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Outcomes of lower extremity bypass performed for acute limb ischemia

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Objective: Acute limb ischemia remains one of the most challenging emergencies in vascular surgery. Historically, outcomes following interventions for acute limb ischemia have been associated with high rates of morbidity and mortality. The purpose of this study was to determine contemporary outcomes following lower extremity bypass performed for acute limb ischemia.

Methods: All patients undergoing infrainguinal lower extremity bypass between 2003 and 2011 within hospitals comprising the Vascular Study Group of New England were identified. Patients were stratified according to whether or not the indication for lower extremity bypass was acute limb ischemia. Primary end points included bypass graft occlusion, major amputation, and mortality at 1 year postoperatively as determined by Kaplan-Meier life table analysis. Multivariable Cox proportional hazards models were constructed to evaluate independent predictors of mortality and major amputation at 1 year.

Results: Of 5712 lower extremity bypass procedures, 323 (5.7%) were performed for acute limb ischemia. Patients undergoing lower extremity bypass for acute limb ischemia were similar in age (66 vs 67; $P = .084$) and sex (68% male vs 69% male; $P = .617$) compared with chronic ischemia patients, but were less likely to be on aspirin (63% vs 75%; $P < .0001$) or a statin (55% vs 68%; $P < .0001$). Patients with acute limb ischemia were more likely to be current smokers (49% vs 39%; $P < .0001$), to have had a prior ipsilateral bypass (33% vs 24%; $P = .004$) or a prior ipsilateral percutaneous intervention (41% vs 29%; $P = .001$). Bypasses performed for acute limb ischemia were longer in duration (270 vs 244 minutes; $P = .007$), had greater blood loss (363 vs 272 mL; $P < .0001$), and more commonly utilized prosthetic conduits (41% vs 33%; $P = .003$). Acute limb ischemia patients experienced increased in-hospital major adverse events (20% vs 12%; $P < .0001$) including myocardial infarction, congestive heart failure exacerbation, deterioration in renal function, and respiratory complications. Patients who underwent lower extremity bypass for acute limb ischemia had no difference in rates of graft occlusion (18.1% vs 18.5%; $P = .77$), but did have significantly higher rates of limb loss (22.4% vs 9.7%; $P < .0001$) and mortality (20.9% vs 13.1%; $P < .0001$) at 1 year. On multivariable analysis, acute limb ischemia was an independent predictor of both major amputation (hazard ratio, 2.16; confidence interval, 1.38-3.40; $P = .001$) and mortality (hazard ratio, 1.41; confidence interval, 1.09-1.83; $P = .009$) at 1 year.

Conclusions: Patients who present with acute limb ischemia represent a less medically optimized subgroup within the population of patients undergoing lower extremity bypass. These patients may be expected to have more complex operations followed by increased rates of perioperative adverse events. Additionally, despite equivalent graft patency rates, patients undergoing lower extremity bypass for acute ischemia have significantly higher rates of major amputation and mortality at 1 year. (J Vasc Surg 2013;58:949-56.)

Acute lower extremity ischemia resulting from arterial embolus, in situ thrombosis, or bypass graft thrombosis remains one of the most common vascular surgery

emergencies. The postprocedure rates of mortality and limb loss have traditionally been reported to be as high as 20%-40% and 12%-50%, respectively.¹⁻⁶ Conventional treatment of patients with acute lower extremity ischemia has been systemic anticoagulation and emergent open surgical intervention, specifically thromboembolectomy or bypass. However, the therapeutic approach to patients presenting with acute lower extremity ischemia underwent a transformation in the mid-1990s with the advent of endovascular therapy, and more specifically, the use of catheter-directed thrombolysis. As reported in several randomized controlled trials,⁷⁻¹² this endovascular approach offers a less invasive approach to conventional surgical revascularization but often requires more time to restore arterial flow, can be associated with higher rates of hemorrhage, and has not been shown definitively to improve limb salvage. Despite advances in endovascular techniques and equipment,¹³⁻¹⁵ along with improvements

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in preventative care and early diagnosis, a significant proportion of patients presenting with acute lower extremity ischemia still require urgent surgical bypass for limb salvage.

The characteristics of patients who present with acute lower extremity ischemia remain ill-defined, particularly in the setting of contemporary application of both elective endovascular and surgical interventions for peripheral vascular disease. Such patients may represent a subgroup of patients with peripheral vascular disease who have more advanced disease or may not be medically optimized, placing them at risk for acute events. The purpose of this study was to utilize data from the prospectively collected Vascular Study Group of New England (VSGNE) database to better characterize the acute lower extremity ischemia patient population and to determine outcomes following lower extremity bypass performed for acute lower extremity ischemia. We hypothesized that patients undergoing lower extremity bypass for acute ischemia represent a less medically optimized subgroup of patients with peripheral vascular disease who are at higher risk for perioperative adverse events and worse outcomes at 1 year.

METHODS

Study design and database. This study was a retrospective analysis of patients undergoing infrainguinal lower extremity bypass between January 1, 2003 and December 31, 2011 at all 30 centers that participate in the VSGNE. The VSGNE is a regional cooperative quality improvement initiative developed by community and academic centers in New England in 2002 to evaluate regional outcomes in vascular surgery. Details regarding this registry have been previously published and are available at www.vsgne.org.¹⁶ All data are self-reported and sent to a central data repository where it is aggregated and reviewed.

Data are collected at the time of the initial operation, including preoperative, intraoperative, and postoperative information. Follow-up data are then collected at 1 year. One-year data collected includes ambulation status, symptom status, graft patency, ankle-brachial index, need for graft revisions, and amputations. Vital status is entered directly into the database and matched to the Social Security Death Index.

Definitions. Patient information for more than 100 clinical and demographic variables was collected (complete list available at www.vsgne.org). Specific comorbidities examined included coronary artery disease (CAD, prior myocardial infarction, or angina), chronic obstructive pulmonary disease (medication-dependent or home oxygen-dependent), congestive heart failure (CHF, by history), diabetes mellitus (insulin-dependent diabetes mellitus or noninsulin-dependent diabetes mellitus, controlled by oral medication or diet), hypertension (history of hypertension or blood pressure $\geq 140/90$ mm Hg on the preoperative evaluation), and history of tobacco use (never, <1 year prior, or current). Renal disease was classified as normal (serum creatinine ≤ 1.8 mg/dL), renal insufficiency (serum creatinine >1.8 mg/dL), or dialysis-

dependent. Relevant surgical history is also obtained at the time of initial operation, including prior ipsilateral and contralateral endovascular and open revascularizations along with prior ipsilateral and contralateral amputations.

Indications for bypass are classified as asymptomatic, claudication, rest pain, tissue loss, and acute ischemia. Urgency of bypass is specified as elective, urgent, or emergent. Pathology treated is identified as occlusive or aneurysm. Patients were included in the study group if the indication for bypass was acute ischemia and the urgency was either urgent or emergent. The study group as defined here was subsequently compared with all other patients undergoing infrainguinal lower extremity bypass.

Immediate postoperative data relating to major in-hospital adverse events including the occurrence of myocardial infarction, dysrhythmia, CHF, change in renal function, respiratory complications, and stroke are recorded. Long-term follow-up data included vital status, graft patency, and amputation status. Graft patency is determined at 1 year by the practitioners via one of the following methods: Doppler examination, palpable graft pulse, palpable distal pulse, ankle-brachial index increase >0.15 from preoperative value, or duplex. Postoperative graft surveillance is not standardized across institutions.

Study end points. The primary study end points were bypass graft occlusion, major amputation, and mortality at 1 year postoperatively. Secondary end points included in-hospital major adverse events (specifically myocardial infarction, dysrhythmia, CHF, change in renal function, and respiratory complications), along with freedom from major adverse limb events (combined end point of major amputation, new bypass graft, graft revision, or thrombectomy/thrombolysis of bypass) at 1 year and amputation-free survival at 1 year.

Statistical analysis. Baseline characteristics were compared between groups using Pearson χ^2 analysis for categorical variables and the *t*-test for continuous variables. Kaplan-Meier life table analyses were used to calculate all time-to-event end points. Intergroup differences were evaluated using the log rank test. Cox proportional hazards models were constructed to determine independent predictors of major amputation, graft occlusion, and mortality at 1 year. Variables with $P < .2$ in univariate analysis were included in a backward stepwise selection multivariable analysis. Covariates with $P < .05$ were included in the final model. All software analyses were performed using SAS 9.1 software (SAS Institute, Cary, NC).

RESULTS

Cohort characteristics. Three hundred twenty-three (5.7%) of 5712 lower extremity bypasses were performed for the indication acute limb ischemia and classified as an emergent or urgent procedure. Specifically, 64% of these bypasses were documented as urgent and 36% as emergent. When compared with those patients undergoing lower extremity bypass for all other indications, this population was no different in age or sex distribution (Table I). Additionally, there were no differences in the rates of CAD,

Table I. Patient demographics

Variable	Bypass performed for acute limb ischemia (n = 323)	All other bypasses (n = 5389)	P value
Age, mean, years	66.3	67.4	.084
Male sex, %	67.8	69.1	.617
CAD, %	30.3	35.7	.051
CHF, %	13.9	15.7	.393
COPD, %	32.2	26.2	.017
Diabetes, %			
NIDDM	18.0	25.3	<.001
IDDM	18.9	25.2	<.001
Hypertension, %	81.4	86.5	.010
Renal insufficiency, %	13.9	13.1	.687
Hemodialysis, %	5.3	6.0	.193
Current tobacco use, %	48.5	39.4	<.001
Beta-blocker usage, %	71.1	76.7	.023
Aspirin usage, %	62.5	74.8	<.001
Statin usage, %	54.8	68.1	<.001
Prior ipsilateral bypass, %	32.8	23.5	.004
Prior ipsilateral percutaneous intervention, %	41.1	28.8	<.001
Aneurysm as indication, %	14.0	6.8	<.001

CAD, Coronary artery disease; CHF, congestive heart failure; COPD, chronic obstructive pulmonary disease; IDDM, insulin-dependent diabetes mellitus; NIDDM, noninsulin-dependent diabetes mellitus.

CHF, renal insufficiency, or hemodialysis dependence between the two groups. However, patients undergoing lower extremity bypass for acute ischemia had a higher incidence of chronic obstructive pulmonary disease but a lower incidence of diabetes and hypertension. Furthermore, patients undergoing lower extremity bypass for acute ischemia were more likely to be current smokers, and less likely to be taking a beta-blocker, an aspirin, or a statin.

Patients undergoing lower extremity bypass for acute ischemia were more likely to have had undergone a previous ipsilateral endovascular intervention than those undergoing bypass for all other indications (41.1% vs 28.8%; $P < .001$). Additionally, these patients were more likely to have undergone a prior ipsilateral bypass (32.8% vs 23.5%; $P = .004$). Aneurysm as the indication for bypass was more frequent for the acute ischemia group (14.0% vs 6.8%; $P < .001$).

Intraoperative differences were noted between the two groups. Specifically, patients undergoing lower extremity bypass for acute ischemia had longer operative times than those undergoing lower extremity bypass for all other indications (270 minutes vs 244 minutes; $P = .007$). These procedures were associated with higher rates of blood loss (363 vs 272 mL; $P < .001$) and more common use of prosthetic conduit (40.6% vs 32.6%; $P = .003$). There were no differences seen in the rates of tibial targets (42.4% vs 38.0%; $P = .110$) between the groups but the use of completion imaging studies was less frequent in the acute ischemia group (46.8% vs 53.7%; $P = .039$).

Perioperative major adverse events. Patients undergoing lower extremity bypass for acute ischemia experienced an increased rate of in-hospital major adverse

Table II. Perioperative major adverse events

Variable	Bypass performed for acute limb ischemia (n = 323)	All other bypasses (n = 5389)	P value
Any in-hospital major adverse event, %	19.8	11.6	<.0001
Myocardial infarction, %	7.5	3.6	.001
Dysrhythmia, %	4.4	4.0	.727
CHF, %	5.6	3.3	.028
Deterioration in renal function, %	6.6	4.4	.001
Respiratory, %	3.7	1.4	.004

CHF, Congestive heart failure.

events compared with those undergoing bypass for all other indications (19.8% vs 11.6%; $P < .0001$). Specifically, these patients had higher rates of postoperative myocardial infarctions (7.5% vs 3.6%; $P = .001$), CHF exacerbations (5.6% vs 3.3%; $P = .028$), deterioration in renal function (6.6% vs 4.4%; $P = .001$), and respiratory complications (3.7% vs 1.4%; $P = .004$) (Table II).

In addition to these medical adverse events, patients undergoing lower extremity bypass for acute ischemia were more likely to return to the operating room (including for amputation) during their hospitalization than those undergoing bypass for all other indications (23.7% vs 11.2%; $P < .0001$).

One-year outcomes. Although patients undergoing lower extremity bypass for acute ischemia experienced no difference in rates of graft occlusion at 1 year compared with patients undergoing bypass for all other indications (18.1% vs 18.5%; $P = .77$) (Fig 1), these patients did experience higher rates of both major amputation (22.4% vs 9.7%; $P < .0001$) and mortality at 1 year (20.9% vs 13.1%; $P < .0001$) (Figs 2 and 3). As a result, amputation-free survival at 1 year was significantly lower for patients undergoing lower extremity bypass for acute ischemia compared with patients undergoing bypass for all other indications (62.8% vs 77.4%; $P < .0001$) (Fig 4). Freedom from major adverse limb events was lower in patients undergoing lower extremity bypass for acute ischemia (60.4% vs 66.7%; $P < .0001$). Of the patients undergoing lower extremity bypass for acute ischemia with pathology classified as aneurysm, the 1-year major amputation rate was 13.6% and the 1-year mortality was 20%.

Multivariable analysis. Acute ischemia was an independent predictor of both amputation (hazard ratio, 2.16; confidence interval, 1.38-3.40; $P < .0001$) (Table III) and mortality at 1 year (hazard ratio, 1.41; confidence interval, 1.09-1.83; $P = .0009$) (Table IV) on multivariable analysis.

DISCUSSION

Despite advances in preventative care along with the increased treatment of both peripheral arterial disease and cardiac dysrhythmias, a significant number of patients

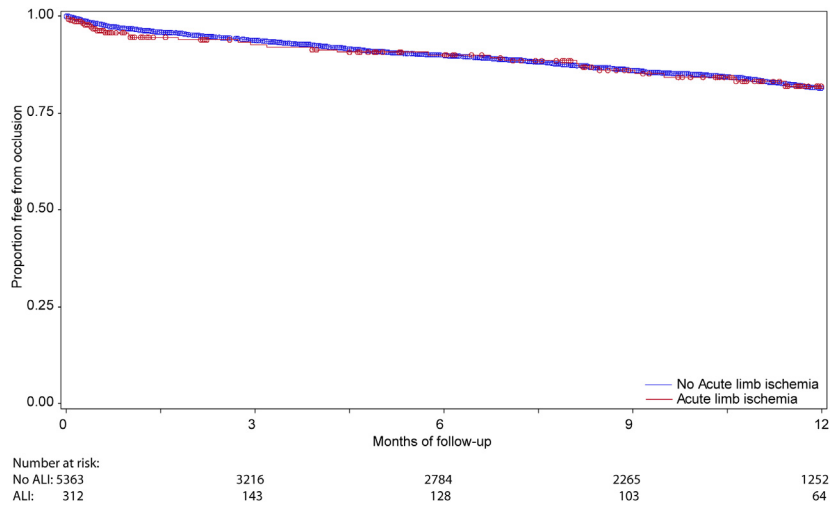


Fig 1. Freedom from graft occlusion.

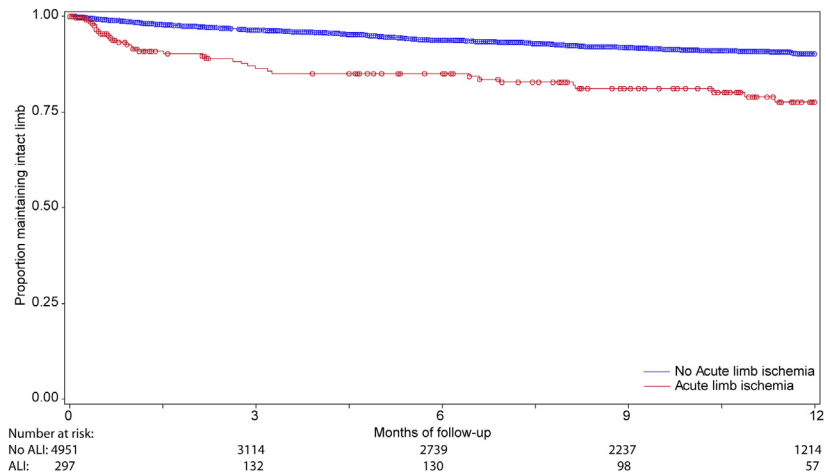


Fig 2. Freedom from major amputation.

continue to present with acute lower extremity ischemia. These patients most often require urgent intervention and have been traditionally thought to be at high risk for both limb loss and death. Therapeutic options include endovascular approaches, most commonly with the use of thrombolytic therapy, surgical approaches including thromboembolectomy and bypass, and primary amputation. Although clinical experience and anecdote might suggest that patients requiring urgent or emergent surgical revascularization will fare worse than their elective counterparts, these outcomes have not been rigorously compared. This study demonstrates that patients with acute lower extremity ischemia who undergo lower extremity bypass, when compared with patients undergoing elective bypass, represent a distinct group who are at higher risk for both perioperative adverse events and worse outcomes, specifically mortality and limb loss, at 1 year.

Although a variety of risk factors predisposing patients to the development of acute lower extremity ischemia have been identified, including peripheral arterial disease, atrial fibrillation, and known hypercoagulable disorders, the characteristics of those patients undergoing lower extremity bypass for acute ischemia remain ill-defined. Patients in this study who presented with acute lower extremity ischemia requiring surgical bypass represented a less medically optimized group of patients when compared with those undergoing elective bypass. While the incidence of multiple medical comorbidities including CAD, CHF, and renal insufficiency were no different between the two groups, there were significantly more active tobacco users in the acute lower extremity ischemia group along with significantly fewer patients on aspirin, beta-blockers, and statins. These lower rates of cardioprotective medication utilization likely not only placed these

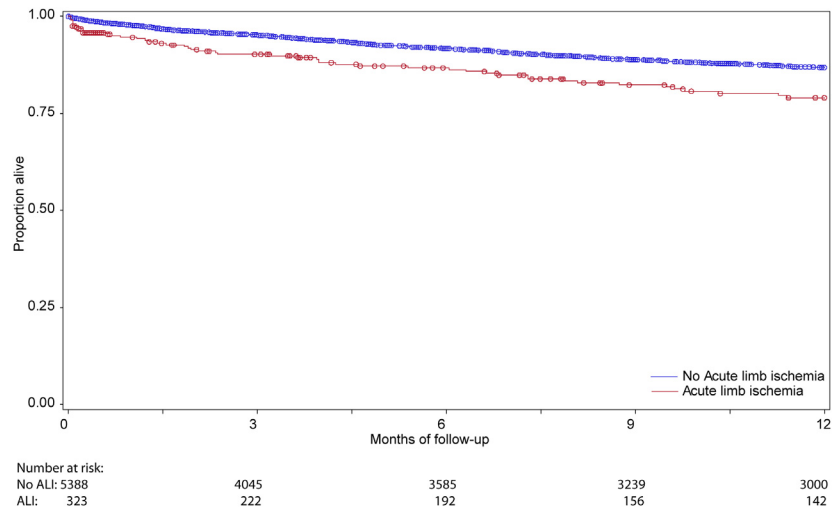


Fig 3. Survival.

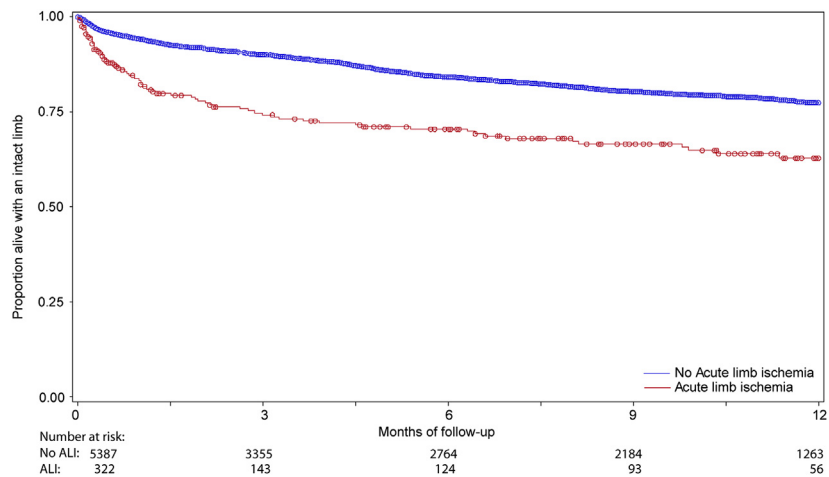


Fig 4. Amputation-free survival.

patients at risk for the inciting acute ischemia event but also predisposed these patients to higher rates of perioperative adverse events. The effect of statin use specifically has been studied previously for patients with lower extremity atherosclerotic disease undergoing elective surgery and has been shown to be associated with decreased perioperative cardiac complications¹⁷ along with improved graft patency and limb salvage¹⁸ and 1-year postoperative survival.¹⁹ Consistent with these findings, our multivariable analysis of predictors of 1-year mortality identified statin use as protective.

In addition to the differences in medical characteristics between patients undergoing bypass for acute lower extremity ischemia and those undergoing elective bypass, there were also significant differences in the rates of both prior ipsilateral bypasses and prior ipsilateral peripheral vascular interventions. Nearly one-third of patients in the acute lower extremity ischemia group had a prior ipsilateral

bypass, and over 40% had undergone a prior ipsilateral peripheral vascular intervention. Previously VSGNE investigators, Bypass versus Angioplasty in Severe Ischaemia of the Leg (BASIL) trial study investigators, and others have demonstrated that failed percutaneous interventions lead to worse outcomes after subsequent bypass with lower rates of limb salvage.²⁰⁻²² However, to date, the need for acute intervention at the time of percutaneous intervention failure has not been well reported. Although it is not possible to determine the denominator of patients undergoing prior percutaneous intervention in this dataset, it is evident that at the time of failure, a significant proportion will present acutely and require urgent intervention, including the need for surgical bypass. When compared with elective bypass, patients requiring bypass for acute lower extremity ischemia are subject to longer operations with greater blood loss and the more frequent use of prosthetic conduit. The role of previous interventions, both

Table III. Independent predictors of amputation at 1 year

	HR	95% CI	P value
NIDDM	1.56	1.09-2.24	.016
IDDM	1.98	1.44-2.74	<.0001
Prosthetic conduit	2.03	1.51-2.72	<.0001
Prior ipsilateral percutaneous intervention	2.08	1.23-3.53	.007
Acute ischemia	2.16	1.38-3.40	<.0001
Tibial target vessel	2.75	2.05-3.69	<.0001

CI, Confidence interval; HR, hazard ratio; IDDM, insulin-dependent diabetes mellitus; NIDDM, noninsulin-dependent diabetes mellitus.

Table IV. Independent predictors of mortality at 1 year

	HR	95% CI	P value
Statin therapy	0.80	0.71-0.91	.0007
Tibial target	1.15	1.01-1.32	.036
CAD	1.19	1.05-1.36	.009
IDDM	1.26	1.08-1.48	.004
NIDDM	1.29	1.10-1.51	.029
Prosthetic conduit	1.30	1.13-1.49	.0002
Acute ischemia	1.41	1.09-1.83	.009
COPD	1.46	1.28-1.67	<.0001
Renal insufficiency	1.58	1.36-1.83	<.0001
CHF	1.63	1.41-1.89	<.0001
Perioperative major adverse event	1.73	1.48-2.02	<.0001

CAD, Coronary artery disease; CHF, congestive heart failure; CI, confidence interval; COPD, chronic obstructive pulmonary disease; HR, hazard ratio; IDDM, insulin-dependent diabetes mellitus; NIDDM, noninsulin-dependent diabetes mellitus.

surgical and percutaneous, likely contributes to this increased complexity of such urgent bypasses and their subsequent inferior outcomes.

Given the patient characteristics along with the increased operative time and blood loss, it is not unexpected that patients undergoing lower extremity bypass for acute ischemia are at higher risk for perioperative major adverse events. In this study, patients undergoing lower extremity bypass for acute ischemia had a nearly 20% rate of major adverse perioperative adverse events including a twofold higher incidence of myocardial infarction compared with elective bypass patients. Additionally, these patients were twice as likely to return to the operating room during their initial admission. Unfortunately, patients with acute lower extremity ischemia most often necessitate urgent intervention and many may lack any revascularization option aside from surgical bypass. Accordingly, the ability to medically optimize these patients preoperatively is relatively limited. However, these rates of in-hospital adverse events should prompt the use of strict adherence to the best medical management in the perioperative period.

Along with inferior perioperative outcomes, patients undergoing bypass for acute lower extremity ischemia had inferior outcomes at 1 year, specifically mortality and limb loss, despite no differences in rates of graft secondary

patency compared with patients who underwent bypass for all other indications. Although not all of the anatomic factors are known for these patients, specifically the status of their runoff, it is evident that a significant number of patients undergoing bypass for acute lower extremity ischemia will require a major amputation in the setting of a patent bypass. Previously, in a review of nearly 900 patients with thrombosed popliteal artery aneurysms, it has been shown that the adjunctive use of thrombolysis improves graft patency rates but does not reduce the number of amputations, demonstrating that improving patency does not equate to limb salvage in the setting of acute lower extremity ischemia.²³ An additional factor that likely contributes to limb loss is the extent of irreversible muscle damage at the time of revascularization necessitating amputation despite adequate revascularization. In review of the Kaplan-Meier curves for amputation, it is evident that the majority of the amputations occur relatively early following surgery as the curves are parallel beyond the first few postoperative months.

In a previous review of factors associated with death after lower extremity bypass in the VSGNE database, emergent nature of the procedure was the strongest predictor of death at 1 year with a hazard ratio of 3.4.²⁴ In this review, acute lower extremity ischemia was an independent predictor of 1-year mortality as well. Furthermore, the occurrence of a perioperative adverse event was also a predictor of 1-year mortality, which patients with acute lower extremity ischemia suffered from at significantly higher rates than other patients. As with the amputations, the Kaplan-Meier curves for survival are parallel beyond the early postoperative period, indicative that the worse 1-year outcomes for patients with acute limb ischemia stem from their initial postoperative courses.

Unfortunately, the VSGNE database cannot be used to make any direct comparisons between the outcomes of patients with acute limb ischemia treated with endovascular interventions vs those treated with surgical bypass. Data on peripheral interventions only began being collected by the VSGNE in 2011, and they have not yet been validated and released for analysis. Taken in aggregate, the earlier randomized trials that attempted to address this specific comparative effectiveness question demonstrated that endovascular intervention could be beneficial in certain clinical settings such as thrombosis (as opposed to embolization) in a limb without motor and sensory compromise.⁷⁻¹¹ As these studies are now 15 years old, further work is necessary to better understand which patient subgroups might benefit more from an endovascular approach compared with an open surgical bypass. However, it remains apparent that surgical intervention in these patients continues to be associated with poor outcomes at 1 year.

The primary limitation of this study was its retrospective nature. An additional limitation is that this study is reporting only on outcomes following surgical bypass and does not include patients with acute limb ischemia who were treated with either thromboembolectomy alone or with endovascular techniques. While data in the VSGNE

are collected prospectively, the database is queried in a retrospective fashion. Despite the breadth and detail of the information, which is obtained at the time of lower extremity bypass, certain patient factors are not captured. Specifically relevant to this study is the lack of information regarding the exact etiology of the acute ischemia. Although pathology is differentiated between aneurysmal disease and occlusive disease, there is no means of determining whether the occlusive disease is due to an embolic or a thrombotic event. However, in each case, the pathology did require surgical bypass. There is, however, no means of determining if patients in this cohort underwent attempts at thrombolytic therapy or surgical thromboembolectomy immediately prior to their surgical intervention. Furthermore, the presence of a documented hypercoagulable state is not captured nor is a history of atrial fibrillation, both of which would be of relevance to this patient population. Additionally, the data are self-reported, which may lead to observer bias. VSGNE data are collected from multiple institutions and multiple surgeons within those institutions, and, as such, postoperative surveillance protocols may differ, which may also contribute to disparate outcomes.

Despite these important limitations, it is important to recognize that the VSGNE has successfully collected data with very high accuracy and that these data have been validated with regularly scheduled audits.¹⁶ These data are generalizable secondary to the diversity of the practitioners and hospitals participating in this quality improvement registry. This report is the largest study to date describing the characteristics of patients undergoing lower extremity bypass for acute limb ischemia and documenting the in-hospital and 1-year outcomes that can be anticipated in this setting.

CONCLUSIONS

Lower extremity bypass remains an important tool among the treatment options for patients presenting with acute ischemia despite advances in endovascular therapy. Of patients undergoing lower extremity bypass, patients who present with acute ischemia represent a less medically optimized subgroup that often have had a failed prior endovascular or surgical intervention and can be expected to require longer operations with higher associated blood losses. Postoperatively, these patients will have increased rates of in-hospital perioperative adverse events. Additionally, despite equivalent graft patency rates, patients undergoing lower extremity bypass for acute limb ischemia have significantly higher rates of amputation and mortality at 1 year. Although treatment for these patients most often cannot be delayed or altered, these outcomes should be factored into the decision making process for patients presenting with acute lower extremity ischemia.

AUTHOR CONTRIBUTIONS

Conception and design: DB

Analysis and interpretation: DB, NH, AS, DJ, JM, JC

Data collection: DB, NH, AS

Writing the article: DB, VP, JC, AS

Critical revision of the article: DB, VP, DJ, PG, JM, NH, JC, AS

Final approval of the article: DB, VP, DJ, PG, JM, NH, JC, AS

Statistical analysis: NH

Obtained funding: Not applicable

Overall responsibility: DB

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