The value of a low profile device

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Disclosure

Speaker name:

........Giovanni Torsello................................................................

I have the following potential conflicts of interest to report:

☒ Consulting
☐ Employment in industry
☐ Stockholder of a healthcare company
☐ Owner of a healthcare company
☐ Other(s)

☐ I do not have any potential conflict of interest
TEVAR vs. Open Repair

Early mortality
Paraplegia
Renal insufficiency
Cardiac complications
Pneumonia
Hemorrhage
Hospitalization

Figure 1. The rates of thoracic and thoracoabdominal repair (triangles), open repair (squares), and endovascular repair in the Medicare population from 1998 to 2007.

Problem: Difficult Access

- Large grafts

- More female and asian pts.

- Applicability
  - Exclusion of female pts.

- Complications

- Morbidity & mortality w/ access related compl
Profile of the Zenith TX2 and of the new Zenith Alpha Endograft

<table>
<thead>
<tr>
<th>TX-2</th>
<th>36 – 42 mm</th>
<th>28 – 34 mm</th>
</tr>
</thead>
<tbody>
<tr>
<td>22 F</td>
<td>20 F</td>
<td>18 F</td>
</tr>
<tr>
<td>Alpha</td>
<td></td>
<td></td>
</tr>
<tr>
<td>40 - 46 mm</td>
<td>32 – 38 mm</td>
<td>18 - 30 mm</td>
</tr>
</tbody>
</table>
Access vessel diameter as a limiting factor

Based on M2S anatomical data for 45K cases in the U.S.
Represents mean responses of all specialties and regions.
Study design

Retrospective analysis of prospectively collected data of patients w/ TAA or PAU, treated between August 2010 and May 2014 with:

<table>
<thead>
<tr>
<th></th>
<th>Zenith Alpha</th>
<th>Zenith TX-2</th>
</tr>
</thead>
<tbody>
<tr>
<td>n</td>
<td>33</td>
<td>34</td>
</tr>
<tr>
<td>m:f</td>
<td>21:12</td>
<td>25:9</td>
</tr>
<tr>
<td>Age (y)</td>
<td>73.2 ± 9.0</td>
<td>70.3 ± 8.5</td>
</tr>
</tbody>
</table>
Risk profile and demanding anatomy

<table>
<thead>
<tr>
<th>Parameter</th>
<th>Alpha</th>
<th>TX-2</th>
<th>p</th>
</tr>
</thead>
<tbody>
<tr>
<td>Iliac tortuosity</td>
<td>1.34±0.15</td>
<td>1.25±0.14</td>
<td>0.022</td>
</tr>
<tr>
<td>Min. iliac diameter</td>
<td>5.07±1.21</td>
<td>6.65±2.09</td>
<td>0.002</td>
</tr>
<tr>
<td>Iliac calcification</td>
<td>14</td>
<td>10</td>
<td>0.520</td>
</tr>
<tr>
<td>Femoral calcification</td>
<td>6</td>
<td>3</td>
<td>0.296</td>
</tr>
</tbody>
</table>
Results

Technical success
- 94% (31/33)
- 91% (31/34)

Mortality
- 9% (3/33)
- 0%

Sec. Procedures
- 6% (2/33)
- 18% (6/34)

Access vessel complications
- 3% (1/33)
- 12% (4/34)

p = 0.67
p = 0.07
p = 0.14
p = 0.17
Results

Fewer access vessel complications
(3 vs. 12%, p=0.17) in pts w/
more difficult access (smaller
(p=0.002) more tortuous (p=0.022)
iliacs)

Greater share of female pts.
12/33 vs 9/34 (p=0.383)
Results: increased applicability of thoracic endografting!

6 pts (18%): unsuccessful initial treatment attempt w/ other graft (p=0.01)
- TEVAR attempted with other graft
- Restenosis of the right iliac
- Wound infection left groin
Angiography after TEVAR and PTA of the right iliac artery
Aneurysm Exclusion with Zenith Alpha

1-month CT

24-month CT

48-month CT
Conclusions

• Initial experience with a non-preselected patient cohort:
  – adequate 30-Day-results
  – fewer access-related complications
  – Inclusion of pts with more demanding access vessel anatomy

• Further questions
  – Different deployment mechanics in aortic arch?
  – Long-term performance?
Thank you very much!
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