EndoAnchors Can Increase EVAR Durability: Comparison Of Matched Patients With And Without EndoAnchors

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OVER 5,000 CASES WITH ENDOANCHORS

- Demonstrated safety
  - No evidence of graft damage or late anchor fracture in over 3,000 EndoAnchors implanted
  - No evidence of aneurysm dilatation after successful implantation

- Favorable performance
  - Despite majority hostile anatomy, 90.9% patients free from type I endoleaks at follow-up
  - 8 of 10 type I endoleaks in challenging anatomy successfully treated at final angiography

- Benefits
  - On-the-spot, targeted treatment of type I endoleaks
  - Augment seal in complex neck anatomies without augmenting seal area
  - Preserve all other ancillary and future options for the patient

DISCLOSES

- Consultant
  - Medtronic
  - Cook
  - Endologix
- Research Grants
  - TriVascular

ANCHORegistry

Results of the ANCHOR prospective, multicenter registry of EndoAnchors for type Ia endoleaks and endograft migration in patients with challenging anatomy

- Over 80% of patients in Anchor registry had hostile neck anatomy
- EndoAnchors are effective in treating proximal Type Ia endoleaks
- EndoAnchor implantation useful adjunct to EVAR as prophylaxis against in patients with hostile aortic neck

Major Studies Show Higher 2nd 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 late increase with time
- Open surgery remains a ‘more durable option’
  - In ACE, 10% re-interventions in EVAR vs. 2.4% for open repair at 3 yr follow-up
The Question and a Potential Solution

- The question: Do EndoAnchors have value in preventing proximal neck complications in all patients undergoing EVAR?
- Ideally, a randomized study would be conducted.
- In its absence, propensity analysis can provide some adjustment for differences in baseline characteristics between a test and a historical control group.
- Two groups of patients:
  - EndoAnchor Group: The current “Primary Prophylaxis” cohort from the ANCHOR trial: 235 patients
  - Control Group: A group of 115 patients treated over the 4 years prior to availability of EndoAnchors at three institutions (nine of these were excluded based on CT quality).

Methodology

- Pre-EVAR baseline CT scans evaluated by a Core Laboratory 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 endoleak, sac enlargement, endograft migration, or neck dilatation.

Baseline Anatomic Measures 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>.874</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>
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<tr>
<td>Neck Calcium</td>
<td>201 ± 29</td>
<td>19 ± 10</td>
<td>.045</td>
</tr>
<tr>
<td>Necks &lt;10mm Length</td>
<td>8.4%</td>
<td>26.5%</td>
<td>.007</td>
</tr>
</tbody>
</table>

Initial Results: Composite endpoint of Proximal Neck Failure

Mean follow-up only 6 months with this data (range 1-12 months).
No statistical tests performed, pending acquisition of longer term data in the ANCHOR test group.

Initial observations:
- While the numbers are small, there are trends toward a reduction in Proximal Neck Failure in the EndoAnchor group.
- Definitive results will be forthcoming, with full 12-month data for both groups.

Conclusions

- In the absence of a randomized clinical trial, the availability of 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 that the methodology is feasible, but longer term data will be necessary to compare outcome in patients undergoing EVAR with and without EndoAnchors.