Novel Approaches to Endovascular Management of Aortic Aneurysms

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Anatomy of the Aorta

Ascending aorta (aortic arch)
Heart
Kidney
Thoracic aorta
Abdominal aorta
Iliac artery

Advances In Vascular Imaging
**Advanced Vascular Imaging**

**CT Angiography**
- Maximum-intensity projection (MIPs)
  - Angiographic like representation
- Volume rendering
  - Preserves depth information
- Multi-planar reformat
- Curved planar reformat (CPR)
  - Perpendicular to median arterial centerline

**MR Angiography**
- Traditional: Time of flights
- Contrast-enhanced MRA
  - Improves speed of exam, anatomic coverage, and small-vessel resolution
- Time-resolved gadolinium enhanced sequences
  - Time-resolved imaging of contrast kinetics (TRICKS)
  - Provides angiographic like dynamic contrast passage
- Moving-table technique or multi-array, parallel-imaging
  - Optimize large field-of-view imaging

**INTRAVASCULAR ULTRASOUND**

- **B-Mode**
  - Mechanical rotating crystal
  - Eccentric over wire (wire artifact)

- **Phase Array**
  - Electronically rotating signal
  - Concentric over wire
  - Color Flow
Room Setup: High Resolution Imaging
Endovascular Aortic Procedures

Advances In Vascular Interventions

- Open Surgical repair developed in 1950s - dramatically changed (launched) modern vascular surgery and cardiovascular techniques
- Introduction of endovascular techniques, and particularly endografts in the early 1990s
Operative Mortality
30 day all-cause death

- Endograft (IDE) 1.7%
- Surgical control 1.4% (ns)
- Endograft (PMS) 1.2%
- Endograft (n=2908) 1.7%
Secondary Interventions

- 10 – 15% reintervention at 5yrs with both conventional surgery and endovascular repair
- 10 – 35% mortality with repeat surgeries for complications of conventional surgeries
- 2 – 3% mortality for secondary endovascular procedures
- Endovascular repair possible in a percentage of patients requiring intervention after conventional surgery
Endovascular abdominal aortic aneurysm repair: Long-term outcome measures in patients at high-risk for open surgery

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Purpose: The study was conducted to determine the outcome in the United States after endovascular repair (EVAR) of infrarenal abdominal aortic aneurysms (AAA) in patients at high-risk for open surgery by using independently audited, high-compliance, chart-verified data sets, and to compare those results with open surgery.

Methods: High-risk was defined as more than 80 years old, male gender, history of major coronary artery disease, New York Heart Association class III or IV, posteroanterior chest x-ray showing oxygen saturation <95%, and history of aortic thrombosis. EVAR, was performed in 122 patients, the mean age was 76 years. Primary outcome comparisons included AAA-related death, all-cause death, and aneurysm rupture. Secondary measures were endoleak, AAA sac enlargement, and migration.

Results: Average age of the high-risk EVAR subset was 76 ± 7 years vs 74 ± 6 years OPEN (P = 0.07), mean EVAR AAA size was 6.4 ± 0.8 cm vs 6.6 ± 1.0 cm OPEN (P = .33), and average EVAR follow-up was 2.7 years vs 2.5 years OPEN. The 30-day operative mortality was 3.3% in EVAR vs 5.3% in OPEN (P = .32). The AAA-related death rate after EVAR was 3.0% at 1 year and 4.2% at 4 years compared with 8.1% at both time points after OPEN (P = .58). Overall survival at 4 years after EVAR was 86% vs 96% in OPEN (P = .23). After stent-grafting, EVAR successfully prevented rupture in 92.5% in 1 year and in 97.2% at 4 years.

Conclusions: Endovascular repair of large infrarenal AAs in anatomically suited high-surgical-risk patients using FDA-approved devices in the United States is safe and provides lasting protection from AAA-related mortality. EVAR mortality remained comparable with OPEN up to 4 years. The decision to treat AAs in patients with advanced age and significant comorbidity must be individualized and carefully considered, but repair provides excellent protection from AAA-related death. (J Vasc Surg 2008...)

Appropriate Informed Consent For Aortic Endograft Patients

- 2% risk of conversion to conventional repair at 5 yrs
- Reduces risk of aneurysm rupture to 1% at 5 yrs (similar to open repair)
- 10% reintervention rate at 5yrs (most for treatment of endoleak ie., catheter embolization or cuff addition)

-similar reintervention rate to open surgery with reduced morbidity and mortality for catheter procedures compared to open surgery
Endovascular repair of ruptured infrarenal abdominal aortic aneurysm is associated with lower 30-day mortality and better 5-year survival rates than open surgical repair

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Objective: Endovascular aneurysm repair (EVAR) decreases 30-day mortality for patients with ruptured abdominal aortic aneurysms (r-AAA) compared with open surgical repair (OSR). However, which patients benefit or whether there is any long-term survival advantage is uncertain.

Methods: From 2002 to 2011, 283 patients with r-AAA underwent EVAR (n = 120 [42.4%]) or OSR (n = 163 [57.6%]) at Albany Medical Center. All data were collected prospectively. Patients were analyzed on an intention-to-treat basis, and outcomes were evaluated by a logistic regression multivariable model. Kaplan-Meier analysis was used to compare long-term survival.

Results: The EVAR patients had a significantly lower 30-day mortality than did the OSR patients (29/120 [24.2%] vs 72/163 [44.2%]; P < .005) and better cumulative 5-year survival (37% vs 20%; P < .005). Men benefited more from EVAR (mortality: 20.9% for EVAR vs 44.3% for OSR; P < .001) than did women (mortality: 32.4% vs 43.9%; P = .39). Age ≥80 years was a significant predictor of death for EVAR (odds ratio [OR], 1.07; P = .001) but not for OSR (OR, 1.04; P = .98). Preexisting hypertension was a significant predictor of survival for both EVAR (OR, 0.17; P < .001) and OSR (OR, 0.4; P = .021). Almost one fourth of EVAR patients (21/91 [23.1%]) required secondary interventions. Survival advantage was maintained for EVAR patients to 5 years.

Conclusions: For r-AAA, EVAR reduces the 30-day mortality and improves long-term survival up to 5 years. However, whereas open survivors require few graft-related interventions, up to 23% of EVAR patients will require reintervention for endoleaks or graft migration. Close follow-up of all EVAR survivors is mandatory. (J Vasc Surg 2013;57:368-75.)

Endograft Exclusion of Ruptured AAA

- 2002-2011, 283 patients with ruptured AAA
  - 163 open repair
  - 120 EVAR
- 30 day mortality lower with EVAR 24% compared to open 42%
- Also better cumulative 5 yr survival (37% vs 26%)
- 23% 2ndary interventions with EVAR

Aortic aneurysm in females

About 1 in 5 AAAs rupture. It is often not until an aneurysm ruptures or grows large enough to press on nearby parts of the body or block blood flow that it produces any signs or symptoms. Most abdominal aortic aneurysms (AAAs) develop slowly over years and have no signs or symptoms until (or if) they rupture.

Aortic Aneurysm - WomenHeart: The National Coalition for Women ...

www.womenheart.org/?page=SupportAortic_Aneur

People also ask

What size aortic aneurysm requires surgery?

Abdominal aortic aneurysm. In men, repair is typically recommended for abdominal aortic aneurysms that are causing symptoms, are growing rapidly, or that are 5.5 cm or larger in diameter. In women, repair may be recommended for smaller aneurysms.

Aortic Aneurysm-Surgery - WebMD

www.webmd.com/heart-disease/aortic-aneurysm-surgery
ENDOGRAFTS FOR THORACIC AORTIC PATHOLOGIES
Devices

Talent TAI TX2 Valiant

Descending Thoracic Aortic Aneurysms (DTA)
Penetrating Ulcers & Intramural Hematomas
Pre-deployment

3 days post

1 mo post

Traumatic Transections
Estimated 7500 – 8000 per year (most die immediately)

40% mortality in hospital
- moribund on arrival 100%
- unstable 85-90%
- stable 20-30%

Associated injuries
- Pulmonary contusion 38%
- Closed head injury 50%
  (intracranial hemorrhage 24%)

274 patients
- 38.7 years (8-88) / 199 males (72%)

Mechanism of injury: MVA 81%, MCA 9%

Associated injuries:
- Closed head (CGS 12.1) 51%
- Significant chest injury 62%
- Abdominal 22%
- Pelvic / long bone fx 34%

Dx: Aortogram 80%, TEE 11%, CT 32%
Prospective Study of Blunt Aortic Injury: Multicenter Trial of AAST (J Trauma 1996)

- 207 stable patients:
  - Injury to ER arrival 2.8 hrs (+ 2.8)
  - Dx to thoracotomy 10.1 hrs (+ 73.3)
  - Injury to thoracotomy 16.5 hrs (+ 70.8)

- Method of repair: Bypass Clp & Sew
  - % of patients 65% 35%
  - Paraplegia 4.5% 16.4%
  - Mortality 14.9% 15.1%
Acute & Chronic Dissections
Etiology/Pathogenesis

Why next to the LSA?

Finite element stress analysis:
In normal thoracic aorta there are peaks in wall stress above the STJ and distal to LSA ostium


Aortic Dissection (US)

- 10-15 cases/100,000 adults/year
  - 10-12,000 new cases yearly
- 2/3 type A, 1/3 type B
- Acute Type B
  - 30% complicated, uncomplicated 70%
- Acute Aortic Syndrome
  - Acute AD, IMH, PAU, rTAA
Aortic Dissection
• Intimomedial tear: “primary entry tear”
• Aortic blood flow rips into wall creating a FL
• FL spirals down (and up), sometimes straight down
Acute DTA Dissection
Indications for Treatment

- Malperfusion
- Acute Enlargement
- Persistent Pain
- Uncontrolled hypertension
- Failure of medical management
- Asymptomatic

DTD with Malperfusion

- Medical management not an option
- Operative repair has significant morbidity & mortality
- Endograft repair has demonstrated reduced morbidity (12-13% 30 d) & low paraplegia rate (1%)
  - enables assessment of organ viability following revascularization enabling repair ie, bowel resection & definition of margins
Report on the results of thoracic endovascular aortic repair for acute, complicated, type B aortic dissection at 30 days and 1 year from a multidisciplinary subcommittee of the Society for Vascular Surgery Outcomes Committee

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Objective: This study analyzed 1-year outcomes after thoracic endovascular aortic repair (TEVAR) in patients with complicated type B aortic dissection (CTAAD) who had required or underwent medical and symptomatic relief in 14 days (acute), 15 to 30 days (subacute), and 31 to 90 days (chronic) and required intervention. The main focus of this report is primarily on the acute cohort.

Methods: Clinical data were prospectively collected from the physician-sponsored investigational device exemption (IDE) clinical trials between 2000 and 2008 using standardized definitions and forms. Adverse events were reported early (<30 days) and late (≥30 days) by body systems. Major adverse events included death, stroke, myocardial infarction, renal failure, respiratory failure, paralysis, and bowel ischemia.

Results: There were 99 TEVAR A patients: 85 were acute, 11 were subacute, and 3 were chronic. Among the acute patients, 31.8% had rupture and 71.8% had malperfusion, including 34.7% lower extremity, 84.1% renal, 19.7% visceral, 8.2% other, and 3.3% spinal cord (patients may have more than one system). Rupture and malperfusion were both reported for three acute patients. Additional findings for the acute cohort included pain (76.8%), hypotension (44.4%), and bleeding (8.2%) comorbidities included hypertension (85.6%), current/past smoking history (69.3%), and diabetes (12.9%). The main focus of this analysis was the acute cohort (n = 85). Age averaged 59 years (72.9% male). Early adverse events included pulmonary (56.5%), vascular (28.2%), renal (25.0%), and neurological (23.0%). Early major adverse events occurred in 27.6% of patients, including death (10.6%), stroke (9.4%), renal failure (9.4%), and paralysis (9.4%); late adverse events included vascular (15.8%), cardiac (16.0%), gastrointestinal (6.0%), and hemorrhage (6.0%). The point estimate mortality rate was 10.9% (95% confidence interval [CI], 4.1-17.6) at 30 days and 29.4% (95% CI, 18.4-40.9) at 1 year, when 34 patients remained at risk.

Conclusions: Early outcomes with TEVAR (malperfusion or rupture) provided acceptable mortality and morbidity results out to 1 year. Manufacturers can use this 2-year mortality points estimate of 10.8% (95% CI, 4.1-17.6) for the acute cohort to establish a performance goal for use in single-arm commercial IDE trials if the Food and Drug Administration and other regulatory bodies concur. (J Vasc Surg 2011;53:1082-90.)
Endovascular Repair of Type B Aortic Dissection: Long-Term Results of the Randomized Investigation of Stent Grafts in Aortic Dissection Trial

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for the INSTEAD-XL trial

Background—Thoracic endovascular aortic repair (TEVAR) represents a therapeutic concept for type B aortic dissection. Long-term outcomes and morphology after TEVAR for uncomplicated dissection are unknown.

Methods and Results—A total of 140 patients with stable type B aortic dissection previously randomized to optimal medical treatment and TEVAR (n=72) versus optimal medical treatment alone (n=68) were analyzed retrospectively for aorta-specific, all-cause outcomes, and disease progression using landmark statistical analysis of years 2 to 5 after index procedure. Cox regression was used to compare outcomes between groups; all analyses are based on intention to treat. The risk of all-cause mortality (11.1% versus 19.3%; P=0.13), aorta-specific mortality (6.9% versus 19.3%; P=0.04), and progression (27.9% versus 46.1%; P=0.04) after 5 years was lower with TEVAR than with optimal medical treatment alone. Landmark analysis suggested a benefit of TEVAR for all end points between 2 and 5 years; for example, for all-cause mortality (0% versus 16.9%; P=0.0003), aorta-specific mortality (0% versus 16.9%; P=0.0005), and for progression (4.1% versus 28.1%; P=0.004). Landmarking at 1 year and 1 month revealed consistent findings. Both improved survival and less progression of disease at 5 years after elective TEVAR were associated with stent graft induced false lumen thrombosis in 96.6% of cases (P=0.0001).

Conclusions—In this study of survivors of type B aortic dissection, TEVAR in addition to optimal medical treatment is associated with improved 5-year aorta-specific survival and delayed disease progression. In stable type B dissection with suitable anatomy, prophylactic TEVAR should be considered in appropriate patients.

Clinical Trial Registration—URL: http://www.clinicaltrials.gov. Unique identifier: NCT01415804. (Circ Cardiovasc Interv. 2013;6:00.00.)

Key Words: aortic dissection • aorta remodeling • prognosis • stent graft
INSTEAD Trial

- Randomized trial of Chronic Type B dissections
  * >14 days to 1 yr
  - 70 pts endograft treatment
  - 66 best medical treatment
- No difference in outcome at 2 yrs
  * 7 medical therapy crossovers
- At 5 yrs – approx 30% crossover from medical treatment to interventional arm (AHA 2010)

Endograft Repair of DTD Summary

- For asymptomatic patients on medical management offers immediate reduction to risks of hemorrhage & other catastrophic events
- Prevents long-term complications of late dilation or interventions for other complications of dissection that occur in 30-40% over first 5 yrs
- Alleviates the debilitation effects of intense medical therapy that are not frequently considered., drug depression and limited lifestyle
Regression of aneurysmal thoracic segment occurs in most cases.

Persistant flow in visceral and abdominal segment leads to unpredictable aneurysmal enlargement in the abdomen.
Fully Supported Device
OTHER BRANCHED TEVAR DEVICES UNDER DEVELOPMENT

Physician-Sponsored IDE Application

<table>
<thead>
<tr>
<th>Study Title:</th>
<th>Proposed Single Center Investigational Device Exemption: Feasibility of Endovascular Repair of Ascending Aortic Pathologies</th>
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<tbody>
<tr>
<td>Investigational Device:</td>
<td>Valiant® Thoracic Stent Graft with the Captivia Delivery System*</td>
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*CAUTION-Investigational device. Limited by Federal (or United States) law to investigational use.
Patient must have a Type A thoracic aortic dissection, retrograde Type A thoracic aortic dissection, intramural hematoma, penetrating ulcer or pseudoaneurysm of the ascending thoracic aorta affecting the area between the Sinus of Valsalva and the innominate artery orifice (with no involvement of the aortic valve) and be considered candidates for endovascular repair;

- Patient must also have at least one cm proximal and distal landing zones in the ascending aorta
- Aorta between 28-44 mm in diameter;

The patient must be deemed high-risk surgical candidate according to the following established criteria:

- ASA class IV
48% of surgery treats the mid asc. aorta¹

24% of surgery treats root and arch¹

¹Williams et al, Contemporary Results for Proximal Aortic Replacement in North American, J Am Coll Cardio 2012;60:1156-62
Technical challenges for Endovascular Repair

- **Anatomical**
  - Short Distance between the LSCA and LCCA
  - Arch angulation
  - Ascending – descending aortic size discrepancy
- **Technical**
  - Device Delivery
  - Orientation, conformability
- **Physiological**
  - Coronary/cerebral perfusion
  - High hemodynamic forces
- **Complications**
  - Stroke, type A dissection, valve interactions

Diagram showing high pressure and flow in the aorta.
From the Western Vascular Society

Feasibility of endovascular repair of ascending aortic pathologies as part of an FDA-approved physician-sponsored investigational device exemption

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Objective: Endovascular treatment of ascending aortic lesions has been reported, but to date, no FDA-approved studies have been conducted to define feasibility and the use of endograft in this particular location or to analyze the critical factors involved.

Methods: Patients were consented for entry into an FDA approved physician-sponsored investigational device exemption study to investigate the outcome of those with ascending aortic pathologies. These patients were suitable according to the instructions for use for endovascular repair with a Wallaby Captivia (Medtronic, Inc, Minneapolis, Minn) thoracic stent graft, a device designed specifically for deployment in the ascending aorta. All patients had sequential gated-cardiac computed tomography scans, with data being entered into the YQI Complex TEVAR software (West Lebanon, NH). All procedures were performed in a hybrid room, with the capability to convert to an open repair to ensure maximal patient protection. The first five patients constituted the feasibility study, with continued enrollment based on initial results and submission of an annual report to the FDA.

Results: Thirty-nine patients were screened, and six patients were entered into the physician-sponsored investigational device exemption study. Although there was no early mortality, there was one late death. All patients had sequential computed tomographic angiography and cardiovascular imaging with no evidence of migration, one type I endoleak, one postoperative stroke, and regression of the aortic lesion in the excluded aortic segment.

Conclusion: In this feasibility study, the preliminary evaluation of endovascular treatment for ascending aortic pathologies demonstrates uniform accuracy of deployment and secure fixation up to 17.8 months of follow-up. There is positive remodeling of the excluded aortic segments similar to surveillance studies involving the descending aorta. (J Vasc Surg 2016;63:1483-95.)
Endovascular Bentall
Conclusions

- Proof of concept: TEVAR for ascending aorta
- Need dedicated devices and clinical trials confirming safety and efficacy
- Many technical challenges still to be tackled
- Total endovascular solution will probably not be applicable to many patients.
- Long-term results of endovascular repair is not known.