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EVOLVING APPROACHES TO THE ILIACS, FEMORALS, POPLITEALS, AND RENALS

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EXECUTIVE SUMMARY

The prevalence of peripheral artery disease in the general population is high, but remains under-recognized and undertreated. The continuously expanding array of interventional device technologies available may eventually result in a shift of this pattern. Disease in the iliac arteries are associated with favorable early and late clinical outcomes, particularly with recent procedural and technical advances including direct stenting and the use of self-expanding stents. Disease in the femoral and popliteal (FP) arteries has proven to be more difficult to treat due to its more complex, diffuse, and typically calcified nature. High rates of restenosis and reocclusion, even with stenting, have limited the enthusiasm for endovascular therapies of FP disease, but newer stents may hold promise. The goal in renal percutaneous revascularization is to improve hypertension, attenuate renal function decline, and ameliorate cardiovascular derangements brought on by labile blood pressure. While creating mechanically patent renal arteries is technically possible, evidence of clinical benefit remains limited.

Introduction

Endovascular therapy for peripheral arterial disease (PAD) is an evolving practice. The already vast array of interventional device technologies continues to expand, and physician expertise and preference varies within a given institution and over time. As a result, treatment strategy and interventional technique may vary considerably for any given lesion in a given patient. Because of these treatment disparities, the 2000 statement from the TransAtlantic Inter-Society Consensus (TASC) Working Group presented a set of guidelines to standardize nomenclature and treatment for lesions recommended for percutaneous (Type A) and surgical (Type D) revascularization strategies (1). Firm recommendations for Type B and C lesions were not included in the guidelines due to a paucity of relevant clinical evidence. At the time of the publication of the guidelines, Type B lesions were most commonly treated with endovascular approaches, whereas Type C lesions were most commonly treated surgically. However, an increasing number of Type C lesions are successfully treated with percutaneous revascularization.

The clinical manifestations of peripheral arterial disease are myriad and are a function of the end-organ fed by the vascular distribution. While the prevalence of PAD in the general population is high, recognition and treatment of disease is often infrequent, contributing to a considerably high risk of adverse cardiovascular events, including mortality (2). Accordingly, against the background of evolving pharmacologic and endovascular therapies intended to improve clinical outcomes, there remains a need to focus public health programs on the identification and treatment of patients with PAD. In particular, disease recognition with noninvasive imaging and treatment with catheter-based revascularization strategies may improve clinical outcomes as part of a comprehensive medical program for patients with systemic atherosclerosis.

Iliac Arterial Disease

Interventional procedures in the iliac arteries are associated with favorable early and late clinical outcomes. The TASC recommendations for approaching the iliac arteries are summarized in Table 1 and Figure 1. Procedural success rates with angioplasty alone in iliac arteries exceed 90% in all major series and approach 100% with more discrete lesions (1). Limitations of balloon angioplasty, however, include abrupt vessel closure, spastic recoil, dissection, and residual translesion gradients, especially among initially occluded arteries, but these features have largely been mitigated by the use of stents. Provisional stenting was performed in a case series of 118 patients with iliac disease and the primary patency rates at 1, 2, and 4 years were 95%, 88%, and 82%, respectively (3). Primary stenting was studied in a series of 103 patients with chronic iliac occlusions (4). A procedural success rate of 98% was observed, with 2- and 4-year patency rates of 83% and 78%, respectively. A meta-analysis of six angioplasty studies (N = 1300 patients) versus eight stent studies (N = 816) in aorto-iliac disease demonstrated that immediate procedural success rates improved by stent utilization (96% vs. 91%; $p < 0.05$), mean post-procedural ankle-brachial indices (ABI) were significantly higher (0.87 vs. 0.76; $p = 0.03$), and 4-year follow-up showed a 39% relative risk reduction for failure of primary patency (5). These findings were achieved despite a trend toward longer lesions

among patients who received stents (mean lesion length 41.0 mm vs. 26.4 mm; $p = 0.1$). Complication and mortality rates were similar between the two groups.

Recent procedural and technical advances include direct stenting and the use of self-expanding stents. Findings from a study by Thalhammer et al. (6) suggest that direct stent placement without balloon predilatation may decrease the risk of peripheral embolic complications. Therefore, many operators practice this technique when lesions are morphologically favorable (focal, low degree of calcification, absence of angulation or vessel tortuosity). Self-expanding stents made of nickel-titanium alloy (nitinol) have a thermal memory property which allows them to be compressed into a low-profile housing sheath for delivery and “spring” to a predefined shape after release in the blood vessel. In the expanded state, these stents exert a constant radial pressure on the endothelial surface, and their longitudinal flexibility makes them ideally suited for implantation in areas subject to mechanical stress. In a series of 172 patients with iliac disease treated with self-expanding nitinol stents (mean lesion length 5.2 cm), 3-year patency rates exceeded 80%, similar to historical surgical patency rates (7). Thus, an endovascular approach for iliac artery disease has been shown to be suitable for the majority of lesions.

Femoropopliteal Arterial Disease

Unlike the iliac arteries, disease in the femoral and popliteal arteries is typically more complex and characterized by lengthy, diffuse involvement and extensive calcification (8). Multi-segmental lesions are common, and patients with femoropopliteal (FP) disease are also more likely to have coexisting coronary artery disease than those with isolated aorto-iliac disease (2,9). The TASC guidelines for FP disease are categorized in a similar manner as those for iliac disease (Table 2, Figure 2). Procedural success rates for the treatment of FP disease from studies performed more than a decade ago were greater than 90% for non-occlusive stenoses and approximately 85% for total occlusions with angioplasty alone (10).

High rates of restenosis and reocclusion have limited the enthusiasm for endovascular therapies for FP disease. Unlike treatment of iliac arteries, the use of stents in FP revascularization has yielded inconsistent benefit compared with balloon angioplasty alone. Predictors of favorable outcomes include the absence of diabetes, claudication prior to therapy, proximal and shorter lesions, palpable distal pulses, and improvements of ABI by greater than 0.1 (11). Nitinol stents may provide some benefit for FP revascularization, with 1-year patency rates as high as 85% in several studies. However, cost analyses of a primary stenting trial have suggested that stent use is markedly more expensive than balloon angioplasty alone (12). Furthermore, a recent screening analysis reported a high rate of stent fracture with nitinol stents in the superficial femoral artery, which was associated with a significantly greater likelihood of reduced vessel patency (13). Among 93 patients (121 treated legs) followed for a mean duration of 10.7 months, stent fracture was observed in 45 of 121 (37.2%) treated legs, or 64 of 261 (24.5%) placed stents. Of these stent fractures, 48% were characterized as minor (involvement of only one strut), 27% were moderate (involvement of more than one strut), and 25% were severe (complete separation of stent segments). Stent length appeared to impact fracture rates, with fractures occurring 13% of stents shorter than 8 cm, 42% of stents 8-16 cm, and 52% of stents

longer than 16 cm. A third of the fracture sites developed binary restenosis (> 50%) while another third developed total reocclusion.

Given the success of drug-eluting stents in the coronary arteries, recent studies have evaluated the potential of antiproliferative agents eluted from stents to reduce neointimal hyperplasia and the need for repeat revascularization following stenting in FP disease. In a recent randomized double-blind study, 59 patients with FP disease were treated with either sirolimus-eluting stents (SES) or conventional bare metal nitinol stents (BMS) (14). Approximately two-thirds of the patients enrolled had complete occlusion of the superficial femoral artery and the mean lesion length was 81.2 mm. The primary endpoint, in-stent minimal lumen diameter at 6 months determined by quantitative angiography, did not differ significantly between the two groups (4.94 mm \pm 0.69 and 4.76 mm \pm 0.54 mm for the SES and BMS groups, respectively; $p = 0.31$). Although the angiographic percent diameter stenosis tended to be lower in the arteries treated with the SES, there were no statistically significant differences in any of the angiographic variables between the treatment groups. The mean late loss was 0.38 mm \pm 0.64 mm and 0.68 mm \pm 0.97 mm for the SES and BMS groups, respectively ($p = 0.20$); angiographic binary restenosis occurred in none of the patients treated with the SES and in 7.7% of patients treated with the BMS ($p = 0.49$). Although SES may have some efficacy in reducing neointimal hyperplasia in FP disease, the finding that angiographic outcomes do not replicate those produced in the coronary arteries indicates that further research is required. Possible explanations include the dose of antiproliferative agent, drug-delivery elution rates, and/or mechanical issues related to stent design (e.g., strut fracture). The Drug-Eluting Stent IN the SFA/Femoropopliteal ArterY (DESTINY) trial evaluating paclitaxel-eluting Zilver® PTX nitinol-based stents (Cook Medical Inc.), in FP disease is ongoing.

Based on disappointing long-term patency rates and additional cost, primary stenting is presently a Class III indication according to the 2006 American College of Cardiology/American Heart Association (ACC/AHA) guidelines for the management of FP arterial disease (15). The guidelines suggest that endovascular therapy of the FP segment is best approached by using balloon angioplasty with provisional stenting for a suboptimal result (a Class IIa recommendation). However, since development of the guidelines, a study in 104 patients found that a strategy of planned stenting of the SFA using a newer nitinol-based stent was superior to provisional stenting in both angiographic and clinical outcomes at 6 and 12-month follow-up (16). As devices such as this new nitinol stent are refined and improved, further studies to assess the role of primary stenting will be needed.

Renal Arterial Disease

Renal artery stenosis (RAS) is perhaps the most common identifiable cause of hypertension, occurring in approximately 5% of all hypertensive patients and in up to 10% to 30% of hypertensive patients with evidence of atherosclerosis elsewhere or with renal dysfunction. Although the method and role of routine screening for RAS remains controversial, identification of significant ($\geq 50\%$ stenosis) disease may occur in 10% to 20% of patients with abdominal aortography performed at the time of diagnostic cardiac catheterization. The presence of RAS has been identified as an independent predictor of mortality, and long-term survival is particularly worse with increasing stenosis severity or the presence of bilateral disease (17).

The clinical rationale for renal revascularization has been to 1) improve control of hypertension, 2) attenuate the progressive decline in renal dysfunction, and/or 3) treat and stabilize cardiovascular syndromes (e.g., acute pulmonary edema) associated with labile hypertension. Given the relatively high rates of mortality, graft failure, and need for repeat revascularization with surgical bypass and endarterectomy, percutaneous angioplasty and stent treatment is the preferred revascularization method (18-20).

The technical evaluation of endovascular therapy for atherosclerotic RAS has included studies comparing percutaneous balloon angioplasty with stent implantation. In a randomized trial comparing these two techniques, both the primary technical success rate (88% vs. 57%; $p = 0.02$) and 6-month patency (75% vs. 29%; $p = 0.01$) were improved with stenting compared to angioplasty (21). Among 208 patients treated with renal artery stenting following an inadequate angioplasty result (defined as $\geq 50\%$ residual stenosis, translesional pressure gradient, or flow-limiting dissection), the 9-month restenosis rate assessed by angiography or duplex ultrasonography was 17.4% (22). Similar to outcomes following coronary stenting, the probability of restenosis appears directly related to the target vessel diameter, with restenosis rates less than 10% in arteries exceeding 6 mm in diameter (23).

Despite the pathophysiologic rationale for renal revascularization, supportive clinical evidence is limited. Regarding treatment of hypertension, for example, results have varied widely, with improvement occurring in approximately two-thirds of patients and no effect in one-quarter to one-third of patients. Among 106 hypertensive patients randomized to angioplasty vs. medical therapy alone in the DRASTIC (Dutch Renal Artery Stenosis Intervention Cooperative) trial, angioplasty was not associated with a significant benefit in blood pressure compared with anti-hypertensive therapy (24). Aside from the absence of stenting for inadequate angioplasty results, however, conclusions from this study were limited since 44% of patients crossed over at 3 months from the medical management arm to the angioplasty arm yet were analyzed according to the intention-to-treat principle. In a recent registry of hypertensive patients with RAS who were treated with stenting, the systolic/diastolic blood pressure decreased from $168 \pm 25/82 \pm 13$ mmHg at baseline to $149 \pm 24/77 \pm 12$ mmHg at 9 months ($p < 0.001$), and remained unchanged at $149 \pm 25/77 \pm 12$ mmHg at 24-month follow-up ($p < 0.001$ compared with baseline) (22). The mean serum creatinine was not significantly changed at 9 and 24 months compared with baseline.

In addition to treatment of hypertension, percutaneous revascularization of RAS may also prevent deterioration of renal dysfunction and preserve kidney size. In one study, patients with a serum creatinine >1.5 mg/dL and global renovascular obstruction, defined as bilateral obstruction or obstruction to a solitary kidney, underwent renal artery stenting (25). Renal dysfunction was assessed by comparing the slope of the regression line of the reciprocal of the serum creatinine ($1/\text{creatinine}$) over time before and after the stenting procedure, and renal size was measured with ultrasound. Renal stenting led to a mean slope increase of 0.043 mg/month ($p < 0.001$) and 18 of 23 patients had a complete reversal to a positive slope. Additionally, the kidney size remained the same before and after stenting at 10.4 ± 1.1 cm.

Aside from renal artery revascularization, both medical and endovascular management of RAS must be evaluated against the background of contemporary therapies intended to improve

blood pressure management and/or renal function. To examine the potential benefit of percutaneous renal artery revascularization on both blood pressure and renal function, the ongoing CORAL (Cardiovascular Outcomes in Renal Atherosclerotic Lesions) trial has been designed to randomize 1080 patients with significant renal artery stenosis and hypertension to treatment with endovascular stenting and medical therapy or medical therapy alone. The trial will evaluate a composite endpoint of cardiovascular and renal outcomes over a median follow-up period of 3.5 to 5 years.

Additional advances in endovascular therapy for RAS include trials investigating the potential benefit of distal embolic protection and DES. A study using a distal embolic protection device in 46 treated renal arteries (N = 37 patients) demonstrated a 95% procedural success rate with 65% of the filter baskets containing embolic material including fresh thrombus, chronic thrombus, atheromatous fragments, and cholesterol clefts (26). Investigating DES in the renal arterial bed, the GREAT (Palmaz® Genesis™ Peripheral Stainless Steel Balloon Expandable Stent in Renal artery Treatment) trial has recently completed enrollment. In this open-label Phase II study, consecutive patients with de novo or restenotic renal artery lesions consisting of $\geq 50\%$ stenosis in reference vessels 4.0-8.0 mm in diameter have been treated with a bare Palmaz Genesis Peripheral Stent (Cordis, Miami, FL) (N = 52) or a sirolimus-eluting Palmaz Genesis stent (N = 53). Follow-up is 24 months post-procedure, with all patients undergoing clinical assessments at discharge, 1, 6, 12, and 24 months. Outcomes for the set of patients receiving the BMS were reported to compare favorably with historical controls (27). The SES data are pending.

Conclusions

Significant advances have occurred in terms of endovascular therapies for peripheral arterial disease involving the axial, limb, and renal locations. These advances will hopefully allow for less invasive methods of limb salvage, resolution of claudication symptoms, and prevention of renal failure. As with many advances in cardiovascular disease, innovation needs to be supported with rigorous scientific methods. Specifically, systematic clinical trials of novel endovascular technologies performed in a concerted effort by researchers and clinicians prior to their routine adoption into clinical practice will optimize outcomes in the patients for whom these therapies were originally designed.

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Tables and Figures

Table 1. TASC Morphologic Strata of Iliac Lesions

TASC type A iliac lesions:

1. Single stenosis <3 cm of the CIA or EIA (unilateral/bilateral).

TASC type B iliac lesions:

2. Single stenosis 3–10 cm in length, not extending into the common femoral artery (CFA).
3. Total of two stenosis <5 cm long in the CIA and/or EIA and not extending into the CFA.
4. Unilateral CIA occlusion.

TASC type C iliac lesions:

5. Bilateral 5–10-cm-long stenosis of the CIA and/or EIA, not extending into the CFA.
6. Unilateral EIA occlusion not extending into the CFA.
7. Unilateral EIA stenosis extending into the CFA.
8. Bilateral CIA occlusion.

TASC type D iliac lesions:

9. Diffuse, multiple unilateral stenoses involving the CIA, EIA, and CFA (usually >10 cm).
10. Unilateral occlusion involving both the CIA and EIA.
11. Bilateral EIA occlusions.
12. Diffuse disease involving the aorta and both iliac arteries.
13. Iliac stenoses in a patient with an abdominal aortic aneurysm or other lesion requiring aortic or iliac surgery.

Abbreviations: CIA, common iliac artery; EIA, external iliac artery; CFA, common femoral artery.

Table 2. TASC Morphologic Strata of Femoropopliteal Lesions

TASC type A iliac lesions:

1. Single stenosis <3 cm of the CIA or EIA (unilateral/bilateral)

TASC type B iliac lesions:

2. Single stenosis 3-10 cm in length, not involving the distal popliteal artery*
3. Heavily calcified stenoses up to 3 cm in length
4. Multiple lesions, each less than 3 cm (stenoses or occlusions)
5. Single or multiple lesions in the absence of continuous tibial runoff to improve inflow for distal surgical bypass

TASC type C femoropopliteal lesions:

6. Single stenosis or occlusion longer than 5 cm*
7. Multiple stenoses or occlusions, each 3-5 cm, with or without heavy calcification

TASC type D femoropopliteal lesions:

8. Complete common femoral artery or superficial femoral artery occlusions or complete popliteal and proximal trifurcation occlusions.

Figure 1. Summary of TASC Recommendations for Iliac Revascularization

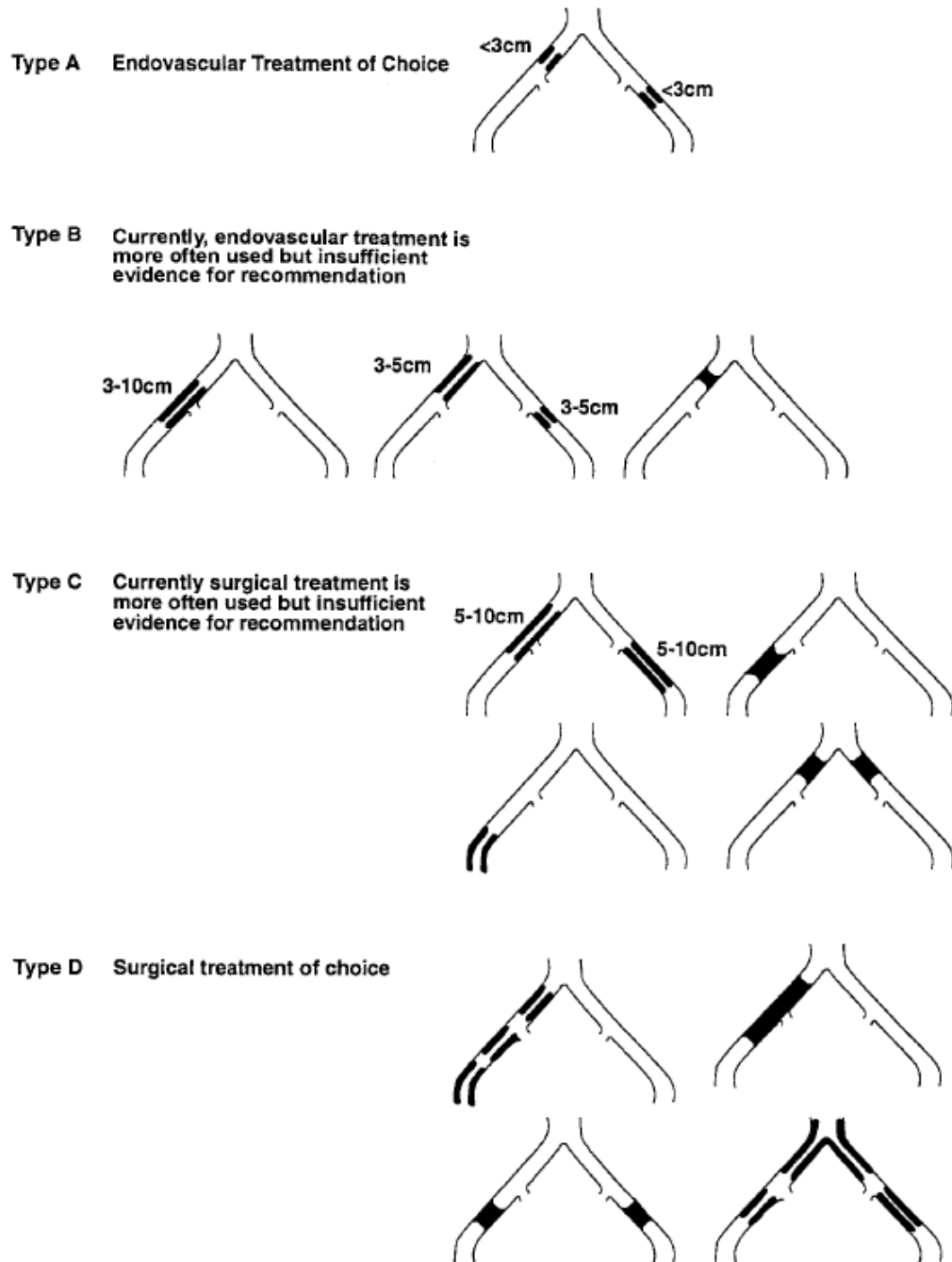


Figure 2. Summary of TASC Recommendations for Femoropopliteal Revascularization

