

Selected Abstracts from the November Issues of the Journal of Vascular Surgery and the Journal of Vascular Surgery: Venous and Lymphatic Disorders[☆]

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Selected Abstracts from the Journal of Vascular Surgery

Results from a prospective multicenter feasibility study of Zenith p-Branch stent graft

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Objective: To evaluate the Cook Zenith p-Branch stent graft (William A. Cook Australia, Brisbane, Queensland, Australia) for the treatment of patients with asymptomatic juxtarenal or pararenal abdominal aortic aneurysms in a prospective, nonrandomized, multicenter, feasibility study conducted in the United States.

Methods: The off-the-shelf p-Branch endograft incorporates a celiac scallop, superior mesenteric artery (SMA) fenestration, and two conical-shaped pivot renal fenestrations. Patients were eligible if the aneurysm did not extend above the distal margin of the SMA and the anatomy of renal and visceral arteries were compatible with one of the two p-Branch configurations (configuration A, renal fenestrations at the same longitudinal position; configuration B, offset renal fenestration).

Results: A total of 30 patients (93% men; mean age, 73 years; mean aneurysm diameter, 64.7 ± 11.4 mm) were enrolled from January 2013 to June 2015. The mean follow-up period was 28.7 ± 12.5 months (as of October 2017). The technical success rate was 93% (28/30), with technical failure occurring in the first two study cases (device deliberately repositioned below the renal arteries because of difficulty in cannulating the renal arteries in one and an inability to place a renal stent in the other; both patients survived the procedure and withdrew from the study before the 12-month follow-up visit). No additional technical failures occurred after these first two cases, when an updated physician training and proctoring program was implemented. No 30-day mortality occurred. Of the remaining 28 patients, three died during the follow-up period; none within 30 days and none related to the device or procedure as determined by Clinical Events Committee adjudication. No treated aneurysm ruptures, conversion, or core laboratory-reported migration, or stent fracture were reported. The primary renal artery patency (interval to occlusion or reintervention for stenosis) rate was

$88.6\% \pm 4.4\%$ at 1 and 2 years. Two patients (7%) developed renal insufficiency secondary to a right renal artery stenosis in one patient and progression of chronic renal insufficiency in one patient. No patient required dialysis or developed mesenteric ischemia. Of the 28 patients, nine (32%) had undergone 13 secondary interventions for renal artery occlusion ($n = 2$), SMA occlusion ($n = 1$), renal or SMA stenosis (5 interventions in 4 patients), renal stent kinking ($n = 1$), lower extremity claudication ($n = 2$ in the same patient), type III endoleak between the p-Branch and renal stent ($n = 1$), and type II endoleak ($n = 1$).

Conclusions: These early and intermediate results, which incorporated physician learning curves, support the safety and feasibility of the off-the-shelf Zenith p-Branch device. Follow-up examinations through 5 years will continue to assess the long-term results.

Differences in patient selection and outcomes based on abdominal aortic aneurysm diameter thresholds in the Vascular Quality Initiative

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Objective: Randomized trials have shown no benefit for repair of small abdominal aortic aneurysms (AAAs), although repair of small AAAs is widely practiced. It has also been suggested that repair of large-diameter AAAs may incur worse outcomes. We sought to examine differences in patient selection, operative outcomes, and survival after elective endovascular aneurysm repair (EVAR) based on AAA diameter thresholds.

Methods: Elective EVARs for asymptomatic AAAs in the Vascular Quality Initiative were studied from 2003 to 2017. AAAs were classified by diameter as small (<5 cm in women, <5.5 cm in men), medium (5-6.5 cm in women, 5.5-6.5 cm in men), and large (≥ 6.5 cm). Patient characteristics and operative factors were compared using univariate analyses and established risk prediction models. Effects of AAA diameter on reintervention and mortality were assessed using Kaplan-Meier and multivariable Cox regression analyses.

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Results: Of 22,975 patients undergoing EVAR, 41% (9353), 47% (10,842), and 12% (2780) had small, medium, and large AAAs, respectively. Patients with small AAAs were younger and had fewer comorbidities. Consequently, patients with small AAAs were more likely to have low predicted operative mortality risk and 5-year mortality risk based on risk models ($P < .001$ for both). For operative outcomes, 30-day mortality was significantly different across diameter categories (small, 0.4%; medium, 0.9%; large, 1.6%; $P < .001$). EVAR for large AAAs had the highest rates of multiple medical complications, including myocardial infarction ($P < .001$), respiratory complications ($P = .001$), and renal complications ($P < .001$). In contrast, EVAR for small AAAs had the lowest rates of type I endoleak at completion and reoperation during index hospitalization, shortest operative times, and shortest hospital length of stay ($P < .001$ for all). Aneurysm diameter was associated with differential 1-year reintervention-free survival (92% small vs 89% medium vs 82% large; $P < .001$) and 5-year overall survival (88% small vs 81% medium vs 75% large; $P < .001$). Multivariable models showed that compared with medium AAAs, small AAAs had an independent protective effect against 1-year reintervention or death (hazard ratio [HR], 0.82; $P = .003$) and 5-year mortality (HR, 0.78; $P = .001$). Conversely, compared with medium AAAs, large AAAs carried an independent increased risk of 1-year reintervention or death (HR, 1.75; $P < .001$) and 5-year mortality (HR, 1.50; $P < .001$).

Conclusions: Small AAAs represent >40% of elective EVARs in the Vascular Quality Initiative. Patients with small AAAs selected for repair are younger and have fewer comorbidities. Consequently, EVAR for small AAAs carries lower risk of operative and 5-year mortality. Aneurysm diameter is independently associated with reinterventions and mortality after EVAR, suggesting that AAA diameter may have an important clinical effect on outcomes.

Last neurologic event is associated with risk of in-hospital stroke or death after carotid endarterectomy or carotid artery stenting: Secondary data analysis of the German statutory quality assurance database

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Objective: We sought to analyze the association between last neurologic event and the risk of stroke or death among patients treated with carotid endarterectomy (CEA) or carotid artery stenting (CAS) under routine conditions in Germany.

Methods: Secondary data analysis was performed based on the German statutory quality assurance database for carotid procedures. A total of 144,347 patients treated by CEA and 14,794 patients treated by CAS were included in the analysis. Primary outcome was any in-hospital stroke or death. To analyze the association between the last neurologic

event and outcome, multilevel multivariable regression analysis was performed.

Results: In patients treated by CEA, raw risk for any in-hospital stroke or death was 2.0% (2923/144,347), with a risk of 1.4% in asymptomatic and 3.0% in symptomatic patients. In patients treated by CAS, raw risk for any in-hospital stroke or death was 3.6% (538/14,794), with a risk of 1.7% in asymptomatic and 6.1% in symptomatic patients. Regression analysis revealed that increasing severity of last neurologic event was significantly associated with an increasing risk of any in-hospital stroke or death in patients treated by both CEA and CAS ($P < .004$). However, the risk of any stroke or death did not significantly differ between asymptomatic patients and patients with amaurosis fugax before CEA or CAS ($P = .219$ for CEA, $P = .124$ for CAS).

Conclusions: Increasing severity of last neurologic event is associated with an increasing risk of any in-hospital stroke or death in patients treated by CEA and CAS. The risk of any stroke or death did not differ between asymptomatic patients and patients with amaurosis fugax.

Sarcopenia predicts mortality and adverse outcomes after endovascular aneurysm repair and can be used to risk stratify patients

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Background: Endovascular aneurysm repair (EVAR) is currently the most common treatment of abdominal aortic aneurysms. Potential predictors of long-term survival after EVAR include physiologic, functional, and cognitive status, but assessments of these conditions have been difficult to standardize. Objective radiographic findings, such as skeletal muscle atrophy, or sarcopenia, may provide an additional means for selection of patients. This study investigates sarcopenia as a method to predict 1-year survival in patients undergoing EVAR.

Methods: A single-institution retrospective review was conducted of all patients who underwent elective EVAR from September 2002 to June 2014. Patients with an available periprocedural computed tomography (CT) scan and clinical data were included in the analysis. Normalized total psoas cross-sectional area (nTPA) was measured on axial CT images using the area of the bilateral psoas muscle at the third lumbar vertebral level normalized to the square of patient height. A threshold for optimal estimate of sarcopenia based on nTPA was determined using a receiver operating characteristic curve. Sarcopenia was evaluated as an independent risk predictor using univariate, multivariate, and survival analysis.

Results: A total of 272 EVAR-treated patients were evaluated, including 237 men and 35 women with a median age of 72 years and mean body mass index of 28.6 kg/m². There was a significant increase in overall mortality in patients in the lowest quartile of nTPA (Q1, 23.53%; Q2, 13.24%; Q3,

7.35%; Q4, 5.88%; $P = .01$). The estimated nTPA threshold for increased mortality after EVAR was $500 \text{ mm}^2/\text{m}^2$. Using this threshold, sarcopenia accounted for 57% of the risk effect in our 1-year survival model.

Conclusions: Sarcopenia can assist in identifying EVAR candidates who are less likely to benefit from surgery. It can be readily evaluated from preoperative CT scans and may be a useful tool in evaluation of abdominal aortic aneurysm patients with applications in risk evaluation and telemedicine.

Unplanned 30-day readmissions after endovascular aneurysm repair: An analysis using the Nationwide Readmissions Database

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Background: Endovascular aneurysm repair (EVAR) is the preferred method for addressing abdominal aortic aneurysms (AAAs), with proven reduction in perioperative morbidity and mortality. There are, however limited data examining the readmissions after EVAR that are associated with increased patient morbidity and cost. As EVAR use continues its dominance in the management of AAAs, it becomes imperative to identify and mitigate risk factors associated with unplanned hospital readmissions.

Methods: The Nationwide Readmissions Database (NRD) was queried for all 30-day readmissions after an index EVAR procedure from 2012 to 2014. Preoperative patient demographics, hospital characteristics, readmission diagnosis, and costs were compared between those who were and were not readmitted within 30 days of the index operation. Multivariable logistic regression was used to identify potential risk factors associated with unplanned readmissions within 30 days.

Results: We identified 120,646 patients who underwent an EVAR from 2012 to 2014 in the United States. The overall unplanned readmission rate during this period was 11.6% ($n = 14,073$) within 30 days of the index EVAR procedure. The readmission rate was the highest in 2012, with a rate of 12.3% ($P = .02$). Multivariate regression analysis showed that EVAR readmissions were significantly higher in patients who were of younger age (18 to 49 years) compared with other age groups (odds ratio [OR], 1.9-2.17; $P < .001$), female sex (OR, 1.367; $P < .001$), had Medicare (OR, 1.39) or Medicaid (OR, 1.25) insurance, or a combination of these. Underlying patient comorbidities significantly associated with readmissions included congestive heart failure (OR, 2.4), peripheral vascular disease (OR, 1.1), chronic pulmonary disease (OR, 1.2), cancer with no metastasis (OR, 1.5), metastatic cancer (OR, 2.2), renal failure (OR, 1.8), and diabetes (OR, 1.5).

Conclusions: The trend in 30-day readmission rates after EVAR has decreased slightly since 2012, but overall rates are at 11.6%, which is not insubstantial. Patient factors strongly associated with hospital readmission were younger age and

patient comorbidities, including congestive heart failure, concurrent cancer diagnosis, renal failure, and diabetes.

Benefit of multidisciplinary wound care center on the volume and outcomes of a vascular surgery practice

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Objective: Multidisciplinary care is recommended for the treatment of patients with ischemic and diabetic wounds. In addition to integrating care from multiple specialties, outpatient wound care centers provide an opportunity for continuity and organization of care after revascularization or hospitalization. The purpose of this study was to assess changes in the practice patterns and outcomes of patients treated by a tertiary care vascular surgery practice after the introduction of an affiliated outpatient wound care center.

Methods: A prospective institutional database was used to identify patients who underwent lower-extremity revascularization, amputation, or surgical debridement during consecutive 3-year periods before (BWC; $n = 735$) and after (AWC; $n = 1503$) the opening of an affiliated wound care center. Patients were included if they underwent intervention for atherosclerotic peripheral arterial disease or diabetic foot ulcers (DFUs). Changes in case volume, surgical indication, and procedural characteristics were assessed. Clinical outcomes included freedom from lower-extremity amputations and mortality.

Results: We identified a total of 1751 procedures performed in 1249 limbs that met inclusion criteria. After the opening of the wound clinic, procedures related to limb salvage represented a greater proportion of overall cases performed by the vascular service (19% vs 26%; $P < .0001$). The volume of lower-extremity interventions increased by 64%, from 662 procedures in the BWC period to 1085 procedures in the AWC period. There was no difference in type of revascularization performed between the two study periods, although surgical debridements (from 8.9% to 13%; $P = .01$) and infrapopliteal endovascular interventions (from 21% to 28%; $P = .04$) significantly increased. Compared with BWC patients, AWC patients more frequently presented with DFUs (7.3% vs 13%; $P = .002$) and chronic wounds (39% vs 45%; $P = .05$). At 1 year of follow-up, major amputation rates were significantly lower in the AWC group than in the BWC cohort (5.5% vs 8.8%; $P = .04$). Treatment during the AWC period was associated with a reduced risk of major amputation (adjusted hazard ratio, 0.41; 95% confidence interval, 0.27-0.62; $P < .001$), but no difference in all-cause mortality.

Conclusions: The opening of an outpatient wound center affiliated with a tertiary vascular surgical practice was associated with a higher volume of limb salvage patients and procedures. The risk of major amputation decreased following the opening of the wound care center. Integrating vascular surgeons into wound centers may result in a synergistic system that promotes more aggressive and effective limb salvage.

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

Prevention and treatment of dilator injuries during central venous catheter placement

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Background: Misuse of vascular dilators during the placement of central venous catheters has been infrequently reported and can lead to devastating intrathoracic hemorrhage and death. These injuries should be preventable in most cases. If a major intrathoracic vascular injury is recognized intraoperatively, less invasive treatment options are available to minimize the consequences.

Methods: The records of 20 patients who suffered 21 major vascular injuries during insertion of central venous catheters, ports, or dialysis catheters and resulted in malpractice claims over the course of 8 years were analyzed to determine the mechanism of injury, the timing of diagnosis, and how these injuries were treated. How the injury could have been prevented, why earlier diagnosis was not made, and what treatment options were possible were also examined.

Results: Twelve women and eight men were documented to have sustained intrathoracic major venous injuries during catheter insertions. There were five injuries to the superior vena cava, six to the right innominate vein, and 10 to the left innominate vein. All procedures were done using fluoroscopic guidance, and resistance to passage of the dilators was documented in eight cases. In most cases, the operator reported inserting the dilators to their maximum length. In four cases, the catheter could be seen intraoperatively in the thoracic cavity. Bleeding was diagnosed in the operating room in 11 cases, in the postanesthesia care unit in seven cases, and on postoperative days 2 and 5 after misplaced catheters were removed. Ten patients underwent thoracotomies and one patient each underwent thoracoscopy and placement of a covered stent in an attempt to stop the hemorrhage. Eight patients died before the diagnosis was made. Seventeen patients died.

Conclusions: In spite of U.S. Food and Drug Administration warnings, dilators are still inserted too far in patients, resulting in devastating hemorrhage. These complications are preventable if proper technique is used. When a catheter is noted to be misplaced, it must not be removed before either a covered stent or thoracoscopy is available; otherwise, uncontrolled hemorrhage into the chest may occur. If a patient becomes unstable in the operating room or immediate postoperative period injury to a major vein must be considered and corrected quickly.

Significant physician practice variability in the utilization of endovenous thermal ablation in the 2017 Medicare population

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Background: There has been a substantial increase in the use of procedures to treat lower extremity venous disease in the United States over the past decade. A specialty society-selected metric was applied to evaluate the use of endovenous thermal ablation (EVTA) in Medicare beneficiaries and factors associated with physician practice variations. We used confidential physician reports of this benchmark data to increase physician recognition of individualized usage relative to their peers.

Methods: We used 100% Medicare fee-for-service claims data to identify all patients 18 years of age and older who underwent at least one lower extremity EVTA over a 1-year period (January 1, 2017, to December 31, 2017). A physician-specific annual rate of EVTA performed per patient was calculated. Individual physician results were shared confidentially with each provider billing Medicare for more than 10 ablations during the study period by mail, benchmarked to the distribution of use by their peers nationally. Hierarchical multivariable linear regression was used to identify patient and provider characteristics associated with high rates of thermal ablations per patient.

Results: A total of 102,145 Medicare beneficiaries (median age, 72.1 years; 67.8% female) underwent an EVTA by 2462 physicians during the study period. The majority (96.4%) of patients underwent 1 to 5 ablations, 3.3% underwent 6 to 10 ablations, and 0.3% underwent 11 or more ablations. The median and mean physician ablation rates were 1.6 (interquartile range, 1.3-2.2) and 1.9 ± 0.8 ablations per patient annually, respectively. There were 106 physicians (4.3%) who had an ablation rate of 3.4 or greater, which is two or more standard deviations above the national mean. After adjusting for patient-level variables, characteristics independently associated with outlier physicians included specialties other than vascular surgery, fewer years in practice, and higher overall venous ablation practice volume ($P \leq .03$).

Conclusions: Using a physician-generated metric of performance, the physician use EVTA performed annually per patient is highly variable, and this variability correlated with physician discipline, years in practice, and is more common in physicians who perform ablation the most. Our data show that there is considerable variability in the use of EVTA in Medicare beneficiaries, and that outlier physicians performing a high number of venous ablation procedures per patient are identifiable using a peer-benchmarked practice pattern measure via claims-based data.