

From the New England Society for Vascular Surgery

Lifelong limb preservation: A patient-centered description of lower extremity arterial reconstruction outcomes

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ABSTRACT

Background: Life expectancy is short for patients with critical limb ischemia (CLI), many of whom may fear amputation more than death. In light of the reduced life expectancy of these patients, the traditional 5-year freedom from amputation (FFA) statistic may not accurately address their concern. We developed a more relevant patient-centered calculation of major amputation risk during a patient's remaining lifetime to better answer the question, Will I ever lose my leg?

Methods: We identified all limbs undergoing first-time intervention for CLI in a large institutional database from 2005 to 2013. We calculated the traditional metrics of amputation-free survival (AFS, for which failure is death or amputation) and FFA (for which failure is amputation but deaths are censored and removed from further analysis). In addition, we propose a new term, lifelong limb preservation (LLP). LLP defines amputation as failure, but deaths are not censored and therefore reflect that LLP has been achieved. All deaths before 30 days were considered a failure in all three metrics, reflecting the risk of surgery.

Results: There were 1006 limbs identified as having first-time intervention for CLI (22% rest pain, 45% ulcer, 27% gangrene; 46% treated by angioplasty with or without stenting, 54% bypass). Using life-table analysis, 7-year AFS was 14% (561 events), FFA was 78% (123 events), and LLP was 86% (123 events). LLP was similar between patients undergoing angioplasty with or without stenting and bypass (7-year rates, 86% and 85%, respectively). For patients undergoing intervention for rest pain, 7-year rates were 14% for AFS, 84% for FFA, and 92% for LLP. For those undergoing treatment for ulcer, 7-year rates were 14% for AFS, 77% for FFA, and 86% for LLP. Finally, in those with gangrene, rates were 10% for AFS, 67% for FFA, and 79% for LLP. Using LLP, patients presenting with an ulcer can be told that although we cannot guarantee how long they will live, with revascularization there is approximately an 86% chance they will not lose the leg.

Conclusions: These results show that the durability of our limb preservation efforts often exceeds the life expectancy of our patients. Using LLP as an outcomes assessment provides a more accurate and patient-centered answer to the question, If I have this procedure, will I ever lose my leg? (*J Vasc Surg* 2017;■:1-6.)

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Peripheral arterial disease affects >8.5 million patients older than 40 years in the United States,^{1,2} and approximately 1% of all peripheral arterial disease patients will go on to develop critical limb ischemia (CLI).^{3,4} The diagnosis of CLI has a poor prognosis, with as many as half of all patients ultimately undergoing amputation.^{5,6} In addition, up to 20% of CLI patients will die within 6 months of diagnosis, and 5-year survival has been reported to be as low as 50%.⁷⁻¹²

Previous studies have described the grim prognosis for those with CLI, and work has been done to try to stratify patient risk. The Society for Vascular Surgery developed a classification system for CLI patients that classified amputation risk on the basis of three major influences: Wound, Ischemia, and foot Infection (WIFI). The Society for Vascular Surgery WIFI classification system allowed more precise organization of patients on the basis of their disease burden.¹³ In addition, work by Conte et al designated objective performance goals for the treatment of CLI.¹⁴ They defined two important end points: amputation-free survival (AFS) and major adverse limb event (defined as amputation or major reintervention).

This provided an additional tool for preoperative risk assessment in CLI patients regarding the two major outcomes, amputation and death.

Although the current literature provides a framework for categorizing the prognosis and risk of amputation for patients, the estimate given is reflective of those who survive to the end of the analysis. This analysis certainly has its benefits, but it fails to account for those patients who died without ever undergoing an amputation. Many patients are aware of their limited life span, and their priority is to remain amputation free for their remaining time. Consequently, providing them with a statistic from only the surviving patients may not sufficiently address their concerns.

Our study seeks to improve the current communication with CLI patients. We sought to develop a new risk metric, designed to give patients a more realistic assessment of their prognosis for undergoing amputation. In a population of patients in which as many as half will not survive 5 years, communication is essential in helping to guide patients in their treatment decisions. By not censoring out those patients who died during the course of the analysis, we hope to better answer the question, Will I ever lose my leg?

METHODS

Database. All limbs undergoing first-time intervention for CLI at our institution from 2005 to 2013 were used for this retrospective analysis. Individual medical records were reviewed for all patients within the database. Patients who underwent either lower extremity bypass or percutaneous transluminal angioplasty with or without stenting were included. There were no hybrid cases in this population of patients. In addition, as this database was designed to compare bypass and percutaneous transluminal angioplasty with or without stenting, the majority of endarterectomy-only cases performed at our institution were not included in the initial query. Therefore, the remaining patients who underwent endarterectomy were subsequently excluded from this analysis. Amputations were counted on a per-limb basis and death on a per-patient basis. There were 1006 limbs treated for CLI in our series in 902 patients. The Beth Israel Deaconess Medical Center Institutional Review Board approved this study, and patient consent was waived because of the deidentified nature of this data set.

Variables. Demographics, comorbid conditions, and operative details were identified for all patients. The indication for the procedure included rest pain, ulcer, or gangrene, and overall survival was calculated within each of these populations. Our primary end points included both of the previously established outcomes in this population, AFS and freedom from amputation (FFA), as well as a novel end point, lifelong limb

Table I. Patient demographics and comorbidities

Variable (N = 902)	%	No.
Gender, male	58	584
Race, white	80	805
Coronary artery disease	52	522
Hypertension	84	843
Diabetes mellitus	74	744
Chronic renal insufficiency	34	338
Hemodialysis	21	211
Hyperlipidemia	58	578
Chronic obstructive pulmonary disease	12	120
Congestive heart failure	32	317
Myocardial infarction	27	273
Coronary artery bypass grafting	25	254
Current smoker	21	213
Mortality	59	596
Indication for procedure		
Rest pain	22	220
Ulcer	45	457
Gangrene	27	275

preservation (LLP). Major amputation was defined as below-knee transtibial or above-knee amputation. For AFS, a terminal event was defined as death or major amputation within the follow-up period. For FFA, a terminal event was defined as a major amputation, with those patients who died without amputation being censored (removed from further analysis without being considered to have had an event) at time of death. LLP, our novel end point, defined a terminal event as a major amputation; however, patients who died without an amputation were not censored. Therefore, patients who died with their limbs intact within the 7-year interval were considered a success as they had irrevocably achieved LLP. All deaths before 30 days were considered a failure in all three metrics, reflecting the risk of surgery. Seven-year end points were selected to take advantage of the extended follow-up in our series of patients and to highlight the differences between these three outcomes.

Statistical analysis. Significant differences in freedom from each respective event, AFS, FFA, and LLP, were analyzed using Kaplan-Meier analysis with the log-rank test. Life-table analysis was used to calculate cumulative rates for each of the three end points. Missing data were <3% for all variables, except for follow-up time, which was 9%. Statistical analysis was conducted using SPSS Statistics version 23 (IBM Corp, Armonk, NY).

RESULTS

A total of 1006 limbs in 902 patients underwent first-time interventions for CLI: 46% treated by angioplasty

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