What role do EndoAnchors play in AAA sac dynamics?

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Department of Integrated Surgical and Diagnostic Sciences (DISC) - University of Genoa
Chief: Prof. D. Palombo
Disclosures

• Consulting: Abbott, Cook, Cordis, Medtronic, WL Gore & Associates, Terumo Aortic
Consistent sac regression rates with Endurant at 5 years

Durability in Real-world Patients
89.4% of AAA Show a Sac Decrease/Stable

ENGAGE – AAA Diameter Change

- 61.4% Decrease
- 28.0% Stable
- 10.6% Increase
A significantly higher rate of type I endoleaks within 30 days was seen in Challenging (CHA) compared with Regular (REG) and Intermediate (INT).

Broos PP et al., J Vasc Surg 2015
Outcome-based anatomic criteria for defining the hostile aortic neck

William D. Jordan Jr, MD, a Kenneth Ouriel, MD, b Manish Mehta, MD, MPH, c David Varnagy, MD, d William M. Moore Jr, MD, e Frank R. Arko, MD, f James Joyce, DO, g and Jean-Paul P. M. de Vries, MD, h Birmingham, Ala; New York and Albany, NY; Orlando, Fla; West Columbia, SC; Charlotte, NC; Mountain View, Calif; and Nieuwegein, The Netherlands

Table III. Binary logistic regression: Final model

<table>
<thead>
<tr>
<th>Variable</th>
<th>Coefficient</th>
<th>Standard error</th>
<th>Odds ratio</th>
<th>P value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Aortic neck diameter at lowest renal artery (mm)</td>
<td>0.102</td>
<td>0.033</td>
<td>1.11</td>
<td>.002</td>
</tr>
<tr>
<td>Anatomic neck length (10% threshold, mm)</td>
<td>-0.028</td>
<td>0.012</td>
<td>0.97</td>
<td>.017</td>
</tr>
<tr>
<td>Neck circumference with mural thrombus (mm)</td>
<td>-0.007</td>
<td>0.002</td>
<td>0.99</td>
<td>.001</td>
</tr>
<tr>
<td>Intercept</td>
<td>-2.133</td>
<td>0.871</td>
<td>.014</td>
<td></td>
</tr>
</tbody>
</table>

Conclusions: A limited number of independent anatomic variables are predictive of type Ia endoleak after EVAR, including aortic neck diameter and aortic neck length, whereas mural thrombus in the neck is protective. This study suggests that anatomic measures with identifiable threshold cutoff points should be considered when defining the hostile aortic neck and assessing the risk of complications after EVAR. (J Vasc Surg 2015;61:1383-90.)
In vivo dynamics are significant

Aortic Dynamics during Cardiac Cycle and risk of undetected type I endoleak

Systolic cross-sectional area 35 ± 15% greater than diastole
Asymmetrical differences in wall motion
Anterior wall motion 3.3 x’s greater than posterior

Dynamic seal at the aortic neck-endograft interface studied using a novel method of cohesive zone modeling

«Every EVAR has a complex mechanical stability, especially in pts with challenging necks»
Open Surgery: gold standard for Aneurysm Repair
Heli-fx™ endoanchor™ implant system

Mechanically prevent aorta-endograft separation

Supersede strength of a hand-sewn anastomosis

1 Melas et al. JVS. 2012;55(6):1726-33
2 Tassiopoulos AK et al. JVS. 2017;66(1):45-52
ESAR (EndoSuture Aneurysm Repair)
Endovascular fixation with Heli-FX EndoAnchors

- Endovascular suture of the endograft similar to a surgical anastomosis
- No additional access/techniques required
- Infrarenal sealing maintenance
- Visceral vessels are not involved
- Does not prevent any future option (Ch-EVAR, F-EVAR)

Endurant+Heli-Fx EndoAnchors: CE & FDA approved for short neck indication
Evidence is large and consistent

5-Year Safety and Efficacy by Core Lab

**STAPLE-I Trial:**
Safety & Feasibility; 2006-7
- 21 pts across 5 US sites

<table>
<thead>
<tr>
<th>Endoleak</th>
<th>1-Yr</th>
<th>2-Yr</th>
<th>3-Yr</th>
<th>4-Yr</th>
<th>5-Yr</th>
</tr>
</thead>
<tbody>
<tr>
<td>Type 1a</td>
<td>0%</td>
<td>0%</td>
<td>0%</td>
<td>0%</td>
<td>0%</td>
</tr>
</tbody>
</table>

**AAA Sac Dynamics**
- No AAA ruptures

**STAPLE-II Trial:**
Safety & Efficacy; 2007-9
- 155 pts across 33 US sites

<table>
<thead>
<tr>
<th>Endoleak</th>
<th>1-Yr</th>
<th>2-Yr</th>
<th>3-Yr</th>
<th>4-Yr</th>
<th>5-Yr</th>
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<tr>
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<td>0%</td>
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<td>0%</td>
<td>0%</td>
<td>0%</td>
</tr>
</tbody>
</table>

**AAA Sac Dynamics**
- No AAA ruptures
10 pts at 4yrs experienced AAA sac enlargement

- 6/10 (60%) were off-label for the endograft at baseline including:
  - Excessive thrombus, Wide neck, Severe angulation, Short neck, Too few EndoAnchors
- The other 4/10 (40%) had persistent/late type IIIs driving sac enlargement

*Data cut June 13, 2019*
Infrarenal Diameter: 25.7 mm
Infrarenal Angulation: 20.6°
Neck Length*: 6.86 mm (4.06-9.97 mm)
Aneurysm Diameter: 57.7 mm
Avg Neck Calcium Thickness: 1.31 mm
Avg Neck Calcium Thickness: 0.85 mm

Baseline Anatomical Characteristics* (N=70) Core Lab

*Neck length: portion of the neck within 10% of diameter increase

Arko F et al., J Vasc Surg 2019
Endosuture aneurysm repair in patients treated with Endurant II/IIIs in conjunction with Heli-FX EndoAnchor implants for short-neck abdominal aortic aneurysm

<table>
<thead>
<tr>
<th>Core Lab</th>
<th>1 month</th>
<th>12 months</th>
</tr>
</thead>
<tbody>
<tr>
<td>Type 1a Endoleak</td>
<td>6.8% (4/59)</td>
<td>1.9% (1/53)</td>
</tr>
<tr>
<td>Endograft Migration</td>
<td>N/A</td>
<td>0.0% (0/41)</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Core Lab</th>
<th>12 months</th>
</tr>
</thead>
<tbody>
<tr>
<td>AAA sac decrease</td>
<td>42.6%</td>
</tr>
<tr>
<td>AAA sac stable</td>
<td>57.4%</td>
</tr>
<tr>
<td>AAA sac increase</td>
<td>0.0%</td>
</tr>
</tbody>
</table>

*Arko F et al., J Vasc Surg 2019*
Endurant + Heli-FX Short Neck Cohort

2-Year Outcomes

Initial Implant Procedure

<table>
<thead>
<tr>
<th>Metric</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Avg. Duration of Procedure (min)</td>
<td>148</td>
</tr>
<tr>
<td>Avg. time to EndoAnchor implant (min)</td>
<td>17</td>
</tr>
<tr>
<td>Avg. Fluoro Time (min)</td>
<td>35</td>
</tr>
<tr>
<td>Avg. number of EndoAnchor implants</td>
<td>5.5</td>
</tr>
</tbody>
</table>

- Investigator-Determined Procedural Success: 97.1% (68/70)

<table>
<thead>
<tr>
<th>Core Lab</th>
<th>1-YEAR</th>
<th>2-YEAR</th>
</tr>
</thead>
<tbody>
<tr>
<td>Type 1a EL</td>
<td>2.0%</td>
<td>0.0%</td>
</tr>
<tr>
<td></td>
<td>(1/49)</td>
<td>(0/32)</td>
</tr>
<tr>
<td>Migration</td>
<td>0.0%</td>
<td>0.0%</td>
</tr>
</tbody>
</table>

AAA Sac Dynamics Core Lab

1-YEAR (N=52)
- Regression: 44%
- Stable: 56%

2-YEAR (N=34)
- Regression: 35%
- Stable: 65%
Endovascular fixation: when and how?
Endovascular fixation: the ideal EndoSuture
Endovascular fixation: the ideal EndoSuture

Influence of aortic neck characteristics on successful aortic wall penetration of EndoAnchors in therapeutic use during endovascular aneurysm repair

Seline R. Goudeketting, MSc, a, b Kim van Noort, MSc, a, b Kenneth Ouriel, MD, c William D. Jordan Jr, MD, d Jean M. Panneton, MD, e Cornelis H. Slump, MSc, PhD, b and Jean-Paul P. M. de Vries, MD, PhD, a Nieuwegein and Enschede, The Netherlands; New York, NY, Atlanta, Ga; and Norfolk, Va

<table>
<thead>
<tr>
<th>Variable</th>
<th>Type I A endoleak group</th>
<th>No endoleak group</th>
<th>Total</th>
<th>P value</th>
</tr>
</thead>
<tbody>
<tr>
<td>EndoAnchors, No.</td>
<td>247 (42.6)</td>
<td>8 (4.10)</td>
<td>333 (57.4)</td>
<td>6 (4.8)</td>
</tr>
<tr>
<td>Good penetration</td>
<td>39 (39.7)</td>
<td>3 (2.4)</td>
<td>235 (70.6)</td>
<td>4 (3.5)</td>
</tr>
<tr>
<td>Borderline penetration</td>
<td>43 (47.4)</td>
<td>1 (0.2)</td>
<td>32 (9.6)</td>
<td>0 (0.1)</td>
</tr>
<tr>
<td>No penetration</td>
<td>106 (42.9)</td>
<td>3 (1.3)</td>
<td>66 (9.8)</td>
<td>1 (0.2)</td>
</tr>
<tr>
<td>Distance from LRA, mm</td>
<td>9 (6-13)</td>
<td>8 (4-12)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Fabric distance, mm*</td>
<td>7.5 (4.5-11.8)</td>
<td>7.5 (4.5-10.5)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Clock face location, degrees</td>
<td>156 (50-278)</td>
<td>188 (58-285)</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

*Data are represented as number (%) and median (interquartile range).

Conclusions: Adequate EndoAnchor penetration into the aortic wall is less likely when the aortic neck diameter is large or when the neck contains significant mural calcium. No penetration of the EndoAnchor was the only factor predictive of postprocedural type IA endoleak. This study stresses the importance of careful selection of patients based on preoperative assessment of the infrarenal neck on CT angiography and emphasizes careful deployment of EndoAnchors into the aortic wall to improve successful treatment of type IA endoleaks.

J Vasc Surg 2018
Heli-Fx EndoAnchors malposition occurs more often than we think, up to 30% of cases in this revision cohort

J Vasc Surg 2019
Endovascular fixation in very short aortic neck: how to increase precision?
Increased precision in endovascular fixation: fusion-guided Heli-Fx deployment
Increased precision in endovascular fixation: fusion-guided Heli-Fx deployment
Increased precision in endovascular fixation: fusion-guided Heli-Fx deployment
EndoSuture Aneurysm Repair Conclusions

- ESAR safety and efficacy has been proven across multiple studies and large numbers of patients.

- Like every technology, proper patient selection and device technique are necessary to achieve best results.

- By recreating the durability of a sutured anastomosis, ESAR seems to promote sac regression.
What role do EndoAnchors play in AAA sac dynamics?

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