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Perioperative Outcomes of Infrainguinal Bypass Surgery in Patients with and without Prior Revascularization

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Abstract

Objective—Although an increasing number of patients with peripheral arterial disease undergo multiple revascularization procedures, the effect of prior interventions on outcomes remains unclear. The purpose of this study was to evaluate perioperative outcomes of bypass surgery in patients with and those without prior ipsilateral treatment.

Methods—Patients undergoing non-emergent infrainguinal bypass between 2011 and 2014 were identified in the NSQIP-Targeted Vascular module. After stratification by symptom status (chronic limb-threatening ischemia [CLTI] and claudication), patients undergoing primary bypass were compared to those undergoing secondary bypass. Within the secondary bypass group, further analysis compared prior bypass to prior endovascular intervention. Multivariable logistic regression analysis was used to establish the independent association between prior ipsilateral procedure and perioperative outcomes.

Results—A total of 7302 patients were identified, of which 4540 (62%) underwent primary bypass (68% for CLTI), 1536 (21%) underwent secondary bypass after a previous bypass (75% for CLTI), and 1226 (17%) underwent secondary bypass after a previous endovascular intervention (72% for CLTI). Prior revascularization on the same ipsilateral arteries was associated with increased 30-day major adverse limb event in patients with CLTI (9.8% vs. 7.4%; OR: 1.4, 95% CI: 1.1–1.7) and claudication (5.2% vs. 2.5%; 2.1, 1.3–3.5). Similarly, secondary bypass was an independent risk factor for 30-day major reintervention (CLTI: 1.4, 1.1–1.8; claudication: 2.1, 1.3–

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3.5), bleeding (CLTI: 1.4, 1.2–1.6; claudication: 1.7, 1.3–2.4), and unplanned reoperation (CLTI: 1.2, 1.0–1.4; claudication: 1.6, 1.1–2.1), whereas major amputation was increased in CLTI patients only (1.3, 1.0–1.8). Perioperative mortality was not significantly different in patients undergoing secondary compared to primary bypass (CLTI: 1.7% vs. 2.2%, P = .22; claudication: 0.4% vs. 0.6%, P = .76). Among secondary bypass patients with CLTI, those with prior bypass had higher 30-day reintervention rates (7.8% vs. 4.9%; OR: 1.5, 95% CI: 1.0–2.2), but fewer wound infections (7.3% vs. 12%; 0.6, 0.4–0.8) compared to patients with prior endovascular intervention.

Conclusions—Prior revascularization, in both patients with CLTI and claudication, is associated with worse perioperative outcomes compared to primary bypass. Furthermore, prior endovascular intervention is associated with increased wound infections, whereas those with prior bypass had higher reintervention rates. The increasing prevalence of patients undergoing multiple interventions stresses the importance of patient selection for initial treatment and should be factored into subsequent revascularization options in an effort to decrease adverse events.

Introduction

Peripheral arterial disease (PAD) affects 12–20% of people in the United States older than 60 years and is associated with substantial morbidity and mortality.[1] As the proportion of elderly patients continues to increase, as well as the utilization of endovascular procedures, rates of reintervention for PAD have been steadily rising.[2,3] Among patients undergoing lower extremity bypass surgery in the current era, it is estimated that 22–25% underwent prior ipsilateral endovascular interventions and 13–19% had prior ipsilateral open bypass.[4–6] Despite increased rates of reintervention, the impact of subsequent revascularization procedures has only recently been studied.

Long-term outcomes comparing primary and secondary bypass have been reported with conflicting results. Several studies demonstrated worse outcomes in those patients undergoing secondary bypass, yet others found equivocal long-term outcomes in patients with prior endovascular interventions.[6–12] Interestingly, despite data on the long-term impact of secondary bypass, differences in perioperative outcomes remain unclear. Previous studies suggest that prior unsuccessful treatment is not associated with worse perioperative performance of bypass surgery.[9–12] However, a study of 3504 patients undergoing bypass surgery, of which 33% were secondary bypass, found prior revascularization to be a risk factor for in-hospital return to the operating room and graft occlusion at discharge.[6] The body of literature on this topic is still limited, most recent studies included only single-institution data with small sample sizes, and were unable to adjust for prior procedure type.

Therefore, the purpose of this study was to assess perioperative outcomes in patients undergoing bypass surgery following prior ipsilateral bypass surgery or endovascular intervention using a large national representative clinical registry.

Methods

Data source

Data were obtained from the prospectively collected Targeted Vascular module of the American College of Surgeons National Surgical Quality Improvement Program (NSQIP).

NSQIP is a national, multi-institutional, quality improvement initiative of academic and community-based centers that provides 30-day outcomes in an effort to improve overall patient care. Standardized definitions capture demographics, comorbidities, intraoperative variables, and 30-day postoperative outcomes in a randomly selected subset of patients at each participating institution. The Targeted Vascular module includes additional disease and procedure-specific characteristics, as well as procedure-related outcomes chosen by vascular surgeons. Trained clinical reviewers identify potential procedures by reviewing operative case logs then collect data and categorize procedures using Current Procedural Terminology (CPT) codes at both the targeted and non-targeted NSQIP. To ensure data quality, NSQIP data collection is validated by rigorous audits as well as comprehensive studies.[13–15] Further details on NSQIP and the Vascular Targeted module are available on https://www.facs.org/quality-programs/acs-nsqip. This study was approved by the Beth Israel Deaconess Medical Center Institutional Review Board, and informed consent was waived due to the de-identified nature of this registry.

Patients

All patients undergoing a non-emergent infrainguinal bypass between 2011 and 2014 were included. Patients were stratified by symptom status: intermittent claudication vs. chronic limb-threating ischemia (CLTI). Those without documented symptom status and asymptomatic patients were excluded (n=313; 4.1%). Secondary bypass was defined as a new bypass with a prior endovascular intervention or bypass treating the same ipsilateral arteries as the current procedure. Additional procedural detail from previous interventions was not captured by NSQIP, which subsequently did not allow us to determine the timing or indication of the prior procedure. Patients without any history of ipsilateral revascularization procedures were designated as undergoing primary bypass. Baseline and intraoperative characteristics, as well as 30-day postoperative outcomes were compared between patients undergoing primary and secondary bypass. In a subgroup analysis among patients undergoing secondary bypass, results were stratified according to the type of prior ipsilateral procedures (endovascular vs. bypass).

Clinical and outcome variables

Baseline characteristics included demographics, comorbidities, and pre-procedural medication. Age was evaluated as a continuous variable; however, all patients 90 years of age or older are recorded as 90+ by NSQIP to prevent individual patient identification. Antiplatelet medication preoperatively was considered when one of the following agents was documented: Aspirin, Clopidogrel, Eptifibatide, or Aggrenox. Intraoperative details analyzed included: procedure type, type of graft/conduit, and procedure time. Type of conduit was grouped by NSQIP into single segment greater saphenous vein (without documentation of an ipsilateral or contralateral harvested vein), or prosthetic or spliced/composite vein conduit (basilic, cephalic, or lesser saphenous vein). Concurrent suprainguinal procedures were identified with corresponding CPT codes (Supplemental table I). Since concurrent procedures did not affect outcomes when forced into the multivariable models or removed from the overall cohort, we did not exclude these patients from the analysis. Postoperative outcomes including 30-day mortality and adverse events were evaluated. Major adverse limb event (MALE), a composite variable endorsed by the

Society for Vascular Surgery's Objective Performance Goals,[16] was defined as major amputation (below-knee or more proximal) or major reintervention (new or revision lower extremity bypass operation, jump/interposition graft revision, bypass graft thrombectomy/thrombolysis) of the index limb. Major adverse cardiovascular event (MACE) included death from any cause, myocardial infarction, or stroke. Wound infection included superficial, deep, or organ space surgical site infections. Postoperative renal insufficiency was defined as a serum creatinine concentration > 2 mg/dL and/or the need for dialysis. A respiratory complication was considered when one of the following was documented: pneumonia, unplanned reintubation, or ventilator requirement > 48 hours. Bleeding was defined as any transfusion or secondary procedure with the indication of bleeding. Variable definitions were provided by NSQIP prior to data collection and thus were not modifiable (user guides for targeted and non-targeted variables available at: https://www.facs.org/quality-programs/acs-nsqip/program-specifics/participant-use). Unplanned readmissions and reoperations to any hospital within 30 days of the index bypass were also collected. Since more granular NSQIP data on readmission and reoperation became available from 2012, analysis of indications for related unplanned readmission and reoperation were restricted to 2012–2014. Indications for related unplanned readmissions were captured by a NSQIP variable listing specific complications or *International Classification of Disease* (ICD-9) codes (Supplemental table II). CPT codes were used to group indications for related unplanned reoperations (Supplemental table III). Limb-related reoperations or readmissions were defined as all reinterventions or rehospitalizations respectively related to the ipsilateral index limb or procedure.

Statistical analysis

Differences between primary and secondary bypass, as well as between prior endovascular intervention and prior bypass, were evaluated using Pearson's χ^2 and Fisher's exact test for categorical variables, and Student's t-test and Mann Whitney U test for continuous variables, where appropriate. All analyses were stratified by symptom status. Multivariable logistic regression was used to establish the independent association between prior ipsilateral procedures and perioperative outcomes. Purposeful selection of covariates was performed to populate the multivariable models, with a cutoff point of $P \leq .1$ for inclusion of covariates on univariate screen.[17] Separate models were constructed for each perioperative outcome. All tests were two-sided and a value of $P < .05$ was considered significant. Statistical analysis was performed using SPSS Statistics 23 (IBM Inc., Chicago, IL).

Results

A total of 7302 patients were included, with 4540 (62%) undergoing primary bypass (68% of these were performed for CLTI) and 2762 (38%) undergoing secondary bypass (74% for CLTI). Among patients undergoing secondary bypass, 1536 (56%) had prior ipsilateral bypass (75% for CLTI) and 1226 (44%) had prior ipsilateral endovascular intervention (72% for CLTI).

Baseline characteristics

Baseline characteristics are detailed in Table I. Compared to CLTI patients undergoing primary bypass, those undergoing secondary bypass were younger (67.6 vs. 68.8 years, P < .001), more likely to be white (68% vs. 61%, P < .001) and less frequently had tissue loss (51% vs. 63%, P < .001). In terms of comorbidities, CLTI patients with prior revascularization had less renal insufficiency (23% vs. 28%, P < .001) and were less often on dialysis preoperatively (6% vs. 9.1%, P < .001). Finally, secondary bypass patients were more likely to be treated with an antiplatelet agent (87% vs. 76%, P < .001) or statin preoperatively (74% vs. 67%, P < .001).

Among patients with claudication, demographics and comorbidities were similar. However, patients with prior revascularization were more likely to be treated with an antiplatelet agent (88% vs. 81%, P < .001) or statin preoperatively (77% vs. 67%, P < .001).

Operative details

Operative details are listed in Table II. Secondary bypass was associated with a significantly longer procedure time compared to primary bypass in patients with CLTI (240 min vs. 223 min, P < .001). Among patients with CLTI undergoing secondary bypass, saphenous vein conduits were less frequently used (54% vs. 64%, P < .001) and prosthetic or spliced/composite vein conduits were more commonly used (46% vs. 36%, P < .001). In addition, femoral-tibial/pedal bypass procedures were performed more often in CLTI patients with prior revascularization (39% vs. 32%, P < .001), whereas femoropopliteal bypass (51% vs. 56%, P < .001) and popliteal-tibial/pedal bypass (9.9% vs. 12%, P < .01) were less common in those undergoing secondary bypass. Concurrent suprainguinal procedures were evenly distributed between primary and secondary bypass.

Similar to patients with CLTI, those with claudication undergoing secondary bypass had longer procedure times (207 min vs. 187 min, P < .001), were less frequently revascularized with a saphenous vein conduit (53% vs. 59%, P = .02) and more often with prosthetic or spliced/composite vein conduits (47% vs. 41%, P = .02). Finally, those undergoing a second revascularization were more likely to have a femoral-tibial/pedal bypass (22% vs. 14%, P < .001), and less likely to undergo a femoropopliteal bypass (72% vs. 81%, P < .001).

Postoperative outcomes

Among CLTI patients undergoing secondary compared to primary bypass, similar rates of 30-day mortality were observed (1.7% vs. 2.2%, P = .22; Table III). Secondary bypass was associated with various adverse events, including MALE (9.8% vs. 7.4%, P < .01), major reintervention (6.5% vs. 4.7%, P < .01), bleeding leading to transfusion or secondary procedure (22% vs. 18%, P < .001), wound infection (9.5% vs. 7.8%, P = .04), and untreated loss of patency (3.6% vs. 2.1%, P < .01). In addition, CLTI patients with prior revascularization were more likely to be discharged to home (72% vs. 67%, P < .001).

Among claudication patients, 30-day mortality did not differ between secondary and primary bypass (0.4% vs. 0.6%, P = .76). Patients with prior revascularization had significantly more MALE (5.2% vs. 2.5%, P < .01), major reintervention (4.4% vs. 2.2%, P < .01), bleeding

leading to transfusion or secondary procedure (12% vs. 6.7%, P < .001), unplanned reoperation (9.8% vs. 6.9%, P = .02), and longer hospital stay (4 days vs. 3 days, P < .01).

In a subgroup analysis of secondary bypass patients, we compared outcomes of those with prior bypass to those with prior endovascular intervention. Among CLTI patients with prior bypass, there was a trend towards lower mortality, although significance was not achieved (1.2% vs. 2.3%, P = .07). Similarly, no difference in mortality was observed in patients with claudication between prior bypass and endovascular intervention (0.8% vs. 0%, P = .25). Prior endovascular intervention was associated with more wound infections for CLTI (12% vs. 7.8%, P < .001) and claudication patients (9.1% vs. 5.4%, P = .049). In addition, revascularization with saphenous vein conduits was more common in patients with prior endovascular intervention compared to those with prior bypass in CLTI (64% vs. 45%, P < .001) and claudication (58% vs. 49%, P = .01). Patients with CLTI and a prior bypass had higher rates of MALE (11% vs. 8%, P = .02), major reintervention (7.8% vs. 4.9%, P < .01), and were more likely to be discharged to home (75% vs. 68%, P < .01) than those with prior endovascular intervention. Untreated loss of patency occurred more frequently in patients undergoing secondary bypass after prior bypass with CLTI (4.4% vs. 2.6%, P = .03) and claudication (2.6% vs. 0.6%, P = .04) compared to those with prior endovascular intervention.

Reoperations and readmissions

Unplanned reoperations were more common in patients undergoing secondary compared to primary bypass for both CLTI (15% vs. 13%, P = .01) and claudication (9% vs. 5.6%, P < .01; Table IV). Unplanned reoperations were primarily limb-related, with more open and endovascular revascularizations in CLTI patients undergoing secondary bypass (7.1% vs. 4.7%, P = .001), whereas major and minor amputations were higher in those undergoing bypass with prior endovascular intervention (4.9% vs. 3.0%, P = .04). There was no significant difference in reoperation rates between claudication patients with a prior bypass and a prior endovascular intervention.

Comparable rates of unplanned readmissions were observed between primary and secondary bypass for CLTI (13% vs. 14%, P = .25) and claudication (7.6% vs. 8.7%, P = .38; Table V). Additionally, the most common reason for readmission was infection in patients with CLTI (55%) and claudication (54%).

Multivariable analysis

Primary vs. secondary bypass—In adjusted analysis (Table VI), secondary bypass was found to be an independent predictor of MALE for both CLTI (OR: 1.4, 95% CI: 1.1–1.7) and claudication patients (OR: 2.1, 95% CI: 1.3–3.5). Prior revascularization in CLTI patients was also associated with major amputation (OR: 1.3, 95% CI: 1.01–1.8), major reintervention (OR: 1.4, 95% CI: 1.1–1.8), bleeding leading to transfusion or secondary procedure (OR: 1.4, 95% CI: 1.2–1.6), untreated loss of patency (OR: 1.9, 95% CI: 1.3–2.7), and unplanned reoperation (OR: 1.2, 95% CI: 1.02–1.4). In claudication patients, prior revascularization proved to be an important risk factor for major reintervention (OR: 2.1,

95% CI: 1.3–3.5), bleeding leading to transfusion or secondary procedure (OR: 1.7, 95% CI: 1.3–2.4), and unplanned reoperation (OR: 1.6, 95% CI: 1.1–2.1).

Prior bypass surgery vs. prior endovascular intervention—To assess associations with adverse events and prior procedure type, an additional subgroup analysis in the secondary bypass cohort was performed. Among patients undergoing secondary bypass for CLTI, prior bypass was associated with MALE (OR: 1.4, 95% CI: 1.03–1.9) and major reintervention (OR: 1.5, 95% CI: 1.03–2.2) compared to prior endovascular intervention. After adjusting for several covariates (e.g. graft type, diabetes, tissue loss), CLTI patients with a prior bypass had a decreased risk of wound infection (OR: 0.6, 95% CI: 0.4–0.8) compared to those with a prior endovascular intervention. A similar trend was seen in patients with claudication but this did not reach significance (OR: 0.6, 95% CI: 0.3–1.05). To further evaluate the effect of prior endovascular treatment on wound infection, we compared primary bypass to secondary bypass with prior endovascular intervention only, and still found a higher risk of wound infection following prior endovascular treatment (12% vs. 7.8%; OR: 1.5, 95% CI: 1.2–2.0; Supplemental table IV).

Discussion

This study demonstrates increased risk of adverse perioperative outcomes in patients undergoing a secondary compared to primary bypass. Patients undergoing secondary bypass for CLTI or claudication were at increased risk of 30-day MALE, major reintervention, and unplanned reoperation. Subgroup analysis found that secondary bypass with prior endovascular intervention was a prominent predictor of wound infections, whereas 30-day major reintervention was more commonly performed following bypass after prior bypass.

In 2005, the randomized BASIL trial compared endovascular- or bypass-first strategy in limb ischemia patients and found similar morbidity and mortality rates up to two years after surgery.[18] Although the BASIL trial has been criticized for multiple shortcomings in study design, further analysis demonstrated that bypass surgery was associated with decreased mortality from 2 years onward compared to endovascular intervention alone (HR: 0.61, 95% CI: 0.50–0.75).[19] Therefore, current ACC/AHA guidelines recommend that bypass surgery be preferentially performed over endovascular intervention in CLTI patients with a life expectancy of greater than two years.[20] Nonetheless, a bypass-first approach is not widely accepted as the optimal treatment option and results of the BEST-CLI trial are still pending.[21] Additionally, many institutions have adopted an endovascular-first approach in PAD patients because it is less invasive and therefore associated with less perioperative risk, although perioperative mortality is similar. Since management of PAD does not end with the first intervention in many cases, several studies were undertaken to assess whether failed initial treatment affects the outcome of subsequent revascularization.[6–12] In the BASIL trial, further analysis showed that patients undergoing a secondary bypass with prior endovascular intervention had a notable one-year failure rate (defined as death, major amputation, recurrent symptoms, or reintervention) of 54% compared to 70% in the bypass group with prior bypass.[22]

In 2011, Nolan et al. studied the Vascular Study Group of New England (VSGNE) database and demonstrated that, for 1880 bypass surgeries performed for CLTI, both prior endovascular intervention and prior bypass surgery were independently associated with one-year amputation and graft occlusion.[9] However, there were no demonstrable differences in 30-day outcomes.

Subsequently, Jones et al. studied an expanded cohort of 3504 patients undergoing bypass surgery from the VSGNE and, using inverse probability weighted analyses, demonstrated inferior one-year outcomes associated with secondary compared to primary bypass in CLTI patients, including MALE-free survival (55% vs. 63%, $P < .01$) and reintervention or amputation-free survival (53% vs. 60%, $P < .01$).[6] Interestingly, adverse events following secondary bypass were not affected by the type of primary treatment, either endovascular or bypass. In the perioperative period, patients undergoing secondary bypass were also more likely to return to the operating room for graft thrombosis during their index hospitalization and more frequently had graft occlusion at discharge. Despite these findings, no differences were found for secondary bypass patients with regards to other major in-hospital adverse events, including mortality, myocardial infarction, or ipsilateral amputation, regardless of indication. In accordance with these findings, our data also indicated that patients undergoing secondary bypass more often had 30-day adverse limb events, with both ipsilateral major amputation and reintervention as driving factors in CLTI patients, whereas major reintervention alone was the primary driver in those with claudication.

Several other studies reported short-term outcomes. In comparison to primary bypass treatment, Uhl et al. found no association between prior endovascular intervention and 30-day mortality, graft failure, or major amputation.[11] In addition, Santo el al. determined that prior endovascular intervention was not associated with 30-day mortality or myocardial infarction and was not a predictor for overall wound complication compared to primary bypass.[12] Although we showed similar short-term mortality rates, our data indicated that prior endovascular intervention was associated with a 1.5-fold increased risk of wound infection compared to primary treatment as well as secondary bypass following prior bypass surgery after adjusting for multiple confounders such as graft type, diabetes, and tissue loss. The published rate of surgical site infections after bypass has varied, with a reported incidence of 5–23%; however, no recent studies identified prior revascularization as a risk factor.[18,23,24] This could be related to the more frequent use of saphenous veins as conduits compared to prosthetic or arm veins and the increased likelihood of wound infections associated with ipsilateral autogenous vein harvesting. However, we still observed an increased risk of wound infections comparing prior endovascular intervention to primary bypass, while the proportion of revascularization with saphenous vein conduits between these groups was similar. Unmeasured confounding variables such as ipsilateral vs. contralateral vein harvest, length and number of incisions, and basilic/cephalic vs. saphenous vein conduits may impact this study and cannot be accounted for. In addition, the type and number of previous endovascular interventions were unfortunately not captured by NSQIP, and could therefore not be evaluated to better answer why prior endovascular intervention patients were at increased risk for wound infections.

The increased risks of adverse events following secondary revascularization may be explained by a more aggressive disease process. Patients who have already suffered failure of a primary procedure are likely to represent a selected group that is at greater general risk for treatment failure and other adverse outcomes. In addition, due to unfavorable anatomy and hampered inflow or runoff vessels caused by previous procedures, these patients may be predisposed to an increased risk of complication. We attempted to account for this with multivariable modeling; however, unmeasured indicators of more aggressive disease phenotype cannot be controlled for. This study does not attempt to shed light on the optimal primary treatment strategy, nor does it answer which secondary treatment strategy is superior. However, there are important clinical implications to this study. First, these short-term outcomes may provide clinicians valuable guidance in the selection and counseling of PAD patients. Furthermore, physicians should factor in the significant association of failed prior ipsilateral treatment with future interventions and recognize inferior outcomes of repeated procedures.

This study has several limitations. First, NSQIP has potential errors in coding and misreporting of data. Second, the lesion severity characteristics and extent of PAD, as well as explicit detail of the timing and procedural information from patients' previous interventions, are not available in this clinical registry. Prior procedures were taken directly from the patients' medical records by clinical reviewers; however, with these strict variable definitions we were unable to identify patients with both a prior endovascular and surgical revascularization. We believe that these patients were most likely coded as having had a prior bypass rather than a prior endovascular intervention, which should be factored in when considering these study results. This would most likely bias our outcomes towards the null and thus we feel that the observed differences are likely to be real and perhaps underestimated. The importance of disease severity and type of prior procedure, particularly single or multilevel treatment and placement of stents, has been confirmed in previous studies,[25,26] but NSQIP-variables lack this level of granularity. The clinical registry also lacks detail on incision type, graft configuration (in situ vs. transposed/reversed anatomically tunneled graft), and severity of tissue loss (ulcers vs. gangrene), all of which could have added further detail to our comparison. However, the strength of NSQIP is the large sample size and its national representation. Although we could determine that primary treatment failure is associated with worsened outcomes of secondary bypass, we cannot establish causation given the retrospective nature of the study design. Finally, NSQIP captures follow-up data only up to 30 days. Therefore, we were unable to determine long-term outcomes such as graft patency and amputation-free survival in those patients with prior revascularization.

Conclusions

This study demonstrates that bypass surgery following prior ipsilateral revascularization is associated with increased 30-day major adverse limb events in both CLTI and claudication patients. Other adverse events included major reintervention, bleeding leading to transfusion or secondary procedure, and unplanned reoperation. Furthermore, this study shows that the type of prior procedure is associated with outcomes of secondary bypass. In particular, prior endovascular intervention proved an important predictor for wound infections, and prior

bypass was associated with MALE and major reintervention. The present findings should be considered in patient selection and during operative planning, particularly since the proportion of patients undergoing multiple revascularization procedures is rising.

Supplementary Material

Refer to Web version on PubMed Central for supplementary material.

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Table I

Baseline characteristics and comorbidities in patients undergoing primary bypass versus bypass with prior revascularization

	CLTI									
	Primary Bypass ***(N=3102)***		**Secondary Bypass** ***(N=2031)***		**P-value**	**Prior Bypass** ***(N=1145)***		**Prior Endovascular** ***(N=886)***		**P-value**
	N	***%***	***N***	***%***		***N***	***%***	***N***	***%***	
Male gender	1954	(63)	1230	(61)	.08	715	(62)	515	(58)	.048
Age – (y ± SD)	68.8 (12)		67.6 (11)		<.001	67.4 (11)		67.9 (12)		.29
Current smoker	1208	(39)	836	(41)	.11	471	(41)	365	(41)	.98
BMI > 30	894	(30)	584	(29)	.92	316	(28)	268	(31)	.27
Race					<.001					<.01
White	1890	(61)	1372	(68)		806	(70)	566	(64)	
Non-White	878	(28)	462	(23)		232	(20)	230	(26)	
Unknown/not reported	334	(11)	197	(9.7)		107	(9.3)	90	(10)	
Symptom status					<.001					.001
Rest pain	1158	(37)	987	(49)		594	(52)	393	(44)	
Tissue loss	1944	(63)	1044	(51)		551	(48)	493	(56)	
Hypertension	2584	(83)	1731	(85)	.07	957	(84)	774	(87)	.02
Diabetes	1592	(51)	1005	(50)	.20	515	(45)	490	(55)	<.001
CHF	108	(3.5)	68	(3.3)	.80	36	(3.1)	32	(3.6)	.56
Renal Insufficiency	846	(28)	453	(23)	<.001	233	(21)	220	(25)	.02
Dialysis	281	(9.1)	122	(6)	<.001	56	(4.9)	66	(7.4)	.02
COPD	392	(13)	269	(13)	.53	168	(15)	101	(11)	.03
Pre-procedural medication										
Antiplatelet	2354	(76)	1755	(87)	<.001	983	(86)	772	(87)	.45
Statin	2061	(67)	1497	(74)	<.001	848	(74)	649	(73)	.69
Beta blocker	1931	(63)	1322	(65)	.08	744	(65)	578	(65)	.97
	Claudication									
	Primary Bypass ***(N=1438)***		**Secondary Bypass** ***(N=731)***		**P-value**	**Prior Bypass** ***(N=391)***		**Prior Endovascular** ***(N=340)***		**P-value**

	CLTI									
	Primary Bypass *(N=3102)*		**Secondary Bypass *(N=2031)***		**P-value**	**Prior Bypass *(N=1145)***		**Prior Endovascular *(N=886)***		**P-value**
	N	***%***	***N***	***%***		***N***	***%***	***N***	***%***	
	N	*%*	*N*	*%*		*N*	*%*	*N*	*%*	
Male gender	990	(69)	521	(71)	.25	278	(71)	243	(72)	.91
Age – (y ± SD)	65.9 (10)		66.0 (10)		.82	66.1 (10)		65.9 (10)		.72
Current smoker	662	(46)	314	(43)	.17	165	(42)	149	(44)	.66
BMI > 30	476	(33)	237	(33)	.75	121	(31)	116	(34)	.37
Race					.85					.04
White	1103	(77)	554	(76)		307	(79)	247	(73)	
Non-White	213	(15)	115	(16)		49	(13)	66	(19)	
Unknown/not reported	122	(8.5)	62	(8.5)		45	(9)	27	(7.9)	
Hypertension	1141	(79)	590	(81)	.45	320	(82)	270	(79)	.41
Diabetes	460	(32)	260	(36)	.09	130	(33)	130	(38)	.16
CHF	17	(1.2)	8	(1.1)	.86	7	(1.8)	1	(0.3)	.07
Renal Insufficiency	208	(15)	108	(15)	.91	63	(16)	45	(14)	.29
Dialysis	20	(1.4)	7	(1)	.39	5	(1.3)	2	(0.6)	.46
COPD	207	(14)	97	(13)	.48	51	(13)	46	(14)	.85
Pre-procedural medication										
Antiplatelet	1150	(81)	639	(88)	<.001	338	(87)	301	(89)	.28
Statin	962	(67)	558	(77)	<.001	298	(77)	260	(77)	.97
Beta blocker	755	(53)	414	(57)	.08	223	(58)	191	(57)	.79

y: years; SD: standard deviation; CHF: congestive heart failure; COPD: chronic obstructive pulmonary disease

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Table II

Procedure details in patients undergoing primary bypass versus bypass with prior revascularization

	CLTI									
	Primary Bypass ***(N=3102)***		**Secondary Bypass** ***(N=2031)***		**P-value**	**Prior Bypass** ***(N=1145)***		**Prior Endovascular** ***(N=886)***		**P-value**
	N	***%***	***N***	***%***		***N***	***%***	***N***	***%***	
Type procedure					<.001					.001
Femoropopliteal bypass	1732	(56)	1029	(51)		559	(49)	470	(53)	
Femoral-tibial/pedal bypass	987	(32)	800	(39)		489	(43)	311	(35)	
Popliteal-tibial/pedal bypass	383	(12)	202	(9.9)		97	(8.5)	105	(12)	
Graft type					<.001					<.001
Saphenous vein	1975	(64)	1088	(54)		518	(45)	570	(64)	
Prosthetic/spliced/composite vein	1127	(36)	943	(46)		627	(55)	316	(36)	
Concurrent suprainguinal procedure	121	(3.9)	77	(3.8)	.84	41	(3.6)	36	(4.1)	.57
Procedure time – (min ± IQR)	223 (171–296)		240 (179–325)		<.001	234 (178–331)		246 (183–318)		.38
Femoropopliteal bypass	204 (153–173)		218 (166–301)		<.001	213 (164–296)		229 (170–305)		.12
Femoral-tibial/pedal bypass	251 (193–322)		266 (199–345)		<.01	262 (193–352)		269 (204–338)		.55
Popliteal-tibial/pedal bypass	244 (197–307)		268 (202–337)		.02	270 (203–343)		264 (199–325)		.42
	Claudication									
	Primary Bypass ***(N=1438)***		**Secondary Bypass** ***(N=731)***		**P-value**	**Prior Bypass** ***(N=391)***		**Prior Endovascular** ***(N=340)***		**P-value**
	N	*%*	*N*	*%*		*N*	*%*	*N*	*%*	
Type procedure					<.001					.001
Femoropopliteal bypass	1168	(81)	526	(72)		258	(66)	268	(79)	
Femoral-tibial/pedal bypass	205	(14)	164	(22)		106	(27)	58	(17)	
Popliteal-tibial/pedal bypass	65	(4.5)	41	(5.6)		27	(6.9)	14	(4.1)	
Graft type					.02					.01
Saphenous vein	841	(59)	389	(53)		191	(49)	198	(58)	
Prosthetic/spliced/composite vein	597	(41)	342	(47)		200	(51)	142	(42)	
Concurrent suprainguinal procedure	47	(3.3)	27	(3.7)	.61	15	(3.8)	12	(3.5)	.83

	CLTI								
	Primary Bypass *(N=3102)*		**Secondary Bypass *(N=2031)***		**P-value**	**Prior Bypass *(N=1145)***		**Prior Endovascular *(N=886)***		**P-value**
	N	***%***	***N***	***%***		***N***	***%***	***N***	***%***	
Procedure time – (min ± IQR)	187 (135–253)		207 (158–282)		<.001	210 (163–281)		202 (153–283)		.35
Femoropopliteal bypass	175 (129–241)		198 (149–273)		<.001	198 (148–273)		196 (150–274)		.88
Femoral-tibial/pedal bypass	238 (186–302)		228 (187–314)		.83	232 (191–307)		222 (178–334)		.53
Popliteal-tibial/pedal bypass	199 (165–279)		240 (164–328)		.16	230 (141–314)		274 (197–368)		.38

min: minutes; IQR: interquartile range

Table III

Perioperative outcomes in patients undergoing primary bypass versus bypass with prior revascularization

	CLTI									
	Primary Bypass ***(N=3102)***		**Secondary Bypass** ***(N=2031)***		**P-value**	**Prior Bypass** ***(N=1145)***		**Prior Endovascular** ***(N=886)***		**P-value**
	N	***%***	***N***	***%***		***N***	***%***	***N***	***%***	
Mortality	67	(2.2)	34	(1.7)	.22	14	(1.2)	20	(2.3)	.07
MALE	231	(7.4)	200	(9.8)	<.01	129	(11)	71	(8)	.02
Major amputation	116	(3.7)	88	(4.3)	.29	52	(4.5)	36	(4.1)	.60
Major reintervention	147	(4.7)	132	(6.5)	<.01	89	(7.8)	43	(4.9)	<.01
MACE	155	(5)	103	(5.1)	.91	49	(4.3)	54	(6.1)	.06
Wound infection	242	(7.8)	192	(9.5)	.04	84	(7.3)	108	(12)	<.001
Wound dehiscence	63	(2)	36	(1.8)	.51	22	(1.9)	14	(1.6)	.56
Sepsis	48	(1.5)	33	(1.6)	.83	15	(1.3)	18	(2)	.20
Bleeding (leading to transfusion or secondary procedure)	563	(18)	453	(22)	<.001	249	(22)	204	(23)	.49
Creatinine >2 mg/dL	42	(1.4)	25	(1.2)	.70	15	(1.3)	10	(1.1)	.71
Requiring dialysis	21	(0.7)	10	(0.5)	.40	7	(0.6)	3	(0.3)	.53
Respiratory complications	110	(3.5)	56	(2.8)	.12	31	(2.7)	25	(2.8)	.88
Urinary tract infection	44	(1.4)	33	(1.6)	.55	13	(1.1)	20	(2.3)	.047
Unplanned reoperation	537	(17)	389	(19)	.09	209	(18)	180	(20)	.24
Untreated loss of patency	65	(2.1)	73	(3.6)	.001	50	(4.4)	23	(2.6)	.03
Length of hospital stay – (d ± IQR)	7 (4–12)		7 (4–12)		.91	7 (4–11)		7 (4–12)		.56
Discharge to home	1923	(67)	1374	(72)	<.001	814	(75)	560	(68)	.001
Unplanned readmission	559	(18)	367	(18)	.96	199	(17)	168	(19)	.36
	Claudication									
	Primary Bypass ***(N=1438)***		**Secondary Bypass** ***(N=731)***		**P-value**	**Prior Bypass** ***(N=391)***		**Prior Endovascular** ***(N=340)***		**P-value**
	N	***%***	***N***	***%***		***N***	***%***	***N***	***%***	
Mortality	9	(0.6)	3	(0.4)	.76	3	(0.8)	0	(0)	.25

	CLTI									
	Primary Bypass *(N=3102)*		**Secondary Bypass *(N=2031)***		**P-value**	**Prior Bypass *(N=1145)***		**Prior Endovascular *(N=886)***		**P-value**
	N	***%***	***N***	***%***		***N***	***%***	***N***	***%***	
MALE	36	(2.5)	38	(5.2)	.001	25	(6.4)	13	(3.8)	.12
Major amputation	7	(0.5)	7	(1)	.20	3	(0.8)	4	(1.2)	.71
Major reintervention	32	(2.2)	32	(4.4)	<.01	22	(5.6)	10	(2.9)	.08
MACE	27	(1.9)	17	(2.3)	.48	9	(2.3)	8	(2.4)	.96
Wound infection	101	(7)	52	(7.1)	.94	21	(5.4)	31	(9.1)	.049
Wound dehiscence	16	(1.1)	9	(1.2)	.81	8	(2)	1	(0.3)	.04
Sepsis	14	(1)	5	(0.7)	.49	4	(1)	1	(0.3)	.38
Bleeding (leading to transfusion or secondary procedure)	97	(6.7)	84	(12)	<.001	49	(13)	35	(10)	.34
Creatinine >2 mg/dL	9	(0.6)	4	(0.5)	>.99	3	(0.8)	1	(0.3)	.63
Requiring dialysis	3	(0.2)	3	(0.4)	.41	2	(0.5)	1	(0.3)	>.99
Respiratory complications	15	(1)	10	(1.4)	.50	6	(1.5)	4	(1.2)	.76
Urinary tract infection	8	(0.6)	5	(0.7)	.72	1	(0.3)	4	(1.2)	.19
Unplanned reoperation	99	(6.9)	72	(9.8)	.02	43	(11)	29	(8.5)	.26
Untreated loss of patency	11	(0.8)	12	(1.6)	.06	10	(2.6)	2	(0.6)	.04
Length of hospital stay – (d ± IQR)	3 (2–5)		4 (3–6)		<.01	4 (2–6)		4 (3–5)		.91
Discharge to home	1298	(91)	658	(90)	.63	353	(90)	305	(90)	.98
Unplanned readmission	141	(9.8)	76	(10)	.66	45	(12)	31	(9.1)	.29

MALE: major adverse limb event; MACE: major adverse cardiovascular event; d: days; IQR interquartile range

Table IV

Unplanned reoperations and indications in patients undergoing primary bypass versus bypass with prior revascularization (analysis restricted to 2012–2014)

	CLTI									
	Primary Bypass *(N=2854)*		**Secondary Bypass** *(N=1801)*		**P-value**	**Prior Bypass** *(N=1028)*		**Prior Endovascular** *(N=773)*		**P-value**
	N	*%*	*N*	*%*		*N*	*%*	*N*	*%*	
Related to principle procedure					.04					.39
1 Unplanned reoperation	292	(10)	218	(12)		116	(11)	102	(13)	
>1 Unplanned reoperation	69	(2.4)	57	(3.2)		35	(3.4)	22	(2.8)	
Indications of related reoperations										
Limb-related reoperations	343	(12)	261	(15)	.01	143	(14)	118	(15)	.42
Incision & drainage/debridement	124	(4.3)	82	(4.6)	.74	40	(3.9)	42	(5.4)	.12
Major/minor amputation	103	(3.6)	69	(3.8)	.70	31	(3)	38	(4.9)	.04
Open or endovascular revascularization	125	(4.7)	128	(7.1)	.001	82	(8)	46	(6)	.10
Other vascular	11	(0.4)	8	(0.4)	.76	5	(0.5)	3	(0.4)	>.99
Other reoperations	14	(0.5)	13	(0.7)	.31	7	(0.7)	6	(0.8)	.81
	Claudication									
	Primary Bypass *(N=1302)*		**Secondary Bypass** *(N=652)*		**P-value**	**Prior Bypass** *(N=346)*		**Prior Endovascular** *(N=306)*		**P-value**
	N	*%*	*N*	*%*		*N*	*%*	*N*	*%*	
Related to principle procedure					.01					.57
1 Unplanned reoperation	64	(4.9)	48	(7.4)		29	(8.4)	19	(6.2)	
>1 Unplanned reoperation	9	(0.7)	11	(1.7)		6	(1.7)	5	(1.6)	
Indications of related reoperations										
Limb-related reoperations	68	(5.2)	49	(7.5)	.04	28	(8.1)	21	(6.9)	.55
Incision & drainage/debridement	29	(2.2)	22	(3.4)	.13	10	(2.9)	12	(3.9)	.47
Major/minor amputation	7	(0.5)	6	(0.9)	.33	3	(0.9)	3	(1)	>.99

	CLTI									
	Primary Bypass *(N=2854)*		**Secondary Bypass *(N=1801)***		**P-value**	**Prior Bypass *(N=1028)***		**Prior Endovascular *(N=773)***		**P-value**
	N	***%***	***N***	***%***		***N***	***%***	***N***	***%***	
Open or endovascular revascularization	33	(2.5)	23	(3.5)	.22	15	(4.3)	8	(2.6)	.24
Other vascular	1	(0.1)	4	(0.6)	.05	2	(0.6)	2	(0.7)	>.99
Other reoperations	7	(0.5)	8	(1.2)	.10	6	(1.7)	2	(0.7)	.29

Table V

Unplanned readmissions and indications in patients undergoing primary bypass versus bypass with prior revascularization (analysis restricted to 2012–2014)

	CLTI									
	Primary Bypass *(N=2854)*		**Secondary Bypass** *(N=1801)*		**P-value**	**Prior Bypass** *(N=1028)*		**Prior Endovascular** *(N=773)*		**P-value**
	N	***%***	***N***	***%***		***N***	***%***	***N***	***%***	
Related to principle procedure					.44					.22
1 Unplanned readmission	359	(13)	245	(14)		131	(13)	114	(15)	
>1 Unplanned readmission	10	(0.4)	9	(0.5)		7	(0.7)	2	(0.3)	
Indications of related readmissions										
Limb-related readmissions	299	(11)	218	(12)	.09	123	(12)	95	(12)	.83
Infection	212	(7.4)	132	(7.3)	.90	70	(6.8)	62	(8)	.33
Non-healing/open surgical wound	24	(0.8)	17	(0.9)	.71	12	(1.2)	5	(0.6)	.26
Restenosis/occlusion/complication bypass	25	(0.9)	33	(1.8)	<.01	20	(1.9)	13	(1.7)	.68
Thromboembolic events	11	(0.4)	3	(0.2)	.27	2	(0.2)	1	(0.1)	>.99
Hemorrhage/seroma	19	(0.7)	23	(1.3)	.03	12	(1.2)	11	(1.4)	.63
Pain complications	5	(0.2)	7	(0.4)	.16	5	(0.5)	2	(0.3)	.71
Other complications	6	(0.2)	8	(0.4)	.16	6	(0.6)	2	(0.3)	.48
Other readmissions	60	(2.1)	34	(1.9)	.61	16	(1.6)	18	(2.3)	.23
	Claudication									
	Primary Bypass *(N=1302)*		**Secondary Bypass** *(N=652)*		**P-value**	**Prior Bypass** *(N=346)*		**Prior Endovascular** *(N=306)*		**P-value**
	N	*%*	*N*	*%*		*N*	*%*	*N*	*%*	
Related to principle procedure					.60					.31
1 Unplanned readmission	96	(7.4)	56	(8.6)		34	(9.8)	22	(7.2)	
>1 Unplanned readmission	3	(0.2)	1	(0.2)		1	(0.3)	0	(0)	
Indications of related readmissions										

	CLTI									
	Primary Bypass *(N=2854)*		**Secondary Bypass *(N=1801)***		**P-value**	**Prior Bypass *(N=1028)***		**Prior Endovascular *(N=773)***		**P-value**
	N	***%***	***N***	***%***		***N***	***%***	***N***	***%***	
Limb-related readmissions	81	(6.2)	46	(7.1)	.48	28	(8.1)	18	(5.9)	.27
Infection	57	(4.4)	27	(4.1)	.81	14	(4)	13	(4.2)	.90
Non-healing/open surgical wound	9	(0.7)	5	(0.8)	.85	4	(1.2)	1	(0.3)	.38
Restenosis/occlusion/complication bypass	2	(0.2)	4	(0.6)	.10	3	(0.9)	1	(0.3)	.63
Thromboembolic events	1	(0.1)	2	(0.3)	.26	2	(0.6)	0	(0)	.50
Hemorrhage/seroma	4	(0.3)	6	(0.9)	.09	5	(1.4)	1	(0.3)	.22
Pain complications	5	(0.4)	1	(0.2)	.67	0	(0)	1	(0.3)	.47
Other complications	3	(0.2)	1	(0.2)	>.99	0	(0)	1	(0.3)	.47
Other readmissions	17	(1.3)	9	(1.4)	.89	7	(2)	2	(0.7)	.18

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Table VIA

Adjusted associations between prior revascularization and perioperative outcomes in CLTI patients

	CLTI					
	Secondary bypass vs. primary bypass			Prior bypass vs. prior endovascular		
	OR	***95% CI***	***P-value***	***OR***	***95% CI***	***P-value***
Mortality	0.9	0.6–1.4	.62	0.6	0.3–1.2	.13
MALE [a]	1.4	1.1–1.7	<.01	1.4	1.03–1.9	.03
Major amputation [b]	1.3	1.01–1.8	.049	1.1	0.7–1.8	.54
Major reintervention [c]	1.4	1.1–1.8	.02	1.5	1.03–2.2	.04
MACE	1.1	0.8–1.4	.68	0.7	0.5–1.1	.16
Wound infection [d]	1.2	0.96–1.5	.12	0.6	0.4–0.8	.001
Bleeding (leading to transfusion or sec. procedure) [e]	1.4	1.2–1.6	<.001	1.0	0.8–1.2	.98
Untreated loss of patency [f]	1.9	1.3–2.7	.001	1.5	0.9–2.5	.12
Unplanned reoperation [g]	1.2	1.02–1.4	.03	0.9	0.7–1.2	.59

All adjusted for: age, sex, tissue loss, and type of procedure. Additionally adjusted for:

[a] current smoking, obesity, race, hypertension, diabetes mellitus, preoperative antiplatelet use, graft type;

[b] race, diabetes mellitus, renal insufficiency, dialysis, preoperative antiplatelet use;

[c] current smoking, obesity, hypertension, diabetes mellitus, preoperative antiplatelet use, graft type;

[d] obesity, diabetes mellitus, preoperative statin use, graft type;

[e] race, congestive heart failure, renal insufficiency, dialysis, preoperative antiplatelet/statin/beta blocker use;

[f] obesity, renal insufficiency, preoperative antiplatelet use, graft type;

[g] obesity, race, diabetes mellitus, dialysis, preoperative antiplatelet/beta blocker use, graft type

Table VIB

Adjusted associations between prior revascularization and perioperative outcomes in patients with claudication

	Claudication					
	Secondary bypass vs. primary bypass			Prior bypass vs. prior endovascular		
	OR	***95% CI***	***P-value***	***OR***	***95% CI***	***P-value***
Mortality *	-	-	-	-	-	-
MALE [a]	2.1	1.3–3.5	<.01	1.7	0.8–3.4	.14
Major amputation *	-	-	-	-	-	-
Major reintervention [b]	2.1	1.3–3.5	<.01	2.1	0.9–4.5	.07
MACE	1.1	0.6–2.1	.66	0.9	0.3–2.3	.80
Wound infection	1.0	0.7–1.5	.81	0.6	0.3–1.05	.07
Bleeding (leading to transfusion or sec. procedure) [c]	1.7	1.3–2.4	.001	1.1	0.7–1.8	.71
Untreated loss of patency	2.2	0.9–5.3	.07	3.7	0.8–17.4	.10
Unplanned reoperation [d]	1.6	1.1–2.1	<.01	1.2	0.7–2.0	.41

*Too few events

All adjusted for: age, sex, and type of procedure. Additionally adjusted for:

[a] race, diabetes mellitus, renal insufficiency, preoperative antiplatelet use, graft type;

[b] diabetes mellitus, renal insufficiency, graft type;

[c] obesity, race, hypertension, preoperative antiplatelet/statin use;

[d] diabetes mellitus, renal insufficiency, dialysis, preoperative antiplatelet use

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