Atlantic Intersocietal Conference (TASC) II guidelines. The aim of this study was to determine the proportion of patients with chronic critical limb ischemia (CLI) who failed to adhere to current guidelines of medical therapy and to quantify the effect of suboptimal medical management on amputation-free survival (AFS).

Methods: The patient cohort was identified from a prospectively maintained database of consecutive patients presenting with CLI to the vascular surgery service at one hospital. The primary outcome variable was AFS. The effects of baseline demographics, comorbid medical conditions, ambulatory status, optimal medical management, and Rutherford classification were assessed. Optimal medical management was defined as adherence to TASC II recommendations for the management of atherosclerotic risk factors. Significant univariate predictors ($P < .10$) of AFS were entered into a multivariate Cox proportional hazards model.

Results: From August 1, 2010, through January 1, 2012, 98 patients (mean [standard deviation] age, 59.9 ± 10.1 years; 58 men and 40 women) were evaluated with rest pain (n = 38) or tissue loss (n = 60). The mean follow-up for the cohort was 333.3 ± 196.1 days. Optimal medical management was identified in 32% of patients at initial presentation, including compliance rates of 63% for statin use, 71% on antiplatelet therapy, 51% for angiotensin-converting enzyme inhibitor use, and 49% for β-blocker use. Significant univariate predictors of major amputation or death included nonambulatory status (hazard ratio [HR] 2.17; 95% confidence interval [CI], 1.68-2.81; $P < .01$), un-revascularized patients (HR, 2.77; 95% CI, 1.32-5.85; $P < .01$), a history of tobacco abuse (HR, 1.49; 95% CI, 0.57-3.86; $P = .09$), a history of end-stage-renal disease (HR, 7.97; 95% CI, 3.10-20.52; $P < .01$), suboptimal medical management (HR, 4.25; 95% CI, 1.28-14.07; $P = .02$), and an absence of antiplatelet agents (HR, 1.94; 95% CI, 0.92-4.11; $P = .08$). Independent predictors of major amputation or death included initial nonambulatory status (HR, 2.43; 95% CI, 1.03-2.05; $P < .01$), un-revascularized status (HR, 2.43; 95% CI, 1.76-3.34; $P = .01$), and suboptimal medical management at presentation (HR, 8.54; 95% CI, 2.05-35.65; $P < .01$).

Conclusions: Despite guidelines advocating the optimization of atherosclerotic risk factors in peripheral arterial disease, less than one-third of patients with CLI present with their risk factors appropriately managed. Patients who are suboptimally medically managed have greater than a fourfold risk of major amputation or death, or both. Of the risk factors affecting amputation-free survival, medical therapy optimization is the variable that can be most significantly improved by vascular surgeons and the medical community. Population-based efforts to improve outcomes in CLI require attention to improving the medical management.

Carotid-Subclavian Bypass and Subclavian-Carotid Transposition in the TEVAR Era

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Introduction: Beyond traditional indications, subclavian revascularization is increasingly performed to allow for aortic arch debranching in the setting of thoracic endovascular aortic repair (TEVAR). Endovascular approaches have also emerged as a therapeutic option for subclavian artery disease, perhaps altering the patient population undergoing open procedures. We leveraged prospectively collected National Surgical Quality Improvement Program (NSQIP) data to delineate evolving stroke and mortality rates after carotid-subclavian bypass (CSB) and subclavian-carotid transposition (SCT) in this dynamic context.

Methods: The American College of Surgeons NSQIP database (2005-2010) was used to examine adult patients who underwent CSB or SCT. Patients admitted for emergency procedures were excluded. Factors associated with the primary outcome (30-day postoperative stroke or death) were defined using univariable and multivariable analyses.

Results: Of 877 patients who met inclusion and exclusion criteria, 738 underwent CSB, 139 underwent SCT, and 88 (10.0%) also underwent TEVAR. CSB comprised 41% of subclavian revascularizations associated with TEVAR and 89% of isolated subclavian revascularizations. The CSB and SCT group had similar baseline age (65.0 vs 63.3 years, $P = .67$), race (Caucasian, 83.8% vs 79.4%, $P = .21$), and prevalence of comorbid conditions. There were a greater proportion of TEVARs performed in the SCT group (37.4% vs 4.9%, $P < .01$). The groups were otherwise similar in demographic characteristics and prevalence of comorbid conditions. Overall stroke, mortality, and combined cerebrovascular accident (CVA)/death (D) rates were 3.5% (n = 31), 3.3% (n = 29), and 5.8% (n = 51), respectively. Surgical approach did not affect the CVA/D rate (odds ratio [OR], 1.51; 95% confidence interval [CI], 0.71-3.19; $P = .28$); however, increasing age (adjusted OR, 1.06; 95% CI, 1.03-1.10; $P < .01$), congestive heart failure (OR, 3.49; 95% CI, 1.04-11.64; $P = .04$), and American Society of Anesthesiologists class >3 (OR, 2.06; 95% CI, 1.11-3.83; $P = .02$) were significantly associated with CVA/D in the overall group. The CVA/D rate was 10.2% (n = 9) for revascularization in conjunction with TEVAR and 5.3% (n = 42) for isolated reconstruction ($P = .06$). Without excluding emergency cases, the TEVAR cohort's CVA/D rate was 14.7%. For patients undergoing TEVAR, no factors were significantly associated with CVA/D, including surgical approach (SCT vs CSB; OR, 0.52; 95% CI, 0.13, 2.08; $P = .35$). For patients undergoing isolated revascularization, increasing age (OR, 1.06; 95% CI, 1.03-1.10; $P < .01$) and nonindependent functional status (OR, 3.49; 95% CI, 1.41-8.68; $P < .01$) were significantly associated with CVA/D.

Conclusions: Despite improvements in surgical, anesthetic, and critical care technology, open cervical reconstruction of the subclavian artery for occlusive disease carries a persistent combined CVA/D rate >5% in this contemporary work. With TEVAR, this rate is as high as 10.2%. There was no significant difference in CVA/D by surgical approach after adjustment for other factors. CVA/D continues to complicate contemporary CSB and SCT, especially among elderly and nonindependent patient subsets.

Table. Outcome, stratified by TEVAR and surgical approach

Variable	*No.*	*CVA/D No. (%)*	*Death No. (%)*	*CVA No. (%)*
All patients	877	51 (5.8)	29 (3.3)	31 (3.5)
TEVAR				
Overall	88	9 (10.2)	6 (6.8)	5 (5.7)
CSB	36	5 (13.9)	3 (8.3)	3 (8.3)
SCT	52	4 (7.7)	3 (5.8)	2 (3.9)
Non-TEVAR				
Overall	789	42 (5.3)	23 (2.9)	26 (3.3)
CSB	702	36 (5.1)	20 (2.9)	22 (3.1)
SCT	87	6 (6.9)	3 (3.5)	4 (4.6)

Improved Procedural, Hemodynamic, and Late Clinical Outcomes Using Intravascular Ultrasound Anatomic Guidance During Carotid Artery Stent-Angioplasty

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Introduction: This study evaluates carotid artery stenting (CAS) with and without intravascular ultrasound (IVUS) interrogation assessing the region of stent deployment and angioplasty.

Methods: A retrospective review of a carotid stent registry from 2003 to 2012 identified 412 CAS procedures (399 patients) to treat de novo atherosclerosis or recurrent stenosis of the carotid bulb and internal carotid artery. Imaging with IVUS was performed before and after stent-angioplasty. Residual stent stenosis on angiography or IVUS was treated with additional percutaneous transluminal angioplasty (PTA). Surveillance duplex ultrasound imaging was performed at 30 days, followed by 6-month intervals. Outcome measures included procedure time, final balloon diameter for PTA, contrast volume, hemodynamic parameters on duplex, cardiac events, neurologic outcome, and mortality.

Results: CAS was performed using digital C-arm angiography alone (AA) in 167 or in conjunction with IVUS (AI) in 241; 314 patients (77%) were asymptomatic. Using AA or AI, accurate single carotid stent deployment was achieved. Mean procedure times were similar between AA and AI groups (63.0 vs 63.4 min, $P = .87$). Compared with AA, AI altered procedural conduct by using lower contrast volumes (mean 50 mL; range 5-120 mL) compared with AA (mean, 90 mL; range, 40-170 mL) due to fewer angiogram runs for stent sizing and verification of adequate stent deployment. AI directed use of larger-diameter balloons, ranging in size from 5.5 to 7 mm (median 6 mm), for final stent PTA based on assessment of normal luminal diameter, whereas AA balloons were 4.5 to 6 mm (median, 5 mm; $P < .0001$). AI also detected more residual stent abnormalities (n = 24 [10%]) vs CAS using AA (n = 3 [2%], $P = .002$). The early (30-day) duplex scan showed 24 of 27 stents (89%) receiving adjunctive PTA for residual stent stenosis demonstrated <50% DR. Early neurologic event rates were low, and there was no different between groups (AA 1.2% vs AI 1.2%). Duplex at 30-days and last surveillance interval is recorded in the Table. Mean follow-up was 54 months (range, 6-120 months). Duplex at 30-days showed DR 50% to 75% was more likely in the AA group ($P = .02$). At the last duplex, DR >50% were recorded for 26 AA (16%) and 9 AI CAS (4%; $P < .0001$). Six CAS sites (5 AA, 1 AI, $P < .0001$) developed >75% asymptomatic restenosis and underwent secondary percutaneous intervention with PTA, with one AA stent later developing an asymptomatic thrombosis. Each group had one late neurologic event, one stroke (AA), and one transient ischemic attack (AI; 0.6%, 0.4% respectively). One early cardiac death was recorded in an AI patient.

Conclusions: IVUS guidance allows operators to accurately define disease distribution, vessel size, and target stent landing zones without adding independent risk or increasing procedural time. IVUS affords a measure of quality control that directs optimal stent and balloon selection. Adjunctive use of IVUS can improve early and late carotid stent

hemodynamics, which may enhance outcomes and reduce secondary interventions for recurrent stenosis.

Table. Hemodynamic parameters

Variable	*30-day duplex scan*			*Most recent duplex scan*		
	<50% DR	*50-75% DR*	*>75% DR*	*<50% DR*	*50-75% DR*	*>75% DR*
Angio alone, No. (%)	152	15 (9)	0	141	21 (13)	5 (3)
Mean PSV (cm/s)	98 ± 46	198 ± 47	. . .	106 ± 38	204 ± 51	422 ± 45
Angio + IVUS, No. (%)	233	8 (3)	0	232	8 (3)	1 (0.4)
Mean PSV (cm/s)	84 ± 50	182 ± 31	. . . .	82 ± 40	186 ± 28	347

Stress Tests Are Overutilized in the Preoperative Evaluation of Endovascular Aneurysm Repair

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Introduction: The ideal approach for cardiac risk stratification in patients undergoing elective endovascular aortic aneurysm repair (EVAR) remains unresolved. Multiple algorithms are used to evaluate patients, with significant variability amongst institutions, and cardiac stress testing remains a widely used modality. Recent American College of Cardiology/American Heart Association guidelines suggest clinical risk factors can identify patients at highest risk for adverse events. We compared the clinical efficacy and cost-savings of risk factor assessment using the revised cardiac risk index (RCRI) vs cardiac stress testing in predicting perioperative cardiac complications after EVAR.

Methods: A single-center retrospective study was conducted to identify patients undergoing EVAR between 2009 and 2011. Of 248 patients who were identified, 42 were excluded due to emergent repair, and 206 patients were included in the analysis. The preoperative assessment was identified and a cost analysis was performed based on CMS reimbursement rates for our geographic area. The RCRI was calculated for each patient and used to stratify them according to predicted risk for a perioperative cardiac event. The 30-day event rates for death or symptomatic cardiac events were calculated.

Results: Complete records for preoperative evaluations were available for 197 of the 206 patients. Of those, 168 (85%) underwent cardiac stress testing, of which 26 patients (13%) were positive, resulting in further testing. Twenty patients with a positive stress test underwent cardiac catheterization, three underwent percutaneous coronary intervention (PCI), and one underwent coronary artery bypass grafting. There were no perioperative deaths. Six patients (2.9%) had clinical symptoms prompting measurement of serum troponin levels, which were elevated. In patients with a negative stress test, five myocardial infarctions (MIs) occurred (3%) vs one MI in patients with a positive stress test (3.8%; $P = .86$). When stratified by the RCRI, patients with fewer than three risk factors had an MI rate of 2.5% vs 16.7% in patients with three or more factors ($P = .04$). Including the resultant procedures, the per-patient cost for routine preoperative stress testing was $3500.

Conclusions: Routine preoperative cardiac stress testing for patients undergoing elective endovascular aneurysm repair is unwarranted. It results in additional invasive testing and therapy with a concomitant cost increase. The RCRI is a reliable tool for risk stratification and guiding preoperative workup in patients scheduled for elective EVAR. The RCRI should replace qualitative physician determination of fitness for EVAR. This represents a potential area for improved resource utilization strategies.

Table. Stress test and perioperative MI by risk score

	Stress test, No. (%)		*MI, No. (%)*	
RCRI risk score	*Yes*	*No.*	*Yes*	*No.*
<3	163 (85)	28 (15)	5 (2.5)	195 (97.5)
≥3	5 (83)	1 (17)	1 (17)	5 (83)

Percutaneous Endovascular Aortic Aneurysm Repair (PEVAR): Results From the First Prospective, Multicenter Randomized Trial

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Introduction: The first randomized controlled trial was designed and conducted to assess the safety and effectiveness of totally percutaneous endovascular aortic aneurysm repair (PEVAR) using a 21F endovascular stent graft system and an 8F or 10F suture-mediated closure system. A noninferiority trial design was chosen to compare percutaneous access to standard open femoral exposure.

Methods: Between 2010 and 2012, 20 United States institutions participated in a prospective, U.S. Food and Drug Administration-approved randomized trial to evaluate the safety and effectiveness of percutaneous femoral artery access and closure using a "preclose" technique in conjunction with EVAR. A total of 192 patients were enrolled, 41 in a nonrandomized roll-in phase, and then 151 in the randomized phase where patients were allocated 2:1 to percutaneous closure (group C, n = 101) or open femoral exposure (group S, n = 50). PEVAR procedures were performed using the 8F Perclose ProGlide (group C1, n = 50) or the 10F Prostar XL (group C2, n = 51) closure device. All EVAR procedures were performed with the 21F profile IntuiTrak System. Patients were screened using computed tomography with 3-dimensional reconstruction and independent physician review for anatomic suitability and adequate femoral artery anatomy for percutaneous access (eg, absence of anterior wall or circumferential calcification, aneurysm, or extensive scarring). Primary treatment success was defined as procedural technical success and absence of adverse systemic and access-related vascular events at 30 days. Secondary clinical utility and procedural outcomes, ankle-brachial index, blood laboratory analyses, and quality of life were also evaluated with continuing follow-up to 6 months.

Results: Baseline characteristics were similar among all groups. EVAR technical success was 100%, 100%, and 98% in groups C1, C2, and S, respectively. Primary treatment success at 1 month was 88% (C1), 78% (C2), and 78% (S) with a one-sided Blackwelder's test of noninferiority yielding $P = .0036$ for C1 vs S and $P = .1021$ for C2 vs S. Secondary outcomes procedurally to within 1 month are shown in the Table. PEVAR (group C) compared favorably with respect to time to hemostasis, anesthesia time, total procedure time, analgesic use, ipsilateral groin pain, blood transfusion requirement, and quality of life metrics. Final 6-month follow-up is ongoing.

Conclusions: Among trained operators and patients with suitable femoral artery anatomy, a totally percutaneous approach to EVAR is safe, with minimal access-related complications. The ProGlide suture-mediated device specifically performed noninferiorly to standard open femoral exposure. Training, experience, and careful application of the "preclose" technique is of paramount importance in ensuring successful, sustainable outcomes.

Table.

Outcome measure	*Group C1*	*Group C2*	*Group S*
Anesthesia time, minutes	181 ± 65	152 ± 54[a]	203 ± 93
Time to hemostasis, minutes	9.8 ± 17[a]	13 ± 19[a]	23 ± 23
Total procedure Time, minutes	101 ± 43[a]	95 ± 35[a]	136 ± 71
Estimated blood loss, mL	213 ± 205	193 ± 198	280 ± 290
Blood transfusion, % patients	4.0%	16%	14%
Time to ambulation, hours	17 ± 7.2	16 ± 9.1	19 ± 16
Time to normal diet, hours	14 ± 9.4	10 ± 8.4	15 ± 22
Ipsilateral groin pain pre-discharge[b]	2.1 ± 2.2	1.4 ± 2.0[a]	2.6 ± 2.4
Analgesics for groin pain pre-discharge, % patients	18%	12%[a]	30%
Time to hospital discharge, days	1.3 ± 0.7	1.4 ± 0.9	1.8 ± 2.4
Ipsilateral groin pain at 1 month[b]	0.4 ± 0.9	0.1 ± 0.5[a]	0.6 ± 1.5
SF-36 health-related quality of life change at 1 month	9.4 ± 26	8.3 ± 29	1.6 ± 24
Ipsilateral ankle-brachial index at 1 month	1.06 ± 0.16	1.05 ± 0.15	1.06 ± 0.13

Results shown as mean ± SD unless otherwise specified.

[a]$P < .05$ vs group S result.

[b]Scale of 0 (no pain) to 10 (worst pain imaginable).

Sequential Catheterization Amid Progressive Endograft Deployment for Fenestrated and Branched Endovascular Aortic Aneurysm Repair

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Introduction: Fenestrated and branched endovascular aneurysm repair (FEVAR) is an alternative to open repair of complex aortic aneurysms in high-risk patients. Unfortunately, patients with unfavorable anatomy are frequently denied FEVAR because of the risk of technical failure with loss of visceral arteries. The purpose of this study was to assess technical success of FEVAR using a sequential catheterization amid progressive endograft deployment (SCAPED) technique, particularly in patients with unfavorable anatomy.

Methods: During a 12-month period, 39 high-risk patients (31 men and 8 women) underwent FEVAR using customized, physician-modified Zenith endografts that were fenestrated or branched using the SCAPED technique. The visceral vessels were sequentially catheterized through the fenestrations via left brachial artery access in a cranial-to-caudal direction as the endograft was progressively deployed. Each fenestration was deployed, aligned, and catheterized separately while the distal endograft was constrained within the delivery sheath. Technical success was defined as com-