Patient selection in Hostile Necks and how to prevent endoleaks – a word of caution

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Conflict of Interest

Piotr Kasprzak – consulting, speaker, intelectual properties, grants

Cook
W.L. Gore & Associates
Bard
Maquet
Medtronic
Bentley
Vascutek
UCB
Philips
Hostile neck

Short neck
Angulation
Taper
Calcification
Thrombus

> Diameter

A: suprarenal angulation ≤ 60°
B: proximal neck length ≥ 15 mm
C: proximal neck diameter 18-28 mm
   (19-26 mm)*
C-C': diameter increase ≤ 10%
   (no conical shape)
D: distal fixation length ≥ 10 mm
E: distal fixation diameter 7.5-20 mm
   (8-18.5 mm)*

1 Thrombosis of calcification ≤ 25% of circumference
Short and hostile neck.
I don´t see any problem...
Which Proximal Necks are Hostile?

Study by Jordan WD et al. assesses proximal neck anatomic criteria that are most predictive of success or failure after EVAR

- Evaluated N=221 patients from ANCHOR post-market registry
- Failure defined as:
  - Type Ia endoleak upon endograft implantation
  - Type Ia endoleak identified in post-op follow-up*

*In endografts without EndoAnchors

| Identified proximal neck variables that independently predict type Ia endoleak: |
|-------------------------------|-----------------|-----|
| Neck diameter ≥ 26 mm         | P = .002        |
| Neck length ≤ 17 mm           | P = .017        |

Certain ‘on-label’ necks can be at-risk
Tailored Seal and Fixation of EndoAnchors

CREATE THE STABILITY OF A SURGICAL ANASTOMOSIS IN EVAR AND TEVAR

Surgical Anastomosis

EndoAnchoring


Case images courtesy of John Aruny MD, Bart Edward Muhs, MD, PhD.
Risk of Typ Ia Endoleak - Hostile Neck

- short infrarenal neck
- short infrarenal neck and kinking
- conical, calcified or partly thrombosed infrarenal neck
- (non alignment)

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Option 1: fenestrated endograft (<10mm)
Option 2: chimney or periscope (bail-out)
Option 3: endovascular fixation using EndoAnchors (10-15mm)

EndoAnchors in 142 Patients with EVAR, TEVAR, FEVAR and BEVAR

- TAA (n=305) 10%
- BEVAR/FEVAR (n=283) 5%
- EVAR (n=289) 33%
Infrarenal Aorta (EVAR) and indication for use of EndoAnchors

<table>
<thead>
<tr>
<th>Condition</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td>Short neck</td>
<td>45</td>
</tr>
<tr>
<td>Short neck and Kinking</td>
<td>28</td>
</tr>
<tr>
<td>Conical neck</td>
<td>11</td>
</tr>
<tr>
<td>Type I endoleak</td>
<td>16</td>
</tr>
</tbody>
</table>

Heli-FX endoanchors: Improving results in hostile neck anatomy
Prospective use of Endoanchors in EVAR with Hostile Neck
Regensburg University Hospital

• Neck length 10-15mm vs. IFU or > 15mm and
• Neck angulation >60
• Conical neck
• Primary I a endoleak / non alignment

Preliminary results, C3-Excluder (n=42)
Mean age 73 years, diameter AAA 5,6cm, FU>1,5 years

n=13 n=29
7 Endoanchors (6-10)

No I a endoleak
# ANCHOR Results vs. Antoniou et al. Meta-Analysis

<table>
<thead>
<tr>
<th>Studies</th>
<th>Median Follow-Up</th>
<th>Type 1 Endoleaks in Hostile Necks</th>
</tr>
</thead>
<tbody>
<tr>
<td>Meta-analysis, Antoniou et al&lt;sup&gt;1&lt;/sup&gt;</td>
<td>12-Months</td>
<td>20/205* (9.8%)</td>
</tr>
<tr>
<td>ANCHOR Registry&lt;sup&gt;2&lt;/sup&gt;</td>
<td>14.3-Months</td>
<td>2/178** (1.1%)</td>
</tr>
</tbody>
</table>

* Hostile neck criteria: neck length <15 mm and neck angulation > 60 degrees
** Hostile as determined by physician in Primary Arm

No EndoAnchor Related SAEs or Re-Interventions Reported To-Date
Regensburg concept in EVAR

<table>
<thead>
<tr>
<th>&gt; 15 mm (IFU 10mm)</th>
<th>10 - &lt;15 mm</th>
<th>0 - &lt; 10 mm</th>
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<tr>
<td>EVAR</td>
<td>EVAR + EndoAnchors</td>
<td>FEVAR/BEVAR</td>
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Regensburg concept in EVAR

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<tr>
<th>Proximal neck with Thrombus</th>
<th>or Kinking &gt; 45° or tapered</th>
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</table>
Treatment
Fenestrated Endografting
2007: Y-Prothese

2014: prox Anastomose erweitert
Shuttering of the superior mesenteric artery (SMA) is calculated as the amount of scallop misalignment (short white arrow, A) relative to the SMA ostium divided by the width of the scallop (longer white arrow, B).

FEVAR + distal EndoAnchors
Ch-EVAR
Ch-EVAR
Primary and secondary problems after BEVAR

- Endoleak I a and I b
- Endoleak II and III
- Migration
- Infolding, Collaps, Coarctation
- Material deterioration, Fistulas
Partial debranching for descendens aneurysm

Endoleak Ia after 6 months

Arch stent graft with scalop

Cook ®
Fenestrated TEVAR / BEVAR
Migration of Fenestrated (LSA) TEVAR in BEVAR for TAAA

04 / 2013

11/2015
Proximal EndoAnchorong of the TEVAR with Scalop for Brachiocephalic Trunk and Fenestration for the left CCA in Patient with Multibranched Stentgraft for Type II TAAA
Length of Seal in BEVAR/FEVAR?  Role of EndoAnchors?

M, 60, symptomatic TAAA
How (and where) to get a secure fixation with Endoanchors?

Fixation in:
- hostile neck ✔
- distal kinking ✔
- fenestrated arch devices ?
- nonaligment ✔
- graft prolaps ±
- gutter in chimps ?
- lack of oversizing —
Limitations of EndoAnchors in TEVAR

- Lack of apposition between stentgraft and aortic wall or
- Endoleak I a/b and distance to the aortic wall > 3mm
- Thick thrombus formation / calcification
- Stentgraft underseized
Conclusions:

- Endoanchors are additional endovascular option to prevent Type Ia endoleak and migration in patients with Hostile Neck

- Secondary repair for complications of nonalignment, migration or type I endoleak frequently with additional cuff extension

- However: other therapeutic options have to be considered - no EndoAnchors application in patients anatomically unsuitable (very short or no neck)

- Long term data are required