Clinical Ramifications of an Extended Proximal Seal Zone with a Novel Endograft System: First Report of 108 Consecutive Cases


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Objectives: The AFX Endograft with ActiveSeal™ technology features highly conformable STRATA fabric enabling increased conformability within an irregularly shaped aortic neck, with the potential to extend the zone of sealing beyond the aortic neck. This study comprises the first report of the early clinical experience with the device in a consecutive series of patients with infrarenal abdominal aortic aneurysms (AAA).

Methods: A retrospective review of the baseline characteristics, imaging findings, clinical data, and outcomes of consecutive AAA patients treated with the AFX device (Endologix, Irvine, Calif) at two US centers was performed by independent monitors. Computed tomographic (CT) imaging measurements in the overall study population were reported. An independent core laboratory assessed aortic neck characteristics and fabric apposition from three-dimensional reformatted CT datasets in an imaging cohort subset of the study population. The anatomic neck was defined as the proximal aortic neck where the aortic diameter remained within 10% of its infrarenal reference. Median follow-up was 4 (0-14) months overall and 6 (1-14 months) in the imaging cohort. Values are expressed as mean ± standard deviation or median and range.

Results: Among the 108 patients, 103 (95.4%) were treated electively and 5 (4.6%) were treated urgently for rupture; 80 (74.1%) were male and 28 (25.9%) female with a median age of 70 (56-83) years. An average of 2.3 ± 0.7 AFX components was implanted per patient; no proximal neck stents were employed. There were no perioperative deaths in elective procedures and two deaths in patients with ruptured AAA (40%). Major adverse events occurred in four elective cases (3.9%) and two ruptured cases (40%). Over short-term follow-up, two type 1 endoleaks (one 1a, 0.9%; one 1b, 0.9%) and one type 3 endoleak (0.9%) were observed. Type 2 endoleaks were evident on completion angiography in 18 patients (16.7%), all but one of which resolved spontaneously by the first post procedure CT study. There were two type 2 endoleaks observed on follow-up CT studies (1.9%); one of which was not evident at the implant procedure. There were four aneurysm-related reinterventions; three in elective cases (2.9%) performed for an iatrogenic iliac arteriovenous fistula, renal stenting for partial ostial coverage, and a type III endoleak. No patient experienced endograft migration, limb occlusion, rupture, or open surgical conversion.

In the imaging cohort (37 patients), 360-degree fabric-to-wall apposition continued over a mean length of 25 ± 17 mm and extended an average of 5 mm distal to the end of the anatomic neck. Fabric apposition length exceeded the anatomic neck length in 20 (54%) of the patients in the Imaging Cohort.

Conclusions: Satisfactory short-term outcome was achieved in an initial series of patients treated with a new endograft and fabric with the potential to improve proximal neck sealing. Circumferential fabric apposition continued beyond the anatomic neck in approximately one-half of the cases, and there was a low rate of endoleaks and device-related complications. Definitive results, however, await the availability of longer term follow-up data.

Race and Gender Impact Early Outcomes of Lower Extremity Bypass


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Objectives: Race and gender have individually been associated with affecting outcomes in vascular interventions. We hypothesized that race and gender stratification would help explain variations in outcomes of lower extremity bypass (LEB) procedures.

Methods: LEB procedures were identified using current procedural terminology codes from the 2011 ACS NSQIP database. Persons of races other than Black or White were excluded because of small sample size. Preoperative variables such as age, demographics, medical comorbidities, and laboratory values were evaluated across race-gender groups using χ², Student t, and least square means testing. Significant predictors were entered into a multivariable logistic regression model. Six primary outcomes were evaluated: major complications, minor complications, 30-day mortality, early graft failure, readmission, and length of stay (LOS). Major complications included renal failure, pulmonary embolism, stroke, cardiac arrest, and myocardial infarction. Minor complications included superficial or wound infections, dehiscence, pneumonia, acute kidney injury, urinary tract infection, nerve injury, deep vein thrombosis, sepsis, and reoperation. SAS was used for all statistical computations.

Results: There were a total of 4518 LEB procedures performed on Black (n = 839, male (BM): females (BF) - 56.6%/43.5%) or White (n = 3679, male (WM): female (WF) - 66.4%/33.6%) patients. Black patients were more likely to be female, diabetic, smokers, and have chronic obstructive pulmonary disease, critical limb ischemia, or end-stage renal disease (P < 01). Multivariate analysis revealed no statistically significant gender differences within the white cohort with respect to complications, death, graft failure, readmission rates, or length of stay (Table). BM had longer LOS than WM (7.7 ± 7.3 vs 5.7 ± 6.1; P = 0.007) following LEB procedures, but there were no other statistically significant differences in outcomes between these groups. BF had a longer LOS than WM (7.7 ± 9.0 vs 5.7 ± 6.1, P < 0.001) as well as a higher chance of being readmitted than WM (hazard ratio, 1.32; 95% confidence interval, 1.00-1.74; P = 0.5). BF also had a much higher risk of early graft failure than WM (hazard ratio, 3.00; 95% confidence interval, 1.59-6.03; P = 0.001) and trended toward increased risk of 30-day mortality (Table).

Conclusions: After LEB procedures, race-gender stratification may predict outcomes that may not be predicted by gender or race analysis alone. To our knowledge, this is the largest population analysis of racial and gender differences in LEB to date. Further studies using this stratification methodology may help provide better insight into optimal therapeutic strategies and preventative measures for these subgroups of patients. Investigation into causes of increased LOS in Black patients and increased graft-failure and readmission rates in Black females may help improve outcomes in these groups of patients.

Upper Extremity Access for Fenestrated Endovascular Aortic Aneurysm Repair Is Not Associated With Increased Morbidity


Objectives: Fenestrated endovascular aortic aneurysm repair (FEVAR) is an alternative to open repair in patients with complex abdominal aortic aneurysms, who are neither fit nor suitable for standard open or endovascular repair. Chimney and snorkel grafts are other endovascular alternatives, but require upper extremity access that has been associated to a 3.2%-9.5% risk of stroke. However, because of the caudal orientation of the visceral vessels, upper extremity access is also frequently required for FEVAR. The purpose of this study was to assess the use of upper extremity access for FEVAR and associated morbidity.

Table. Outcomes by race-gender strata

<table>
<thead>
<tr>
<th>Race and Gender</th>
<th>Male (n = 474)</th>
<th>Female (n = 365)</th>
<th>Male (n = 2444)</th>
<th>Female (n = 1235)</th>
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</thead>
<tbody>
<tr>
<td>Major complications¹</td>
<td>0.95 (0.52, 2.22)</td>
<td>1.13 (0.68, 1.88)</td>
<td>1.10 (0.84, 1.70)</td>
<td>1.20 (0.84, 1.70)</td>
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<tr>
<td>Minor complications²</td>
<td>1.00 (0.34, 2.97)</td>
<td>0.97 (0.77, 1.22)</td>
<td>1.10 (0.94, 1.30)</td>
<td>1.10 (0.94, 1.30)</td>
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<tr>
<td>Death³</td>
<td>1.67 (0.91, 3.11)</td>
<td>0.87 (0.41, 1.83)</td>
<td>1.24 (0.79, 1.92)</td>
<td>1.24 (0.79, 1.92)</td>
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<tr>
<td>Graft failure⁴</td>
<td>3.00 (1.59, 5.63)</td>
<td>1.45 (0.47, 1.73)</td>
<td>1.32 (0.68, 2.16)</td>
<td>1.32 (0.68, 2.16)</td>
</tr>
<tr>
<td>Readmission⁵</td>
<td>1.32 (1.00, 1.74)</td>
<td>1.25 (0.96, 1.62)</td>
<td>1.10 (0.91, 1.34)</td>
<td>1.10 (0.91, 1.34)</td>
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<tr>
<td>Length of stay⁶</td>
<td>7.7 ± 9.0</td>
<td>7.1 ± 7.3</td>
<td>5.8 ± 5.1</td>
<td>5.7 ± 6.1</td>
</tr>
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¹Presented as hazard ratio (confidence interval) and [P-value] vs referent group.
²Presented as days ± standard deviation and [P-value] vs referent group.
Methods: During a 5-year period, 148 patients underwent EVAR. Upper extremity access for FEVAR was used in 98 (66.2%) patients. The median number of vessels fenestrated was 3 (interquartile range, 2-4), with a total of 457 vessels stented. Twelve were percutaneous (12.2%) and 86 (87.8%) were open. All patients that required a sheath size $\geq 7$ underwent high brachial open access, with the exception of 1 patient who underwent percutaneous axillary access with a 12F sheath. The median sheath size was 12F (interquartile range, 10-12), which was advanced into the descending thoracic aorta allowing multiple wire and catheter exchanges.

Results: One (1/98; 1.0%) hemorrhagic stroke in the upper extremity access group and one (1/54; 1.9%) ischemic stroke in the femoral-only access group occurred ($P = .87$). The stroke in the upper extremity access group occurred 5 days after FEVAR and was related to uncontrolled hypertension, whereas the stroke in the femoral group occurred on postoperative day 3. Neither patient had signs or symptoms of a stroke immediately after FEVAR. The right upper extremity was accessed six times without a stroke (0/6; 0%), compared with the left being accessed 92 times with one stroke (1/92; 1.1%) ($P = .8$). Four (4.1%) patients had complications related to upper extremity access; one (1.0%) required exploration for an expanding hematoma after manual compression for a 7F sheath, one (1.0%) required exploration for hematoma and neurologic symptoms after open access for a 12F sheath; and two (2.0%) patients with small hematomas did not require intervention. Two (2/12; 16.7%) of these complications were in the percutaneous access group, which were significantly more frequent than in the open group (2/86; 2.3%) ($P = .02$).

Conclusions: Upper extremity access appears to be a safe and feasible approach for patients undergoing FEVAR. Open exposure in the upper extremity may be safer than percutaneous access during FEVAR. Unlike chimney and snorkel grafts, upper extremity access during FEVAR is not associated with an increased risk of stroke, despite the need for multiple visceral vessel stenting.

Bedside Vena Cava Filter Placement Using Intravascular Ultrasound: A 5-Year Experience in Critically Ill Patients

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Objectives: Initial experience with a prospectively implemented algorithm for bedside vena cava filter placement with intravascular ultrasound (IVUS) has previously been shown to be a safe and effective technique especially for critically ill patients. The purpose of this study is to evaluate the effectiveness of IVUS guided filter placement in critically ill patients with experience now extending out 5 years from implementation.

Methods: All patients undergoing bedside IVUS-guided inferior vena cava (IVC) filter placement from 2008-2012 were identified. Records were reviewed based on IVC filter reporting standards. Outcome data including technical success, complications, and mortality were analyzed at 30 days.

Results: Three-hundred ninety-eight patients underwent bedside IVC filter placement with IVUS. Overall technical success was 97.9% with inability to place filter due to poor visualization (2), and malpositioned filters either above or below the intended infrarenal position (11). An optional filter (Gusten Tulip or Collect) was used in 374 (93.9%) and a permanent filter (Greenfield) in 26 (6.1%). Single puncture technique was performed in 388 (97.4%) with additional dual access required in 10 (2.6%). Periprocedural complications were rare (3.0%) and included malpositioning requiring retrieval and repositioning or additional filter (3), filter tilt $\geq 20^\circ$ (4), arteriovenous fistula (2), insertion site thrombosis (2), and hematoma (1). Comparison of the first and last 100 procedures in the sample population showed that there was a trend toward improved complication rates in the later experience (7.0% vs 2.0%; $P = .08$, respectively). There were no deaths related to pulmonary embolism or filter related problems.

Conclusions: Based on a 5-year experience with bedside IVC filter placement in critically ill patients, IVUS-guided filter techniques continue to be a safe and effective option in this high risk population with a time-dependent improvement in outcome measures.

C-Reactive Protein and Brain Natriuretic Peptide as Predictors of Adverse Events Following Lower Extremity Endovascular Revascularization

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Objectives: High sensitivity-C-reactive protein (CRP) and brain natriuretic peptide (BNP) have been shown to be independent predictors of adverse cardiovascular outcomes and potentially increased risk of secondary interventions or limb loss in patients with peripheral arterial disease (PAD). To assist clinicians in predicting postprocedure mortality and morbidity and decision-making regarding treatment approaches, we retrospectively examined patients with preprocedure CRP and BNP levels who underwent elective angioplasty and/or stent placement for lower extremity PAD.

Methods: The study period included patients treated between 2007 and 2012. Minimal required follow-up was at least one postoperative ankle brachial index or duplex imaging of the treated limb. Events of interest included clinical limb failure (loss of patency, target vessel revascularization, decrease in ankle brachial index $>0.15$ or limb amputation) by 1 year and MACE (stroke, myocardial infarction or death) by 2 years. Elevated/abnormal values for our biomarkers of interest were established by the upper limit of our institution’s clinical laboratory reference range hs-CRP (<80 mg/dl), BNP (<100 pg/ml).

Results: A total of 159 limbs in 118 patients were included in analysis (42% male, mean age 64 ± 11 years). All limbs were symptomatic (Rutherford classification, 2-5). Iliac artery revascularization without other adjunct lower extremity intervention was performed in 60% of the limbs. High CRP levels (>80 mg/dl) were present in 32 (27%) patients and high BNP values (>100 pg/ml) in 24 (20%) patients. Kaplan-Meier analysis with log-rank comparison demonstrated that elevated CRP levels associated with clinical limb failure but only in limbs receiving interventions distal to the external iliac artery ($P < .01$). High BNP levels did not affect limb failure (0.91). Conversely, high BNP levels associated with a statistically elevated MACE rate at 2 years of 36% vs 14% in patients with normal BNP levels ($P = .01$). Patients with high CRP tended toward having higher rates of MACE (33% vs 14%) but failed to meet statistical significance ($P = .053$). Patients with high preintervention values of CRP and BNP were 10.6 times (95% confidence interval, 2.6-42.6; $P < .01$) more likely to experience MACE than patients with normal CRP and BNP values.

Conclusions: Preprocedure biochemical markers in endovascular interventions for PAD can aide in predicting future limb related complications and late cardiovascular events. Potentially, improving biochemical markers prior to intervention could improve outcomes.

The Impact of Personality Type on Objective Ambulatory Measures in Patients with Intermittent Claudication

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Objectives: A type D (or distressed) personality is associated with negative affectivity and social inhibition and is an independent predictor of morbidity and mortality in patients with cardiac disease. There is little data on this personality type in patients with intermittent claudication (IC). The purpose of this study is to evaluate the difference in objective measures of ambulation in patients with IC stratified by personality type.

Methods: Over a 1-year period, routine history, and physical, ankle brachial index (ABI), and pulse volume recording were performed on IC patients. Questionnaires assessing personality type, psychosocial factors and perception of disease severity were recorded (Vascular Quality of Life, Walking Impairment Questionnaire, Hospital Anxiety and Depression Scale, Positive Health Expectations, and Type D Scale). A 6-minute walk test (6MWT) was performed measuring distance to symptoms, total distance