PERCUTANEOUS TREATMENT FOR ABDOMINAL AORTIC ANEURYSM (PEVAR)

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Cardiovascular Institute of the South
Off label use of products and investigational devices will be discussed in this presentation
BACKGROUND OF AAA DISEASE
ABDOMINAL AORTIC ANEURYSMS
AAA ANATOMY AND PATHOPHYSIOLOGY
PATHOPHYSIOLOGY: AORTIC ANEURYSM

• A permanent localized dilatation with a diameter at least twice the normal diameter of the given segment
ANEURYSM CLASSIFICATION
AAA RISK FACTORS

• Male
• Over age 55
• Smoking
• Caucasian
• Family history

• Atherosclerosis
• Hypertension
• Diabetes
• Hypercholesterolemia
PATHOPHYSIOLOGY OF AAA

Pathological changes cause the aorta to:

• Become thinner
• Bulge
• Tear
• Rupture
• Stenosis
• Dissect
INCIDENCE/PREVALENCE

• 13th leading cause of death in US
• Estimated 1.5–2 million in US
• Incidence increases with age
• Occurs 4–5 times more frequently in males
• Occurs more frequently in Caucasians
SYMPTOMS OF AAA

• Most nonruptured AAA patients asymptomatic at diagnosis
• Vague abdominal pain—most common complaint
  • Constant or “throbbing”
  • Rapid abdominal expansion may cause intense pain
  • AAA should be considered for any elderly patient with abdominal, flank or back pain
• Tender, pulsating abdominal mass may be visible upon physical examination
• GI symptoms
  • Early satiety, nausea, weight loss may indicate intestinal compression
• Lower extremity emboli—if cardiac cause ruled out, AAA should be considered
AAA CONSEQUENCES: RUPTURE

- Presents as “extreme distress”
- Severe back pain
- Hypotension
  - Tachycardia
  - Pallor
  - Diaphoresis
  - Shock (depending on extent of blood loss)
AAA RUPTURE CONSEQUENCES: 50-50 RULE

• High mortality due to rapid circulatory collapse
• Up to 50% of patients with untreated aneurysms >5.5 cm will die of rupture in 5-year period
• 50% of emergent cases arrive in ER alive
  • 50% of this group survives surgical conversion
AAA TREATMENT OPTIONS

- Watch and wait
- Open surgical repair
- Endovascular repair
WATCH AND WAIT:
RUPTURE RISK OF UNTREATED ANEURYSMS

Risk of Rupture for Untreated Aneurysm Within 5 Yr (%)

Aneurysm Size

5–5.9 cm 6–7 cm >7 cm

25% 35% 75%

Mitchell, MD, Rutherford RB, Krupski WC. “Infrarenal Aortic Aneurysm” in Vascular Surgery
CURRENT THERAPY: OPEN SURGICAL REPAIR

- Aneurysm opened, graft sewn in, aorta wrapped and closed around graft
- Established procedure (>50 years)
- Excludes aneurysm and prevents sac growth
- Proven, long-term results
- Considered the “gold standard”
OPEN REPAIR: DRAWBACKS

• Significant incision in the abdomen
• 30–90 minute cross-clamp
• Up to 4-hour procedure
• Contraindicated in many patients
• 1–2 days intensive care, 7–14 days hospitalization, 4–6 weeks recovery time
OPEN REPAIR: DRAWBACKS

• Many patients considered “unfit”
  • High anesthesia risk
  • Significant cardiac comorbidities
  • Previous abdominal surgery/hostile abdomen

• Difficult recovery for patient
  • Risks losing independence*
  • Reoperation risk*
  • Risk of impotence

*J Vasc Surg 2001; 33:913–20
†Ann Vasc Surg 2000; 14:13 – 19
RISKS OF OPEN REPAIR
DATA FROM OREGON HEALTH SCIENCE CENTER

• 1 in 20 chance of perioperative death
• Hospital stay of at least 10 days, almost half spent in ICU
• 1 in 10 chance of discharge to a care facility
• 1 in 20 surviving patients will require another vascular procedure for aneurysm at mean of 1.5 years
DETERMINANTS OF OUTCOME

Patient Factors
- ECG ischemia
- Heart failure
- Renal dysfunction
- Pulmonary dysfunction
- Gender
- Age

Technical Factors
- Patient
- Surgeon and hospital
- Extent of AAA
- Disease at clamp site
- Inflammatory AAA
- Venous abnormalities
- Hostile abdomen
- Experience
OPEN AAA REPAIR
REPRESENTATIVE MORTALITY RATES

A  Collective reviews  
   (n=11,780)

B  Multicenter experience  
   (n=4648)

C  National Hospital Discharge Survey  
   (n=407,360)

D  Statewide audits  
   (n=14,090)
ANNUAL IMPACT IN UNITED STATES

- >100,000 new cases per year
  - approximately 80% men, 20% women
- 40,000 elective operations
- 13,000 deaths from rupture
- Utilizes 400,000 hospital days
THE RESULTS OF AAA REPAIR ARE DEPENDENT UPON PATIENT CO-MORBIDITIES AND THE EXPERIENCE OF THE PHYSICIAN AND HOSPITAL.
IS THERE ANOTHER WAY?

• Less invasive
• Less morbid
• Less lethal
• Equally effective
ENDOVASCULAR REPAIR

• Preserves limb blood flow
• Protects sac from arterial pressure
PATIENT SELECTION PROCESS

- Factors predictive of rupture, such as aneurysm size and rate of growth
- Risk of AAA surgical treatment based on demographic factors, patient history, and co-morbidities
- Risks of endovascular treatment based on anatomic criteria
- Patient’s ability to comply with required follow-up
  - Serial CT scans
- Relative risks and benefits of available treatment strategies
EVAR HISTORY

• Parodi – 1991- First report of Endovascular AAA repair
• Feb 10\textsuperscript{th} 1993 – The first industry-manufactured aortic endograft repair of Abdominal Aortic Aneurysm was performed under a IDE at UCLA Medical Center
• Thoracic Repair – Gore TAG 2005
• Graft Evolution –
  • Unibody ➤ Tube Graft 1991
  • Bifurcated ➤ Chutter 1996
• Only a handful of 16 developed devices FDA Approved
The First EVAR Devices
FIRST COMMERCIALY APPROVED GRAFT
Guidant ANCURE
<table>
<thead>
<tr>
<th>September 1999</th>
<th>November 2002</th>
<th>May 2003</th>
<th>October 2004</th>
<th>April 2008</th>
<th>December 2010</th>
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<tr>
<td>Ancure</td>
<td>AneuRx</td>
<td>Excluder</td>
<td>Zenith</td>
<td>Powerlink</td>
<td>Talent</td>
</tr>
<tr>
<td>Guidant</td>
<td>Medtronic</td>
<td>Gore</td>
<td>Cook</td>
<td>Endologix</td>
<td>Medtronic</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Endurant</td>
</tr>
</tbody>
</table>

![Images of medical devices](image1.png) ![Images of medical devices](image2.png) ![Images of medical devices](image3.png) ![Images of medical devices](image4.png) ![Images of medical devices](image5.png) ![Images of medical devices](image6.png)
<table>
<thead>
<tr>
<th>Company</th>
<th>Devices</th>
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<tr>
<td>APTUS, INC.</td>
<td>Aptus</td>
</tr>
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<td></td>
<td>Zenith</td>
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<tr>
<td></td>
<td>Zenith Flex</td>
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<tr>
<td></td>
<td>Zenith LP</td>
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<tr>
<td>COOK MEDICAL</td>
<td>Incraft</td>
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<tr>
<td>Cordis Corporation</td>
<td>Powerlink</td>
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<tr>
<td></td>
<td>Nellix</td>
</tr>
<tr>
<td>Endologix</td>
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</tr>
<tr>
<td>Gore &amp; Associates</td>
<td>Excluder</td>
</tr>
<tr>
<td>Lombard</td>
<td>Aorfix</td>
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<tr>
<td>Medtronic, Inc.</td>
<td>AneuRx</td>
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<tr>
<td></td>
<td>Talent</td>
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<tr>
<td></td>
<td>Endurant</td>
</tr>
<tr>
<td>Trivascular</td>
<td>Ovation</td>
</tr>
<tr>
<td>Vascutek</td>
<td>Anaconda</td>
</tr>
</tbody>
</table>
FENESTRATION GRAFTS

- Custom Made
- Allows Necks as short as 4mm
- Much more difficult to implant
- Higher risk of complications specifically covering a vessel
MULTIPLE MEASUREMENTS

- AAA Neck at the Renals
  - Diameter and overall length
- Distance from the Renals to the Bifurcation
- Distance from the Renals to the Hypogastrics
- Diameter at the iliacs
- Other measurements and considerations
  - External iliac (access)
  - Calcification
  - Tortuosity
PARADIGM SHIFT

• As EVAR entered the Surgical arena it was indicated for those patients that were too sick (medically) for open surgical repair.

• As all the studies comparing the 2 modalities were reporting very similar endpoints.

• Patients now are being referred to surgical repair when they don’t fit the anatomical criteria.
ANATOMIC ASSESSMENT: PROXIMAL AORTIC NECK

Aortic neck morphology is critically related to effective sealing and stability.

- Adhere to neck criteria stated in the Indications for Use (length, diameter, angulation, shape, thrombus, calcification) because they may affect successful exclusion of the aneurysm.

- Avoid extremely tortuous aortas, because the proximal sealing stent must be parallel to axis of non-dilated aorta.
SECOND MOST IMPORTANT IS ACCESS

- 18-22 F delivery systems
  - ID vs OD
- Tortuosity in the combination with calcification need to be recognized
- 6mm minimum vessel size
- Consider 6.5 -7mm if calcification is significant and the vessels are tortious
- Can “push” 5.5mm in a “normal vessel” but need to be very cautious
  - “iliac on a stick”
TECHNIQUE OVERVIEW

• Percutaneous femoral access
  • Micropuncture technique
  • Ultrasound guidance
  • Confirm with arteriogram
  • Anterior puncture

• ProGlide Deployment
  • Dilate tract w/ 7F sheath
  • Advance first ProGlide over 0.035” guidewire
  • Remove guidewire
  • Advance device until pulsatile bleeding from side port
  • Rotate 30° medially, set footplate, and deploy suture
PROCEDURAL STEPS: PROGLIDE SUTURE ORIENTATION

Crosshair (“10 and 2”) approach

30° lateral second

30° medial first
Procedural Steps: Surgical Field Organization

• Sutures tagged and left for later closure
PROCEDURAL STEPS: CLOSURE

At completion of EVAR procedure

- Manual control of hemostasis while removing sheath
- Pull up on rail to remove slack and position knot at the arteriotomy
- Tighten down knot with knot pusher
- Repeat with second suture
- Then lock both sutures
- Remove wire when hemostasis achieved
PROCEDURAL STEPS: CLOSURE

• “Guitar-string” tension
• Remove wire when hemostasis evident
• Lock and cut sutures
• Reverse heparin - ACT <150 sec (selectively)
  • Small amount residual bleeding, spinal catheter, etc.
• Manual pressure 5 min
PROCEDURAL STEPS: PROGLIDE SUTURE ORIENTATION

Remove wire and lock knots if closure is hemostatic.

Can deploy a third ProGlide suture vertically if necessary.
PROCEDURE STEPS: RESULTS
1999-2012: more than 2200 cases reported – > 3,600 access sites

- High technical success, fewer complications, shorter operative time, shorter length of stay
- Increased risk: BMI > 40, sheath >20Fr, CFA <5mm or calcified
- Decrease risk: use of ultrasound guidance
<table>
<thead>
<tr>
<th>Variable</th>
<th>Variable present</th>
<th>Variable absent</th>
<th>$P$ value$^a$</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>US-guided access</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Success rate</td>
<td>447</td>
<td>96.4 (431)</td>
<td>3159</td>
</tr>
<tr>
<td>Groin complication rate</td>
<td>447</td>
<td>3.6 (16)</td>
<td>3159</td>
</tr>
<tr>
<td><strong>Antibiotic prophylaxis</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Groin infection</td>
<td>592</td>
<td>0.003 (2)</td>
<td>3014</td>
</tr>
<tr>
<td><strong>Anticoagulation reversal</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Success</td>
<td>817</td>
<td>95 (776)</td>
<td>432</td>
</tr>
<tr>
<td>Hemorrhagic complications</td>
<td>817</td>
<td>2 (16)</td>
<td>432</td>
</tr>
<tr>
<td>Ischemic complications</td>
<td>817</td>
<td>0.5 (4)</td>
<td>432</td>
</tr>
<tr>
<td><strong>Sheath size &lt;20F</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Success</td>
<td>1297</td>
<td>94.2 (1222)</td>
<td>654</td>
</tr>
<tr>
<td><strong>Obesity (BMI &gt;30 kg/m$^2$)</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Success</td>
<td>44</td>
<td>93.2 (41)</td>
<td>94</td>
</tr>
<tr>
<td><strong>Severe vascular calcification</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Success</td>
<td>84</td>
<td>87 (73)</td>
<td>164</td>
</tr>
</tbody>
</table>
### Table II. Intraoperative characteristics and outcomes stratified by access technique

<table>
<thead>
<tr>
<th>Variable</th>
<th>Access technique</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>PFA (n, %)</td>
<td>US-guided (n, %)</td>
</tr>
<tr>
<td>Sheath size ≥20F</td>
<td>22 (24%)</td>
<td>24 (41%)</td>
</tr>
<tr>
<td>Operative time (min)</td>
<td>154 (±64)</td>
<td>101 (±51)</td>
</tr>
<tr>
<td>Access complications</td>
<td>6 (7%)</td>
<td>0 (0%)</td>
</tr>
<tr>
<td>All conversions</td>
<td>6 (7%)</td>
<td>1 (2%)</td>
</tr>
<tr>
<td>Technical success</td>
<td>87 (94%)</td>
<td>58 (98%)</td>
</tr>
</tbody>
</table>

### Table V. Multivariate analysis of the effect of treatment characteristics on conversion rate

<table>
<thead>
<tr>
<th>Treatment characteristics</th>
<th>OR (95% CI)</th>
<th>P value</th>
</tr>
</thead>
<tbody>
<tr>
<td>US-guided PEVAR</td>
<td>0.21 (0.02–1.95)</td>
<td>0.1690</td>
</tr>
<tr>
<td>Severe calcification</td>
<td>2.81 (0.26–30.3)</td>
<td>0.3954</td>
</tr>
<tr>
<td>Mechanical failure</td>
<td>14.0 (2.49–78.7)</td>
<td>0.0028</td>
</tr>
</tbody>
</table>
## Table: Comparison of Fluoroscopy vs Ultrasound for Femoral Arterial Access

<table>
<thead>
<tr>
<th>Characteristic</th>
<th>Fluoroscopy (n=500)</th>
<th>Ultrasound (n=502)</th>
<th>P Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Number of Attempts</td>
<td>3.0 ± 3.2</td>
<td>1.3 ± 0.9</td>
<td>&lt;0.000001</td>
</tr>
<tr>
<td>First Pass success</td>
<td>232 (46.4%)</td>
<td>415 (82.7%)</td>
<td>&lt;0.000001</td>
</tr>
<tr>
<td>Venipuncture</td>
<td>79 (15.8%)</td>
<td>12 (2.4%)</td>
<td>&lt;0.000001</td>
</tr>
<tr>
<td>Number of Arterial Punctures</td>
<td>1.14 ± 0.43</td>
<td>1.09 ± 0.36</td>
<td>0.076</td>
</tr>
<tr>
<td>Mean Time of insertion (min)</td>
<td>213 ± 194</td>
<td>185 ± 175</td>
<td>0.016</td>
</tr>
<tr>
<td>Median Time of Insertion (min)</td>
<td>148 (102-242)</td>
<td>136 (90-212)</td>
<td>0.003</td>
</tr>
</tbody>
</table>

*Seto, et al JACC Intv 2010;3:751*
REAL-TIME ULTRASOUND GUIDANCE FACILITATES FEMORAL ARTERIAL ACCESS AND REDUCES VASCULAR COMPLICATIONS
FAUST (FEMORAL ARTERIAL ACCESS WITH ULTRASOUND TRIAL)

<table>
<thead>
<tr>
<th>Complications</th>
<th>Fluoroscopy (n=501)</th>
<th>Ultrasound (n=503)</th>
<th>P Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Hematoma</td>
<td>11 (2.2%)</td>
<td>3 (0.6%)</td>
<td>0.034</td>
</tr>
<tr>
<td>Pseudoaneurysm</td>
<td>0</td>
<td>1</td>
<td>NS</td>
</tr>
<tr>
<td>Dissection</td>
<td>3</td>
<td>2</td>
<td>NS</td>
</tr>
<tr>
<td>Access Bleeding, Transfusion</td>
<td>2</td>
<td>1</td>
<td>NS</td>
</tr>
<tr>
<td>Hematoma with DVT</td>
<td>1</td>
<td>0</td>
<td>NS</td>
</tr>
<tr>
<td>Any Complication</td>
<td>17 (3.4%)</td>
<td>7 (1.4%)</td>
<td>0.041</td>
</tr>
</tbody>
</table>

Seto, et al JACC Intv 2010:3:751
WHY ULTRASOUNDS GUIDED ACCESS? CONCLUSION

• Ultrasound guided access provides added safety and reduces our most common complications.
• Readily available.
• More accurate puncture placement.
• Enhances use of closure devices.
• Fewer complications and conversions.
Objective: Least Invasive Fast-Track EVAR (LIFE) Study

The primary objectives of the LIFE Study are to demonstrate the clinical and cost benefits associated with using the Ovation® Abdominal Stent Graft platform under the least invasive approach defined in the Fast-Track EVAR protocol: percutaneous access, no general anesthesia, no ICU admission, next-day discharge.

Economic Benefits

The preliminary data from the LIFE Study demonstrate improvement in procedure time and length of stay as compared to nationwide benchmark of hospitals performing EVAR1.

<table>
<thead>
<tr>
<th>Variables</th>
<th>50th Percentile Tier</th>
<th>LIFE Study Fast-Track Arm (N=114)³</th>
<th>Time / Cost Improvement (LIFE vs 50th Tier)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Procedure Time (mean)</td>
<td>179 minutes</td>
<td>90 minutes</td>
<td>89 minutes / case</td>
</tr>
<tr>
<td>Estimated OR Costs³ (mean)</td>
<td>$5400</td>
<td>$2700</td>
<td>$2700 / case</td>
</tr>
<tr>
<td>Length Of Stay (mean)</td>
<td>3.0 days</td>
<td>1.2 days</td>
<td>1.8 days / patient</td>
</tr>
<tr>
<td>Estimated LOS Costs⁴ (mean)</td>
<td>$3600</td>
<td>$1000</td>
<td>$2600 / patient</td>
</tr>
</tbody>
</table>

¹Source: Advisory Board Company research and analysis.
²EVAR defined as ICD-9 procedure codes 39.71.
³Assumes an average OR cost per minute of $30.
⁴Assumes an average ICU cost per stay of $1200 and Progressive Care Unit stay of $800.
⁵As of October 19, 2016
CONCLUSION

• EVAR has become the dominate strategy for the repair of AAA
• Patients are now referred for surgery that do not meet anatomical criteria
• PEVAR offer the patient the same benefits of EVAR without the groin issues
  • Ultrasound access has an advantage over blind stick
• Conscious sedation becomes an option, which may allow earlier discharge, and cost savings
THANK YOU