Chapter 24
Surgical Management: Open Surgical Treatment of Infra-Inguinal Occlusive Disease

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24.1 Infra-Inguinal Occlusive Disease Distribution

Atherosclerotic disease affecting the infra-inguinal arteries differs significantly between diabetic and non-diabetic patients. Femoral-popliteal disease characteristically affects non-diabetic patients causing stenotic and complete occlusive lesions sparing the profunda femoris artery (Fig. 24.1), whereas in diabetic patients the disease is typically infra-popliteal crural disease with sparing of the dorsalis pedis and pedal plantar arteries in some patients but not all (Fig. 24.2). This distribution of the disease with its variance between diabetic and non-diabetic population of patients dictates the different modalities in treatment including open surgery and endovascular techniques. Distal and ultra-distal bypasses are more commonly used to treat diabetic patients with severe tissue loss to try to achieve fast healing (Figs. 24.3 and 24.4). Similarly, crural and pedal arterial arch angioplasty, are generally more commonly performed in diabetic patients, whereas, femoro-popliteal bypass surgery and angioplasty are more common in non-diabetic patients.

24.2 Basil Trial and TASC Recommendations

The choice between different modalities in the treatment of patients with critical leg ischaemia (CLI) depends on different criteria. Few randomised trials are available to aid the decision making. However, the largest trial is the Bypass versus Angioplasty in Severe Ischaemia of the Leg (BASIL) trial which was set up to

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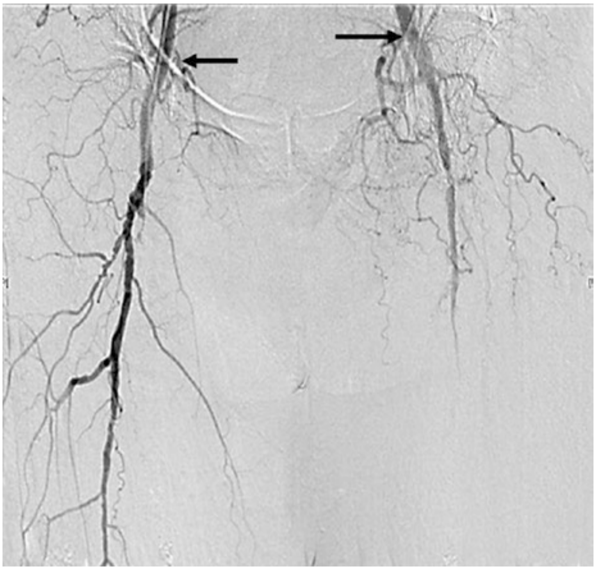

Fig. 24.1 Digital subtraction angiography (DSA) showing bilateral flush occlusion of the superficial femoral artery with sparing of the profunda femoris artery (arrows) in a non-diabetic patient

Fig. 24.2 DSA showing a vein bypass graft to an isolated dorsalis pedis artery (arrow) in a diabetic patient with proximally occluded crural arteries

Fig. 24.3 Severely necrotic and infected hallux and second toe amputations stump with gangrene of the adjoining toe

Fig. 24.4 Post-plantar bypass with synchronous wound debridement and toe amputation showing excellent bleeding bed

evaluate outcomes comparing bypass surgery-first to angioplasty-first strategies. Amputation-free and overall survivals were used as end-points for the outcome. The interim analysis of this trial published in 2005 [1] showed that in patients with severe lower limb ischemia (rest pain, ulceration, gangrene) due to infra-inguinal disease, bypass surgery-first and balloon angioplasty-first revascularisation strategies led to similar short-term clinical outcomes, although in the bypass-first group there were more expenses and morbidity compared to the angioplasty-first group.

In 2010, the trial authors published a 2.5-year final intention-to-treat analysis of 'amputation-free survival and overall survival of 452 enrolled patients randomised to either bypass surgery-first or angioplasty-first revascularisation strategy [2]. The results showed that there was no significant difference in amputation-free survival or overall survival between the two strategies. However, for those patients who survived for at least 2 years after randomisation, a bypass surgery-first revascularisation strategy was associated with a significant increase in overall survival and a trend towards improved amputation-free survival.

There are 3 new clinical randomised controlled trials comparing outcomes in patients with infra-inguinal disease and CLI. BASIL 2 is a multi-centre randomised controlled trial comparing outcomes between 'vein bypass first' and 'endovascular first' revascularisation strategy, in terms of clinical and cost-effectiveness, for severe limb ischaemia involving infra-popliteal disease. BASIL 3 is a multi-centre randomised controlled trial of clinical and cost-effectiveness of drug coated balloons, drug eluting stents, and plain balloon angioplasty revascularisation strategies for severe limb ischaemia due to femoro-popliteal disease. The BEST-CLI is a prospective, multicentre, randomized, open label, comparison trial to evaluate the effectiveness of best surgical (OPEN) compared to best endovascular (EVT) revascularization in patients with critical limb ischaemia in centres in USA and Canada-2100 subjects will be recruited from approximately 120 multidisciplinary vascular centers and practices in the US and Canada [3].

The Trans-Atlantic Inter-Society Consensus Document on Management of Peripheral Arterial Disease (TASC) was published in January 2000 as a result of cooperation between fourteen medical and surgical vascular, cardiovascular, vascular radiology and cardiology societies in Europe and North America [4]. In this document recommendations for either endovascular or open surgery were based on the symptoms as well as the extent and degree of the disease and its anatomical territory. In 2007, an update of the recommendations (TASC II) was published with a focus on the aorto-iliac and femoro-popliteal territories [5]. Recently the European Society of Cardiology together with the European Society for Vascular Surgery have published joint guidelines on the diagnosis and treatment of peripheral arterial diseases [6].

The chapter authors firmly believe that infra-inguinal disease patient selection for either angioplasty, open bypass surgery or hybrid techniques should be tailored to each patient each on their own merits on the basis of regular multidisciplinary meeting discussions covering all aspect of care to ensure the best outcome. This is a dynamic process that will require close monitoring in the acute phase of managing CLI to be able to adapt promptly to evolving complications and unexpected deterioration of the revascularisation process.

Post-revascularisation wound care plays an essential role in the success of these different modalities. This can be a challenging and time-consuming process that could require plastic surgery in-put. The authors rely heavily on offering patients with significant tissue loss split-thickness skin grafts to enhance healing and reduce the time-to-healing in these patients (Fig. 24.5).

24.3 Imaging and Planning

Several imaging modalities are available for clinicians to use in patients with CLI requiring revascularisation. The authors rely heavily on the use of duplex scans in the diagnosis and planning of treatment tailored for each patient. Duplex scan allows the choice of either to proceed with angioplasty as a definitive treatment or

Fig. 24.5 Split-thickness skin graft of the amputation wound with good healing result

as a part of a hybrid strategy (see below) or to proceed to another non-invasive diagnostic modality if open bypass surgery is deemed necessary. Computerised tomography angiography (CTA) or magnetic resonance angiography (MRA) (Figs. 24.6 and 24.7) can be used to delineate the extent of the disease and to select the distal anastomosis site in patients requiring infra-inguinal bypass surgery. Both techniques have their own merits and limitations but both are non-invasive. This avoids the use of the more invasive digital subtraction angiography (DSA) that should be only reserved for patients requiring angioplasty.

Based on the duplex scan, the length and the site of stenosis and or occlusion will dictate which treatment modality should be used. In symptomatic long occlusions affecting the superficial femoral artery following duplex assessment, the patient should be offered an attempt at angioplasty and stenting if not fit for open surgery. However, although the authors apply the “angioplasty-first strategy” in CLI, they prefer to offer patients with long occlusions extending from the trifurcation into the crural and pedal arteries, open distal bypass surgery as a primary treatment option if these patients are fit to undergo major surgery.

In patients requiring pedal bypass surgery, when standard imaging modalities as CTA or MRA are not able to visualise a suitable pedal artery for bypass, the authors have regularly relied on duplex scanning of either the dorsalis pedis artery or the plantar arteries for target runoff (Figs. 24.8, 24.9, 24.10, and 24.11). Duplex can also assess the quality of these arteries by identifying the extent of calcification that could cause difficulty during surgery. This imaging modality is very reliable in patients with severe CLI with very low blood flow that cannot be detected in either foot by dedicated CTA or MRA.

24.4 Conduit for Infra-Inguinal Bypass

There is strong evidence that autologous venous conduits are superior to synthetic grafts from the short and long term outcomes in infra-inguinal bypass especially in distal bypass surgery. The majority of diabetic patients with tissue loss suffer a

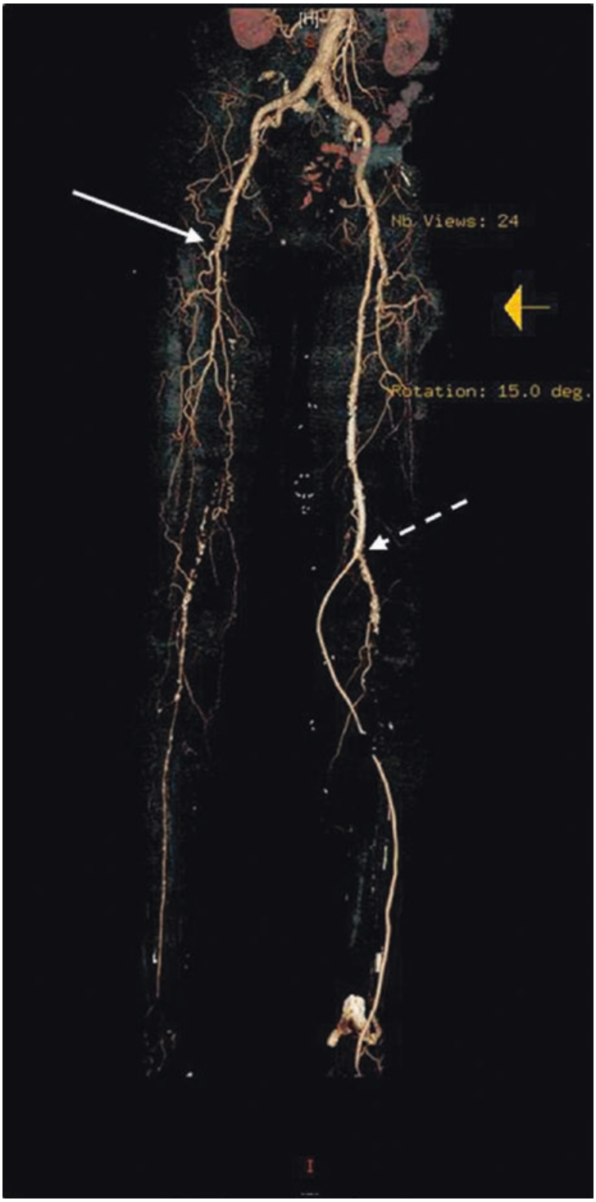

Fig. 24.6 Computerised tomography angiogram (CTA) showing occlusion of the right superficial femoral artery(unbroken white arrow) with diffuse calcification and severe disease of the crural arteries. On the left side, a patent popliteal to pedal bypass can be seen (broken white arrow)

high burden of microbial contamination with a significant risk of antibiotic resistant bacteria which increases the risk of synthetic graft infection and hence limb loss. The authors have a strong preference to using autologous venous conduits and have previously even shown that the great saphenous veins of small internal diameter calibre (less than 3 mm) have a favourable outcome in patients undergoing distal bypass surgery with primary, assisted primary, and secondary patency rates at 1 year for vein conduits <3 mm of 51.2%, 82.6%, and 82.6%, respectively, compared to

Fig. 24.7 Magnetic resonance angiography (MRA) showing bilateral patent trifurcation of the crural arteries

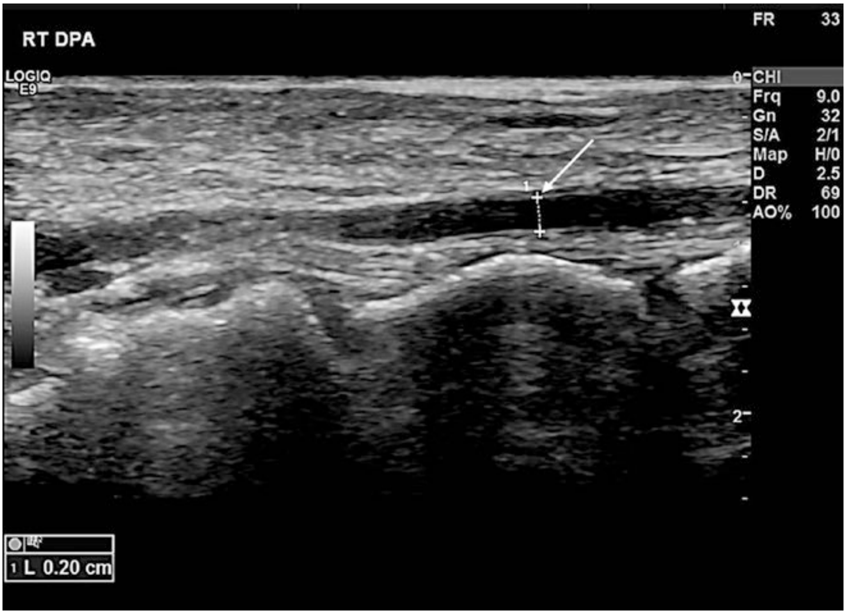

Fig. 24.8 Duplex scan of the dorsalis pedis artery (arrow) showing minimal wall calcification and an internal diameter of 0.20 cm

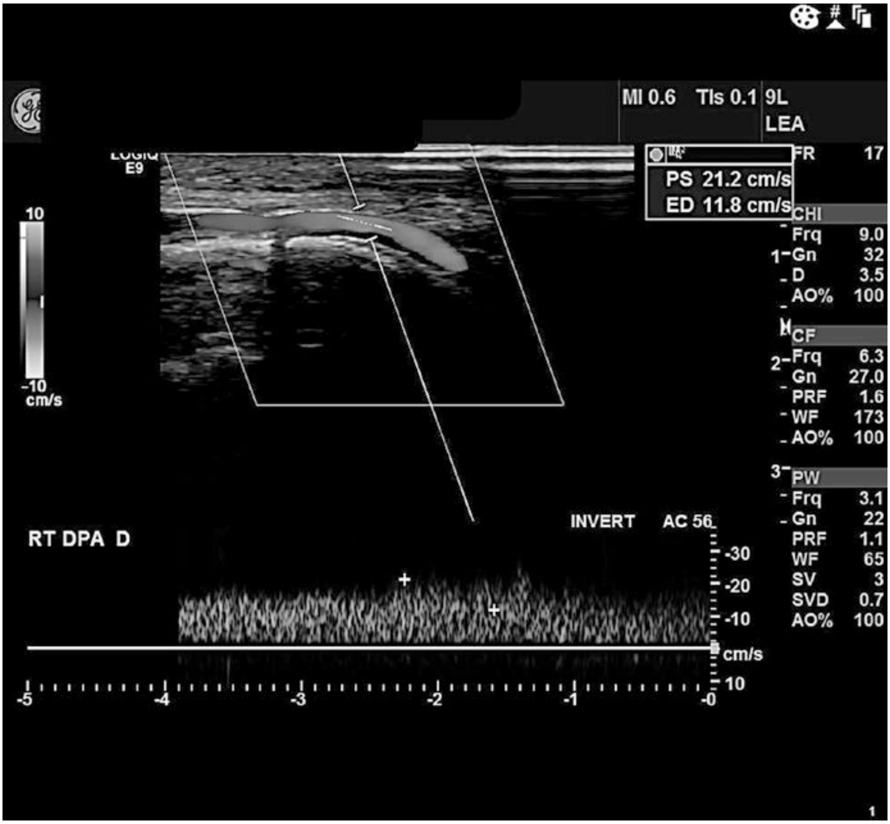

Fig. 24.9 Pre-operative duplex scan of the dorsalis pedis artery showing a patent artery with damped blood flow and a peak systolic velocity of 21.2 cm/s

68.4%, 93.3%, and 95.2% in venous conduit ≥3 mm group [7]. Secondary patency rate was significantly better in the larger venous conduit (P = .0392).

There is also good evidence supporting the use of arm veins to perform infra-popliteal bypass surgery with better outcomes compared to synthetic grafts. Using other surgical techniques, such as the profunda femoris artery as an inflow for infra-inguinal bypass or the use of hybrid techniques (see below) to help shorten the length of the venous conduit, helps in patients undergoing redo surgery or in patients who have previously undergone cardiac bypass surgery using the autologous veins.

24.5 Surgical Infra-Popliteal Bypass; Distal and Ultra-Distal Bypass

The authors have published a series comparing the outcomes of distal (bypass to the crural arteries) versus ultra-distal (bypass to the pedal arteries) in patients with CLI [8]. Two hundred and thirty bypasses were performed in 209 consecutive

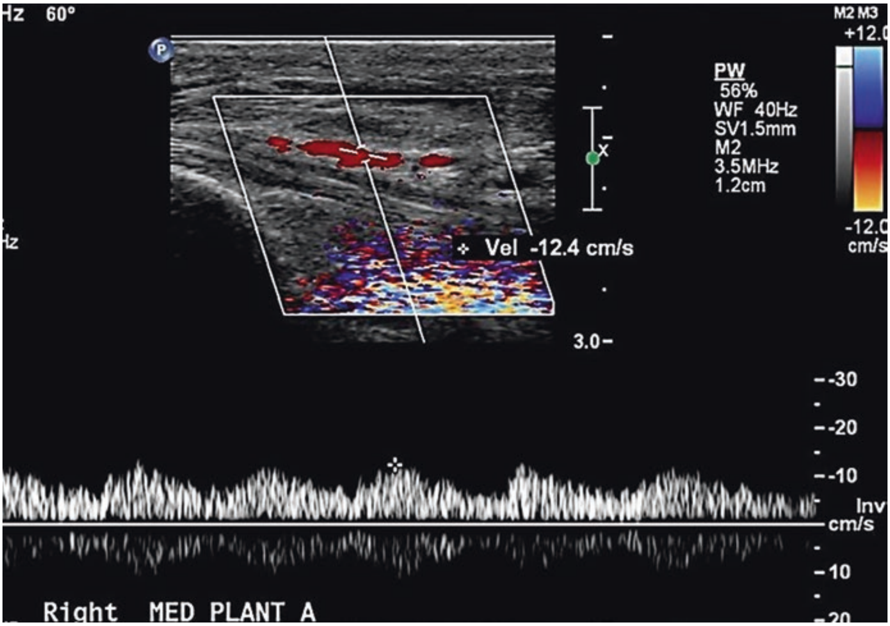

Fig. 24.10 Pre-operative duplex scan of the medial plantar artery showing a patent artery with severely damped blood flow

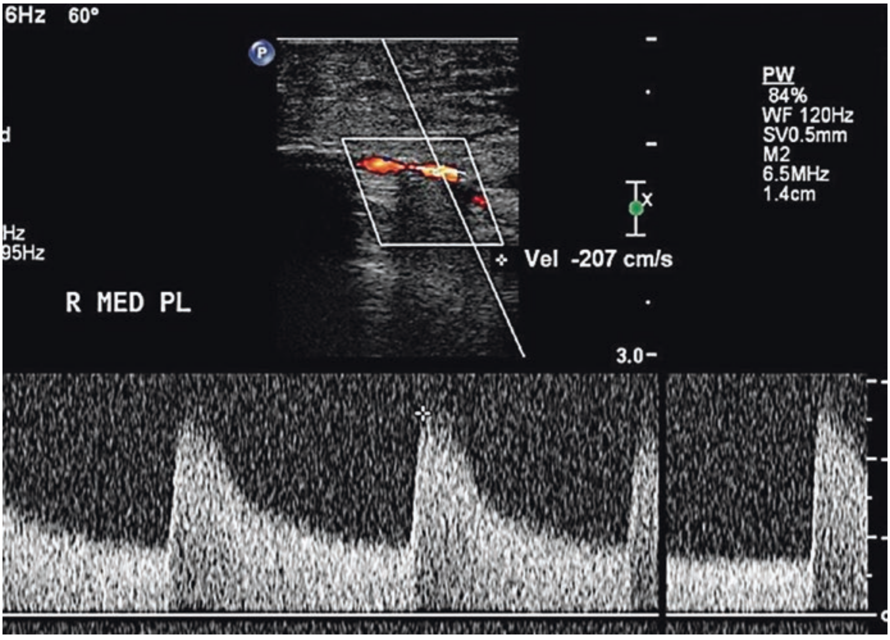

Fig. 24.11 Post-operative duplex scan of the medial plantar artery showing a significant improvement in blood flow with pulsatile waveform

patients of whom the majority were elderly males. One hundred and seventy-nine (78%) bypasses were classified as distal and 51 (22%) as ultra-distal. As expected the incidence of diabetes mellitus was significantly higher in the ultra-distal group ($p = 0.0025$) due to significant crural vessel disease in diabetic patients, with sometimes sparing of the dorsalis pedis and plantar arteries. At 1-year, the distal group primary, assisted-primary and secondary patency rates were 61.7%, 83.1% and 87.4% compared to 61.9%, 87.4% and 87.4% in the ultra-distal group respectively. Amputation-free survival at 12 and 48 months was 82.9% and 61.5% in the distal group compared to 83.0% and 64.9% in the ultra-distal group. This study show that both distal and ultra-distal bypass have comparable outcome regardless of the co-morbidities. The authors believe that medically fit elderly patients should still be offered ultra-distal bypass if indicated to avoid major amputation.

24.6 Outcome Of Distal and Ultra-Distal Bypass

Different outcomes have been reported in different races undergoing distal bypass surgery. In the majority of the American literature, poorer outcomes have been reported in the African-American population with a higher amputation rate and lower graft patency. The authors have published a series of Afro-Caribbean population undergoing distal bypass surgery with comparable results to the Caucasian population [9]. Despite more significant tissue loss as the presenting symptom in the Afro-Caribbean population, the primary, primary-assisted and secondary patency rates, and amputation-free survival at 12 months were similar in both groups.

24.7 Intra-Operative Monitoring and Optimisation and Post-Operative Mortality

Mortality rates following infra-inguinal bypass varies significantly in different studies. Analysis of surgical revascularisation procedures performed each year in England [10], and their outcome using hospital episode statistics, demonstrated a total of 21,675 femoro-popliteal and 3458 femoro-distal bypasses with a mean in-hospital mortality rates of 6.7 and 8.0% respectively. The 1-year survival rates were 82.8 and 79.1% which both increased over the study interval. The chapter authors have reported significantly lower mortality rates in 209 elderly high-risk patients undergoing 203 distal and ultra-distal bypasses (median age of 76 and 73 years respectively). Thirty -day mortality was 1.7% and 1-year mortality rate was 12.2% [8]. The authors have always attributed these low mortality rates to the meticulous intra-operative monitoring and optimisation of these patients.

In an observational case series, the authors also reported 120 elderly patients undergoing major infra-inguinal bypass between 2007 and 2012 [11]. Intra-

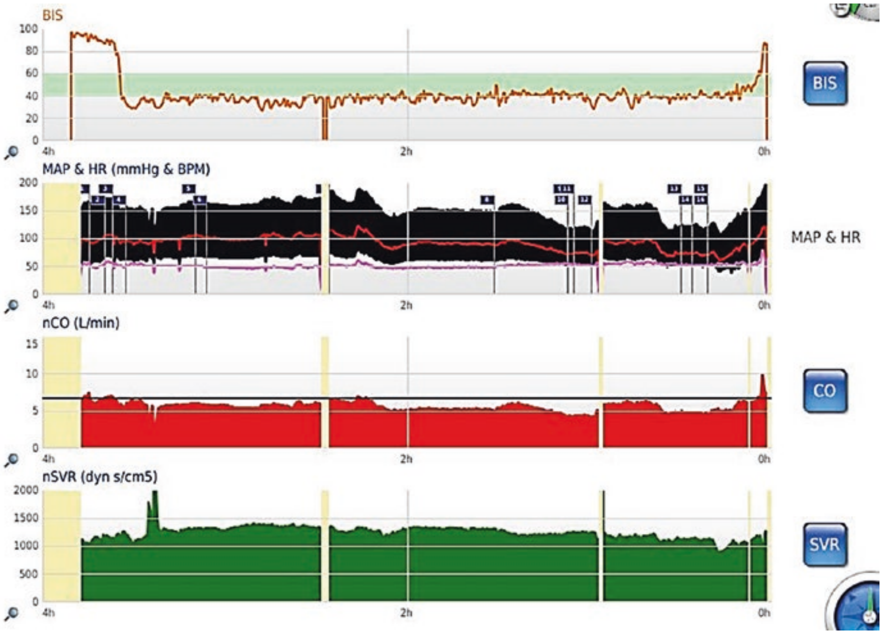

Fig. 24.12 Intra-operative trace of a patient undergoing a distal bypass showing the bi-spectral index (BIS), heart rate (HR), mean arterial pressure (MAP), cardiac output (CO) and systemic vascular resistance (SVR). (Courtesy of Dr. David Green, Consultant Vascular Anaesthetist, King's College Hospital, London, UK)

operative haemodynamic monitoring was used to maintain the nominal cardiac output and oxygen delivery throughout the surgery to within 10% of the pre-induction value (Fig. 24.12) so as to minimise build-up of oxygen debt which is a predictor of morbidity and mortality. Thirty-day mortality rate was only 0.8%, whereas, the V-POSSUM scoring indicated a predicted mortality of 9%. Similarly, the amputation rate was less than 2% at one year. Only 8% of patients were admitted to a high dependency unit postoperatively. The authors concluded that using this multimodal intra-operative monitoring with the specific aim of limiting build-up of oxygen debt had a positive impact on this group of high risk patients.

Figure 24.12 demonstrates the intra-operative monitoring trace of a patient undergoing a distal bypass. The bispectral index (BIS) trace at the top of the graph emphasises the importance of maintaining an adequate depth of anaesthesia. This sustains the blood pressure, as seen in the second trace and even more importantly cardiac output in the third trace. The horizontal black line indicates the starting cardiac output prior to induction of anaesthesia in the awake elective patient and demonstrates that the cardiac output has been maintained pretty well throughout the operation. This conserves oxygen delivery provided the haemoglobin concentration is also maintained and thus virtually eliminates build-up of oxygen debt and the necessity to repay this post operatively, a difficult task for these high-risk very frail patients.

These parameters are also maintained without excessive infusion of intravenous fluids which would tend to overload the patients and increase the risk of pulmonary oedema. The systemic vascular resistance (SVR) trace at the bottom of the graph in green indicates that there are no major changes in systemic vascular resistance which might cause problems in the blood supply to the ischaemic area of the limb.

24.8 Hybrid Revascularisation

Complex patients with CLI, especially treated in redo cases with limited venous conduit and poor distal run-off, may not be suitable for either distal bypass surgery or angioplasty alone. Some primary cases are also very complex for one modality of treatment only. Performing a pedal bypass from the common femoral artery down to the foot level is very challenging and crossing several joints that could cause mechanical failure of these grafts. Hybrid revascularisation involves the timely use of angioplasty of the inflow arteries followed by bypass surgery, or bypass surgery followed by distal outflow angioplasty to achieve straight-line flow to the ischaemic area. In few patients both inflow and outflow angioplasty is required before and after bypass surgery. The rational is the ability to treat multilevel extensive disease, by reducing the length of graft and by crossing fewer joints and hence achieving better outcome.

Angioplasty of the inflow arteries (stage I angioplasty) is performed to allow the proximal anastomosis to be taken from the most patent artery distally. This is followed by a bypass to the patent crural or pedal artery (stage II bypass). The distal run-off arteries could be treated if required by an angioplasty through the bypass graft (stage III angioplasty) to allow good blood flow to the pedal arterial arch (Figs. 24.13, 24.14, 24.15, 24.16, 24.17, 24.18, 24.19, 24.20, and 24.21).

This hybrid technique can achieve successful revascularisation in patients who otherwise would have been doomed to major amputation as they are labelled

Fig. 24.13 Intra-operative hybrid retrograde angioplasty of the popliteal and superficial femoral arteries with synchronous posterior tibial bypass at the ankle level

Fig. 24.14 Antegrade DSA demonstrating occlusion of the superficial femoral artery (arrow)

"no-option" for treatment CLI. This "no-option" for treatment is defined as CLI with no suitable treatment available using either revascularisation modalities. This is obviously a very subjective definition that will vary significantly between one surgeon or department to another.

Dosluoglu et al, have published a large series of 654 patients undergoing 770 procedures of which 67% of the cases had CLI [12]. The revascularisation procedures included 29% open bypass (226 cases), 57% endovascular (436 cases) and 14% (108 cases) hybrid procedures of both endovascular and surgical bypass. The study showed a patency rate similar between three groups, as well as, overall survival. However, the limb salvage in CLI was better in the hybrid group although this group had increased morbidity and mortality rates which was due to the higher risk patients in this group.

Fig. 24.15 DSA demonstrating reconstitution of the popliteal artery (arrow) above the knee level

24.9 Graft Surveillance Program

Postoperative bypass graft surveillance program using regular duplex scanning to detect graft abnormalities that could threaten blood flow and graft patency has been implemented for many years by different clinicians. The program's cost-effectiveness has been questioned in a publication by Davies et al. in a randomized controlled study published in 2005 [13]. In this study, patients were randomized either to duplex surveillance program or clinical examination only. The study showed that programed surveillance with duplex scanning did not demonstrate any additional benefit in terms of limb salvage rates for patients undergoing vein bypass graft operations compared to clinical follow-up only, but it incurred a £495 additional cost.

The chapter authors run a very strict duplex surveillance program for all patients undergoing bypass surgery. The majority are non-claudicant diabetic patients with

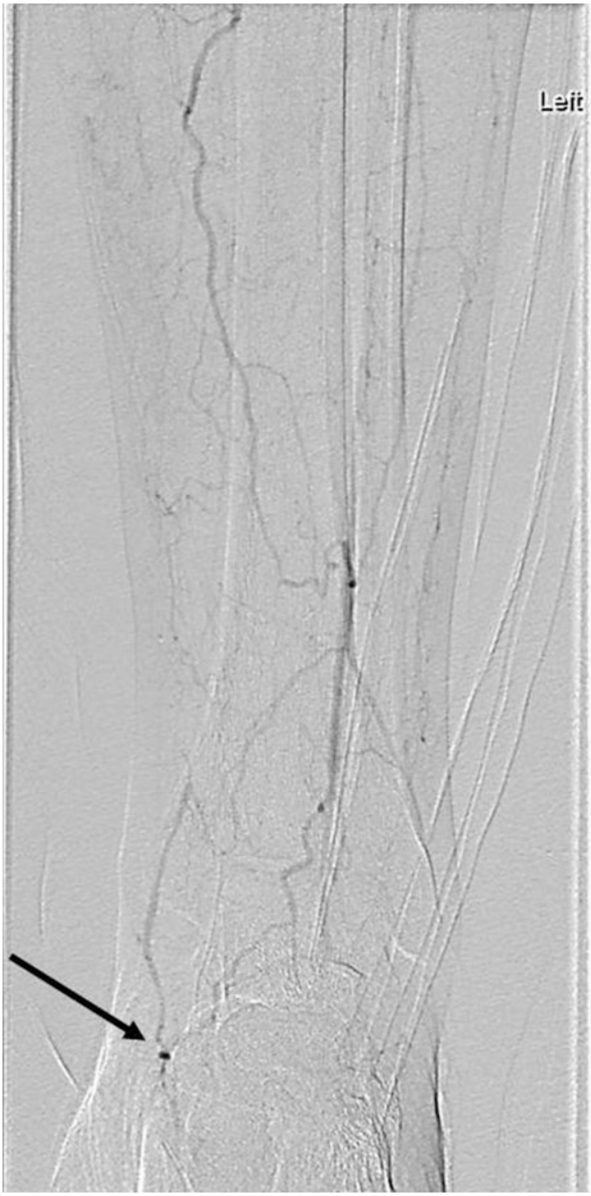

Fig. 24.16 DSA demonstrating a diseased but patent posterior tibial artery at the ankle level (arrow)

CLI and significant peripheral neuropathy. Hence, clinical assessment only is not reliable to assess them for recurring critical ischaemia. These patients can present acutely with recurrent CLI and occluded graft without clinical warning. All patients undergo a duplex scan at one week, then three monthly thereafter. Due to financial constraints, the program runs for one year only. However, if a bypass graft requires

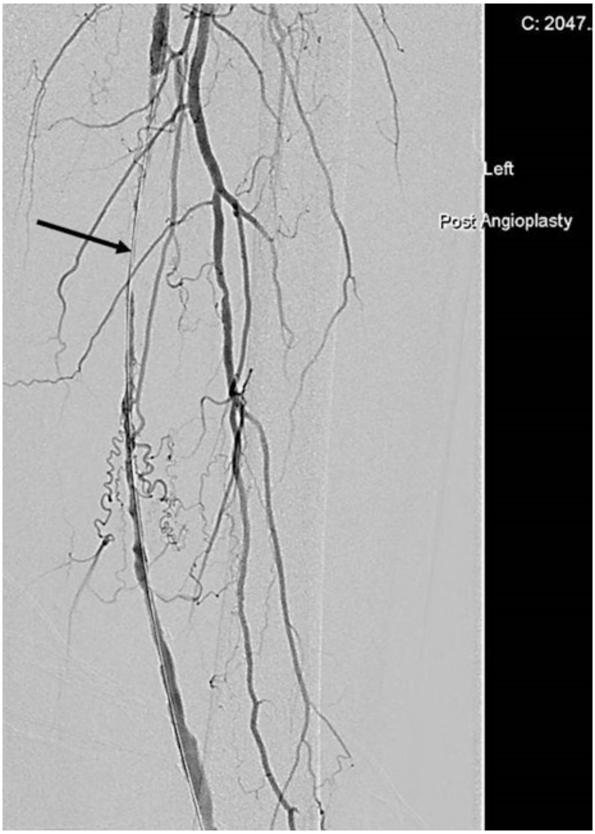

Fig. 24.17 DSA demonstrating a guide wire (arrow) passed through the occlusion in the SFA down to the patent popliteal artery as a stage I angioplasty of hybrid revascularisation

any surgical or radiological intervention, the program is extended for another year following each intervention.

24.10 Revascularisation in Acute Ischaemia

Acute limb ischaemia is caused by an abrupt decrease in arterial perfusion of the limb. Potential causes are progression of arterial disease, cardiac embolization, aortic dissection or embolization, graft thrombosis, thrombosis of a popliteal aneurysm or cyst, popliteal artery entrapment syndrome, trauma,hypercoagulable states and iatrogenic complications related to vascular procedures [6].

The acute ischaemic limb is recognised as a limb with severe hypoperfusion characterized by pain, pallor, pulselessness, poikilothermia (cold), paresthesiaes, and paralysis [14]. Within this presentation, there is a spectrum of symptoms. A patient with no underlying arterial occlusive disease who has an acute embolic occlusion at the femoral bifurcation can present with a profoundly ischaemic lower extremity, necessitating urgent intervention. In contrast, an acute embolic or throm-

Fig. 24.18 DSA demonstrating balloon angioplasty of the SFA

botic occlusion of a chronically diseased but somewhat partially patent artery may be associated with only minor progression of chronic symptoms and moderate deterioration in haemodynamics [15]. Also, the diabetic patient with peripheral neuropathy may not feel the severe pain of acute ischaemia compared with a patient without neuropathy.

Acute limb ischaemia is a medical emergency and must be recognized quickly. Skeletal muscle can tolerate ischaemia for roughly 4–6 hours [16]. The acutely ischaemic lower limb can be divided into three categories. Category I refers to viable

Fig. 24.19 DSA demonstrating successful SFA angioplasty and stenting

limbs that are not immediately threatened. There is no sensory loss nor muscle weakness and arterial and venous Dopplers are audible . Category II refers to threatened limbs. Category IIa limbs are marginally threatened and salvageable if promptly treated. Category IIb limbs are immediately threatened limbs and require immediate revascularization if salvage is to be achieved. Category III are irreversibly damaged limbs, in which case resultant major tissue loss or permanent nerve damage is unavoidable [17].

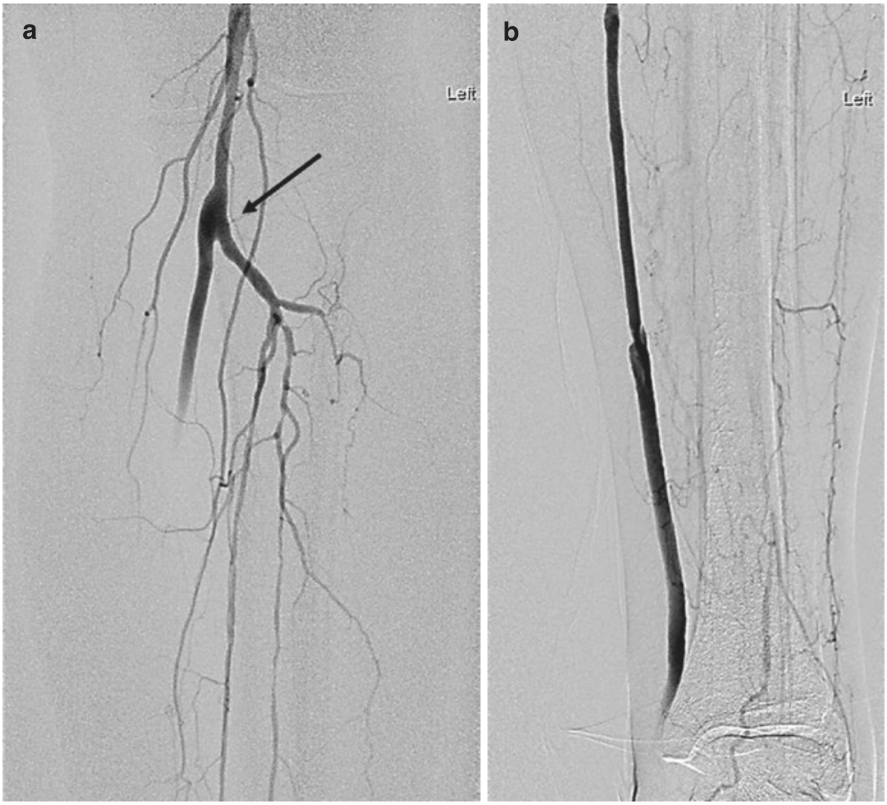

Fig. 24.20 (**a**) DSA demonstrating proximal anastomosis (arrow) of the distal bypass from the below knee popliteal artery to the posterior tibial artery at the ankle level as a stage II bypass of hybrid revascularisation. (**b**) DSA demonstrating bypass graft with slow flow at the level of the posterior tibial artery at the ankle

Once the clinical diagnosis is established, treatment with unfractionated heparin should be given, along with appropriate analgesia. For viable limbs (Category I), revascularization should be performed an on urgent basis (within 6–24 hours). For immediately threatened limbs (Category IIa and IIb), revascularization should be performed as an emergency (within 6 hours).

Although surgical or catheter-based thromboembolectomy and bypass grafting have been used in the treatment of acute ischaemia, thrombolytic therapy and percutaneous transluminal angioplasty are also treatment options. Thus revascularisation strategies include percutaneous catheter–directed thrombolytic therapy, percutaneous mechanical thrombus extraction or thrombo-aspiration (with or without thrombolytic therapy) and surgical thrombectomy, bypass and/or arterial repair [6]. In patients with severe comorbidities., endovascular therapy is often favoured, owing to decreased morbidity and mortality. Thrombus extraction, thrombo-aspiration and

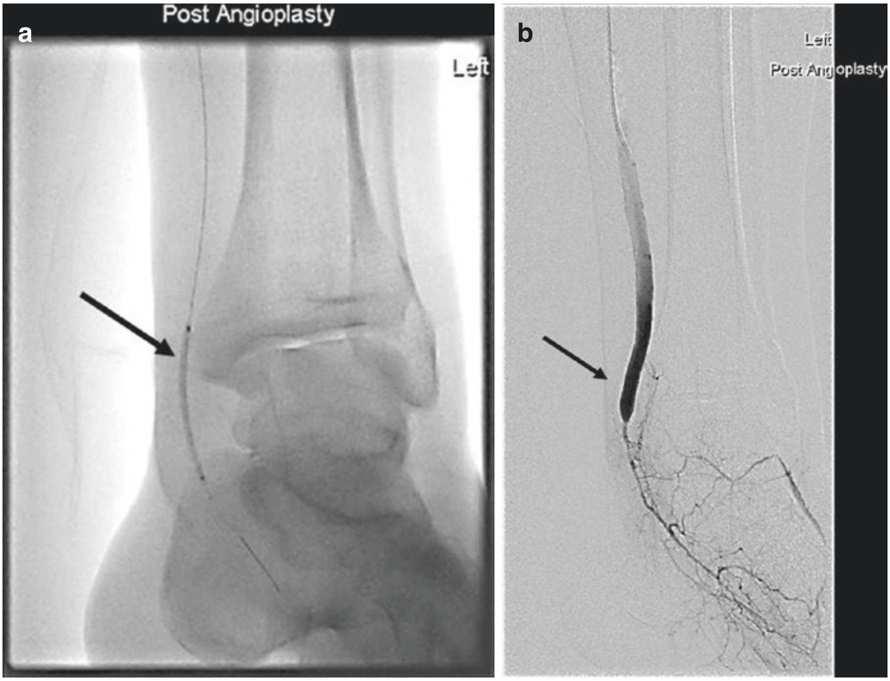

Fig. 24.21 (**a**) DSA demonstrating balloon angioplasty (arrow) of the posterior tibial artery as a stage III angioplasty of hybrid revascularisation. (**b**) DSA demonstrating successful angioplasty of the posterior tibial artery with good flow through the bypass graft (arrow) and patent posterior tibial artery into an incomplete pedal arterial arch

surgical thrombectomy are indicated in the case of neurological deficit, while catheter-directed thrombolytic therapy is more appropriate in less severe cases without neurological deficit. Catheter-directed thrombolysis can provide rapid restoration of arterial flow to a viable or marginally threatened limb, particularly in the context of recent occlusion, thrombosis of synthetic grafts, and stent thrombosis [18]. The modern concept of the combination of intra-arterial thrombolysis and catheter-based clot removal is associated with 6-month amputation rates of <10% [19]. There is no clear superiority of local thrombolysis vs. open surgery regarding 30-day mortality or limb salvage [20]. After thrombus removal, the pre-existing arterial lesion should be treated by endovascular therapy or open surgery. Lower extremity four compartment fasciotomies should be performed in patients with long-lasting ischaemia to prevent a post-reperfusion compartment syndrome.

Prolonged duration of ischemia is the most common factor in patients requiring amputation for treatment of acute limb ischaemia. Patients who have an insensate and immobile limb in the setting of prolonged ischemia (>6 to 8 hours) are unlikely to have potential for limb salvage with revascularization.

24.11 Conclusion

Open surgical treatment of infra-inguinal occlusive disease plays an important role in the management of critical ischemia (and also acute ischaemia) in diabetes. Distal and ultra-distal bypasses are well established in the treatment of the distal peripheral arterial disease in diabetes either as lone procedures or in combination with angioplasty as hybrid procedures.

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