Challenging neck anatomies: Aptus can fix it!

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Disclosure

Speaker name: Jörg Teßarek MD

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☐ I have the following potential conflicts of interest to report:

☐ Consulting
☐ Employment in industry
☐ Stockholder of a healthcare company
☐ Owner of a healthcare company
☒ Other(s)

☐ I do not have any potential conflict of interest
EVAR /FEVAR… success is based on

- optimal sealing and maximum fixation
- in a durable fashion (AAA treatment is for the long term)
- To prevent distal or proximal migration with subsequent device failure (limb collapse and thrombosis, target vessel loss)
- and procedure failure due to EL or rupture
- to keep the number of secondary interventions and secondary costs as low as possible
- and the patients QoL as high as possible
How to do it?

• respect the IFU`s
• accept limitations determined by the AAA morphology, graft characteristics
• and operators experience
• optimal follow up including best medical treatment for secondary prevention
• use the device that offers „plan b“ in case of migration or type Ia/b EL
But if migration or rotation occurs…

- Fixation for target vessel rescue/preservation
- Additional sealing
No damage post 400M cycles, equivalent to 10 years *in vivo*
Performance

- Verified equivalence to the strength of a surgical anastomosis (Melas et al., JVS 2012;55;1726-33)
- Designed to provide and maintain close contact of graft and aortic wall and resist neck dilatation
Benefits
The anchors prevent further migration (9 cases & Anchor Registry)

and

Helical Endostaple Fixation Blunts Aortic Neck Dilatation
after Endovascular Aortic Aneurysm Repair
Gomero-Cure W et al.

JVS 96S Abstracts June Supplement 2012
Aortic neck stability (AND <15%) was documented in 101 (95.3%) of patients at 2 years.
When to use it?

- Any detected migration and remaining wall contact
- Should we try to expand EVAR indications going “off label”?
- Primary option in hostile necks (too short, conical shaped with thrombus) when complications can be expected

<table>
<thead>
<tr>
<th>Outcome</th>
<th>N</th>
<th>Hostile Neck</th>
<th>Favorable Neck</th>
<th>Odds Ratio (95% CI)</th>
<th>p</th>
</tr>
</thead>
<tbody>
<tr>
<td>30-Day: All studies</td>
<td></td>
<td></td>
<td></td>
<td></td>
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<tr>
<td>Primary technical success</td>
<td>6</td>
<td>1036 (96.8%)</td>
<td>3497 (98.3%)</td>
<td>0.45 (0.19, 1.06)</td>
<td>0.07</td>
</tr>
<tr>
<td>Intraoperative adjuncts</td>
<td>5</td>
<td>991 (15.4%)</td>
<td>3199 (8.8%)</td>
<td>1.88 (1.15, 3.07)</td>
<td>0.01</td>
</tr>
<tr>
<td>Stent-graft migration</td>
<td>4</td>
<td>1245 (1.6%)</td>
<td>4225 (0.9%)</td>
<td>2.08 (1.20, 3.62)</td>
<td>0.009</td>
</tr>
</tbody>
</table>
Speziale et al. (Ann Vasc Surg 2014) shows greater proximal seal complication risks as the number of hostile neck parameters increases.
When to use it?

- Any detected migration and remaining wall contact
- Primary option in hostile necks (short, conical shaped with thrombus) when complications can be expected?
- "off label use" has become a legal issue and a reimbursement issue.
- Off label use of grafts (short neck) and Aptus (off label) cannot be officially recommended.
- Devices have not been tested under these conditions.
- ...it remains a "individual" decision for elective cases with FEVAR (CE marked/CMD) and OR at hand.
- much easier in an emergency situation (especially taking into account the expectable neck dilatation)
When to use it

- What is about complex EVAR procedures
Durability of branches in branched and fenestrated endografts

Fig 1. Schematic diagram of redefinition of endoleaks derived from branch stent pathology. This level of detail is important because the differences between B, C, D, and E imply different modes of failure. B and C suggest the branch–main body or branch–branch interface is inadequate, D suggests material fatigue in the branch stent graft, and E implies pathologic change in aortic morphology that may have resulted from either poor apposition of branch walls or endoleak causing sac growth from another source.
Stenosis or fracture of Stents due to graft migration (first European Survey CX 2006)

Stent position at implantation

position of RA Stent after 8 Mo
Oderich G. et al., Results of the US Multicenter Prospective Study evaluating Zenith fenestrated endovascular graft for treatment of juxtarenal AAA

22% Re-Intervention rate in this trial, 75% for RA stenosis or stent related issues
12 mo FU with migration at the outer curve and compression of left RA stent and EL via fenestration
Graft fixation with anchor and balloon inflation
Procedure related data: 9 cases with helifix anchors as secondary procedure for EVAR

- X-ray time  6.44- 11.22 min with 4-8 anchors
- Overall percutaneous procedure time: 21 – 33 min
- Two anchors lost
- They are going upstream!
- Both anchors remained in a stable position
- No further migration of the graft!
- One additional stent for the renal artery and wedge technique with Aorfix cuff as part of repair

None of the cases required further interventions up to now!
Aptus in fenestrated cases

- 3 cases for repair
- 1 additional stent
- 9 primary cases to prevent graft migration or rotation
Hypothesis: „Downsizing“ of graft using Helifix facilitates the procedure
9 cases so far with 4-11 mo FU

- Reliable fixation with ZERO mm migration or rotation !!
  At the level of fenestration
- Performed with local anesthesia
- Lower radiation dose for patient + staff
- Cost reduction ? graft/ CS vs additional costs for Helifix
- Facilitates FU and reduces secondary intervention rate ?
  → further cost reduction
  → influence FU schedules
- Primary endpoints: any migration , Endoleaks, renal function + secondary interventions
- Planned unlimited FU
In conclusion

Aptus represents a necessary tool for endo-repair in dedicated cases

• It is a „must have“

Primary use might be considered for

• Complex infrarenal EVAR cases with „off label“
• „downsizing“ custom made devices to CE marked fenestrated (on label) to facilitate the procedure with risk and cost reduction
Thank you for your attention!

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