CLINICAL RESULTS FROM ANCHOR: HOW DOES THIS DATA INFLUENCE THE TREATMENT ALGORITHM FOR HOSTILE EVAR ANATOMIES

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I have the following potential conflicts of interest to report:

Consulting
  Medtronic, Orzone

Travel and Speakers fees
  Bolton Medical, Gore, Vascutek

Institutional level funding
  Orzone
Proximal neck adequacy and endograft seal zone are key predictors of long-term outcomes and success after EVAR$^{1,2}$
HOSTILE PROXIMAL NECK PREDICTS CHALLENGES

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 at 1-year (P= .013)

Meta-Analysis of 7 major EVAR studies by Antoniou et al¹ 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™<em>, Zenith™</em>, Talent™</td>
</tr>
<tr>
<td>Hoshina et al, 2010</td>
<td>129</td>
<td>Excluder™<em>, Zenith™</em></td>
</tr>
<tr>
<td>Abbruzzese et al, 2008</td>
<td>565</td>
<td>AneuRx™, Excluder™<em>, Zenith™</em></td>
</tr>
<tr>
<td>Choke et al, 2006</td>
<td>147</td>
<td>Talent™, Zenith™<em>, Excluder™</em>, 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>

¹ Antoniou GA et al. JVS. 2013;57(2):527-38.
Hostile neck

- Are you a real man (or woman)?
  - Open repair

- Is your name Eric, Stephan or Tara?
  - Then its not a real neck: Fenestrated

- Are you concerned about the finances of the health system or the feel of polymer?
  - What about a chimney

- Is there a new infrarenal device that is shiny?
  - Ignore IFU, use that and tell everyone it cures all (you have about 5 years before they find you out)

- Like DIY?
  - Endoanchors
HELI-FX™ ENDOANCHOR™ IMPLANT SYSTEM
ENDOVASCULAR INTERRUPTED SUTURE SYSTEM

1.0 mm

3.5 mm

Cross Bar

3 mm
Establishes the strength of a sutured anastomosis
ENDOANCHORS
ANCHOR Registry: Capturing Real-World Usage

Europe: Dr Jean-Paul de Vries – Chief of Vascular Surgery, St. Antonius Hospital

US: Dr William Jordan – Chief of Vascular Surgery/Endovascular Therapy, Emory University School of Medicine

EndoAnchor™ implants placed during Index procedure either prophylactically or to treat an intra-operative type Ia endoleak.

Prospective, observational, international, multi-center, dual-arm Registry with Core Lab Analysis

First enrolment 2012
Five year follow up

Registry Principal Investigators
Europe: Dr Jean-Paul de Vries – Chief of Vascular Surgery, St. Antonius Hospital

US: Dr William Jordan – Chief of Vascular Surgery/Endovascular Therapy, Emory University School of Medicine

*Data cut April 17, 2017
ANCHOR Registry: Primary Use in Index Setting

Reasons for EndoAnchoring
- Concern for Late Failure: 54.4%
- Treatment of Type Ia Endoleak: 26.7%
- Prevention of Neck Dilatation: 18.7%
- Concern for Type Ia Endoleak: 0.2%

89.1% ASA Class III/IV
20.9% Urgent/Emergent Cases
Mean imaging f/u: 588.7 days
(N=436pts)

Male: 77% Female: 23%
Mean Age: 73.0 Years

Hostile Necks: 82.8%
SVS definition

Infracrural Diameter: 25.7 mm
Infracrural Angulation: 25.2°
Conical Neck: (>10%/10mm): 42.3%
Neck Thrombus ≥ 2mm: 15.7%
Neck Length: 11.56 mm (median)
Aneurysm Diameter: 56.3 mm
Neck Calcium ≥ 2mm: 30.5%

*Data cut April 17, 2017
ANCHOR Registry: Primary Use in Index Setting

**Technical Success**
Successful deployment of EndoAnchor implants with adequate penetration into aortic wall

- 95.1% Primary

**Procedural Success**
Technical success without type Ia endoleak at completion arteriography

- 88.8% Primary

<table>
<thead>
<tr>
<th>Average values</th>
<th>12 months</th>
<th>24 months</th>
</tr>
</thead>
<tbody>
<tr>
<td>Avg. duration of Procedure (min)</td>
<td>147</td>
<td></td>
</tr>
<tr>
<td>Avg. number of EndoAnchor implants</td>
<td>5.7</td>
<td></td>
</tr>
<tr>
<td>Avg. fluoroscopic time (min)</td>
<td></td>
<td>33.9</td>
</tr>
</tbody>
</table>

At 12 months N=289

<table>
<thead>
<tr>
<th>Event</th>
<th>12 months</th>
<th>24 months</th>
</tr>
</thead>
<tbody>
<tr>
<td>Type 1a Endoleak</td>
<td>1.0% (3/292)</td>
<td>1.3% (2/159)</td>
</tr>
<tr>
<td>Endograft Migration</td>
<td>0.0% (0/203)</td>
<td>0.0% (0/87)</td>
</tr>
</tbody>
</table>

At 24 months N=159

- Decrease 45.7%
- Increase 1.7%
- Stable 52.6%
- Increase 2.5%
- Stable 38.4%

*Data cut April 17, 2017*
### ANCHOR Registry:
**Primary Use in Index Setting**

**Hostile Necks:**
82.8%
Per the SVS definition

<table>
<thead>
<tr>
<th>Kaplan-Meier Estimates</th>
<th>1 Year</th>
<th>2 Year</th>
</tr>
</thead>
<tbody>
<tr>
<td>Freedom from ACM</td>
<td>94.7% (466)</td>
<td>88.5% (367)</td>
</tr>
<tr>
<td>Freedom from ARM</td>
<td>98.5% (466)</td>
<td>98.5% (367)</td>
</tr>
<tr>
<td>Freedom from Rupture</td>
<td>100.0% (466)</td>
<td>100.0% (367)</td>
</tr>
<tr>
<td>Freedom from 2^{nd} Procedures</td>
<td>95.8% (459)</td>
<td>93.3% (352)</td>
</tr>
</tbody>
</table>

*Data cut April 17, 2017*
ENDURANT™ + HELI-FX™ SHORT NECK COHORT (N=70)

Baseline Anatomical Characteristics* (N=70) – Core Lab

Clinical Evaluation
ANCHOR Registry Hostile Neck Cohort

- Anchor Registry Patients
  - Primary
  - Revision
- Endurant Stent Graft
- Other Brands

70 Patients with Hostile Necks (<10 mm down to 4 mm)

Infrarenal Diameter: 25.7 mm
Neck Length: 6.86 mm (4.06-9.97 mm)
Avg Neck Calcium Thickness: 1.31 mm
Avg Neck Thrombus Thickness: 0.85 mm
Infrarenal Angulation: 20.6°
Aneurysm Diameter: 57.7 mm

* Mean Core Lab measurements
ENDURANT™ + HELI-FX™ INDICATION

ANCHOR Short Neck Cohort (N=70)

Initial Implant Procedure

- Avg. duration of Procedure (min): 148
- Avg. time to EndoAnchor implant (min): 17
- Avg. Fluoro time (min): 35
- Avg. number of EndoAnchor implants: 5.5

Technical Success: 88.6% (62/70)

Procedural Success: 97.1% (68/70)

At 12 months, N=54

<table>
<thead>
<tr>
<th></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>
</table>
CONCLUSIONS

- Aortic diameter and graft oversizing appear to be independent risk factors for early aortic neck dilatation.
- Endoanchors have a protective effect on neck dilatation at their usual level of deployment.
Summary

- EndoAnchors (with aortic engagement) are safe and potentially very effective in prevention and treatment of type Ia endoleaks and in prevention of migration even in short neck cohort
- Significant increase rate of sac regression
- EndoAnchors don’t preclude future interventions

Conclusions – how does the algorithm change

- Increased confidence in treating IRAAA with shorter, angled, wider and conical necks
- Potential to reduce the incidence of reinterventions
- The data from the short neck cohort is interesting…encouraging to one year and certainly this makes it a viable option for some, perhaps with limited options/urgent cases
THE CLINICAL ALGORITHM (DIFFICULT NECK)

Hostile neck

Fit, young, difficult anatomy for EVAR
Open repair
Endoanchors

Short, wide, conical neck or angulated
Urgent or rupture

Short neck, or severely disease neck and suitable anatomy
Less fit group but expected to live a few years
Fenestrated approach

Emergency, urgent or maybe well within IFU for CE marking of chimneys and experienced
2 vessel chimney

Elective, unfit, difficult anatomy
Consider setting higher threshold for repair
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