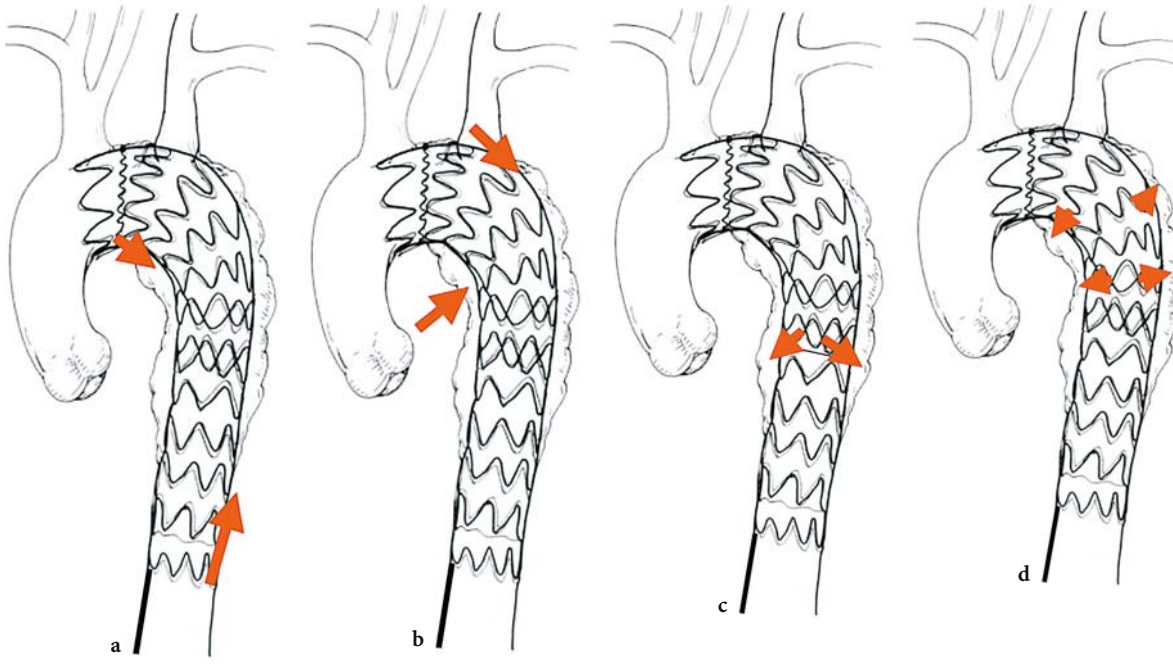


Fig. 13.4a–d. Endoleak definitions for TAA. **a** Type I attachment leak; **b** Type II branch flow; **c** Type III defect in graft or modular disconnection; **d** Type IV fabric porosity

13.5 Specific Indications

13.5.1 Type B Dissection

Since their first description more than 250 years ago, the morbidity and mortality of thoracic aortic dissections remain high despite the improvement of medical and surgical treatments. Whilst there is a general consensus in favour of surgical treatment for ascending aortic dissections, treatment of descending aortic dissections is still a matter of debate (Daily et al. 1970; Glower et al. 1990). The 30-day mortality rates of patients not requiring emergency operation is similar for those treated medically (10%) or surgically (19%) (Daily et al. 1970; Wheat 1980). Therefore, surgical intervention in type B dissections only justified if ischemic complications occur, if hypertension cannot be controlled or if thoracic pain persists despite medical treatment (Miller et al. 1984).

The introduction of endovascular techniques, especially stent grafts, fenestration or implantation of non-covered stents in the treatment of ischemic complications has led workers in this field to reconsider the indications for treatment (Slonim et al. 1996; Williams et al. 1997). The various endovascular techniques are complimentary and the choice of which to use depends on dissection type, clinical status of the patient and the urgency of treatment.

Recent clinical studies have shown stent graft treatment in patients with complicated and uncomplicated acute type B dissection, as well as chronic dissection with false lumen aneurysm formation to be efficacious. It should be emphasized that endovascular techniques used to treat aortic dissections are much more complex compared with those employed in aneurysmal disease. In acute aortic dissection, the large discrepancy between true and false lumen diameters makes stent graft implantation in a relatively disease-free aorta difficult. In chronic dissections, thickening of the intimal layer may impede adequate stent graft expansion.

To prevent aortic rupture or progressive aneurysmal dilatation, we aim to achieve stent graft coverage of the dissection entry tear. The aim of this technique is to exclude antegrade blood flow in the false lumen, therefore decreasing pressure and allowing thrombosis of the false channel in order to restore blood flow in the true lumen and its side branches. In vitro models of dissection have shown that primary entry tear coverage is the optimal method to relieve true lumen collapse and achieve false lumen thrombosis (Chung et al. 2000). Kato et al. (1994) showed that false lumen thrombosis is not initiated by mechanical obliteration but simply by decreasing the blood flow. Progressive thrombosis proceeds distally, irrespective of the location of the primary intimal disruption. Over time, the false lumen thrombus consolidates and the dissection resolves.

The speed and degree of false lumen thrombosis is variable and influenced by several factors. These include the size of the false lumen and amount of residual false lumen flow through additional uncovered tears. In a registry of 50 patients, we demonstrated that a significant increase in true lumen and reduction in false lumen diameters was observed only when complete thrombosis of the false lumen occurred. If flow persisted in the false lumen, no significant reduction in aortic diameter was observed (Gaxotte et al. 2005). Similar observations were made by other authors in patients treated medically for type B aortic dissection (Akutsu et al. 2004; Onitsuka et al. 2004). Akutsu et al. (2004) demonstrated that patency of the false lumen and maximal aortic dilatation at the distal arch were strong independent prognostic factors of dissection-related death and dissection-related events. For these reasons, we must conclude that persistent flow inside the proximal part of the false lumen represents a technical failure requiring further treatment if possible. This would include stent graft extension if more distal thoracic entry tears are present or embolization of any type II endoleaks, particularly from the left subclavian artery.

False lumen thrombosis is almost always observed at the stent graft level but is less common distal to the device (Fig. 13.5). By using longer stent grafts, we can expect more extensive thrombus formation inside the false lumen, thus allowing better true lumen expansion. However, we need to remember that long stent graft coverage that includes the distal third of the descending thoracic aorta increases the risks of spinal cord ischemia, though the risk remains very low in dissections. In order to reduce the ischemic risks, stent grafts with longer distal bare segments may be used to preserve intercostal flow. The chronicity of the disease process may also play a role in the degree of false lumen thrombosis; Shimono et al. (2002) demonstrated a 38.5% rate of complete false lumen thrombosis in chronic dissection versus 70% in acute dissection treated within 6 months of presentation.

In acute dissection, stent graft insertion can rapidly relieve dynamic or static branch vessel obstruc-

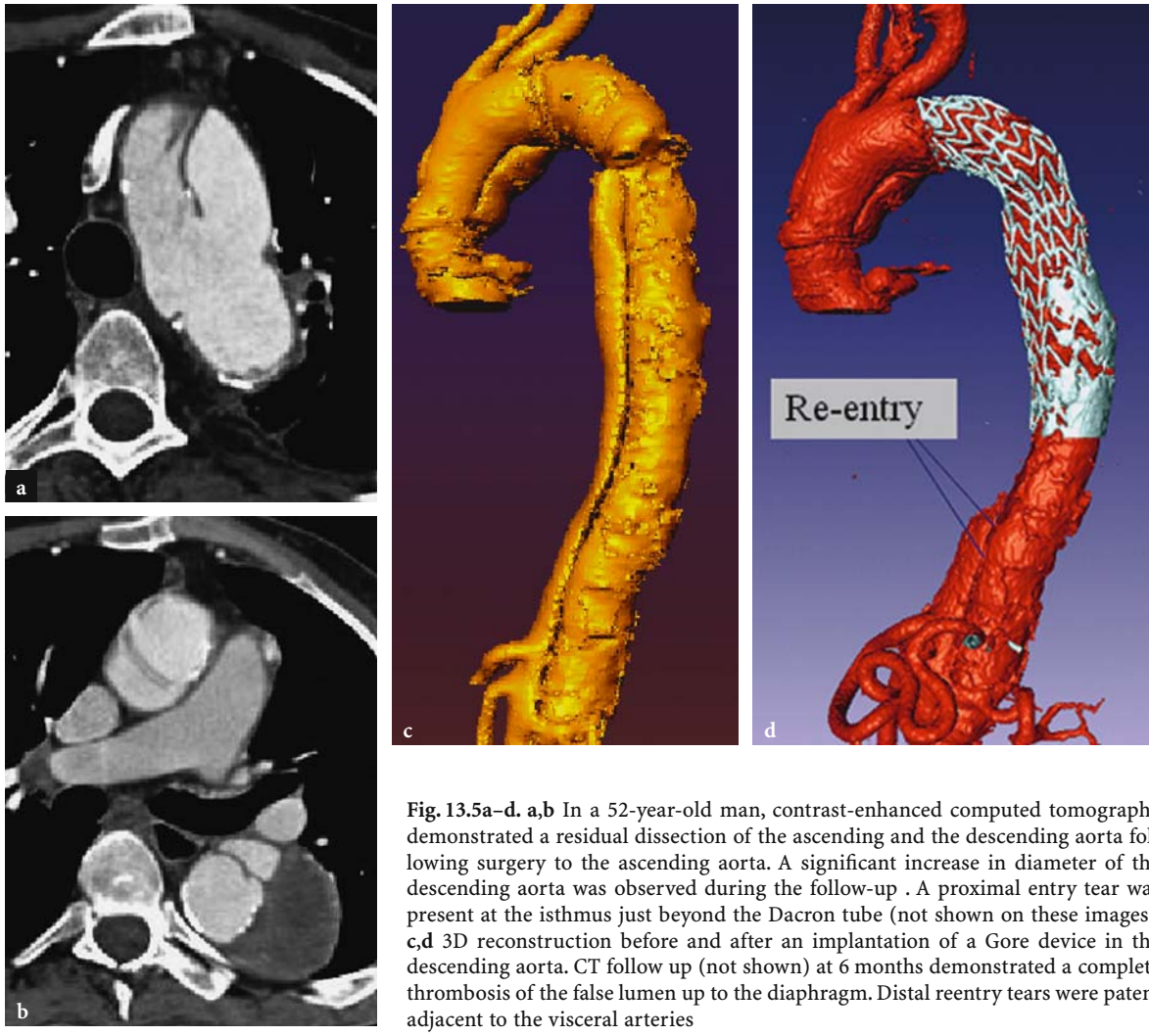


Fig. 13.5a–d. a,**b** In a 52-year-old man, contrast-enhanced computed tomography demonstrated a residual dissection of the ascending and the descending aorta following surgery to the ascending aorta. A significant increase in diameter of the descending aorta was observed during the follow-up . A proximal entry tear was present at the isthmus just beyond the Dacron tube (not shown on these images). **c**,**d** 3D reconstruction before and after an implantation of a Gore device in the descending aorta. CT follow up (not shown) at 6 months demonstrated a complete thrombosis of the false lumen up to the diaphragm. Distal reentry tears were patent adjacent to the visceral arteries

tion. Dake (1999) observed that all 22 (100%) of the dynamic and 6 of the 15 (40%) combined dynamic and static branch vessel occlusions in their series were immediately relieved after stent graft placement. If necessary, other endovascular techniques can be used to fully restore blood flow.

It is difficult to compare the results of stent graft treatment with those of conventional surgery. Despite reimplantation of intercostal arteries, extracorporeal circulation and profound hypothermia, the majority of surgical series show considerable morbidity and mortality rates. Age, cross-clamp time and extent of involved intercostal arteries seem to be the main morbidity and mortality risk factors (Dake et al. 1999). Regarding stent grafts, Nienaber et al. (1999) published excellent 3-month clinical results following endovascular treatment, with no morbidity or mortality. In comparison, patients treated surgically had mortality and morbidity rates of 33% and 42%, respectively, although the number of patients was limited.

The question remains whether or not to treat patients with uncomplicated type B dissections. From the literature, it is well known that false lumen patency contributes to progressive aortic dilatation and is a predictor of late mortality (Bernard et al. 2001) Similarly, dissections with naturally thrombosed false lumens are associated with better prognosis (Miller et al. 1984; Ergin et al. 1994). In light of these results, the INSTEAD trial (Investigation of Stent Graft in Patients with Type B Aortic Dissection), a prospective multicenter randomized controlled clinical study is underway to compare the 1-year outcome of uncomplicated type B aortic dissection treated by stent graft placement versus conventional anti-hypertensive therapy.

13.5.2 Traumatic Rupture

Traumatic ruptures usually involve the aortic isthmus in proximity to the LSA. When a graft is placed just distal to the LSA origin, it is usually in a relatively straight position. Therefore, the proximal part of the stent may protrude into the aortic lumen on the inner side of the aortic arch and cause type I endoleak, stent graft collapse or migration. Complete apposition of the stent graft on the wall is easier to achieve if the graft presents a proximal bare section placed over the LSA origin. However, some interventional radiologists are reluctant to use grafts with a proximal bare stent or with built-in hooks because of concern that they may erode the friable traumatized aortic wall. Experience shows that this potential risk is limited if the proximal graft is placed in the healthy portion of the aorta.

So far, most of the reported cases of aortic rupture treated endovascularly have been performed in subacute or chronic settings. Lachat et al. (2002) has advocated stent grafting in the acute situation. Unfortunately, current device costs make it impractical to stock a wide range of sizes in most hospitals, a distinct disadvantage in emergencies. However, most cases of rupture involve a short segment of aorta. Therefore, we keep a few stent grafts of various diameters and the same length in stock, thus permitting implantation in emergency situations. Furthermore, because the procedure is short and has little physiological effect, stent graft can be placed without anticoagulation in trauma cases with major neurological complications.

As the smallest commercially available endovascular graft is 26 mm in diameter, its use in young patients may be problematic, since the healthy aortic diameter is usually less than 20 mm. If used, this more than 30% oversizing may cause wrinkling of the prosthesis at the landing zones making the graft more susceptible to collapse or endoleaks, especially proximally. Furthermore, as the aortic diameter will increase with time, there is a potential risk of secondary pseudo-coarctation syndrome or distal migration if small grafts are used.

13.5.3 Other Indications

Intra-mural haematoma (IMH) may be successfully treated by stent graft insertion. A meta-analysis of 11 IMH studies found a cumulative mortality rate for type B IMH of 14% with little difference between surgically (15%) and medically (13%) treated groups (Sawhney et al. 2001). At present, no therapeutic consensus exists although an aggressive endovascular approach is being increasingly considered, especially in symptomatic patients (Maraj et al. 2000; Sawhney et al. 2001; Dake 2004).

Penetrating aortic ulcers are usually focal and almost always located in the descending aorta. Therefore, stent graft treatment, using short devices to reduce the risks of paraplegia, seem to be ideal. In a meta-analysis of 13 studies, complete sealing of the ulcer was achieved in 94% of cases with relatively low neurological complications (6%) and in-hospital mortality rates (5%) (Eggebrecht et al. 2003).

13.6 Conclusions

Short-term morbidity and mortality rates of stent graft treatment compare favourably with those of surgery for thoracic aortic aneurysms. It is already the best option in poor surgical candidates, but remains controversial in good surgical candidates because long-term results are unknown. Application on a larger scale, for uncomplicated type B dissections, cannot be considered before comparative studies have evaluated the long-term results of endovascular and medical treatments. A strong collaboration between cardiovascular surgeons, cardiologists and interventional radiologists is needed to guarantee perfect preoperative assessment and subsequent optimal endovascular treatment.

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14 Endovascular Repair of Iliac, Visceral and False Aneurysms

Ralph Jackson and John Rose

CONTENTS

14.1 Introduction

This chapter deals with a pot-pourri of aneurysms of visceral and peripheral arteries that are infrequently seen but are often difficult to manage. The clinical presentation may be dramatic and associated with a life-threatening episode of hypotension or haemorrhage. However, in many instances these aneurysms will remain undetected until the patient undergoes investigation for an unrelated problem or the secondary effect of the mass on adjacent structures.

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14.2 Visceral Arterial Aneurysms and False Aneurysms

True and false, visceral and renal aneurysms are relatively rare but often present with rupture (about 25%) and a high associated mortality rate (25%–70%). Surgical techniques for their management are well described (Abbas et al. 2002; Calligaro et al. 2000; Panayiatopoulos et al. 1996; Zelenock 2000). There has been, however, a steady increase in endovascular treatment aided by improvements in catheters, stents and embolic materials. Indeed interventional radiologists now play a major role in managing both elective cases and patients who are stable enough not to need emergency surgery.

The published evidence for endovascular management, however, is confined to multiple small to medium sized case series and very many case reports. Shanley et al. reviewed the literature in 1996 (Shanley et al. 1996a,b). Between 1985 and 1995, embolisation of aneurysms accounted for the management of 12% (10/83) of splenic artery and 37% (38/103) of hepatic artery aneurysms. Between 1970 and 1995 embolisation was used in 14% (8/56) of pancreaticoduodenal and 8% (3/36) of gastroduodenal aneurysms. In 2003 Grego et al. reported embolisation of only 2/17 visceral aneurysms otherwise treated surgically. Sessa et al. (2004) reported embolisation rates of 41% (11/27) of non-ruptured and 2/12 (17%) of ruptured aneurysms. Success rates of 57%–92% have been published in the results of three other recent series of embolised visceral aneurysms (Gabelmann et al. 2002; Guillon et al. 2003; Pilleuil and Dugougeat 2002). In comparison to the published surgical series (Calligaro 2000;

Henke and Stanley 2003), the evidence for the endovascular treatment of renal artery aneurysms is very sparse. Klein et al. (1997) reported 12 aneurysms successfully treated with coil occlusion of the aneurysm sac but the majority of the other reports are individual cases.

14.2.1 Aetiology and Natural History of Visceral Aneurysms

True visceral aneurysms are most commonly due to congenital or acquired medial dysplasia and weakened elastic lamina with secondary arteriosclerosis. Whilst there is a clear association with systemic fibrodysplasia, they are not particularly associated with aortoiliac aneurysms. False aneurysms are commonly secondary to complications of pancreatitis and iatrogenic trauma, such as percutaneous biliary drainage and renal biopsy. Mycotic aneurysms are less frequent except in the proximal superior mesenteric artery in patients with infective endocarditis. Renal aneurysms are very often associated with, and may be a cause of, hypertension.

The incidence and natural history of visceral and renal aneurysms are not fully known. Most information comes from either autopsy or angiographic case series and there are wide variations in reported frequency. Renal artery aneurysms are found in approximately 0.1%–0.3% of aortograms. The overall incidence of visceral aneurysms in autopsy or imaging series is in the region of 1%. The splenic and hepatic arteries are by far the most commonly affected vessels, accounting for 60% and 20% of cases, respectively. There is a <5% incidence of lesions in each of the superior mesenteric, celiac, gastric, gastroduodenal, pancreaticoduodenal and colic arteries (Shanley et al. 1996a,b).

14.2.2 Presentation and Management of Visceral Aneurysms

Given that most patients do not present with symptoms or rupture, the majority (approximately 60%) of visceral and renal aneurysms are discovered as incidental findings during angiography or cross-sectional imaging. Many of these true aneurysms do not go on to rupture and there is therefore a great deal of controversy within the surgical literature about the indications for elective repair. There are, however, some widely accepted indications for active management. These include any aneurysm in a woman of child-bearing age and most false aneurysms. Other less common indications are splenic aneurysms in patients with portal hypertension or who are undergoing liver transplantation (Arepally et al. 2002; Heestand et al. 2003). The generally accepted size limit for the conservative management of splenic or renal aneurysm is 2 cm (Abbas et al. 2002; Henke and Stanley 2003), but individual circumstances have to be taken into account prior to what is often major abdominal surgery. Where endovascular techniques are considered, because these are generally associated with lower morbidity and mortality, the size criteria may be relaxed.

14.2.3 Endovascular Treatment of Visceral Aneurysms

The precise origin of an aneurysm is not always obvious on cross-sectional imaging. Intra-arterial angiography is therefore usually required to fully evaluate the aneurysm and the possible treatment options. Recent advances in CT and MR angiography will now often allow precise non-invasive preoperative planning (Pilleuil and Beuf 2004).

Prior to embarking on visceral arterial intervention it is important to check the patency of all the mesenteric arteries and veins. For example, portal vein occlusion will affect the approach to hepatic artery aneurysms. Coeliac axis occlusion is often associated with pancreaticoduodenal aneurysms, which result from the increased collateral flow to supply the liver and spleen.

However, irrespective of the presentation, aetiology and location of the aneurysm, there are only a few basic endovascular techniques described in the literature. Factors such as parent vessel size and tortuosity, location and morphology of the aneurysm (saccular or fusiform), level of urgency, availability of equipment and operator experience will all determine the exact approach. Because of the small numbers and great heterogeneity of the patient populations it is difficult to give definitive success and complication rates. However, procedural rupture of false aneurysms and non-target embolisation can occur and complete embolisation may not be possible. Early re-imaging is advised, particularly when treating false aneurysms, given their high associated mortality rates (Pilleul and Dudougeat 2002).

14.2.3.1 Parent Vessel Occlusion

This is the simplest and most commonly described treatment particularly for splenic and peri-pancreatic aneurysms. The feeding vessel on either side of the aneurysm (the "front and back door") is occluded, usually with embolisation coils (Fig. 14.1). This is generally safe due to the rich collateral networks in the splanchnic circulation. Coil embolisation of the pancreaticoduodenal artery has even been reported to be safe in the presence of celiac axis occlusion (Weber et al. 2005). However, the more distal the aneurysm the less sure is the collateral supply and when treating end-arteries such as in the kidney, tissue loss may occur. But partial splenic or renal infarction may be preferable to the surgical options of splenectomy or nephrectomy, for example.

In addition to standard steel or platinum coils, other agents such as gelfoam, polyvinyl alcohol particles and glue have been used. N-butyl cyanoacrylate glue injection has salvaged incomplete aneurysm treatment where distal catheterisation is prevented by the underlying anatomy or by proximal coiling (Kim et al. 2004; Ishimura et al. 2004). Special care is needed when using such agents, as unintentional distal embolisation is possible.

14.2.3.2 Aneurysm Filling

Depending on its nature and size the aneurysm may be packed with coils, leaving the parent vessel patent. This has been applied to splenic and particularly to renal aneurysms (Fig. 14.2). As in the cerebral circulation saccular aneurysms with narrow necks are ideally suited to this method. Borrowing from neuro-radiological techniques, less suitable aneurysms with wider necks can also be occluded with balloon remodelling of the neck and packing with detachable coils or the liquid embolic agent, Onyx

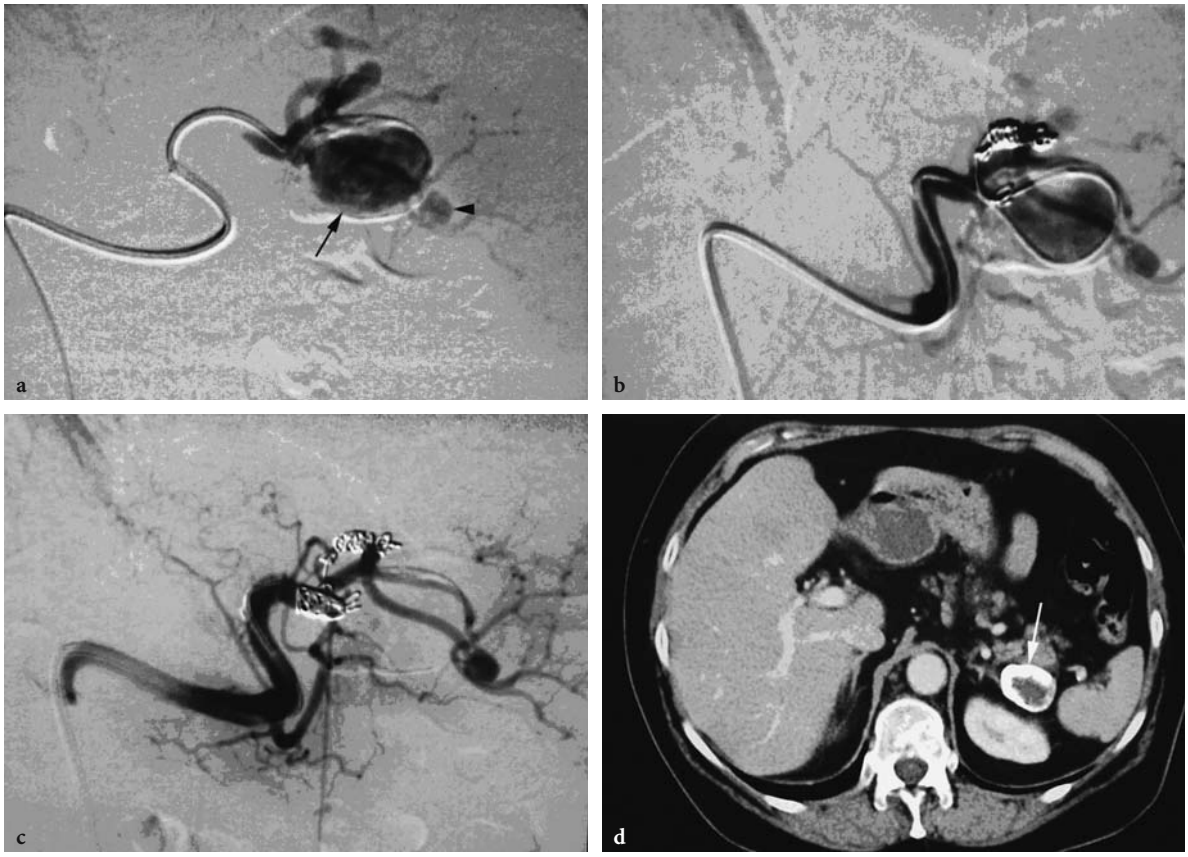

Fig. 14.1a–d. a A 3-cm aneurysm arises from the distal splenic artery (*arrow*) with a small lower pole intra-splenic aneurysm noted (*arrowhead*). **b** Coaxial 7-F guide sheath and 5- and 2.3-F catheters allow the vessel distal to the aneurysm to be catheterised. **c** The aneurysm is successfully excluded using coils. **d** Follow-up CT at 6 months confirms aneurysm thrombosis (*arrow*) and a perfused spleen

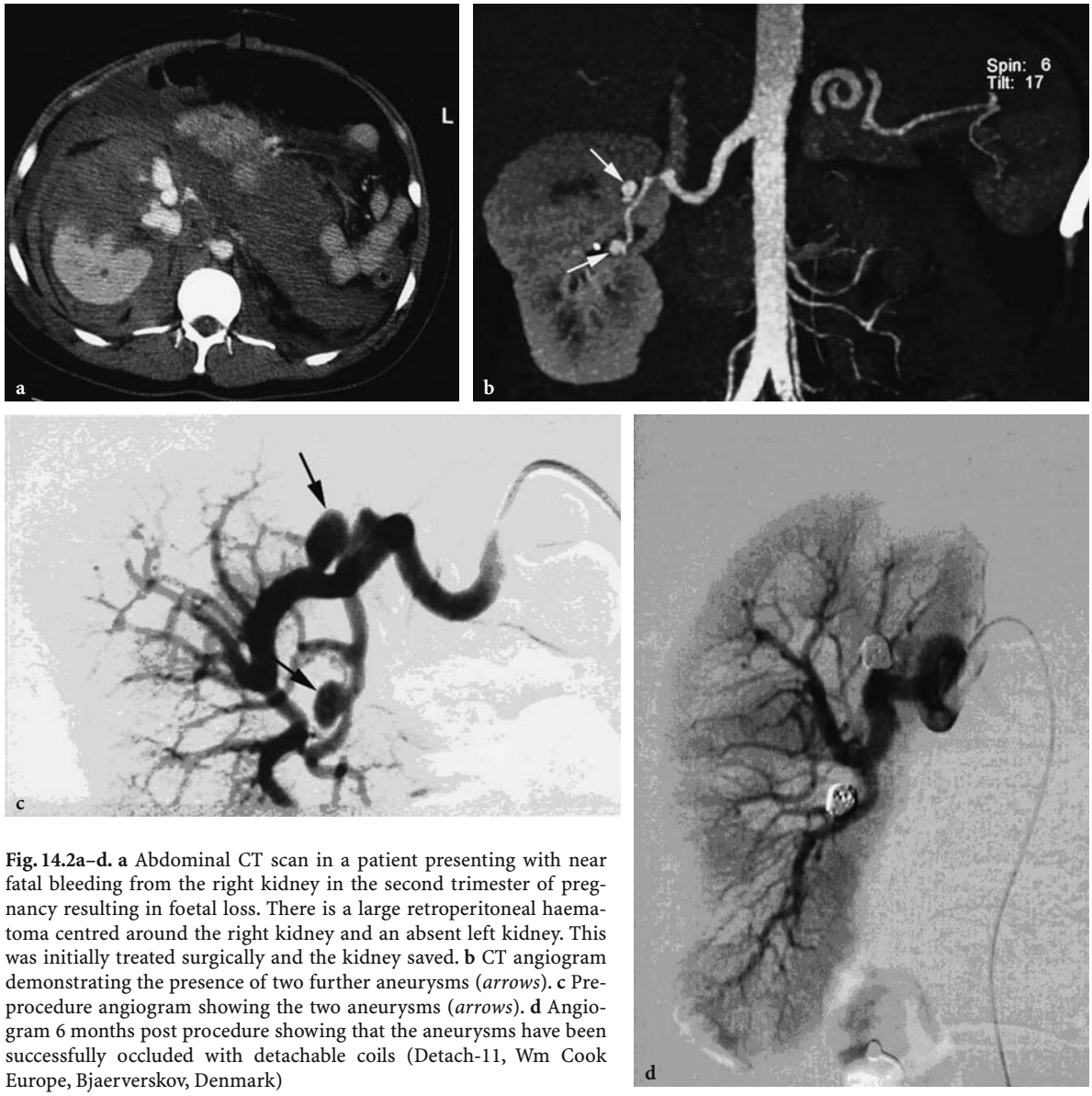

Fig. 14.2a–d. a Abdominal CT scan in a patient presenting with near fatal bleeding from the right kidney in the second trimester of pregnancy resulting in foetal loss. There is a large retroperitoneal haematoma centred around the right kidney and an absent left kidney. This was initially treated surgically and the kidney saved. **b** CT angiogram demonstrating the presence of two further aneurysms (*arrows*). **c** Preprocedure angiogram showing the two aneurysms (*arrows*). **d** Angiogram 6 months post procedure showing that the aneurysms have been successfully occluded with detachable coils (Detach-11, Wm Cook Europe, Bjaerverskov, Denmark)

(MicroTherapeutics, California, USA) (Centenera et al. 1998; Mounayer et al. 2000; Owens et al. 2002; Lupatelli et al. 2003). This approach is generally not suitable for pseudoaneurysms due to their fragile nature and the danger of provoking bleeding. In addition there have been reports of the late erosion of balls of coils into adjacent structures.

14.2.3.3 Thrombin Injection

Thrombin has been used to treat false aneurysms in almost every part of the body and it is therefore not surprising that it has been used for visceral false aneurysms as well. Such use has been rarely described but this is an excellent option when coil embolisation may jeopardise other important vessels (Manazer et al. 2003; Sparrow et al. 2003) or when the false aneurysm arises from small vessels that cannot be catheterised (Kemmeter et al. 2000). Using ultrasound or CT guidance and fluoroscopy a narrow gauge needle, typically 20 G, is positioned within the false aneurysm. Its position can be confirmed with angiography prior to thrombin injection. With growing experience this procedure may become the treatment of choice for visceral false aneurysms where transcatheter embolisation is not possible.

14.2.3.4 Stent-Grafts

Stent-grafts would appear to be the ideal solution. The aneurysm is occluded and distal perfusion maintained. In practice, however, this has been the exception rather than the rule (Rikimaru et al. 2001; Yoon et al. 2001; Arepally et al. 2002; Larson et al. 2002). Splenic arteries in particular are usually very tortuous and most aneurysms arise from the middle and distal segments. Renal artery aneurysms usually arise at the main artery bifurcation rather than the trunk. However, the introduction of stent-grafts designed for the coronary arteries has made this an increasingly attractive and achievable approach (Bruce and Yew-Ming 2002; Venturini et al. 2002; Appel et al. 2003; Schneideret et al. 2003; Gandini et al. 2005). The Jostent stent-graft (Abbot Vascular Devices, Ill, USA) has been used in most cases. This is a balloon mounted, expandable PTFE graft sandwiched between two stents which will pass through a 7-F guide catheter.

The advantages of this technique include the maintenance of vessel patency and tissue perfusion, which is particularly desirable in the renal and hepatic circulations. However, target vessel tortuosity and size are still limiting factors in many cases and the long-term patency rates are unknown. Patients will also require an anti-platelet agent, at least in the short term.

14.3 Iliac Arterial Aneurysms

14.3.1 Aetiology and Natural History of Iliac Aneurysms

It is well recognised that aneurysmal dilation of the iliac segments is most commonly associated with atheromatous aneurysms of the abdominal aorta. The iliac vessels are involved in 10%–20% of abdominal aortic aneurysms and iliac aneurysms are prone to develop in a significant proportion of cases where an aortic aneurysm has been repaired with an aorto-aortic tube graft. The 'isolated' iliac aneurysm is unusual and accounts for probably less than 5% of all aortoiliac aneurysms. A combined autopsy and surgical series from a well-defined stable urban population of 230,000 in Sweden, demonstrated a 0.03% frequency of isolated iliac aneurysms (Brunkwall et al. 1989). In the same study, the overall frequency of abdominal aortic aneurysms was 3.8% at autopsy and 17% of these abdominal aneurysms were associated with iliac aneurysms. As with aortic aneurysms, isolated iliac aneurysms are most frequently due to arteriosclerosis although mycotic iliac aneurysms have been reported, as well as cases secondary to Behçet's disease, fibromuscular dysplasia, and congenital connective tissue disorders such as Ehlers-Danlos syndrome and Marfan's disease.

The majority of publications on iliac artery aneurysms take the form of small case series or autopsy series and their natural history is thus difficult to establish. However, historically the iliac aneurysm has a reputation as a lesion very prone to spontaneous rupture. The incidence of rupture is said to exceed 30% (Richardson and Greenfield 1988), although a recent survey of 189 patients with 323 asymptomatic common iliac artery aneurysms found that aneurysms under 3 cm diameter expand extremely slowly and rarely rupture (Santilli et al. 2000). This group further suggested that the expansion rate of iliac artery aneurysms is directly related to their size and that those less than 3 cm in diameter could be safely followed up with annual ultrasound examinations. Those aneurysms larger than 3 cm should be screened at 6 monthly intervals and all asymptomatic lesions exceeding 4 cm in size, or symptomatic aneurysms of any size, should undergo elective repair. The overall consensus of opinion would seem to be that all aneurysms greater than 5 cm in diameter require an urgent repair.

14.3.2 Anatomical Distribution of Iliac Artery Aneurysms

Whether associated with aortic aneurysms or arising as 'isolated' iliac aneurysms, it is apparent that these lesions arise much more frequently in the common iliac segment than the other two iliac segments. Most series report common iliac lesions in 85%–90% of cases, internal iliac aneurysms in 5%–10% and external iliac lesions in less than 1%. Paradoxically, a recent series from Japan (Matsumoto et al. 2004) showed a 44% prevalence of internal iliac lesions and it is possible that there is a true geographical variation. There is also a tendency towards multiple and bilateral lesions in patients with iliac aneurysms, even in those not associated with aortic aneurysm (McCready et al. 1983; Richardson and Greenfield 1988; Dosluoglu et al. 1999).

14.3.3 Clinical Presentation of Iliac Artery Aneurysms

Classical descriptions of the isolated iliac aneurysm imply that the diagnosis is inapparent until the time of aneurysm rupture, causing acute onset of lumbo-sacral pain or haemodynamic disturbance. However, in many instances, because of the limited space in the pelvis, these aneurysms may also present as the result of the chronic compression of adjacent organs and structures. Thus the reported presentations include leg swelling, urinary retention, ureteric obstruction, bowel obstruction or fistulation and sciatic, femoral or obturator neuropathy. Those aneurysms of less than 4 cm diameter may well be impalpable and if asymptomatic will generally be overlooked during clinical examination. Such lesions will usually be discovered incidentally during imaging tests for unrelated problems.

14.3.4 Endovascular Treatment of Iliac Aneurysms

14.3.4.1 Common Iliac Aneurysms

Endovascular techniques are now firmly established in the treatment of iliac aneurysms, although there are still only relatively small case series demonstrating mid-term success (Parsons et al. 1999; Sahgal et al. 2001; Fahrni et al. 2003; Matsumoto et al. 2004).

The factors that most influence treatment choices for large common iliac aneurysms, are the presence of a proximal neck (below the aortic bifurcation) and the level of the iliac bifurcation. Where the proximal iliac segment between the aortic bifurcation and the aneurysm is at least 20 mm in length and no more than 20 mm in diameter, then a simple tube stent-graft will suffice. The position of the ostium of the internal iliac artery will determine whether coil occlusion of this vessel is also required. The presence of a distal neck below the aneurysm and above the internal iliac origin indicates that the distal end of the stent-graft can be placed above the internal iliac artery.

If the internal iliac ostium is within the aneurysm sac or even partially involved by the inferior margin, then occlusion will be essential to prevent backfilling of the sac via pelvic collateral vessels. The technique of coil occlusion in this situation concentrates on blocking the proximal main trunk of the internal iliac above the anterior and posterior divisions (Fig. 14.3). Where the internal iliac ostium originates from a relatively normal segment but the distal neck is too short to enable secure placement of the stent-graft proximal to the ostium, then the

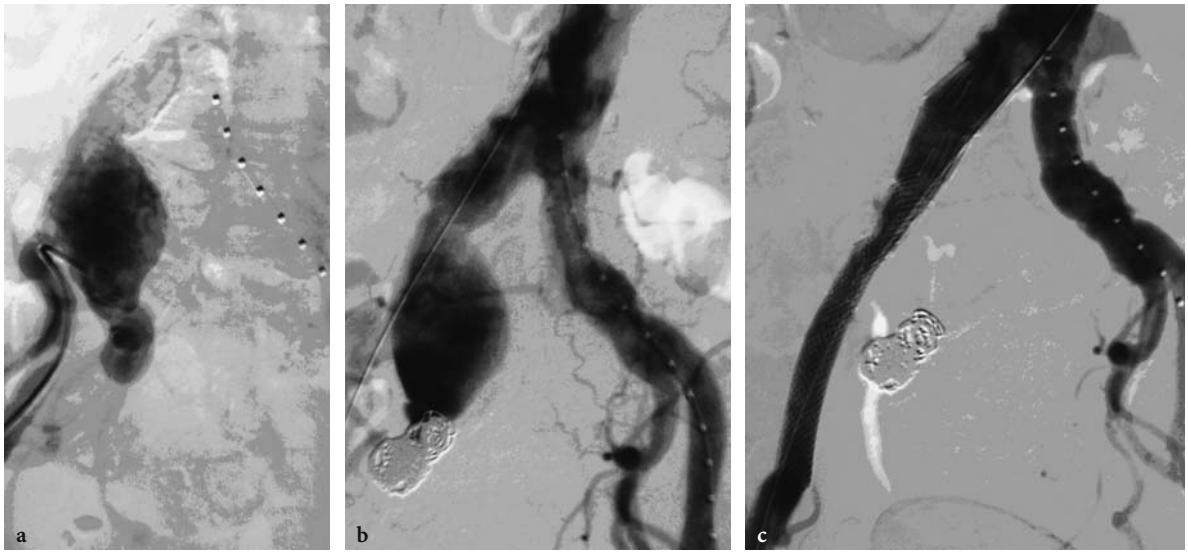

Fig. 14.3a–c. a This selective angiogram shows an isolated 4-cm right common iliac aneurysm involving the main trunk of the internal iliac artery. **b** Embolisation coils have been placed in the distal internal iliac trunk adjacent to the bifurcation. The divisional branches are still opacified at this stage but complete cessation of flow is not necessary. **c** Deployment of a Zenith stent-graft limb extension (Wm Cook Europe, Bjaerverskov, Denmark) has excluded the aneurysm and there is no backfilling via the previously embolised internal iliac artery. A co-axial Wallstent (Boston Scientific, St Albans, Herts) was required to treat a kink in the external iliac segment

device is extended across the internal iliac artery origin without the need for coil occlusion. Providing the device is appropriately oversized (5%–10% is usually adequate) then the graft material will usually block the mouth of the internal iliac artery and backfilling of the sac cannot occur.

In circumstances where the proximal neck is too short to allow secure fixation of a stent-graft in the common iliac artery, or the aneurysm extends into the aortic bifurcation, then either a bifurcated stent-graft or a tapered aorto-monoiliac stent-graft will be required. In general terms, bifurcated devices are preferred as they maintain normal vascular anatomical relationships, whereas aorto-monoiliac devices require the simultaneous insertion of a femorofemoral cross-over graft.

Where coil occlusion is thought to be necessary but internal iliac catheterisation proves very difficult then coiling of the sac after deployment of the stent-graft limb can be a useful technique.

14.3.4.2 Internal Iliac Aneurysms

These lesions often extend deep within the true pelvis and may therefore present a formidable challenge at open surgery. The most important determinant of successful treatment, by open or endovascular means, is the complete occlusion of outflow branches from the aneurysm. The classic surgical treatment of internal iliac aneurysms was with proximal ligation and this was described as long ago as the early twentieth century. Although this proved an easy option with low morbidity and mortality, the reperfusion and subsequent enlargement of internal iliac aneurysms treated by simple proximal ligation is well recorded. Even small aneurysms, less than 3 cm in diameter, may fail to completely thrombose after proximal ligation alone (Nakajima et al. 2001). It is currently accepted that the best open surgical procedure involves the stitching of the branch vessel ostia from within the aneurysm sac (endo-aneurysmorrhaphy) as well as proximal ligation. This operation can be technically difficult, carries an appreciable mortality (5%–10%) and should probably be reserved for fit patients with symptoms related to compression of adjacent structures (Parry et al. 2001).

The endovascular options include placement of a stent-graft across the internal iliac origin after coil occlusion of the outflow, packing of the entire aneurysm sac with multiple thrombogenic coils or coil embolisation of the inflow and outflow vessels (Parry et al. 2001; Fahrni et al. 2003).

The simplest method of transcatheter intervention is the placement of an appropriate stent-graft, as described above for the common iliac segment, across the internal iliac ostium. This technique is not dependent on the presence of a proximal neck and may be reserved for those cases with little or no normal artery between the internal iliac ostium and the aneurysm sac. The internal iliac artery bifurcation is catheterised prior to stent insertion and the anterior and posterior divisions blocked as proximally as possible with platinum coils (Fig. 14.4).

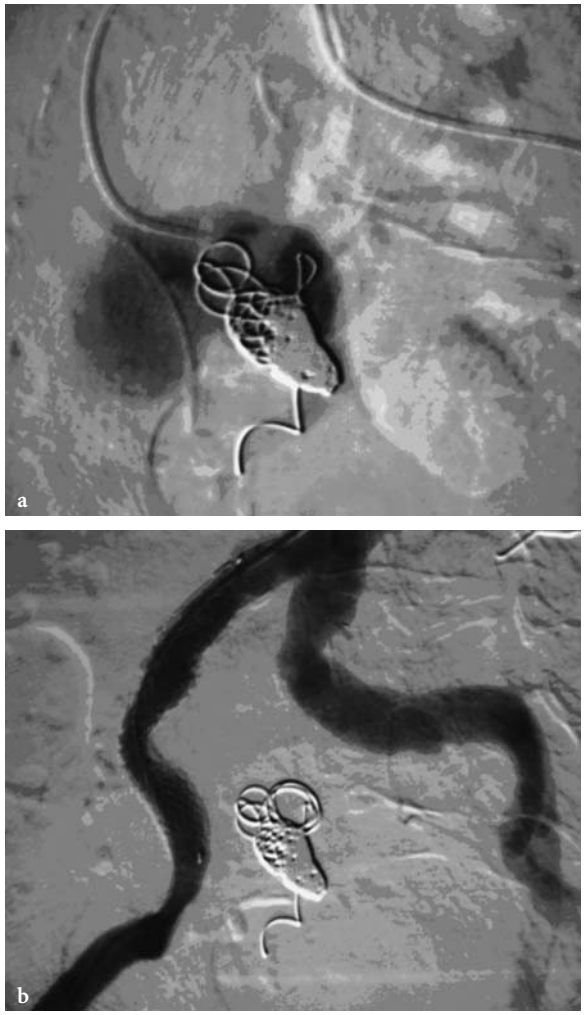

Fig. 14.4a,b. a This large, isolated, right internal iliac aneurysm was selectively catheterised via a left femoral approach in order to allow coil occlusion of the distal trunk. **b** As the aneurysm had no proximal neck, proximal inflow has been excluded with an Excluder stent-graft limb (WL Gore, Flagstaff, Arizona). Because of their tapered shape and highly flexible nature these devices are very useful in tortuous vessels

This means that the coil diameter must be carefully chosen to be oversized by 1–2 mm in order to avoid distal extension and branch vessel occlusion. The use of fluid embolic material in these circumstances is not advisable, because of the risk of severe pelvic ischaemia and potential damage to sensitive adjacent organs and nerves.

Where there is a well defined 'proximal neck' of internal iliac main-stem leading into the aneurysm and suitable exit vessels in terms of an anterior and a posterior divisional branch, then selective coil occlusion of inflow and outflow vessels will suffice. Once again, appropriately oversized platinum coils are used to block the iliac artery bifurcation, taking care not to prolapse the coils too far distally into the branch vessels.

If the aneurysm is large and complex with multiple small outflow branches, it may prove impossible to safely occlude these outflow vessels individually. In such cases it may be possible to pack the aneurysm sac completely with a mixture of coils, generally starting with larger coils and filling in the residual spaces with medium and small coils. In exceptional cases thrombin may be injected through the same catheter in order to produce a more complete thrombotic effect.

14.3.4.3 External Iliac Aneurysms

The external iliac segment is very rarely involved by atheromatous aortoiliac aneurysms and is only occasionally found as the site of an isolated iliac aneurysm. In general, as for common iliac lesions, the endovascular treatment consists of stent-graft insertion. Where there is no suitable proximal neck in the external iliac, the proximal end of the stent-graft may be placed in the common iliac.

14.4 Femoral False Aneurysms

Requests to examine a painful expansile swelling in the groin following femoral artery catheterisation is an extremely familiar scenario in all ultrasound departments within hospitals that provide an interventional vascular or cardiology service. The diagnosis and subsequent management of peripheral false aneurysms has been taken over completely by the radiologist during the last decade. In addition to ultrasound-guided compression, all the techniques described previously in this chapter have been used to treat femoral false aneurysms. Without doubt, however, percutaneous thrombin injection has been shown to be the quickest, most pain-free and effective treatment. Success rates of over 90% are to be expected with a single injection and complications are rare (Morgan and Belli 2003).

In most institutions thrombin injection is now the treatment of choice for stable false aneurysms, which have failed to resolve after 48 h of observation. Human thrombin (Tisseel, Baxter, Glendale, Ca, USA) is used at low doses, usually less than 500 IU. Balloon protection is no longer used. Whilst femoral false aneurysms are by far the most commonly encountered, other sites have also been treated with percutaneous thrombin (Fig. 14.5).

14.5 Conclusion

This chapter has focussed on endovascular treatment for a variety of aneurysms. Visceral and isolated iliac aneurysms are relatively uncommon, but with the exception of common iliac aneurysms they can be very challenging to treat by open surgical methods. Although their incidence makes it highly unlikely that firm evidence will ever be available from randomised studies, it is clear that a variety of endovascular therapies are now available which provide successful treatment, at least in the medium term, whilst avoiding the potential complications of difficult surgery. The use of ultrasound compression and more recently percutaneous thrombin injection has been a revolution in the management of femoral, and other, false aneurysms occurring after catheterisation, so that few of these patients now need to be managed with open surgery.

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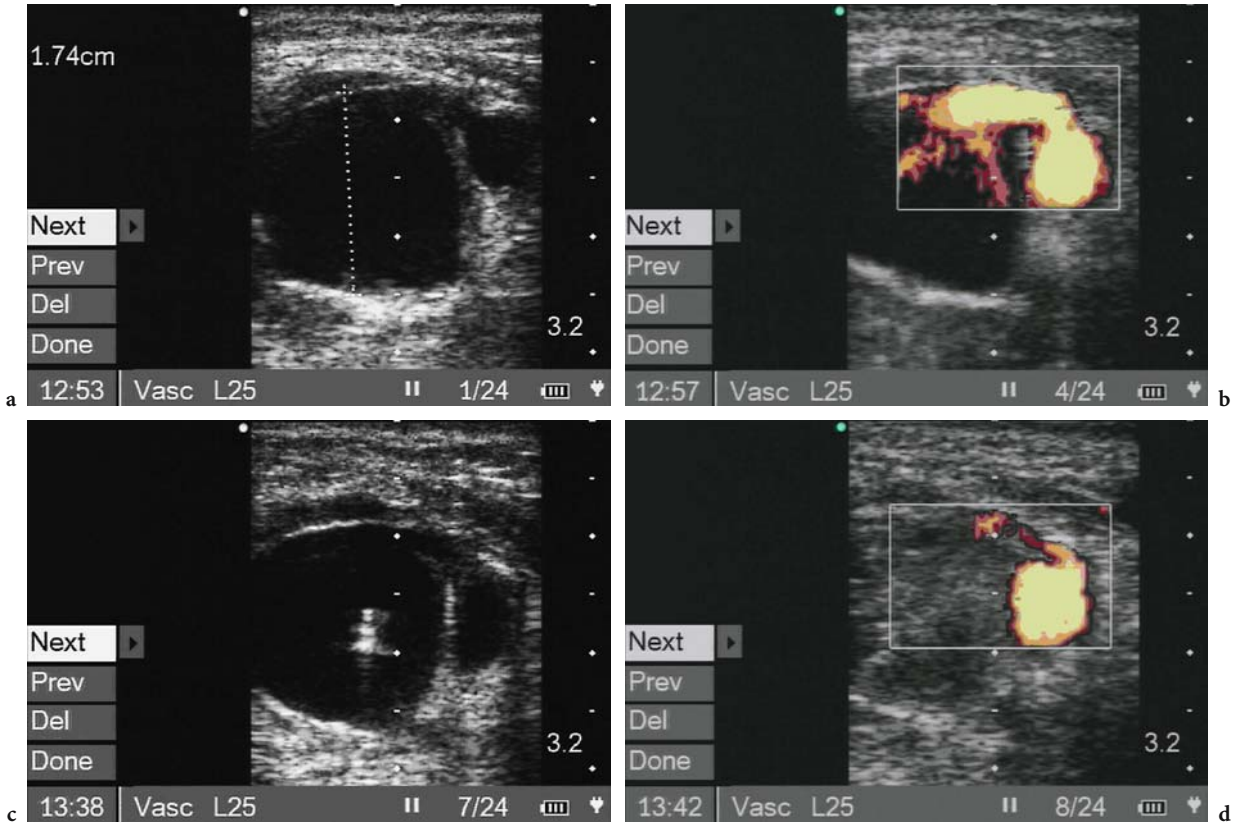

Fig. 14.5a–d. a,b There is a 17-mm false aneurysm arising from the left brachial artery. **c,d** Under US guidance a 21-G needle is positioned within the false aneurysm and thrombin injected leading to immediate almost complete thrombosis

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15 Dialysis Access Management

John R. Asquith

CONTENTS

15.1 Introduction

The aim of this chapter is to review the increasingly prominent role of the interventional radiologist in the multidisciplinary management of haemodialysis vascular access and its complications. This encompasses the placement and management of haemodialysis catheters and percutaneous procedures to deal with the complications of grafts and fistulas. The interventional radiologist is an integral part of the dialysis team with an ability to provide significant benefits in preserving vascular access.

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15.2 Dialysis Line Insertion and Management

15.2.1 Dialysis Line Insertion

Temporary, non-tunnelled haemodialysis catheters are for short-term haemodialysis, which is between several days and a few weeks duration. Short-term haemodialysis line insertion has a low complication rate and is usually carried out by non-radiologists.

Long-term haemodialysis catheters are tunnelled through a short subcutaneous route between the skin and the site of venous puncture. Tunnelled dialysis lines are recommended by the American National Kidney Foundation clinical guidelines (National Kidney Foundation 2001) in patients requiring temporary venous access for periods greater than 3 weeks. At the skin exit site of tunnelled lines a cuff reduces infection rates and decreases the inadvertent removal of tunnelled catheters compared to non-tunnelled catheters (Flowers et al. 1989; Maki et al. 1988).

Tunnelled lines can provide good haemodialysis access for many months. They are particularly useful during the maturation of a fistula or graft, which may take up to 3 months before dialysis is possible. Tunnelled catheters are also used 'permanently' when all other access routes for fistula formation have been exhausted. In addition many patients present late to renal units with end-stage renal failure and hence tunnelled catheters are often required until definitive dialysis access is available (Chesser and Baker 1997). Disadvantages of tunnelled lines compared to native fistulas include the risk of infection, development of venous stenosis or occlusion, which is often central, and the presence of the external lines.

Traditionally tunnelled dialysis lines were inserted without imaging guidance. However, line placement using ultrasound and fluoroscopy has been shown to produce better results than using anatomical landmarks alone. Ultrasound provides a greater puncture success rate with fewer complications than blind

insertion (Mallory et al. 1990; Lameris et al. 1990; Forauer and Glockner 2000). Published series show lower rates of primary line malposition, fewer complications and less catheter infections with radiological placement when compared to blind insertion (McBride et al. 1997; Trerotola et al. 1997).

There are numerous types of tunnelled dialysis catheters in use. They include the Tesio system of two separate single-lumen 10-F silastic catheters, which produce higher flow rates than the older dual lumen step-tip designs of catheters (Prabhu et al. 1997). The main disadvantage of Tesio lines is the requirement for two separate tunnels (Tesio et al. 1994). It was initially anticipated that twin catheters would have a longer survival rate than the dual lumen devices, but there is evidence that this is not the case (Caridi et al. 1999). An alternative is the Ash Split 14.5-F catheter which has two independent lumens and hence the theoretical advantages of twin catheters, but only requires a single subcutaneous tunnel.

15.2.2 Choice of Vein for Access: Conventional Central Veins

There are several venous access sites for tunnelled line insertion including the internal jugular and subclavian veins. Subclavian lines have a higher incidence of procedural complications, venous thrombosis and stenosis compared to internal jugular lines (Cimochowski et al. 1990; Schillinger et al. 1991; Macdonald et al. 2000; Trerotola et al. 2000). With subclavian line induced stenosis there is the possible exclusion of use of the ipsilateral extremity for future fistula formation. Therefore, the subclavian approach should be avoided. The right internal jugular vein should be used preferentially, followed by the left internal jugular vein. If the internal jugular vein is punctured high then the tunnelled catheter is more likely to kink in the neck due to the acute angle formed. The internal jugular vein puncture should therefore be low in the neck (approximately 2 cm above the clavicle), which facilitates tunnelling by avoiding the sternocleidomastoid muscle (Silberzweig and Mitty 1998).

15.2.3 Optimal Catheter Position

The optimal position for the tip of a dialysis catheter is in the region of superior vena cava-right atrial junction (National Kidney Foundation 2001). If the catheter is positioned too low in the right atrium there is the risk of perforation of the right atrial wall and arrhythmias. During catheter positioning it is also important to realise that due to traction on the catheter in the subcutaneous tissues the tip of the catheter will move cephalad by approximately 3 cm when the patient moves from the supine to the upright position (Nazarian et al. 1997; Kowalski et al. 1997). A routine, post-procedural chest radiograph is not required for lines inserted using imaging guidance because malposition and complications are rare (Gladwin et al. 1999; Chang et al. 1998).

15.2.4 Alternative Dialysis Line Access Routes

Alternative routes have been described for when both the internal jugular and subclavian veins are unavailable for line insertion. These approaches include femoral veins, neck collaterals (Funaki et al. 2001), external jugular veins (Forauer et al. 2000) the translumbar inferior vena cava (Markowitz et al. 1998; Rajan et al. 1998) and percutaneous hepatic veins (Po et al. 1994; Duncan et al. 1995). The femoral vein has a slightly higher risk of infection and dysfunction compared to the subclavian or internal jugular veins (Zaleski et al. 1999). A further potentially useful technique is venous recanalization of occluded veins for central venous catheter placement (Ferral et al. 1996; Funaki et al. 2001).

15.2.5 Fibrin Sheath Formation

Dialysis lines usually fail due to the formation of a pericatheter fibrin sheath or intracatheter thrombosis (Crain et al. 1996; Trerotola et al. 1997). The clinical signs of fibrin sheath formation include poor flow and an inability to aspirate blood through the catheter. A fibrin sheath can be detected by performing a linogram, which will demonstrate contrast being retained around the tip of the line and backtracking around it (Fig. 15.1a).

The treatment options for fibrin sheath formation include thrombolytic infusions, line stripping, catheter exchange or line replacement. Stripping of a fibrin sheath is performed by capturing the end of the dialysis line with a gooseneck snare and repeat-

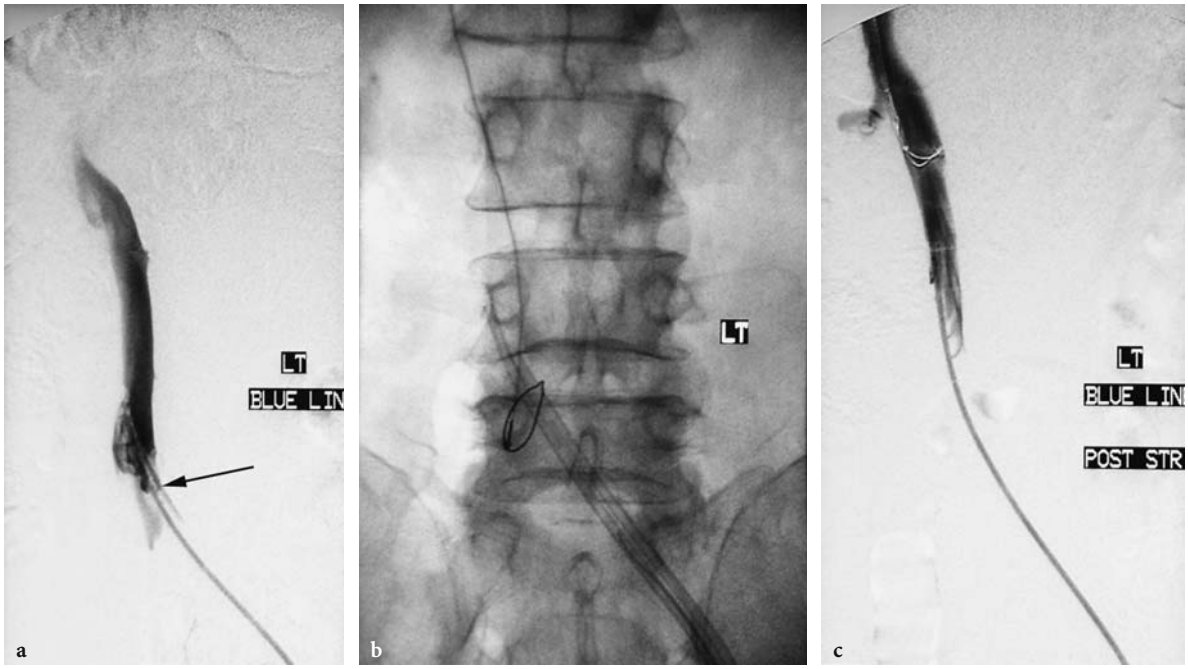

Fig. 15.1. a Twin Tesio catheters placed via a left common femoral vein approach. Linogram shows contrast is retained around the catheters due to fibrin sheath formation (*arrow*). Urokinase infusion produced no improvement. **b** Line stripping was performed using a gooseneck type snare with a left internal jugular vein approach. **c** The final image shows contrast flowing freely from the catheter side holes

edly pulling the tightened snare down over the end of the line to remove the fibrin (Fig. 15.1) (Crain et al. 1996). Findings from a randomised study show that line stripping and urokinase infusion are equivalent in immediate restoration of catheter function and maintenance of long-term patency (Gray et al. 2000). This study would suggest that thrombolytic infusion is preferable to stripping because it is non-invasive, cheaper to perform, administered on the dialysis unit, preferred by patients and safer. Catheter exchange or line stripping is reserved for those patients in whom thrombolytic infusions have failed. Furthermore, another randomised trial has shown longer patency rates with line exchange compared to stripping for the treatment of fibrin sheath formation (Merport et al. 2000).

15.2.6 Catheter Repositioning

The radiologist can assist in repositioning catheters that have become misplaced due to either spontaneous migration of the catheter tip or primary misplacement during insertion without fluoroscopic guidance. A transfemoral approach is usually used to reposition central lines. The repositioning is performed by dragging the line down with a pigtail catheter or by grabbing the tip of the line with a gooseneck snare (Hartnell et al. 1996; Boardman and Hughes 1998). Radiological repositioning of lines is quick, simple to perform and avoids replacement of the line.

15.3 Management of Dialysis Fistulas and Grafts

15.3.1 Imaging of Dialysis Fistulas and Grafts

The commonest indications for fistula and graft imaging are poor flows, high venous pressures during dialysis and failure to mature. The main imaging modalities are Doppler ultrasound, digital subtraction angiography (DSA) and magnetic resonance angiography (MRA). DSA is still the mainstay of fistula imaging, because it is quick, easy to perform, depicts the entire length of the venous return and can be followed immediately by an interventional procedure.

The optimal approach for performing a diagnostic fistulogram depends upon the clinical indica-

tion. When there is delayed maturation the arterial inflow and the arteriovenous anastomosis should be studied and this can be performed by retrograde puncture of the ipsilateral brachial artery at the elbow. When there is hand ischaemia due to steal syndrome then subclavian arterial catheterisation from the femoral route allows complete visualization of the upper limb arteries and the entire venous outflow. When the indication is poor flows or high venous pressures a simple technique for fistulography is retrograde cannulation of the venous side of the fistula and injection of contrast medium during inflation of a sphygmomanometer cuff on the arm to a level above systolic blood pressure. This method allows demonstration of the arteriovenous anastomosis by reflux of the contrast.

Pullback pressure gradient measurement from the SVC to the arterial anastomosis may be helpful when no significant stenosis is identified on the angiogram despite abnormality with dialysis. Pressure measurements may also be useful as an adjunct to angiography for identifying venous stenoses persisting after apparently successful angioplasty (Funaki et al. 2002).

Carbon dioxide gas has been used as an alternative to iodinated contrast for angiography of the venous side of a fistula. This is particularly useful in patients who have not yet used their fistula for dialysis and where residual renal function is preserved by avoiding nephrotoxic contrast. However, carbon dioxide must be used with caution due to the risk of reflux into the cerebral circulation and consequently it cannot be used to study the arterial anastomosis (Ehrman et al. 1994; Spinosa et al. 1998). Gadolinium has also been used as an alternative to iodinated contrast (Spinosa et al. 1998; Sancak et al. 2002). Contrast-enhanced MRA is an alternative to invasive fistulography and avoids ionising radiation. Until recently MRA has been limited by an inability to show the whole of the venous outflow to the superior vena cava (Cavagna et al. 2000). However, using contrast enhanced techniques with a 1.5-Tesla machine the complete inflow and venous outflow tract can be imaged. In a small series (Han et al. 2003) a sensitivity of 100% was found for MRA when compared to DSA for the detection of significant stenoses. MRA does, however, still tend overestimate the severity of these stenoses.

Doppler ultrasound is an accurate technique for the detection of problems in fistulas and grafts (Finlay et al. 1993; Bacchini et al. 2000). A major limitation with ultrasound is the difficulty in detecting central venous stenoses.

15.3.2 Angioplasty of Dialysis Fistulas and Grafts

The first radiological reports of angioplasty in grafts and native fistulas were published in the early 1980s (Gordon et al. 1982; Hunter et al. 1984). Currently dilatation of stenoses greater than 50% with an associated clinical or haemodynamic abnormality is recommended by the clinical practice guidelines of the American National Kidney Foundation (National Kidney Foundation 2001). Angioplasty of these significant stenoses reduces the thrombosis rate and increases the longevity of the access (Turmel-Rodrigues et al. 2000a; Manninen et al. 2001). Angioplasty has a low complication rate, may be performed on an outpatient basis and dialysis can resume immediately.

An antegrade approach should be used for stenoses located away from the arterial anastomosis and a retrograde approach for stenoses close to the arterial anastomosis. The diameter of the angioplasty balloon should be equal to or 1 mm greater than the diameter of the adjacent normal vessel or graft. Unless the vessel is unusually small then 6- to 8-mm diameter balloons are used in both grafts and native fistulas. Pressures of 10–12 atm will treat most stenoses.

Stenoses do recur relatively rapidly and patency rates depend on the type of access being treated and on the location of the stenosis. Technical success for angioplasty is usually defined as a less than 30% residual diameter stenosis. The technical success rates are high at 92% for forearm native fistulas with a 1-year primary patency rate of 44% and 1-year secondary patency of 87% (Manninen et al. 2001). Similarly several large series in grafts show angioplasty has a high clinical success rate of up to 98%, but with a primary patency rate of 17%–44% at 1 year. After a year secondary patency rates of 92% can be achieved in grafts (Kanterman et al. 1995; Aruny et al. 1999; Beathard 1992; Safa et al. 1996).

15.3.3 Treatment of Resistant Stenoses

Some fistula and graft stenoses are resistant to balloon angioplasty using standard pressure balloons. These resistant lesions have been treated with high pressure balloons for example the Boston Scientific Blue Max balloon which has a rated burst pressure of 20 atm. and the Bard Conquest balloon that has

a rated burst pressure of 30 atm. A recent paper (Trerotola et al. 2004) has even advocated the use of the Conquest balloon inflated to 40 atm, which is above the recommended burst pressure. Using these very high pressures a high technical success rate of 100% was achieved which is comparable to cutting balloon angioplasty. However, there is only limited data to determine the patency rates with very high pressure angioplasty.

Use of the cutting balloon to treat resistant haemodialysis stenoses was first described in the mid 1990s (Vorwerk et al. 1995a, 1996). The blades of a cutting balloon produce microincisions allowing controlled intimal disruption (Fig. 15.2). Cutting balloons can achieve high technical success rates of 95%–100% in treating resistant stenoses in fistulas and grafts (Vorwerk et al. 1996; Song et al. 2004). In the series by Song et al. (2004) there were two ruptures in eight cases of native fistulas, but one of these was located at the cephalic arch, which is notorious for complications (Turmel–Rodrigues et al. 2000a). Cutting balloons may play an important role in treating resistant stenoses, but there is limited information regarding long-term patency rates, safety and cost effectiveness when compared to ultra high pressure balloons.

15.3.4 Stenting of Dialysis Fistulas and Grafts

There has been considerable interest in the stenting of fistulas and grafts, but randomised trials have not shown significant advantages of stents over angioplasty in recurrent venous stenosis (Hoffer et al. 1997; Quinn et al. 1995; Beathard 1993). Primary patency rates of only 47% and 20% at 6 months and 1 year, respectively, were obtained in one study for a small subgroup of native fistulas (Turmel-Rodrigues et al. 1997a). Most studies with stenting suggest the need for close follow-up and multiple secondary interventions to maintain patency. Therefore, stents are generally only used selectively to treat complications and when angioplasty fails to maintain patency, particularly in patients who are unsuitable for surgical revision (Turmel-Rodrigues et al. 1997a; Pan et al. 2005).

Covered stents have been advocated for the treatment of pseudoaneurysms of dialysis access grafts and fistulas (Fig. 15.3). A large pseudoaneurysm can cause difficulty with needling and be unsightly for the patient. Traditionally large pseudoaneurysms have been dealt with surgically. Small series have been published in which covered stents have salvaged dialysis grafts and fistulas (Ryan et al. 2003; Hausegger et al. 1998). In these reports concern about pseudoaneurysm recurrence and infection have divided opinion as to whether the stent can subsequently be needled.

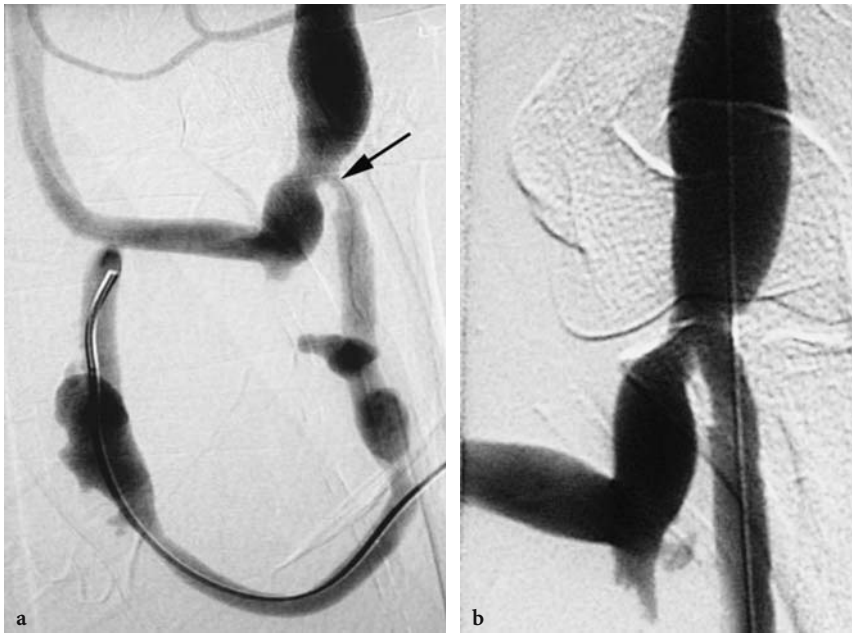

Fig. 15.2. a The arterial anastomosis of this forearm loop graft has already been unsuccessfully angioplastied using a conventional balloon. Cutting balloon angioplasty was therefore performed to treat the resistant stenosis (*arrow*). **b** The final fistulagram after cutting balloon angioplasty shows no residual stenosis

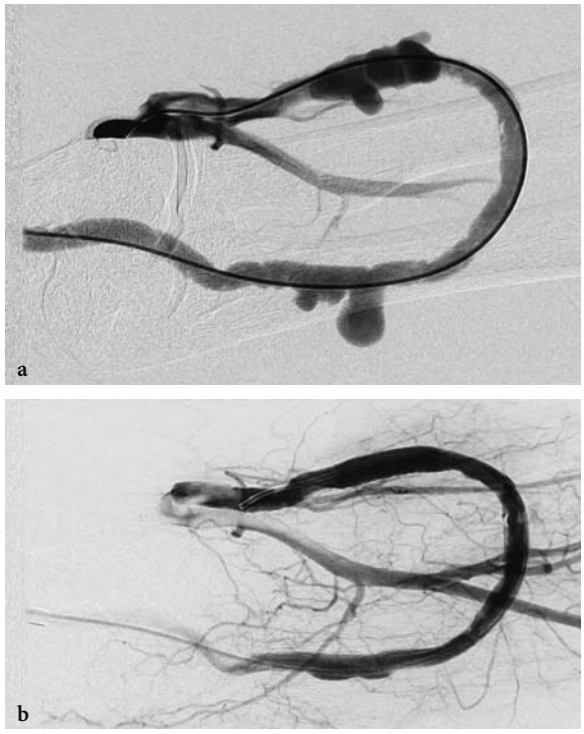

Fig. 15.3. a The arterial and venous sides of this forearm loop graft developed large false aneurysms at the needling sites. **b** Both false aneurysms were successfully excluded using Viabahn stent grafts (Gore, Flagstaff, CA)

15.3.5
Central Venous Stenosis in Dialysis Patients

Haemodialysis patients are at particular risk for the development of central venous stenosis or thrombosis and much of this is due to multiple central venous catheterisations (Cimochowski et al. 1990). Central venous stenoses are associated with clinical symptoms such as arm swelling or functional impairment of haemodialysis. Central veins respond relatively poorly to angioplasty with a 23%–29% primary patency rate at 6 months (Beathard 1992; Quinn et al. 1995). Published data and opinion regarding stenting of central venous stenosis is divided. Some authors recommend stents in central veins (Mickley et al. 1997; Haage et al. 1999; Vorwerk et al. 1995b), whereas others claim no advantage of stenting over angioplasty (Quinn et al. 1995). Stent placement for central venous stenosis refractory to angioplasty has excellent initial technical results (Fig. 15.4), but variable 1-year primary patency rates ranging from 25% to 70% (Haage et al. 1999; Vesely et al. 1997; Mickley et al. 1997). In the subclavian vein there is concern about early stent failure caused by positional compression, which can result in stent fracture (Maleux et al. 1998; Maintz et al. 2001). More encouragingly a recent retrospective study (Vogel and Parise 2004) suggests that nitinol

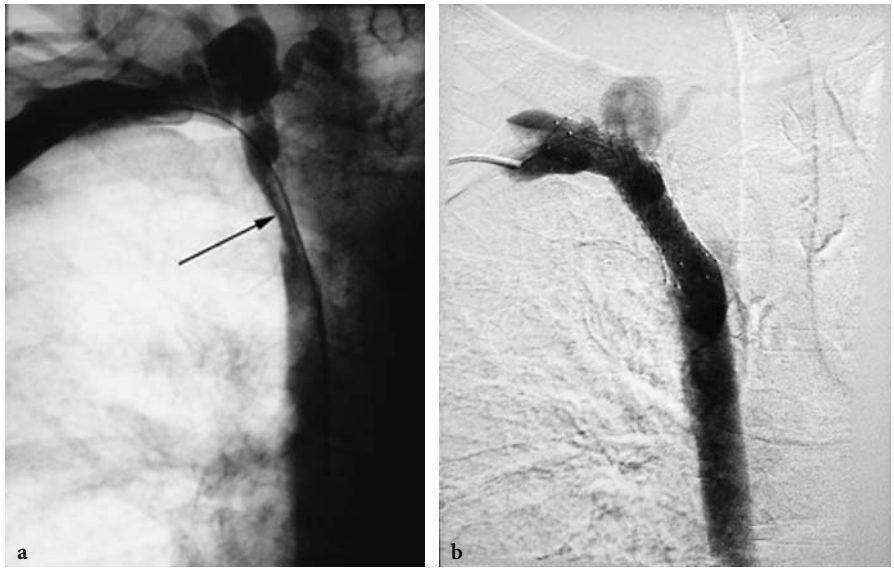

Fig. 15.4. a This patient presented with deteriorating function of the forearm fistula and swelling of the right arm. The fistulagram shows a stenosis at the confluence of the right subclavian and jugular veins and stenosis of the adjacent brachiocephalic vein (*arrow*). **b** The stenoses were initially treated by angioplasty with no benefit due to immediate elastic recoil. A 12-mm SMART (Cordis, Waterloo, Belgium) stent was therefore used to treat both stenoses with rapid resolution of the arm swelling and improvement in fistula function. The stent overlapped the right internal jugular vein but not the contralateral brachiocephalic vein

stents can be used in central venous stenoses with improved patency rates. If a stent is used it should not overlap and exclude adjacent vessels from future access use. Therefore, in summary, angioplasty should be the preferred treatment in central venous stenosis with stent placement reserved for failed angioplasty or recurrence of a stenosis within a 3-month period (Aruny et al. 1999). Larger randomised studies are still needed to clarify the role of stents, particularly with newer stent designs.

15.3.6 Management of Thrombosed Dialysis Grafts and Fistulas

Acute graft or native fistula thrombosis should ideally be avoided. Monitoring with flow measurements and by clinical examination can help by allowing the earlier detection and angioplasty of stenoses (Safa et al. 1996; Schwab et al. 2001). Where thrombosis does occur, salvage procedures should be performed to preserve the anatomically limited number of vascular access sites. Most acute access thromboses are related to underlying stenoses (Hodges et al. 1997) and in at least 85% of thrombosed prosthetic grafts there is an associated stenosis at the venous anastomosis (Aruny et al. 1999). Thrombosis of a graft or fistula can also be precipitated by hypotension, hypovolaemia, hypercoagulability or extrinsic compression.

There are many treatment options for graft and fistula declotting. These include percutaneous methods such as aspiration thrombectomy, pharmacological thrombolysis, mechanical thrombectomy or surgical thrombectomy. Of the radiological options there is limited comparative information and no definite advantage of one individual technique over another (Middlebrook et al. 1995). The only absolute contraindication to percutaneous declotting is local infection.

Pharmaco-mechanical methods include the 'lyse and wait' technique (Cynamon et al. 1997; Duszak and Sacks 1999) where the thrombosed graft is catheterised outside the interventional radiology department and a thrombolytic agent infused. Subsequently when a radiologist is available any residual clot is aspirated or mechanically macerated with a balloon and the underlying stenosis is also angioplastied. The 'lyse and wait' technique has the advantage that it may be started when a radiologist is unavailable and reduces time in the interventional radiology suite.

The pulse-spray method uses two multiside-hole catheters with tip-occluding wires inserted in a criss-cross fashion within the thrombus. Small volumes of a mixture of thrombolytic agent and heparin are then forcefully injected at frequent intervals over approximately 20 min to fragment and lyse the clot. Any residual clots are then macerated with a balloon.

Mechanical methods include declotting by the deliberate embolization of thrombus from a graft into the central veins and lungs by pushing and pulling a balloon through the clot (Trerotola et al. 1994). The consequent pulmonary embolization is asymptomatic in most patients, presumably because the volume of clot in a thrombosed graft is small, averaging 3.2 ml (Winkler et al. 1995). Manual catheter directed thromboaspiration has also been described (Turmel-Rodrigues et al. 1997b, 2000b). The major concern with these techniques has been the possibility of clinically significant pulmonary emboli. Two deaths due to pulmonary embolism have been reported using the pulse-spray and thrombolysis technique in a series of 43 cases. Both mortalities were in patients with underlying cardiopulmonary disease (Swan et al. 1995). Therefore, several mechanical devices have been developed to pulverize clots into tiny particles. These include the Arrow-Trerotola PTD, which uses a spinning fragmentation cage to strip away clot and macerate it. The resultant slurry is then aspirated with a catheter (Trerotola et al. 1998). Other devices use the Venturi effect; they include the Hydrolyser (Vorwerk et al. 1996) and Angiojet (Vesely et al. 1999).

There may be a choice in the treatment of a thrombosed dialysis access between surgery and endovascular management. Two prospective randomised trials that compared surgical therapy with thrombolysis in grafts concluded that surgery was superior to thrombolysis (Schuman et al. 1994; Marston et al. 1997), whereas another randomised trial in grafts showed no significant difference in median patency between surgery and thrombolysis (Vesely et al. 1996). Surgical treatment has the disadvantage that if the underlying venous stenosis is also treated at the time of thrombectomy by graft revision or replacement then there will be loss of at least a segment of vein. Endovascular treatment has the advantages that it may be performed as an outpatient and that dialysis through the graft may resume immediately. Often the choice between surgery and endovascular treatment is based on localised expertise and the availability of scheduling.

Long-term graft patency following thrombectomy is not particularly good regardless of the technique used and is related to the effectiveness of treatment to the underlying cause of the thrombosis. When

reporting thrombectomy success rates most literature combines native fistulas and grafts, with grafts contributing the majority of the experience. For thrombolysis or mechanical thrombectomy in grafts a clinical success (resumption of normal dialysis for at least one session) should be achieved in 75%–94% of cases. However, in these patients a 3-month primary patency of 37%–58% is obtained and drops to 18%–39% at 6 months (Aruny et al. 1999). In native fistulas using mechanical and thromboaspiration techniques primary patency rates at 1 year are up to 27% in the upper arm and 47% in the forearm (Haage et al. 2000; Turmel-Rodrigues 2000a). The American National Kidney Foundation guidelines recommend the goal of a 40% 3-month patency rate after thrombectomy (National Kidney Foundation 2001).

15.3.7 Complications of Dialysis Fistula and Graft Interventions

There is a low frequency of complications with dialysis fistula and graft intervention, but one of the commonest complications is angioplasty induced rupture (Beathard 2003). This should be suspected when a patient experiences sudden acute pain at the angioplasty site, particularly if it worsens after balloon deflation. Rupture can be confirmed by extravasation of contrast or the appearance of a haematoma. If possible haematoma should be externally compressed manually. Initial treatment should be tamponade by reinflation of the balloon to 2 atm for a prolonged, 10-min inflation. Most ruptures are controlled by prolonged balloon reinflation, but a stent should be deployed if extravasation continues despite prolonged ballooning (Sapoval et al. 1996; Raynaud et al. 1998). In the series by Raynaud et al. (1998) uncovered stents were effective at treating the ruptures.

The overall major complication rate in a large series of graft and native fistula angioplasties was 2% (Turmel-Rodrigues et al. 2000a). In this series the incidence of all ruptures (including minor rupture) was lower in grafts at 3.8% compared to 8.3% of forearm native fistulas. Other complications include arterial embolization, haematoma or bleeding and symptomatic pulmonary embolization. Access thrombosis may occur if an introducer sheath occludes flow or during prolonged balloon inflation. Thrombosis can also be caused by excessive manual compression or puncture site haematoma. Infection is rare.

15.4 Conclusion

Maintaining dialysis access can be complex and challenging. It requires a considerable commitment of time and resources. However, whether it is in the arena of line insertion or resolving line problems, or in the context of management of native fistula or graft complications, interventional radiology has a large part to play.

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16 Management of Venous Stenoses

John R. Asquith

CONTENTS

16.1 Introduction

Vascular radiologists have seen a rise in their venous interventional workload. This is largely due to the greatly increased demand for central venous access and the management of its complications. Venous stenotic conditions such as superior vena cava obstruction, subclavian-axillary vein thrombosis and iliac vein compression syndrome are rewarding areas for interventional radiologists to treat.

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16.2 Superior Vena Cava Obstruction

Superior vena cava obstruction (SVCO) is characterised by a range of distressing symptoms including swelling of the face, chest and upper limbs, dyspnoea, headache and dysphagia. Symptoms typically worsen with bending forwards or lying down. Physical signs include chest wall collaterals and facial plethora (Lochridge et al. 1979).

SVCO is predominantly caused by malignant tumours with bronchial carcinoma being the most common underlying pathology (Escalante 1993). This and other primary or secondary thoracic malignancies cause SVCO by encasement, compression or direct invasion of the central veins. Benign causes account for 3%–25% of cases of SVCO (Qanadli et al. 1999) and include central venous lines, pacemakers, thoracic aortic aneurysms, radiation fibrosis and fibrosing mediastinitis (Mahajan et al. 1975; Chamorro et al. 1978; Escalante 1993; Rossi et al. 2001). SVCO due to benign causes is increasing in incidence due to the greater use of central venous devices.

16.2.1 Treatment of Superior Vena Cava Obstruction

In most patients the malignant lesion causing SVCO is at an advanced stage and is therefore usually unresectable. Treatment by surgical venous bypass has been reported (Lochridge et al. 1979; Doty et al. 1999), but is invasive, technically challenging and rarely indicated because of the limited life expectancy of these patients.

Historically treatment with radiotherapy (Davenport et al. 1978; Perez et al. 1978; Chan et al. 1997) or chemotherapy (Citron et al. 1983; Spiro et al. 1983) has been the mainstay of SVCO management. Often with chemotherapy or radiotherapy a period of approximately 2 weeks is required before the venous obstruction is relieved and symptoms

resolve (Rowell and Gleeson 2002). Chemotherapy and radiotherapy can cause significant side effects including anorexia, oesophagitis, nausea, vomiting and skin irritation. Furthermore, despite radiotherapy or chemotherapy a proportion of patients fail to respond to treatment and symptoms persist.

The endovascular management of SVCO with angioplasty alone has a poor technical success rate and a high incidence of early restenosis (Gross et al. 1997). This is due to the non-compliant nature of malignant tumours. Hence angioplasty of SVCO does not provide adequate palliation and consequently the use of stents has been extensively investigated.

Self-expandable metallic stents were introduced in the early 1980s and the first report of superior vena cava (SVC) stenosis stenting was in 1986 (Charnsangavej et al. 1986). Subsequently several papers using different types of stents have confirmed the effectiveness of SVC stenting. Stent insertion should be considered for patients to provide the rapid palliation of symptoms (National Institute for Clinical Excellence Guidelines 2005). Many different types of stents have been used, but early experience was predominantly with the Gianturco Z stent (Uchida et al. 1988; Rosch et al. 1988; Gaines et al. 1994; Furui et al. 1995). However, the large strut interspaces of the Gianturco Z stent are potentially poor at fixing fresh thrombus and may allow restenosis by tumour ingrowth through the stent (Crowe et al. 1995). More recently other self-expandable metallic stents have come into use and these include the Wallstent (Hennequin et al. 1995). The Wallstent has greater flexibility than the Gianturco Z stent, which is beneficial when deploying the stent around a bend into a brachiocephalic vein. The Wallstent has the disadvantage that radial expansion occurs over several weeks after deployment and it may therefore shorten to uncover the SVC obstruction (Qanadli et al. 1999).

16.2.2 Technique for Superior Vena Cava Stenting

Planning with cross-sectional imaging before intervention is helpful to detect the presence of central venous thrombus and to determine the size of the SVC (Fig. 16.1). The extent of the stenosis should be accurately delineated by a venogram in two different projections. Stent placement is usually possible via a femoral or internal jugular vein approach. Stents must be introduced over a stiff guidewire to prevent

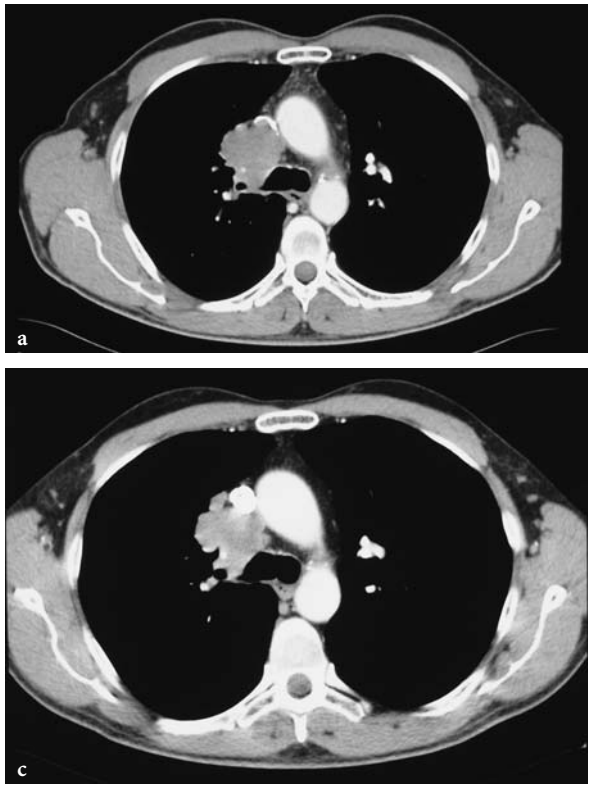


Fig. 16.1a–c. a CT image in a patient with symptoms of SVCO showing large mass at right trachiobronchial angle almost occluding the SVC. **b** Venography confirms the severe SVC stenosis. **c** Follow-up CT 6 weeks after successful placement of SMART stent (Cordis, Waterloo, Belgium) within the SVC stenosis. The SVC remains widely patent

prolapse into the right atrium. After deployment self-expanding stents should be balloon dilated to an appropriate size, which is usually 12–16 mm. When the SVCO has associated bilateral brachiocephalic venous occlusion only unilateral recanalisation of the brachiocephalic veins is required for symptomatic relief (Crowe et al. 1995). There is also evidence that bilateral stent placement has a shorter primary patency and causes more complications than unilateral brachiocephalic extension of the stent (Lanciego et al. 2001; Dinkel et al. 2003).

Superimposed thrombus commonly occurs in patients with SVCO and as much thrombus as possible should be cleared prior to stenting to reduce the risk of pulmonary embolus. Primary stenting is preferable in order to prevent emboli by trapping thrombus between the stent and the vein wall. However, angioplasty may be required prior to stenting to allow the introduction of a stent through a very tight stenosis. A number of studies support the use of thrombolysis, mechanical thrombectomy or aspiration prior to stenting when thrombus is present (Crowe et al. 1995; Kee et al. 1998; de Gregorio Ariza et al. 2003). Mechanical thrombectomy or aspiration has the advantage of avoiding the haemorrhagic complications of thrombolysis.

16.2.3 Results of Superior Vena Cava Obstruction Treatment

There are no randomised, prospective trials comparing the results of SVCO stenting with other forms of treatment. In a systematic review of the relative effectiveness of steroids, radiotherapy, chemotherapy and stents for SVCO in carcinoma of the bronchus, stent insertion provided relief of symptoms in the highest proportion of patients and most rapidly (Rowell and Gleeson 2002). Stenting relieved SVCO in 95%. Of these patients 11% had recurrence of symptoms, which in the majority of patients could be recanalized giving a long-term patency rate of 92%. In comparison relief of SVCO by chemotherapy and/or radiotherapy in small cell or non-small cell lung cancer was 77% and 60%, respectively. In many cases of SVCO stenting, symptomatic relief is almost immediate and quality of life is markedly improved (Lanciego et al. 2001). Therefore, stents are advocated as the first line treatment in patients with symptomatic SVCO secondary to malignancy (Nicholson et al. 1997; Lanciego et al. 2001).

Most published results are for treatment of malignant SVCO, and therefore the long-term durability and patency of the stents has not been tested. For benign causes of SVCO stenting is also effective with up to 100% technical success reported (Petersen and Uchida 1999; Qanadli et al. 1999; de Gregorio Ariza et al. 2003). However, in these series the follow-up periods for treatment of benign disease are limited and more long-term follow-up is needed.

16.2.4 Complications of Superior Vena Cava Stenting

Major complications of SVC stenting are uncommon. Overall complication rates of 8%–10% have been reported in two large series (Kee et al. 1998; Nicholson et al. 1997). Complications include haemorrhage from thrombolysis, stent migration, fatal and non-fatal pulmonary embolus, access site thrombosis, pulmonary oedema (Kishi et al. 1993) and SVC rupture (Brown and Getrajdman 2005). Most of the major complications reported in the literature are related to thrombolysis (Gaines et al. 1994; Crowe et al. 1995; Kee et al. 1998).

16.3 Subclavian-Axillary Vein Thrombosis

Subclavian-axillary vein thrombosis or upper limb deep vein thrombosis (DVT) has been classified as primary or secondary. Primary subclavian-axillary vein thrombosis (Paget–Schroetter syndrome) can be related to physical activity and have anatomical compression at the thoracic outlet. Secondary subclavian-axillary vein thrombosis has an identifiable cause, most commonly due to long-term venous access catheters or pacemakers (Hingorani et al. 2005). Other secondary causes include a thrombophilia, local tumour invasion, trauma or radiotherapy (Ellis et al. 2000). Upper limb DVT has a higher incidence of pulmonary embolism (PE) than previously thought with 5% of patients developing PE in a recent series (Hingorani et al. 2005). The long-term sequelae of untreated subclavian-axillary vein thrombosis include functional disability of the affected limb in up to one third of patients (Holzenbein et al. 1991). Therefore subclavian-axillary vein thrombosis is an important condition to recognise and treat.

16.3.1
Primary Subclavian-Axillary Vein Thrombosis (Paget–Schroetter Syndrome)

Paget–Schroetter syndrome most often occurs in otherwise healthy young adults, typically after a period of unaccustomed exercise or prolonged shoulder abduction. Hence the alternative name of effort thrombosis (Crowell 1960). It is more common in young males with the dominant limb most frequently affected. The presenting symptoms are arm swelling, limb cyanosis, pain, paraesthesia and venous congestion.

The subclavian vein passes through the space between the clavicle and first rib, which is narrowed by arm abduction and external rotation. There is resultant compression of the subclavian vein (Adams and DeWeese 1971). When repetitive, this compressive trauma can induce thickening of the vein wall, stenosis and intraluminal webs. These patients may also have normal anatomical variants including cervical ribs and hypertrophy of the scalenus or subclavius tendons contributing to the neurovascular compression.

Doppler ultrasound is frequently used as the first line investigation for confirmation of thrombus in the subclavian and axillary veins, but will not directly image the brachiocephalic veins or SVC (Longley et al. 1993; Nazarian and Foshager 1995). The presence of large collaterals can make ultrasound interpretation difficult. Digital subtraction venography can be performed to confirm the ultrasound findings (Fig. 16.2a). More recently contrast-enhanced three-dimensional MR venography (MRV) has been used and can accurately demonstrate the patency of the central thoracic veins (Shinde et al. 1999; Thornton et al. 1999; Ruehm et al. 2001). MRV may also demonstrate the anatomical anomaly causing the venous compression and exclude other underlying pathology (Charon et al. 2004).

16.3.2
Treatment of Primary Subclavian-Axillary Vein Thrombosis

There are numerous studies concerning the management of this condition, but they vary widely in their recommendations for treatment. The numbers of patients presenting with Paget–Schroetter syndrome are small with no published randomised trials. Current treatment methods are largely based on consensus of opinion (Rutherford and Hurlbert 1996; Khan and Stansby 2004).

The historical treatment of limb elevation can result in persistent residual limb swelling, early exercise fatigue and discomfort. Some patients may be unable to return to work or sport (Swinton et al. 1968; Tilney et al. 1970; Hicken and Ameli 1998). Treatment with anticoagulation results in a reduced incidence of residual symptoms when compared to conservative management due to collateral vein formation and prevention of thrombus propagation (Thomas and Zierler 2005). Some reports suggest

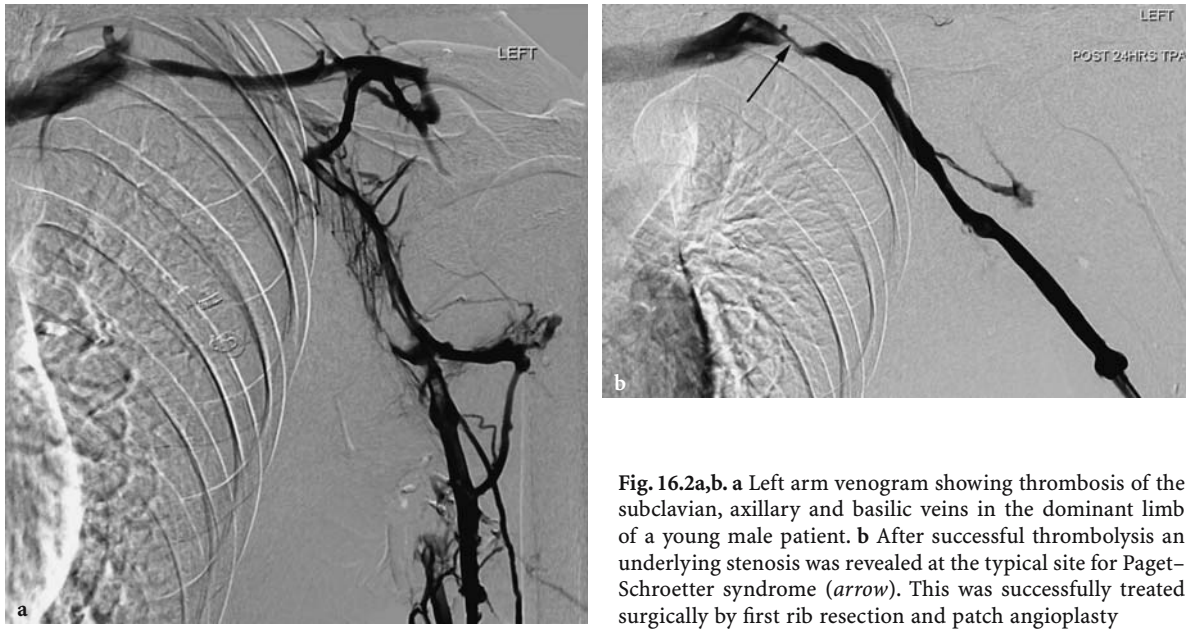


Fig. 16.2a,b. a Left arm venogram showing thrombosis of the subclavian, axillary and basilic veins in the dominant limb of a young male patient. **b** After successful thrombolysis an underlying stenosis was revealed at the typical site for Paget–Schroetter syndrome (*arrow*). This was successfully treated surgically by first rib resection and patch angioplasty

up to 80% of patients being treated by anticoagulation within 7 days of the thrombotic episode will have no residual symptoms (Coon and Willis 1967; Gloviczki et al. 1986). Anticoagulation alone is not supported by all authors (Sanders and Haug 1990; Urschel and Razzuk 2000). This is because anticoagulation will not restore normal flow and treatment of the underlying anatomical cause is required to prevent recurrent thrombosis. There has therefore been a move towards more active radiological and surgical treatment.

Consensus supports the use of catheter directed thrombolysis and surgical decompression (Fig. 16.2). This technique delivers the thrombolytic agent directly into the thrombus using multiple side hole infusion catheters, with access via the ipsilateral basilic vein. For lysis to be effective the catheter should be advanced into the thrombus, otherwise the drug will bypass the occlusion via collaterals. Repeat venography should be performed every 4–6 h and the infusion catheter position advanced so that it remains within the thrombus. Early intervention is important for effective thrombolysis (Molina 1995; Urschel and Razzuk 2000). Most patients with acute symptoms of less than 8 days will achieve a successful outcome with thrombolysis (Adelman et al. 1997). In a large series treated with thrombolysis and surgical decompression 95% of patients were able to resume normal work (Urschel and Razzuk 1998). Those patients who present with symptoms of greater than 2 weeks duration have a lower successful thrombolysis rate (Molina 1995). Complications with thrombolysis are rare, but access site haematoma or bleeding may be seen (Sheeran et al. 1997; AbuRahma and Robinson 2000).

The literature suggests that angioplasty should be avoided in treating post-thrombolysis extrinsic compression and is unlikely to improve luminal calibre without thoracic decompression (Machleder 1996; Glanz et al. 1988). If there is a tight intrinsic stenosis remaining after surgery some authors suggest that angioplasty should be performed, otherwise thrombosis is likely to recur (Perler and Mitchell 1986, Machleder 1996).

Stenting should not be performed without surgical decompression, because persistent compression at the thoracic outlet can produce stent kinking or fragmentation (Urschel and Patel 2003; Meier et al. 1996; Phipp et al. 1999). A damaged stent may also impede any subsequent surgical decompression. One study has reported good long-term patency for stenting, but this was after decompressive surgery (Kreienberg et al. 2001).

Surgical decompression usually includes excision of the first rib and subclavius tendon. The optimal timing of surgical decompression relative to successful thrombolysis remains unclear. Some centres recommend early surgical decompression during the same admission as thrombolysis (Molina 1995; Urschel and Razzuk 2000; Kreienberg et al. 2001). Others suggest late surgical decompression following a 3-month period of anticoagulation (Machleder 1996). A non-randomised comparative study (Angle et al. 2001) suggests that early surgical decompression is as safe as the delayed approach. Postoperative anticoagulation is recommended for a variable period depending on symptoms and presence of any residual venous stenosis.

In summary the management of primary subclavian-axillary vein thrombosis remains controversial, but has evolved into a staged combined radiological and surgical approach. Confirmed cases should undergo immediate catheter directed thrombolysis followed by surgical decompression and possible angioplasty of significant residual intrinsic stenoses. There may be a role for anticoagulation alone in patients with mild symptoms. It is unlikely that a randomised study will ever be performed due to the relatively small numbers of these patients.

16.3.3 Secondary Subclavian-Axillary Vein Thrombosis

The increase in the number of patients who require lines for chemotherapy, haemodialysis or permanent pacemakers has resulted in an increase in upper limb deep vein thrombosis. This is such that secondary causes are now the most common reason for subclavian-axillary vein thrombosis. Secondary subclavian-axillary vein thrombosis is often asymptomatic due to the numerous collaterals in the neck and chest wall (Valerio et al. 1981, Lokich and Becker 1983).

Long-term central venous catheters probably cause venous stenosis by local vein wall trauma and response to a foreign body. Central vein stenosis is more common with the use of the subclavian rather than the jugular approach and with malpositioning of the lines (Cimochowski et al. 1990). Patients with subclavian lines have been studied by routine follow-up venograms. For subclavian Hickman lines partial thrombosis was seen in 30% and complete thrombosis in 6% by 6 weeks (Horne et al. 1995). In a second study 40% of patients with subclavian lines

were found to have central vein thrombus at 7 days (Koksoy et al. 1995). Even peripherally inserted central lines, despite having a relatively narrow calibre, can cause central vein stenosis or occlusion in 7% of patients (Gonsalves et al. 2003).

16.3.4 Treatment of Secondary Subclavian-Axillary Vein Thrombosis

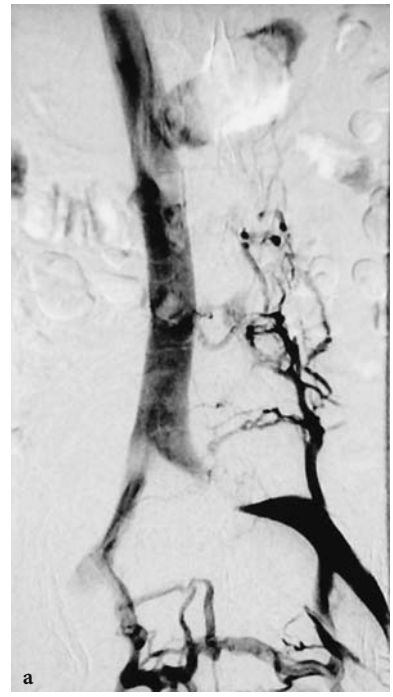
Anticoagulation is the mainstay of treatment. The aim of anticoagulation is to relieve symptoms, prevent propagation of clot and prevent complications such as pulmonary embolus. Occasionally in young, highly symptomatic patients or in patients with limited venous access routes endovascular recanalization may be required.

16.4 May–Thurner Syndrome (Iliac Vein Compression Syndrome)

It has long been recognised that iliofemoral DVT occurs more frequently on the left. In 1957 May and Thurner described intraluminal spurs occurring in the common iliac vein close to the inferior vena cava (May and Thurner 1957). These spurs are thought to represent intimal hyperplasia caused by chronic arterial compression of the iliac vein walls with resultant formation of endothelial bridges. They were eight times more common in the left iliac vein compared to the right and were found in 22% of autopsy specimens. It is postulated that the spurs are a predisposing factor for left-sided iliofemoral DVT.

Patients with May–Thurner syndrome tend to be young with a female predominance and usually present with acute, painful left leg swelling (Hurst et al. 2001). The major short-term risk of iliofemoral DVT is pulmonary embolus (Havig 1977). Iliofemoral DVT is also associated with a high risk of developing the major long-term sequelae of post-phlebitic syndrome. Post-phlebitic syndrome is due to chronic venous insufficiency and is characterised by chronic limb oedema, pain, venous claudication, venous stasis ulcers and varicosities (O'Donnell et al. 1997).

The diagnosis of iliofemoral DVT is often made by ultrasound, but the iliac veins can be technically difficult to visualise. A digital subtraction venogram may be required to confirm the diagnosis (Fig. 18.3). MR venography can also be used (Ruehm et al. 2001



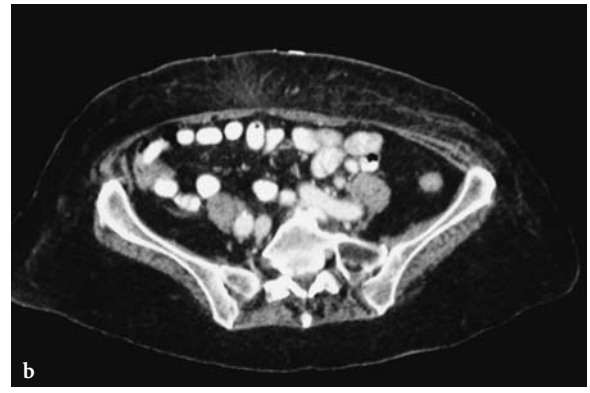


Fig. 16.3a,b. a Ascending Venogram demonstrating a focal left common iliac vein extrinsic stenosis and abundant collaterals. **a** CT confirms that the extrinsic stenosis is secondary to compression from the overlying left common iliac artery typical of May–Thurner syndrome

16.4.1 Treatment of May–Thurner Syndrome

When iliofemoral DVT is treated with anticoagulation alone any underlying causative mechanical compression (May–Thurner syndrome) is not treated. Effective treatment of iliofemoral DVT should involve thrombolysis and treatment of any

underlying stenosis to reduce the incidence of post-phlebitic syndrome. Thrombolysis has now been extensively recommended as the treatment for symptomatic May–Thurner syndrome (Semba and Dake 1994; Bjarnason et al. 1997; O'Sullivan et al. 2000; Patel et al. 2000).

Access for thrombolysis is usually via an ipsilateral common femoral or popliteal venous approach depending on extent of the thrombus (Hurst et al. 2001). When the clot extends into the popliteal vein a posterior tibial venous approach can also be used (Cragg 1996). Ultrasound guidance is recommended to perform a single wall puncture and avoid inadvertent arterial puncture. For thrombolysis an infusion catheter with multiple side holes is embedded in the thrombus. An inferior vena cava filter may be used when the patient has free-floating iliofemoral thrombus. Repeat venography is performed approximately every 4–6 h. If no lysis is achieved then the infusion is stopped and the clot considered to be too organised. When complete lysis has been demonstrated any underlying iliac vein stenosis should be angioplastied followed by stent insertion (Semba and Dake 1996; Neglen and Raju 2000; Lamont et al. 2002). The stent should not extend across the contralateral common iliac vein orifice. A flexible stent such as the Wallstent is advantageous to accommodate curvature in the iliac veins and should be post-dilated with a balloon.

Pharmacomechanical thrombolysis has also been described using catheter directed thrombolysis followed by mechanical thrombectomy. This has the advantage of decreasing the lysis infusion time compared to thrombolysis alone (Vedantham et al. 2004).

16.4.2 Results of Treatment of May–Thurner Syndrome

The traditional treatment for iliofemoral DVT has been anticoagulation. However, anticoagulation alone is ineffective at restoring patency and despite treatment with heparin only 6% of patients will have lysis of their DVT within 10 days. Up to 40% will continue to experience clot propagation (Sherry 1985; Krupski et al. 1990). Long-term studies have demonstrated the potentially disabling sequelae of iliofemoral DVT. By 10 years over 50% of these patients treated by anticoagulation alone develop venous claudication and 86% develop venous stasis ulcers (Akesson et al. 1990). Significantly improved quality of life has been shown in patients treated with catheter directed thrombolysis compared to those receiving anticoagulation alone (Comerota et al. 2000).

A prospective multicentre registry study (Mewissen et al. 1999) has shown 1-year patency of 74% after thrombolysis and stent placement for iliofemoral DVT. Primary patency rate of 100% with an average follow up of 3 years has been reported in a series of eight patients (Binkert et al. 1998). Longer-term patency rates for stents in May–Thurner syndrome are not available. A study using pharmacomechanical thrombolysis has shown a 96% clinical success rate for treatment of iliofemoral DVT and most patients were either asymptomatic or only slightly symptomatic at a mean follow-up interval of 20 months (Vedantham et al. 2004).

Complications of thrombolysis and stenting for May–Thurner syndrome include puncture site haematomas, bleeding, pulmonary embolus and acute rethrombosis of the treated segment (O'Sullivan et al. 2000). Major bleeding complications have been reported in 11% of patients treated by catheter directed thrombolysis for iliofemoral and lower limb DVT (Mewissen et al. 1999).

16.5 Conclusion

The endoluminal management of venous pathology has lagged behind that of arterial disease to some extent. However, it is clear that stent insertion in SVCO can be of immense clinical benefit with minimal complications. Similarly there is strong evidence that endovascular techniques should be employed in the management of upper and lower limb DVT, and the treatment of any underlying intrinsic venous lesion.

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17 Inferior Vena Caval Filters

Matthew Matson

CONTENTS

17.1 Introduction

Pulmonary embolism (PE) is a major cause of mortality, accounting for 30,000–40,000 deaths per year in the UK, exceeded only by coronary artery disease and malignancy. The mainstay of treatment is anticoagulation, initially with intravenous unfractionated heparin or subcutaneous low molecular weight heparin, followed by warfarin. This treatment is usually very successful in preventing further pulmonary emboli, and allowing endogenous thrombolytic mechanisms to disperse existing thrombus. In a minority of patients, further intervention is required.

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17.2 History

Just under two decades after Virchow in 1846 hypothesised that pulmonary embolism was the result of migration of clot from the lower limb veins, Trousseau, in 1865, suggested that embolization to the pulmonary arteries could be prevented by interrupting the vessels providing the route. This led, in the 1930s, to the development of the technique of femoral vein ligation, with or without clot removal from the femoral vein. However, ligation of the femoral vein was associated with a high incidence of lower limb swelling, and obviously was ineffective in preventing more central, or contralateral deep venous thrombus (DVT) from migrating to the lungs. For these reasons, in the 1940s, the focus switched to ligation of the inferior vena cava (IVC). At around the same time, heparin and warfarin became available, and were introduced into clinical practice in conjunction with these techniques. However, ligation of the IVC resulted in an immediate significant drop in cardiac output of around 50% and a significant incidence of bilateral lower limb swelling of around 15%. The mortality was up to 15%. In addition, further pulmonary emboli could occur from migration of thrombus above the level of ligation, a risk minimised by ligating the IVC just below the level of the renal veins. Embolisation could also occur through the collateral veins that invariably developed following IVC ligation and could approach the diameter of the original IVC. Alternatives to ligation of the IVC were therefore developed, including surgical plication of the IVC and surgical clips, allowing partial interruption of blood flow. Whilst demonstrating an advantage over ligation, these procedures still necessitated laparotomy.

The late 1960s saw the introduction of the first IVC filter, the Mobin Uddin umbrella, consisting of six struts placed with the apex inferiorly supporting a silastic membrane. The Mobin Uddin umbrella could be inserted via open femoral venotomy. However, the device suffered from problems with migration, caval occlusion and persisting pulmonary emboli.

The next significant development was the release of the Greenfield filter. Initially also requiring surgical venotomy, since its release it has undergone modifications to allow percutaneous implantation to reduce complications of insertion site thrombosis. Other Changer have reduced the incidence of caval penetration by filter struts. The Greenfield filter remains available as a permanent device, with good follow-up data.

17.3 Efficacy of IVC Filters

The vast majority of the literature on IVC filters consists of observational studies, usually retrospective, of various devices. A number of recent, extensively referenced reviews have been published, critically evaluating the evidence for their use (Kinney 2003; Hann and Streiff 2005).

The only prospective randomised controlled study to investigate the effectiveness of caval filters is the PREPIC study (Decousus et al. 1998). In this study, 400 patients with proven DVT seen on venography were assigned to receive either anticoagulation alone, in the form of unfractionated heparin or enoxaparin followed by oral anticoagulants for a minimum of 3 months, or anticoagulation and an IVC filter. At 10 days, the incidence of PE was significantly lower in the filter group, but there was no significant difference in the incidence of fatal PE. No significant difference was seen in overall mortality between the groups at 10 days or at follow-up of 2 years, but at 2 years there was a significant increase in the number of DVTs seen in the filter group.

The PREPIC study has been criticised; the indications for filter placement were not the generally accepted criteria and the number of patients recruited was half the originally intended number. Given that DVT is commoner than PE, it is possible that with a larger study population, the difference in recurrent PE at 2 years may have reached significance in the same way that the difference in recurrent DVT did.

Table 17.1. Results of PREPIC study

At 12 days:
Significant reduction in recurrent PE at 12 days in filter group
Non-significant reduction in fatal recurrent PE at 12 days in filter group
No difference in mortality
At 2 years:
Non-significant reduction in recurrent PE in filter group
Non-significant reduction in fatal recurrent PE in filter group
Significant increase in recurrent DVT in filter group
No difference in mortality

17.4 Indications and Contraindications

Table 17.2. Indications for IVC filter placement

Accepted Indications
PE and contraindication to, or serious complication of, anticoagulation
Recurrent PE despite adequate anticoagulation
Uncertain Indications
Free-floating thrombus
Before thrombolysis/mechanical thrombectomy
Prophylactic filters (trauma, high-risk orthopaedic surgery, bariatric surgery)

17.4.1 Accepted Indications

The firmest and commonest indication for IVC filter insertion is pulmonary embolism with a contraindication to anticoagulation or severe complication of anticoagulation. Examples would include pulmonary embolism and recent intracranial haemorrhage or active gastrointestinal bleeding.

The other generally accepted indications for an IVC filter are pulmonary embolism despite adequate anticoagulation or propagation of DVT despite anticoagulation. The diagnosis of pulmonary embolism while on treatment should be confirmed by investigation, since only a minority of symptomatic patients will have objective evidence of further emboli. If confirmed, before filter placement is contemplated other measures first require consideration, such as ensuring compliance with anticoagulation, increasing oral anticoagulation to a higher target therapeutic ratio or transferring to a different anticoagulant. True failure of anticoagulation is rare.

Propagation of thrombus during anticoagulation occurs in 5%–10% of patients. However, the link between propagation of thrombus and embolisation to the lungs is not firmly established. Moreover, the placement of a filter does not prevent, and may exacerbate thrombus propagation. Therefore, the initial

treatment strategy in this scenario should be to optimise anticoagulant therapy.

17.4.2 Uncertain Indications

The remaining proposed indications for IVC placement are more contentious, often described as "relative" or "possible" indications. They may perhaps be best regarded as indications for which there is no good evidence at present.

Some authors have advocated the presence of "free-floating" thrombus in the proximal lower limb veins or IVC as an indication for IVC filter, citing a very high incidence of pulmonary embolism of up to 60%. However, in some of the studies the diagnosis of free-floating thrombus was made after PE had occurred and another prospective study (Pacouret et al. 1997) showed no increased risk of PE in this patient group.

Similarly there are advocates of filter placement to prevent PE when performing thrombolysis or mechanical thrombectomy of proximal venous thrombus, while others consider it safe to perform these procedures without protection.

17.4.3 Prophylactic Filters

Use of IVC filters has been recommended in certain high-risk groups of patients, including trauma patients, patients undergoing orthopaedic procedures and those having bariatric surgery for morbid obesity.

In patients with polytrauma, there is a high incidence of venous thrombo-embolic disease, with observed rates of deep venous thrombosis of up to 58% and pulmonary embolism in up to 4%. There is some evidence that heparin prophylaxis is not completely effective in this group and studies comparing filter use with historical controls or low dose heparin suggest an advantage to filter use. However, the level of evidence is not sufficient to recommend their routine use. Instead, they should be considered in very high risk groups, such as complex orthopaedic lower limb injury and spinal injury.

In orthopaedic procedures, there is an incidence of venous thromboembolism of up to 20% without prophylaxis, particularly following total hip or knee replacement. However, that risk can be substantially lowered by the correct prescribing of low molecular weight heparin, such that routine IVC filters are not indicated prophylactically.

An incidence of PE of up to 3% is seen in patients undergoing bariatric surgery, but with a high associated mortality rate, most likely because the underlying morbid obesity results in reduced cardiopulmonary reserve. This has led to some surgeons using prophylactic IVC filters, but there is no evidence for their use in this group and, as for high-risk orthopaedic procedures, heparin prophylaxis probably remains a more logical choice.

17.4.4 Supra-renal Filters

The commonest indication for supra-renal placement of a filter is thrombus extending up into the IVC, such that there is no room for infra-renal placement. If a filter is required in a pregnant woman, then the supra-renal location should be used. Some workers have extended this argument to advocate supra-renal placement in all women with the capacity for future pregnancy, though this is less important if a non-permanent filter is used.

17.5 Choice of Filter

17.5.1 The Ideal Filter

The concept of the "ideal filter" is useful as a comparison for the currently available devices. The ideal filter is cheap and easy to insert and reposition through a small introducer system, so as never to cause entry point thrombosis. It has a 100% capture rate of emboli without causing impedance to flow and is atraumatic to the IVC with a 0% incidence of caval occlusion. It does not migrate and may be retrieved easily following an indefinite period. It is biocompatible and MRI compatible.

17.5.2 Currently Available Filters

17.5.2.1 Permanent Filters

There are currently five permanent filter devices available in the UK: the Greenfield filter (Boston Scientific, Natick, Mass, USA)), the Bird's Nest filter

(Cook, Bloomington, Ind, USA), the LGM Vena-Tech filter (Braun, E-Z-EM, Boulogne, France), the Simon Nitinol filter (Bard, Temper, Arizona, USA) and the TrapEase filter (Cordis, Johnson + Johnson, New Brunswick, New Jersen, USA). These devices vary in their appearance, deployment mechanisms and construction materials but there are no controlled trials to show that any one device is superior to the others. The greatest volume of data exists for the Greenfield filter. The Bird's Nest filter is perhaps more complex to deploy than the others, but is the filter of choice for patients with a large diameter caval lumen, up to 40 mm.

17.5.2.2 Temporary Filters

As stated above, the major indication for IVC filter insertion is contraindication to anticoagulation. In many instances, the contraindication to anticoagulation may be temporary: for example, the requirement for surgery. From the PREPIC study there is evidence of an increased incidence of DVT in patients with a filter in situ. Temporary filters were developed as an attractive means of avoiding the long-term complications of filters. The disadvantage of these purely temporary filters is that the introducing catheter remains in place, which risks the catheter and filter becoming displaced, restricts movement of the patient and carries a risk of infection.

Recent years have, for these reasons, seen the withdrawal of most purely temporary filters in favour of retrievable filters.

17.5.2.3 Retrievable Filters

Retrievable filters offer the advantages of temporary filters, without the disadvantages mentioned above. They may also be left in place to act as permanent devices. The potential disadvantage is that they require two separate procedures, one to insert the device and one to remove it. Currently available retrievable filters in the UK are the Gunther Tulip filter (Cook), the Optease filter (Cordis), the ALN filter (Pyramed) and the Recovery filter (Bard).

The Gunther Tulip vena cava filter consists of a stainless steel, half basket with four wires meeting at the apex and smaller wires attached to the main wires giving a 'tulip' appearance. It can be retrieved via an 11-F coaxial sheath by snaring a hook attached at the apex of the device. It is recommended by the manufacturer that it is retrieved within 10 days, after which time it becomes a permanent filter. In practice, a number of workers have reported its safe retrieval after longer periods of time.

The Optease filter is a variant of the permanent Trapease filter, but has a hook for snare retrieval. It may be delivered via either femoral, jugular or antecubital vein through a 6-F system. It is MRI compatible. It can be used in IVCs up to 30 mm in diameter. It may be left in situ as a permanent device, but if it is to be retrieved, the maximum recommended duration is 12 days.

Filters that can be left in situ for 10–12 days are ideal for situations where the contraindication to anticoagulation is short term, such as uncomplicated surgery. There are, however, a number of situations where the contraindication to anticoagulation is likely to be more prolonged: for example, a patient with major trauma or following neurosurgery may well not be recovered and ambulant within the 12-day period. For these indications, the concept of a filter that may be left in situ for longer, indefinite periods before removal is attractive. Two filters, the Recovery and the ALN filter, are licensed for long-term implantation prior to removal.

The ALN filter is a stainless steel alloy device with six short legs to fix it to the IVC wall and three long legs to ensure a central position within the IVC. It can be deployed from a jugular, antecubital or femoral venous access through a 7-F delivery sheath and retrieved from the jugular route through a 9-F sheath. Pieri et al. (2003), Barral et al. (2003) and Pancione and Mecozzi (2004) have presented abstracts reporting 100% retrieval rates in a total of 48 patients after a period of 11–192 days. Imberti et al. (2005) prospectively studied 30 patients who received ALN filters, in whom 18 retrievals were attempted. Successful retrieval was achieved in 78% of cases after a median interval of 123 days (range 30–345). Interestingly, the success rate was 100% in filters that had been in situ for less than 3 months, but was only 50% in the remaining eight patients, where adherence to the IVC wall prevented retrieval in three patients, and tilting prevented retrieval in one patient.

The Recovery filter is a nitinol device with six short legs and six hooked long legs. It is delivered through a 6-F system only from the femoral route, and may be retrieved from the jugular route, using a retrieval cone with nine metal claws delivered through a 10-F system. It is MRI compatible. Asch et al. (2002) studied its use in 32 patients, attempting retrieval in 24 patients. Retrieval was successful in 100% of cases

after a mean period of 53 days (range 5–134), even when there was capture of large thrombus.

17.6 Insertion Technique

17.6.1 Pre-procedural Imaging

The IVC is formed by the union of the common iliac veins at the L4/5 level. It ascends to the right of the aorta, receiving tributaries from lumbar veins, renal veins and hepatic veins before draining into the right atrium.

The most usual site for placement of an IVC filter is infra-renally. Many devices are recommended to be placed ideally with the cranial tip at the level of the renal veins, where there is increased flow, to minimise the risk of caval occlusion.

Placement is normally monitored using venography and fluoroscopy, although grey-scale ultrasound, duplex scanning and intravascular ultrasound have all been reported. The pre-procedural evaluation of anatomy has to assess the diameter of the IVC and accurately localise the number and levels of the renal veins. Anomalies of the venous anatomy are relatively common. Duplication of the IVC (0.2%–3%) may require two filter devices to be used, or at least the selection of the correct IVC (Fig. 17.1). A retro-aortic left renal vein (1.8%–2.4%) usually enters more inferiorly and requires lower placement of the filter. Multiple renal veins may communicate at the renal hilum, offering a bypass route for emboli; this is particularly true in the case of circumaortic left renal vein (1.5%–8.7%).

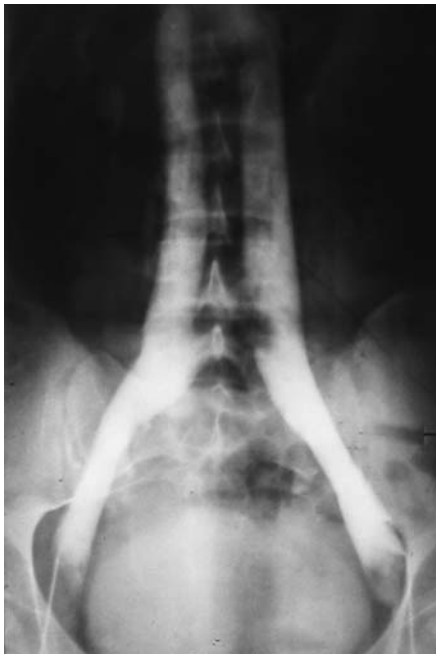

Fig. 17.1. Cavagram demonstrating duplicated IVC

In addition, imaging also serves to assess the extent of thrombus in the venous system and allow for planning of site of delivery access and desired position of the filter. For example, thrombus extending into the iliac veins would be an indication for trans-jugular placement, and thrombus extending into the IVC up to the renal veins is an indication for supra-renal placement of the filter.

17.6.2 Filter Placement

The deployment of the filter is usually straightforward. The manufacturers' instructions are always comprehensive but can be, in the author's opinion, somewhat technical and confusing; when using a device for the first time it is useful to have an experienced person present to help and advise.

17.6.3 Retrieval Technique

Before removal of a retrievable filter a cavagram is required to assess filter position and exclude significant thrombus within it. If thrombus is present, a further period of anticoagulation may be required, if time allows, or thrombolysis may be considered, accepting the inherent risks and assuming no contraindication. Retrieval into a large sheath is appropriate for small trapped clots, again with consideration of the risks for the patient of inadvertent emboli. All retrievable filters may be left in situ as permanent devices.

The retrieval technique itself is essentially that of foreign body retrieval and should be performed according to the manufacturers' instructions.

17.7 Complications

Complications of IVC filter placement can be divided into immediate and longer term. Immediate include

access site complications associated with central venous puncture, such as inadvertent arterial puncture or pneumothorax. With early devices, access site thrombosis was a common problem, but this appears to be less so with modern devices. It has even been suggested that the rate can be lowered by less enthusiastic manual compression following the procedure. A number of operator error complications have been described, including incorrect sizing of the IVC for the device, deployment of a femoral device via the jugular route and deployment of devices into renal veins, gonadal veins, iliac veins and the aorta (Kaufman et al. 1995). These complications can be easily avoided by careful choice of device and appropriate imaging.

Filter migration, defined as 2 cm movement of the device, was similarly seen with early devices. It is now rare (<1%) with modern filters, mostly as a result of hooks being incorporated into them. The downside of this is an increased incidence of caval penetration by the hooks. This is seen not uncommonly in patients followed up on CT or venography, though clinically significant perforation into the aorta, duodenum or other retroperitoneal structures is fortunately rare.

Filter fracture has led to withdrawal of some devices, such as the Antheor filter (Fig. 17.2), but the fracture rate with other devices, such as the Greenfield filter, appears to be very low. The incidence of long term fractures with the newer devices has yet to be established, but the incidence in the short and medium term is low.

IVC thrombosis is an important long term complication of IVC filters. It is generally reported with an incidence of around 2%–10%, although one study found an incidence as high as 33% at 9-month follow-up. About half of patients who have IVC thrombosis develop symptoms, such as lower limb swelling. IVC thrombosis may involve the renal veins, though this in itself may not alter renal function.

From the PREPIC study, we know that DVT occurs more frequently in patients with IVC filters. Long-term sequelae of DVTs include post-phlebitic limb, with deep venous incompetence, limb swelling and venous ulceration.

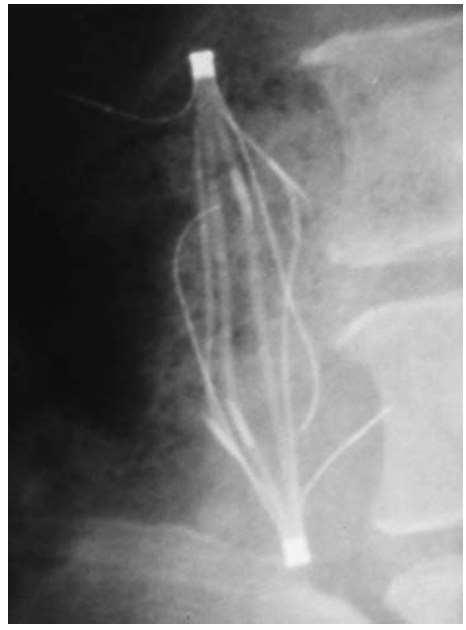

Fig. 17.2. Fracture of an Antheor filter

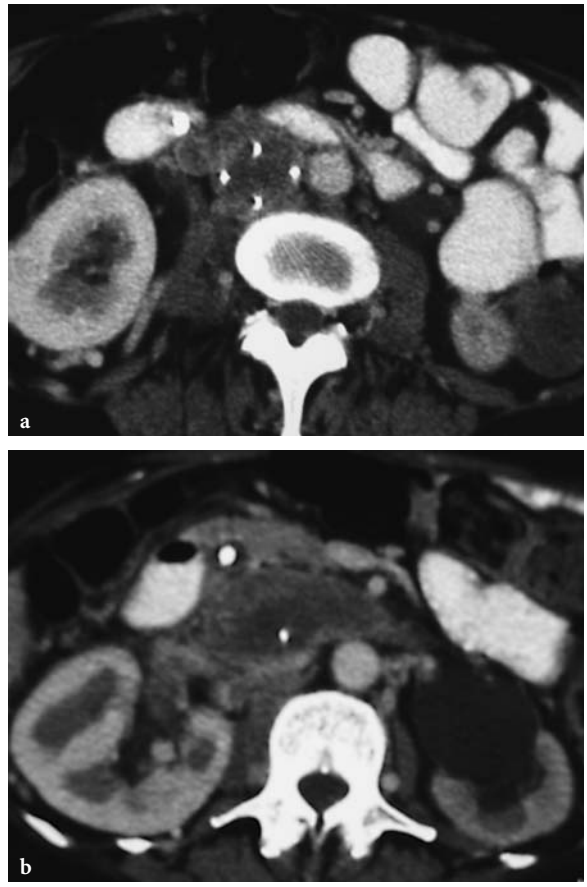

Fig. 17.3. a Gunther Tulip filter in thrombosed IVC. **b** More cranial section demonstrating associated renal vein thrombosis

17.8 Conclusion

There is evidence that IVC filters reduce the risk of pulmonary embolism in the short term in patients

with proximal deep venous thrombosis. They should not be considered a substitute for anticoagulation: unlike anticoagulants, they do not prevent propagation of DVTs, they do not help prevent long-term sequelae of DVT such as post-phlebitic limb and they increase rather than decrease the risk of recurrent DVT. The best accepted indication for their use is pulmonary embolism with a contraindication to anticoagulation. These contraindications are often temporary, such as bleeding peptic ulcer or surgery. The development of retrievable filters that may be left in situ for a number of weeks before removal may avoid their long-term complications, such as recurrent DVT and caval occlusion. The continued improvements in filter design will no doubt be paralleled by advances in anticoagulant medication, such that the place for IVC filters will have to be continually re-evaluated.

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18 Management of Venous Insufficiency

David J. West

CONTENTS

18.1 Introduction

Venous insufficiency is perhaps the commonest chronic disorder in the Western world affecting an estimated 32% of women and 40% of men (Evans et al. 1999). Its effects range from mild cosmetic disturbances to painful and infected ulcers and in extreme cases even death from haemorrhage (Morrow et al. 1994). It is a much neglected and often misunderstood health problem and studies have shown patients to be very dissatisfied with existing treatment options (Davies et al. 1995). Chronic ulceration in particular is a considerable problem with a prevalence of 0.5%–1.5% and a source of great pain and distress to this large group of patients (Callam 1994).

18.2 Anatomy and Physiology of the Venous System

The venous system serves two functions; first to carry deoxygenated blood back to the heart and secondly to act as a reservoir of blood which can be utilised in the event of sudden volume loss. In the leg, there are two main sets of veins, superficial and deep. Superficial veins lie near the surface enclosed between layers of superficial fascia. The two main superficial veins are the greater saphenous vein (GSV) and the small saphenous vein (SSV). Deep veins lie between the muscle groups of the leg, and these muscles in turn are surrounded by the deep fascia. The main deep veins are the posterior tibial vein, anterior tibial vein, peroneal vein (all these three are usually paired making six in all), gastrocnemius vein, popliteal vein, deep femoral vein, femoral vein and the common femoral vein. [Note that the vein which accompanies the superficial femoral artery is called the femoral vein rather then the superficial femoral vein to avoid confusing deep venous thrombosis (DVT) for superficial thrombophlebitis]. In addition to these main trunks, there are numerous other veins of great importance in the genesis and explanation of the sequelae of venous insufficiency. There are innumerable perforating veins, which connect the deep and superficial systems together through

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natural defects in the deep fascia. Some common ones have names: Hunterian, mid/upper thigh; Dodd, just above the knee; Boyd, just below the knee; Cockett, just above the ankle. Tributaries to the saphenous veins lie above the superficial fascia. Communicating veins join veins which lie within the same fascial plane. Finally there is an important plexus of small superficial veins on the outside of the thigh; the lateral subdermic venous system (LSVS).

Within the main truncal veins, both deep and superficial, lie bicuspid valves, which allow flow only in a proximal direction. Similar valves lie in the perforators which allow flow only from the superficial to the deep veins. The mechanisms by which the peripheral veins perform their dual functions are described below.

The reservoir function is quite simple to understand. In the erect position blood tends to pool under the effect of gravity and the veins distend accommodating considerable quantities of blood (Buckley et al. 1988).

At times of crisis when extra blood is required these veins can be emptied. For example, when there is significant blood loss due to haemorrhage venoconstriction will occur. In addition, the casualty is placed in the supine position with the legs raised.

The most important function of the veins, however, is to carry blood back to the heart. In the erect position this is accomplished by the action of what is sometimes referred to as the peripheral heart (Bouissou et al. 1988) or muscle pump. This comprises the muscles of the leg (especially the calf muscles) and the superficial and deep veins with their valves. Much of the deoxygenated blood from the legs is initially collected in the superficial veins. The cycle starts with the muscles relaxed and the superficial and deep veins full of blood. Contraction of the muscles compresses the deep veins. The valves in the veins prevent the blood within them travelling peripherally to any significant degree and most of the blood is therefore forced upwards towards the heart. The valves in the perforating veins also prevent the blood being pushed out into the superficial veins. On relaxation of the calf muscles, the pressure within the veins surrounded by the muscle reduces and the valves above the muscles close. The valves below and in any associated perforating veins open and blood is allowed into the deep veins. The cycle is then repeated. Normally this mechanism maintains leg venous pressure at low levels and balances leg blood inflow and outflow.

18.3 Venous Insufficiency

Venous insufficiency results when the mechanism described above fails. This can occur for several reasons:

1. Reduced contraction of calf muscles
2. Valve failure
3. Deep vein obstruction

Valve failure and deep venous obstruction are the relevant causes from the perspective of this chapter.

18.3.1 Valve Failure

By far the most common cause for this is a familial predisposition. Other causes include damage from previous thrombosis, primary agenesis of deep vein valves, high pressure transmitted through incompetent perforators into the superficial veins which then distend and prevent the valve cusps closing together and hormonal effects such as in pregnancy, causing the veins and valves to soften and distend.

18.3.2 Deep Vein Obstruction

Deep venous obstruction occurs most commonly as a result of deep venous thrombosis (DVT). This may be precipitated by factors such as surgery, prolonged immobilisation, pregnancy and pelvic tumours. In addition, there are uncommon congenital causes of deep venous obstruction which will not be addressed further.

18.3.3 The Effects of Venous Insufficiency

The most common manifestation is varicose veins. These are superficial veins which are contained only by loose subcutaneous tissues and have been distended as a result of prolonged high pressure. They become enlarged, tortuous and highly visible (except if covered by excessive body fat).

Even more commonly encountered but less distressing are telangiectasias or thread veins. Both varicose veins and telangiectasias are often associated with symptoms which are poorly related to the

severity of the cosmetic abnormality (Browse et al. 1999; Bradbury et al. 1999). Pain is common, while other subjective sensations such as throbbing, itching, burning, restlessness, cramps, particularly at night, and heaviness may also occur (Bergan and Passarella 2005).

More serious signs of damage by venous insufficiency are in approximately order of progression: oedema, hyperigmentation, dermatitis, cellulites, atrophie blanche, ulceration, malignancy. Varicosities themselves may be complicated by haemorrhage and thrombophlebitis. All these effects, apart from malignancy and bleeding, are very common and to illustrate this it is estimated that 0.5%–1.5% of adults have a venous ulcer (Callam 1994). The care of these accounts for a considerable percentage of available district nursing time.

18.4 Clinical History Taking, Examination and Investigations

In order to plan appropriate treatment, it is important to make an accurate diagnosis of the existence of venous insufficiency, any associated pathology (e.g. co-existing arterial disease) any obvious cause and the anatomical basis for the problem.

A limited but efficient history is taken focusing on possible causes for venous insufficiency, contraindications for possible treatments, previous vein problems and treatments, previous DVT or evidence of coagulation abnormality. It is important to be clear about the patient's complaint – how severe the symptoms are and of what type, as well as what the patients want and expect from treatment. Critical questioning is important to determine if there are other likely causes for the symptoms which the patient may be inappropriately attributing to varicose veins. Previous treatment should be looked into in some detail. Knowledge of existing drug usage and any allergies are also important.

Examination needs to be focused on determining the class of the disorder according to the CEAP (clinical severity, etiology or cause, anatomy and pathophysiology) classification shown in Table 18.1, the cause and the precise anatomy and physiological abnormalities.

Simple visual inspection reveals much in this respect and is usually sufficient to classify the disease as the CEAP classification is based entirely on visual effects rather than underlying cause. A note should be made of the distribution of the telangiectasias, reticular and varicose veins, presence and extent of oedema, skin changes, ulceration or evidence of previous ulceration.

Table 18.1. The CEAP classification for venous disease

Class 0	No visible or palpable signs of venous insufficiency
Class 1	Telangiectasia and/or reticular varicosities
Class 2	Varicose veins
Class 3	Oedema
Class 4	Hyperpigmentation, dermatitis
Class 5	Healed venous ulceration
Class 6	Open venous ulceration

Palpation of the legs will help give an accurate picture of the extent of the varicosities, some of which can be felt more easily than seen. It will help discover a saphena varix and is good at detecting the defects in the fascial covering of the leg which point to likely sites of incompetent perforators. Palpation and inspection of the abdomen/pelvis should not be forgotten to avoid missing a relevant mass.

Prior to the use of duplex ultrasound scanning, there were many cumbersome and variably accurate clinical tests to try to determine the presence and sites of reflux, such as the cough test, Schwartz test, Brodie/Trendelenburg (Dodd and Cockett 1986). These have now largely been replaced by duplex ultrasound, which should be carried out on any patient being investigated for venous insufficiency.

The duplex ultrasound examination should be undertaken with the patient erect. The deep veins are assessed for patency, reflux and augmentation of proximal flow on calf compression. The GSV and SSV are scanned along their lengths and tested for reflux and the presence of refluxing perforators. They are measured and their course and communications plotted. Note is made of any duplications or abnormal communications such as the vein of Giacomini connecting the small saphenous to the great. The same procedure is followed in post-operative recurrence. It is important to track any visible varicosities of which the patient is complaining and link them with the refluxing truncal veins, so that one can be reasonably confident of treating the veins which are relevant to the causation of the varicosities. More complex investigations like venography and varicography are rarely required at the diagnostic stage but can be helpful in some cases at the time of endovenous treatment. Intravascular ultrasound may be needed in the investigation of suspected May–Thurner syndrome in order to detect the thin

membranous obstructions characteristic of this condition (Neglen and Raju 2002).

18.5 Conventional Treatments for Venous Insufficiency

Conventionally the treatment of varicose veins and other manifestations of venous insufficiency has been by sclerotherapy or surgery.

It is widely but not universally accepted that the best surgical operation for varicose veins secondary to saphenofemoral junction and GSV incompetence is to tie off all tributaries of the GSV in the groin, to strip the GSV to knee level and to perform micro-avulsions on visible varicosities. Stripping below the knee has largely been abandoned due to the high risk of saphenous nerve injury. The stripping of the GSV not only removes the reflux from the saphenofemoral junction but also eliminates the effects of any thigh perforators. Surgical text books (Rutherford 2000) stress the importance of making special efforts to identify and tie off all saphenous tributaries at the groin down to their first or second branches. This technique is based partly on the description of the residual inguinal network in recurrent varicose veins (Stonebridge et al. 1995). For SSV reflux, most surgeons perform ligation and division at the saphenopopliteal junction rather then stripping because of the risk of damaging the sural nerve. Despite good studies demonstrating clear benefit, especially reduced recurrence, by stripping the GSV rather then simply tying it off at the saphenofemoral junction, some surgeons still persist with the high tie operation (Dwerryhouse et al. 1999; Munn et al. 1981; Sarin et al. 1994). One rationale for this is that it will preserve the GSV for future coronary artery bypass surgery. However, the benefits of conserving the vein for future coronary artery bypasses are dubious as a diseased vein will be of no use for this purpose.

Despite tying and stripping of the GSV, recurrence is not uncommon. The most obvious explanation for this is that the patient either had a duplicated GSV in the first place or another vein was mistakenly removed instead of the GSV. It is also the case that varicose veins tend to progress, so complete cure is unlikely in the long term. Indeed, neovascularisation, with the development of large refluxing truncal venous channels is clearly described (Turton et al. 1999).

18.6 Endovascular Treatments for Venous Insufficiency

Attempts have been made over a number of years to reduce the trauma of surgical stripping and the consequent neovascularisation, recurrent varicosities, pain, long convalescence and scarring, by leaving the vein in place and merely closing it off. These have included diathermy and liquid sclerotherapy (Politowski and Zelazny 1966; Watts 1972; O'Reilly 1977; Scahdeck and Allaert 1991; Vin 1991). Most of these attempts have had only temporary success as they cause acute thrombosis of the GSV, with subsequent recanalisation.

The underlying principles of treatment of venous insufficiency which most practitioners of today accept and which underpin both surgery and minimally invasive treatments are the same. Essentially treatment involves the elimination, where feasible, of all refluxing superficial veins starting with the most proximal (and usually the largest) and working distally.

In the last 10 years, three main methods of in-situ venous ablation have come to the fore: foam sclerotherapy, radiofrequency ablation and laser ablation. These all depend on duplex ultrasound guidance, both to demonstrate the pathophysiology and anatomy clearly and to guide needles and catheters into precise position within and around the vein to be treated.

All three methods use very similar principles, so the most common at the time of writing (laser ablation) will be described in detail and the fundamental differences in technique, applications and outcomes of the other two (radiofrequency and foam sclerotherapy) will follow.

18.6.1 Endovenous Laser Therapy

18.6.1.1 Great Saphenous Vein

Endovenous laser therapy is most commonly performed on the GSV and is achieved by intraluminal delivery of laser energy to the wall of the vessel. The vein wall is heated which causes collagen contraction and endothelial destruction and ultimately the vein will fibrose (Proebstle et al. 2002a,b). The procedure can be carried out in an ordinary clinical room rather than an X-ray facility or operating

theatre. The room has to be suitable and authorised for use of a medical class-4 laser. Essential facilities include a couch which tilts head-up along its whole length, a warm environment, a sterile trolley for the laser fibre kit and a sterile trolley large enough to hold the necessary disposable items (Table 18.2).

Table 18.2. Equipment required for EVLT

Gauze swabs	Scissors
Patient drape	Gallipot with povidone iodine
Jug or bowl with 200 ml of 0.2% lignocaine with adrenaline or 400 ml 0.1% lignocaine with adrenaline	Micropuncture set (for small veins e.g. SSV)
2×20-ml luer lock syringes	1×5-ml syringe
1×25-mg needle	1×22-g spinal needle
Sterile cover for ultrasound probe	Sponge holders
No 11 blade	

The patient is asked to lie down with the whole body turned slightly towards the side under treatment. The inside of the thigh is prepared with Povidone iodine from groin to well below the knee. A sterile drape is applied and a 5-cm wide hole cut out along the length of the thigh. Using a 7.5- to 10-MHz linear ultrasound probe within a sterile cover the GSV is identified and a suitable puncture point chosen around knee level. A tiny drop of 1% lidocaine without adrenaline is injected to numb the skin and a small nick made with an 11-blade. An 18-gauge needle is advanced under ultrasound guidance into the lumen of the vein. Some operators prefer to use a transverse probe position others longitudinal. A 0.035"×1.5 mm J guidewire is advanced into the vein until it is judged to be well above the saphenofemoral junction. In patients with very small veins, it is helpful to use a micro-puncture set to enable initial access with a 20-gauge needle which reduces the chance of spasm and access failure. If resistance to the passage of the wire is felt at any point it is important to stop pushing and to check the anatomy with the ultrasound. There are many possible causes for the wire not to pass including tortuosity of the vein, passage of the wire into a small branch, local large varix formation and malposition of the needle. It is generally possible to overcome these problems by manipulation under ultrasound guidance, and it is only rarely necessary to resort to fluoroscopy.

Once the guidewire is above the level of the saphenofemoral junction a 6-F sheath is passed over the wire, the wire removed and the laser fibre inserted to the end of the sheath. Ultrasound scanning of the saphenofemoral junction reveals the high intensity reflection of the laser fibre and often also the front and back of the sheath. The sheath is then withdrawn until its tip lies just below the saphenofemoral junction. Scanning in longitudinal section is useful at this point, to show the relation of the tip of the sheath to the saphenofemoral junction. Once the sheath and fibre are correctly positioned, about 200 mls of 0.02% dilute local anaesthetic solution with adrenaline is injected into the fascial sheath immediately surrounding the GSV along its whole length, from puncture site to saphenofemoral junction. This is performed under ultrasound guidance, and can be a little uncomfortable, especially as the needle approaches the groin. Once the sheath around the whole length of the GSV is filled and the GSV itself shown to be compressed around the catheter the sheath is withdrawn about 3 cm to expose the tip of the laser fibre but leave it exactly where originally positioned. It is important at this point to note any tendency for a very small skin puncture site to grip the sheath tightly, as it is possible in such a situation for the sheath to spring forward with the laser fibre on releasing the backward pull thus leaving the laser fibre dangerously high and likely to damage the common femoral vein.

It is now time to start the laser treatment. Safety goggles are donned by all present in the room, including the patient. The laser is switched on and set to a pre-determined wattage, duration of pulse and type of pulse – continuous or intermittent on/off. The commonest protocols are 12 watts on for 1 s, off for 1 s or 14 watts continuous. The sheath with the laser fibre is withdrawn at a rate of either 2.5 mm/s during the off phase when using the intermittent protocol or 2.5 mm/s continuously. The laser is switched off when the sheath emerges from the skin incision. Cohesive limited stretch bandages are applied at full stretch or alternatively class 2 compression hose.

18.6.1.2 Results of Great Saphenous Vein EVLT

Many non-randomised, non-controlled studies have been undertaken which demonstrate outcomes which are as good as or better than those reported for traditional surgery. Typical reported results from large case series show technical success of immediate closure of the GSV of 98%, with a recurrence rate of between 4% and 7% at up to 3 years. Patient satisfaction as determined by answers to the question "Would you recommend this to a friend?" is

over 95% (Roizental and Fernandez 2004; Min et al. 2003). Recurrences after EVLT failure can be readily treated by repeat EVLT.

The only complications reported with any frequency in the literature are bruising, pain and tightness which are almost universal. There have been no reports of serious complications apart from one isolated case of an arteriovenous fistula following small saphenous EVLT (Timpernan 2004).

Treatment of the GSV alone is often sufficient to adequately resolve symptoms related to venous insufficiency, but unlikely to be enough to give a satisfactory cosmetic result in unsightly varicosities. There are several strategies available to deal with these. In addition to the GSV closure the varicosities themselves can be treated with either micro-avulsions or sclerotherapy. Sclerotherapy can be performed with liquids or more often with foam. These treatments can be performed at the same time as the EVLT or more commonly after a break of up to 6 weeks. Both sclerotherapy and micro-avulsions can be undertaken using local anaesthesia only, whereby micro-avulsions are often undertaken under general anaesthetic.

18.6.1.3 EVLT of Small Saphenous Vein and Other Truncal Veins

Although GSV reflux is the cause of venous insufficiency in about 70% of cases, reflux of other truncal veins is also common and important. For example, both SSV and GSV may contribute to the venous insufficiency in the same leg. Following the success of treatment of the GSV with EVLT, other truncal veins including the SSV, accessory saphenous vein (ASV) and posterior thigh circumflex vein (PTC) have been treated in a similar manner.

A similar treatment protocol is used relying on duplex ultrasound guidance for needle puncture of the vein, guidewire passage, local anaesthesia injection and laser fibre positioning. The tip of the fibre is positioned about 2 cm from the junction with the deep vein. For these non-GSV truncal veins, the author finds a micro-puncture set and additional fluoroscopic guidance particularly helpful. The point of entry for the needle is chosen to be at the point at which the lower most tributary vein arises to supply the varicosities below which level the truncal vein returns to normal dimension and is not refluxing. Other aspects of the technique and follow-up are identical to the GSV EVLT.

Treatment of the SSV by EVLT is particularly helpful as surgery can be difficult and complicated. The close proximity of the sural nerve to the SSV is associated with a high chance of damage during surgery. There are also many variants of normal drainage of the SSV into the deep veins, which can lead to tying off of incorrect vessels.

At the time of writing there has been very little published on the results of EVLT in non-GSV truncal veins, but the results of a study of 219 patients (Min et al. 2004) has shown over 96% technical success rate rising to 100% at a second attempt. The appearance of the varicose veins improved in all patients and the symptoms also improved in 100%. Side effects reported were bruising and superficial phlebitis (5%).

Laser and the other image guided ablation methods described below have also been usefully employed in closing off perforators, especially those directly pressurising ulcers and preventing them healing (Worthington-Kirsch R and Brookes J, personal communication).

18.6.2 Other Minimally Invasive Treatment Options for Truncal Disease

Although EVLT is perhaps the commonest technique used to treat venous insufficiency as a result of truncal reflux, there are two other options in use – RFA and foam sclerotherapy.

18.6.2.1 Radiofrequency Ablation

Radiofrequency ablation of truncal veins has been in use for slightly longer than laser ablation. The first reports were in 2000 using the commercially available device manufactured by VNUS Medical Technologies (Goldman 2000). The technique is similar to EVLT and relies on a radiofrequency catheter being introduced into the GSV at knee or ankle level and advanced to and positioned just beyond the saphenofemoral junction. Local anaesthesia is then injected into the fascial sheath surrounding the GSV from saphenofemoral junction to knee level. The radiofrequency generator is switched on and the catheter pulled slowly down the vein. The VNUS registry was started in 1998 and has shown absence of reflux in the treated vein in 91.4% at 1 year and 86.1% at 4 years (Nicolini 2005). Two randomised trials have compared radiofrequency ablation with surgery and have shown significant advan-

tages of VNUS over surgery, including less pain, faster recovery, fewer adverse events and superior quality of life scores (Rautio et al. 2002; Lurie et al. 2003). In many countries including the UK, marketing of the VNUS device has been targeted at vascular surgeons. This has led to most VNUS procedures being undertaken under general anaesthetic in the operating theatre. Esmarch bandages rather than tumescent local anaesthesia have been used to empty the blood from the GSV. Multiple avulsions are usually performed at the time of the VNUS procedure. There are advantages and disadvantages of this approach. On the positive side, patients feel no pain at all and the definitive procedure can be undertaken in once visit. On the down side, many patients specifically wish to avoid general anaesthesia, some patients will have avulsions that they do not in fact need, there is a higher theoretical chance of thermal damage to surrounding structures as tumescent anaesthesia is not used and finally, the costs of an operating theatre are considerably higher than a clinical room.

18.6.2.2 Foam Sclerotherapy

Treatment of varicose veins by sclerotherapy was first described 40 years ago (Fegan 1965). Particularly in Northern Europe, it went out of favour following publication of Hobbs' famous paper (Hobbs 1974) showing surgery to be clearly better than sclerotherapy, but remained popular in Southern Europe. The development of foam sclerotherapy was not a one-off invention but a natural progression by experimentation by many different practitioners. The first description of mixing the sclerosants with air was back in 1944 (Orbach 1944). The use of ultrasound to target liquid sclerotherapy more precisely was described in 1991 (Schadek and Allaert 1991), but it was not until 1997 when Cabrera described his experiences with foam injections under ultrasound guidance that the technique became clinically applicable (Cabrera et al. 1997).

Sclerotherapy works by chemical destruction of the endothelial lining of the vein. Liquid forms of sclerosants are limited in the size of vein they can easily treat by the need to displace large volumes of blood and therefore to use large volumes of concentrated agent to have the desired endothelial reaction over a large surface area. Two of the commonest and most efficient agents, sodium tetradecyl (STD) and Polidocanol are both detergents and will mix into a foam with air very easily. With use of foam the limitations of the liquid sclerosants are largely overcome. For the same overall dose of chemical the foam produces five times the volume of agent which can directly displace five times the volume of blood and not dilute and disperse so easily. This effect is magnified by the marked venospasm induced by the foam coming into contact with the vein wall. The foam can be milked along the veins with the aid of the ultrasound probe and shows up strikingly well on ultrasound images. Foam sclerotherapy can be used to manage superficial venous reflux, varicose veins themselves and incompetent perforators. For treatment of the GSV and SSV variations of the technique described by Cabrera (1997) are normally used. The mid GSV or SSV are accessed with a cannula under ultrasound guidance. The limb is elevated to reduce the volume of superficial blood and a small quantity of foam sclerosant, e.g. 4 ml 3% STD ¼ with air is injected. The ultrasound probe is used to massage the foam up the vein until the junction with the deep veins is reached, at which point compression is applied over the junction to prevent passage of foam into the deep veins. The results of foam sclerotherapy in large truncal veins have been impressive. In addition, should the procedure fail, it can easily be repeated. Various studies have shown closure of the truncal vein in 67%–93% of cases (Barrett et al. 2004; Cavezzi et al. 2002; Tessari et al. 2001; Frullini and Cavezzi 2002).

Foam sclerotherapy has also been shown to be excellent at treating reticular veins and spider veins (Henriet 1999). In a comparative trial foam has been shown to be superior to liquid sclerosants (Hamel-Desnos et al. 2003). As with liquid sclerotherapy, it is important to warn patients about the possibility of skin staining and superficial or deep thrombophlebitis. There is also a small risk of transient visual scotomata, presumably due to the foam passing through the lungs or bypassing the lungs (Cavezzi et al. 2002). Particular care should be taken with migraine sufferers who may have a higher chance of right to left shunt through a patent foramen ovale.

18.6.3 Other Minimally Invasive Techniques for the Treatment and Prevention of Venous Insufficiency of the Lower Limbs

18.6.3.1 Embolisation

It is not uncommon to find varicosities of the thigh in a rather unusual pattern which duplex ultrasound suggests are arising from the pelvic venous system.

In keeping with the basic principle of management to tackle the highest point of reflux first, in such cases it is important to undertake catheter based venography of the gonadal and internal iliac veins. It is important to undertake this examination in either an upright position or at least with the X-ray table considerably tilted head-up and with Valsalva manoeuvre. If reflux within these venous systems is demonstrated, appropriate treatment can be planned. If the reflux is originating from the gonadal veins, these can be embolised either in standard fashion using coils via the catheter, or if preferred, with injection of STD foam via the catheter (Lord and Haughton 2003). If the reflux originates in the internal iliac venous system then the major draining veins can be selectively catheterised and embolised with coils.

18.6.3.2 Venous Angioplasty or Stenting

Obstruction of the iliac veins should not be forgotten as a cause of chronic venous insufficiency. Approximately half of these cases are post-thrombotic syndrome and half are a type of May–Thurner syndrome. This topic is more fully covered in Chap. 18, but suffice it to say that more than 50% of venous leg ulcers heal after venous stenting alone. Patients with swollen limbs labelled as lymphoedema have also benefited from venous stenting. We therefore need to thoroughly investigate all patients with chronic limb swelling regardless of the clinical impression. Iliac vein stents are very useful in such obstructive disease with swelling reducing by 33% and 50% of patients becoming symptom free. There is virtually no morbidity or mortality (Raju and Neglen 2004; Neglen et al. 2003).

18.6.3.3 Valve Replacement and Reconstruction

There will remain a small proportion of patients with chronic venous insufficiency who do not respond to saphenous ablation and/or venous stenting. In this small subgroup who have deep venous reflux some type of venous valve reconstruction/replacement may be necessary. The options include various surgical reconstructions of faulty valves and axillary vein transposition. Progress is being made to produce artificial percutaneous venous valves from a frame of metal and cusps of small bowel submucosa (Pavcnik et al. 2004) or bovine jugular vein (De Borst et al. 2003). With further development, hopefully such devices will become available for regular clinical use.

18.7 Active Management of Deep Venous Thrombosis

The immediate concern with DVT is the risk and prevention of pulmonary embolism (Raju and Neglen 2004). Long term, however, post-thrombotic syndrome (PTS) is much more of an issue. PTS is caused by a combination of proximal venous obstruction and reflux. The obstruction (partial or total) is caused by unresolved thrombus; the reflux from valvular damage secondary to thrombus induced inflammation. Obstruction at iliac vein level will naturally cause the greatest clinical problem.

With standard treatment of DVT by anticoagulation, the thrombus rarely resolve completely. Catheter delivered thrombolysis of venous thrombosis is far from standard therapy yet, but is advocated by some in the hope of reducing the incidence of PTS (see Chap. 18). Attempts to dissolve the thrombus using thrombolytic agents have been successful, but not risk free with major bleeding in 11% and intracerebral haemorrhage in 0.4% (Labropoulos and Haughton 1999). Overall risks may be reduced whilst maintaining effectiveness by using mechanical thrombectomy instead of thrombolysis (Murphy 2004).

18.8 Venous Insufficiency in Other Sites

Although most frequently encountered in the lower limbs, venous insufficiency also causes problems in the scrotum in males (varicocele) and the pelvis and external genitalia in women (vulval varices, pelvic congestion syndrome). Varicoceles and vulval varices are easily diagnosed. In fact, sometimes the patient picks up the fact that they have enlarged veins in that area. Pelvic venous congestion on the other hand is very difficult to diagnose and many gynaecologists are skeptical about its very existence and importance. Just as it is important to examine the legs of a patient with varicose veins in the erect position, so it is important to examine a woman with possible pelvic venous congestion in the erect

position. The problem with the most frequently used investigations, e.g. laparoscopy, MR and ultrasound, is that these are almost always undertaken, for obvious reasons, in the supine position when the veins are least distended. With laparoscopy this problem is compounded by the pressurisation of the abdomen, which further flattens the veins. It is possible, although rather difficult, to undertake a transvaginal ultrasound in the erect position but transcatheter ovarian venography is relatively straightforward with most fluoroscopy units. Clues in the history which should make the doctor consider this diagnosis are as follows:

- Chronic pelvic pain worse as the day goes on, better first thing in the morning, pain worse on standing, pain on intercourse and especially at orgasm.
- Significantly symptomatic varicoceles or those associated with poor sperm quality/count in men whose partners are having difficulty conceiving.

Vulval varicosities and pelvic pain associated with pelvic venous congestion can all be easily and effectively treated by embolisation. This is usually accomplished by placement of standard 0.035 coils through a Cobra catheter from a right groin puncture. Alternative embolisation agents can be used, the latest to be proposed being STD foam which has the advantage of being very cheap compared to coils (Lord and Haughton 2003).

18.9 Conclusion

Minimally invasive techniques are becoming much more important in the management of venous disorders. These, carefully and logically applied, promise to improve the quality of life of the large proportion of the population of the developed world, whose lives are affected in some way, either by cosmetic problems and symptoms of primary varicose veins, or the far more serious and disabling chronic venous insufficiency.

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