For Which TAAA Patient Is F/BEVAR The Best Option? In What Type Of Institution?

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Disclosures

- Research support, Consulting
  - Cook Med, GE Healthcare

TAAA Treatment

- Intention:
  - to prevent aortic related death while preserving the quality of life
- Options:
  - Medical
  - Open Surgery
  - Endovascular Repair

What effects Treatment Choice?

- Mortality
  - Perioperative
  - Long-term
- Morbidity
- Durability
  - reinterventions

OPEN TAAA REPAIR

Results in Medicare patients

<table>
<thead>
<tr>
<th>Patient Age</th>
<th>Percent Mortality</th>
<th>Overall Mortality: 19% at 30 days</th>
</tr>
</thead>
<tbody>
<tr>
<td>50-59</td>
<td>18%</td>
<td>56%</td>
</tr>
<tr>
<td>60-69</td>
<td>27%</td>
<td>58%</td>
</tr>
<tr>
<td>70-79</td>
<td>34%</td>
<td>63%</td>
</tr>
<tr>
<td>80-89</td>
<td>40%</td>
<td>69%</td>
</tr>
</tbody>
</table>

OPEN TAAA REPAIR

Results in Medicare patients

Author, Year  n  30-day Mortality (%)

<table>
<thead>
<tr>
<th>Author/Year</th>
<th>n</th>
<th>30-day Mortality (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Coselli et al, 2007</td>
<td>2286</td>
<td>7</td>
</tr>
<tr>
<td>Schepens et al, 2007</td>
<td>500</td>
<td>12</td>
</tr>
<tr>
<td>Etz et al, 2007</td>
<td>858</td>
<td>10</td>
</tr>
<tr>
<td>Auchneck et al, 2007</td>
<td>130</td>
<td>12</td>
</tr>
<tr>
<td>Conrad/Cambria, 2007</td>
<td>455</td>
<td>9</td>
</tr>
<tr>
<td>Jacobs et al, 2004</td>
<td>279</td>
<td>9</td>
</tr>
<tr>
<td>Sofi et al, 2005</td>
<td>1106</td>
<td>15</td>
</tr>
<tr>
<td>Grabitz et al, 1996</td>
<td>260</td>
<td>15</td>
</tr>
<tr>
<td>Svensson et al, 1993</td>
<td>1509</td>
<td>8</td>
</tr>
</tbody>
</table>
eTAAA RESULTS
Single-center studies and prospective IDEs

<table>
<thead>
<tr>
<th>Author</th>
<th>n</th>
<th>Braches (vessels/pts)</th>
<th>Design</th>
<th>30-day mortality</th>
<th>Mean follow up</th>
<th>Re-interv.</th>
<th>Renal occlusion</th>
</tr>
</thead>
<tbody>
<tr>
<td>Greenberg et al</td>
<td>406</td>
<td>-</td>
<td>Helical</td>
<td>4%</td>
<td>29 ± 16</td>
<td>-</td>
<td>2.1%</td>
</tr>
<tr>
<td>Raffy/Chuter et al</td>
<td>81</td>
<td>306 (3.8)</td>
<td>Br</td>
<td>6.2%</td>
<td>21 ± 18</td>
<td>40%</td>
<td>6%</td>
</tr>
<tr>
<td>Kasprzak et al</td>
<td>83</td>
<td>287 (3.6)</td>
<td>Br</td>
<td>7.2%</td>
<td>-</td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td>Bedawi/Ismail et al</td>
<td>46</td>
<td>184 (4)</td>
<td>Br</td>
<td>4.6%</td>
<td>13 ± 11</td>
<td>16%</td>
<td>5.4%</td>
</tr>
<tr>
<td>Verhoeven et al</td>
<td>166</td>
<td>600 (3.6)</td>
<td>Fen/Br</td>
<td>7.8%</td>
<td>29 ± 21</td>
<td>17%</td>
<td>5.1%</td>
</tr>
<tr>
<td>Maurel/Haulon et al</td>
<td>204</td>
<td>695 (3.4)</td>
<td>Fen/Br</td>
<td>5.8%</td>
<td>-</td>
<td>-</td>
<td>4.4%</td>
</tr>
<tr>
<td>Oderich et al (SCVS2015 abstract)</td>
<td>145</td>
<td>514 (3.7)</td>
<td>Fen</td>
<td>3.6%</td>
<td>20 ± 17</td>
<td>18%</td>
<td>1.6%</td>
</tr>
</tbody>
</table>

RESULTS

Early experience group N=43
Late experience group N=161

- Mortality: 11.6 % before 2010 vs 5.6 % after 2010
  \[(RR = 0.481 [0.17-1.36]; p = 0.09)\]

- Spinal Cord Ischemia: 14% vs 1.2%
  \[(RR = 1.148 [1.016-1.296]; p < 0.001)\]

OPEN TAAA REPAIR
Mortality vs hospital and surgeon volume

27% 24%
22% 15%
26% 11%

Greenberg RK. Circulation 2009
Learning Curve / High Volume

Part One: For the Motion. Fenestrated Endografts Should Be Restricted to a Small Number of Specialized Centers

DISPOSITION AFTER REPAIR
Outcomes in 5,776 patients

<table>
<thead>
<tr>
<th>Disposition</th>
<th>n</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td>Dismissal home</td>
<td>3006</td>
<td>31</td>
</tr>
<tr>
<td>Another health care facility</td>
<td>1691</td>
<td>52</td>
</tr>
<tr>
<td>Another hospital</td>
<td>770</td>
<td>12</td>
</tr>
<tr>
<td>Skilled nursing facility</td>
<td>608</td>
<td>32</td>
</tr>
<tr>
<td>Rehabilitation facility</td>
<td>306</td>
<td>6</td>
</tr>
<tr>
<td>Intermediate facility</td>
<td>145</td>
<td>3</td>
</tr>
<tr>
<td>Died in the hospital</td>
<td>940</td>
<td>16</td>
</tr>
</tbody>
</table>


The Endovascular Learning Curve

- Sizing and planning
- Technical skills for implantation
- Peri-operative patient management
- Intra-operative imaging
- Development of a team including nurses, radiographers, anesthetists
- Training other physicians

Phase of Evolution

- Phase I characterized by early development of device, delivery system, patient selection, technique maturation
- Phase II: broadening of technology to including side branches to address complex thoracoabdominal aneurysms
- Phase III: team approach - experience and expanded resources (hybrid endovascular suites)

Risks of Phase

- Early experience
  - Steep learning curve
  - Rapid implant evolution
  - Rapid delivery system evolution
- Sicker patients
  - More complications
  - Increased device options
- Repeat learning curves for each added operator
  - Need for expanded resources

Sizing and Planning

- Initial strategies involved minimizing the incorporation of visceral vessels
  - Fear of inability to cannulate target vessel
  - Limited ability to assess and understand the extent of disease
- Planning the primary procedure in the context of potentially required later repairs

Dr Martinez – CHU Tours
Type Ia endoleaks after fenestrated and branched endografts may lead to component instability and increased aortic mortality

O'Callaghan et al, JVS 2015

Technical success does not mean durability

O'Callaghan et al, JVS 2015

Benefit of Experience

- 288 patients total, grouped in to early and late experience

- Expertise results in
  - Increasing complexity of design
  - Similar perioperative outcomes
  - Lower radiation dose
  - Lower contrast dose

Sveinsson et al, JVS 2015

From the Society for Vascular Surgery

Early versus late experience in fenestrated endovascular repair for abdominal aortic aneurysm

Sveinsson et al, JVS 2015
LEARNING CURVE MAYO CLINIC

<table>
<thead>
<tr>
<th>Patient</th>
<th>1 to 80</th>
<th>81 to 160</th>
<th>161 to 240</th>
<th>P value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pararenal</td>
<td>70%</td>
<td>74%</td>
<td>38%</td>
<td>.01</td>
</tr>
<tr>
<td>TAAA</td>
<td>30%</td>
<td>25%</td>
<td>22%</td>
<td>.01</td>
</tr>
<tr>
<td>No. of Vessels</td>
<td>2.4±1.06</td>
<td>3.04±1.02</td>
<td>3.54±0.75</td>
<td>.001</td>
</tr>
<tr>
<td>2-vessel</td>
<td>50%</td>
<td>29%</td>
<td>10%</td>
<td>.001</td>
</tr>
<tr>
<td>4-vessel</td>
<td>19%</td>
<td>41%</td>
<td>65%</td>
<td>.001</td>
</tr>
<tr>
<td>Fluoroscopy (min)</td>
<td>117±61</td>
<td>84±38</td>
<td>72±23</td>
<td>.05</td>
</tr>
<tr>
<td>Contrast (ml)</td>
<td>237±99</td>
<td>163±73</td>
<td>138±75</td>
<td>.001</td>
</tr>
<tr>
<td>30-day Mortality</td>
<td>5 (6%)</td>
<td>2 (3%)</td>
<td>0</td>
<td>.12</td>
</tr>
</tbody>
</table>

Learning Curve with 3D Imaging

GE DISCOVERY IGS 730

Dose and contrast saving

Dose reduction by 40 to 59% and contrast load by 24 to 26%

3D Angiography
Learning Curve
Patient Selection

Target Vessels

MAJOR AORTIC ANGULATION

'Shaggy' Aorta

Multiple, small renal arteries
Patients with connective tissue disorders?

- 391 patients
- 376 TAAA
- 15 Arch
- 15 (4%)
- 1 (6.7%)

4-Branch - 37y TAAA II

The Learning Curve Revisited

- Long and steep learning curve
- High volume centers will produce the best results
- These issues directly correlate with open surgical treatment of thoracoabdominal aneurysms

Conclusions

- Open repair for
  - Young patients
  - Connective Tissue Disorders
- Limited technical/anatomical limitations
- Redefine "high risk"

KEEP CALM AND LEARN TO SAY NO

VEITHSymposium™
Connecting the Vascular Community