VIVA 16 TODAY
TUESDAY, SEPTEMBER 20, 2016 @VIVAPHYSICIANS #VIVAPVD

Late-Breaking Trials: Embargoed Until 9:10 AM PST

HIGHLIGHTS FROM TODAY'S TRIAL PRESENTATIONS.

ENDOVASCULAR REPAIR IN ACUTE, COMPLICATED TYPE B AORTIC DISSECTION: 3-YEAR RESULTS FROM THE VALIANT US-IDE STUDY

Presenter: Ali Azizzadeh, MD

Acute type B aortic dissection complicated by malperfusion or contained rupture carries a high risk of spontaneous death. Patients with acute, complicated type B aortic dissections are reported to have a > 50% likelihood of dying from this disease.

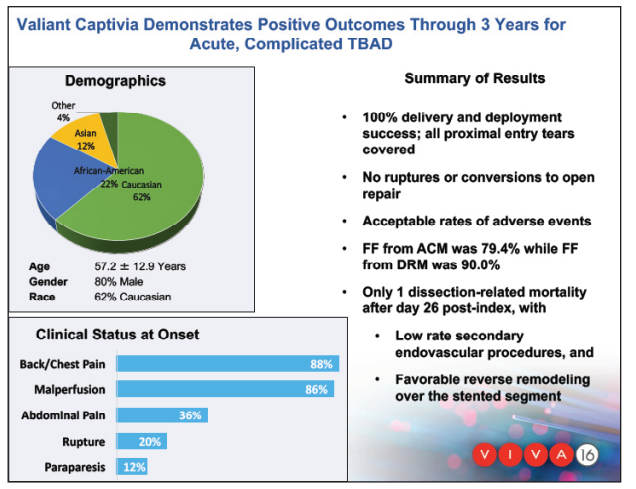
Between June 2010 and May 2012, patients with acute, complicated type B aortic dissection at 16 clinical sites in the United States were included in the Medtronic DISSECTION US IDE trial, a multicenter, prospective, nonrandomized, pivotal trial with planned 5-year follow-up. The primary safety endpoint was all-cause mortality within 30 days from the index procedure.

The 3-year results of endovascular treatment with the Valiant Captivia thoracic stent graft (Medtronic) in acute, complicated type B aortic dissection patients were reported at VIVA.

Fifty patients were enrolled. At 3 years, 32 patients were eligible for follow-up, with 28 patients completing their 3-year follow-up (87.5%). Through 3 years, there have been no postindex ruptures or conversions to open surgical repair reported in the Medtronic DISSECTION US-IDE trial.

At 3 years, true lumen diameter over the stented region (or endograft segment) remained stable or increased in 92.3% of patients, false lumen diameter remained stable or decreased in 69.3%, and the false lumen was partially or completely thrombosed in 75% of patients.

One death occurred between years 2 and 3; the cause of death was sepsis and adjudicated by the clinical events committee as unrelated to the device, the procedure, or the dissection (death occurred on postindex procedure day 812). Through 3 years, freedom from all-cause mortality was 79.4%, while freedom from dissection-related mortality was 90%. Only one dissection-related mortality has occurred between days 27 and 3 years of follow-up.



Midterm results of the Valiant thoracic stent graft in the treatment of acute, complicated type B aortic dissection are encouraging. Longer-term outcomes are needed to assess the durability of TEVAR in this indication.

FAST-TRACK ENDOVASCULAR AORTIC REPAIR: RESULTS FROM THE PROSPECTIVE LIFE REGISTRY

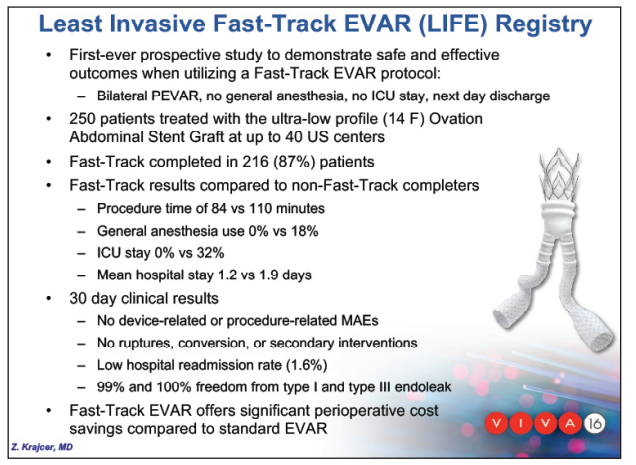
Presenter: Zvonimir Krajcer, MD, FACC

The Least Invasive Fast-Track EVAR (LIFE) study is a prospective, nonrandomized, postmarket registry designed to demonstrate the clinical and cost benefits associated with the ultra–low-profile (14-F) Ovation Prime abdominal stent graft platform (Endologix, Inc.) under the least invasive conditions defined in the fast-track endovascular aneurysm repair (EVAR) protocol. Successful completion of the fast-track EVAR protocol required bilateral percutaneous access, avoidance of general anesthesia and intensive care unit admission, and next-day discharge.

The study enrolled 250 eligible patients treated electively at up to 40 centers in the United States. In 250 patients, vascular access, stent graft delivery, and stent graft deployment were successful. Bilateral percutaneous access was achieved in 97% of cases. The fast-track EVAR protocol was successfully completed in 216 (87%) patients. Comparing the fast-track cohort (n = 216) to the non–fast-track cohort (n = 34), procedure time was 84 versus 110 minutes, use of general anesthesia was 0% versus 18%, need for intensive care unit stay was 0% versus 32%, and hospital stay was 1.2 versus 1.9 days.

Patients were followed through 1 month after treatment. No device- or procedure-related major adverse events, abdominal aortic aneurysm (AAA) ruptures, surgical conversions, or AAA-related secondary interventions were reported in the study. One (0.9%) patient in the fast-track group died from acute respiratory failure. Freedom from type I/III endoleak was 99% and 100%, respectively.

A cost-utility analysis compared fast-track EVAR to an EVAR control group of 8,306 patients identified from a contemporary inpatient discharge database. Completion of the fast-track protocol was associated with over $21,000 in perioperative cost savings relative to standard EVAR, largely driven by differences in hospital stay costs. Additionally, the 30-day hospital readmission rate in the LIFE study was 1.6% compared to 8% reported for EVAR from the American College of Surgeons National Surgical Quality Improvement Program.



Fast-track EVAR using the Ovation Prime stent graft is feasible, safe, and lowers perioperative costs. Results warrant establishment of a fast-track EVAR protocol in experienced EVAR centers.

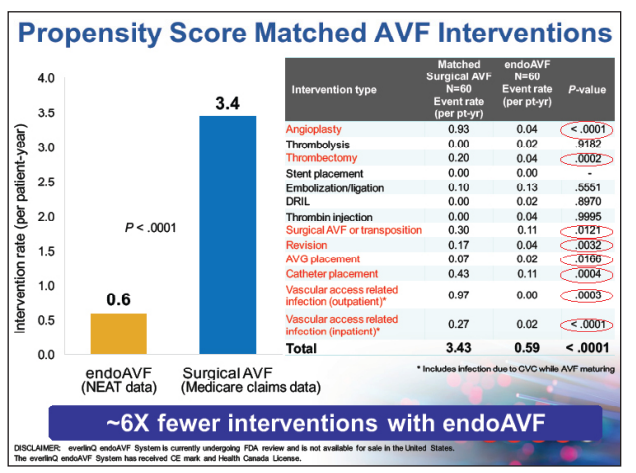
ARTERIOVENOUS FISTULA POST-CREATION INTERVENTIONS: COMPARISON BETWEEN TRADITIONAL SURGICAL AVF CREATION AND A NEW ENDOVASCULAR APPROACH

Presenter: Charmaine E. Lok, MD, FRCPC

Arteriovenous fistulas (AVFs) are the guideline-recommended hemodialysis vascular access. However, AVFs created by traditional surgery (sAVF) are challenged by high failure rates. Post-creation interventions are often required to facilitate maturation and maintain function. This study compared AVF post-creation interventions between patients undergoing sAVF creation and a new endovascular AVF (endoAVF).

Medicare Standard Analytical Files were used to determine patient demographic and clinical characteristics and identify and determine rates of sAVF post-creation interventions in patients with sAVF created from 2011 to 2013. Rates of post-creation interventions per patient-year were determined based on patients' outpatient and physician claims during specified follow-up. Demographics and clinical information for patients with endoAVF were obtained from the single-arm Novel Endovascular Access Trial (NEAT) performed in Canada, Australia, and New Zealand. The technology used is not available in the United States and is pending US Food and Drug Administration review. Propensity score analysis was used to match key demographic and clinical characteristics between Medicare and NEAT patients (n = 60) in a 1:1 ratio.

Balance in all baseline demographic and clinical characteristics was successfully achieved via propensity score matching of 60 Medicare patients to NEAT patients. The overall rate of interventions in the matched sAVF cohort was higher than for the endoAVF cohort (3.4 vs 0.6 per patient-year; $P < .0001$). The associated average annual costs were less with endoAVF by an estimated $11,240 compared with matched sAVF. Compared to the matched sAVF cohort, the endoAVF cohort had lower event rates for angioplasty (0.04 vs 0.93), thrombectomy (0.04 vs 0.20), embolization/ligation of vein (0.13 vs 0.1), revision (0.04 vs 0.17), new AVF or transposition (0.11 vs 0.30), catheter placement (0.11 vs 0.43), vascular access-related infection (0.02 vs 1.23), and arteriovenous graft placement (0.02 vs 0.07).



In this propensity-score matched comparison, after AVF creation, patients with endoAVF required fewer interventions and had fewer health care costs than patients treated with sAVF.

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TWO-YEAR RESULTS FROM THE MAJESTIC TRIAL OF THE ELUVIA DRUG-ELUTING VASCULAR STENT SYSTEM

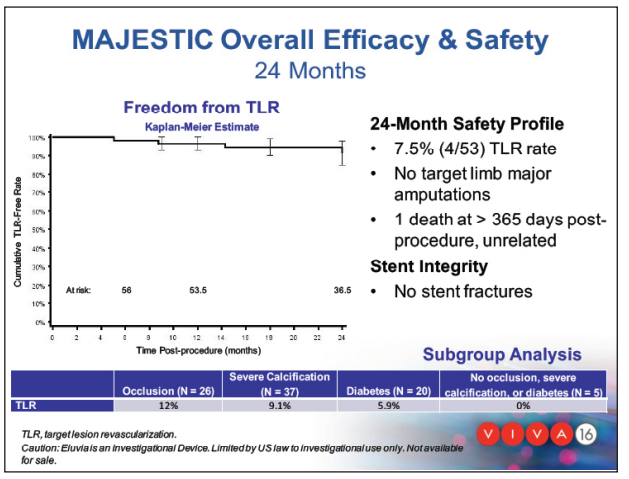
Presenter: Stefan Müller-Hülsbeck, MD

The Eluvia drug-eluting vascular stent system (Boston Scientific Corporation) is composed of the Innova self-expanding nitinol stent platform with a fluoropolymer-paclitaxel coating. The MAJESTIC clinical study was designed to evaluate the performance of the Eluvia stent for treating femoropopliteal artery lesions up to 110 mm in length. MAJESTIC is a prospective, single-arm clinical trial with investigative sites in Europe, Australia, and New Zealand.

Safety and efficacy measures have now been evaluated through 2 years of follow-up. Only four patients had target lesion revascularizations (TLRs), for a 24-month freedom from TLR rate of 92.5%. No major target limb amputations have occurred. At the 24-month follow-up visit, 91% (48/53) of patients presented with no symptoms or minimal claudication (Rutherford category 0–1). No stent fractures have been identified through 24 months upon core lab analysis. Among patients with severe calcification (n = 37), occlusion (n = 26), or diabetes (n = 20) at baseline, the 24-month TLR rates were 9.1%, 12%, and 5.9%, respectively.

Eligible patients had chronic lower limb ischemia and de novo or restenotic lesions in the native superficial femoral artery and/or proximal popliteal artery. Mean age (± SD) of the patients (N = 57) was 69 ± 9 years; 35% had diabetes. At baseline, 35% of patients had symptoms classified as Rutherford category 2, 61% were classified as category 3, and 4% as category 4. Mean lesion length was 70.8 ± 28.1 mm, 65% had severe calcification, and 46% of lesions were occluded.

MAJESTIC results showed that patients whose femoropopliteal arteries were treated with the Eluvia drug-eluting stent, including those with challenging baseline characteristics, sustained a high rate of clinical improvement, a good safety profile, and a low reintervention rate through 24 months.



TWO-YEAR RESULTS OF PACLITAXEL-COATED BALLOONS FOR LONG FEMOROPOPLITEAL ARTERY DISEASE: EVIDENCE FROM THE SFA-LONG STUDY

Presenter: Antonio Micari, MD, PhD

The SFA-Long study is an independent, prospective, multicenter, single-arm study to evaluate outcomes with the In.Pact Admiral paclitaxel-coated balloon (PCB) (Medtronic) in the treatment of long (TASC C and D) femoropopliteal artery disease.

Consecutive patients with Rutherford class 2 to 4 disease due to femoropopliteal lesions > 15 cm long and with 4- to 7-mm reference vessel diameter were prospectively enrolled in a multicenter study. The primary study endpoint was primary patency at 12 months. Secondary endpoints included major adverse events (the composite of death, amputation, or clinically driven target lesion revascularization [CD-TLR]), changes in Rutherford class, ankle-brachial index, and quality of life 12 months after the procedure.

A total of 105 patients (mean age, 68 ± 9 years; 81.9% male) were enrolled and treated with the PCB. The mean lesion length treated was 251.71 ± 78.9 mm, including 50.4% moderate to severely calcified lesions and 49.5% total occlusions. The bailout stent rate was 10.9%. Follow-up after 24 months was obtained in 93 (88.5%) patients. Primary patency rate at 24 months was 70.4%. By Kaplan-Meier estimate, patency in patients with stenotic versus occlusive lesions was 74% versus 68% (*P* = .42), respectively. No significant differences were observed in patency between long lesions (< 25 cm) and very long lesions (> 25 cm) (75% vs 66%; *P* = .25) at 24 months. Freedom from CD-TLR was 84.7%. Significant clinical benefits in Rutherford class and functional measures by WIQ score were seen through 24 months.

Two-year results demonstrate durable safety and efficacy outcomes with the In.Pact Admiral PCB in patients with long femoropopliteal artery disease.