Midterm outcome of Endoanchors for prevention of endoleak and migration in challenging necks

Bart E. Muhs MD, PhD
The Vascular Experts, CT, USA
Disclosure

Consultant
- Medtronic
- Cook
- Endologix

Research grants
- Cook
- Endologix
Major Studies Show Higher 2\textsuperscript{nd} Interventions in EVAR vs. Open Repair

- Late ruptures in EVAR, none in open surgery
- Unlike open repair, endoleaks and migration are major complications of EVAR
  - Predictors for rupture, and risks increase with time
- Open surgery remains a ‘more durable option’
  - In ACE, 16\% re-interventions in EVAR vs. 2.4\% for open repair at 3 yr median f/u
Hostile proximal necks further challenge EVAR

Meta-Analysis of 7 major studies in EVAR by Antoniou et al\(^1\) compared outcomes in hostile vs. friendly neck anatomies (total patients N = 1559)

<table>
<thead>
<tr>
<th>Study</th>
<th>Sample Size</th>
<th>Endografts</th>
</tr>
</thead>
<tbody>
<tr>
<td>Torsello et al, 2011</td>
<td>177</td>
<td>Endurant</td>
</tr>
<tr>
<td>AbuRahma et al, 2010</td>
<td>238</td>
<td>AneuRx, Excluder, Zenith, Talent</td>
</tr>
<tr>
<td>Hoshina et al, 2010</td>
<td>129</td>
<td>Excluder, Zenith</td>
</tr>
<tr>
<td>Abbruzzese et al, 2008</td>
<td>565</td>
<td>AneuRx, Excluder, Zenith</td>
</tr>
<tr>
<td>Choke et al, 2006</td>
<td>147</td>
<td>Talent, Zenith, Excluder, AneuRx</td>
</tr>
<tr>
<td>Fulton et al, 2006</td>
<td>84</td>
<td>AneuRx</td>
</tr>
<tr>
<td>Fairman et al, 2004</td>
<td>219</td>
<td>Talent</td>
</tr>
</tbody>
</table>

- **Type I endoleaks 4.5x more likely at 1-year** after endograft implantation in hostile proximal aortic neck anatomy (P = .010)
- **Aneurysm-related mortality risk 9x greater** in hostile neck anatomy (P= .013)

\(^1\)Antoniou GA et al. JVS. 2013;57(2):527-38.
Influence of multiple hostile neck parameters

Speziale et al. shows greater proximal seal complication risks as the number of hostile neck parameters increases.

<table>
<thead>
<tr>
<th>Neck hostility</th>
<th>Intra-op adjunctive procedures</th>
<th>Intra-op endoleaks</th>
<th>All cause mortality</th>
</tr>
</thead>
<tbody>
<tr>
<td>On label</td>
<td>9.9%</td>
<td>0.5%</td>
<td>1.1%</td>
</tr>
<tr>
<td>2 hostile neck parameters</td>
<td>26.7%</td>
<td>6.7%</td>
<td>13.3%</td>
</tr>
<tr>
<td>&gt;2 hostile neck parameters</td>
<td>50%</td>
<td>16.7%</td>
<td>16.7%</td>
</tr>
</tbody>
</table>

Greater than 1 hostile neck parameter *substantially* increases mortality, major adverse events, intra-op endoleaks and adjunctive procedures.

Speziale et al, Annals VS, 2014
NOT ALL NECKS ARE THE SAME

Tailored Seal and Fixation of EndoAnchors

Create the stability of a surgical anastomosis in EVAR and TEVAR

Surgical Anastomosis

EndoAnchoring

Melas et al. JVS 2012;55(6):1726-33

Case images from John Aruny MD, Bart Edward Muhs, MD, PhD.
## ANCHOR registry capturing real-world usage

<table>
<thead>
<tr>
<th>Registry Principal Investigators</th>
<th>Europe: Dr. Jean-Paul de Vries – Chief of Vascular Surgery, St. Antonius Hospital</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>US: Dr. William Jordan – Chief of Vascular Surgery/Endovascular Therapy, Emory University School of Medicine</td>
</tr>
<tr>
<td>Registry Design</td>
<td>Prospective, observational, international, multi-center, dual-arm Registry</td>
</tr>
<tr>
<td>Treatment Arms</td>
<td>“Primary” – Up to 1000 pts, Prophylactic</td>
</tr>
<tr>
<td></td>
<td>“Revision” – Up to 1000 pts, Therapeutic</td>
</tr>
<tr>
<td>Enrollment &amp; Duration</td>
<td>Enrollment began 2012 and patients will be followed for 5 Years</td>
</tr>
<tr>
<td>Follow-up</td>
<td>Per Standard of Care at each center &amp; discretion of Investigator</td>
</tr>
<tr>
<td>Over 600 Patients enrolled as of November 2015</td>
<td></td>
</tr>
</tbody>
</table>
ANCHOR Registry – Enrollment Status (data cut Aug 10, 2015)

ANCHOR Registry
593 Subjects
(74.9% US/25.1% OUS)

Primary Arm
439 Subjects

Revision Arm
154 Subjects

Stent Grafts - Primary Arm
- Medtronic Endurant
- Gore Excluder
- Cook Zenith
- Jotec
- Other

Stent Grafts - Revision Arm
- Medtronic Endurant
- Medtronic Talent
- Medtronic AneuRx
- Gore Excluder
- Cook Zenith
- Jotec
- Other
This analysis will summarize the outcome in **269** patients.

- **Clinical follow-up:** **21.3 months** (0 – 39 months)
- **CT follow-up:** **8.2 months** (range 0 – 27 months)

- Excludes revisions or treatment of Type Ia endoleaks at Index
- 11.2% urgent cases (rupture or symptomatic)
### Baseline Characteristics

<table>
<thead>
<tr>
<th>Characteristic</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Male (n/n, %)</td>
<td>77.7% (209/269)</td>
</tr>
<tr>
<td>Age</td>
<td>74.4</td>
</tr>
</tbody>
</table>

### Aneurysm Measurements (Core Lab)

<table>
<thead>
<tr>
<th>Measurement</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Number with Baseline CT Scans</td>
<td>205</td>
</tr>
<tr>
<td>Aneurysm Diameter</td>
<td>55.5 mm</td>
</tr>
<tr>
<td><strong>Proximal Neck Length</strong></td>
<td>16.6 mm</td>
</tr>
<tr>
<td>Infrarenal Diameter</td>
<td>25.7 mm</td>
</tr>
<tr>
<td>Suprarenal Angulation</td>
<td>15°</td>
</tr>
<tr>
<td>Infrarenal Angulation</td>
<td>35°</td>
</tr>
<tr>
<td>Average Neck Calcium Thickness</td>
<td>1.1 mm</td>
</tr>
<tr>
<td><strong>Conical Neck (&gt;10%/10mm)</strong></td>
<td>41.0%</td>
</tr>
<tr>
<td><strong>Hostile Necks</strong></td>
<td>77.6%</td>
</tr>
</tbody>
</table>

### Definitions for Hostile Neck Criteria

<table>
<thead>
<tr>
<th>Criterion</th>
<th>Threshold</th>
</tr>
</thead>
<tbody>
<tr>
<td>Aortic Diameter at Renals</td>
<td>28</td>
</tr>
<tr>
<td>Proximal Neck Length</td>
<td>10</td>
</tr>
<tr>
<td>Infrarenal Angulation to Bifurcation</td>
<td>60</td>
</tr>
<tr>
<td>Neck Thrombus Avg Thickness</td>
<td>2</td>
</tr>
<tr>
<td>Neck Thrombus Circum &gt;1mm</td>
<td>180</td>
</tr>
<tr>
<td>Neck Calcium Avg Thickness</td>
<td>2</td>
</tr>
<tr>
<td>Neck Calcium Circum &gt;1mm</td>
<td>180</td>
</tr>
</tbody>
</table>
ANCHOR Registry – Prophylactic Subjects

PROXIMAL ENDOLEAKS AND MIGRATION
MEAN FOLLOW-UP 8.2 MONTHS

<table>
<thead>
<tr>
<th>Type Ia Endoleaks</th>
<th>All Primary Cases</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>1a ELs</td>
</tr>
<tr>
<td></td>
<td>3</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Endograft Migration (&gt;10mm)</th>
<th>All Primary Cases</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Migration</td>
</tr>
<tr>
<td></td>
<td>0</td>
</tr>
</tbody>
</table>

Migration was assessed in comparison to the 1-month CT scan.
### SAC DIAMETER CHANGES

<table>
<thead>
<tr>
<th>Sac Diameter Changes</th>
<th>Patients</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>All Prophylactic Patients</strong></td>
<td></td>
</tr>
<tr>
<td>Mean 8 months</td>
<td></td>
</tr>
<tr>
<td>&gt;5mm Regression</td>
<td>42</td>
</tr>
<tr>
<td>&gt;5mm Enlargement</td>
<td>1</td>
</tr>
<tr>
<td>Patients</td>
<td>154</td>
</tr>
<tr>
<td><strong>Prophylactic Patients with 1-Year CTs</strong></td>
<td></td>
</tr>
<tr>
<td>9-12 month window</td>
<td></td>
</tr>
<tr>
<td>&gt;5mm Regression</td>
<td>25</td>
</tr>
<tr>
<td>&gt;5mm Enlargement</td>
<td>0</td>
</tr>
<tr>
<td>Patients</td>
<td>39</td>
</tr>
</tbody>
</table>

Sac regression/enlargement was assessed in comparison to the 1-month CT scan. Analysis includes only those patients with a 1-month CT and at least one more CT obtained after 1 month.
WHEN TO USE ENDOANCHORS
TO PREVENT/MITIGATE TYPE 1A ENDOLEAKS

- To improve durability of EVAR for “hostile” necks
  - Calcium, thrombus, angulated, conical, short
- Current ANCHOR registry analysis demonstrates no migration and <2% Type 1a EL in Primary Prophylactic cases (8.2 month mean f/u)
Do EndoAnchors have value in preventing proximal neck complications in patients with challenging neck anatomy?
The EVAR Durability Question and a Potential Solution

- In absence of randomized clinical trial, propensity matched analysis of Study vs Control EVAR groups can provide insight.

- Two patient cohorts:
  - **EndoAnchor group** – the current “Primary Prophylaxis” cohort from the ANCHOR registry (235 patients)
  - **Control group** – 115 patients treated over the 4 years prior to EndoAnchor availability at three institutions
The EVAR Durability Question and a Potential Solution

Methodology

- Pre-EVAR baseline CTs evaluated by Core Lab for both groups

- 19 baseline variables entered into a propensity matching algorithm (SPSS v22; binary logistic regression with group as the independent variable)

- Match:
  - 103 patients in each group
  - Well-matched by the 19 baseline variables

- Analysis:
  - Primary Endpoint is a composite indicative of “proximal neck failure”
    - Including Type Ia EL, Sac Enlargement, Migration, Neck Dilatation
The EVAR Durability Question and a Potential Solution

Baseline anatomy in propensity-matched cohorts

<table>
<thead>
<tr>
<th>Anatomic Measures for Propensity Matching</th>
<th>Controls N = 103</th>
<th>EndoAnchors N = 103</th>
<th>P Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Max AAA Diameter</td>
<td>56 ± 13 mm</td>
<td>56 ± 10 mm</td>
<td>.674</td>
</tr>
<tr>
<td>Suprarenal Diameter</td>
<td>27 ± 4 mm</td>
<td>27 ± 3 mm</td>
<td>.999</td>
</tr>
<tr>
<td>Diameter at Lowest Renal</td>
<td>25 ± 4 mm</td>
<td>26 ± 4 mm</td>
<td>.458</td>
</tr>
<tr>
<td>Proximal Neck Length</td>
<td>23 ± 14 mm</td>
<td>20 ± 13 mm</td>
<td>.093</td>
</tr>
<tr>
<td>Suprarenal Angulation</td>
<td>16 ± 11°</td>
<td>17 ± 13°</td>
<td>.664</td>
</tr>
<tr>
<td>Infrarenal Angulation</td>
<td>37 ± 16°</td>
<td>37 ± 18°</td>
<td>.885</td>
</tr>
<tr>
<td>Neck Thrombus</td>
<td>23 ± 54°</td>
<td>38 ± 71°</td>
<td>.107</td>
</tr>
<tr>
<td>Neck Calcium</td>
<td>20 ± 29°</td>
<td>19 ± 30°</td>
<td>.845</td>
</tr>
<tr>
<td>Necks &lt;10mm Length</td>
<td>18.4%</td>
<td>26.5%</td>
<td>.097</td>
</tr>
</tbody>
</table>
The EVAR Durability Question and a Potential Solution

Initial results:
Composite endpoint of proximal neck failure

Mean follow-up only 6 months (range 1-12 months)

No statistical tests performed, pending longer term data in the ANCHOR test group

Initial observations:
- While the numbers are small, there are trends toward reduction in Proximal Neck Failure in EndoAnchor group
- Definitive results forthcoming, with full 12-month data for both groups
The EVAR Durability Question and a Potential Solution

Initial results:
Composite endpoint of proximal neck failure
The EVAR Durability Question and a Potential Solution

Conclusions

- In absence of randomized clinical trial, a historical control group with patient-level data allowed a propensity analysis to be performed.

- An adequate match was obtained with EndoAnchor Primary Prophylactic group and a historical control group of patients undergoing EVAR at three institutions.

- Initial observations suggest the methodology is feasible, but longer term data required to compare outcomes in patients undergoing EVAR with and without EndoAnchors.
Thank you

bmuhs@thevascularexperts.com
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The Vascular Experts, CT, USA