Complementary therapy for juxtarenal AAAs (<10 mm to 4 mm neck length): clinical results and technical insights using the Endurant + Heli-FX short neck indication

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Disclosure

Speaker name:
Giovanni Pratesi

I have the following potential conflicts of interest to report:

☑ Consulting: Abbott, Cook, Cordis, Medtronic, WL Gore & Associates
☐ Employment in industry
☐ Stockholder of a healthcare company
☐ Owner of a healthcare company
☐ Other(s)

☐ I do not have any potential conflict of interest
Endovascular treatment of very short neck: f-EVAR and Ch-EVAR
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
Treating very short neck with standard EVAR: how to prevent complications?
Complementary therapy for very short neck: Endovascular fixation with Heli-FX System

- Cross Bar: 3 mm
- Diameter: 1.0 mm
- Diameter: 3.5 mm
EndoAnchor™ implants placed during Index procedure either prophylactically or to treat an intra-operative type Ia endoleak.
ANCHOR Registry Hostile Neck Cohort
Endurant™ + Heli-Fx™ short neck cohort (N=70)

70 Patients with Hostile Necks
(length ≥ 4 mm and < 10 mm)
Short Neck Indication: Endurant with Heli-FX Endoanchors

Proximal neck length <10 mm down to 4 mm

Neck Length definition: 10% diameter increase

FDA and CE approved/indicated
Short Neck Indication: Endurant with Heli-FX Endoanchors
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Baseline Anatomical Characteristics* (N=70) Core Lab

- Infrarenal Diameter: 25.7 mm
- Infrarenal Angulation: 20.6°
- Neck Length: 6.86 mm (4.06-9.97 mm)
- Avg Neck Calcium Thickness: 1.31 mm
- Avg Neck Calcium Thickness: 0.85 mm
- Aneurysm Diameter: 57.7 mm
84% (59/70) received a ≥ 28mm Endurant graft

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Reason for EndoAnchor Placement
(site-reported)

- Concern for late failure 56%
- Treatment of type Ia endoleak 21%
- Prevention of neck dilatation 23%

84% (59/70) received a ≥ 28mm Endurant graft
ANCHOR Registry Hostile Neck Cohort
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**Technical Success**: 88.6% (62/70)
*defined as deployment of the desired number of EndoAnchor(TM) Implants, adequate penetration of the vessel wall, and absence of EndoAnchor fracture

**Procedural Success**: 97.1% (68/70)
**defined as technical success without a type la endoleak at completion angiography

<table>
<thead>
<tr>
<th>Initial Implant Procedure</th>
<th></th>
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</thead>
<tbody>
<tr>
<td>Avg. duration of Procedure (min)</td>
<td>148</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Avg. time to EndoAnchor implant (min)</td>
<td>17</td>
<td></td>
<td></td>
<td></td>
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<tr>
<td>Avg. Fluoro time (min)</td>
<td>35</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Avg. number of EndoAnchor implants</td>
<td>5.5</td>
<td></td>
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</tbody>
</table>
Endurant + Heli-FX in short aortic neck: precise endograft deployment
Endurant + Heli-FX in short aortic neck: fix endograft at the proximal edge
<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>
<tr>
<td>2nd Endo Procedure</td>
<td>4.3% (3/70)</td>
<td>4.7% (3/64)</td>
</tr>
</tbody>
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ANCHOR Registry Hostile Neck Cohort
Endurant™ + Heli-Fx™ short neck cohort (N=70)
### ANCHOR Registry Hostile Neck Cohort Endurant™ + Heli-Fx™ short neck cohort (N=70)

<table>
<thead>
<tr>
<th>Adverse Events through 12 months</th>
<th>Patients with Events</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>EndoAnchor™ Implant-Related SAE</strong></td>
<td>0</td>
</tr>
<tr>
<td>Aneurysm Rupture</td>
<td>0</td>
</tr>
<tr>
<td>AAA-Related Mortality</td>
<td>4</td>
</tr>
<tr>
<td>Open Surgical Conversion</td>
<td>0</td>
</tr>
<tr>
<td>Kaplan-Meier Estimates</td>
<td>12 months</td>
</tr>
<tr>
<td>----------------------------------------------------</td>
<td>-----------</td>
</tr>
<tr>
<td>Freedom from ACM</td>
<td>92.7%</td>
</tr>
<tr>
<td>Freedom from ARM</td>
<td>94.3%</td>
</tr>
<tr>
<td>Freedom from 2\textsuperscript{nd} Procedures</td>
<td>95.4%</td>
</tr>
<tr>
<td>Freedom from rupture</td>
<td>100%</td>
</tr>
</tbody>
</table>
ANCHOR Registry Hostile Neck Cohort
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Aneurysm sac at 12 months

<table>
<thead>
<tr>
<th>Core Lab</th>
<th>12 months</th>
</tr>
</thead>
<tbody>
<tr>
<td>AAA sac decrease</td>
<td>42.6% (1/53)</td>
</tr>
<tr>
<td>AAA sac stable</td>
<td>57.4% (0/41)</td>
</tr>
<tr>
<td>AAA sac increase</td>
<td>0.0% (3/64)</td>
</tr>
</tbody>
</table>
Endurant with Heli-FX Endoanchors in short neck: how to increase deployment precision?
Conclusion

- Endurant + Heli-FX Endoanchors demonstrated to be a safe approach in very short necks, with no sac increase over 70 patients through 1-year.

- For necks below 10 mm (mean neck length in ANCHOR short neck cohort was 6.86 mm), quality of imaging is mandatory to achieve required precision.

- Heli-FX Endoanchors represent a complimentary treatment option for very short neck AAA that doesn’t preclude any eventual further reintervention; short-term results need to be confirmed on a longer run.
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