Fate of 36mm Aortic Endografts: Are Larger Devices a Good Option?

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Disclosures:
- None

EVAR has become the preferred method for treatment of AAA
Large RCTs have confirmed its procedure related and early benefits
Indications for use have expanded with progressive improvements in:
  - materials
  - technology
  - delivery systems
  - physician experience

EVAR advancements include the development of larger devices for treating challenging proximal aortic necks
36 mm devices available in US:
  - Cook Zenith Flex
  - Medtronic Talent
  - Medtronic Endurant II
  - Bolton Treovance/Cook Zenith LP (trial only)
Since FDA approval of these larger devices, there remains a paucity of data supporting their use

Anatomic Limitations for EVAR

- EVAR have hostile infrarenal aortic necks:
  - Length <10-15 mm
  - Diameter >28 mm
  - Angle > 60°
  - ≥50% circumferential thrombus
  - ≥50% calcified neck
  - Reverse taper

*Skepticism exists about the use of 36mm devices placed in “diseased aortic tissue”

Introduction

A meta-analysis of outcomes of endovascular abdominal aortic aneurysm repair in patients with hostile and friendly neck anatomy

Ample evidence exists linking hostile aortic necks to poor outcomes after EVAR:
  - Early and late type I endoleaks are more frequent
  - Increased need for secondary interventions
  - Larger aortic neck diameters and shorter lengths appear to be disadvantageous

Clinical outcomes for hostile versus favorable aortic neck anatomy in endovascular aortic aneurysm repair using modular devices

* References included in presentation.
Study to define anatomic criteria most predictive of success or failure at the aortic neck

- 221 patients in Heli-FX aortic securement system global registry (ANCHOR)
- 100 (45.2%) developed type Ia endoleaks
- 58% post deployment and 42% during follow-up

Binary logistic regression analysis determined that aortic neck diameter (26mm) at the level of the renal arteries (P=.002) and shorter aortic neck length (P=.017) were the only independent predictors of type Ia endoleaks.

Follow-up of 17 patients (55%):
- No conversions, aortic ruptures or AR mortality
- No Type Ia endoleaks or migration
- 3 secondary interventions (type Ib or type II)

36mm Zenith endografts are not associated with increased incidence of type I endoleaks or device migration
Multi-center retrospective review of elective EVAR from 1998-2012

- 908 EVAR patients: 783 implants ≤32 mm, 170 implants >32 mm diameter
- Follow-up 38±28.2 months

Larger devices were associated with a higher incidence of type Ia endoleaks over time

No difference in postoperative rates of complications, technical failure, endoleak or death

Long term:
- Proximal endoleak rates were higher (13% v. 3.9%, P<0.0001)
- Reintervention rates were higher (24.1% v. 14.7%, P=0.009)

EVAR for larger aortic necks (<32 mm) are associated with higher rates of endoleaks and need for reinterventions

UPMC experience with 36mm grafts

- 6 year study (2010-2015)
- 26 patients identified (Cook Zenith 10, Medtronic Endurant 18)
- 4 lost in follow-up
- 2 follow-up <30 days
- 16 patients with ≥12 months follow-up
- 14 elective & 2 ruptures (Zenith 8, Endurant 8)

n=16

<table>
<thead>
<tr>
<th>Mean (range)</th>
</tr>
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<tbody>
<tr>
<td>Proximal aortic neck length</td>
</tr>
<tr>
<td>Proximal neck diameter</td>
</tr>
<tr>
<td>Infrarenal neck angulation</td>
</tr>
<tr>
<td>AAA diameter</td>
</tr>
<tr>
<td>EVAR % oversizing</td>
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</tbody>
</table>
Early results

<table>
<thead>
<tr>
<th>Early results</th>
<th>n=16</th>
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</thead>
<tbody>
<tr>
<td>Technical success</td>
<td>100%</td>
</tr>
<tr>
<td>Length of stay</td>
<td>4.8 days (1-27 days)</td>
</tr>
<tr>
<td>30 day mortality</td>
<td>6.25% (1/16)</td>
</tr>
<tr>
<td>30 day type Ia endoleak</td>
<td>0%</td>
</tr>
<tr>
<td>30 day reintervention</td>
<td>0%</td>
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</tbody>
</table>

30 day mortality 6.25% (1/16)
30 day type Ia endoleak 0%
30 day reintervention 0%

Follow-up (n=)

<table>
<thead>
<tr>
<th>Follow-up</th>
<th>1 month (16)</th>
<th>12 month (11)</th>
<th>24 month (6)</th>
<th>36 month (2)</th>
<th>48 month (2)</th>
<th>60 month (1)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Device migration &gt;10mm</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>Type Ia endoleak</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>Type II endoleak</td>
<td>3</td>
<td>4</td>
<td>2</td>
<td>1</td>
<td>1</td>
<td>0</td>
</tr>
<tr>
<td>Intervention</td>
<td>0</td>
<td>4</td>
<td>1</td>
<td>0</td>
<td>0</td>
<td>0</td>
</tr>
</tbody>
</table>

* no aneurysm related deaths (24 month all-cause mortality 25%)

Conclusion

- Wider aortic necks probably reflect an advancing state of arterial wall degeneration
- Limited data suggests there is an increased incidence of type Ia endoleaks with larger aortic necks (>26mm)
- Industry sponsored data and 2 single center reviews suggest that 36mm devices placed in larger aortic necks appear to be safe and effective
- Hostile necks with more than one risk factor should be treated with caution