Endovascular Revascularization of Symptomatic Infrapopliteal Arteriosclerotic Occlusive Disease: Comparison of Atherectomy and Angioplasty

Tze-Woei Tan, M.D.,¹ Elie Semaan, M.D.,¹ Wael Nasr, M.D.,¹ Robert T. Eberhardt, M.D.,¹ Naomi Hamburg, M.D.,¹ Gheorghe Doros, Ph.D.,¹ Denis Rybin, Ph.D.,¹ Palma M. Shaw, M.D.,¹ and Alik Farber, M.D., F.I.C.A.¹

ABSTRACT

The preferred method for revascularization of symptomatic infrapopliteal arterial occlusive disease (IPAD) has traditionally been open vascular bypass. Endovascular techniques have been increasingly applied to treat tibial disease with mixed results. We evaluated the short-term outcome of percutaneous infrapopliteal intervention and compared the different techniques used. A retrospective analysis of consecutive patients undergoing endovascular treatment for infrapopliteal arterial occlusive lesions between 2003 and 2007 in a tertiary teaching hospital was performed. Patient demographic data, indication for intervention, and periprocedural complications were recorded. Periprocedural and short-term outcomes were measured and compared. Forty-nine infrapopliteal arteries in 35 patients were treated. Twenty vessels (15 patients) underwent angioplasty and 29 vessels (20 patients) were treated with atherectomy. Demographic and angiographic characteristics were similar between the groups. Twenty-six patients had concurrent femoral and/or popliteal artery interventions. Overall, technical success was 90% and similar between angioplasty and atherectomy groups (85% versus 93%, $p = \text{NS}$). The vessel-specific complication rate was 10% and was similar between both groups (angioplasty 5% versus atherectomy 14%, $p = \text{NS}$). One dissection occurred in the angioplasty group; one perforation and three thromboembolic events occurred in the atherectomy group. Limb salvage and freedom from reintervention at 6 months were 81% and 68%, respectively, and were not significantly different between the angioplasty and atherectomy groups. Endovascular intervention for IPAD had acceptable periprocedural and short-term success rates in our high-risk patient population. Both atherectomy and angioplasty can be used successfully to treat symptomatic IPAD.

KEYWORDS: Angioplasty, atherectomy, atherosclerosis, infrapopliteal, plaque excision, tibial, stent

¹Section of Vascular and Endovascular Surgery, Boston University Medical Center, Boston, Massachusetts.

Address for correspondence and reprint requests: Alik Farber, M.D., F.I.C.A., Section of Vascular and Endovascular Surgery, Boston University Medical Center, 88 East Newton Street, Collamore Building 5th Floor, Boston, MA 02119-2393 (e-mail: alik.farber@bmc.org).

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Peripheral arterial disease has a prevalence of up to 20% in the United States, and approximately one-third of these patients have infrapopliteal arterial occlusive disease (IPAD).¹ Patients suffering from chronic limb ischemia secondary to IPAD have been traditionally treated with surgical bypass.²⁻⁴ Open revascularization, however, can be associated with a significant risk of perioperative systemic and wound complications.²⁻⁵ Endovascular techniques have increasingly been used to treat symptomatic IPAD to avoid the morbidity and mortality of open surgery.⁶⁻¹⁰ Although initial results were mixed, case series with acceptable short-term outcomes of endovascular infrapopliteal intervention for symptomatic occlusive disease were published.^{6,7}

Several different techniques and devices, including angioplasty and atherectomy, have been used for infrapopliteal endovascular intervention. These have been associated with mixed results.^{8,11} These procedures may present an acceptable option for limb salvage in high-risk patient with IPAD. In this study, we sought to evaluate periprocedural and short-term outcomes of endovascular revascularization of symptomatic IPAD using both infrapopliteal angioplasty and atherectomy.

METHODS

A retrospective review was conducted of consecutive patients who underwent endovascular treatment of IPAD between September 2003 and December 2007 at Boston University Medical Center. Patients included in this study underwent balloon angioplasty or atherectomy (SilverHawkTM Plaque Excision Device, Covidien, MA) of infrapopliteal vessels (tibioperoneal trunk, anterior tibial artery, posterior tibial artery, and peroneal artery). Inpatient, office and radiology records were reviewed; patient's characteristics, comorbidities, interventions, and complications were recorded. Periprocedural and short-term follow-up outcome were measured and compared. This study was reviewed and approved by the Boston University School of Medicine Institutional Review Board.

Patient's procedural angiograms were reviewed to determine extent of disease as characterized by the type of vessels treated, treatment length, presence of calcification, presence of occlusive lesions, adjunctive procedures, intraprocedural complications, and runoff score. Runoff score was calculated from completion arteriograms based on recommended standards.¹² Periprocedural outcomes included overall technical success, technical success as a stand-alone modality, vessel-specific complications, need for adjunctive procedures, and change in ankle brachial index (ABI). Outcomes of limb salvage and freedom from reintervention were assessed during subsequent follow-up.

Patients were selected for endovascular revascularization based on presence of comorbid conditions that would increase the risk for open operation, absence of adequate autogenous vein conduit, poor distal outflow target for bypass, or physician preference. All endovascular procedures were performed in a dedicated endovascular suite. Once the target lesion was identified, the decision to treat with either atherectomy or angioplasty was at the discretion of the interventionalist. All patients were anticoagulated to maintain an activated clotting time above 260 seconds. If the decision was to use atherectomy, the appropriate Silverhawk device was introduced through a 6- or 7-French sheath, advanced over a 0.014-inch guide wire to the proximal aspect of the lesion, and activated without use of an embolic protection device. If angioplasty was chosen, a 6-French sheath was placed and an appropriately sized balloon was selected. The balloon was inflated above the nominal pressure for total duration of 1 minute. Completion angiograms were obtained in all patients to assess technical results and evaluate for any associated complications.

Technical success was defined as residual stenosis less than 30% with or without the use of adjunctive procedures. Reasons for failure to achieve technical success were recorded. Vessel-specific complications were defined as thrombosis, embolization, perforation, arteriovenous fistula, or dissection related to the treated lesion. Adjunctive procedures were defined as any interventions required at the time of the atherectomy or angioplasty to achieve adequate revascularization and included placement of stents, thrombolysis (chemical or mechanical), or urgent open surgical intervention. Noninvasive hemodynamic testing was performed before and after intervention. The change in ABI between groups was calculated based on the difference between preprocedural and postprocedural ABI values. Postprocedural ABI values were obtained after 1 month of the procedure. Adverse events occurring within 30 days of the procedure were recorded as a complication. Freedom from reintervention was defined as freedom from any secondary endovascular or surgical intervention during the follow-up period. Limb salvage was defined as avoidance of a major amputation above the ankle.

Statistical analysis was performed using Statistical Analysis Software (SAS Institute Inc., Cary, NC). Results for continuous variables were presented as mean $\pm$ standard deviation. Two-group comparisons of continuous variables were assessed by the independent Wilcoxon rank sum test. Results for categorical variables were presented as frequency (percent). Group comparisons of categorical variables were assessed by Fisher exact test. Survival, limb salvage, and freedom from reintervention were estimated using the Kaplan-Meier method and compared using the log-rank test.

Table 1 Patient Demographics*

	All Patients (n = 35)	Angioplasty (n = 15)	Atherectomy (n = 20)
Age (y)	74 ± 10	74 ± 13	73 ± 9
Sex (male)	26 (74%)	12 (80%)	14 (70%)
Critical limb ischemia	29 (82%)	12 (80%)	17 (85%)
Smoking	18 (51%)	9 (60%)	9 (40%)
Diabetes	25 (71%)	9 (60%)	16 (80%)
Hypertension	32 (91%)	13 (87%)	19 (95%)
Chronic kidney disease	13 (37%)	5 (33%)	8 (40%)
Coronary artery disease	27 (77%)	13 (87%)	14 (70%)
Hyperlipidemia	24 (69%)	11 (73%)	13 (65%)
Cerebrovascular disease	16 (46%)	4 (27%)	12 (60%)
Statins	22 (63%)	10 (67%)	12 (60%)
Clopidogrel	20 (57%)	9 (60%)	11 (55%)
Aspirin	25 (71%)	11 (73%)	14 (70%)
Coumadin	9 (26%)	5 (33%)	4 (20%)

*All *p* values comparing the angioplasty and atherectomy groups are not significant.

RESULTS

There were 35 patients who underwent 49 infrapopliteal artery interventions for chronic limb ischemia using angioplasty or atherectomy. Twenty vessels in 15 patients underwent treatment with angioplasty, and 29 vessels in 20 patients underwent atherectomy. The mean age of all patients treated was 74 ± 10 years. Demographic characteristics including gender, indication for intervention, comorbidities, use of oral anticoagulation, antiplatelet therapy, and statins (Table 1) were comparable between the angioplasty and atherectomy groups. The mean preprocedural ABI was not significantly different between the two groups: 0.35 ± 0.27 for the angioplasty group and 0.43 ± 0.30 for the atherectomy group ($p = \text{NS}$). Both groups were similar with respect to the specific tibial artery treated (Fig. 1), the number of occlusive lesions, the presence of calcifications, the weighted runoff score, and the length

of the vessel treated (Table 2). Twenty-six patients (74%) had a concurrent femoral and/or popliteal artery intervention, and 9 patients (26%) had an isolated infrapopliteal intervention.

Overall, technical success was achieved in 90% of all interventions and was similar between groups (85% in angioplasty and 93% atherectomy, $p = \text{NS}$; Table 3). Each group had two technical failures due to inability to cross the lesion. Technical success as a stand-alone modality was achieved in 76% of all interventions and was similar between groups (65% angioplasty versus 83% atherectomy, $p = \text{NS}$). Seven technical failures occurred in the angioplasty group due to residual stenosis (five vessels), and inability to cross the lesion (two vessels). Five technical failures in the atherectomy group were due to residual stenosis (one vessel), inability to cross the lesion with a wire (two vessels), inability of the atherectomy device to cross the lesion (one vessel), and device malfunction (one vessel).

The overall vessel-specific complication rate was 10% (5% angioplasty versus 14% atherectomy, $p = \text{NS}$). There was one dissection in the angioplasty group. The atherectomy group had one vessel perforation and three thromboembolic events (one thrombosis and two embolisms; Table 3).

Adjunctive interventions were performed in 20% of cases and were similar between both groups. In the angioplasty group, three stents were placed and one atherectomy was performed for residual stenosis. In the atherectomy cohort, three thromboembolic complications were successfully treated with chemical and mechanical thrombolysis, two stents were placed for residual stenosis, and one balloon angioplasty was performed due to inability of the Silverhawk catheter to cross the lesion. Urgent open surgical revascularization was not required in any patient.

Figure 1 The nature of infrapopliteal arteries treated did not vary between treatment groups. TPT, tibioperoneal trunk; AT, anterior tibial artery; PT, posterior tibial artery; Per, peroneal artery.

Table 2 Anatomic Description of Tibial Vessel Intervention*

Tibial Vessel Treated	All Interventions (n = 49)	Angioplasty (n = 20)	Atherectomy (n = 29)
Tibioperoneal trunk	15 (31%)	6 (30%)	9 (31%)
Anterior tibial	13 (27%)	4 (20%)	9 (31%)
Posterior tibial	8 (16%)	4 (20%)	4 (14%)
Peroneal	13 (27%)	6 (30%)	7 (24%)
Occlusive lesions	14 (29%)	5 (25%)	9 (31%)
Calcification	12 (24%)	5 (25%)	7 (24%)
Weighted runoff score	6.7 ± 2.3	6.8 ± 2.8	6.6 ± 1.9
Treatment length (cm)	2.8 ± 2.5	2.6 ± 1.3	3.0 ± 3.3

*All *p* values comparing the angioplasty and atherectomy groups are not significant.

Freedom from reintervention at 6 months was 68% overall and was similar between groups (70% angioplasty versus 60% atherectomy, *p* = NS; Fig. 2). Overall limb salvage in both cohorts was 81% and similar between both groups at 6 months (78% angioplasty versus 88% atherectomy, *p* = NS; Fig. 3). The mean postprocedural ABI was not significantly different between the two groups (0.61 ± 0.27 angioplasty versus 0.64 ± 0.28 atherectomy, *p* = NS). The mean change in ABI was similar between the both groups (0.24 ± 0.25 angioplasty versus 0.23 ± 0.16 atherectomy, *p* = NS).

Thirty-day morbidity was similar between groups, and there was no mortality. There was one retroperitoneal bleed requiring blood transfusion in the angioplasty group. There were two antegrade access site complications in the atherectomy group including one common femoral artery pseudoaneurysm and one groin hematoma. There was one major amputation in the atherectomy group due to extensive tissue lost despite technical success.

DISCUSSION

Endovascular techniques have increasingly been used to treat chronic lower-extremity ischemia⁹ and in

many instances have replaced open surgery as first-line treatment for iliac and femoropopliteal occlusive disease.^{9,13} The role of endovascular intervention in IPAD is less clear. At Boston University Medical Center, endovascular interventions have been used to treat infrapopliteal lesions to avoid the perioperative morbidity and mortality associated with open surgical revascularization. Our data demonstrate that low perioperative complications, reasonable hemodynamic improvement, and acceptable limb salvage can be achieved using both angioplasty and atherectomy to treat IPAD.

Although a variety of endovascular modalities are available to treat the infrapopliteal arterial bed, angioplasty is the most commonly used.^{8–10} Catheter-based plaque excision has also been used to treat tibial lesions.^{14–16} However, no modality is clearly established as the technique of choice in these vessels. In this series, balloon angioplasty and atherectomy were used almost equally to treat IPAD. Atherectomy was used more commonly in anterior tibial artery intervention due to more proximal lesions. Although the numbers failed to reach statistical significance, more occlusions were treated with atherectomy in an attempt to recanalize the arterial lumen.

Table 3 Immediate Results and Vessel-Specific Complications*

	All Interventions (n = 49)	Angioplasty (n = 20)	Atherectomy (n = 29)
Technical success	44 (90%)	17 (85%)	27 (93%)
Stand-alone procedure	37 (76%)	13 (65%)	24 (83%)
Vessel-specific complications	5 (10%)	1 (5%)	4 (14%)
Perforation	1 (2%)	0 (0%)	1 (3%)
Dissection	1 (2%)	1 (5%)	0 (0%)
Thromboembolism	3 (6%)	0 (0%)	3 (10%)
Adjunctive interventions	10 (20%)	4 (20%)	6 (21%)
Thrombolysis	3 (6%)	0 (0%)	3 (10%)
Stent use	5 (10%)	3 (15%)	2 (7%)
Atherectomy	1 (2%)	1 (5%)	—
Angioplasty	1 (2%)	—	1 (3%)
Open surgery	0 (0%)	0 (0%)	0 (0%)

*All *p* values comparing the angioplasty and atherectomy groups are not significant.

Figure 2 Kaplan-Meier estimate of freedom from reintervention rates.

Tibial angioplasty and atherectomy have been reported to have high technical success rates in these vessels, but these studies are difficult to compare due to difference in definition of residual stenosis in the literature.^{10,14,17} Technical success for angioplasty ranges from 61 to 100%.¹⁴ Relatively few authors have investigated directional atherectomy in the tibial vessels. Zeller et al reported a 71% primary success rate and a 96% overall technical success rate using less than 30% residual stenosis. These data were for infragenicular atherectomy and included treatment for in-stent restenosis.¹³ Ramaiah et al¹⁴ recorded a 94.7% device success rate in achieving less than or equal to 50% residual stenosis in the TALON registry where infrapopliteal lesions accounted for 24.4% (307/1258) of the lesions treated.

In our series, we defined overall technical success as less than 30% residual stenosis with or without the use of adjunctive procedure and found an overall technical success rate of 90% in all interventions. Atherectomy as a stand-alone modality had higher technical success than angioplasty, although the difference did not reach statistical significance. Plaque excision may account for the higher rate of technical success in the atherectomy group as the excised plaque is not subject to recoil or incom-

plete dilatation. Although this failed to reach statistical significance, more reinterventions were required in the atherectomy group despite early technical success. Despite higher restenosis rate, compared with the angioplasty group, limb salvage was equivalent between both groups. Overall, our technical success rate, freedom from reintervention, and limb salvage at 6 months of 90%, 68%, and 81%, respectively, demonstrate that endovascular revascularization of infrapopliteal occlusive disease is a reasonable first-line option in this relatively high-risk population.

The main limitations of this study are a small sample size and retrospective design. Another potential weakness is the use of freedom from reintervention and changes in ABI as surrogate for primary patency data. This is especially true for patients with diabetes and renal failure. The ABI in these patients can be unreliable due to the noncompressibility and calcification of their peripheral vessels. We were not able to address cost differences between angioplasty and atherectomy approach due to the retrospective nature of our study. These limitations, as well as the lack of randomized trials or long-term follow-up after endovascular intervention, reflect the need for further research in this area.

CONCLUSION

Endovascular infrapopliteal intervention has acceptable periprocedural and short-term success rates in a high-risk patient population. Atherectomy and angioplasty can be used successfully to treat symptomatic IPAD.

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Figure 3 Kaplan-Meier estimate of limb salvage rates.

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