Long-Term Results of Endovascular Femoropopliteal Interventions

Robert Hacker, MD, FACS¹ Luke Marone, MD²

¹Department of Vascular Surgery, Mercy St. Vincent Medical Center, Toledo, Ohio

²Department of Vascular Surgery, West Virginia Medical Center, Morgantown, Pennsylvania

Address for correspondence Robert Hacker, MD, FACS, Department of Vascular Surgery, Mercy St. Vincent Medical Center, 2222 Cherry Street MOB2, 1250 Toledo, OH 43608 (e-mail: Roberthackerm@gmail.com).

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Abstract

Background and Objective Short-term results of endovascular intervention for femoropopliteal lesions have been extensively reported; however, there exists a paucity of long-term objective data related to outcomes of these interventions. We sought to characterize these long-term results including patency, limb salvage, and mortality.

Methods From May 2003 to July 2009, all patients who underwent technically successful endovascular balloon angioplasty and/or stenting for Trans-Atlantic Inter-Societal Consensus (TASC) II B, C, and D lesions were identified in a retrospective fashion. Patient demographics, clinical characteristics, arterial noninvasive data, and angiographic anatomic data were evaluated.

Results A total of 236 limbs in 186 patients (mean age 74, range 37–94) were treated. Lesion distributions by TASC II classification B, C, and D were 121 (51.3%), 37 (15.7%), and 78 (33%), respectively. Critical limb ischemia (CLI) was the indication for intervention in 42.4% of patients. Five-year primary and primary-assisted patency rates stratified by TASC II classification were B: 55.1%, 91.9%; C: 37.4%, 74.6%; D: 35.5%, 67%, respectively ($p = 0.23$). Secondary patency based on TASC II classification was B: 92.9%, C: 83%, and D: 75.9%, respectively. Univariate analysis identified age > 75 , CLI, and cerebrovascular disease as predictors for loss of patency. Reinterventions to maintain patency were required in 26.5% of TASC II B, 43.2% of TASC II C, and 25.6% of TASC II D lesions ($p = \text{NS}$) and mean time to reintervention ranged from 22 to 29 months with no significant difference related to TASC II classification. A total of eight limbs (3.38%) were converted to open revascularization with two (0.85%) having a change in their initial preoperatively identified bypass target site. Three limbs (1.27%) required a major amputation during follow-up. Survival at 5 years was 44.3%; CLI and smoking were identified as risk factors for death (hazard ratio [HR] 2.6, 1.75–3.84, $p < 0.001$, HR 3.33, 1.70–6.52, $p < 0.001$), respectively.

Conclusion Long-term patency of endovascular interventions for complicated femoropopliteal lesions is acceptable across TASC II classification and is associated with excellent limb salvage. Mortality in this patient cohort is significant with CLI and smoking being identified as predictors of death.

Keywords

- TASC II
- SFA disease
- stenting
- limb salvage
- amputation
- iliofemoral occlusive disease
- tibioperoneal disease

Greater than 30% of all Americans over the age of 74 or over the age of 55 with past medical history of tobacco usage or diabetes^{1,2} suffer from peripheral arterial disease with symptoms ranging from claudication to gangrene. Treatments of peripheral arterial disease consist of both conservative medical management and invasive revascularizations. Revascularization hinges on two main treatment algorithms: open bypass or endovascular angioplasty and stenting.

In 2007, the second revision of the Trans-Atlantic Inter-Societal Consensus document (TASC II) was published.³ It recognized the merits and limitations of endovascular approaches based on the available published data at the time and promoted its selective use for the treatment of

femoral popliteal lesions. ►**Fig. 1** graphically represents each lesion class.

TASC II guidelines currently recommend that A and B lesions initially be approached with endovascular techniques. Type C lesions are suggested to be treated with open surgery in good-risk patients, but the paper does not dismiss the merits of endovascular approaches, while D lesions are recommended to be treated with an open bypass for revascularization. Since the adoption of these recommendations, improvements in technique, devices, and specialized fellowship training has led to the ability to treat many of these vascular pathologies far beyond the boundaries of the TASC II recommendations. Since 2007 these advances have contributed to the improved technical success of endovascular

Fig. 1 TASC-II classification.

surgery specifically in the treatment of the more complex TASC II C and D lesions.^{4,5}

While short-term results of endovascular interventions for these complex femoropopliteal lesions have been well reported,^{2,6–8} little is known about long-term patency limb salvage and patient outcome.^{9–11} It has been published that an aggressive endovascular approach for severe limb ischemia is associated with equivalent short-term results when compared with open revascularization; however, in the long-term open revascularization is associated with significantly improved results.¹²

This retrospective review of a prospectively maintained database reports the results of long-term predictors of patency, limb salvage, and any alterations of radiographically identified distal target outflow vessels for an open bypass in those patients with TASC II B, C, and D lesions initially treated with endovascular modalities but may have converted to an open surgical bypass.

Methods

Methods have been previously published but in brief.⁶

Patient Selection

Patients undergoing endovascular interventions for femoropopliteal occlusive disease between May 2003 and July 2009 were identified from a prospectively maintained physician database for 5 years. A total of 236 limbs underwent endovascular interventions, 121 (51.3%) were TASC II B, 37 (15.7%) were TASC II C, and 78 (33.0%) were TASC II D, respectively. Patients who underwent failed attempts at endovascular intervention were not included in the outcomes analysis. Indications for intervention were either lifestyle-limiting claudication (Rutherford 3/4) or limb salvage (Rutherford 4/5). Therapy for the individual patient was dictated at the preference of the attending surgeon based on clinical presentation, noninvasive laboratory findings, and findings at the time of angiography.

Collected patient data included patient demographics, comorbidities, pre- and postprocedure ankle-brachial indices (ABIs), duplex velocity data, and the utilization of adjuvant medical therapy. Additionally, all angiograms and corresponding angiographic reports were retrospectively reviewed to determine TASC II classification of the treated lesions and to determine the status of the runoff vessels.

Procedures

Procedures were performed in either a fixed-imaging hybrid operating room or in the interventional angiography suite by vascular surgeons. All procedures were performed with patients receiving local anesthesia in addition to conscious sedation. Standard digital subtraction techniques were employed to maximize image quality while minimizing use of contrast agent. Patients with preoperative renal insufficiency (baseline Cr > 1.5 mg/dL) were routinely treated periprocedurally with oral *N-acetylcysteine* and intravenous hydration. Arterial access was performed via the common femoral artery through a contralateral retrograde

approach or an ipsilateral antegrade approach using 5F or 6F sheaths. A standard aortogram and unilateral or bilateral runoff were performed utilizing a power injector.

Interventions were performed following the administration of systemic heparin (40–100 U/kg). Lesions were crossed with a 0.035-inch wire. For complete occlusions, a soft 0.035-inch glide wire (Terumo Medical Corp, Somerset, NJ) and a 4F or 5F glide catheter (Terumo Medical Corp, Somerset, NJ) were utilized to cross in a subintimal fashion. When necessary, a re-entry device, Outback LTD (Cordis Endovascular, Warren, NJ) was employed to gain access to the flow lumen. Re-entry was confirmed with contrast injection prior to intervention. Balloon angioplasty was subsequently performed with a noncompliant balloon (various manufacturers) for superficial femoral artery lesions or a semicompliant balloon (various manufacturers) for popliteal artery lesions to minimize dissection at that anatomic location. Balloon diameter was selected based on the angiographic measurements of the nondiseased artery proximal and distal to the lesion. Nominal inflations were maintained for a minimum of 1 minute. Stents were implanted following balloon angioplasty for the treatment of flow-limiting dissections or residual stenosis of > 30% after angioplasty or at the discretion of the operating surgeon. All stents utilized were nitinol self-expanding stents (various manufacturers). Whenever multiple stents were utilized, a minimum overlap zone of 5 mm was achieved. Access site closure was performed using manual compression or with a closure device (various manufacturers) following access site arteriography.

All patients were administered a 300-mg loading dose of clopidogrel immediately following the procedure and subsequently maintained on 75 mg daily for a minimum of 6 months. Patients who had previously been intolerant of clopidogrel secondary to bleeding complications or known allergy were administered 325 mg of aspirin and maintained on 325 mg/day.

Follow-Up

Patients were seen in follow-up initially at 1, 3, and 6 months after their procedure. Patients were then evaluated at 6-month intervals. Follow-up visits included an office visit with a physician and noninvasive studies including ABIs, pulse volume recordings, and complete arterial duplex ultrasound examinations of the treated limb. Patients who developed recurrent symptoms, evidence of recurrent or novel stenoses on ultrasound, or significant ABI decreases (>0.15) underwent angiography. Follow-up data were gathered from hospital visits and in-hospital imaging via our electronic medical record system in addition to reports of patients' clinic visits. Additional mortality data were obtained from the Social Security Death Index.

All angiographic imaging in patients who were converted to an open surgical revascularization during follow-up was reviewed. Images were analyzed for the distal extent of the original treated lesion, runoff score, evidence of distal embolization, and distal target selection for bypass after endovascular interventions.

Definitions and Classifications

Coronary artery disease was defined as a history of angina, myocardial infarction, or prior coronary artery revascularizations. Chronic renal impairment was defined as a serum creatinine level of 1.5 mg/dL or greater or a patient on permanent dialysis. Cerebrovascular disease included a history of stroke, transient ischemic attack, or previous carotid artery revascularization. Hypertension was defined by medication requirement to maintain a systolic blood pressure < 140 mm Hg. Hypercholesterolemia and diabetes were defined based on patients who had elevated cholesterol levels (either total or reduced high-density lipoprotein/low-density lipoprotein ratios) including those who were on lipid-lowering agents and the use of insulin or oral hypoglycemics, respectively.

TASC II classification was determined by the extent of the lesion at time of initial diagnostic angiogram and therapeutic intervention. Patients who required reintervention were not crossed over into the TASC C category.

Endovascular procedures were considered technically successful when all lesions treated had a < 20% residual stenosis on completion angiography. Primary patency was defined as the absence of restenosis or occlusion in the treated arterial segment. Restenosis was defined as either a return of patients' symptoms in conjunction with noninvasive testing, which confirmed recurrent disease (ABI decrease > 0.15, dampened pulse volume recordings, or evidence of stenoses by duplex ultrasound peak systolic velocity > 300 cm/s or ratio > 3.0 or based on duplex findings indicative of recurrent disease alone for select patients who had no clinical symptoms. Occlusion was defined as a return of the patients' symptoms in conjunction with absence of arterial flow on color duplex in the treated vessel or, in asymptomatic patients, based on duplex findings alone. Assisted-primary patency was achieved via secondary endovascular interventions to treat restenosis involving the originally treated arterial segment. Additional procedures to treat lesions proximal or distal to the initially treated segment were also considered secondary interventions to achieve assisted-primary patency. Secondary patency was achieved utilizing additional endovascular procedures, which involved recanalizing occluded arterial segments. Patients who underwent surgical bypass after occlusion of a segment which had been treated using endovascular techniques were not considered patent for this analysis and were considered converted to open by bypass.

Statistical Analysis

An independent statistician performed all advanced statistical analyses. Freedom from restenosis, freedom from reintervention, primary patency, and assisted-patency were calculated using survival curve analysis. Univariate regression analysis was used to determine possible preprocedural and anatomic predictors of restenosis including comorbidities, indications for treatment, and anatomic factors. Variables with a *p*-value < 0.25 on univariate analysis were then assessed in a multivariate regression analysis using Cox proportional hazards modeling.

Results

During the study period, a total of 236 limbs in 186 patients were treated. Average age was 74.2 years (range 37–94). Number of limbs in each TASC II classification were B: 121 (51.3%), C: 37 (15.7%), and D: 78 (33.0%), respectively. Overall survival for the 5-year study period was 44% with the number of patients alive in each TASC II group being B: 34, C: 13, and D: 35, respectively. Patient characteristics are shown in ►Table 1. Indication for treatment was critical limb ischemia (CLI) (Rutherford 5 and 6) in 42.4% of patients; the remainders were treated for debilitating claudication. Limb salvage was 99.17% for TASC II B (1/121), 100% for TASC II C (0/37), and 97.4% for TASC II D (2/78), respectively.

Primary and primary-assisted patencies based on TASC II classification are B: 55.1%, 91.9%; C: 37.4%, 74.6%; and D: 35.5%, 67.0% at 5 years, respectively. Evaluation of patency based upon initial indication for intervention (claudication vs CLI) stratified by TASC II classification revealed that claudicants had a primary and primary-assisted patency rate of 48.4% and 84.3%, respectively, while CLI patients had patency rates of 44.0% and 83.7%, respectively (►Table 2, ►Fig. 2). Secondary patency rates at 5 years for B, C, and D lesions were 93%, 83%, and 76%, respectively, and for claudication versus CLI were 89.3% and 81.8%, respectively. Univariate analysis of factors associated with loss of primary patency identified age > 75, CLI, and the presence of cerebrovascular disease (►Table 3). Cox regression analysis failed to identify any significant predictors of failure.

Table 1 Demographics

Claudication		55.2%		
Cerebrovascular disease		14.6%		
Chronic renal insufficiency		16.1%		
Congestive heart failure		10.4%		
Diabetes		41.1%		
High cholesterol		52.6%		
Hypertension		77.6%		
Male sex		57.3%		
Popliteal stent		24.5%		
<2 Infrapopliteal runoff		39.4%		
Smoking		Never	Former	Current
		35.9%	41.2%	22.9%
Limbs by TASC II Classification	Number	B 121	C 37	D 78
	Percent	51.3%	15.7%	33.1%
Age:	Mean = 74.2			
	SD = 11.35			
	Range = [37.0 ... 94.7]			

Abbreviations: SD, standard deviation; TASC II, Trans-Atlantic Inter-Societal Consensus II.

Table 2 Patency at 5 years

Patency at 5 years: TASC II			
TASC	Primary patency	Primary-assisted patency	
B	55.10%	91.90%	$p = 0.237$ $p = 0.058$
C	37.40%	74.60%	
D	35.50%	67.00%	
Patency at 5 years: claudication versus CLI			
	Primary patency	Primary-assisted patency	
Claudication	48.40%	84.30%	$p = 0.989$ $p = 0.568$
CLI	44.00%	83.70%	

Abbreviations: CLI, critical limb ischemia; TASC II, Trans-Atlantic Inter-Societal Consensus II.

Data on reintervention and conversion rates to open procedures, amputations, and change in target sites are listed in ►Table 4. No significant differences were identified when analyzed by TASC II classification or indication for intervention. A total of eight limbs were converted to open surgical revascularization TASC II B: 4, TASC II C: 3, and TASC II D: 1. Two of the converted patients had their bypass target sites changed from what was originally identified prior to endovascular intervention. The first patient was a 65-year-old male who had a TASC II B lesion and had two-vessel runoff pre- and post-bypass. His target sites changed from an above knee popliteal artery to a below knee popliteal artery. This patient underwent a total of four endovascular interventions over the course of 35 months.

Fig. 2 Primary and primary-assisted patency.**Table 3** Factors associated with loss of primary patency

Univariate analysis				
	Patients with condition			<i>p</i>
Age > 75	20.2%			0.01
Male sex	27.6%			0.84
CLI	20.0%			0.35
Cerebrovascular disease	42.1%			0.23
Chronic renal insufficiency	22.5%			0.47
Congestive heart failure	25.0%			0.80
Diabetes	32.3%			0.13
High cholesterol	28.8%			0.53
Hypertension	25.5%			0.31
Popliteal stent	24.1%			0.72
<2 infrapopliteal runoff	24.7%			0.49
Smoking	Never	Former	Current	<i>p</i>
	19.8%	33.3%	27.5%	0.12
TASC II	B	C	D	<i>p</i>
	23.1%	43.2%	25.6%	0.052

Abbreviations: CLI, critical limb ischemia; TASC II, Trans-Atlantic Inter-Societal Consensus II.

Eventually after these multiple interventions, endovascular treatments were no longer an option. The second patient was a 57-year-old male with a TASC II C lesion and three-vessel runoff pre- and post-bypass. His bypass target site also changed from an above knee popliteal artery to a below knee popliteal artery due to a stenosis in the proximal popliteal artery and his endovascular treatments lasted a total of 51 months prior to him requiring a bypass.

Three limbs were amputated during the study period. The first patient was from the TASC II B group and was a 42-year-old female with claudication. Initially, she was treated with angioplasty and stenting, which failed, necessitating a bypass to the below knee popliteal artery, which was actually identified as her preintervention target site. Her bypass became infected and was removed; a second bypass was placed after treatment; however, this failed and she required an amputation 49 months after her initial endovascular procedure. Two patients from group D underwent amputation. The first was an 81-year-old female who previously had a lower extremity bypass that occluded in 2007. Her native system was salvaged to her only runoff vessel in the leg. She underwent an above knee amputation 60 months after her first endovascular intervention. The second patient was a 76-year-old female who had a single vessel runoff. She underwent an above knee amputation 48 months after her initial endovascular procedure due to a severe diabetic foot infection.

Analysis of survival during the study period was conducted focusing on TASC II type lesion or indication for intervention. Based on TASC II classification alone, survival

Table 4 Data on reintervention and conversion rates to open procedures, amputations, and change in target sites

TASC II	Reintervention	Mean months to first intervention	Conversion to bypass	Conversion to amputation	Change in bypass target site
B	26.5%	30	4	1	1
C	43.2%	23.5	3	0	1
D	25.6%	22	1	2	0
<i>p</i>	0.107				

Abbreviations: CLI, critical limb ischemia; TASC II, Trans-Atlantic Inter-Societal Consensus II.

at 5 years was 37.4%, 48.2%, and 47.3% for TASC II B, C, and D, respectively. Survival at 5 years for patients with claudication versus CLI was 53.35 % and 39.9%, respectively ($p < 0.001$) (►Fig. 3) Univariate analysis identified deaths to be associated with age > 75 and CLI (►Table 5). Cox regression analysis identified both CLI and smoking as significant predictors of death (hazard ratio [HR] 2.6, 1.75–3.84, $p < 0.001$, HR 3.33, 1.70–6.52, $p < 0.001$).

Discussion

In 2000 and revised in 2007, the TASC II document was published to serve as a guide to physicians for the treatment of lower extremity ischemia. This document was framed around the available data at the time using both long- and

short-term data to construct its recommendations. Short-term data demonstrated good results for TASC II A and B, but both C and D lesions often had worse outcomes; little long-term data was available. This resulted in the recommendation of endovascular first treatments for A and B lesions and open approached for C and D lesions.

Since the publication of the TASC II guidelines, physicians and industry have been pushing the limits of endovascular therapies. Both endovascular techniques and technology have made major advances over the past decade allowing for the common treatment of more advanced vascular pathology. Despite all these advances, a few long-term studies have been published leaving a paucity of long-term data. Little is available demonstrating treatment patency, limb salvage rates, and mortality.

Fig. 3 Survival: TASC-II and symptoms.**Table 5** Factors associated with mortality

Univariate analysis				
	With condition	<i>p</i>		
Age > 75	61.3%	< 0.001		
Male sex	49.1%	0.901		
CLI	65.1%	< 0.001		
Cerebrovascular disease	55.2%	0.506		
Chronic renal insufficiency	64.5%	0.067		
Congestive heart failure	60.0%	0.320		
Diabetes	55.7%	0.150		
Hypercholesterol	44.1%	0.114		
Hypertension	47.0%	0.197		
Popliteal stent	51.0%	0.768		
< 2 Infrapopliteal runoff	57.0%	0.072		
Smoking	Never	Former	Current	<i>p</i>
	50.7%	46.8%	52.3%	0.818
TASC II	B	C	D	<i>p</i>
	50.6%	40.7%	51.4%	0.616

Abbreviations: CLI, critical limb ischemia; TASC II, Trans-Atlantic Inter-Societal Consensus II.

This study evaluated 236 limbs in 186 patients with a survival of 44.3% at 5 years. Primary and primary-assisted patency rates were acceptable and treatments were well tolerated. Previous studies have reported primary patency rates for endovascular interventions to be¹³ consistent with this data. Primary and primary-assisted patency had no single predictor of failure, cox univariate analysis identified age over 75 years, CLI and cerebrovascular disease as predictors of loss of primary patency. Additionally, secondary patency was over 76% in all categories, which is comparable to historically accepted patency rates for open revascularization with patency rates between 60% and 80%.^{14,15}

Reintervention rates were between 25% and 43%; conversion to bypass occurred in only eight patients and three patients required major amputations. Although these values seem lower than expected, a factor that may be associated with the high rate of endovascular patency and low rate of conversion to open was the frequency of follow-up and screening to identify potentially problematic lesions. Coupled with an aggressive treatment strategy for recurrent stenosis, such a strategy resulted in good primary-assisted patency rates. Another unusual finding was the mean time to reintervention between 22 and 29 months. This is far longer than the expected reintervention rate; however, it is felt that this is due to the number of patients enrolled. Post hoc analysis demonstrated that some patients required upward of four procedures at 6-month intervals and others required no reintervention at all. Unfortunately, no specific differences between these two observed groups were identified making it impossible to predict why some patients may be poor endovascular responders. It is obvious, however, that differences in the population do exist; however, this study lacks the resolution to answer this question.

Most surprising in this study was the 5-year survival rate of 44.3%. This was much lower than pretest predictions expected and raised some interesting questions. Cox analysis identified CLI and smoking, former and current, as the strongest predictors of death (HR 2.19 and 1.17—former and 3.33—current). Although these predictors of mortality in themselves are not surprising, the implications of having these risk factors and choosing a treatment strategy open versus endovascular revascularization do become interesting. A criticism of endovascular therapies is that it has poor long-term patency compared with the open approach and is thus inferior. However, with 66% of the patients deceased at 5 years perhaps long-term patency is not a realistic end point for this population; rather these are true and unrelated. This leaves limb salvage as the probable best measurement of success for revascularization. In this current report, nearly 50% of patients were treated for CLI (5/6) with an acceptable amputation rate at 5 years (reference).

In summary, this study supports the concept that an endovascular first approach is not only safe and effective but also provides a reasonably durable repair option for

patients who present with CLI or refractory claudication. This treatment strategy does not appear to jeopardize future bypass options and offers a low risk for conversion to amputation.

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