Endovascular Femoropopliteal Interventions: Evolving Devices

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Introduction

Peripheral arterial disease (PAD) is caused by systemic atherosclerosis and is strongly associated with cardiovascular and cerebrovascular disease. Important risk factors for PAD include age > 70, history of smoking, diabetes, hypertension, and hyperlipidemia, all known markers for cardiovascular disease [1]. While medical management in conjunction with an exercise regimen is the recommended initial approach, according to the American Heart Association/American College of Cardiology guidelines for the management of PAD, patients with lifestyle-compromising pain, nonhealing ulcers, or critical limb ischemia require invasive endovascular or surgical intervention [2]. There is some disagreement about the appropriate management of femoral-popliteal lesions among various groups of interventionalists, but the Inter-Society Consensus for the Management of PAD (TASC) provides a general approach. Because of the rapidly changing technology, for many interventionalists the endovascular option is the first line of therapy, despite very poor evidence for many of the products currently on the market.

According to the 2007 TASC II updated guidelines, TASC A and B lesions requiring intervention should be managed with endovascular intervention. TASC C lesions in patients who can tolerate open surgery should receive open bypass, but many patients will have comorbid conditions that limit surgical options, and in that case endoluminal intervention is appropriate [3]. These recommendations are supported with only level C evidence, meaning no randomized or well-conducted clinical trials have been performed and the evidence is based on solely expert opinion. According to the BASIL trial, the only multi-center randomized controlled trial (RCT) of angioplasty versus open surgical bypass for infrainguinal disease, the angioplasty first strategy was associated with similar amputation-free survival and decreased costs [4]. This, however, did not take into account the early endovascular failure rate of 20 % that required re-intervention. It is estimated that the reason endovascular interventions looked so good was that patients often go on to have a surgical bypass later, and so probably overall surgical results are better in spite of short-term drawbacks. In practice, interventions have moved far beyond the scope of the consensus guidelines (which in 2000 addressed only percutaneous transluminal angioplasty (PTA), bare metal stents, and open surgical bypass). Since first being introduced, widespread development of new technologies for peripheral endovascular interventions has occurred. This is true not only for the therapeutic device, but also for the platform that provides access to and the ability to treat the pathology. Flexible robotics offers the ability to reliably provide a stable platform through which one can deliver a variety of therapeutic devices. This has been demonstrated in a recent first-in-man study in which the technical success rate was 100 % for the navigation of 20 iliofemoral lesions and 95 % for successful delivery of therapeutic interventions (the only failure occurring when a surgeon with no previous endovascular experience was unable to cross the lesion). Safety of the device was demonstrated with no peri-procedural complications (Duran et al., article in press). In this chapter, we describe the pathophysiology of femoral atherosclerosis and restenosis, followed by an overview of current endovascular therapies for femoral-popliteal atherosclerotic disease and the role of inflammation in the durability of endovascular interventions.

Pathophysiology of PAD

PAD results from atherosclerosis of the aortoiliac and lower extremity vasculature. It occurs concurrently with atherosclerotic processes throughout the body, including the extracerebral and coronary vasculature, and is associated with the same risk factors. Atherosclerosis develops slowly over time

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and in the majority of individuals will not become symptomatic. The initial step in the development of atherosclerotic plaques involves diffuse initimal thickening and formation of a fatty streak of lipid-filled macrophages and smooth muscle cells (SMCs). These lesions are not pathologic, but retain the potential to develop into fibrous plaques that contain lipids and fibrous connective tissues. These fibrous plaques become calcified and can rupture, erode into the endothelium, or hemorrhage within the plaque, all processes that are associated with clinical sequelae. Ultimately, the plaques develop a necrotic core that is surrounded by inflammatory cells and SMCs, which are prone to rupture, intraplaque hemorrhage, and occlusion [5]. Not all plaques are created equal, however, and atheromatous lesions are known to differ by vascular bed [6]. Examination of plaque morphology demonstrates that fibrous cap atheromas predominate in the carotid arteries, while fibrocalcific plaques form in the femoral arteries [7]. The implication is that lesions with higher levels of inflammatory cells, while unstable, are less prone to recurrent stenosis, while more stable plaques are highly calcified and prone to restenosis. However, because the time between the initial insult of lower extremity ischemia and intervention is prolonged compared to cerebral ischemia resulting from carotid disease, it is unclear if these differing plaque characteristics represent differing linear progressions of disease.

Restenosis Following Infrainguinal Intervention

Rates of recurrent stenosis following endovascular interventions are significantly different in the femoral system as compared to the carotid and coronary arteries. Histopathologic evaluation of atherosclerotic plaques suggests that following intervention; stable plaques are actually more susceptible to restenosis [8]. In the carotid arteries, unstable, inflammatory plaques with high levels of macrophages and lipid cores were associated with lower restenosis rates, presumably related to extensive remodeling of the tissue induced by the inflammatory cells [9]. As opposed to the extensive remodeling induced by inflammatory mediators, which appears to result in positive remodeling in the carotid system, the fibrotic characteristics of femoral plaques lead to constrictive remodeling and progressive vessel occlusion [10], and constrictive remodeling may be the primary driver for luminal compromise in patients with recurrent disease [11]. Understanding this process may ultimately guide the choice of intervention or device.

Percutaneous Transluminal Angioplasty

The primary endovascular intervention for treatment of flow-limiting femoropopliteal atherosclerosis is balloon angioplasty or PTA. According to a 2008 Cochrane Database review, mortality and amputation rates did not differ significantly between bypass surgery and PTA. Primary patency was significantly higher in the bypass group after 12 months (OR 1.6) but not after 4 years ($P = 0.14$) [12]. The outcomes for PTA, however, depend on lesion characteristics, and the best results are seen in the group with short, focal lesions [3]. A 2008 meta-analysis of PTA found a pooled estimate of success was 89.0 ± 2.2 % for immediate technical results. Results at 1–36 months were 77.4 ± 4.1 % and 48.6 ± 8.0 % for primary patency, 83.3 ± 1.4 % and 62.9 ± 11.0 % for secondary patency, 93.4 ± 2.3 % and 82.4 ± 3.4 % for limb salvage, and 98.3 ± 0.7 % and 68.4 ± 5.5 % for patient survival, respectively [13]. Outcomes following PTA depend on a number of known factors, including lesion length, presence of total occlusion, size of vessel, vessel overdilation, residual stenosis, and dissection, all parameters that influence the degree of vessel disruption and resultant inflammation following angioplasty. Following PTA, the resultant injury to the vascular intima and media leads to proliferation of vascular smooth muscle cells and induces local and systemic inflammatory responses [14–16]. Though the process has been more extensively studied in coronary interventions, the phenomenon has been shown to occur in peripheral vasculature as well [17]. Sheer stress during PTA induces a vascular inflammatory process in which polymorphonuclear neutrophils (PMNs) and monocytes are localized to the injured endothelium. These inflammatory mediators induce the migration of smooth muscle cells (SMC) from the medial layer of the vessel to the subendothelium. In turn, SMCs induce proliferation of extracellular matrix proteins and myofibroblasts that are responsible for neointimal hyperplasia, negative vascular remodeling, and ultimately restenosis [18].

Alternative Modalities for Angioplasty (Table 26.1)

Cryoplasty

Because of the high restenosis rates following PTA alone, alternative endovascular modalities have been developed to improve patency rates. One approach designed to limit the inflammatory response following angioplasty is endovascular cryoplasty in which cold thermal energy is delivered simultaneously inside an angioplasty balloon. Experimentally, cryotherapy induces SMC apoptosis, which would theoretically halt the inflammatory response to vessel injury during balloon angioplasty. However, a single-center experience with 86 patients failed to demonstrate improved outcomes over expected patency rates from PTA (48–37 % at 12–24 months, respectively) [19]. Schmidt published a series in which 109 infrapopliteal lesions (the most challenging of the lower extremity lesions) were treated and reported

Table 26.1 Outcomes following traditional PTA and alternative angioplasty approaches for femoropopliteal lesions

Intervention	Study type	Technical success (%)	Amputation free (%)	Survival (%)	Primary patency (%)	Secondary patency (%)	Time to f/u (months)
PTA	Meta-analysis	95.8	93.4	98.3	77.4	83.3	1
			82.4	68.4	48.6	62.9	36
	RCT (BASIL)	80	NR	78	50	NR	12
Cryoplasty	Prospective	88	NR	NR	47	NR	12
					38		24
	RCT (COLD)	35	NR	NR	79	NR	9
CBA	Prospective	91	100	NR	88	NR	3
	RCT	NR	93	100	38	NR	6
Subintimal angioplasty	Prospective	87	75	99	45	76	12
					25	50	36
Drug-coated balloon	RCT	NR	95.6	83.6	96	NR	12
					91.5		24
	Prospective	NR	96	84.6	91.7	NR	12

NR = not reported

improvement in 94 %, healing in 74 %, and a limb salvage rate of 95 % [20]. The single RCT of comparing cryotherapy to balloon angioplasty (COLD trial) demonstrated a mean patency of 79 % in the cryoplasty arm versus 67 % in the PTA arm ($P = 14$) at 9 months and a 30 % rate of stent placement for residual stenosis or dissection following cryoplasty versus 39 % in the PTA group [21]. Long-term results are pending, but at this time cryoplasty does not appear to offer significant advantages over PTA.

Cutting Balloon Angioplasty (CBA)

Cutting balloons are designed with atherotome blades that score atherosclerotic plaques. This technique treats lesions while limiting overdilation of the vessel and therefore elastic recoil as well as distal dissection. Reports on their use in the coronary, pulmonary and peripheral vasculature indicated that there is in fact a reduction in vessel trauma and elastic recoil during CBA, with a positive impact in remodeling [22–28]. Initial results of this technology in femoropopliteal lesions demonstrated high rates of technical success (93 %), limb salvage (100 %), and primary patency (88 %) [29]. However, in a RCT of CBA versus PTA in short (<10 cm) SFA stenosis, CBA yielded increased restenosis rates at 6 months (62 %) compared to PTA (38 %) [30].

Subintimal Angioplasty

The theories on the precise role of endovascular interventions in femoropopliteal chronic total occlusions are in flux. Open surgical bypass remains the de facto gold standard, but dedicated re-entry catheters designed for subintimal angioplasty have been shown to be safe and the procedure technically feasible [31]. In light of the improvements in endovascular tools for subintimal navigation and vessel re-entry, as well as high rates of morbidity and mortality following open surgery in a subset of high-risk patients, increasing numbers of threatened limbs are being treated percutaneously [32]. Scott and colleagues published their single-center experience with 506 infrainguinal occlusions. Primary patency at 12–36 months was 45 % (SE 3.0 %) and 25 % (SE 3.6 %), respectively, and secondary patency was 76 % (SE 2.6 %) and 50 % (SE 4.8 %) at 12–36 months. Patients with femorotibial occlusions and critical limb ischemia had worse outcomes. Limb salvage in patients with CLI was 75 %, and open surgical bypass was avoided in 77 % at 36 months [33]. These results indicate that in experienced hands, subintimal angioplasty is a reasonable first-line therapy for patients with infrainguinal occlusions. The aforementioned results are unlikely to be a true representation of the outcomes to be expected in the average interventional community practice, as the procedure is anecdotally plagued by being extremely operator dependent.

Stents (Table 26.2)

Disappointing long-term patency rates following PTA in the femoropopliteal segment prompted the use of stents following angioplasty. Balloon angioplasty leads to thrombus formation, recoil, intimal hyperplasia, and ultimately negative remodeling, while stents are impacted only by thrombus formation and inflammatory-mediated intimal hyperplasia [34, 35]. Additionally, stents in the muscular infrainguinal arteries are subject to stresses that result in stent fracture, which also induces intimal hyperplasia and in-stent stenosis.

In the early years of infrainguinal endovascular interventions, stainless-steel stents were deployed with disappointing results. Studies failed to demonstrate improved outcomes over angioplasty alone, and the indication for stents was

Table 26.2 Outcomes following standard and alternative stent deployment and atherectomy for femoropopliteal lesions

Intervention	Study type	Technical success (%)	Amputation free (%)	Survival (%)	Primary patency (%)	Secondary patency (%)	Time to f/u (months)
Nitinol stent	RCT (RESILIENT)	95.8	100	92.8 (30 day)	87.3	100	12
	RCT	NR	NR	95.8	66.6	NR	12
Stent-graft	RCT	100	98	92	72	83	12
					63	74	24
DES	RCT	100	NR	NR	100	NR	6
Atherectomy	Prospective	100	100	98	80	100	6

NR = not reported

limited to bail-out for residual stenosis or arterial dissection following PTA [36]. The role of primary stent placement has been revisited using nitinol stents. Second generation nitinol stents have spirally oriented interconnections, which have reduced rates of stent fracture and the resultant stenosis [37]. Recently, the RESILIENT trial demonstrated that primary deployment of self-expanding nitinol stents in moderate length femoral and popliteal lesions yielded better results than angioplasty alone [38]. Overall, studies examining the role of nitinol stents have yielded variable results, with moderate improvement in outcomes over PTA alone, and results varying significantly based on lesion specifics (TASC classification, lesions length, outflow vessel status) [39, 40].

Stent-Grafts

Efforts to overcome the challenges of percutaneous interventions in the femoropopliteal segment have led interventionalists to consider a role for covered stents. The idea is that covered stents will slow tissue in-growth and delay in-stent re-stenosis. In 2000, Lammer and colleagues established feasibility in a multicenter, international trial [41]. In 2005, ePTFE-covered stent-grafts (Viabahn, WL Gore and Associates, Flagstaff, AZ) were approved for deployment in the superficial femoral artery, and in 2007, approval was extended to a heparin-bonded Viabahn for SFA lesions. A 2007 single-center randomized study of Viabahn versus surgical bypass in 100 limbs showed that primary and secondary patency rates were comparable at 12 months [42], and in 4-year follow-up of patients randomized to surgical bypass versus stent-graft for SFA lesions, differences in primary and secondary patency rates were not statistically significant. Additionally, stent-grafts were much less likely to fracture, making them less vulnerable to failure from in-stent stenosis at the fracture site, and unlike bare-metal stents, successful outcomes were not dependent on lesion length [43]. Therefore, it is likely preferable to treat long lesions with stent-grafts, and these results indicate that stent-grafts should be considered a viable alternative to bypass in these patients.

Drug-Eluting Stents

Drug-eluting stents (DES) have been used with great success in the coronary vasculature, and their use is now well defined [44]. The utility of DES use in the infrainguinal arteries has begun to be explored. In a non-randomized, single-arm trial, everolimus-eluting stents use was found to be feasible with success rates comparable to established endovascular approaches [45]. The SIROCCO II trial randomized 57 patients to sirolimus-eluting stents versus nitinol bare metal stents for treatment of SFA disease. Despite a trend toward improved outcomes in the DES group, there were no statistically significant differences in outcomes between the two groups [46]. Given the significant cost of DES stents, currently treatment with DES cannot be recommended, although more data are on the way, which may very well influence that.

Drug-Coated Balloons

Local administration of the antiproliferative drug paclitaxel has also been found to effectively reduce rates of re-stenosis following PTA, but unlike DES, drug-coated balloons are effective in both the coronary and peripheral vessels. In a multicenter randomized trial of 154 patients with femoral or popliteal artery stenosis/occlusions, at 12 months 20 of 54 (37 %) lesions in the control group required revascularization compared with 2 of 48 (4 %) in the group treated with paclitaxel-coated balloons ($P<0.001$ vs. control); at 24 months, the re-intervention rates increased to 28 of 54 (52 %) in the control group and 7 of 48 (15 %) in the paclitaxel group [47]. These early results are promising, but require further investigation before definitive recommendations can be made. Currently, two large European studies are recruiting patients to further elucidate the role of drug-coated balloons in the treatment of peripheral vascular lesions.

Atherectomy

In contrast to the aforementioned devices, atherectomy devices aim to treat peripheral lesions through excision of an

atherosclerotic plaque using percutaneous means. The SilverHawk directional atherectomy device (EV3, Minneapolis, MN) has a highspeed carbide cutting disc that cuts ribbons of atheroma and stores the excised plaque in the nose cone of the device. In 2004, Zeller reported his initial experience in 52 patients using the SilverHawk device. Although <50 % stenosis was found in 96 % and <30 % in 78 % of patients following atherectomy, additional percutaneous procedures were performed in 58 % of the patients. The device was safe, and rates of recurrent disease were not higher in the atherectomy-only group compared to the group in which additional procedures were performed [48]. Recently, the group with the largest experience (579 infrainguinal lesions) reported on their outcomes. The primary patency at 12–18 months was 59.1–49.4 % with a limb-salvage rate of 87.9 % at 18 months for patients with critical limb ischemia and 100 % limb salvage in patients with claudication [49]. At this time, no RCTs have compared atherectomy to angioplasty and stenting in the setting of lower extremity atherosclerotic disease. In our experience, atherectomy has been marred by distal embolization, and as we recently showed, distal embolization has the ultimate of consequence, limb loss [50].

Medical Management

Endovascular interventions permit interventionalists to treat the consequences of atherosclerosis, which are an important corollary for limb salvage, wound healing, and overall quality of life. However, interventional procedures do not target the underlying disease process itself, and as illustrated above, likely intensify the inflammatory process that underlies the atherosclerotic process. Furthermore, these patients are at high risk of cardiac or cerebrovascular death due to their systemic disease, with 25 % 1-year mortality from myocardial infarction or stroke among patients with CLI [51]. As such, irrespective of the type of intervention employed in treating these patients, appropriate medical management of their systemic atherosclerotic disease is of paramount importance. This includes aggressive management of LDL cholesterol (<100 for all PAD patients, <70 for PAD with diabetes) using HMG-CoA reductase inhibitors, maintenance of blood pressure <140/90 (or 130/80 for diabetics) using beta-blockade and ACE-inhibitors, anti-platelet therapy with aspirin or clopidogrel, and smoking cessation [52].

Conclusion

Infrainguinal atherosclerosis resulting in lifestyle-altering limb ischemia is a challenging entity to treat. Formerly open surgical bypass was the only option available for restoration of flow to the extremities, but the rapid pace of technologic advances in endovascular interventions has led to a paradigm shift in disease management. While there is no silver bullet for treating these complex lesions, increasingly endovascular interventions are being utilized as a first line therapy in even the most diseased segments. Interventionalists should closely scrutinize their approach to devices as clearly not all devices and techniques are created equal. Expectations often need to be tempered as the few and relatively poor studies are generally performed in centers with vast experience. Furthermore, the key to any success in the interventional space is the understanding that we are managing the complications of an inflammatory disease and long-term success is in great part based on the continued management of the medical aspects of this disease.

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