PEVAR
Percutaneous Endovascular Aortic Aneurysm Repair

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Conflicts of Interest

I proctor for:
- St. Jude/AGA Medical
- Endologics/Trivascular

I speak for:
- Abbott Vascular
- AngioDynamics
Abdominal Aortic Aneurysms (AAA)

Localized dilatation of the abdominal aorta exceeding the normal diameter by more than 50%.

Aortic diameter $\geq 30$mm.

Healthy Aorta

Aorta with abdominal aneurysm
Definition

• Normal aortic measurements
  • Root: 3.0 cm.
  • Descend Thoracic: 2.5 cm
  • Infrarenal: 2.0 cm

• 2 Types
  • Fusiform - cylindrical
  • Saccular - asymmetric outpouching

• Definition of AAA
  • Expansion of all 3 layers of aorta such that the AP diameter of aorta ≥ 3.0 cm.
  • Does not account for body size variations.
    some consider > 50% increase in size compared to proximal normal segment as valid definition.

3. www.daviddarling.info/images/aneurysms.jpeg
Infrarenal aorta prior to an open surgical repair
Pathophysiology

AAA’s develop as a result of a chronic aortic wall inflammation

- Arterial Injury
  - Hypertension
  - Hyperlipidemia
  - Toxins (nicotine)
- Inflammation
- Degradation of elastin
- AAA growth and rupture

Pathophysiology
Abdominal aortic aneurysm

- 41 to 49 per 100,000 men
- 7 to 12 per 100,000 women

<table>
<thead>
<tr>
<th>RISK FACTOR</th>
<th>OR</th>
</tr>
</thead>
<tbody>
<tr>
<td>History of smoking</td>
<td>3.59 (3.0 – 4.28)</td>
</tr>
<tr>
<td>Family history</td>
<td>1.88 (1.58 – 2.24)</td>
</tr>
<tr>
<td>Age</td>
<td>1.52 (1.44 – 1.62)</td>
</tr>
<tr>
<td>Hyperlipidemia</td>
<td>1.46 (1.29 – 1.65)</td>
</tr>
<tr>
<td>Hypertension</td>
<td>1.14 (1.02 – 1.26)</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>MAXIMAL DIAMETER</th>
<th>5 YEAR RUPTURE RATE</th>
</tr>
</thead>
<tbody>
<tr>
<td>&lt;4.0 cm</td>
<td>2%</td>
</tr>
<tr>
<td>4.0 – 4.9 cm</td>
<td>3-12%</td>
</tr>
<tr>
<td>5.0 – 5.9 cm</td>
<td>25%</td>
</tr>
<tr>
<td>6.0 – 6.9 cm</td>
<td>35%</td>
</tr>
<tr>
<td>&gt;7.0 cm</td>
<td>75%</td>
</tr>
</tbody>
</table>


AAAs in the USA

• AAA affects as many as eight percent of people over the age of 65\(^1\)
  • Prevalence 5 times higher in men \(^2\)

• Account for approximately 15,000 deaths annually\(^3\)

• 200,000 people are diagnosed with AAA each year\(^4\)

• 13th leading cause of death\(^5\)

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## AAA rupture risk

<table>
<thead>
<tr>
<th>Factor</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Female</td>
<td>2-4 X more likely than men</td>
</tr>
<tr>
<td>Smoker</td>
<td>The greater the length of smoking, the greater the risk of rupture.</td>
</tr>
<tr>
<td>↓FEV</td>
<td>COPD, decrease lung function</td>
</tr>
<tr>
<td>Transplant patients</td>
<td>Cause unknown</td>
</tr>
<tr>
<td>Higher mean blood pressure</td>
<td>Increase stress on vessel walls.</td>
</tr>
</tbody>
</table>
The main predictor for rupture is the aneurysmal diameter.

Population Less At Risk:

- **Diabetic**: Diabetes disease progression is the opposite of AAA: narrowing vessels vs. dilating vessels.
- **Women**: Genetic BUT 4X more likely to rupture.
- **African-Americans**: Genetically pre disposed to diabetes

Small vessel disease is common in diabetics. African Americans are genetically pre-disposed to diabetes.
Presentation

• Most AAA’s are small and discovered incidentally.

• Symptoms
  – Pain
    • Dull vague pain in the abdomen, back or flank
    • Can be acute and severe in ruptured AAA’s
  – Mass
    • Sensation of a pulsatile mass in the abdomen
  – Hypotension
    • Usually manifesting as syncope
    • Occurring in cases of ruptured AAA’s
  – Embolization

AAA Symptoms

- Estimated 1 million Americans are living with undiagnosed AAAs¹
- Vast majority of AAAs are asymptomatic
- Symptoms may include:
  - Pain (abdomen, chest, lower back, or groin area)²
  - Pulsing feeling in your abdomen³
- 75% of AAAs are detected incidentally, usually during imaging scans⁴

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Presentation

Associated complications

- Diminished femoral pulses
- “Blue Toe” Syndrome
  - microemboli from aortic thrombus
- Duodenal obstruction leading to vomiting and weight loss
- Vertebral body erosion leading to severe back pain

Screening Options

- 75% of AAAs are detected incidentally, usually during imaging scans

Abdominal Ultrasound¹

CT

Angiography

Open surgical repair for an AAA of at least 5.5 cm leads to an estimated 43-percent reduction in AAA-specific mortality in older men who undergo screening. However, there is no current evidence that screening reduces all-cause mortality in this population.²

1. Abdominal Ultrasound image provided by AnasthesiaUK, http://www.frca.co.uk
USPTF screening for AAA recommendations

<table>
<thead>
<tr>
<th>Population</th>
<th>Recommendation</th>
</tr>
</thead>
<tbody>
<tr>
<td>Men</td>
<td></td>
</tr>
<tr>
<td>65 - 75</td>
<td>One-time ultrasonography</td>
</tr>
<tr>
<td>(+) Smoking Hx</td>
<td></td>
</tr>
<tr>
<td>65 – 75</td>
<td>Selectively offer screening for AAA</td>
</tr>
<tr>
<td>Never Smoked</td>
<td></td>
</tr>
<tr>
<td>Women</td>
<td></td>
</tr>
<tr>
<td>65 – 75</td>
<td>Current evidence is insufficient</td>
</tr>
<tr>
<td>(+) Smoking Hx</td>
<td></td>
</tr>
<tr>
<td>Never Smoked</td>
<td>Do not screen</td>
</tr>
</tbody>
</table>
What if a AAA is diagnosed?

<table>
<thead>
<tr>
<th>Aneurysm diameter</th>
<th>Follow-up action</th>
</tr>
</thead>
<tbody>
<tr>
<td>Small bulge (3.0-3.9 cm)</td>
<td>Re-check in 2-3 years</td>
</tr>
<tr>
<td>Medium bulge (4.0-5.4 cm)</td>
<td>Discuss with provider. Most likely need re-check in 6 months.</td>
</tr>
<tr>
<td>Large bulge (more than 5.4 cm), or growing by more than .5 cm per year.</td>
<td>Discuss with provider. May need treatment.</td>
</tr>
</tbody>
</table>


RF Modification, GDMT

Smoking cessation is strongly recommended: “likely the most important recommendation that can be made to a patient with AAA”

Appropriately treat hypertension, hyperlipidemia, diabetes or other atherosclerotic risk factors.

“A statin and ACE inhibitor should be initiated given their broad potential benefits and acceptable safety profile.”

Counsel that physical activity might limit expansion rate

Screen family members

Treatment Options for AAA

<table>
<thead>
<tr>
<th></th>
<th>Surgery</th>
<th>EVAR</th>
<th>Source</th>
</tr>
</thead>
<tbody>
<tr>
<td>30 day Mortality</td>
<td>4.3%</td>
<td>1.8%</td>
<td>New England Journal of Medicine 2010; 362:1863-1871</td>
</tr>
<tr>
<td>Length of Hospital stay (days)</td>
<td>10.4</td>
<td>3.6</td>
<td>Journal of the American Medical Association 2012; 307(15): 1621-1628</td>
</tr>
</tbody>
</table>
FDA-Approved EVAR Devices 2016

- W.L. Gore and Associates
  - Excluder C3

- Medtronic, Inc.
  - Endurant
  - Talent
  - AneuRx

- Cook Medical
  - Zenith Flex
  - Zenith Fenestrated (limited)

- Trivascular
  - Ovation

- Endologix
  - AFX

Modular Devices

Unibody Device
Endovascular Aortic Repair

- Approximately 70% of all diagnosed AAAs are treated by EVAR\textsuperscript{1}
- Approximately 44,000 EVAR procedures performed annually in the US\textsuperscript{2}

- Procedure Overview
  - Requires two small incisions (femoral cutdown) or punctures (PEVAR) in the groin area
  - Stent graft is introduced into the arteries through a catheter and then deployed within the aorta.
  - Stent graft creates a new pathway for the blood to flow, reducing pressure on the aneurysm and the risk of rupture

Advantage of Percutaneous EVAR (PEVAR)

PEVAR provides an opportunity for several clinical benefits, including:

• Fewer access site complications
• Less blood loss
• Option to use regional or local anesthesia versus general
• Shorter procedure times
• Shorter hospital stays

Femoral Artery Access
Pre-close technique
EVAR trials

• Randomized trials
  – **EVAR 1** (UK) – Pts. fit for open repair- (EVAR vs. OR)
  – **EVAR 2** (UK) - Pts. unfit for open repair- (EVAR vs. best medical)
  – **DREAM Trial** (Dutch – EVAR vs. OR)

• Nonrandomized large trials
  – Lifeline registry (US Trials)
  – Other large registries (Medicare recipients)
  – Single institution trials
EVAR-1: All cause mortality

Cox regression hazard ratio:
0.90 [95% CI 0.69–1.18], p=0.46

Number at risk

<table>
<thead>
<tr>
<th>Number at risk</th>
<th>Years after randomisation</th>
</tr>
</thead>
<tbody>
<tr>
<td>Open repair</td>
<td>539 484 314 195 88</td>
</tr>
<tr>
<td>EVAR</td>
<td>543 503 316 187 94</td>
</tr>
</tbody>
</table>

EVAR (26%)
Open repair (29%)
EVAR-1: Aneurysm-related mortality

Cox regression hazard ratio:
0.55 [95% CI 0.31–0.96], p=0.04

Number at risk

<table>
<thead>
<tr>
<th>Years after randomisation</th>
<th>Open repair</th>
<th>EVAR</th>
</tr>
</thead>
<tbody>
<tr>
<td>0</td>
<td>539</td>
<td>543</td>
</tr>
<tr>
<td>1</td>
<td>484</td>
<td>503</td>
</tr>
<tr>
<td>2</td>
<td>314</td>
<td>316</td>
</tr>
<tr>
<td>3</td>
<td>195</td>
<td>187</td>
</tr>
<tr>
<td>4</td>
<td>88</td>
<td>94</td>
</tr>
</tbody>
</table>

EVAR (4%)
Open repair (7%)

Case Presentations
Patient WT

- Patient is an 86 year old man referred by Dr. Rogers/Elizardi for evaluation and treatment of his AAA.
- Patient has history of HTN, HLP, CKD, AAA (4.0x4.3cm) with ulceration which is an interval change since last evaluation 1 yr prior. No complaints of chest pain, shortness of breath, palpitations, syncope or pre-syncope. Patient did report fatigue & nonspecific abdominal pain.
- CTA 12/17/2012:
  1. Abdominal aortic aneurysm measuring 4.0 x 4.3 cm. Ulceration of the proximal portion of the aneurysm aneurysm. This does not involve the renal arteries or the common iliac arteries.
  2. Single renal arteries bilaterally without evidence of aneurysm or renal artery stenosis.
  3. Mesenteric vessels are widely patent.
CT Scan
Aortic Views
# Device Planning Iliacs

<table>
<thead>
<tr>
<th>Length(mm)</th>
<th>Iliac Diameter (ID) Measurement</th>
<th>Device Recommendation</th>
</tr>
</thead>
<tbody>
<tr>
<td>IR to Native Aortic Bifurcation</td>
<td>134</td>
<td></td>
</tr>
<tr>
<td>IR to Right Internal Iliac Artery Origin</td>
<td>199</td>
<td></td>
</tr>
<tr>
<td>IR to Left Internal Iliac Artery Origin</td>
<td>187</td>
<td></td>
</tr>
<tr>
<td>Right Iliac Artery (Mid/Distal)</td>
<td>10.7mm/10.3mm</td>
<td>12x140</td>
</tr>
<tr>
<td>Left Iliac Artery (Mid/Distal)</td>
<td>9.3mm/10.7mm</td>
<td>12x120</td>
</tr>
<tr>
<td>Additional Components</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Alt Lifcanfit</td>
<td>12x140</td>
<td></td>
</tr>
<tr>
<td>R/L Ext</td>
<td>12x45</td>
<td></td>
</tr>
<tr>
<td>Alt Riftoolong</td>
<td>12x120</td>
<td></td>
</tr>
<tr>
<td>Additional backup plan A</td>
<td>12x100</td>
<td></td>
</tr>
<tr>
<td>Notes</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
CT Scan 3 months post procedure
Summary

• Surveillance is key!
  - institute a surveillance algorithm

• Preventing aneurysm rupture is only a small component
  - repair 5.5 cm in males, 4.5 to 5 cm in females

• AAA size is a marker of global vascular disease and atherosclerosis
  - 3 cm in females, 3.5 cm in males
  - smoking cessation, statins, ace, asa, bblocker

• Atherosclerosis causes the vast majority of deaths in these patients (60-70%)

• Long term follow-up is necessary