Methods: This was a prospective, single arm, multicenter trial conducted at 26 sites in the US. From April 2008 to May 2009, 150 patients with AAA were treated with the Endurant bifurcated stent graft. The main inclusion criteria were an AAA diameter >5 cm, proximal neck length >10 mm, bilateral iliac fixation length >15 mm, and a neck angulation of >60 degrees. A clinical events committee (CEC) adjudicated all adverse events except blood loss, and a core laboratory reviewed all imaging. The primary safety endpoint was freedom from major adverse events at 30 days, and the primary effectiveness endpoint was successful aneurysm treatment at 12 months.

Results: One hundred forty-nine patients (99.3%) had a successful stent graft implant, 83.3% under general anesthesia. One failure was due to inability to cannulate the contralateral gate. One patient developed a neck rupture during the procedure, but was still treated successfully. Patients were predominantly male (91.3%), elderly (mean age, 73.1 years) with significant comorbidities. Mean estimated blood loss was 185 mL (range, 0-1450 mL), with blood transfusion required in one patient. Average hospital stay was 2.1 days. At 1 month, the major adverse events rate was only 4% with no operative mortality. Serious adverse events were recorded in 43 of 150 (28.7%) patients. Cardiac (8.7%), fever (6%), urological (4.7%), pulmonary (4%), and vascular events (4%) were the most frequent. Through 12 months of follow up, there were no migrations, ruptures, or conversions. No type I or III endoleaks were identified during the first year. Fifteen of 129 patients (11.6%) had endoleaks at 6 months and 13 of 130 (10%) at 1 year, all type II except for one indeterminate endoleak. One Type II endoleak proved to be a Type IB on later angiography. Ten aneurysm related reinterventions were performed during the first year of follow up, mostly for limb thrombosis or stenosis (5) or for type II endoleak (2). Four of the procedures were endovascular.

One year outcomes of the United States regulatory trial of the Endurant Stent Graft System
Michel S. Makaroun, Michael Tuchek, Doug Massop, John Henretta, Robert Rhee, Clifford Buckley, Manish Mehta, Sharif Ellozy, for the Endurant US Pivotal Trial Investigators

Objective: To report the 1-year outcomes of the United States (US) regulatory trial of the Endurant Stent Graft System (Medtronic Vascular), a new device for the treatment of abdominal aortic aneurysms (AAA).

Methods: This was a prospective, single arm, multicenter trial conducted at 26 sites in the US. From April 2008 to May 2009, 150 patients with AAA were treated with the Endurant bifurcated stent graft. The main inclusion criteria were an AAA diameter >5 cm, proximal neck length >10 mm, bilateral iliac fixation length >15 mm, and a neck angulation of >60 degrees. A clinical events committee (CEC) adjudicated all adverse events except blood loss, and a core laboratory reviewed all imaging. The primary safety endpoint was freedom from major adverse events at 30 days, and the primary effectiveness endpoint was successful aneurysm treatment at 12 months.

Results: One hundred forty-nine patients (99.3%) had a successful stent graft implant, 83.3% under general anesthesia. One failure was due to inability to cannulate the contralateral gate. One patient developed a neck rupture during the procedure, but was still treated successfully. Patients were predominantly male (91.3%), elderly (mean age, 73.1 years) with significant comorbidities. Mean estimated blood loss was 185 mL (range, 0-1450 mL), with blood transfusion required in one patient. Average hospital stay was 2.1 days. At 1 month, the major adverse events rate was only 4% with no operative mortality. Serious adverse events were recorded in 43 of 150 (28.7%) patients. Cardiac (8.7%), fever (6%), urological (4.7%), pulmonary (4%), and vascular events (4%) were the most frequent. Through 12 months of follow up, there were no migrations, ruptures, or conversions. No type I or III endoleaks were identified during the first year. Fifteen of 129 patients (11.6%) had endoleaks at 6 months and 13 of 130 (10%) at 1 year, all type II except for one indeterminate endoleak. One Type II endoleak proved to be a Type IB on later angiography. Ten aneurysm related reinterventions were performed during the first year of follow up, mostly for limb thrombosis or stenosis (5) or for type II endoleak (2). Four of the procedures were endovascular.

Conclusion: Early results of the Endurant pivotal trial are quite encouraging and suggest a safe and effective new device for the treatment of abdominal aortic aneurysms.

Frequency, risk factors, and management of perigraft seroma after open abdominal aortic aneurysm repair

Objective: Perigraft seroma (PGS) causing enlargement of the native aneurysm sac after open abdominal aortic aneurysm (AAA) repair is a rarely recognized complication with unknown clinical consequences. This study was undertaken to determine the frequency of PGS, identify associated risk factors, and review resulting complications and their management strategies.

Methods: Charts of all patients who underwent open AAA repair at our institution from 1995 to 2009 and had at least one postoperative abdominal cross-sectional imaging study (the study subjects) were retrospectively reviewed. PGS was defined as a perigraft fluid collection present >3 months postoperatively, >3-cm in diameter and having a radiodensity <25 Hounsfield units on computed tomography (CT). Patient records were reviewed for demographics, comorbidities, operative and postoperative variables, and long-term outcome.
Risk factors, outcomes, and clinical manifestations of spinal cord ischemia following thoracic endovascular aortic repair
Brant W. Ullery, Albert T. Cheung, Ronald M. Fairman, Benjamin M. Jackson, Edward Y. Woo, Joseph Bavaria, Alberto Pochettino, Grace J. Wang

Objective: The purpose of this study was to assess the incidence, risk factors, and clinical manifestations of spinal cord ischemia (SCI) after thoracic endovascular aortic repair (TEVAR).

Methods: A retrospective review of a prospectively collected database was performed for all patients undergoing TEVAR at a single academic institution between July 2002 and June 2010. Preoperative demographics, procedure-related variables, and clinical details related to SCI were examined. Logistic regression analysis was performed to identify risk factors for the development of SCI.

Results: Of the 424 patients who underwent TEVAR during the study period, 12 patients (2.8%) developed SCI. Mean age of this cohort with SCI was 69.6 years (range, 44-84 years), and 7 were women. One-half of these patients had prior open or endovascular aortic repair. Indication for surgery was either degenerative aneurysm (n = 8) or dissection (n = 4). Six TEVARs were performed electively, with the remaining done either urgently or emergently due to contained rupture (n = 2), dissection with malperfusion (n = 2), or severe back pain (n = 2). All 12 patients underwent extent C endovascular coverage. Multivariate regression analysis demonstrated chronic renal insufficiency to be independently associated with SCI (odds ratio [OR], 4.39; 95% confidence interval [CI], 1.2-16.6; P = .029). Onset of SCI occurred at a median of 10.6 hours (range, 0-229 hours) postprocedure and was delayed in 83% (n = 10) of patients. Clinical manifestations of SCI included lower extremity paraesthesia in 9 patients and paraplegia in 3 patients. At SCI onset, average mean arterial pressure (MAP) and lumbar cerebrospinal fluid (CSF) pressure was 77 mm Hg and 10 mm Hg, respectively. Therapeutic interventions increased blood pressure to a significantly higher average MAP of 99 mm Hg (P = .001) and decreased lumbar CSF pressure to a mean of 7 mm Hg (P = .001) at the time of neurologic recovery. Thirty-day mortality was 8% (1 of 12 patients). The single patient who expired, never recovered any lower extremity neurologic function. All patients surviving to discharge experienced either complete SCI (n = 9) or incomplete SCI (n = 2) neurologic recovery. At mean follow-up of 49 months, 7 of 9 patients currently alive continued to exhibit complete, sustained neurologic recovery.

Conclusion: Spinal cord ischemia after TEVAR is an uncommon, but important complication. Preoperative renal insufficiency was identified as a risk factor for the development of SCI. Early detection and treatment of SCI with blood pressure augmentation alone or in combination with CSF drainage was effective in most patients, with the majority achieving complete, long-term neurologic recovery.
Objective: Previous observational studies suggest that children with hand ischemia following elbow trauma can be safely observed if Doppler signals present in the wrist arteries (pink pulseless hand, PPH). Nonoperative management of PPH is predicated on the assumption that PPH results from local arterial spasm, but the mechanism of arterial compromise has not been investigated. We hypothesized that PPH signifies a brachial artery injury that requires surgical repair.

Methods: Retrospective review of operations performed on children with hand ischemia following elbow trauma at a level I trauma center pediatric hospital.

Results: Between 2003 and 2010, 12 children (seven males, mean age 7.4 years) underwent brachial artery exploration for hand ischemia following elbow trauma (11 supracondylar fractures, one elbow dislocation) due to falls (n = 10) or motor vehicle crashes (n = 2). At presentation, three subjects had normal radial pulses, eight subjects had Doppler signals but no palpable pulses, and one had weak Doppler flow with advanced hand ischemia. Six of the nine subjects without palpable pulses also had neurosensory changes. All 12 subjects underwent brachial artery exploration either initially (n = 2) or following orthopedic fixation (n = 10) due to persistent pulselessness. At operation, eight of 12 patients (67%) had focal brachial artery thrombosis due to intimal flaps, and four had brachial artery and median nerve entrapment within the pinned fracture site. At discharge, all 12 subjects had palpable radial pulses, but three with entrapment had dense median nerve deficits. One of the three subjects with dense neurologic deficit had complete recovery of neurologic function at ten months. The other two subjects had residual median nerve deficits with partial recovery at 3 and 6 months follow-up, respectively. No patient developed Volkmann’s contracture.

Conclusions: Brachial artery injuries should be anticipated in children with hand ischemia associated with elbow trauma. Neurovascular entrapment at the fracture site is a possible complication of orthopedic fixation. Absence of palpable wrist pulses after orthopedic fixation should prompt immediate brachial artery exploration. PPH should not be considered a consequence of arterial spasm in these patients.

Resident and fellow experiences after the introduction of endovascular aneurysm repair for abdominal aortic aneurysm

Teviah Sachs, Marc Schermerhorn, Frank Pomposelli, Philip Cotterill, James O’Malley, Bruce Landon

Objectives: This study assessed trends in open and endovascular repair (EVAR) of intact and ruptured abdominal aortic aneurysm (AAA) in the Medicare population and evaluated recent trends in AAA repair at vascular fellowship training programs.

Methods: We identified all Medicare beneficiaries with a diagnosis of AAA who underwent repair or had a primary diagnosis of rupture (1995-2008). Cohorts were compared by type of repair (open vs EVAR) and presentation (intact vs ruptured AAA). Demographics of age, sex, and race were evaluated. We used unique hospital identifier codes to compare trends and 30-day mortality between hospitals that participate in vascular surgery fellowship training and those that do not. American Council on Graduate Medical Education data, only available for the years 1999 to 2008, were further used to better understand the changes in number of EVAR and open repairs of AAA performed each year for vascular fellows and general surgery residents, over time.

Results: We identified 449,122 patients (76% men), with 376,355 intact AAAs (84%) and 72,767 ruptured AAAs (16%). Mean age was 75.1 years. Use of EVAR for intact AAA rose to from 35% in 2001 to 63% in 2005 and comprised 78% of repairs by 2008. During the same period, the number of ruptured AAAs decreased by 40% overall, with nonoperative ruptured AAAs decreasing by 29% and EVAR increasing to 31% of rupture repairs. Hospitals training vascular fellows were quicker to adopt EVAR (2-year lag time) for intact AAA and had higher rates of EVAR for ruptured AAA (41.1% vs 29.2%; P = .001) than did hospitals without fellows. Mortality rates for open repairs of intact (4.0% vs 5.0%; P = .001) and ruptured AAA (34.1% vs 41.0%; P = .031) were lower at fellowship hospitals. The average number of open AAA repairs performed by vascular fellows dropped 50% (44.1 to 21.6/year) from 1999 to 2008.

Conclusions: Contrary to the expectation of a plateau, use of EVAR for intact AAA continues to rise at fellowship and nonfellowship hospitals. Use of EVAR for rupture is being used more often at fellowship programs. The decline in open repairs performed by vascular fellows, and at fellowship and non-fellowship hospitals, may have important implications for future attending experience.