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

**Editors: Peter Gloviczki and Peter F. Lawrence**

## Antihypertensive medication adherence in chronic type B aortic dissection is an important consideration in the management debate

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**Objective:** Early aortic stenting in chronic type B aortic dissection (TBAD) may lead to long-term benefit, although the optimal treatment strategy is hotly debated. A robust comparison to outcomes seen in medically managed patients is challenging as the rate of antihypertensive medication adherence is unknown. The aims of this study were therefore to identify the rate of antihypertensive medication adherence and predictors of adherence in TBAD.

**Methods:** This was a cross-sectional mixed methods study of patients with TBAD. Medication adherence was assessed by the eight-item Morisky Medication Adherence Scale together with an assessment of demographic, behavioral, and psychological variables and disease-specific knowledge.

**Results:** There were 47 patients (mean age, 59 years; 81% male) who were recruited from a tertiary vascular unit. The mean total number of medications taken was 5.8 (2-14), and the mean number of antihypertensive medications was 1.9 (1-6). Of the 47 patients, 20 (43%) reported high levels of medication adherence, 17 (36%) reported moderate adherence, and 10 (21%) reported low adherence. Previous aortic surgery was associated with higher levels of adherence ($\beta$ = 0.332; $P$ = .03), as was taking a greater number of medications ($\beta$ = 0.332; $P$ = .026), perceived benefit from treatment ($\beta$ = 0.486; $P < .001$), good memory ($\beta$ = 0.579; $P < .001$), and low fears of side effects ($\beta$ = 0.272; $P < .014$).

**Conclusions:** Medical management remains the mainstay of treatment in uncomplicated TBAD; however, the majority of patients are poorly adherent to their antihypertensive medications. The merits of thoracic endovascular aortic repair in TBAD are argued, and poor adherence is an important factor in the debate; one cannot robustly compare two strategies when half of a treatment group may not be receiving the stated intervention. To develop an evidence-based treatment strategy for TBAD, we must take into account the direct and indirect effects of medical therapy and thoracic endovascular aortic repair. Further work to improve medication adherence and to understand its impact on disease progression is vital to inform the debate and to deliver the best outcomes for patients.

## Refinement of anatomic indications for the Nellix System for endovascular aneurysm sealing based on 2-year outcomes from the EVAS FORWARD IDE trial

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**Background:** The Nellix System (Endologix, Inc, Irvine, Calif) for endovascular aneurysm sealing (EVAS) is a novel approach to abdominal aortic aneurysm treatment and conceptually different from endovascular aneurysm repair, whereby polymer is employed to fill and actively manage the abdominal aortic aneurysm sac. One-year safety and effectiveness results of the Nellix pivotal trial demonstrated encouraging outcomes with very low morbidity and mortality and high procedural and treatment success. Two-year imaging revealed a signal of migration, leading to a field safety notification issued by the manufacturer on October 21, 2016, and a dedicated root cause analysis, resulting in refinements to the instructions for use (IFU). We report the 2-year results of the investigational device exemption pivotal trial stratified according to the new and original criteria for selection of patients.

**Methods:** Comprehensive engineering evaluations, statistical analyses, and clinical assessments were conducted looking at patients enrolled in the pivotal trial (N = 150), roll-in cohort (N = 29), and continued access program (N = 154). All patients in all cohorts were treated on-IFU at the time of enrollment. Logistic regression models supported the mechanism that migration with Nellix is associated with a small aortic flow lumen relative to a large aneurysm thrombus burden and large aortic neck diameters. Based on these findings, refinements to the IFU criteria were applied, excluding patients with a thrombus index (maximum aneurysm sac/maximum flow lumen diameter) >1.4, aortic neck diameter >28 mm, and aortic neck conicity (>10% diameter change along the infrarenal neck) and requiring a 10-mm distal seal zone in the iliac artery.

**Results:** Freedom from all-cause mortality at 2 years was 94%. Patient outcomes were then stratified on the refined morphologic criteria and analyzed retrospectively. Two-year freedom from composite endoleak was high among both cohorts (95% on-IFU vs 92% off-IFU). Freedom from

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migration was 97.7% on-IFU vs 93.2% off-IFU ($P$ = .0125). Freedom from aneurysm enlargement was 98.1% on-IFU vs 93.5% off-IFU ($P$ value is not available because of failure of log-rank test assumptions). Composite freedom from migration, type IA endoleak, or aneurysm expansion was 95.9% among the on-IFU cohort vs 85.1% in the off-IFU cohort ($P$ = .0017).

**Conclusions:** Consistent with the introduction of a novel therapy, the presentation of failure modes of EVAS over time was inevitable. Using detailed imaging as well as engineering and statistical analysis, we were able to understand risk factors for adverse events specific to EVAS and defined those patients best suited for Nellix. With this EVAS-specific approach to defining IFU, on-IFU patients were identified as those with large aneurysms with little thrombus that would be prone to type II endoleaks and sac expansion with traditional devices. When treated with Nellix, these patients were predicted to experience exceptional results, especially with regard to a low composite endoleak rate and low all-cause mortality.

## Regional variation in patient outcomes in carotid artery disease treatment in the Vascular Quality Initiative

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**Objective:** Quality metrics were developed to improve outcomes after carotid artery revascularization; however, few studies have evaluated regional differences in perioperative outcomes. This study aimed to evaluate regional variation in mortality and perioperative outcomes after carotid endarterectomy (CEA) and carotid artery stenting (CAS).

**Methods:** We identified all patients who underwent CEA or CAS from 2009 to 2016 in the Vascular Quality Initiative. Patients were analyzed on the basis of their symptom status. We assessed variation in perioperative outcomes using $\chi^2$ analysis, Fisher exact test, and $t$-test, where appropriate.

**Results:** A total of 78,467 carotid interventions were identified; 85% were CEAs, with 69% of those asymptomatic. Within CAS, 39% were asymptomatic. Perioperative stroke/death varied across regions within both CAS groups (asymptomatic, 0%-5.8% [$P$ = .03]; symptomatic, 2.4%-8.1% [$P$ = .1]), and several regions did not meet the American Heart Association (AHA) guidelines of 3% for asymptomatic patients and 6% for symptomatic patients, which persisted after risk adjustment. For CEA, the stroke/death rates fell within the standards set by the AHA guidelines in all regions for both the unadjusted and risk-adjusted models; however, there was significant regional variation in the cohorts (asymptomatic, 0.9%-3.1% [$P < .01$]; symptomatic, 1.3%-4.9% [$P < .01$]). Variation in 30-day mortality was significant in symptomatic patients (asymptomatic: CEA, 0%-1.3% [$P$ = .2], CAS, 0%-2.4% [$P$ = .2]; symptomatic: CEA, 0%-1.8% [$P < .01$], CAS, 0%-4.6% [$P$ = .01]). Rates of in-hospital stroke, postoperative myocardial infarction, prolonged length of stay (>2 days), and use of intravenous blood pressure medications all varied significantly across the regions. After CEA, there was significant variation in the rates of cranial nerve injuries (asymptomatic, 0.9%-4.9% [$P < .01$]; symptomatic, 1.5%-7.7% [$P < .01$]), return to the operating room (asymptomatic, 0.9%-3.4% [$P < .01$]; symptomatic, 0.6%-3.4% [$P$ = .02]), and discharge on antiplatelet and statin (asymptomatic, 75%-87% [$P < .01$]; symptomatic, 78%-91% [$P < .01$]). After CAS, significant variation was found in the rates of access site complications (asymptomatic, 2.3%-18.2% [$P < .01$]; symptomatic, 1.4%-16.9% [$P < .01$]) and discharge on dual antiplatelet therapy (asymptomatic, 79%-94% [$P < .01$]; symptomatic, 83%-93% [$P < .01$]).

**Conclusions:** Unwarranted regional variation exists in outcomes after carotid artery revascularization across the regions of the VQI. Significant variation was seen in a number of outcomes for which quality metrics currently exist, such as length of stay and discharge medications. In addition, after CAS, several regions failed to meet the AHA guidelines for stroke and death. Given these results, quality improvement projects should be targeted to improve adherence to current guidelines to promote best practices.

## Persistent symptom relief after revascularization in patients with single-artery chronic mesenteric ischemia

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**Objective:** An isolated stenosis of the celiac artery (CA) or the superior mesenteric artery (SMA) is frequently detected in patients with abdominal complaints. The dilemma is whether these patients suffer from chronic mesenteric ischemia (CMI) and whether they will benefit from revascularization. We evaluated the long-term clinical success rates for single CA or SMA revascularization in patients with gastrointestinal symptoms and confirmed mucosal ischemia.

**Methods:** This was a retrospective cohort analysis of 59 consecutive patients with gastrointestinal symptoms and a single atherosclerotic mesenteric artery stenosis who were referred to our tertiary care institution between 2006 and 2010 for standardized diagnostic workup of CMI, including measurement of mucosal ischemia with visible light spectroscopy or gastric-jejunal tonometry. Patients with multidisciplinary consensus diagnosis of CMI underwent surgical or endovascular revascularization. The primary outcome was clinical response to revascularization, defined as relief of presenting symptoms as experienced by the patient.

**Results:** Consensus diagnosis of CMI was obtained in 37 of 59 patients. Isolated CA stenosis was present in 30 of 37 patients (81%) and isolated SMA stenosis in seven patients. After a mean follow-up of 5.0 ± 3.0 years, 27 of 37 patients (73%) experienced sustained symptom relief after revascularization. Response was not related to lesion localization (CA, 73%; SMA, 71%; $P$ = .919).