2-Year ANCHOR Data Show That EndoAnchors Can Prevent Neck Dilatation After EVAR With Self-Expanding Devices

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Disclosures
- Consulting Agreement Medtronic

Aortic Neck Dilation After EVAR Has Been Described And Calculated To Be Approximately 20% At 2-years When Compared To The Pre-implantation Diameter

Factors Contributing To Aortic Neck Dilatation
- Continuous outward pressure due to endograft radial force
- Progression of aortic wall degeneration
- Endoleaks
- Incomplete seal at the proximal neck

HeliFX EndoAnchors Were Designed To Stabilize And Improve Apposition Of The Endograft To The Aortic Neck

85 year old male 11 years after EVAR
Aortic diameter at proximal neck has increased overtime to exceed the nominal diameter of the endograft

EVAR: LONG TERM FAILURES
Aim Of This Study
Identify Predictors Of Aortic Neck Dilatation in Patients Undergoing EVAR With EndoAnchors

1st Year Analysis Methods

• 267 patients prospectively enrolled in the ANCHOR Registry undergoing EVAR with HeliFX EndoAnchors
• Indication for EndoAnchor Use
  – Repair of intraoperative Type Ia endoleak
  – Prophylactic in patients with hostile neck anatomy
• Aortic diameter measured by independent core lab at:
  – Suprarenal level (20mm proximal to lowest main renal artery)
  – Three (3) levels within proximal neck (distal to lowest main renal artery)
    • 0mm
    • 5mm
    • 10mm

1st Year Analysis Methods

• Baseline of aortic neck diameter measured on preoperative CT angiogram
• Same level measured at 1-month and 12-month postoperative CT scan
  • Adaptive Enlargement to accommodate the endograft; expressed as difference between baseline and 1-month post-EVAR diameter
  • Dilatation expressed as the difference between 1-month and 12-month post-EVAR

Statistical Analysis

• Multivariable analyses (backward stepwise linear regression) performed
  – Six (6) clinical variables identified
  – Fourteen (14) anatomic variables identified

  – Four models run, one (1) at each of the four (4) aortic levels

1st Year Analysis Results

• Perioperative Diameter Change
  • Using a 3mm threshold, aortic neck enlargement (ADAPTIVE ENLARGEMENT) occurred in 4.9%, 11.7% and 14.5% of patients at the three infrarenal levels respectively, and in 1.8% of patients at the SR level
• Postoperative Diameter Change
  • Using a 3mm threshold, aortic neck enlargement (DILATATION) occurred in 3.1%, 7.7% and 4.6% of patients at the three infrarenal levels respectively, and in 1.5% of patients at the SR level
### Predictors of Aortic Neck Adaptive Enlargement Between The Pre-operative and 1-month Post-operative CT

<table>
<thead>
<tr>
<th>Aortic Level</th>
<th>Predictors of Adaptive Enlargement at Specified Level</th>
<th>Coefficient*</th>
<th>Effect</th>
<th>P Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Lowest renal</td>
<td>Endograft type</td>
<td>-0.30 (-0.60, 0.01)</td>
<td>*</td>
<td>.011</td>
</tr>
<tr>
<td></td>
<td>Aortic diameter at lowest renal</td>
<td>-0.11 (-0.17, -0.04)</td>
<td>Protective</td>
<td>.001</td>
</tr>
<tr>
<td>Svn distally</td>
<td>Endograft type</td>
<td>-0.43 (-0.86, -0.01)</td>
<td>*</td>
<td>.038</td>
</tr>
<tr>
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<td>Aortic diameter at lowest renal</td>
<td>-0.11 (-0.20, -0.01)</td>
<td>Protective</td>
<td>.001</td>
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<tr>
<td>Lbrm distally</td>
<td>Neck mural calcium (circumference)</td>
<td>-0.03 (-0.05, -0.01)</td>
<td>Protective</td>
<td>&lt;.001</td>
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<tr>
<td></td>
<td>Aortic diameter at lowest renal</td>
<td>-0.22 (-0.37, -0.08)</td>
<td>Protective</td>
<td>.005</td>
</tr>
<tr>
<td>Suprarenal level</td>
<td>Suprarenal aortic diameter</td>
<td>No Variables</td>
<td>Protective</td>
<td>N/A</td>
</tr>
</tbody>
</table>

### Predictors of Aortic Neck Dilation Between The 1-month Post-operative and 12-month CT

<table>
<thead>
<tr>
<th>Aortic Level</th>
<th>Predictors of Dilatation at Specified Level</th>
<th>Coefficient*</th>
<th>Effect</th>
<th>P Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Lowest renal</td>
<td>Endograft type</td>
<td>0.62 (0.12, 1.04)</td>
<td>*</td>
<td>.006</td>
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<tr>
<td></td>
<td>Aortic aneurysm sac diameter</td>
<td>-0.04 (-0.07, 0.00)</td>
<td>Protective</td>
<td>.020</td>
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<tr>
<td></td>
<td>Aortic diameter at lowest renal</td>
<td>0.16 (0.08, 0.24)</td>
<td>Risk factor</td>
<td>&lt;.001</td>
</tr>
<tr>
<td></td>
<td>Aortic neck length</td>
<td>-0.01 (-0.1, 0.00)</td>
<td>Protective</td>
<td>.021</td>
</tr>
<tr>
<td></td>
<td>Inferior Angulation</td>
<td>0.02 (0.00, 0.04)</td>
<td>Risk factor</td>
<td>.016</td>
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<tr>
<td></td>
<td>Endograft oversizing</td>
<td>5.37 (2.44, 9.31)</td>
<td>Risk factor</td>
<td>.001</td>
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<tr>
<td>Svn distally</td>
<td>Aortic diameter at lowest renal</td>
<td>0.17 (0.07, 0.27)</td>
<td>Risk factor</td>
<td>.001</td>
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<tr>
<td></td>
<td>Endograft oversizing</td>
<td>6.00 (0.8, 9.93)</td>
<td>Risk factor</td>
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<tr>
<td>Lbrm distally</td>
<td>Aortic diameter at lowest renal</td>
<td>0.17 (0.04, 0.29)</td>
<td>Risk factor</td>
<td>.033</td>
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<tr>
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<td>Endograft oversizing</td>
<td>4.86 (1.13, 9.58)</td>
<td>Risk factor</td>
<td>.027</td>
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<td>Number of EndoAnchors placed</td>
<td>-0.29 (-0.55, -0.05)</td>
<td>Protective</td>
<td>.037</td>
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<tr>
<td>Suprarenal level</td>
<td>Suprarenal aortic diameter</td>
<td>0.05 (0.01, 0.15)</td>
<td>Risk factor</td>
<td>.025</td>
</tr>
</tbody>
</table>

### 2-Year Preliminary Analysis Methods
- Now analyzing 674 patients prospectively enrolled in the ANCHOR Registry undergoing EVAR with HeliFX EndoAnchors
- Indication for EndoAnchor Use
  - Repair of intraoperative Type Ia endoleak
  - Prophylactic in patients with hostile neck anatomy
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### 2-Year Preliminary Analysis

#### Time Course and Location of Aortic Neck Dilatation

**In the Presence of EndoAnchors:**
- Suprarenal neck enlargement is negligible through 24 months
- Neck enlargement greatest 5mm distal to lowest renal artery, but very few endografts at this level
- At 10mm distal (closest to the AAA pathology), neck diameter appears to stabilise with < ½ mm dilatation after 12 and 24 months

### Interesting Insights from the Preliminary 2-Year Analysis
- In our preliminary 2-year analysis:
  - Female sex and graft oversizing play a significant role in post-op neck dilatation, understandably.
  - With EndoAnchors implanted at index procedure, neck dilatation 10mm distal to lowest renal artery appears to be negligible at 12mo and 24mo
  - More robust scientific analyses ongoing on this larger sample size, further follow-up cohort of EndoAnchor patients to quantify the protective benefit of EndoAnchors on neck dilatation

**THANK YOU**