

The effect of ambulatory status on outcomes of percutaneous vascular interventions and lower extremity bypass for critical limb ischemia in the Vascular Quality Initiative

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ABSTRACT

Objective: Ambulatory status has been shown to be an important predictor of postoperative morbidity and mortality for a variety of surgical procedures. We sought to assess contemporary practice patterns in treating critical limb ischemia (CLI) and outcomes based on ambulatory status.

Methods: The Vascular Quality Initiative (2010-2015) was queried for patients undergoing percutaneous vascular interventions (PVI) or lower extremity bypass (LEB) for CLI. Ambulatory status was classified as ambulatory, ambulatory with assistance, and nonambulatory (composite of wheelchair bound and bedridden). Perioperative and postoperative outcomes were recorded. Multivariable analyses were performed to identify the effect of ambulatory status.

Results: There were 11,522 ambulatory (PVI, 63%; LEB, 37%), 4443 ambulatory with assistance (PVI, 67%; LEB, 33%), and 1732 nonambulatory (PVI, 77%; LEB, 23%) patients with CLI treated ($P < .01$ across ambulatory status groups). Perioperative mortality for PVI and LEB for ambulatory, ambulatory with assistance, and nonambulatory status was 1.5% and 1.7%, 3.0% and 3.1%, and 4.7% and 4.9%, respectively ($P < .01$ across ambulatory status groups). Worsening ambulatory status was associated with higher perioperative complications with PVI and LEB. Multivariable analysis showed that worsening ambulatory status predicted higher postprocedural mortality, amputation or death, and major adverse limb events or death.

Conclusions: In the Vascular Quality Initiative, as ambulatory status declines, perioperative morbidity and mortality increase. Impaired ambulatory patients are more likely to receive PVI than LEB for the treatment of CLI, although even among nonambulatory patients, there are still a significant number who receive LEB. (J Vasc Surg 2017;■:1-7.)

Peripheral arterial disease (PAD) has a prevalence of 3% to 10% and may lead to significant morbidity.¹ The most severe form of PAD is critical limb ischemia (CLI), defined by rest pain or tissue loss. There are 500 to 1000 reported cases of CLI per million per year.² Revascularization for CLI can be performed by percutaneous vascular interventions (PVI) or open vascular surgery, including lower extremity bypass (LEB). PVI often involves balloon

angioplasty or stenting; open vascular surgery often includes endarterectomy, arterial bypass, or both.³⁻⁵ The optimal treatment for patients with CLI is controversial.⁶ Both endovascular and open operations are commonly performed to treat CLI, but there is much debate as to which treatment specific patients should receive.

Ambulatory and functional status has been shown to be an important predictor of postoperative morbidity and mortality for patients undergoing treatment for CLI.⁷⁻¹² In fact, it is often one of the strongest predictors of periprocedural complications. In addition, ambulatory status has been shown to be a predictor of choice of revascularization strategy as patients with impaired ambulatory status and more comorbidities are more likely to be offered PVI rather than LEB.¹³ Nevertheless, it is unclear as to which option is best for patients with impaired ambulatory status.

Our goal was to assess current practice patterns of limb revascularization and outcomes stratified by ambulatory status. To gauge contemporary, real-world data, we queried the Vascular Quality Initiative (VQI) to assess the functional status of patients with CLI and to analyze postoperative outcomes for patients undergoing PVI and LEB.

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Author conflict of interest: none.

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The editors and reviewers of this article have no relevant financial relationships to disclose per the JVS policy that requires reviewers to decline review of any manuscript for which they may have a conflict of interest.

0741-5214

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METHODS

The VQI collects perioperative and long-term data about vascular surgery from >350 academic and community hospitals across North America.¹⁴ The VQI database was started in 2010 and prospectively collects data that include >100 clinical, demographic, and treatment-specific variables.^{15,16} Therefore, the VQI can be used to retrospectively evaluate current practice patterns of open and endovascular treatments and their respective outcomes in patients with CLI. The Boston University School of Medicine Institutional Review Board approved this study, and informed consent was waived.

We excluded patients aged <35 years, those with peripheral aneurysms, and those with concomitant PVI and LEB interventions. The PVI data set included 54,654 patients. Excluding non-CLI patients left 15,530 patients remaining. Excluding aorta and iliac artery interventions left 11,800 patients. After removal of those with missing preoperative ambulatory status, 11,769 remained. LEB included 19,164 patients, of whom 6664 had CLI. Exclusion of those with missing preoperative ambulatory status left 6640 patients. The total amount was 18,409. We then excluded those who had both PVI and LEB, leaving 17,688.

We prospectively separated patients into three preoperative ambulatory statuses: ambulatory, ambulatory with assistance, and nonambulatory. In the VQI, ambulatory was defined as capable of independent ambulation, including walking with a prosthesis. Ambulatory with assistance was defined as requiring assistance, such as with a cane, walker, or person, for ambulation. Nonambulatory, a composite category that we created, comprises the use of a wheelchair as the predominant means of getting around or being bedridden.

Outcomes of interest were hospital and 30-day mortality, long-term mortality, and 1-year combined amputation and death. These outcomes were assessed for each of the three ambulatory statuses between patients receiving PVI and LEB treatments. Survival in the VQI is determined by Social Security information, and reinterventions are dependent on follow-up and assessment. Demographics, comorbidities, and perioperative outcomes in patients with CLI treated by PVI or LEB were compared for each ambulatory status using the *t*-test for continuous measures and the χ^2 test for categorical measures. One-year morbidity assessment was motivated by proximity to the procedure and limited long-term follow-up. A total of 2610 subjects had 1-year morbidity data.

Multivariable logistic regression analyses of mortality (5-year), amputation or death (1-year), and major adverse limb events (MALEs, defined as amputation or reintervention) or death (1-year) were performed for the three ambulatory statuses stratified by procedure. The adjusted hazard ratios and corresponding

ARTICLE HIGHLIGHTS

- **Significance:** This paper evaluated practice patterns and the effect of ambulatory status on procedure selection to treat patients with critical limb ischemia (CLI).
- **Type of Research:** Retrospective analysis of prospectively collected multicenter Vascular Quality Initiative registry data
- **Take Home Message:** Of 17,688 patients with CLI, those with impaired ambulatory status received percutaneous vascular interventions more frequently than lower extremity bypass because of the decreased perioperative morbidity and mortality.
- **Recommendation:** The data suggest that patients with CLI with decreased ambulatory status more frequently receive percutaneous interventions and not open surgical bypass to decrease the risk of perioperative morbidity and mortality.
- **Strength of Recommendation:** 2. Weak
- **Level of Evidence:** B. Moderate

95% confidence intervals were reported. For all multivariable models, the covariates were selected if different (at the .2 level) across the groups or clinically important and in both types of multivariable models, including demographics (age, gender, race, smoking, and preadmission living status), medical history of the patient (hypertension, diabetes, coronary artery disease, congestive heart failure, chronic obstructive pulmonary disease, previous cardiac interventions, dialysis, history of bypass, PVI, and major amputation), and procedure characteristics (PVI or LEB; target artery; urgency; indication; postoperative use of aspirin, statin, and P2Y₁₂ antagonist). Backward elimination procedure was used for each model with .5 level to stay to construct parsimonious models. Data analyses were performed using SAS 9.3 software (SAS Institute, Cary, NC).

RESULTS

There were 17,688 eligible patients with CLI and infringuinal PAD: 11,522 ambulatory patients, 4443 ambulatory with assistance patients, and 1723 nonambulatory patients. For ambulatory patients, 7295 (63.3%) were treated with PVI and 4227 (37.7%) were treated with LEB. For ambulatory with assistance patients, 2992 (67.3%) were treated with PVI and 1451 (32.7%) were treated with LEB. Of the nonambulatory patients, 1332 (77.3%) were treated with PVI and 391 (22.7%) with LEB. The use of procedures was significantly different across ambulatory status groups ($P < .01$; Fig). Demographics and comorbidities of the cohort are listed in Tables I and II. Across all ambulatory statuses, patients treated

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