From the New England Society for Vascular Surgery

Determinants of survival and major amputation after peripheral endovascular intervention for critical limb ischemia

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Objective: **Our objective was to analyze periprocedural and 1-year outcomes of peripheral endovascular intervention (PVI) for critical limb ischemia (CLI).**

Methods: **We reviewed 1244 patients undergoing 1414 PVIs for CLI (rest pain, 29%; tissue loss, 71%) within the Vascular Study Group of New England (VSGNE) from January 2010 to December 2011. Overall survival (OS), amputation-free survival (AFS), and freedom from major amputation at 1 year were analyzed using the Kaplan-Meier method. Cox proportional hazards models were used to calculate hazard ratios (HRs) and 95% confidence intervals (CIs).**

Results: **The number of arteries treated during each procedure were 1 (49%), 2 (35%), 3 (12%), and ≥4 (5%). Target arterial segments and TransAtlantic Inter-Society Consensus classifications were aortoiliac, 27% (A, 48%; B, 28%; C, 12%; and D, 12%); femoral-popliteal, 48% (A, 29%; B, 34%; C, 20%; and D, 17%); and infrapopliteal, 25% (A, 17%; B, 14%; C, 25%; D, 44%). Technical success was 92%. Complications included access site hematoma (5.0%), occlusion (0.3%), and distal embolization (2.4%). Mortality and major amputation rates were 2.8% and 2.2% at 30 days, respectively. Overall percutaneous or open reintervention rate was 8.0% during the first year. At 1-year, OS, AFS, and freedom from major amputation were 87%, 87%, and 94% for patients with rest pain and 80%, 71%, and 81% for patients with tissue loss. Independent predictors of reduced 1-year OS (C index = .74) included dialysis (HR, 3.8; 95% CI, 2.8-5.1; $P < .01$), emergency procedure (HR, 2.5; 95% CI, 1.0-6.2; $P = .05$), age >80 years (HR, 2.2; 95% CI, 1.7-2.8; $P < .01$), not living at home preoperatively (HR, 2.0; 95% CI, 1.4-2.8; $P < .01$), creatinine >1.8 mg/dL (HR, 1.9; 95% CI, 1.3-2.8; $P < .01$), congestive heart failure (HR, 1.7; 95% CI, 1.3-2.2; $P < .01$), and chronic β-blocker use (HR, 1.4; 95% CI, 1.0-1.9; $P = .03$), whereas independent preoperative ambulation (HR, 0.7; 95% CI, 0.6-0.9; $P = .014$) was protective. Independent predictors of major amputation (C index = .69) at 1 year included dialysis (HR, 2.7; 95% CI, 1.6-4.5; $P < .01$), tissue loss (HR, 2.0; 95% CI, 1.1-3.7; $P = .02$), prior major contralateral amputation (HR, 2.0; 95% CI, 1.1-3.5; $P = .02$), non-Caucasian race (HR, 1.7; 95% CI, 1.0-2.9; $P = .045$), and male gender (HR, 1.6; 95% CI, 1.1-2.6; $P = .03$), whereas smoking (HR, .60; 95% CI, 0.4-1.0; $P = .042$) was protective.**

Conclusions: **Survival and major amputation after PVI for CLI are associated with different patient characteristics. Dialysis dependence is a common predictor that portends especially poor outcomes. These data may facilitate efforts to improve patient selection and, after further validation, enable risk-adjusted outcome reporting for CLI patients undergoing PVI. (J Vasc Surg 2015;62:655-64.)**

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A list of VSGNE members is available in Supplementary Table III (online only).

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The incidence of peripheral arterial disease (PAD) is increasing, affecting ~8 million Americans and 12% to 20% of Americans aged >65 years.[1] Endovascular peripheral vascular intervention (PVI) is increasingly used to treat lower extremity PAD, including critical limb ischemia (CLI), with a concomitant decline in the rate of lower extremity bypass (LEB).[2,3]

The Bypass versus Angioplasty in Severe Ischaemia of the Leg (BASIL) trial demonstrated similar rates of overall survival (OS) and amputation-free survival (AFS) between the PVI and LEB groups at 2 years, but clinical outcomes >2 years were improved in patients initially randomized to surgery.[4,5] This finding suggests that infrainguinal bypass is a more durable treatment but that PVI is more suitable for older, less healthy patients who are poor surgical candidates with limited life expectancy.

Despite this evidence, patient selection remains challenging given the heterogeneity of patient presentation,

variability in lesion severity, and evolving endovascular technology. Several models have been proposed to predict survival after LEB but few exist exclusively for PVI.[6-13] The BASIL survival prediction model is the only one derived from a randomized cohort treated by infrainguinal bypass or angioplasty.[11] Although determinants of survival and major amputation have been studied extensively in patients undergoing open surgical bypass, they have not been extensively studied in a multicenter cohort of patients undergoing a range of PVIs, including angioplasty, stenting, and atherectomy. The primary aim of this study was to examine factors predicting OS and major amputation after PVI for CLI using the Vascular Study Group of New England (VSGNE) Peripheral Vascular Intervention registry. Secondary aims included analysis of procedural technical details, morbidity, and 1-year reintervention rates.

METHODS

The use of deidentified data from the VSGNE, with waiver of informed consent for this analysis, was approved by the University of Vermont College of Medicine Institutional Review Board.

Patients and procedures. We reviewed 1414 PVI procedures performed for CLI within the VSGNE from January 2010 to December 2011. The VSGNE registry is a prospective, multi-institutional, regional quality improvement initiative that has been previously described.[14] A total of 108 surgeons from 23 academic and community institutions contributed to the VSGNE PVI registry. The study included 1244 patients with 1301 limbs at risk. For the 155 patients (12%) undergoing more than one PVI during the study time period, only the first intervention was analyzed. The study analysis ended in December 2011 to allow for adequate long-term follow-up at 1 year.

Patients had rest pain (29%) or tissue loss (71%) as the indication for intervention. The study excluded patients with claudication (n = 3092), acute ischemia (n = 313), and aneurysmal (n = 17) disease and those who underwent concomitant PVI and infrainguinal (n = 47) or suprainguinal bypass (n = 5). Additional exclusions included 181 procedures performed in the absence of symptoms, including interventions on native vessels proximal or distal to failing bypass grafts and 17 procedures where the type of pathology requiring intervention was not recorded.

VSGNE PVI database. The VSGNE PVI registry includes procedures performed for lower extremity arterial occlusive disease of the aorta, iliac, femoral-popliteal, or infrapopliteal arteries or for peripheral aneurysms. Interventions on multiple arterial levels and concomitant femoral endarterectomy and PVI were included. Diagnostic angiograms and peripheral arterial thrombolysis-only procedures are not captured in the database.

Demographics, comorbidities, and indications were designed to mirror those collected for the VSGNE infrainguinal bypass database. The unit of analysis for demographics and comorbidities was the individual patient. The indication for PVI was classified as (0) asymptomatic, defined as documented peripheral disease with no symptoms, (1) claudication, (2) rest pain, (3) tissue loss, (4) acute ischemia, or (5) no documented peripheral disease. The pathology was classified as occlusive or aneurysmal disease according to the primary disease process.

An extensive list of 27 procedural variables was developed from a working group of surgeons representing centers across the VSGNE. Emergency procedures were defined as those requiring an operation ≤12 hours of admission to prevent limb loss. Procedural variables included access type and location, medications, fluoroscopy time, contrast volume, and method of arterial closure. Aortoiliac and femoral-popliteal lesions were classified based on the TransAtlantic Inter-Society Consensus (TASC I) for the Management of Peripheral Arterial Disease (TASC II) classification.[15] Tibial-peroneal lesions were stratified by the TASC I classification because an updated infrapopliteal scoring system was not published with TASC II.[16]

Interventions were performed at the discretion of the interventionalist and included balloon angioplasty, including cryoplasty or cutting balloon, stent or stent graft placement, and atherectomy, including laser, excisional, or orbital techniques. The VSGNE PVI registry records interventions on up to six arteries. For this analysis, arteries were classified in four arterial segments: aortoiliac, common femoral-profunda, superficial femoral-popliteal, and infrapopliteal. Interventions performed on more the one arterial segment were classified as multilevel. For each case, a primary and secondary treatment was designated. If more than two treatment types were used, the two that most contributed to the final outcome in the opinion of the interventionalist were recorded. Adjunctive treatments were recorded, including mechanical or pharmacologic thrombolysis, use of re-entry or embolic protection devices, or simultaneous femoral endarterectomy.

Technical success was defined as residual stenosis of ≤30% or resting systolic pressure gradient of <10 mm Hg. If an intervention was attempted but the interventionalist could not cross the lesion or the procedure resulted in vessel occlusion, it was considered a technical failure.

Immediate, in-hospital, or periprocedural complications were reported, including arterial dissection or perforation, distal embolization, access site occlusion or hematoma, and medical complications requiring admission. Hematoma was defined as (1) minor if visible or symptomatic but requiring no treatment beyond compression and might require admission for observation, (2) moderate if transfusion or thrombin injection was required, or (3) severe if surgery was required for repair. Postprocedure discharge medications were recorded. The unit of analysis for procedure indication, pathology type, and outcome measures was the individual limb.

Data were entered on-line by physicians, nurses, or trained data entry personnel into a Web-based form (Pathways; M2S, West Lebanon, NH) on a secure Web site. A long-term follow-up form was also constructed to capture key 1-year outcomes, including symptomatic status,