Risk Factors for Long-Term Mortality and Amputation after Open and Endovascular Treatment of Acute Limb Ischemia

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Background: Acute limb ischemia (ALI) is a highly morbid and fatal vascular emergency with little known about contemporary, long-term patient outcomes. The goal was to determine predictors of long-term mortality and amputation after open and endovascular treatment of ALI.

Methods: A retrospective review of ALI patients at a single institution from 2005 to 2011 was performed to determine the impact of revascularization technique on 5-year mortality and amputation. For each main outcome 2 multivariable models were developed; the first adjusted for preoperative clinical presentation and procedure type, the second also adjusted for postoperative adverse events (AEs).

Results: A total of 445 limbs in 411 patients were treated for ALI. Interventions included surgical thrombectomy (48%), emergent bypass (18%), and endovascular revascularization (34%). Mean age was 68 ± 15 years, 54% were male, and 23% had cancer. Most patients presented with Rutherford classification IIa (54%) or IIb (39%). The etiology of ALI included embolism (27%), in situ thrombosis (28%), thrombosed bypass grafts (32%), and thrombosed stents (13%). Patients treated with open procedures had significantly more advanced ischemia and higher rates of postoperative respiratory failure, whereas patients undergoing endovascular interventions had higher rates of technical failure. Rates of postprocedural bleeding and cardiac events were similar between both treatments. Excluding Rutherford class III patients ($n = 12$), overall 5-year mortality was 54% (stratified by treatment, 65% for thrombectomy, 63% for bypass, and 36% for endovascular, $P < 0.001$); 5-year amputation was 28% (stratified by treatment, 18% for thrombectomy, 27% for bypass, and 17% for endovascular, $P = 0.042$). Adjusting for comorbidities, patient presentation, AEs, and treatment method, the risk of mortality increased with age (hazard ratio [HR] = 1.04, $P < 0.001$), female gender (HR = 1.50, $P = 0.031$), cancer (HR = 2.19, $P < 0.001$), fasciotomy (HR = 1.69, $P = 0.204$) in situ thrombosis or embolic etiology (HR = 1.73, $P = 0.007$), cardiac AEs (HR = 2.25, $P < 0.001$), respiratory failure (HR = 2.72, $P < 0.001$), renal failure (HR = 4.70, $P < 0.001$), and hemorrhagic events (HR = 2.25, $P = 0.003$). Risk of amputation increased with advanced ischemia (Rutherford IIb compared with IIa, HR = 2.57, $P < 0.001$), thrombosed bypass etiology (HR = 3.53, $P = 0.002$), open revascularization (OR; HR = 1.95, $P = 0.022$), and technical failure of primary intervention (HR = 6.01, $P < 0.001$).

Conclusions: After the treatment of ALI, long-term mortality and amputation rates were greater in patients treated with open techniques; OR patients presented with a higher number of

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comorbidities and advanced ischemia, while also experiencing a higher rate of major postoperative complications. Overall, mortality rates remained high and were most strongly associated with baseline comorbidities, acuity of presentation, and perioperative AEs, particularly respiratory failure. Comparatively, amputation risk was most highly associated with advanced ischemia, thrombosed bypass, and failure of the initial revascularization procedure.

INTRODUCTION

Acute limb ischemia (ALI) is the sudden onset of decreased arterial perfusion with an imminent threat to limb viability.[1] This is a highly morbid condition with 1-year mortality and amputation rates ranging between 16–42% and 11–37%, respectively.[2–5] Older reports estimate 5-year mortality to be as high as 33–83%.[6–8] ALI patients are extremely heterogeneous with numerous comorbidities and limited physiologic reserve. Compared with patients treated electively for peripheral arterial disease, ALI patients are not medically optimized and present with advanced disease states contributing to significantly higher postoperative complications, mortality, and limb loss.[2,4,5,9,10]

Revascularization options for ALI patients include open revascularization (OR) and endovascular revascularization (ER). Given the reduced physiological stress of ER on frail ALI patients, there has been a dramatic increase in use and experience with ER over the past decade.[5,11] However, these less invasive procedures may require greater time to reestablish arterial flow and have historically been associated with higher rates of hemorrhagic complications, distal embolization, and lower rates of technical success compared with OR.[12–17]

Older studies have demonstrated similar short-term limb salvage and survival rates for ER and OR, despite the different adverse event (AE) profiles of each therapy.[11–13,16,18,19] Moreover, there has been a paucity of information reported on the long-term outcomes of these patients. Given this, especially in the contemporary era with increased experience and usage of ER, our goal was to determine predictive risk factors of mortality and limb loss to better guide the choice of therapy and optimize long-term outcomes.

METHODS

This is a single institution, retrospective analysis of a prospectively collected database of all adult patients (≥18 years of age) who were treated by the Division of Vascular Surgery at the University of Pittsburgh Medical Center for lower-extremity ALI from January 1, 2005 to May 31, 2011, with follow-up data collected through August 1, 2014. This study was approved by the Institutional Review Board of the University of Pittsburgh. No study-specific consent was required as no patient identifiers were collected, and the study received an exempt status. All patients gave informed consent to undergo the revascularization procedures.

Patient Selection

Lower-extremity ALI was defined as the sudden onset or deterioration of arterial perfusion of one or both lower extremities causing a threat to limb viability from an arterial thromboembolism, in situ thrombosis of the native vessels, or thrombosis of a previous bypass graft or stent.[1] Blue toe syndrome and ALI secondary to trauma, aortic dissection, or thrombosed aneurysms were excluded from the study. The severity of ALI was determined based on Rutherford classification.[1]

Preoperative Data

Data were collected on demographics (age, gender, and race), baseline comorbidities (coronary artery disease [CAD], congestive heart failure, atrial fibrillation, history of coronary artery bypass graft, chronic obstructive pulmonary disease (COPD), smoking status, cerebrovascular accident, cancer, hypertension, hyperlipidemia, chronic renal insufficiency including hemodialysis, and diabetes mellitus), preoperative medications (warfarin, clopidogrel, aspirin, and statins), and previous vascular interventions. Pertinent clinical presentation information was also collected, including etiology of the ALI (embolism, in situ arterial thrombosis, thrombosed vein or prosthetic bypass graft, and thrombosed stent) and degree of ischemia at presentation (defined by Rutherford classification).

Procedures

Patients underwent either ER or OR at the discretion of the treating vascular surgeon. Although there is no clear divisional protocol for ALI, patients with advanced ischemia were more likely to be treated with OR in an attempt to establish prompt reperfusion, whereas patients with less severe ischemia were more likely to undergo ER. Similar to the