ELSEVIER

Factors Associated with Amputation or Graft Occlusion One Year after Lower Extremity Bypass in Northern New England

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Background: Optimal patient selection for lower extremity bypass surgery requires surgeons to predict which patients will have durable functional outcomes following revascularization. Therefore, we examined risk factors that predict amputation or graft occlusion within the first year following lower extremity bypass.

Methods: Using our regional quality-improvement initiative in 11 hospitals in northern New England, we studied 2,306 lower extremity bypass procedures performed in 2,031 patients between January 2003 and December 2007. Sixty surgeons contributed to our database, and over 100 demographic and clinical variables were abstracted by trained researchers. Cox proportional hazards models were used to generate hazard ratios and surrounding 95% confidence intervals (CIs) for our combined outcome measure of major amputation (above-knee or below-knee) or permanent graft occlusion (loss of secondary patency) occurring within the first year postoperatively.

Results: We found that within our cohort of 2,306 bypass procedures 17% resulted in an amputation or graft occlusion within 1 year of surgery. Of the 143 amputations performed (8% of all limbs undergoing bypasses), 17% occurred in the setting of a patent graft. Similarly, of the 277 graft occlusions (12% of all bypasses), 42% resulted in a major amputation. We identified eight preoperative patient characteristics associated with amputation or graft occlusion in multivariate analysis: age $<$50, nonambulatory status preoperatively, dialysis dependence, diabetes, critical limb ischemia, need for venovenostomy, tarsal target, and living preoperatively in a nursing home. While patients with no risk factors had 1-year amputation/occlusion rates that were $<$1%, patients with three or more risk factors had a nearly 30% chance of suffering amputation or graft occlusion by 1 year postoperatively. When we compared risk-adjusted rates of amputation/occlusion across centers, we found that one center in our region performed significantly better than expected (observed/expected ratio 0.7, 95% CI 0.6-0.9, $p < 0.04$).

Conclusion: Preoperative risk factors allow surgeons to predict the risk of amputation or graft occlusion following lower extremity bypass and to more precisely inform patients about their operative risk and functional outcomes. Additionally, our model facilitates comparison of risk-adjusted outcomes across our region. We believe quality-improvement measures such as these will allow surgeons to identify best practices and thereby improve outcomes across centers.

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INTRODUCTION

Lower extremity peripheral arterial disease (PAD) affects over 8 million Americans, with significant associated morbidity and mortality.[1-5] While lower extremity bypass surgery provides durable, effective treatment for PAD,[5] significant morbidity and mortality are encountered when elderly, medically complex patients undergo prolonged, invasive arterial reconstruction.[3] One of the key elements in minimizing morbidity and mortality is optimal patient selection, especially in the current era where endovascular alternatives may exist.[6]

However, optimal patient selection requires that surgeons have insight into several key decisions about the outcomes of lower extremity surgical revascularization. First, surgeons must have the ability to predict which patients will survive surgery and the perioperative period. Second, surgeons must decide to operate only on those who are likely to remain ambulatory with a functional limb after surgery. Third, surgeons must select patients who are likely to avoid graft occlusion and amputation in order to ensure a durable functional outcome.

Toward this end, we sought to refine our ability to improve patient selection for lower extremity bypass, focusing on the third decision outlined above. To accomplish this, we examined those risk factors associated with amputation or graft occlusion 1 year after surgery, using information from 11 community and academic centers that participate in our regional quality-improvement initiative. Using preoperative information about the patient's physiology, anatomy, and functional status, we developed a multivariate prediction model for permanent graft occlusion or major amputation within the first year following lower extremity bypass surgery.

METHODS

Subjects and Databases

We utilized data collected prospectively by the Vascular Study Group of Northern New England (VSGNNE), a regional cooperative quality-improvement initiative developed in 2002 to study regional outcomes in vascular surgery. Further details on this registry have been published previously,[7] and others are available at vsgnne.org.

We included only patients who underwent open infrainguinal bypass procedures. Bypass inflow could be iliac, femoral, or popliteal. Bypass targets could be above-knee or below-knee and popliteal, tibial, or pedal vessels. Patients with concomitant endovascular procedures (e.g., an iliac stent done at the time of bypass surgery) were included in the analysis. Bypass procedures could be performed in an in situ fashion, with reversed vein, with vein cuffs or adjuncts, or with prosthetic conduit.

Definitions and Outcome Measures

Our unit of analysis was the bypass graft. Our main outcome was a combined measure of either permanent graft occlusion (loss of secondary patency) or major amputation (above- or below-knee) following surgery. Between January 1, 2003, and December 31, 2006, we identified 2,036 patients in our database who underwent 2,301 bypass procedures. As shown in Table I, several patients underwent more than one bypass procedure. A bypass graft revision on the same leg was considered a revision of the index bypass, whereas a new bypass on an ipsilateral leg was examined as a new and distinct bypass. While graft occlusions were considered on a per-graft basis, major amputation was censored on each extremity after the occurrence of a major amputation on that extremity.

Patients were evaluated for preexisting medical comorbidities, and these data were prospectively entered into our registry by trained personnel. Comorbidities included chronic obstructive pulmonary disease (COPD, chart history), congestive heart failure (CHF, chart history or documented ejection fraction $<50\%$ on preoperative testing), coronary artery disease (CAD; any history of angina, myocardial infarction [MI], prior coronary intervention, or electrocardiographic changes consistent with previous MI), chronic renal insufficiency (CRI, Cr ≥ 1.8 mg/dL), end-stage renal disease (ESRD, on dialysis), diabetes mellitus (DM; chart history, designated as diet-controlled, on oral hypoglycemic agents, or on insulin), hypertension (HTN, chart history or blood pressure $\geq 140/90$), hyperlipidemia (documented by chart history), and prior lower extremity bypass surgery or lower extremity endovascular therapy. Ambulation status was categorized as independently ambulatory, ambulatory with assistance, wheelchair-bound, or bedridden. Preoperative living situation was determined (home or nursing home), as was the indication for surgery (asymptomatic, claudication, rest pain, tissue loss, acute ischemia) and discharge destination (home or nursing home). Ankle–brachial indices were recorded, as was history of prior bypass or endovascular intervention, either preoperatively or concomitantly. History of prior ipsilateral or contralateral amputation was similarly recorded. Patient comorbidities are outlined in Table I.

Graft patency and major amputation rates were determined at several stages: first, preoperatively,