Treating Aortic Aneurysms With Large Necks: What Are The Considerations?

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Disclosures

• Medtronic
• WL Gore
• Philips
• Endologix
• Arsenal AAA
EVAR has expanded to treat more challenging anatomies although it is associated with increased risk of adverse events.

In patients with wide necks, EVAR has acceptable short-term results but longer-term results are contradictory.

To expand eligibility, industry has increased graft diameters, allowing implants in attachment zones that are aneurysmal.
Objective

• To determine longer-term outcomes following EVAR in patients with large neck diameters, using a single endograft

Hypothesis

• Standard EVAR in patients with an infrarenal neck ≥ 30 mm is associated with an increased risk of neck-related complications
**Methods**

- Retrospective case-control study based on prospective database from 3 high-volume centers in the Netherlands

- Consecutive patients undergoing standard EVAR with Endurant between 2008-2012

- Exclusion: ✓ Anastomotic, infectious, or iliac aneurysms
  ✓ Andoanchors
  ✓ No CTA available
Methods

• **Study group:** Patients with infrarenal neck diameter of $\geq 30$ mm

• **Controls:** Remaining population
Methods

- Measurements by 2 experienced, independent observers using dedicated post-processing software (3Mensio)
- Analysis: preoperative, 30-day, and last available CTA

- **Primary end point:** Neck-related adverse events
- **Secondary end points**
  - Type 1A EL
  - FF neck-related reinterventions
  - Clinical success
  - EL
  - AR secondary interventions
Results

- 427 patients were included, median FU time of 3.9 years

- **Study group:** 74 Patients with infrarenal neck diameter \( \geq 30 \text{ mm} \)

- **Controls:** 353 Patients
# Results

## Neck-related adverse events

<table>
<thead>
<tr>
<th></th>
<th>Univariate</th>
<th>OR</th>
<th>95% CI</th>
<th>P value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Proximal neck-related adverse events</td>
<td>12 (16.2)</td>
<td>3.76</td>
<td>1.55-9.12</td>
<td>.003</td>
</tr>
<tr>
<td>Aneurysm-related adverse events</td>
<td>14 (18.9)</td>
<td>1.71</td>
<td>0.83-3.51</td>
<td>.15</td>
</tr>
<tr>
<td>Any endoleak</td>
<td>18 (24.3)</td>
<td>1.37</td>
<td>0.72-2.59</td>
<td>.34</td>
</tr>
<tr>
<td>Type Ia endoleak</td>
<td>7 (9.5)</td>
<td>2.67</td>
<td>0.96-8.30</td>
<td>.05</td>
</tr>
<tr>
<td>Type I and III endoleaks</td>
<td>11 (14.9)</td>
<td>3.06</td>
<td>1.30-7.19</td>
<td>.01</td>
</tr>
<tr>
<td>Type II endoleak</td>
<td>11 (14.9)</td>
<td>0.91</td>
<td>0.44-1.91</td>
<td>.81</td>
</tr>
<tr>
<td>Migration &gt;10 mm</td>
<td>0 (0.0)</td>
<td>1.85</td>
<td>0.93-3.69</td>
<td>.08</td>
</tr>
<tr>
<td>Aneurysm sac growth</td>
<td>13 (20.6)</td>
<td>1.45</td>
<td></td>
<td>.95</td>
</tr>
<tr>
<td>Aneurysm rupture</td>
<td>1 (1.4)</td>
<td>.82</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Aneurysm-related mortality</td>
<td>1 (1.4)</td>
<td>.69</td>
<td></td>
<td>.22</td>
</tr>
<tr>
<td>Open conversion</td>
<td>0 (0)</td>
<td>.22</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Neck-related secondary interventions</td>
<td>7 (9.5)</td>
<td>3.19</td>
<td>1.11-9.17</td>
<td>.03</td>
</tr>
<tr>
<td>Secondary interventions</td>
<td>13 (17.6)</td>
<td>1.20</td>
<td>0.58-2.46</td>
<td>.62</td>
</tr>
<tr>
<td>Primary clinical success</td>
<td>56 (75.7)</td>
<td>0.92</td>
<td>0.49-1.73</td>
<td>.79</td>
</tr>
<tr>
<td>Secondary clinical success</td>
<td>61 (82.4)</td>
<td>0.78</td>
<td>0.38-1.61</td>
<td>.51</td>
</tr>
</tbody>
</table>
Results

**FF Neck-related adverse events**
Results
Clinical success

![Graph showing clinical success over follow-up time with data Table:]

<table>
<thead>
<tr>
<th>Proximal neck diameter ≥30mm</th>
<th>N at risk</th>
<th>Freedom from event</th>
<th>SE</th>
</tr>
</thead>
<tbody>
<tr>
<td>74</td>
<td>51</td>
<td>41</td>
<td>30</td>
</tr>
<tr>
<td>-</td>
<td>72.5</td>
<td>62.3</td>
<td>52.5</td>
</tr>
<tr>
<td>-</td>
<td>.08</td>
<td>.06</td>
<td>.06</td>
</tr>
<tr>
<td>17</td>
<td>41</td>
<td>30</td>
<td>17</td>
</tr>
<tr>
<td>-</td>
<td>62.5</td>
<td>52.5</td>
<td>36.3</td>
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<tr>
<td>-</td>
<td>.06</td>
<td>.06</td>
<td>.06</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Proximal neck diameter &lt;30mm</th>
<th>N at risk</th>
<th>Freedom from event</th>
<th>SE</th>
</tr>
</thead>
<tbody>
<tr>
<td>353</td>
<td>306</td>
<td>271</td>
<td>226</td>
</tr>
<tr>
<td>-</td>
<td>90.4</td>
<td>83.4</td>
<td>72.5</td>
</tr>
<tr>
<td>-</td>
<td>.02</td>
<td>.02</td>
<td>.03</td>
</tr>
<tr>
<td>169</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
Results

• No independent risk factor:

  Reversed tapered neck
  Thrombus in the neck (≥ 25%)

• No difference in neck dilatation over time between groups
Conclusion

• Standard EVAR in patients with wide infrarenal aneurysm necks is associated with increased risk of adverse events.

How’s that on a more global scale?
Methods – ENGAGE Registry
Largest Contemporary EVAR Registry with single stent graft (Endurant)

• N=1263 pts; Prospective/Consecutive Enrollment (2009-2010)
  • Initiated <1yr post-CE mark, to evaluate Endurant in real-world popula

• 79 Centers, across 30 Countries, on 6 Continents
  • Diverse patient and physician population

• Adherence to IFU advised; Off-IFU pts permitted

• High-Quality Data
  • 100% data management review
  • Independent data monitoring
  • Independent Clinical Event Committee
Methods

• Primary end point: - Type 1A endoleak

• Secondary end points - sec. interventions for type 1A EL
  - AAA sac growth
  - MAE
  - Rupture
  - ACM & ARM
Results

• 1257 patients were included, median FU time of 4.04 years

• Study group: 97 Patients with infrarenal neck diameter $\geq 30$ mm

• Controls: 1160 Patients
Results

Patients with neck diameters $\geq 30$ mm:

- 3-fold greater risk of developing type 1A EL
- 5-fold greater risk of aneurysm rupture
Conclusion

- Standard EVAR in patients with wide infrarenal aneurysm necks is associated with increased risk of type 1A EL, secondary interventions and ruptures.

- Other treatments (CHEVAR/FEVAR/OR) should be considered, weighing risks, costs, and expected outcomes.

- CT imaging should not be waived during surveillance as DUS / X-ray will not detect dilatation and loss of proximal seal before type 1A EL development.
Conclusion

• Loss of proximal seal with the Endurant is mainly due to progressive neck dilatation, not to migration.

• The primary use of endoanchors in wide necks to prevent further neck dilatation is an interesting concept, but still unproven.

• Our studies may serve as a standard to which this new concept can be compared.
Thank you
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