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Clinical Outcomes After Endovascular Treatment of Superficial Femoral Disease in Patients With Disabling Claudication and Critical Limb Ischemia: Midterm Analysis

A. J. Misselt¹, M. D. Zielinski², O. I. Garcia Medina¹, G. Oderich², H. Bjarnason¹, M. A. McKusick¹, and Sanjay Misra, MD, FSIR, FAHA¹

¹Division of Vascular and Interventional Radiology, Mayo Clinic, Rochester, MN, USA

²Department of Surgery, Mayo Clinic, Rochester, MN, USA

Abstract

We present the midterm clinical outcomes and predictors of balloon angioplasty and stent placement in atherosclerotic femoropopliteal (FP) arterial disease. Between January 2002 and August 2006, 155 patients (men = 56%; 71.4 ± 10.5 years) underwent 171 FP angioplasty or stent for claudication (n = 82, 54%) or critical limb ischemia ([CLI] n = 70, 46%). Follow-up was obtained through September 30, 2009. The average follow-up was 3.25 ± 1.73 years. In claudicants versus CLI, the 12-month patency for TransAtlantic InterSociety Consensus II (TASC II) classification (TASC A/B) was 93% versus 80%, respectively, and TASC C/D 83% versus 80%. At 3 years, TASC A/B was 82% versus 80%, respectively, and TASC C/D was 56% versus 80%, respectively. The predictor of clinical failure in claudicants was chronic renal insufficiency (CRI) and in CLI, the predictor of amputation was hyperlipidemia.

Keywords

angioplasty; stent; superficial femoral arterial disease; outcomes

Introduction

Peripheral arterial disease (PAD) involving the superficial femoral and popliteal arteries is a common and challenging medical problem. The incidence of PAD increases with age and is estimated¹ to afflict 4.3% of the population over 40 years of age and 14.5% of those over 70. Depending on the severity and extent of the disease, patients may be asymptomatic or present with clinical symptoms ranging from claudication to tissue loss. The incidence of

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Corresponding Author: Sanjay Misra, Mayo Clinic, 200 First Street SW, Department of Radiology, Division of Vascular and Interventional Radiology, Vascular and Interventional Translational Lab, Rochester, MN 55902, USA misra.sanjay@mayo.edu.

Declaration of Conflicting Interests

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critical limb ischemia (CLI) is from 500 to 1000 patients per million in the Western world.² Once diagnosed with CLI, the natural history at 1 year is poor (25% mortality and 30% amputation rate).²

Increasingly, angioplasty or stent placement for femoropopliteal (FP) disease is the first-line treatment, while open surgical bypass is reserved for patients who are either unsuitable for endovascular management or whose PAD progresses despite prior intervention.² Some authors have noted that the transition to first-line use of catheter-based therapy represents a paradigm shift.³⁻⁵ Many randomized trials involving the superficial femoral artery (SFA) exclude patients with CLI and chronic renal insufficiency (CRI), thereby excluding the ability to translate their results to the “real world.” The purpose of our study is to present our outcomes after FP angioplasty or stent placement in terms of patency, freedom from revascularization, wound healing, and freedom from amputation for patients with claudication and CLI.

Materials and Methods

Our institutional review board approved this study. We performed a retrospective review of patients who underwent percutaneous FP arterial revascularizations from January 2002 to December 2006. The study group comprised of 155 patients who underwent 171 angioplasty or stent placement procedures of the SFA or popliteal artery. Patients with stenosis involving bypass grafts or stenosis after common femoral endarterectomy were excluded. The average age of the patients was 71.5 ± 10.3 years (median age = 72.1, men = 87; 56%; Table 1). The cardiovascular risk factors included hypertension (n = 135, 88%), dyslipidemia (n = 114, 74%), smoking history (n = 114, 75%), coronary artery disease (n = 96, 62%), diabetes mellitus (n = 83, 54%), and CRI (n = 48, 31%). The mean baseline ankle-brachial index (ABI) was 0.58 ± 0.2 . In total, 51 (30%) patients had noncompressible vessels and therefore an ABI could not be obtained. The indications for revascularization were claudication (n = 95, 56%) and CLI (n = 73, 43%) of which the majority of patients (n = 62, 85%) had tissue loss. Baseline and follow-up data were obtained from the electronic medical records through September 30, 2009. The primary end points included restenosis, endovascular revascularization, surgical bypass, amputation, and death.

Typically, as part of the initial clinical evaluation, patients with suspected PAD underwent ABI assessment. Further evaluation using duplex US or computed tomography angiography was performed at the discretion of the treating physician.

Ankle-Brachial Index

Standard ABI technique was performed as outlined in the Inter-Society Consensus for the Management of Peripheral Arterial Disease document.² Briefly, brachial blood pressure measurements were obtained in both arms and anterior and posterior tibial blood pressure measurements were obtained in the limb of interest using a standard blood pressure cuff and continuous wave Doppler transducer. The higher of either limb measurements in the arm and leg were used to derive the ratio.

Duplex US

Duplex US was used for screening, quantification, and follow-up of the FP stenoses. Baseline and follow-up duplex US studies were performed with a 2.5- to 4.5-MHz phased-array transducer (128/XP; Acuson, Mountain View, California; or Sequoia 512; Siemens Medical Systems, Erlangen, Germany).

Computed Tomography Angiography

A 16 or 64 multichannel computed tomography (CT) scanner (General Electric, Wisconsin) was used. Nonionic iodinated contrast material (Visipaque 320, GE Healthcare, Princeton, New Jersey) was intravenously injected with dosing based on the patients' weight and renal function ranging between 100 and 150 mL. Axial, multiplanar, and 3-dimensional (3-D) reconstructed images were used in the interpretation. Stenoses were quantified based on the percentage of cross-sectional luminal narrowing with respect to the normal reference vessel diameter.

Femoropopliteal treatment—All procedures were performed according to the standard technique after obtaining informed consent. Depending on the anatomic considerations, access was obtained from either an ipsilateral or contralateral common femoral approach, or from an ipsilateral popliteal approach. Typically, a 6F to 8F vascular sheath (Terumo, Somerset, New Jersey) was placed in the artery over a 0.035-inch guide wire after systemic heparinization (50 U/kg). A variety of standard angioplasty balloons and stents were used. The majority of stents deployed were self-expanding. However, in some instances, at the discretion of the treating physician, balloon expandable stents were used. The following stents were used: Herculink and Absolute stent (Abbott Vascular, Redwood City, California), Conformex and Luminex stent (Bard Peripheral Vascular Inc, Tempe, Arizona), Zilver stent (Cook Medical Inc, Bloomington, Indiana), S.M.A.R.T. and Precise stent (Cordis Corporation, Bridgewater, New Jersey), Protégé stent (ev3 Endovascular Inc, Plymouth, Minnesota), Racer stent (Medtronic Inc, Minneapolis, Minnesota). The length and diameter of the stent used was based on the length of the stenosis and the diameter of the nondiseased artery distal to the stenosis. Pressure gradients were obtained only if there was a question of lesion severity. A gradient measured above and below stenosis >10% of the peak systolic pressure was considered hemodynamically significant.

Tibial runoff vessels were described as patent if they provided inline flow to the foot or occluded if they contained proximal or midlevel occlusions with or without distal refilling. The numbers of patent tibial runoff vessels to the foot were classified as 1, 2, or 3. Tibial vessels with stenosis or occlusion were typically treated with angioplasty in patients with CLI. Tibial stenoses were not treated routinely in patients with claudication. After the procedure, patients were started on antiplatelet therapy using either 81-mg daily oral dose of aspirin for life or 300-mg initial oral dose of clopidogrel (Sanofi-Aventis, Bridgewater, New Jersey), followed by 75 mg daily oral dose for a minimum of 3 months followed by 81-mg daily oral dose of aspirin for life. Patients were treated for other comorbidities such as hyperlipidemia with the initiation of statin therapy as needed.

Follow-up—Follow-up was advised at 1 week, then at 3, 6, and 12 months, and then every 6 months after the procedure. At each time point, clinical evaluation was performed including ABIs with noninvasive vascular studies and an US. If indicated, additional follow-up was obtained including CT angiography or conventional angiography as needed to determine the patency of the treated arteries.

Definitions—Femoropopliteal stenoses and occlusions were defined according to the Inter-Society Consensus for the Management of Peripheral Arterial Disease (TASC II) document.² Patients were divided based on the treatment approach into groups receiving angioplasty or stent and into claudication or CLI groups. Technical success of the procedure was defined by <30% residual stenosis by visual estimate of the completion angiogram. Clinical success of the procedure was defined as freedom from amputation, absence of restenosis, or revascularization of the target artery after index procedure. In-stent restenosis was defined as more than 50% blockage by visual estimate on follow-up conventional angiography or CT; or 3 times increment in the translesional peak systolic velocities obtained with at a Doppler angle of $\leq 60^\circ$ based on US. All complications were recorded according to the guidelines published by the Society of Interventional Radiology.⁶

Statistical methods—SAS software (version 9; SAS, Cary, North Carolina) was used for all statistical analyses. Categorical variables were expressed as ratios and percentages and continuous variables as means $\pm$ SD. Comparison for continuous variables before and after SFA intervention was performed with a 2-tailed Student *t* test. To determine the predictive factors associated with limb loss and clinical success or failure, univariate and multivariate analysis was performed using the Cox proportional hazards method. Lifetable survival analysis with Kaplan-Meier estimates was performed to calculate cumulative survival from primary end points including death, amputation, and freedom from restenosis or revascularization. Comparison among the subgroups was performed using the Wald test. A *P* value of <.05 was considered significant.

Results

Angiographic Characteristics

A total of 155 patients with a mean age of 71.5 ± 10.3 years (median age = 72.1, men = 87; 56%) underwent 171 procedures. Procedural access was obtained via the contralateral common femoral artery in 125 (74%), antegrade common femoral artery in 42 (25%), and ipsilateral popliteal artery in 2 (1%). The angiographic and lesion characteristics according to the TASC classification are summarized in Tables 2-5. A total of 25 patients had iliac artery stenosis treatment using either balloon-expandable or self-expanding stents in conjunction with SFA treatment. In total, 4 SFA stenosis were treated with a balloon-expandable stent and the remainder had self-expanding stents of which the majority was Everflex self-expanding stents (50 out of the 88 limbs [57%]). In total, 64 (38%) patients had TASC A stenosis or occlusion, 73 (43%) patients had TASC B, 27 (16%) had TASC C, and 6 (4%) had TASC D class. The number of patent tibial arteries prior to treatment was 3 arteries in 55 (32%) patients, 2 arteries in 68 (40%) patients, 1 artery in 45 (26%) patients, and no artery runoff in 2 (1%) patients. As expected, patients with CLI had worse runoff

when compared with those with claudication ($P = .02$). Patients with CLI had 1-vessel runoff in 37% compared with 20 for claudication, 2-vessel runoff in 30% compared with 43%, and 3-vessel runoff in 26% compared with 37%.

Follow-up

The average follow-up was 3.25 ± 1.73 years (median = 3.1). In all, 8 patients did not have any follow-up after their procedure other than during the hospital admission. In total, 88 patients had follow-up with noninvasive studies and 25 patients had an additional vascular imaging such as US. An additional 51 patients had imaging studies along with a clinical evaluation. Finally, an additional 24 patients had only a clinical evaluation. There were 50 deaths over the study period.

Outcomes

The mean baseline ABI was 0.58 ± 0.2 ($n = 120$) and increased to 0.79 ± 0.21 ($n = 88$, $P < .001$) and to 0.82 ± 0.21 ($n = 88$, $P < .001$) after the procedure as measured in the dorsalis pedis and posterior tibial, respectively. The 1-year survival rates for the study group, claudication, and CLI groups were 96%, 97%, and 94%, respectively ($P = .23$ for the difference between patients with severe claudication and CLI at 1 year).

The average length of follow-up for limb salvage was 20.3 ± 16.8 months (median = 16.2 months, 1 day, 86.5 months) and the 1-year limb salvage rate was 85%, 97%, and 72% for the study group, claudication, and CLI subgroups, respectively ($P < .001$ for the difference between severe claudication and CLI). The average length of follow-up for primary patency was 21.7 ± 18.1 months (median = 17.3, 1 day, 86.5 months) and the primary patency rates at 1-year for the study group, claudication, and CLI groups were 87%, 91%, and 82%, respectively ($P = .07$ for the difference between claudication and CLI groups). Among those with restenosis and occlusion, 7 patients had major amputation (either above knee or below knee), 26 had repeat percutaneous revascularizations, and 11 had surgical bypass.

In the study group, angioplasty alone was performed in 88 (48%) and stents were placed in 80 (52%). In the claudication group, 52 (55%) had angioplasty alone and 43 (45%) had stent placement, whereas in the CLI group 36 (49%) had angioplasty alone and 37 (51%) had stent placement. We estimated the primary patency rates for the interventions by TASC class status for the study group, claudication, and CLI groups. At 12 months, the patency for the study group for TASC A/B was 90% and TASC C/D 81% and by 3 years, it was 83% and 69%, respectively (Figure 1; $P = .08$). In claudicants, the 12-month patency for TASC A/B was 93% and TASC C/D 83% (Figure 2; $P = .10$) and by 3 years, it was 82% and 56%, respectively. For CLI, the 12-month patency for TASC A/B lesions was 83% and TASC C/D 80% ($P = NS$). By 3 years, the patency rates were 80% and 80%, respectively. The predictors of clinical failure in the study group were diabetes mellitus (DM) and CRI, whereas in claudicants it was CRI alone and in CLI, the predictor of amputation was hyperlipidemia.

Using Cox proportional hazards analysis, the following variables including age at intervention, sex, history of smoking, DM, coronary artery disease, hyperlipidemia, CRI,

TASC classification, and number of patent tibial vessels were studied for their predictability of clinical success or failure (Tables 6 and 7) and for amputation (Tables 8 and 9). Diabetes mellitus at baseline (Table 6; $P = .049$, hazard ratio [HR] = 1.699) and history of chronic renal failure ($P = .009$, HR = 2.096) predicted clinical failure for the study group by univariate analysis. History of chronic renal failure (Table 7; $P = .03$, HR = 2.957) predicted clinical failure for the claudication group. The risk of amputation was greater in patients with DM in the study group (Table 8; $P = .004$, HR = 2.952) with a trend toward patients with CRI ($P = .10$, HR = 1.76). The risk of amputation was analyzed in the claudication group and found to be significantly increased in patients with hyperlipidemia ($P = .005$, HR = 0.111) and patients with TASC C and D lesions (Table 9; $P < .001$, HR = 0.57).

Complications

The minor complication rate was 10.5% ($n = 18$). The minor complications included groin hematoma ($n = 2$), dissection ($n = 6$), arterial rupture ($n = 1$), arteriovenous fistula ($n = 1$), thrombosis ($n = 4$), and distal embolization ($n = 4$). The major complication rate was 1.1% ($n = 2$). The major complications included myocardial infarction ($n = 1$) and contrast medium-induced nephropathy ($n = 1$). The mortality rate was 1.1% with 2 deaths occurring within 30 days of the procedure and both of which were not procedurally related.

Discussion

Percutaneous intervention of FP disease is an evolving topic. The first balloon angioplasty⁷ was performed in 1974. Over the next decades, angioplasty gained acceptance as a treatment for short focal lesions and later as a treatment for longer and more complex lesions. In the late 1990s, stent placement was introduced as a method of salvaging a failed angioplasty in order to improve the luminal gain and decrease elastic recoil.⁸ Concerns over stent fracture secondary to the complex mechanical stresses placed on stents in the FP distribution led to the use of self-expanding nitinol stents.⁹ In 2006, Schillinger and colleagues published a prospective trial comparing angioplasty alone with primary stent placement and concluded that primary stent placement yields lower restenosis rates at 1 year and better clinical improvement in walking distance.¹⁰

Most randomized studies which have investigated the role of SFA stents for patients with claudication and not those with CLI or those with CRI and DM, thus making it difficult to assess the efficacy of this therapy in these patients.¹⁰ Recently, the results from the Resilient trial were published, which randomized patients to SFA stenting or angioplasty.¹¹ In this trial, a patency rate of 80% with stenting of 7.05 cm lesions when compared to angioplasty (6.44 cm) was observed. However, it excluded many patients, which are typically seen in our practice. For example, in the present study, 46% of the patients had CLI and the rest had Rutherford stage 4 claudication. In addition, patients with chronic renal failure or those receiving dialysis were ineligible for inclusion in the trial. In our study, we had 30% of the patients with CRI.

In the present study, we had nearly equivalent numbers of patients with claudication and CLI. These 2 groups were treated in similar proportions with either angioplasty alone (55% claudication and 49% CLI) or stent placement. For the entire study group, patients had a

trend toward improved patency for shorter lesions than the longer lesions according to the TASC classification ($P = .08$). This observation continued in patients with claudication did better with shorter TASC lesions (A and B) than with longer lesion (C and D). However, in patients with CLI, this observation did not hold true, possibly due to the small number of patients. Recent publications have focused on the factors which may be predictive of procedural success. Davies and colleagues investigated the impact of popliteal and tibial runoff on SFA interventions in the setting of both claudication and CLI.^{12,13} Not surprisingly, the authors concluded that poor runoff lowers the patency rate of SFA intervention and the results in diminished freedom from symptom recurrence and limb salvage.

We determined the predictors of a successful outcome using univariate analysis of several important comorbidities and angiographic criteria. Using this analysis, we found that patients who had CRI and DM did worse than those who did not. Furthermore, we evaluated the same factors in patients with claudication and found that patients with CRI did worse than those who had normal kidney function. Finally, we determined the predictors of amputation in the study group and found that patients with DM were at increased risk when compared with those without it. There was a trend toward increased amputation risk in patients with CRI. Finally, we determined this for the claudication group and found that there was increased risk of amputation in patients with hyperlipidemia and longer SFA lesions TASC C and D. Using a similar data set, Bakken and colleagues investigated the impact of DM on endovascular SFA intervention outcomes. Their study found that patients with claudication with DM had lower assisted patency rates and higher restenosis rates, whereas patients with CLI and DM demonstrated worse limb salvage rates than their nondiabetic counterparts, despite equivalent SFA patency rates.

This study is associated with inherent limitations due to its relatively small scale and retrospective design. The results may have selection bias as majority of study participants are primarily Caucasians referred to a tertiary care center. A comparison between stent and angioplasty cannot be performed because of the retrospective nature of the study and therefore not determined.

In this retrospective study, we observed a trend toward improved patency in TASC A and B lesions when compared to TASC C and D. The predictors of clinical failure in the study group were DM and CRI, whereas in patients with claudication, it was CRI. The predictor of amputation in the study group was DM and in patients with CLI, it was hyperlipidemia. Studies in patients with SFA disease and CLI with CRI and DM need to be conducted to validate these observations.

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Figure 1. Kaplan-Meier estimates for patency by TASC classification for the study group. TASC indicates TransAtlantic InterSociety Consensus.

Figure 2. Kaplan-Meier estimates for patency by TASC classification for the severe claudication group. TASC indicates TransAtlantic Inter-Society Consensus.

Table 1

Patient Demographics and Clinical Data

	n or Mean for Continuous Variables	(%) or s.d. for Continuous Variables	Data Available
Demographics			
# of Patients	155	(100%)	155
# of Procedures	171	(100%)	171
Age at intervention (years)	71.53	±10.29	171
Men	87	(56%)	155
Cardiovascular risk factors			
Hypertension	135	(88%)	154
Diabetes	83	(54%)	154
Smoking history	114	(75%)	152
Hyperlipidemia	114	(74%)	154
Coronary artery disease	96	(62%)	154
Chronic renal insufficiency	48	(31%)	154
Indication			
Claudication	82	(54%)	152
Critical limb ischemia	70	(46%)	152
Noncompressible vessels	51		
Preankle–brachial index of the target limb (in patients with compres- sible vessels)	0.58 ± 0.2		

Table 2

Angiographic Data: TransAtlantic InterSociety Consensus II (TASC II) Class by Claudication and Critical Limb Ischemia (CLI)

Variable	Overall (N = 171)	0 = CLI (N = 73)	1 = Claudication (N = 95)	Pearson Chi-Square <i>P</i> Value
TASC, N (%)				.07 ^a
1 = A	64 (38%)	23 (32%)	39 (41%)	
2 = B	73 (43%)	29 (40%)	43 (45%)	
3 = C	27 (16%)	15 (21%)	12 (13%)	
4 = D	6 (4%)	5 (7%)	1 (1%)	

^a*P* value based on TASC as a 3-level variable, grouped as A, B, C, or D.

Table 3

Angiographic Data: TransAtlantic InterSociety Consensus (TASC) Class by Treatment

Variable	Overall (N = 171)	Angioplasty Only (N = 91)	Stent (N = 80)	P Value ^a
TASC, N (%)				<.001
1 = A	64 (38%)	46 (51%)	18 (23%)	
2 = B	73 (43%)	38 (42%)	35 (44%)	
3 = C	27 (16%)	4 (4%)	23 (29%)	
4 = D	6 (4%)	2 (2%)	4 (5%)	

^a P value based on TASC as a 3-level variable, grouped as A, B, C, or D.

Table 4

Angiographic Data: Runoff by Severe Claudication (SC) and critical limb ischemia (CLI)

Variable	Overall (N = 171)	0 = CLI (N = 73)	1 = SC (N = 95)	Pearson's Chi-Square <i>P</i> Value
Runoff treatment, No. (%)				.002
0 = No	141 (92%)	55 (83%)	83 (98%)	
1 = Yes	13 (8%)	11 (17%)	2 (2%)	

Table 5

Angiographic Data: Runoff by Treatment

Variable	Overall (N = 171)	Angioplasty only (N = 91)	Stent (N = 80)	P Value ^a
Runoff treatment, N (%)				.66
0 = No	141 (92%)	67 (91%)	74 (93%)	
1 = Yes	13 (8%)	7 (9%)	6 (8%)	

Table 6

Univariate Analysis for Predictors of Clinical Failure in the Study Group

Variable	Reference	Hazard Ratio	95% Lower Confidence Limit for Hazard Ratio	95% Upper Confidence Limit for Hazard Ratio	P Value ^a
Age at intervention	(per 10)	0.922	0.657	1.293	.64
Gender, male	Female	0.726	0.431	1.223	.23
Smoking history 1 = Yes	0 = No	0.679	0.392	1.175	.17
Hypertension 1 = Yes	0 = No	0.967	0.509	1.838	.92
Diabetes mellitus 1 = Yes	0 = No	1.699	1.002	2.880	.049
Coronary artery disease 1 = Yes	0 = No	1.274	0.748	2.171	.37
Hyperlipidemia 1 = Yes	0 = No	1.201	0.687	2.100	.52
Chronic renal insufficiency 1 = Yes	0 = No	2.096	1.204	3.648	.009
TASC (3 level) 2 = B	1 = A	0.939	0.510	1.730	.26
TASC (3 level) 3 = C or D	1 = A	1.582	0.819	3.055	
TASC (2 level) 1 = C or D	0 = A or B	1.634	0.910	2.932	.10
# of Patent tibial vessels = 2	0 or 1 vessels	0.798	0.426	1.495	.48
# of Patent tibial vessels = 3	0 or 1 vessels	0.671	0.352	1.281	

Abbreviation: TASC, TransAtlantic InterSociety Consensus II.

^aWald test, using sandwich estimate for the covariance matrix.

Table 7

Univariate Analysis for Predictors of Clinical Failure Within the Claudication Group

Variable	Reference	Hazard Ratio	95% Lower Confidence Limit for Hazard Ratio	95% Upper Confidence Limit for Hazard Ratio	P Value ^a
Age at intervention	(per 10)	1.140	0.735	1.771	.56
Gender, male	Female	0.542	0.224	1.312	.17
Smoking history 1 = yes	0 = No	0.675	0.260	1.753	.42
Hypertension 1 = yes	0 = No	0.985	0.380	2.555	.98
Diabetes mellitus 1 = yes	0 = No	1.236	0.516	2.961	.63
Coronary artery disease 1 = yes	0 = No	1.082	0.466	2.508	.85
Hyperlipidemia 1 = yes	0 = No	0.717	0.317	1.619	.42
Chronic renal insufficiency 1 = yes	0 = No	2.957	1.111	7.871	.030
TASC (3 level) 2 = B	1 = A	1.053	0.394	2.815	.44
TASC (3 level) 3 = C or D	1 = A	1.924	0.675	5.487	
TASC (2 level) 1 = C or D	0 = A or B	1.878	0.703	5.013	.21
# of Patent tibial vessels = 2	0 or 1 vessels	0.904	0.268	3.053	.98
# of Patent tibial vessels = 3	0 or 1 vessels	0.907	0.277	2.971	

Abbreviation: TASC, TransAtlantic InterSociety Consensus II.

^aWald test, using sandwich estimate for the covariance matrix.

Table 8

Univariate Analysis for the Predictors of Amputation for the Study Group

Variable	Reference	Hazard Ratio	95% Lower Confidence Limit for Hazard Ratio	95% Upper Confidence Limit for Hazard Ratio	P Value ^a
Age at intervention	(per 10)	0.887	0.575	1.368	.59
Gender, Male	Female	1.030	0.539	1.970	.93
Smoking history 1 = yes	0 = No	0.727	0.363	1.455	.37
Hypertension 1 = yes	0 = No	0.902	0.397	2.051	.81
Diabetes mellitus 1 = yes	0 = No	2.952	1.409	6.184	.004
Coronary artery disease 1 = Yes	0 = No	1.290	0.652	2.551	.46
Hyperlipidemia 1 = yes	0 = No	0.631	0.339	1.174	.15
Chronic renal insufficiency 1 = yes	0 = No	1.760	0.896	3.456	.10
TASC (3 level) 2 = B	1 = A	0.558	0.266	1.169	.30
TASC (3 level) 3 = C or D	1 = A	0.793	0.324	1.939	
TASC (2 level) 1 = C or D	0 = A or B	1.040	0.446	2.425	.93
# of Patent tibial vessels = 2	0 or 1 vessels	1.046	0.470	2.329	.77
# of Patent tibial vessels = 3	0 or 1 vessels	0.787	0.329	1.885	

Abbreviation: TASC, TransAtlantic InterSociety Consensus II.

^aWald test, using sandwich estimate for the covariance matrix.

Table 9

Univariate Analysis for the Predictors of Amputation Within the Claudication Group

Variable	Reference	Hazard Ratio	95% Lower Confidence Limit for Hazard Ratio	95% Upper Confidence Limit for Hazard Ratio	P Value ^a
Age at intervention	(per 10)	1.226	0.568	2.643	.60
Gender, male	Female	1.299	0.384	4.392	.67
Smoking history 1 = yes	0 = No	1.047	0.246	4.457	.95
Hypertension 1 = yes	0 = No	0.415	0.119	1.449	.17
Diabetes mellitus 1 = yes	0 = No	3.551	0.945	13.343	.06
Coronary artery disease 1 = yes	0 = No	0.699	0.196	2.497	.58
Hyperlipidemia 1 = yes	0 = No	0.111	0.024	0.519	.005
Chronic renal insufficiency 1 = yes	0 = No	1.891	0.403	8.882	.42
TASC (3 level) 2 = B	1 = A	0.570	0.150	2.166	<.001
TASC (3 level) 3 = C or D	1 = A	0.000	0.000	0.000	
TASC (2 level) 1 = C or D	0 = A or B	—	—	—	—
# of Patent tibial vessels = 2	0 or 1 vessels	1.652	0.185	14.770	.87
# of Patent tibial vessels = 3	0 or 1 vessels	1.790	0.204	15.716	

Abbreviation: TASC, TransAtlantic InterSociety Consensus II.

^aWald test, using sandwich estimate for the covariance matrix.