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Is Atherectomy the Best First-Line Therapy for Limb Salvage in Patients With Critical Limb Ischemia?

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Abstract

Objective—To determine the efficacy of atherectomy for limb salvage compared with open bypass in patients with critical limb ischemia.

Methods—Ninety-nine consecutive bypass and atherectomy procedures performed for critical limb ischemia between January 2003 and October 2006 were reviewed.

Results—A total of 99 cases involving TASC C (n = 43, 44%) and D (n = 56, 56%) lesions were treated with surgical bypass in 59 patients and atherectomy in 33 patients. Bypass and atherectomy achieved similar 1-year primary patency (64% vs 63%; $P = .2$). However, the 1-year limb salvage rate was greater in the bypass group (87% vs 69%; $P = .004$). In the tissue loss subgroup, there was a greater limb salvage rate for bypass patients versus atherectomy (79% vs 60%; $P = .04$).

Conclusions—Patients with critical limb ischemia may do better with open bypass compared with atherectomy as first-line therapy for limb salvage.

Keywords

angioplasty; amputation; atherosclerosis; claudication; ischemia; leg ulcer; lower extremity; peripheral arterial disease

Introduction

Critical limb ischemia is associated with a high risk of limb loss, myocardial infarction, and stroke.^{1–3} In the setting of critical limb ischemia and complex athero-occlusive disease, several studies have demonstrated the benefit of lower extremity arterial bypass.^{4–9} However, these procedures can be associated with higher morbidity and mortality rates in patients with comorbidities such as diabetes, renal insufficiency, or coronary artery disease (CAD).^{10–13} Unfortunately, patients requiring infrainguinal revascularization in the current era are presenting with worsening comorbidities and increasingly complex lesions.⁵ This dilemma has led many clinicians to adopt an “endovascular first” strategy for dealing with advanced peripheral vascular disease.^{14,15}

Recently, endovascular directional atherectomy has re-emerged as a minimally invasive alternative to the treatment of advanced atherosclerotic occlusive disease. This technique uses a cutting blade advanced through segments of diseased vessels to recanalize the occluded

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lumen.^{16–18} It can be used as an isolated technique or it can facilitate the use of adjunctive procedures such as angioplasty and stent deployment. Results, thus far, have demonstrated its ability to treat a variety of different lesions, including severe long-segment stenoses and occlusions, with variable success.^{19–21} The TALON registry demonstrated an 80% revascularization-free survival at 1 year for patients treated with atherectomy.²² In a subgroup analysis of a prospective series of 579 lesions treated with atherectomy, the group of McKinsey et al showed a limb salvage rate of 80% for patients with critical limb ischemia. These studies suggest that atherectomy is an efficacious option in patients with advanced infrainguinal disease whom are not candidates for open bypass due to a lack of suitable conduit, lack of distal target vessel, or severe comorbidities.

However, it is important to note that there is a paucity of data comparing the outcomes of peripheral atherectomy with open bypass. In the setting of TransAtlantic Inter-Society Consensus (TASC) C and D lesions, open bypass is regarded as the gold standard for lower extremity revascularization.¹ Although the data for atherectomy are promising, it is difficult to reach conclusions without a comparison with the gold standard. For instance, should patients with critical limb ischemia and tissue loss have an atherectomy as first-line therapy even if they are candidates for a surgical bypass? Although this approach has been supported in lesions that are amenable to transluminal angioplasty, less is known about its efficacy in the treatment algorithm for patients with critical limb ischemia whom are candidates for either an atherectomy or open bypass.¹⁴ Such patients may not have the luxury of time to spend on an atherectomy if an open bypass ensures a better chance of limb salvage.

The current series review consecutive patients with TASC type C and D lesions and critical limb ischemia, which were managed by either open revascularization methods (bypass) or atherectomy at a tertiary care center between January 2003 and 2006. Patency, limb salvage, morbidity, and mortality outcomes are compared.

Methods

All infrainguinal procedures performed at a tertiary care institution from January 2003 to January 2006 were reviewed. Of a total of 453 infrainguinal procedures, 99 cases involving TASC C (n = 43, 44%) and D (n = 56, 56%) lesions were treated with surgical bypass (n = 64, 64%) in 59 patients (64 limbs) and atherectomy (n = 35, 36%) in 33 patients (34 limbs). Demographics, operative details, outcomes, and follow-up were gathered from hospital, clinic, and vascular laboratory records and entered into a computerized database for analysis. This study was approved by the University of Chicago's Institutional Review Board (IRB).

Patient Characteristics

Patients in both groups had comorbidities commonly associated with atherosclerosis (Table 1). Patients treated by atherectomy had a greater prevalence of diabetes and cerebrovascular disease. There was a trend toward greater numbers of patients with CAD in the bypass group and a trend toward older patients in the atherectomy group (68.6 ± 1.9 years vs 64.4 ± 1.3 ; $P = .08$).

There was no significant difference in other comorbidities including recent history of smoking, hypertension (HTN), or chronic obstructive pulmonary disorder (COPD) nor was there a difference between the bypass and the atherectomy groups in the number of patients who had a prior arterial intervention in the contralateral limb.

All angiograms were interpreted by 1 of 4 attending vascular surgeons. These lesions were classified according to the TASC II classification system for infrainguinal athero-occlusive disease.²³ Distal runoff was scored according to the Rutherford classification scheme, ranging

from 0 to 9.²⁴ The decision to perform an atherectomy was left to the discretion of the individual attending physician, but, in general, was based on technical feasibility, lack of optimal target for bypass, lack of autologous conduit, patient preference, or the presence of severe comorbidities.

Table 2 summarizes the lesion characteristics according to TASC II classification, runoff score, and location, as well as preoperative ankle brachial indexes (ABIs), indication for revascularization, and postoperative anticoagulation regimens. A significantly greater number of femoral-popliteal lesions were treated in the bypass group. Rest pain was a more common indication for revascularization in the open bypass group, while more patients had tissue loss as the primary indication in the atherectomy group. Preoperative ABIs were similar in both groups. A greater number of TASC D lesions were treated in the open bypass group than in the atherectomy group (65% vs 40%; $P = .01$). Similarly, more TASC C lesions were present in the atherectomy cohort than in the bypass group (60% vs 34%; $P = .01$). Of note, lesions treated with surgical bypass had better runoff on preoperative angiogram manifested by significantly lower runoff scores than lesions treated by atherectomy (3.2 ± 0.3 vs 5.9 ± 0.4 ; mean $\pm$ SE, $P < .001$). Postoperative treatment with an antiplatelet regimen was more common in the atherectomy group than in the bypass group.

Preoperative Evaluation

All patients underwent preoperative lower extremity angiograms. Arterial duplex was performed in 88% of atherectomy patients and 52% of open bypass patients.

Procedures

Bypasses were performed by 1 of 4 vascular surgeons under general or regional anesthesia. Standard operative techniques were used, including the use of loupe magnification, intraoperative heparin, and completion arteriography. Open procedures included 29 femoral-popliteal (45%), 32 femoral-distal (48%), and 3 popliteal-distal (1%) bypasses. Conduits included polytetrafluoroethylene (PTFE, 47%) and vein (53%).

Atherectomy procedures were performed in a dedicated endovascular suite. Percutaneous access was used with wire traversal of the lesion after systemic anticoagulation with heparin (100 IU/kg intravenously). The Silverhawk directional atherectomy device (FoxHollow, Redwood City, CA) was used to perform atherectomy in at least 4 quadrants, with additional passes used for residual disease. The initial technical success rate was 95%. For significant residual stenosis that was not amenable to repeat atherectomy, adjunctive angioplasty with or without stenting was used. There were 21 procedures (60%) involving the femoral-popliteal segments, 8 procedures (23%) involving infrageniculate vessels, and 6 procedures (17%) involving both supra- and infrageniculate vessels. Eight procedures required an adjunctive procedure including PTA ($n = 8$) and stenting ($n = 4$).

Postoperative Follow-up

Patients underwent follow-up evaluation by physical examination and duplex ultrasound graft surveillance with a mean follow-up of 17 ± 1.6 months. The general protocol for graft surveillance included duplex ultrasound every 3 to 6 months in the first year, every 6 months in the second year, and yearly exams thereafter. Graft patency was determined by physical examination, duplex ultrasound evaluation, or angiography as recommended by the SVS/ISCVS (Society for Vascular Surgery/International Society for Cardiovascular Surgery) reporting standards.²⁴ Follow-up clinic notes were available for the determination of limb salvage in 99 cases (100%). Postoperative duplex ultrasound examinations were available in 87 cases (76%). All noninvasive duplex ultrasound examinations were performed at a

laboratory accredited by the Inter-societal Committee for the Accreditation of Vascular Laboratories.

Statistics

Student *t* tests were used to evaluate continuous variables (<http://www.physics.csbsju.edu/stats/t-test.html>). Chi-square analysis was used to assess discrete variables (Excel; Microsoft Corp, Redmond, WA). Kaplan-Meier calculations and log-rank tests were used for comparisons of patency and limb salvage data (SPSS for windows 15th edition). All Kaplan-Meier data were reported where standard error was less than or equal to 0.10. All results were expressed as mean $\pm$ SEM when appropriate. $P < .05$ were considered significant. A Cox proportional hazards regression model was used for univariate and multivariate analysis of limb salvage in the atherectomy cohort. The Cox hazards regression model was also used to control for runoff scores, diabetes, lesion location, tissue loss, and TASC classification in the final limb salvage analysis comparing infrainguinal bypass and atherectomy.

Results

The length of hospital stay was significantly shorter for atherectomy versus open bypass (3.7 ± 1.3 vs 6.8 ± 1.3 days; $P = .01$). There was no difference in the occurrence of major complications between groups, although there were a significantly greater number of minor complications in the atherectomy patients. Major complications in the bypass group ($n = 8$ cases) included an MI ($n = 1$), pulmonary insufficiency ($n = 1$), acute renal failure ($n = 1$), and acute graft occlusion ($n = 5$). In the atherectomy group, 3 cases were complicated by a major occurrence including acute renal failure ($n = 2$), a large retroperitoneal hematoma ($n = 1$), and acute occlusion ($n = 1$). In the atherectomy group, minor complications occurred in 9 cases including self-limited dye extravasations ($n = 2$), pseudoaneurysm ($n = 1$), intraoperative emboli ($n = 2$), intimal dissection ($n = 2$), and vasospasm ($n = 3$). These minor complications were not limb threatening and did not affect length of stay. There was no statistically significant difference in the 1-year survival rate between these groups (87%—atherectomy vs 76%—bypass, $P = .82$; Figure 1). Moreover, 16 of 18 patients (89%) in the open bypass group and 2 of 4 patients (50%) in the atherectomy cohort died with their limbs intact ($P = .01$).

After a mean follow-up of 12.2 ± 1.7 months (range 1–40 months), bypass and atherectomy achieved similar 1-year primary (64% vs 63%; $P = .19$), primary assisted (69% vs 74%; $P = .28$), and secondary (75% vs 76%; $P = .15$) patency rates (Figure 2). Similarly, when considering isolated femoral-popliteal lesions, there was no difference between primary patency in open bypass versus atherectomy at 7 months (62% vs 66%; $P = .14$).

Longer follow-up data were available for the open bypass group. The 37-month primary, primary-assisted, and secondary patency rates for open bypass were 54%, 58%, and 75%, respectively (Kaplan-Meier analysis; SE < 10%). Patients in the open bypass group had a greater increase in ABIs compared to patients in the atherectomy group after a mean follow-up of 17 ± 1.6 months (Figure 3).

The mean follow-up for limb salvage was 13.2 ± 1.2 months. One-year limb salvage rates were significantly greater in the bypass group (87% vs 69%; $P = .004$; Figure 4A). The amputation-free survival for the open bypass group at 37 month was 87% by Kaplan-Meier analysis (SE < 0.10; data not shown). When considering strictly femoral-popliteal lesions, the 1-year limb salvage rates were also significantly greater in the open bypass cohort (87% vs 73%; $P = .01$; Figure 4B).

Among patients with tissue loss, there were better outcomes with bypass versus atherectomy (79% vs 60% at 12 months, SE < 0.10; $P = .07$; Figure 5). Kaplan-Meier analysis showed no difference in limb salvage at 12 months between atherectomy and open bypass for patients with diabetes (82% vs 71%, SE < 0.10, $P = .11$). Moreover, Cox hazard regression analysis was used to control for individual variables that may have contributed to worse outcomes in the atherectomy group with regards to limb salvage. When controlling for distal runoffs, diabetes, lesion location, tissue loss, and TASC classification, the limb salvage rate remained superior in the bypass cohort.

Univariate analysis was performed for patients who underwent atherectomy procedures to identify factors that may alter the prognosis for limb salvage (Table 3). All variables listed in Table 1 and Table 2 were included with the addition of ulcer or gangrene location (toe, foot, heel, and ankle), evidence of cellulitis, osteomyelitis, overall infection, patency of the profunda artery, and preoperative ABI. Of these variables, tissue loss, toe gangrene, cellulitis, and overall infection were associated with poorer limb salvage (Table 3A). Conversely, isolated femoral-popliteal lesions were associated with better outcomes than infrageniculate lesions. The only variable on multivariate analysis that was an independent predictor of worsening limb salvage after atherectomy was toe gangrene (Table 3B).

Discussion

The current study reviews our experience with the treatment of patients with critical limb ischemia using either open bypass or atherectomy. Both techniques were safe and achieved excellent initial technical results. The 95% initial success rate with atherectomy supports several studies, showing that TASC C and D lesions can be feasibly approached with atherectomy technology.^{19,21,25–28} Despite a greater prevalence of diabetes and cerebrovascular disease in the atherectomy group in our series, overall morbidity and periprocedural mortality were similar in the 2 groups. There were a greater number of minor complications associated with atherectomy although they were largely self-limited and did not affect length of stay. The length of hospital stay in the atherectomy cohort was significantly shorter than in patients treated with surgical bypass, offering a distinct short-term advantage of this technique. Furthermore, similar patency rates were noted with both groups, despite atherectomy patients manifesting worse runoff than those undergoing open bypass. These patency rates compare favorably with other published series for either atherectomy or infrainguinal bypass.^{6,9,21,25,28–30}

However, limb salvage was consistently poorer in the atherectomy group. Patients treated with an atherectomy had a 69% 1-year limb salvage rate, while patients treated with open bypass achieved a limb salvage rate of 87% at 12 months. These rates are similar to those reported in studies using either atherectomy or open bypass in the setting of advanced infrainguinal disease.^{6,11,19,21,25,31–33} Several factors may have influenced the superior result of open surgery over atherectomy with respect to limb salvage. In the current series, there was a bias toward using atherectomy in patients with more compromised distal runoff. The atherectomy patients had greater incidence of tissue loss and diabetes, which are well-known risk factors for lower amputation-free survival.^{32–34} Clearly, poorer runoff would affect the ability to adequately revascularize the distal extremities and, thus, it would not be surprising that the atherectomy cohort had poorer limb salvage in this setting. However, even when controlling for the compromised runoff, TASC classification, presence of diabetes, lesion location, and tissue loss, surgical bypass still gave superior limb salvage results by Cox hazard regression analysis. In addition, among patients treated specifically for tissue loss, the surgical bypass patients had superior limb salvage. Open bypass may offer a superior hemodynamic result compared to atherectomy, as evidenced by greater improvements in ABIs after open surgery. As such, open bypass may be the preferred approach to TASC C or D infrainguinal lesions in patients who

have an adequate distal target, optimal conduit, and who have an acceptable risk for open surgery.

There is clearly a role for atherectomy in patients who may be too sick to undergo an open bypass procedure. It is evident from published reports that patients with critical limb ischemia have multiple comorbidities and a diminished life expectancy.^{1,5,9,32} In our study, there was no difference in limb salvage between diabetic patients who underwent an atherectomy or open bypass. In addition, atherectomy limb salvage rates (69% in our series) are likely to offer an advantage over local wound care in patients with tissue loss.^{19,21,25,33,35,36} Thus, in our experience, atherectomy was a valuable alternative for patients who were not candidates for open repair.

Moreover, this study identified specific factors that may predict a poorer outcome after atherectomy for limb salvage. On univariate analysis, toe gangrene, tissue loss, cellulitis, and overall infection were associated with worse limb salvage rates. Patients undergoing isolated femoral-popliteal atherectomy did better than those who underwent an atherectomy for infrageniculate lesions. In addition, toe gangrene was an independent predictor of poorer limb salvage on multivariate analysis. Thus, it is unlikely that patients with these negative prognostic factors will gain a benefit with atherectomy beyond the natural history of these diseases.

Several recent studies suggest that endovascular interventions should be offered as the initial treatment modality for complex infrainguinal disease.^{14,28} Our study demonstrates that atherectomy is not the ideal approach for the treatment of TASC C and D infrainguinal lesions in patients with critical limb ischemia. These patients do not have the luxury of time to spend on a procedure that may not confer as good of a benefit for limb salvage as a definitive bypass operation. Although atherectomy is a viable alternative for patients who are not operative candidates, a strong effort should be made to offer patients with critical limb ischemia an open bypass operation for limb salvage.

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Figure 1.
Survival curve showing the difference in survival between groups.

Figure 2.

Primary, primary assist and secondary patency curves were determined using Kaplan-Meier survival curves. Cumulative patency up to a 1-year time point was determined with a standard error (SE) less than 0.10. Results for infrainguinal bypass versus atherectomy were compared by log rank analysis.

Figure 3.

A significant increase in ankle brachial indexes (ABIs) was noted in patients treated by open bypass compared with those treated by atherectomy (* $P < .05$).

Figure 4.

A, Kaplan-Meier survival curves illustrating a significant difference in the 1-year limb salvage rates between infrainguinal bypass patients and atherectomy patients. B, The 1-year limb salvage rates were also significantly different between groups when considering strictly femoral-popliteal lesions.

Figure 5.
Subgroup analysis of open bypass versus atherectomy for patients treated specifically for tissue loss.

Table 1Ninety-Nine TASC C and D Lesions Were Treated by Either Atherectomy or Open Bypass^a

	Atherectomy (Total = 34) Percentage (n)	Open Bypass (Total = 65) Percentage (n)	P Value
Age (years)	68.6 + 1.9	64.4 + 1.3	.08
Female	49 (17)	41 (26)	.31
AA	65 (22)	66 (41)	.53
Smoker	53 (18)	59 (37)	.36
DM	83 (29)	57 (36)	.01
CAD	43 (15)	60 (38)	.07
COPD	11 (4)	7 (4)	.31
HTN	94 (33)	87 (55)	.23
CVA	29 (10)	11 (7)	.03
ESRD	14(5)	25 (16)	.15
History of contralateral intervention	29 (10)	19 (12)	.21

NOTES: CAD = coronary artery disease; COPD = chronic obstructive disease; CVA = cerebral vascular disease; DM = diabetes mellitus; ESRD = end-stage renal disease; HTN = hypertension; TASC = TransAtlantic Inter-Society Consensus.

^aThe patient characteristics are shown. Age is expressed as mean years ± SEM. All other characteristics are expressed as (percentage [n]).

Table 2

Angiographic Characteristics, Indications for Intervention, Preoperative Ankle Brachial Indexes (ABIs), and Postoperative Antiplatelet or Anticoagulant Strategies Are Listed (Percentage [n])

	Atherectomy (Total = 35) Percentage (n)	Open Bypass (Total = 64) Percentage (n)	<i>P</i> Value
Indications			
Rest pain	23 (8)	48 (31)	.01
Tissue loss	77 (27)	51 (33)	.01
Preoperative ABI	0.47 + 0.03	0.43 + 0.04	.52
Primary lesion location			
Supragenulate	28 (21)	81 (53)	.02
Infragenulate	23 (8)	9 (6)	.06
Combination	17(6)	11 (7)	.27
Angiographic characteristics			
TASC C	60 (21)	34 (22)	.01
TASC D	40 (14)	66 (42)	.01
R/O scores	5.9 + 0.42	3.1 + 0.3	<.001
Postoperative medications			
ASA/plavix	90 (26/29)	72 (46/64)	.047
Coumadin/heparin/lovenox	10 (3/29)	20 (13/64)	.19

NOTES: ABIs = ankle brachial indexes; ASA = aspirin; R/O = runoff; TASC = TransAtlantic Inter-Society Consensus.

Table 3

Univariate (A) and Multivariate (B) Analysis for Limb Salvage^a

Variables	Hazards Ratio	Standard Error	Z	P Value	95% Confidence Interval
(A) Univariate analysis—limb salvage					
Isolated femoral-popliteal lesion	0.278	0.180	-1.97	.049	0.078
Tissue loss	9.464	10.196	2.09	.037	1.146
Toe gangrene	9.841	6.850	3.28	.001	2.515
Cellulitis	4.647	3.004	2.38	.017	1.309
Overall infection	4.271	2.769	2.24	.025	1.199
(B) Multivariate analysis—limb salvage					
Isolated femoral-popliteal lesion	0.533	0.432	-0.77	.439	0.1089
Tissue loss	4.853	5.79	1.32	.186	0.467
Toe gangrene	11.023	9.57	2.77	.006	2.012
Cellulitis	3.108	3.85	0.92	.36	0.274
Overall infection	0.147	0.222	-1.27	.206	0.0075
					2.87

^aUnivariate analysis of factors that are associated with improved (isolated femoral-popliteal) or worse (toe gangrene, cellulitis, osteomyelitis, overall infection) outcomes after atherectomy for limb salvage. Multivariate analysis demonstrates that “toe gangrene” was an independent predictor of worse outcomes after atherectomy.