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QUALITY IMPROVEMENT GUIDELINES FOR STENTING IN INFRAINGUINAL ARTERIAL DISEASE

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Introduction

The Superficial Femoral Artery (SFA) is a common site of involvement of peripheral atherosclerotic disease[1]. The lesions are typically long and clinical presentation is diverse. Invasive methods of treatment (percutaneous or surgical revascularisation) should be reserved for patients with lifestyle disabling claudication, ischemic rest pain or non-healing ischemic ulcers and gangrene[2].

Patients with popliteal and below-knee occlusive disease often present with limb-threatening ischemia. These patients are usually elderly and have several co-morbid conditions, such as diabetes and coronary artery disease that increase the surgical risk.

Percutaneous Tranluminal Angioplasty (PTA) is the preferred initial treatment method in patients with disabling claudication and femoropopliteal artery stenosis or occlusion as it has low mortality and morbidity and reduced hospital stay[3]. In the infrapopliteal territory, PTA is reserved for those with critical limb ischaemia, although some recent reports of PTA of tibial arteries have also included patients with severe claudication[4-6]. Only 20-30% of patients with tibial disease have what traditionally has been considered optimal anatomy for percutaneous revascularisation (i.e. a focal lesion with good run-off distally)[7,8]. The majority of patients have severe, extensive three-vessel disease. Even in these cases, percutaneous techniques are feasible and allow “straight line flow” to the foot to be established in at least one tibial vessel, which is sufficient for limb salvage in the majority of patients[9]. In favour of PTA as first line treatment is that failure rarely precludes surgical options. The surgical options of femorodistal and pedal bypasses are technically demanding and associated with 1.8-6% perioperative mortality[10,11]. The Transatlantic Intersociety Consensus recommends that when two techniques give equivalent short- and long-term benefits, the technique with the least morbidity and mortality must be used first[12].

Although PTA is an effective treatment method in infrainguinal arterial occlusive disease, there is a subgroup of patients with non-concentric, calcified and long-segment stenoses, and occlusions, in which results of PTA are poor and where stenting may have a role[13-17].

Lesion Classification and Treatment Options

The Transatlantic Intersociety Consensus (TASC) Document on Management of Peripheral Arterial Disease (PAD)[12] addresses the issue of choice between endovascular therapy and surgery for specific types of lesions in terms of complexity and length. This is based on the grounds that these parameters are important determinants of short- and long-term clinical outcomes of the revascularisation procedure. The lesions are classified into four groups (see Tables 1 and 2).
The endovascular approach is recommended for type A lesions, and bypass surgery is the treatment of choice for type D lesions. Between these two groups are types B and C lesions, which are considered amenable to either technique because there is insufficient evidence to make any firm recommendations. At present, endovascular treatment is more commonly used for type B lesions, and surgical treatment is more commonly used for type C lesions. Additionally, the presence of co-morbid conditions and operator skills are added to the decision making process in patients with type B and C lesions. Patients with femoropopliteal and / or infrapopliteal disease have the highest likelihood of coronary heart disease amongst all patients with symptomatic PAD[18-21]. As PTA is a low-risk procedure, it could be proposed as the first invasive treatment option in all such patients as it does not preclude later bypass surgery, and at the same time preserves the saphenous vein for future coronary or lower extremity distal bypass surgery[1].

The morphologic stratification of femoropopliteal and infrapopliteal lesions is shown in tables 1 and 2 respectively.

TABLE 1 - Morphologic stratification of femoropopliteal lesions

Type A	Single stenosis up to 3cm in length, not at the origin of SFA or distal popliteal artery
Type B	Single stenosis or occlusion up to 10 cm long not involving the distal popliteal artery
	Heavily calcified stenosis up to 3cm long
	Multiple lesions each less than 3 cm long (stenoses and occlusions)
	Single or multiple lesions in the absence of continuous tibial runoff to improve inflow for distal surgical bypass
Type C	Single stenosis or occlusion > 10 cm long
	Multiple stenoses or occlusions, each 3-5 cm, with or without heavy calcification
Type D	Complete common femoral artery and/or superficial femoral artery occlusion or complete popliteal and proximal trifurcation occlusion

TABLE 2 - Morphologic stratification of infrapopliteal lesions

Type A	Single stenoses shorter than 1cm in the tibial or peroneal arteries
Type B	Multiple focal stenoses of the tibial or peroneal vessels, each less than 1cm in length
	One or two focal stenoses, each less than 1cm long, at the tibial trifurcation
	Short tibial or peroneal stenosis in conjunction with femoropopliteal PTA
Type C	Stenoses 1-4 cm in length
Type D	Tibial or peroneal occlusions longer than 2 cm
	Diffusely diseased tibial or peroneal vessels

Technical Aspects of Stenting & Stent Selection

An ipsilateral antegrade approach for mid and distal femoropoliteal lesions and either a contralateral retrograde or ipsilateral retrograde transpopliteal artery approach for proximal SFA lesions may be used[22,23]. An introducer sheath of 6 or 7 Fr is typically required and long, curved sheaths can be used to place stents across the aortic bifurcation.

Current stent lengths are generally too short for extensive disease, so stents are placed across the site of residual stenosis after PTA or across the site of residual occlusion. Several stents may be placed sequentially until patency is achieved[22,24].

Stents are sized one millimetre larger than the reference vessel and either self-expanding or balloon expandable stents may be used. Balloon expandable stents should be avoided at sites where they may be compressed by external forces. Post-dilatation of the deployed stent to imbed the metal struts into the vessel wall is important for all stent designs.

Balloon-expandable stainless steel stents maintain their radial strength and shorten minimally with implantation, allowing for precise placement[2]. However, there is a risk of external compression at the adductor canal[25]. Balloon-expandable tantalum stents are more flexible and possibly more resilient to compression[24,26] but they shorten by about 10% on full expansion[2]. It is postulated that a balloon-expandable stent may cause less sustained stress to the vessel wall than a self-expandable stent[27].

Wallstent (Meditech, Boston Scientific, Boston, MA) was the first self-expanding stent used in the femoropopliteal region. It is made from a cobalt-based alloy, is highly flexible and available in long lengths, allowing a single stent to cover long, diffuse disease[28-32]. Disadvantages include foreshortening during its deployment, making precise placement more difficult and suboptimal vessel wall apposition.

Self-expanding nitinol stents have several favourable characteristics for use in the femoropopliteal artery. Radial expansion occurs with stent warming in the artery, and because of the 10- to 20-fold increase in “spring-like” behaviour of nitinol compared with traditional stainless steel stents, the stent achieves its nominal diameter once deployed with no significant foreshortening[33].

Another important advantage of nitinol stents is their resistance to external deformation which allows for their placement in areas of flexion (i.e. distal SFA and popliteal artery). Finally, nitinol is more stable and less prone to corrosion than stainless steel. It is less prone to strain related fatigue and does not cause the MRI susceptibility artifact of stainless steel.

The Problem of Stent Restenosis

Intimal hyperplasia (IH) is a major limitation of stenting. It contributes to a high rate of restenosis, especially in diffuse long segment stenoses or occlusions or when multiple stents are implanted[2,34]. Vascular injury after intraluminal dilatation causes a cascade of complex events, which are not yet fully understood. The more pronounced IH after stent placement compared to PTA alone is most likely due to constant arterial wall pressure by the stent; it is known from previous studies that increasing degrees of IH are closely correlated with increased severity of vessel injury, especially if the endothelium and internal elastic lamina are violated[35,36]. It is difficult to correlate geometric configuration of the stent with the degree of stent induced arterial overexpansion. However, it seems that stent design and stent surface pattern play a significant role in thrombus adhesion, which affects the magnitude of IH[22,37]. Animal studies have shown that slow flow in the stented area encourages deposition of larger amounts of thrombus followed by more IH[38,39]. As this layer of surface thrombus tends to reduce the lumen more markedly in small arteries, Palmaz suggested that the metal surface in stents intended for use in smaller caliber arteries must be kept as small as possible by improvements in the mesh design[40]. Sapoval et al found that IH and restenosis was more prominent in stented human SFAs of diameters less than 5mm than arteries 5mm or greater[31]. Another study found that stent restenosis rises from 4% in the proximal SFA to 10% in its mid segment and to greater than 18% in the distal SFA[34].

The polymer cover of stent-grafts can potentially reduce tissue ingrowth at the treatment site and thereby improve patency. Pore size of the graft material affects the healing process: a pore size of 60-90 µm was claimed to be optimal for the promotion of graft healing[41]. The role of Dacron and PTFE-covered stent-grafts has been explored in the femoropopliteal artery[42,43].

Inhibition of IH by local pharmacological interventions is also a concept under investigation. Use of stents as drug carrier systems potentially achieves high local drug concentrations over a longer period of time without systemic toxicity. A self-expanding nitinol stent (SMART Nitinol Self-expanding Stent, Cordis) coated with a polymer impregnated with Sirolimus (rapamycin) - a natural macrocyclic, lipophilic lactone with immunosuppressive antibiotic activity - is the first drug-eluting stent to be studied in femoral arterial occlusive disease (SIROCCO study)[44].

Endovascular brachytherapy (EB) is another technology being investigated to reduce restenosis. Adventitial labelling and immunostaining have suggested inhibition of smooth muscle cell proliferation in the adventitia and favourable effects on vessel remodelling as mechanisms by which radiation reduces arterial lumen restenosis[45]. The radiation may either be gamma radiation which has to be delivered by a high dose remote afterloader or beta radiation by the use of radioactive stents. Radioactive 32P-stents have so far only been studied in the coronary arteries; restenosis at the edges of the stent without visible intraluminal stenosis (the candy-wrapper phenomenon) represents a significant drawback of these devices and it is attributed to balloon injury and the lower radiation dose at the edge of the stent[46,47].

The Results of Femoropopliteal Stenting compared with PTA

There are several factors determining long-term outcomes of femoropopliteal PTA. A Cox stepwise multiple regression model in three of the studies[14-16], showed the following variables to be associated with a favourable outcome: claudication; non-diabetic patients; proximally located short lesions; stenoses; good distal run-off; lack of residual stenoses on the post-PTA angiogram; and improvement in the ABI by >0.1. The most consistent and important determinant of long-term clinical success among studies for femoropoliteal PTA is the status of the runoff circulation below the knee.

The primary patency rates for femoropopliteal PTA range from 47-86% at 1 year, 42-60% at 3 years, and 41-58% at 5 years[13-17,48-50].

The primary patency rates for femoropopliteal stenting range from 22-86% at 1 year, and 18-72% at 3 years[2,24,25,28-32,34,51-54]. The results are wider ranging but otherwise similar to those of PTA. Lammer assessed the weighted average of published long-term patency rates after stenting of femoropoliteal artery stenoses and occlusions in 585 patients (600 limbs, 80% claudicants) and found this to be 67% and 58% at 1 year and 3 years, respectively[22].

There are relatively few randomised studies comparing PTA with stenting in the femoropopliteal artery. Cejna et al[55] randomised 154 occlusions up to 5cm in length to PTA (n=77) or PTA plus Palmaz stenting (n=77). The initial technical success was better with stenting (84% for PTA vs. 99% for stenting) but long-term results show no significant difference compared with PTA (cumulative primary patency rates at 12 and 24 months were 64% and 53% respectively for PTA vs. 63% and 58% respectively for stenting). Another two, small randomised studies[56,57] showed no significant difference in primary or secondary patency rates between PTA and stenting using the Palmaz stent. Do et al performed a comparative, non-randomised study of PTA and Wallstent. Primary 1-year patency rates based on clinical status and ABI were not significantly different between PTA and stenting (65% vs. 59% respectively)[30]. No difference in stent-related restenosis or occlusion among the current, commercially available bare stents has been demonstrated.

A recent prospective study using the Haemobahn stent graft for long segment (mean 10.9cm) femoropopliteal disease showed a primary patency rate for both stenoses and occlusions of 78.4% and 74.1% at 12 and 24 months, respectively[43]. Primary assisted patency was 82.4% at 12 months and 80.3% at 24 months. Secondary patency rates for 12 and 24 months were 88.3% and 83.2% respectively. Interestingly, all cases of reocclusion were associated with plaque progression and IH formation in the native artery adjacent to the stent-graft while IH inside the stent-graft was not detected in any of the cases. All patients had a minimum of two patent calf vessels. A prospective phase -1 multicentre trial reported 12-month primary and secondary patency rates of 78.7% +- 4.7 and 93.4%+-2.9 respectively in long femoropopliteal lesions[58].

The trials of drug eluting stents in the femoropopliteal artery are still in their early stages. Duda et al recently reported the 18 month results of the SIROCCO trial which has shown no restenosis in the slow Sirolimus (rapamycin) eluting stent group and restenosis rates of 33% and 30% in the rapid drug eluting stent group and uncoated stent group respectively[59]. Other eluting agents such as paclitaxel and dexamethasone may also prove to be beneficial.

The role of brachytherapy and radioactive stents is being more extensively investigated in the coronary circulation than the peripheral arterial system and very few large trials have been reported. The Vienna 04 Trial[60] evaluated brachytherapy with an Iridium-192 source delivered by a high-dose remote afterloader after peripheral stenting in 33 patients with long-segment (mean length 17 cm) obstructive lesions. Only 12% of arteries had in-stent restenosis caused by IH but there was a high incidence (21%) of thrombotic occlusions, occurring between 3.5 and 6 months after the intervention requiring treatment by thrombolysis. This may be avoidable with administration of antiplatelet agents such as clopidogrel.

Results of Infrapopliteal Stenting compared with PTA

Infrapopliteal PTA is currently reserved for patients suffering from critical limb ischemia. Most of these are elderly with multiple co-morbidities and clinical success is more important than long-term angiographic patency, because once healing has occurred, collateral flow may be sufficient to preserve tissue integrity if there is no further injury[61].

Primary patency rates for PTA in crural vessels range between 40% and 81% at one year[62-64] and can be up to 78% at 2 years[65]. However, the limb salvage rate is higher at between 77% and 89% at one year[62-66]. Predictive factors which lower the limb salvage rate are the presence of diabetes and renal failure[62,67].

The only published data regarding infrapopliteal stenting comes from Rand et al[68] who commenced a prospective, randomised, multicentre trial to compare the Carbofilm coated stents (Carbostent, coronary stent system, Sorin) with PTA in 34 patients with high grade infrapopliteal artery stenoses . Preliminary results show a 3-month patency rate of 75% for Carbostent versus 73.7% for PTA and a 6-month patency rate of 66.7% for Carbostent versus 57.3% for PTA, respectively.

Complications of Infrainguinal Stenting

Major complications are those resulting in an unplanned increase in the level of care, prolonged hospitalisation, permanent sequelae or death. The weighted average of major complications for femoropopliteal stenting versus PTA are 7.3% (0-17%) versus 4.3% (2.4-6.3%)[3,13-17,24,28-32,34,48-49,52-54,69]. These are most commonly due to puncture site problems i.e. haematomas and pseudoaneurysms and thromboembolic occlusions.

Full-dose anticoagulation for patients with infrainguinal stents and stent-grafts is recommended to prevent acute thrombosis of the stented segment which can occur in up to 25% of cases within the first month of treatment[28,42,70]. Heparin in a dose of 3000-5000 units is usually given intra-arterially once the introducer sheath has been placed. Evidence from coronary circulation supports the application of an anticoagulation regime of low-molecular-weight heparin for 2-14 days, and a combination of acetylsalicylic acid (50-350 mg daily) with clopidogrel (300mg starting dose followed by 75 mg daily)[71-74]. However the more frequent use of anticoagulation and anti-platelet regimes during and after stent placement in the infrainguinal vessels will predispose to more puncture site complications[12]. White et al[53] has shown that for short lesion stenting, long-term anticoagulation may not be necessary.

Post-implantation syndrome with fever and local pain complicates Eptfe-covered stent-grafts in up to 5.8%[43] and Dacron-covered stent-grafts in up to 40% of patients[42].
Stent-related infection is a rare but serious complication of endovascular procedures[75-77]. Predisposing factors include prolonged (>24 hours) or repeated catheterisation[78-80]. Use of a sterile technique is mandatory but there is no consensus or evidence to advise routine use of prophylactic antibiotics.

Recommendations for Infra-Inguinal Stenting

1. There is currently insufficient evidence to recommend stenting in the femoropopliteal or tibial arteries as a primary approach to the treatment of symptoms of peripheral vascular disease in the infra-inguinal circulation.

2. There is insufficient evidence to support the use of stents in post PTA restenosis.

3. Stents are indicated when there is a suboptimal result following PTA due to elastic recoil of the artery or haemodynamically significant dissections, which fail to respond to prolonged balloon inflation (2-5 min) and threaten to cause arterial occlusion.

4. The choice of stent may depend on the site and length of disease but otherwise there is no evidence to support the use of a particular stent design and as yet, there is insufficient evidence to justify routine use of covered or coated stents.

5. There is no consensus and insufficient evidence to provide advice on the routine use of prophylactic antibiotics.

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