From the Eastern Vascular Society

Surgeon, not institution, case volume is associated with limb outcomes after lower extremity bypass for critical limb ischemia in the Vascular Quality Initiative

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ABSTRACT

Objective: Studies from large administrative databases have demonstrated associations between institutional case volume and outcomes after lower extremity bypass (LEB). We hypothesized that increased institutional and surgeon volume would be associated with improved outcomes after LEB. Using a national, prospectively collected clinical database, the objective of this study was to determine the effects of both surgeon and institutional volume on outcomes after LEB.

Methods: The Vascular Quality Initiative (VQI) was queried to identify all LEBs for critical limb ischemia or claudication between 2004 and 2014. Average annual case volume was calculated by dividing an institution's or surgeon's total LEB volume by the number of years they reported to the VQI. Institutional and surgeon volumes were analyzed as continuous variables to determine the impact of volume on major adverse cardiac events (MACEs), major adverse limb events (MALEs), graft patency, and amputation-free survival. Hierarchical regression models were used with cases clustered by surgeon and center. Time-dependent outcomes were evaluated with multivariable shared frailty Cox proportional hazards models.

Results: From 2004 to 2014, there were 14,678 LEB operations performed at 114 institutions by 587 surgeons. Average annual institutional volume ranged from 1.0 to 137.5 LEBs per year, with a median of 26.9 (interquartile range, 14-45.3). Average annual surgeon volume ranged from 1 to 52 LEBs per year with a median of 5.7 (interquartile range, 2.5-9.3). Institutional LEB volume was not associated with MACEs or MALEs or with loss of patency. However, average annual surgeon volume was independently associated with reduced MALEs and improved primary patency. Institutional and surgeon volume did not predict MACEs.

Conclusions: In contradistinction to previous studies, there was no relationship in this study between institutional LEB volume and outcomes after LEB. However, greater average annual surgeon volume was associated with improved primary patency and decreased risk of MALEs. Open LEB remains a safe and effective procedure for limb salvage. Limb-related outcomes in critical limb ischemia and claudication will be optimized if surgeons maintain adequate volume of LEB. (J Vasc Surg 2017;■:1-7.)

Procedural volume has been positively associated with patient outcomes across a wide variety of procedures and institutional settings, including vascular surgery.[1-8] This association is studied most often in relation to postoperative mortality, but it has been described for more disease-specific outcomes as well, including stroke after carotid endarterectomy[9] and amputation after lower extremity arterial bypass.[10,11] Traditionally, institutional volume has been the primary independent variable, but several studies examining the role of surgeon volume have been conducted as well.[12-15]

The reasons for the volume-outcome association are thought to be several and include both institutional and provider factors. It has been shown that much of the difference at the institutional level is in the capacity to rescue patients after a complication rather than in lower overall complication rates.[16,17] More technically demanding operations seem to show a stronger volume-outcome relationship than those less technically challenging.[1,17] Lower extremity bypass (LEB) actually describes a collection of several different procedures of varying complexity and technical difficulty, and this heterogeneity has been a problem for studies examining the volume-outcome relationship in LEB.[10,18]

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Notably, the majority of studies demonstrating these relationships have largely been conducted using administrative or billing databases. This was necessary, given the need to measure a large number of patients across multiple institutions and the lack of adequate breadth in most clinical databases. However, the national Vascular Quality Initiative (VQI) is especially well suited to address these questions as it captures deidentified clinical data, including short- and long-term follow-up, at hundreds of centers across the country, and both centers and surgeons are tracked using anonymized identifiers.[19] The aim of this study was to investigate the impact of institutional and surgeon volume on outcomes after LEB for critical limb ischemia (CLI) and claudication using a prospective multi-institutional clinical database with long-term follow-up of a large sample of patients.

ARTICLE HIGHLIGHTS

- **Type of Research:** Retrospective analysis of prospectively collected Vascular Quality Initiative (VQI) data
- **Take Home Message:** Analysis of outcome of 14,678 lower extremity bypass operations performed by 587 surgeons revealed that annual surgeon volume but not institutional volume was associated with improved primary patency and fewer adverse limb events.
- **Recommendation:** The authors suggest that maintaining adequate surgeon volume is essential to achieve good outcomes after lower extremity bypass procedures.

METHODS

Sample. The Society for Vascular Surgery's VQI is a collection of >10 individual procedural registries that prospectively collect patient and clinical data and capture both short- and long-term outcomes from >220 institutions across the country. Deidentified data from the national VQI open LEB registry were provided by the VQI and included operations performed between 2004 and 2014. Exclusion criteria included patients younger than 18 years and those undergoing LEB for acute limb ischemia. Institutional Review Board approval and informed consent were waived, given the deidentified nature of the data.

Definitions. Low, medium, and high surgeon volume was based on the lowest 25th percentile, 25th to 75th percentile, and highest 75th percentile, rounded to the nearest round number of cases. Low, medium, and high center volume was similarly determined. Complex operations were defined as those that included any tibial or more distal target, those with the inflow vessel below the superficial femoral artery, and a femoral to below-knee popliteal bypass with anything other than prosthetic or single-segment saphenous vein. Major adverse cardiac events (MACEs) included death, myocardial infarction (MI), and stroke; MI and stroke were captured only out to 30 days. Major adverse limb events (MALEs) included major amputation and graft revision, either open or endovascular, of the bypass. Primary patency is patency of the original bypass without any intervention required to maintain patency. Primary assisted patency includes primary patency as well as a bypass that was revised because of stenosis but was not completely occluded. Secondary patency includes bypasses in the aforementioned categories as well as those bypasses that are recanalized and patent after occlusion.

Study design. This study design accounts for the clustered, nonindependent nature of outcomes by using hierarchical multilevel mixed-effects regression models. In the case of time-to-event analyses, the standard errors are adjusted using a shared frailty methodology that also accounts for clustering.

Statistical analysis. Preoperative demographic variables and comorbidities as well as outcomes including mortality, amputation, patency, MACE, and MALE were analyzed. Limb outcomes (MALE and amputation-free survival) were evaluated separately in patients with CLI and those with claudication. Differences in categorical variables were tested using Pearson χ^2 test, and differences in continuous variables were tested using the Wilcoxon rank sum test. Measures of central tendency are presented as medians with interquartile range (IQR). Statistical significance for all tests was two tailed and set at $\alpha = .05$. For the purposes of modeling, volume was treated as a continuous function and tested using both restricted cubic spline and linear functions and then compared. These functions were not significantly different, so volume was modeled as a linear function. Multivariable models included all patient and operative characteristics that were significant at the $P \leq .2$ level on univariate analysis for the outcome of interest. Analysis was performed using Stata version 14.0 software (Stata Corp, College Station, Tex).

RESULTS

Sample. From 2004 to 2014, the VQI contained 20,672 LEB operations. After exclusion of operations for acute limb ischemia and asymptomatic patients as well as exclusion of centers with <50% long-term follow-up as defined by the VQI, the sample for this study was 14,678 bypasses performed at 114 institutions by 587 surgeons. Overall, 67% of the patients were male, with a median age of 67 years (IQR, 59-75 years; Table I). Hypertension and smoking were the most common comorbidities at 88% and 84% of the study population, respectively. Almost 70% of bypass patients had CLI, defined as either rest pain or tissue loss (Rutherford 4-6), with the remainder being claudicants (30%). The median