EVAR Technology Makes it the 1st Choice

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Inova Cardiovascular Symposium
April 27th, 2019
Disclosures

• On the speaker’s panel for
• Silk Road Medical
• Endologix
EVAR for 6cm AAA
## Levels of Evidence

<table>
<thead>
<tr>
<th>Level of Evidence</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Level of Evidence A</strong></td>
<td>Data derived from multiple randomised clinical trials or meta-analyses.</td>
</tr>
<tr>
<td><strong>Level of Evidence B</strong></td>
<td>Data derived from a single randomized clinical trial or large non-randomized studies.</td>
</tr>
<tr>
<td><strong>Level of Evidence C</strong></td>
<td>Consensus of opinion of the experts and/or small studies, retrospective studies, registries.</td>
</tr>
</tbody>
</table>
### Classes of Recommendations

<table>
<thead>
<tr>
<th>Classes of Recommendations</th>
<th>Definition</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Class I</strong></td>
<td>Evidence and/or general agreement that a given treatment or procedure is beneficial, useful, and effective.</td>
</tr>
<tr>
<td><strong>Class II</strong></td>
<td>Conflicting evidence and/or a divergence of opinion about the usefulness/efficacy of the given treatment or procedure.</td>
</tr>
<tr>
<td><strong>Class IIa</strong></td>
<td>Weight of evidence/opinions in favor of usefulness/efficacy.</td>
</tr>
<tr>
<td><strong>Class IIb</strong></td>
<td>Usefulness/efficacy is less well-established by evidence/opinion.</td>
</tr>
<tr>
<td><strong>Class III</strong></td>
<td>Evidence or general agreement that the given treatment or procedure is not useful/effective, and in some cases may be harmful.</td>
</tr>
</tbody>
</table>
EVAR I Clinical Trial

- Location: United Kingdom (UK)
- Years: 1999 to 2003
- Sample Size: 1,082
- Outcomes:
  - Better perioperative survival after EVAR (1.7% vs 4.7%)
  - Early survival benefit lost after 2 years, with similar long-term survival
  - Higher aneurysm related mortality for EVAR after 8 years
    - Mainly attributable to secondary aneurysm sac rupture
  - Higher reintervention rate after EVAR
DREAM Clinical Trial

- Locations: Netherlands and Belgium
- Years: 2000 to 2003
- Sample Size: 351
- Outcomes:
  - Better perioperative survival after EVAR (1.2% vs 4.6%)
  - Early survival benefit was lost by the end of the 1st year
  - Similar long-term survival
  - Higher reintervention rate after EVAR
OVER Clinical Trial

- Location: United States
- Years: 2002 to 2008
- Sample Size: 881
- Outcomes:
  - Better perioperative survival after EVAR (0.5% vs. 3.0%)
  - Early survival benefit sustained to 3 years but not thereafter
  - **No difference in:**
    - Reintervention rate
    - Quality of life
    - Cost and cost-effectiveness
ACE Clinical Trial

- Location: France
- Years: 2003 to 2008
- Sample Size: 316
- Outcomes:
  - No difference in perioperative survival (1.3% vs 0.6%)
  - No difference in long-term survival up until 3 years
  - Higher reintervention rate after EVAR
Evolution of Endograft Technology
<table>
<thead>
<tr>
<th>Device Name</th>
<th>Company</th>
<th>Configuration</th>
<th>Min-Max Device Diameter</th>
<th>Fabric; Metal</th>
<th>Active Fixation</th>
<th>Anatomic Fixation</th>
</tr>
</thead>
<tbody>
<tr>
<td>Zenith</td>
<td>Cook</td>
<td>Trimodular</td>
<td>22-36</td>
<td>Woven polyester; Stainless steel</td>
<td>Suprarenal stent w/ barbs</td>
<td></td>
</tr>
<tr>
<td>Aorfix</td>
<td>Lombard Medical</td>
<td>Bimodular</td>
<td>24-31</td>
<td>Woven polyester; Nitinol</td>
<td>Hooks</td>
<td></td>
</tr>
<tr>
<td>Endurant</td>
<td>Medtronic</td>
<td>Bimodular</td>
<td>23-36</td>
<td>Woven polyester; Nitinol</td>
<td>Suprarenal stent w/ barbs</td>
<td></td>
</tr>
<tr>
<td>Excluder</td>
<td>Gore</td>
<td>Bimodular</td>
<td>23-31</td>
<td>ePTFE; Nitinol</td>
<td>Infrarenal barbs</td>
<td></td>
</tr>
<tr>
<td>AFX</td>
<td>Endologix</td>
<td>Unibody</td>
<td>22-34(cuff)</td>
<td>ePTFE; Cobalt chromium</td>
<td>Suprarenal deployment at Aortic bifurcation</td>
<td>Deployment at Aortic bifurcation</td>
</tr>
<tr>
<td>Ovation</td>
<td>Trivascular</td>
<td>Trimodular</td>
<td>20-24</td>
<td>ePTFE; Nitinol</td>
<td>Suprarenal stent w/ barbs and infrarenal sealing rings</td>
<td></td>
</tr>
</tbody>
</table>
Complications of EVAR

Type I

Type II

Type III

Type IV
Durability Issue of EVAR


![Graph showing the probability of no rupture or reintervention over years for endovascular repair and open repair. The graph includes data points for the number at risk over different years.]
Reinterventions for Medicare Beneficiaries – Long-Term Results: EVAR vs Open
EVAR for Short Neck AAA - Encroachment and Snorkel Techniques
Durability Issue of EVAR

- Most common failure mode of EVAR is loss of proximal seal
  - Most often seen in ‘wide neck’ AAA
- Poor or no seal in aneurysmal necks
- Seen with all endografts with outward expansile force from self-expanding metal stents
  - Similar results seen in the GREAT Trial (Excluder), ENGAGE Registry (Endurant), and meta analysis of EVAR for ‘wide neck’ AAA
- Favorable results with OVATION 34mm device in the ENCORE study…
OVATION for Short Wide Neck AAA
ENCORE Study

• **ENCORE**: *Addressing the ‘durability issue of EVAR’*
  – EffectiveNess of Custom seal with Ovation: Review of the Evidence

• OVATION device [34mm]; Largest current device
  – Objective: Determine impact of polymer sealing on neck-related adverse events looking at 5-year patient outcomes

• Retrospective analysis of 6 prospective studies
  – Sample Size: 1,296
    • 242 patients with OVATION device group
    • 1,054 patients = comparison group
  – Results:
    • 5-year results suggest EVAR w/ proximal polymer sealing does not appear to induce neck dilation compared to other devices
      – Suggests the **OVATION device is durable** w/ wide neck anatomy
    • Patients w/ OVATION at largest size had a comparable number of complications of other devices
FEVAR – “Building Up”
## 5-Year Outcomes of Fenestrated EVAR (FEVAR) Grafts

### FEVAR Graft Outcomes - Varlevisser et al., February 2019

<table>
<thead>
<tr>
<th>Outcomes</th>
<th>Effect Values</th>
<th>P-value</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Perioperative: ZFENs vs Open Complex AAA Repairs</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Mortality (%)</td>
<td>1.8% vs 8.8%</td>
<td>0.001</td>
</tr>
<tr>
<td>*Mortality (OR)</td>
<td>4.9 [95% CI:1.4-18.0]</td>
<td>&lt;0.05</td>
</tr>
<tr>
<td>Blood Transfusions (%)</td>
<td>22% vs 73%</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Length of Stay (median)</td>
<td>2 days vs 7 days</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td><strong>Postoperative: ZFENs vs Open Complex AAA Repairs</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Renal Dysfunction (%)</td>
<td>1.4% vs 7.7%</td>
<td>0.002</td>
</tr>
<tr>
<td>*Renal Dysfunction (OR)</td>
<td>13.0 [95% CI:3.6-49.0]</td>
<td>&lt;0.05</td>
</tr>
<tr>
<td>Overall Complications (%)</td>
<td>11% vs 33%</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>*Overall Complications (OR)</td>
<td>4.2 [95% CI:4.2-7.5]</td>
<td>&lt;0.05</td>
</tr>
<tr>
<td><strong>ZFENs vs EVAR (%)</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Perioperative Mortality</td>
<td>1.8% vs 0.8%</td>
<td>0.084</td>
</tr>
<tr>
<td>Postoperative Renal Dysfunction</td>
<td>1.4% vs 0.7%</td>
<td>0.19</td>
</tr>
<tr>
<td>Postoperative Any Complication</td>
<td>11% vs 7.7%</td>
<td>0.09</td>
</tr>
</tbody>
</table>

**Notes:** for % values the % listed to the audience's left = ZFEN and right = Open Complex AAA Repair OR right = infrarenal EVAR. * = Adjusted multivariate logistic regression models (Odds Ratios). OR = Odds Ratios.
FEVAR and BEVAR

FENESTRATIONS
- Less aortic coverage
- Better transverse orientation

BRANCHES
- Better longitudinal orientation
- More branch overlap
- More room for errors
Complex Repairs with IIA Preservation
• AAA repair **is not recommended** in centers with a caseload of <30 repairs/year
  – Class IIA; Evidence Level C

• Centers, networks, and collaborators treating AAA patients **are recommended** to offer both endovascular and open aortic surgery at all times
  – Class I; Evidence Level B
• **Rupture Treatment - Endovascular AAA Repair:**
  – In patients with known ruptured AAA and suitable anatomy, **EVAR is recommended** as a 1st option
    • Class I; Evidence Level B

• **Percutaneous Approach:**
  – Ultrasound-guided percutaneous approach **is recommended** in endovascular AAA repair
    • Class IIa; Evidence Level B
Contraindications:

- Severely scarred groin
- High femoral bifurcation
- Need for frequent introducer sheath changes
- Significant proximal iliac occlusive disease
- Small iliofemoral arteries
- Anterior calcific femoral disease
Elective AAA Repair:
- Normal survival is on average ~9 years
- Not recommended in patients with limited life expectancy
  - Terminal cancer
  - Severe cardiac failure
- A pragmatic definition of “limited life expectancy” is >2–3 years
Summary of Recommendations

• Evidence for EVAR vs Open in AAA Repairs:
  – Most in favor of EVAR:
    • Significant short-term survival benefit
    • Similar long-term outcomes up to 15 years
  – Possible negative EVAR outcomes:
    • Increased rate of complications may occur after ~8–10 years
      – Earlier generation EVAR devices
    • Uncertain durability of current devices
      – Particularly low-profile devices

Therefore: EVAR should be considered the preferred modality in most patients, but it’s reasonable to suggest open first for younger, fit patients, with a life expectancy of at least >10–15 years

- Initial Prediction (2014):
  - Vascular trainees would complete ~5 open aortic repairs by 2020

- Updated Data:
  - BrEVAR and FEVAR:
    - Now appears vascular trainees will complete only 1 to 3 open aortic repairs during training
      - Therefore, ~1.2 open aortic repairs
      - Additionally, the accelerating pace of EVAR use from 2012-2014 contributes to this trend
Which would you rather have?

Open AAA Repair

EVAR AAA Repair
Thank You!