Outcomes and practice patterns in patients undergoing lower extremity bypass

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Background: **The appropriate application of endovascular intervention vs bypass for both critical limb ischemia (CLI) and intermittent claudication (IC) remains controversial, and outcomes from large, contemporary series are critical to help inform treatment decisions. Therefore, we sought to define the early and 1-year outcomes of lower extremity bypass (LEB) in a large, multicenter regional cohort, and analyze trends in the use of LEB with or without prior endovascular interventions.**

Methods: **The Vascular Study Group of New England database was used to identify all infrainguinal LEB procedures performed between 2003 and 2009. The primary study endpoint was 1-year amputation-free survival (AFS). Secondary endpoints included in-hospital mortality and morbidity, including major adverse cardiac events. Trend analyses were conducted to identify annual trends in the proportion of LEBs performed for an indication of IC, in-hospital outcomes, including mortality and morbidity, and 1-year outcomes, including AFS. Analyses were performed on the entire cohort and then stratified by indication.**

Results: **Between 2003 and 2009, 2907 patients were identified who underwent LEBs (72% for CLI; 28% for IC). The proportion that underwent LEB for IC increased significantly over the study period (from 19% to 31%; $P < .0001$). There was a significant increase over time in the proportion of LEBs performed after a previous endovascular intervention among both CLIs (from 11% to 24%; $P < .0001$) and ICs (from 13% to 23%; $P = .02$). Neither in-hospital mortality nor cardiac event rates changed significantly among either group. There was no significant change in 1-year AFS in patients with IC (97% in 2003 and 98% in 2008; P for trend .63) or in patients with CLI (73% in 2003 and 81% in 2008; $P = .10$).**

Conclusions: **Over the last 7 years, significant changes in patient selection for LEBs have occurred in New England. The proportion of LEBs performed for ICs as opposed to CLIs has increased. Patients are much more likely to have undergone prior endovascular interventions before undergoing a bypass. In-hospital and 1-year outcomes after LEB for both IC and CLI have remained excellent with no significant changes in AFS. (J Vasc Surg 2012;55:1629-36.)**

Management of chronic lower extremity ischemia is complex. The severity of symptoms varies widely, from mild claudication to extensive tissue loss. Revascularization strategies differ significantly, with both traditional open approaches and newer endovascular therapies available. Decision-making centers around selecting those patients who require intervention and choosing the type of intervention that will prove most beneficial over the individual patient's anticipated life-span. In order to weigh the risks and benefits of intervention, contemporary estimates of the morbidity and mortality associated with a given procedure are critical.

Much of the current fund of knowledge on outcomes associated with lower extremity bypass (LEB) is derived from highly selected populations of patients studied within randomized trials, or from large series accumulated at single centers of excellence. For example, while the Project or Ex-Vivo vein graft Engineering via Transfection (PREVENT) III[1] and Bypass Versus Angioplasty in Severe Ischaemia of the Leg (BASIL)[2] cohorts have proved invaluable in studying the efficacy of competing treatment options for critical limb ischemia (CLI), the patients and results obtained in these settings may not accurately reflect real-world practice. Further, while single-institution series[3,4] may provide insight into a local surgical practice, these studies may not be broadly generalizable.

In order to define contemporary practice patterns in the real-world management of patients with lower extremity peripheral arterial disease, we analyzed a prospectively collected regional database of patients who underwent LEB for chronic lower extremity ischemia. We evaluated in-hospital and 1-year outcomes, looking separately at patients with intermittent claudication (IC) and those with CLI. We sought to characterize temporal changes in the utiliza-

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tion and the outcomes associated with LEB, focusing on amputation-free survival (AFS), graft patency, and in-hospital morbidity.

METHODS

Cohort assembly. Data were obtained from the prospectively collected Vascular Study Group of New England (VSGNE) registry. The VSGNE is a regional cooperative quality improvement initiative that was developed in 2002 to prospectively evaluate outcomes in patients undergoing vascular surgery. By the end of the period of study, there were a total of 12 teaching and nonteaching hospitals with 52 vascular surgeons (community and academic) who participated in this program by reporting data into the registry. There were seven centers participating in 2003. The dataset used for this analysis did not exclude any of these surgeons or centers; it was not abstracted from any subset. All data are self-reported and sent to a central data repository where they are aggregated and reviewed. Research analysts are blinded to patient, surgeon, and hospital identity.

At the time of discharge after the index operation, in-hospital data comprising preoperative, intraoperative, and postoperative data are completed and submitted to the VSGNE. The study design for the VSGNE registry mandates the collection of follow-up data at 1 year for all patients with procedures entered into the registry. To facilitate compliance with this requirement, the web-based system generates follow-up forms for each operation in advance of the expected 1-year office visit. Data pertaining to ambulation status, symptom status, patency, ankle-brachial index, bypass graft revisions, or amputations are recorded on this form. Since the inception of the study, a claims-based audit system has been used that has demonstrated 99% accuracy in capturing consecutive operations performed at each center. Details relating to the VSGNE study design have been published previously[5] and are available at the VSGNE website (http://www.VSGNE.org). In brief, the VSGNE takes several measures to ensure the accuracy of data entry, including holding biannual meetings for all surgeons and research assistants. They also correlate submitted results from each hospital with hospital claims, which ensures accurate case reporting and validates hospital discharge status. Detailed definitions have been provided to data abstractors along with newsletters addressing specifics of data entry. The central data collection site is also available to answer questions concerning data abstraction.

For the purpose of this study, the VSGNE database was queried to identify patients undergoing elective and urgent infrainguinal LEB performed between January 1, 2003, and December 31, 2009, for an indication of CLI (defined as tissue loss or ischemic rest pain) or IC; patients with acute limb ischemia and those undergoing LEB for aneurysmal disease were not included. Those without an indication specified were excluded ($n = 382$). The urgency of the procedure was determined by the surgeon as elective, urgent, or emergent. All infrainguinal bypass configurations were included for analysis, regardless of the specific inflow site, outflow site, or conduit. For all analyses of 1-year outcomes, data from patients who underwent LEB in 2009 were excluded because 1-year follow-up data were not yet available.

Covariates examined. Patient information for 100 clinical and demographic variables (available at http://www.VSGNE.org) was collected. Preoperative variables examined included the year the procedure was performed, as well as indication for LEB, defined as either IC or CLI. Preoperative use of cardioprotective medications was defined as antiplatelet agents, statins, or beta blockers. Both the individual medication types were investigated as well as a composite variable, any cardioprotective medication. Prior endovascular intervention, either suprainguinal or infrainguinal, on the ipsilateral limb was also evaluated. Other variables collected included comorbidities such as coronary artery disease (CAD; history of myocardial infarction [MI], or angina), chronic obstructive pulmonary disease (medication-dependent or home oxygen-dependent), congestive heart failure (by history), diabetes mellitus (insulin-dependent or controlled by oral medication or diet), hypertension (history of hypertension or blood pressure >140/90 mm Hg on the preoperative evaluation), and history of tobacco use (never, >1 year prior, or current). Variables related to surgical history included previous coronary artery bypass graft or percutaneous coronary intervention, as well as previous carotid or aortic procedure, and major extremity amputation (defined as above- or below-knee amputation).

One-year follow-up data included mortality, graft patency (primary, primary-assisted, or secondary, determined by either angiography or duplex graft surveillance scan), and major amputation (above- or below-knee). Vital status was confirmed for all patients using follow-up visit notes and a recent version of the Social Security Death Index.

Main outcome measures. The primary endpoint was AFS, a composite endpoint defined as freedom from ipsilateral major amputation and freedom from all-cause mortality at 1-year follow-up. Graft patency at 1-year follow-up was also ascertained. Secondary endpoints included in-hospital mortality, wound infection, cardiac complications, and need for reoperation. Cardiac complications were defined as a composite of either MI (defined as either troponin elevation, changes on electrocardiogram, or clinically diagnosed) or new dysrhythmia during the index hospitalization. Need for reoperation was defined as return to the operating room within the index admission for infection, thrombosis, or revision. Length of hospital stay was also ascertained. Trend analyses were conducted to assess for time-dependent changes in these outcomes over the study period.

Statistical analysis. Descriptive statistics were used to identify the proportion of bypasses performed on an annual basis for IC compared to CLI. There were 7 hospitals that contributed data in 2003; this increased to 12 hospitals by 2009. In order to assess whether the addition of new sites to the database on an annual basis had an effect on the proportion of LEBs performed for ICs, annual comparisons

Table I. Demographics of patients who underwent infrainguinal lower extremity bypass in the Vascular Study Group of New England from 2003 to 2009, with univariate analysis by indication

Covariates	*Total* *n = 2907*	*IC* *n = 797 (27.4%)*	*CLI* *n = 2110 (72.6%)*	P *value*
Demographics	No. (%)	No. (%)	No. (%)	
Age (mean ± SD in years)	68.3 (11.4)	64.3 (10.4)	69.9 (11.4)	<.0001
Gender (female)	902 (31.0)	205 (25.7)	697 (33.0)	.0001
Race				.06
White	2859 (99.2)	783 (98.7)	2076 (99.4)	
Nonwhite	22 (0.8)	10 (1.3)	12 (0.6)	
Year of procedure				<.0001
2003	397 (13.6)	76 (9.5)	321 (15.2)	
2004	385 (13.2)	81 (10.1)	304 (14.4)	
2005	383 (13.2)	117 (14.7)	266 (12.6)	
2006	380 (13.1)	99 (12.4)	281 (13.3)	
2007	422 (14.5)	140 (17.6)	282 (13.4)	
2008	463 (15.9)	137 (17.2)	326 (15.5)	
2009	477 (16.4)	147 (18.4)	330 (15.6)	
Preoperative factors				
Smoking status				<.0001
Never smoker	469 (16.2)	82 (10.3)	387 (18.4)	
History of smoking	1310 (45.1)	344 (43.3)	966 (45.9)	
Current smoker	1123 (38.7)	369 (46.4)	754 (35.8)	
CAD	1106 (38.1)	244 (30.7)	862 (40.9)	<.0001
History of CABG or PCI	970 (33.4)	256 (32.1)	714 (33.9)	
CHF	494 (17)	46 (5.8)	448 (21.2)	<.0001
Hypertension	2517 (86.6)	647 (81.2)	1870 (88.6)	<.0001
Insulin-dependent diabetes	761 (26.2)	91 (11.4)	670 (31.8)	<.0001
COPD	853 (29.4)	217 (21.3)	636 (30.2)	.13
Prosthetic conduit	799 (27.5)	278 (34.9)	521 (24.7)	<.0001
Previous surgery				
Endovascular intervention (ipsi)	545 (18.8)	150 (18.8)	395 (18.7)	.95
Aortic surgery	112 (3.9)	37 (4.6)	75 (3.6)	.17
Carotid surgery	311 (10.7)	96 (12.1)	215 (10.2)	.15
Arterial bypass (any)	918 (31.6)	239 (30.0)	679 (32.2)	.25
Major amputation (contra)	112 (3.9)	7 (0.9)	105 (5.0)	<.0001
Cardioprotective medications				
Aspirin	2093 (72.1)	602 (75.7)	1491 (70.8)	.0079
Clopidogrel	295 (10.2)	69 (8.7)	226 (10.7)	.10
Statin	1837 (63.3)	561 (70.5)	1276 (60.6)	<.0001
Beta blocker	2378 (82.3)	609 (77.1)	1769 (84.3)	<.0001

CABG, Coronary artery bypass graft; *CAD,* coronary artery disease; *CHF,* congestive heart failure; *CLI,* critical limb ischemia; *contra,* contralateral; *COPD,* chronic obstructive pulmonary disease; *IC,* intermittent claudication; *ipsi,* ipsilateral; *PCI,* percutaneous coronary intervention.

were made between the proportion of IC vs CLI (as the indication for LEB) in the existing centers and that among the new centers added that same year. Of note, the years of study were divided into 5 time periods in order to maintain anonymity of the individual sites as they were added. Comparisons were made between time periods. Categorical variables were compared using Pearson χ^2 analysis. Cochran Armitage tests of trend were used to evaluate for trends over the study period. Analyses were performed on the entire cohort as well as on each subgroup after stratification by indication for LEB (IC and CLI). For 1-year outcomes, Kaplan-Meier analysis was used to assess graft patency, overall survival, and AFS. Intergroup comparisons were made using log-rank tests. Tests of trend for 1-year endpoints were conducted by linear regression using the 1-year estimates, and assessing the goodness of fit. Significance was accepted at the $P < .05$ level. All analyses were conducted using SAS, version 9.2, software (SAS Institute, Cary, NC).

RESULTS

Patient characteristics. A total of 3289 LEBs, performed on 2850 patients, were identified between 2003 and 2009 in the VSGNE database. Of these, 797 (27%) were performed for IC and 2110 (73%) were performed for CLI (indication was missing in 382). The mean age was 68.3 years and 902 LEBs (31%) were performed on women (Table I). Previous ipsilateral bypass had been performed in 381 patients (13.1%). Patients undergoing LEB for CLI as compared with IC had more comorbid conditions, including CAD, congestive heart failure, insulin-dependent diabetes, and hypertension (Table I). Cardioprotective medications were applied differently, with the IC group being significantly more likely to receive aspirin and statins, while the CLI group was more likely to receive beta blockers. There was no significant difference in the rates of previous endovascular intervention between groups, with 150 (18.8%) in the IC group, and 395 (18.7%) in the CLI group ($P = .95$).

Table II. Outcomes after infrainguinal lower extremity bypass, with univariate analysis by indication

Outcome	*Total n = 907*	*IC n = 797*	*CLI n = 2110*	P *value*
Perioperative	N (%)	N (%)	N (%)	
Mortality	47 (1.6)	2 (0.3)	45 (2.1)	.0003
Complications				
Need for reoperation	360 (12.4)	43 (5.4)	317 (15.0)	<.0001
MI or dysrhythmia	208 (7.2)	24 (3.0)	184 (8.7)	<.0001
Wound infection	154 (5.3)	36 (4.5)	118 (5.6)	.25
Length of stay (days) means (± SD)/median	7.7 (7.7)/5.0	4.0 (4.3)/3.0	9.2 (8.2)/ 7.0	<.0001
One-year follow-up[a]				
Mortality (%)	10.9	3.7	13.6	<.0001
Major amputation (%)	9.1	1.6	12.2	<.0001
Graft patency (%)				<.0001
Primary	70.1	78.9	66.4	
Primary-assisted	78.8	87	75.1	
Secondary	80.9	89	77.4	

CLI, Critical limb ischemia; *IC,* intermittent claudication; *MI,* myocardial infarction.
[a]Data from 2009 excluded.

In-hospital outcomes. In-hospital adverse events were more common among the CLI group. While in-hospital mortality for the total cohort was 1.6%, in-hospital mortality was sevenfold higher in the CLI group (2.1% vs 0.3%; P = .0003). Rates of wound infection, need for reoperation, in-hospital MI or dysrhythmia, and mean lengths of stay were all significantly higher in the CLI group (Table II).

Outcomes at 1-year follow-up. Mean long-term follow up was 331 days. One-year outcomes were more favorable in the IC group (Table II). One-year mortality for the total cohort was 11% (IC 4% vs CLI 14%; $P < .0001$). Patients with IC experienced a lower rate of major amputation at 1 year than patients with CLI (2% vs 12%; $P < .0001$). Graft patency was also significantly better in the IC group when compared to the CLI group (IC: primary 79%, primary-assisted 87%, secondary 89%; CLI: primary 66%, primary-assisted 75%, secondary 77%). Survival data was missing for 7% of cases. When stratified by history of endovascular intervention, AFS among IC met statistical significance (log-rank, P = .05); however, it should be noted that there were no events in the prior endovascular intervention group by 1 year. There was no significant difference in AFS among the CLI group when stratified by history of endovascular intervention (log-rank, P = .14).

Time trends in patient characteristics by indication. Among the total cohort, there was a steady increase in the use of any cardioprotective medication, increasing from 92% in 2003 to 98% in 2009 ($P < .0001$). This trend was observed in both the IC group (90% in 2003 and 97% in 2009; P = .009), and in the CLI group (93% in 2003 and 98% in 2009; $P < .0001$). Utilization of specific cardioprotective medications reveals a significant increase in the use of aspirin ($P < .0001$), clopidogrel ($P < .0001$), statins (P = .006), and beta blockers (P = .028) among claudicants (Fig 1). Utilization of specific cardioprotective medications reveals a significant increase in the use of aspirin ($P < .0001$),

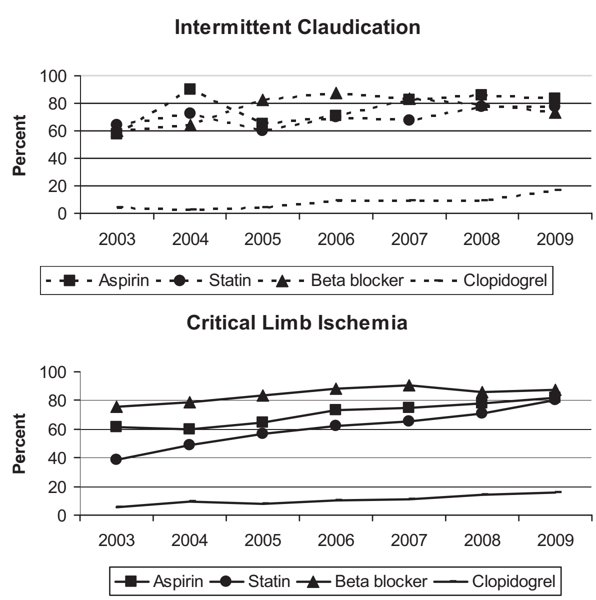

Fig 1. Inpatient trends in use of medical therapies.

clopidogrel ($P < .0001$), statins ($P < .0001$), and beta blockers ($P < .0001$) among the CLI group.

Over the time period of study, there was a significant increase in the proportion of LEBs performed for ICs ($P < .0001$), with 19% in 2003, and 31% in 2009 (Fig 2). This increase corresponded to increasing use of LEB for IC among sites that were added to the database over the interval of study (Fig 3).

The use of endovascular intervention prior to LEB increased significantly between 2003 and 2009. Among the IC group, the rate of prior endovascular intervention increased from 13% in 2003 to 23% in 2009 (P = .02). Among the CLI group, the use of prior endovascular

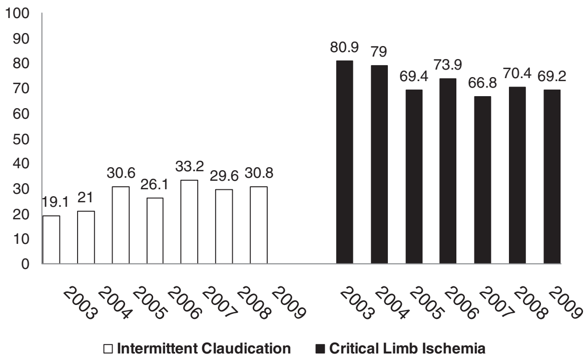

Fig 2. Annual proportion of infrainguinal lower extremity bypasses for claudication and for critical limb ischemia, $P = .001$.

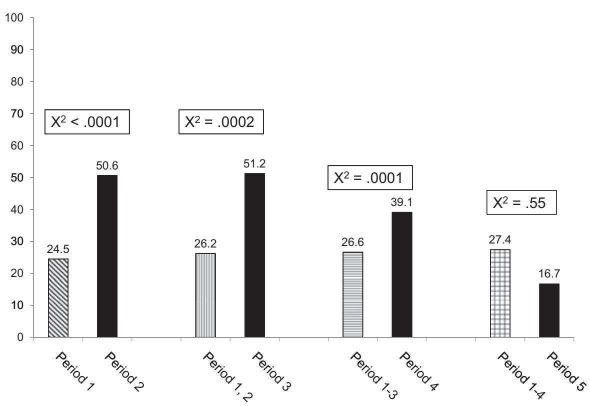

Fig 3. Univariate effect of additional sites to the Vascular Study Group of New England on annual proportion of infrainguinal lower extremity bypasses for intermittent claudication, 2003 to 2009. In order to protect the anonymity of sites as they were added, the analyses were performed as comparisons between year groups to assess the effect of adding new centers over time.

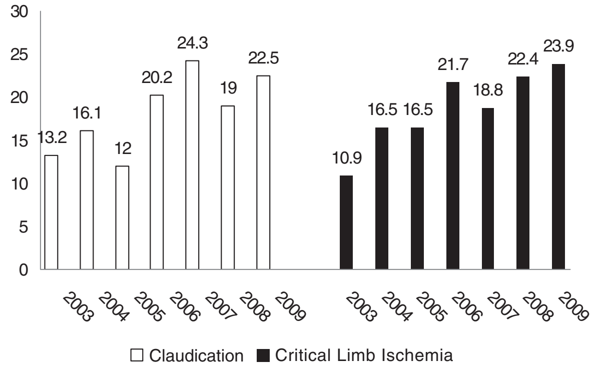

Fig 4. Percentage of patients with history of endovascular intervention prior to infrainguinal lower extremity bypass. P for trend = .0204 for intermittent claudication, P for trend for critical limb ischemia < .0001.

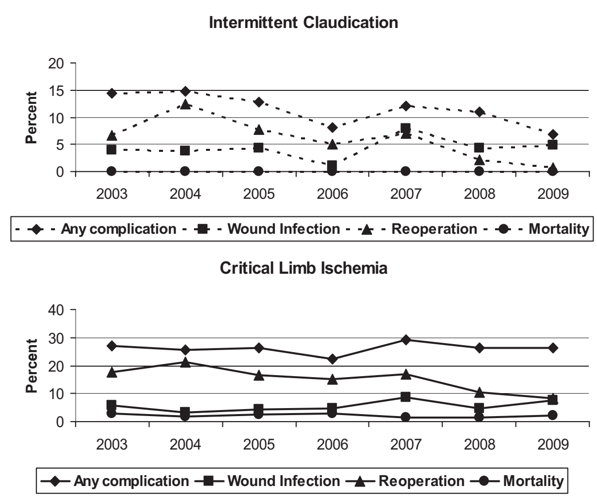

Fig 5. Inpatient trends in complications and mortality.

intervention has more than doubled, from 11% in 2003 to 24% in 2009 ($P < .0001$; Fig 4).

Trends of in-hospital outcomes by indication. In-hospital outcomes demonstrated mixed results over the time period studied (Fig 5). For the total cohort, there were 9 in-hospital deaths (2.3%) in 2003 compared to 7 (1.5%) in 2009 ($P = .27$). In the CLI group, there were 9 in-hospital deaths (3%) in 2003, and 7 in 2009 (2%; $P = .42$). The in-hospital mortality among claudicants did not change significantly, with an extremely low event rate; there were was either zero or one death observed in each year of study.

There was no significant change in the rates of in-hospital MI/dysrhythmia (9% in 2003 and 8% in 2009; $P = .44$; Fig 6). This holds true for the IC group (5.3% in 2003 and 2% in 2009; $P = .71$), and the CLI group (9% in 2003 and 10% in 2009; $P = .15$). Among the total cohort, the need for reoperation (defined as return to the operating room within the index admission for infection, thrombosis, or revision) decreased steadily from 16% in 2003 to 6% in 2009 ($P < .0001$). Similar decreases were seen in the two subgroups (Fig 5). Mean lengths of stay have also decreased significantly (Fig 7); among the total cohort, mean length of stay in 2003 was 9.8 days, which decreased to 5.8 days by 2009 ($P < .0001$).

Trends in 1-year outcomes by indication. There was no significant decrease in 1-year mortality among either group (Table III). Among the CLI cohort, mortality decreased from 18% in 2003 to 10% in 2008 ($P = .24$), while among the IC group, mortality decreased from 3.5% to 2.2% ($P = .32$).

Graft patency has not changed over time. There was no significant change among the CLI group (secondary patency was 75% in 2003 compared to 83% in 2008; $P = .47$); similarly among the IC cohort, secondary patency was 93% in 2003 and 94% in 2008 ($P = .68$). Major amputation rates also did not change over time among the IC group. However, there was a significant decrease in 1-year major

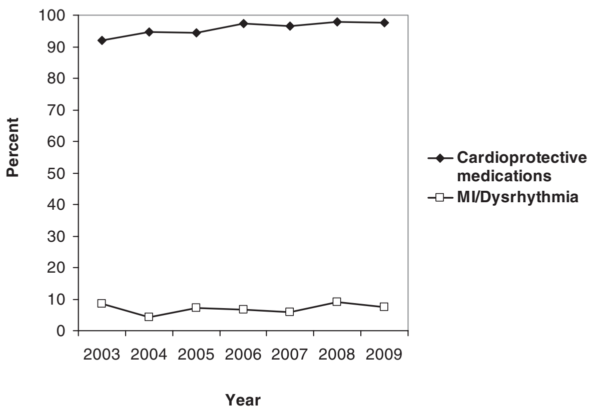

Fig 6. Trends in use of cardioprotective medications (beta blockers, statins, or antiplatelet agents) and in-hospital operative myocardial infarction *(MI)*/dysrhythmia, among the total cohort. *P* for trend $< .0001$ for cardioprotective medications, *P* for trend $= .4384$ for MI/dysrhythmia.

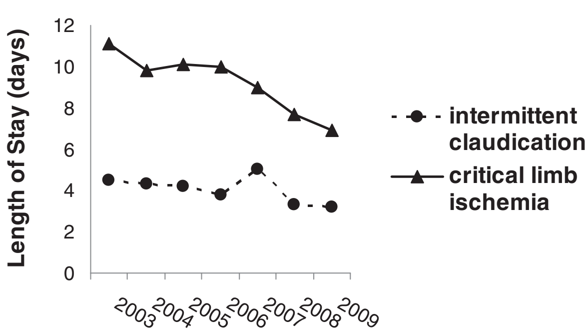

Fig 7. Inpatient trends in mean lengths of stay.

amputation among the CLI group, from 15% in 2003 to 11% in 2008 ($P = .02$).

One-year AFS did not demonstrate a significant change over the time period of study (Table III). Among the CLI group, AFS was 73% in 2003 and 81% in 2008 ($P = .10$). Among the IC group, AFS was 97% in 2003 and 98% in 2008 ($P = .63$).

DISCUSSION

Our analysis of LEB practice patterns and outcomes at community and academic centers in New England provides a snapshot of in-hospital and 1-year treatment results in contemporary, everyday vascular surgery practice. A paucity of literature is available to provide real-world estimates of LEB practice patterns and outcomes due primarily to issues of sample size, selection bias, and limited clinical detail. For example, patients with CLI and BASIL[2] reported a 5.6% in-hospital mortality rate and a 68% 1-year AFS rate among those undergoing open revascularization, and the PREVENT III[1] trial reported a 78% 1-year AFS rate. However, these results represent a highly selected group of patients, and include patients that were treated nearly a decade ago. Other authors, like Nowygrod et al,[6] have used large national administrative databases to overcome the bias imparted by randomized controlled trials and single-institution series. However, studies of this nature are often limited by the temporal delay associated with administrative data availability (all patients were treated prior to 2004).[6] In addition, because administrative datasets rely on discharge abstractions, important patient-level clinical data are often lacking. Last, LaMuraglia et al[7] reported outcomes of LEB using the private sector National Surgical Quality Improvement Project. However, this dataset does not offer significant clinical detail regarding specific vascular outcomes,[8] and is limited to short-term follow-up only.

In addition to describing contemporary LEB outcomes, our study indicates that, although LEB is still more commonly performed for CLI, the proportion of patients receiving surgical bypass for IC has increased significantly. This change correlates with the addition of new centers to the VSGNE over the period of study. Although the exact cause of this shift in practice patterns is unknown, several possible explanations exist. First, a fundamental change may have occurred in the approach to patients with CLI. For example, more patients with CLI may be receiving endovascular intervention as an initial revascularization strategy. If true, this more aggressive posture toward endovascular therapy might have led to a decrease in the number of patients with CLI requiring a surgical bypass.[9] If the proportion of patients with IC receiving endovascular intervention instead of LEB is not increasing at the same rate as patients with CLI, the relative proportion of patients with CLI undergoing LEB compared to patients with IC would decrease. However, in order to address this, more information is needed on the outcomes of patients receiving endovascular intervention only. It would also be useful to know the indication for prior endovascular intervention, particularly to identify patients with CLI for whom the endovascular procedure was for IC but the disease subsequently progressed to CLI when the LEB was performed. Accordingly, our regional quality improvement initiative has been modified in order to begin collecting this data for future study.

A second possible explanation for the observed change in practice pattern may be a shift in strategies for treating IC. Given the ready availability and minimally invasive nature of endovascular interventions, it may be that an increasing number of patients with IC are offered percutaneous revascularization.[10] The high rates of prior endovascular intervention seen among the IC group may reflect a "treatment trap"; once the decision has been made to intervene procedurally for IC, surgeons may feel obliged to perform an open revascularization if a prior endovascular approach has not succeeded in symptom resolution. Again, our future regional efforts to study both open and endovascular treatment strategies, and eventually even disease-based registries that incorporate both treated and untreated patients with both claudication and CLI, will help to support or refute this hypothesis.

Table III. Trends in 1-year outcomes; data from 2009 excluded

Variable	*2003 (%)*	*2004 (%)*	*2005 (%)*	*2006 (%)*	*2007 (%)*	*2008 (%)*	*R-square*	P *for trend*
Claudication								
AFS	96.5	94.4	92.7	94.5	94.5	97.8	0.07	.63
Mortality	3.5	3.9	5.9	2.9	3.2	2.2	0.24	.32
Major amputation	0.0	1.9	1.5	3.1	2.7	0	0.03	.45
Graft patency	93.4	87.7	85.1	91.4	89.8	93.6	0.05	.68
Primary	90.8	78.4	71.5	85.1	79.5	88.8	0.003	.92
Primary-assisted	93.4	87.7	85.1	85.1	83.5	91.2	0.11	.53
Secondary	93.4	87.7	85.1	91.4	89.8	93.6	0.05	.68
CLI								
AFS	72.9	76.7	74.1	74.1	76.4	81.4	0.53	.10
Mortality	18.1	13.2	14.3	18.0	14.8	9.7	0.32	.24
Major amputation	15.4	14.4	15.8	13.0	12.9	11.0	0.75	.02
Graft patency	75.2	77.4	78.9	75.3	73.6	82.8	0.14	.47
Primary	67.3	68.5	67.9	63.6	58.2	77.4	0.02	.81
Primary-assisted	75.2	76.1	75.6	72.5	71.0	80.9	0.03	.77
Secondary	75.2	77.4	78.9	75.3	73.6	82.8	0.14	.47

AFS, Amputation-free survival; *CLI,* critical limb ischemia.

Our results also indicate significant improvements in the use of perioperative cardioprotective medications over time, particularly aspirin and statins. However, there has not been a concomitant reduction in perioperative mortality or cardiac events. While the reason for this is not clear, a plausible explanation may be that this represents a type-2 error. The small numbers of event rates, particularly on subset analyses of either the CLI or IC group, may not allow for detecting a difference over the time period of study. Rather than concluding that these improvements in compliance with medical therapy have had no impact, we would favor re-evaluating this issue as more data becomes available in the future.

The lack of significant improvements in long-term survival and AFS could also potentially relate to sample size, particularly in the IC group where these event rates are very low. However, among the CLI group, this lack of improvement may underscore the severity of systemic illness associated with CLI. In some cases, graft patency does not correlate with limb salvage. Regardless of limb salvage, patients with CLI are still at risk for death due to other causes, with a particular focus on those patients at highest risk.

Certain limitations inherent to this study design must be acknowledged. First, our dataset is currently limited on the specifics of the prior endovascular intervention, including the indication, and we did not provide outcomes associated with endovascular-alone strategies. Accordingly, we revised our registry to capture this information for future analyses. Second, our registry is currently procedurally based, not disease-based. Thus, we do not have data on the natural history of chronic lower extremity ischemia, managed nonoperatively or with primary amputation. We also have noted the effect of additional sites on the increasing proportion of LEBs performed for claudication, but have not pursued further analyses of the effect of these additional centers on any of the major outcome variables. The mission of VSGNE is for quality improvement, rather than comparisons of surgeon outcomes within the registry.

In summary, among 2907 infrainguinal LEBs performed for chronic lower extremity ischemia between 2003 and 2009 in New England, an increasing proportion was performed for IC, up from 19.1% in 2003 to 30.8% in 2009. In addition, rates of prior endovascular interventions have increased in both groups while in-hospital outcomes have remained excellent in patients with either IC or CLI. However, a deeper understanding of the drivers of these changes in practice patterns will require more detail about the use of endovascular interventions in our region. Accordingly, we have expanded our regional quality improvement effort not only to help us understand the volume and outcomes of open and endovascular revascularization for IC and CLI, but also how better to identify patient subgroups that will benefit most from each revascularization strategy.

AUTHOR CONTRIBUTIONS

Conception and design: JS, AS, PG
Analysis and interpretation: JS, AS, BN, JK, JC, PG
Data collection: AS, BN, JK, JC, PG
Writing the article: JS, AS, PG
Critical revision of the article: JS, AS, BN, JK, JC, PG
Final approval of the article: JS, AS, BN, JK, JC, PG
Statistical analysis: JS, AS, JK, PG
Obtained funding: JS, AS, JC, PG
Overall responsibility: PG

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