

Guidelines for Stenting in Infrainguinal Arterial Disease

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Key words: Angioplasty—Stents—Femoropopliteal—Tibioperoneal—Artery—Restenosis

Background

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 revascularization) 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. They are usually elderly and have several comorbid conditions, such as diabetes and coronary artery disease, that increase the surgical risk.

Percutaneous transluminal angioplasty (PTA) is the preferred initial treatment for 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 ischemia, 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 revascularization (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 favor 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 benefit, 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 nonconcentric, 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 outcome of the revascularization 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 in 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 in type B lesions, and surgical treatment is more commonly used in type C lesions. Additionally, the presence of comorbid conditions and operator skills are added to the decision-making process in patients with types B and C lesions. Patients with femoropopliteal and / or infrapopliteal disease have the highest likelihood of coronary heart disease among 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].

Table 1. Morphologic stratification of femoropopliteal lesions

Type A	Single stenosis up to 3 cm long, 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 3 cm long Multiple lesions each less than 3 cm long (stenoses and occlusions)
Type C	Single or multiple lesions in the absence of continuous tibial run-off to improve inflow for distal surgical bypass 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 1 cm in the tibial or peroneal arteries
Type B	Multiple focal stenoses of the tibial or peroneal vessels, each less than 1 cm long One or two focal stenoses, each less than 1 cm long, at the tibial trifurcation Short tibial or peroneal stenosis in conjunction with femoropopliteal PTA
Type C	Stenoses 1–4 cm long Occlusions 1–2 cm long of the tibial or peroneal vessels Extensive stenoses of the tibial trifurcation
Type D	Tibial or peroneal occlusions longer than 2 cm Diffusely diseased tibial or peroneal vessels.

Technical Aspects of Stenting and Stent Selection

An ipsilateral antegrade approach for mid and distal femoropopliteal lesions and either a contralateral retrograde or ipsilateral retrograde transpopliteal artery approach for proximal SFA lesions may be used [22, 23]. A 6 or 7 Fr introducer sheath 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]. Stent sizes are 1 ml 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 and 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 favorable 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” behavior of nitinol compared to 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 on 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. [31] found that IH and restenosis was more prominent in stented human SFAs of less than 5 mm diameter than arteries 5 mm 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 in-growth 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 promotion of graft healing [41]. The role of Dacron and PTFE-covered stent-grafts has been explored in the femoropopliteal artery [42–50].

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 [51].

Endovascular brachytherapy (EB) is another technology being investigated to reduce restenosis. Adventitial labeling and immunostaining have suggested inhibition of smooth muscle cell proliferation in the adventitia and favorable effects on vessel remodeling as mechanisms by which radiation reduces arterial lumen restenosis [52]. 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 ^{32}P -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 [53, 54].

Results of Femoropopliteal Stenting Compared with PTA

There are several factors determining long-term outcome 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 favorable 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 femoropopliteal PTA is the status of the runoff circulation below the knee. Recurrent stenosis after prior femoropopliteal balloon angioplasty seems to be an independent risk factor for restenosis [55].

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, 56–58]. The primary patency rates for femoropopliteal stenting range from 22–86% at 1 year, and 18–76% at 3 years (2, 24, 25, 28–32, 34, 59–62). The results are wider ranging but otherwise similar to those of PTA. Lammer [22] assessed the weighted average of published long-term patency rates after stenting of femoropopliteal artery stenoses and occlusions in 585 patients (600 limbs, 80% claudicants) and found this to be 67% and 58% at 1 and 3 years, respectively.

There are relatively few randomized studies comparing PTA with stenting in the femoropopliteal artery. Cejna et al. [63] randomized 154 occlusions up to 5 cm 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 showed 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 randomized studies [64, 65] showed no significant difference in primary or secondary patency rates between PTA and stenting using the Palmaz stent. Do et al. [30] performed a comparative, non-randomized study of PTA and Wallstent and found that primary 1-year patency rates based on clinical status and ABI were not significantly different between PTA and stenting (65% vs 59%, respectively). However, in patients with recurrent femoropopliteal lesions elective stenting performs better than repeated PTA according to a recent prospective nonrandomized study with a large sample size, which reported a 12-month patency of 52% after stenting versus 33% after PTA of recurrent lesions [55]. No difference in stent-related restenosis or occlusion among the current, commercially available bare stents has been demonstrated.

Stent-graft patency is at least partially dependent on the type of graft material used and device design. Dacron-covered stent-grafts implanted in the femoropopliteal artery are associated with fever and local pain, known as the “postimplantation syndrome.” The patency rates of Dacron-covered stent grafts are as low as 23% at 1 year due to high rates of early thrombosis and high early and late rates of restenosis at the edge of the device, thus making this type of stent-graft unsuitable for the treatment of femoropopliteal arterial occlusive disease [42].

On the other hand, ePTFE covered stent-grafts have shown more promising patency rates. A variety of studies in long (>10 cm) femoro-popliteal disease have reported 1 year primary and secondary patency rates ranging from 40–79% and 83–93%, respectively [43–49]. In one of the latest prospective studies, Jathke et al. [43] reported that reocclusion with this type of stent-graft was associated with plaque progression and IH formation in the native artery immediately adjacent to the stent-graft, and IH inside the stent graft was not detected in any of the cases. The Hemobahn ePTFE endoprosthesis is also the only device to be compared with PTA alone in a prospective randomized study in relatively long (mean length 7 cm) femoropopliteal arterial disease. Despite the small number of patients enrolled in this study, at 6-month follow-up with duplex, a 93% primary patency was reported for the group treated with stent-grafts versus 42% for the angioplasty group; at 2-years the difference was even more striking: 87% versus 25%, respectively [50].

The trials of drug-eluting stents in the femoropopliteal artery are still in their early stages. Preliminary reports suggested an advantage of the slow Sirolimus (rapamycin)

eluting stent (SES) group at 18 months [66], however, this trend disappeared at 24-month follow-up and there was no difference in restenosis rate in the two types of drug-eluting stents and bare-stent groups.

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 [67] 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 that required 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 comorbidities, 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 [68].

Primary patency rates for PTA in crural vessels range between 40% and 81% at one year [69–71] and can be up to 78% at 2 years [72]. However, the limb salvage rate is higher at between 77% and 89% at one year [69–73]. Predictive factors that lower the limb salvage rate are the presence of diabetes and renal failure [69, 74].

The only published data regarding infrapopliteal stenting comes from Rand et al. [75] who commenced a prospective, randomized, multicenter trial to compare the Carbofilm-coated stents (Carbostent, coronary stent system, Sorin) with PTA in 32 patients with high-grade infrapopliteal artery stenoses up to 3 cm in length. The 6-month patency rate for the PTA group was 51.2% versus 81.2% for the Carbostent group. The 12-month patency rate for the stented group was unchanged at 81.2%.

Complications of Infringuinal Stenting

Major complications are those resulting in unplanned increase in the level of care, prolonged hospitalization, 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, 56, 57, 60–62, 76]. These are most commonly due to puncture site problems, i.e., hematomas and pseudoaneurysms and thromboembolic occlusions.

Full-dose anticoagulation for patients with infringuinal 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, 77]. Heparin in a dose of 3000–5000 units is usually given intraarterially 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 (300 mg starting dose followed by 75 mg daily) [78–81]. However, the more frequent use of anticoagulation and anti-platelet regimes during and after stent placement in the infringuinal vessels will predispose to more puncture site complications [12]. White et al. [61] have shown that for short lesion stenting, long-term anticoagulation may not be necessary.

Postimplantation syndrome with fever and local pain complicates PTFE-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 [82–84]. Predisposing factors include prolonged (>24 hours) or repeated catheterization [85–87]. 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 hemodynamically significant dissections that 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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