Selected Abstracts from the May Issues of the Journal of Vascular Surgery and the Journal of Vascular Surgery: Venous and Lymphatic Disorders☆

Editors: Peter Gloviczki and Peter F. Lawrence

Selected Abstracts from the Journal of Vascular Surgery

Outcomes of upper extremity during fenestrated-branched endovascular aortic repair

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Objective: Upper extremity (UE) access is frequently used during fenestrated-branched endovascular aortic repair (F-BEVAR) to facilitate catheterization of downgoing vessels. Limitations include risk of cerebral embolization and of UE arterial or peripheral nerve injury. The aim of this study was to assess outcomes of F-BEVAR using UE access.

Methods: We reviewed the clinical data of 334 consecutive patients (74% males; mean age 75 $\pm$ 8 years) treated by F-BEVAR for thoracoabdominal aortic aneurysms or pararenal aortic aneurysms between 2007 and 2016. Patients who underwent F-BEVAR with an UE approach for catheterization of the renal and/or mesenteric arteries were included in the study. End points were technical success, mortality, and a composite of access-related complications including cerebral embolization (stroke/transient ischemic attack), peripheral nerve injury, and axillary-brachial arterial complications requiring intervention.

Results: There were 243 patients (73%) treated by F-BEVAR with UE access, including 147 patients (60%) with thoracoabdominal aortic aneurysms and 96 patients (40%) with pararenal aortic aneurysms. A total of 878 renal—mesenteric arteries were incorporated by fenestrations or branches with a mean of 3.6 $\pm$ 0.8 vessels per patient. All patients had surgical exposure of the brachial artery. The left side was selected in 228 (94%) and the right side in 15 (6%). The technical success of target vessel incorporation was achieved in 99% of patients (870 of 878). Arterial closure was performed using primary repair in 213 patients (88%) or bovine patch angioplasty in 29 (12%). Patch closure was required in 13% of patients (21 of 159) treated by 10- to 12F sheaths and 8% (7 of 83) of those who had 7- to 8F sheaths ($P = .19$). There were six deaths (2.5%) at 30 days or within the hospital stay, none owing to access-related complications. Major access-related complication occurred in eight patients (3%), with no difference between the 10- to 12F (6 of 159 [4%]) or 7- to 8F sheaths (2 of 83 [2%]; $P = .45$). Two patients (1%) had transient median nerve neuropraxia, which resolved within 1 year. One patient (0.5%) required surgical evacuation of an access site hematoma. There were no UE arterial pseudoaneurysms, occlusions, or distal embolizations. Five patients (2%) had strokes (three minor, two major), occurring more frequently with right side (2 of 15 [13%]) as compared with left-sided access (3 of 228 [1%]; $P = .03$). After a mean follow-up of 38 $\pm$ 15 months, there were no other access-related complications or reinterventions.

Conclusions: UE arterial access with surgical exposure was associated with a low rate of complications in patients treated with F-BEVAR. Closure with patch angioplasty is frequently needed, but there were no arterial occlusions, pseudoaneurysms, or distal embolizations requiring secondary procedures.

Thirty-day outcomes from the Society for Vascular Surgery Vascular Quality Initiative thoracic endovascular aortic repair for type B dissection project

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Objective: The purpose of the Society for Vascular Surgery Vascular Quality Initiative thoracic endovascular aortic repair (TEVAR) for dissection project is to assess the effectiveness of TEVAR for type B dissection by evaluation in a prospective quality improvement registry. Here we describe the project cohort and 30-day outcomes of TEVAR for both acute dissection (AD) and chronic dissection (CD) patients and focus specifically on outcomes of uncomplicated AD patients based on timing of treatment.

Methods: Summary statistics were performed comparing patients with AD ($<$30 days) and patients with CD. Both groups were further divided into those with complicated (ie, malperfusion or rupture) or uncomplicated presentation. Further subdivision of the uncomplicated AD patients into treatment at $\leq$48 hours, $>$48 hours to $<$7 days, $\geq$7 days to $\leq$14 days, and $>$14 days to $<$30 days was performed. Kaplan-Meier analysis was performed for 30-day survival and freedom from reintervention.

Results: Data for 397 patients (204 AD patients and 193 CD patients) were collected from 40 institutions. Overall, AD

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patients were younger than CD patients (58.8 vs 62.2 years; $P = .003$). Technical success, including coverage of the primary entry tear, was 98.0% for AD patients and 99.0% for CD patients, with a trend toward a higher 30-day mortality in AD patients (AD, 9.3%; CD, 5.2%; $P = .126$). Any degree of procedure-related spinal cord ischemia occurred in 4.4% of AD patients vs 2.1% of CD patients ($P = .261$), with a deficit at discharge in 3.4% of AD patients vs 0.5% of CD patients ($P = .068$). Disabling stroke occurred in 2.5% of AD patients vs 1.6% of CD patients ($P = .725$); retrograde type A dissection occurred in 1.1% of AD patients vs 2.6% of CD patients ($P = .412$). There was a trend toward a lower freedom from reintervention in AD patients (90.7% vs 94.8%; $P = .13$). In uncomplicated AD patients, rapid aortic expansion was more common in the treatment groups of $\geq$7 days to $\leq$14 days and $>$14 days to $<$30 days compared with those treated within 7 days of dissection ($P = .042$). The uncomplicated AD cohorts based on timing of treatment were otherwise similar in demographics and presentation, with no significant differences in 30-day mortality or serious complications, such as spinal cord ischemia, stroke, or retrograde type A dissection. The 30-day reintervention rate for uncomplicated AD patients was 5.8%, with no apparent differences in reintervention rates according to timing of treatment of initial TEVAR.

Conclusions: As expected, AD patients demonstrated a trend toward a higher 30-day mortality and lower freedom from reintervention compared with CD patients. Mortality at 30 days after TEVAR for uncomplicated AD was 5.8%, and there were no clear patterns in mortality or reintervention based on timing of treatment. Further study and evaluation at longer follow-up are needed to determine the impact of timing of intervention in uncomplicated AD patients.

Metformin prescription status and abdominal aortic aneurysm disease progression in the U.S. veteran population

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Background: Identification of a safe and effective medical therapy for abdominal aortic aneurysm (AAA) disease remains a significant unmet medical need. Recent small cohort studies indicate that metformin, the world's most commonly prescribed oral hypoglycemic agent, may limit AAA enlargement. We sought to validate these preliminary observations in a larger cohort.

Methods: All patients with asymptomatic AAA disease managed in the Veterans Affairs Health Care System between 2003 and 2013 were identified by *International Classification of Diseases, Ninth Revision* codes. Those with a concomitant diagnosis of diabetes mellitus who also received two or more abdominal imaging studies (computed tomography, magnetic resonance imaging, or ultrasound) documenting the presence and size of an AAA, separated by at least 1 year, were included for review. Maximal AAA diameters were determined from radiologic reports. Further data acquisition was censored after surgical AAA repair, when performed. Comorbidities, active smoking status, and outpatient medication records (within 6 months of AAA diagnosis) were also queried. Yearly AAA enlargement rates, as a function of metformin treatment status, were compared using two statistical models expressed in millimeters per year: a multivariate linear regression (model 1) and a multivariate mixed-effects model with random intercept and random slope (model 2).

Results: A total of 13,834 patients with 58,833 radiographic records were included in the analysis, with radiology imaging follow-up of 4.2 $\pm$ 2.6 years (mean $\pm$ standard deviation). The average age of the patients at AAA diagnosis was 69.8 $\pm$ 7.8 years, and 39.7% had a metformin prescription within $\pm$6 months of AAA. The mean growth rate for AAAs in the entire cohort was 1.4 $\pm$ 2.0 mm/y by model 1 analysis and 1.3 $\pm$ 1.6 mm/y by model 2 analysis. The unadjusted mean rate of AAA growth was 1.2 $\pm$ 1.9 mm/y for patients prescribed metformin compared with 1.5 $\pm$ 2.2 mm/y for those without ($P < .001$), a 20% decrease. This effect remained significant when adjusted for variables relevant on AAA progression: metformin prescription was associated with a reduction in yearly AAA growth rate of -0.23 mm (95% confidence interval, -0.35 to -0.16; $P < .001$) by model 1 analysis and 0.20 mm/y (95% confidence interval, -0.26 to -0.14; $P < .001$) by model 2 analysis. A subset analysis of 7462 patients with baseline AAA size of 35 to 49 mm showed a similar inhibitory effect (1.4 $\pm$ 2.0 mm/y to 1.7 $\pm$ 2.2 mm/y; $P < .001$). Patients' factors associated with an increased yearly AAA growth rate were baseline AAA size, metastatic solid tumors, active smoking, chronic obstructive pulmonary disease, and chronic renal disease. Factors associated with decreased yearly AAA growth rates included prescriptions for angiotensin II type 1 receptor blockers or sulfonylureas and the presence of diabetes-related complications.

Conclusions: In a nationwide analysis of diabetic Veterans Affairs patients, prescription for metformin was associated with decreased AAA enlargement. These findings provide further support for the conduct of prospective clinical trials to test the ability of metformin to limit progression of early AAA disease.

Patients with large neck diameter have a higher risk of type IA endoleaks and aneurysm rupture after standard endovascular aneurysm repair

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Objective: Standard endovascular aneurysm repair (EVAR) is the most common treatment of abdominal aortic aneurysms (AAAs). EVAR has been increasingly used in patients with hostile neck features. This study investigated the outcomes of EVAR in patients with neck diameters $\geq$30 mm in

the prospectively maintained Endurant Stent Graft Natural Selection Global Postmarket Registry (ENGAGE).

Methods: This is a retrospective study comparing patients with neck diameters ≥30 mm with patients with neck diameters <30 mm. The primary end point was type IA endoleak (EL1A). Secondary end points included secondary interventions to correct EL1A, aneurysm rupture, and survival.

Results: This study included 1257 patients (mean age, 73.1 years; 89.4% male) observed for a median 4.0 years (interquartile range, 2.7-4.8 years). A total of 97 (7.7%) patients had infrarenal neck diameters ≥30 mm and were compared with the remaining 1160 (92.3%) with neck diameters <30 mm. At baseline, there were no differences between groups regarding demographics and comorbidities other than cardiac disease, which was more frequent in the ≥30-mm neck diameter group (P = .037). There were no significant differences between the groups regarding neck length, angulation, thrombus, or calcification. Mean preoperative AAA diameter was 64.6 ± 11.3 mm in the ≥30-mm neck diameter group and 60.0 ± 11.6 mm in the <30-mm neck diameter group ($P < .001$). Stent graft oversizing was significantly less in the ≥30-mm neck diameter group (12.2% ± 8.9% vs 22.1% ± 11.9%; $P <$. 001). Five patients (5.2%) in the ≥30-mm neck diameter group and 30 (2.6%) with neck diameters <30 mm developed EL1A, yielding a 4-year freedom from EL1A of 92.4% vs 96.6%, respectively (P = .09). Oversizing was 21.8% ± 13.0% for patients developing EL1A and 21.3% ± 12.4% for the remaining cohort (P = .99). In adjusting for neck length, AAA diameter, and device oversizing, patients with neck diameter ≥30 mm were at greater risk for development of EL1A (hazard ratio, 3.0; 95% confidence interval, 1.0-9.3; P = .05). Secondary interventions due to EL1A did not differ between groups (P = .36). AAA rupture occurred in three patients with neck diameter ≥30 mm (3.1%) and in eight patients with neck diameter <30 mm (0.7%; hazard ratio, 5.1; 95% confidence interval, 1.4-19.2; P = .016); two cases were EL1A related in each group. At 4 years, overall survival was 61.6% for the ≥30-mm neck diameter group and 75.2% for the <30-mm neck diameter group (P = .009), which remained significant on correcting for sex and AAA diameter (P = .016).

Conclusions: In this study, patients with infrarenal neck diameter ≥30 mm had a threefold increased risk of EL1A and fivefold risk of aneurysm rupture after EVAR as well as worse overall survival. This may influence the choice of AAA repair and underlines the need for regular computed tomography-based imaging surveillance in this subset of patients. Furthermore, these results can serve as standards with which new, possibly improved technology, such as EndoAnchors (Medtronic, Santa Rosa, Calif), can be compared.

Influence of multiple stents on periprocedural stroke after carotid artery stenting in the Carotid Revascularization Endarterectomy versus Stent Trial (CREST)

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Background: In the Carotid Revascularization Endarterectomy versus Stent Trial (CREST), carotid artery atherosclerotic lesion length and nature of the lesions were important factors that predicted the observed difference in stroke rates between carotid endarterectomy and carotid artery stenting (CAS). Additional patient-related factors influencing CAS outcomes in CREST included age and symptomatic status. The importance of the operator's proficiency and its influence on periprocedural complications have not been well defined. We evaluated data from CREST to determine the impact of use of multiple stents, which we speculate may be related to technical proficiency.

Methods: CREST includes CAS performed for symptomatic ≥50% carotid stenosis and asymptomatic ≥70% stenosis. Both symptomatic and asymptomatic patients were enrolled in the trial and in the lead-in registry. Data from patients enrolled in the CREST registry and randomized trial from 2000 to 2008 were reviewed for patient- and lesion-related characteristics along with number of stents deployed. The occurrence of 30-day stroke and demographic and clinical features were recorded. Odds ratios for 30-day stroke associated with the use of multiple stents were calculated in univariate analysis and on multivariable analysis after adjustment for demographics (age, sex, symptomatic status), lesion characteristics (length, ulceration, eccentric, percentage stenosis), and risk factors (diabetes, hypertension, dyslipidemia, and smoking).

Results: The registry (n = 1531) and trial (n = 1121) enrolled 2652 patients undergoing CAS. The mean age was 69 years; 36% were women, and 38% were symptomatic. The mean diameter stenosis was 78%, and the mean lesion length was 18 mm (±standard deviation, 8 mm). Risk factors included hypertension (85%), diabetes (32%), dyslipidemia (84%), and smoking (23%). All patients received Acculink stents (Abbott Vascular, Abbott Park, Ill) that were 20, 30, or 40 mm in length (straight or tapered) and Accunet (Abbot Vascular) embolic protection when possible. Most patients received one stent (n = 2545), whereas 98 patients received two stents and 9 patients received three stents ($P < .001$) to treat the lesion. Patients receiving more than one stent were older (P = .01) but did not differ in other demographic or risk factors. Strokes occurred in 118 (4.5%) of all CAS procedures, in 102 (4%) with the use of one stent, and in 16 (15%) with the use of two or three stents. After adjustment for demographics, lesion characteristics, and risk factors, the use of more than one stent resulted in 2.90 odds (95% confidence interval, 1.49-5.64) for a stroke.

Conclusions: Although we know that lesion characteristics (length, ulceration) play an important role in CAS outcomes, in this early experience with carotid stenting, a significant and independent relationship existed between the number of stents used and procedural risk of CAS. We postulate that this was an indicator of the operator's inexperience with the procedure.

Outcomes associated with a transcarotid artery revascularization-centered protocol in high-risk carotid revascularizations using the ENROUTE neuroprotection system

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Objective: This investigation describes the perioperative and early follow-up results associated with transcarotid artery revascularization (TCAR) in patients not participating in the Safety and Efficacy Study for Reverse Flow Used During Carotid Artery Stenting Procedure II (ROADSTER-2) registry using the ENROUTE neuroprotection system (ENPS; Silk Road Medical, Sunnyvale, Calif).

Methods: A retrospective review was performed capturing all TCAR/ENPS procedures in patients deemed to be at high risk for complications after traditional carotid endarterectomy. All patients enrolled in the ROADSTER-2 registry were excluded, leaving only those treated outside trial regulations for analysis. Preoperative demographics, intraoperative variables, and perioperative and follow-up outcomes were abstracted and reported herein.

Results: From December 2015 to January 2018, there were 75 carotid arteries treated at our institution. All interventions were performed on carotid arteries that were symptomatic with $\geq$50% stenosis (46.7%) or asymptomatic with $\geq$80% stenosis (53.3%) by duplex ultrasound and computed tomography angiography. Technical success in our series was 97.3% (73/75), with treatment failures attributed to one case of common carotid artery dissection and another secondary to stent maldeployment in the external carotid artery. Perioperative (30-day) ipsilateral stroke rate was 2.7% (n = 2), myocardial infarction incidence was 0%, and mortality rate was 2.7% (n = 2). We did not observe any cranial nerve injuries. After a mean follow-up of 8.0 $\pm$ 6.7 months, no carotid stents required reintervention. However, we noted one instance of minor ($<$50%) in-stent stenosis and one asymptomatic stent thrombosis. One additional ipsilateral stroke was observed on follow-up, probably from a cardiac source.

Conclusions: We report that dynamic reverse-flow TCAR using the ENPS continues to be safe, feasible, and efficacious with minimal risks of postoperative stroke, myocardial infarction, and mortality outside of ROADSTER-2 regulations.

Selected Abstracts from the Journal of Vascular Surgery: Venous and Lymphatic Disorders

Caliber-targeted reinterventional overdilation of iliac vein Wallstents

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Background: Wallstents (Boston Scientific, Marlborough, Mass) are most commonly used in iliac-caval stenting. Approximately 20% of stented limbs require reintervention to correct in-stent restenosis (ISR) or stent compression (SC). Corrective balloon dilation to rated stent caliber (isodilation) is not always successful. We investigated whether modest overdilation of the Wallstent by 2 to 4 mm (10%-20%) beyond the rated diameter would yield better mechanical clearance of ISR/SC, leading to a larger flow channel, improved conductance, reduction of peripheral venous pressure, and better clinical outcome. Outflow lumen caliber *exponentially* influences peripheral venous pressure, a key mechanism in chronic venous disease. Beyond the mechanical effects, the rationale for overdilation rests on the theory that an improvement in flow channel at the margins may yield an outsized pressure reduction and clinical improvement.

Methods: There were 274 previously stented limbs that underwent reinterventional balloon dilation for clearance of ISR/SC during a recent 3-year period. Isodilation to rated diameter of the stent was judged effective in 71 limbs (isodilated subset); 203 limbs (overdilated subset) for which initial isodilation was ineffective underwent overdilation of the resident Wallstent by 2 to 4 mm (10%-20%) beyond the original rated diameter. IVUS planimetry was used intraoperatively to calculate SC and ISR and their subsequent clearance in the two subsets. The dilated segments were observed by clinical and duplex ultrasound examination afterward. The two subsets were compared in the following outcome measures: intraprocedural efficacy in clearing ISR/SC and achieving target lumen caliber, subsequent clinical outcomes, duplex ultrasound caliber durability, and improvement in supine foot venous pressures. This is a single-center retrospective analysis of data contemporaneously entered into a time stamped electronic medical record system.

Results: The median follow-up was 18 months (range, 1-35 months). Overdilation of the stent resulted in significantly better intraoperative flow channel area improvement per intravascular ultrasound. This was reflected in significantly better clinical outcome and improvement in peripheral venous pressure in the overdilated subset. Overdilation appeared to be durable up to 20 months after intervention by duplex ultrasound monitoring.

Conclusions: Overdilation appears to be a useful technique to correct ISR/SC and to restore target lumen caliber during reinterventional correction of a resident iliac vein Wallstent. More durable caliber improvement, superior clinical outcome, and reduction in peripheral venous hypertension were noticed in overdilated stents compared with isodilation.

Impact of degree of stenosis in May-Thurner syndrome on iliac vein stenting

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Objective: May-Thurner syndrome (MTS) patients with lifestyle-limiting symptoms undergo stenting of the iliac vein for relief of compressive disease. The impact of degree of stenosis on clinical symptoms and outcomes after stenting is unknown and examined in our study.

Methods: Retrospective review of contemporaneously entered data of 202 patients who underwent stenting for MTS between 2005 and 2011 was performed. Classification into three groups based on luminal area obtained by intraoperative intravascular ultrasound interrogation of the involved femoroiliocaval segments was carried out. Normal luminal diameters and areas were defined as 12 mm and 125 mm^2, 14 mm and 150 mm^2, and 16 mm and 200 mm^2 in the common femoral, external iliac, and common iliac veins, respectively. Mild ($<$60%), moderate (60%-89%), and severe ($>$90%) compression groups were defined using the normal values noted previously and observed after stenting to evaluate outcomes. Kaplan-Meier analysis was done to assess primary, primary assisted, and secondary patencies. Visual analog scale for pain scores, grade of swelling, and Venous Clinical Severity Score (VCSS) before and after stenting at 6, 24, and 48 months were analyzed using paired *t*-test and Tukey test. Logistic regression was used to gauge the impact of multiple variables including degree of stenosis on stent reintervention.

Results: There were 55 patients who had mild, 87 patients who had moderate, and 60 patients who had severe iliac vein compression. Baseline demographic characteristics and comorbidities were similar across all groups. In addition, there was no statistically significant difference in median baseline visual analog scale score, grade of swelling, and VCSS among the groups. Compression was treated with angioplasty and stenting encompassing all areas of disease as determined by intravascular ultrasound. Stent technique involved use of Wallstent (Boston Scientific, Marlborough, Mass) only in 183 patients and Wallstent-Z stent (Cook Medical, Bloomington, Ind) combination in the remainder. No difference in median stent patency was noted on follow-up. Clinically, at 48 months, a statistically significant recurrence of pain, swelling, and worsening of VCSS were noted in the severe stenosis group but not in the other two groups. No variable was noted to have an impact on stent reintervention.

Conclusions: Severity of MTS stenosis is not a predictor of initial clinical symptoms. Long term, patients with $\geq$90% initial MTS stenosis experience recurrence of symptoms. The degree of iliac venous stenosis does not appear to affect stent patency. Such information will help counsel patients before intervention.