CCX @ LINC
The Use of EVAR Polymer is a Huge Advantage for Hostile Necks - FOR

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Disclosure

Speaker name:
Andrew Holden

I have the following potential conflicts of interest to report:

☒ Consulting – Clinical Advisory Board Member for Endologix Inc
☐ Employment in industry
☐ Stockholder of a healthcare company
☐ Owner of a healthcare company
☐ Other(s)
The Use of Polymer EVAR is a Huge Advantage for Hostile Necks

- Rule 13: The opening Proposition speaker (sometimes called “Prime Minister”) has to define or interpret the motion
- “Polymer EVAR” – a constrained liquid polymer agent that cures to a solid and is used to seal the proximal neck during EVAR procedures
The Use of Polymer EVAR is a Huge Advantage for Hostile Necks

- Google Search: “Polymer EVAR” – top 10 searches
- 5/10 Endologix Nellix
- 4/10 Trivascular Ovation
EVAR: Hostile Necks

- Neck length < 15mm
- Neck diameter > 28mm
- Neck (beta) angulation > 60°
- Circumferential neck calcification/thrombus
- Conical neck (increased diameter by 20% over neck length)

Stather et al, EJVES 2012:44:556-561
Current EVAR Technology – Proximal Seal

- Seal is achieved by graft–arterial wall apposition at the proximal and distal attachment sites
- HNA is clearly associated with less reliable seal and higher rate of early and late type 1A endoleak
Outcomes of Endovascular Aneurysm Repair in Patients with Hostile Neck Anatomy

P.W. Stather a, R.D. Sayers a, A. Cheah b, J.B. Wild a, M.J. Bown a, E. Choke a,*

• Significant increase (p=0.02) in late type 1 endoleaks in hostile neck anatomy (9.5%) compared to favourable neck anatomy (4.5%)

• Significant increase (p<0.01) in total interventions in HNA (22.8%) compared to FNA (11.0%)

Stather et al, EJVES 2012:44:556-561
Neck Length and EVAR Performance

Influence of Infrarenal Neck Length on Outcome of Endovascular Abdominal Aortic Aneurysm Repair

Lina J. Leurs, MSc1; Jur Kievit, MD1; Pieter C. Dagnelie, PhD2; Patty J. Nelemans, MD, PhD2; and Jacob Buth, MD, PhD1 on behalf of the EUROSTAR Collaborators

1EUROSTAR Data Registry Centre, Department of Surgery, Catharina Hospital, Eindhoven, The Netherlands. 2Department of Epidemiology, University of Maastricht The Netherlands.

...infrarenal neck length <15 mm is associated with significantly increased risk of short and midterm endoleaks.
Trivascular Ovation

- Polymer sealing technology used in the proximal neck seal and composite junction seal
- Shortest IFU neck length for any EVR device (7.5mm)
- 161 patient Core Laboratory adjudicated IDE trial showed 0% incidence of type 1A endoleak @ 30 days and 1 year
Trivascular Ovation Post-Market Registry

- 500 subjects enrolled at 30 sites across Europe
- Significant incidence hostile neck anatomy (21% necks < 15mm long, 42% had moderate/severe calcification, 49% had moderate/severe thrombus)
- Excellent freedom from type 1A endoleak

<table>
<thead>
<tr>
<th>Performance</th>
<th>30 Day (N=454)</th>
<th>6 months (N=339)</th>
<th>1 Year (N=233)</th>
<th>2 Year (N=47)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Freedom from Type I and III Endoleaks</td>
<td>98.7%</td>
<td>99.1%</td>
<td>98.7%</td>
<td>100%</td>
</tr>
<tr>
<td>Freedom from Migration</td>
<td>100%</td>
<td>100%</td>
<td>100%</td>
<td>100%</td>
</tr>
<tr>
<td>Freedom from Iliac Occlusion</td>
<td>99.6%</td>
<td>99.7%</td>
<td>100%</td>
<td>100%</td>
</tr>
</tbody>
</table>
EndoVascular Aneurysm Sealing (EVAS) with Nellix

- Designed to seal entire aneurysm with contained biostable polymer
- May overcome some of the challenges faced by conventional endografts
Nellix EVAS in Hostile Neck Anatomy

- Polymer seal in a compliant endobag
- Precise proximal endobag attachment
- Secure fixation by aneurysm sac filling
VALIDATING EVAS with Clinical Data

**Nellix CE Study**
- N=69
- CE Marking: EU Launch Feb 2013
- Over 50 Independent EVAS Studies and Publications

**EVAS FORWARD Global Registry**
- N=300
- 30 Centers (29 EU, 1 NZ)
- Enrollment Completed: Sept, 2014
- 1 YR FU
- 2 YR FU
- 3 YR FU

**EVAS FORWARD IDE**
- N=180
- 29 Centers (26 US, 3 EU)
- Enrollment Completed: Nov, 2014
- 30 DAY FU
- 1 YR FU
- US Commercial Launch
- Continued Access
- PMA Submission
AAA Complexity across All-Comer Registries

- Neck Length <10mm: 17%
- Conical Neck: 46%
- Neck Angle >60°: 8%
- Chimney Procedure: 5%
- Iliac diameters >25mm: 13%

EVAS Global Registry (n=300)
ENGAGE Registry (n=1262)
GREAT Registry (n=400)
Freedom from All Endoleak

Through 1 yr 94.5%
Endoleaks at 1 Year

ENGAGE Registry: Verhagen et al. *LINC Symposium* 2014

<table>
<thead>
<tr>
<th>Type</th>
<th>EVAS</th>
<th>ENGAGE</th>
</tr>
</thead>
<tbody>
<tr>
<td>Type 1A, 1B</td>
<td>0.7%</td>
<td></td>
</tr>
<tr>
<td>Type II</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Type III</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Type IV</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Undetermined</td>
<td></td>
<td>9.8%</td>
</tr>
</tbody>
</table>
Conclusions from Polymer EVAR Data

- Both devices have been used to treat a significant number of patients with hostile neck anatomy.
- The polymer sealing technology is effective in achieving a proximal neck seal in these challenging anatomies.
- Very low type 1A endoleak rate at 30 days and 1 year.
Full Disclosure: Hostile Neck Anatomy

- Neck length < 15mm – **YES** (IFU for Ovation 7.5mm, Nellix 10mm)
- Neck diameter > 28mm – **YES** (IFU for Ovation 30mm, Nellix 32mm)
- Neck (beta) angulation > 60° – **NO**
- Circumferential neck calcification/thrombus – **YES** (high incidence in Ovation Post-Market Registry)
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A Better Solution for Juxta-renal AAA!
Chimney EVAS (Ch-EVAS)

- Early experience extremely promising
- Compliant endobags appear to minimise the risk of gutter type 1a endoleaks
- ASCEND Registry: Open-label, single-arm, real-world study
- 200 patients, up to 10 international centers
- Retrospective and prospective arms
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straightforward cases at this stage. Although you could always put it to them. Is there enough length up there for a bifurcated graft Bernie?

Hence Verhag

Wow, pretty interesting calcification... If you choose for Nellix, you may not want to do a full prefill as you'll likely puncture the bags with the calcium. Matt can comment on this best, I guess. If the neck fits an Endurant, I'd try a bifur and PTA the heck out of it after implantation. Worst thing is occlusion of 1 limb, which you'll treat with X-over. You may want to implant shortest bifur and extend with Excluder limbs. if neck is too wide: Nellix.
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Polymer EVAR: Conical Necks

“Conical necks are a bigger challenge and problem for EVAR than short necks and angulated necks” Hence Verhagen
Rebuttal – the presentation of evidence and reasoning meant to weaken or undermine the opponent’s claim.
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Hence’s rebuttal of me:

- Outdated publications during the learning phase of a technology
- Point out more famous members of my family!
Rebuttal – the presentation of evidence and reasoning meant to weaken or undermine the opponent’s claim

My rebuttal of Hence:

- He’s an all round good guy!
- Comes from a great country!
Some Unusual Collecting Habits!

Bad Taste Watches

Outback Australian Cowboy Boots
A Chameleon!
A Chameleon!

Hence

Hendrik
...infrarenal neck length <15 mm is associated with significantly increased risk of short- and midterm endoleaks.
ENGAGE Global Registry
Outcomes At Follow-Up

<table>
<thead>
<tr>
<th>Endoleak Type IA</th>
<th>8-15 mm</th>
<th>≥15 mm</th>
<th>P-Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>At 1 yr</td>
<td>0%</td>
<td>0.2%</td>
<td>0.54</td>
</tr>
<tr>
<td></td>
<td>(0/113)</td>
<td>(0/784)</td>
<td></td>
</tr>
<tr>
<td>At 2 yr</td>
<td>0%</td>
<td>0.6%</td>
<td>0.39</td>
</tr>
<tr>
<td></td>
<td>(0/184)</td>
<td>(4/652)</td>
<td></td>
</tr>
<tr>
<td>At 3 yr</td>
<td>0%</td>
<td>0.4%</td>
<td>0.75</td>
</tr>
<tr>
<td></td>
<td>(0/26)</td>
<td>(1/246)</td>
<td></td>
</tr>
</tbody>
</table>

Endurant performs equally well in standard EVAR neck lengths as it does at short necks:
- No differences between short and standard neck length conditions in terms of:
  - Procedural Technical Observations
  - Type I Endoleak
  - Migration
  - Re-intervention
  - Rare instances of rupture
  - Conversion
Challenging anatomy, and the postprocedural risks involved.

What are the possible solutions for overcoming severe proximal aneurysm neck angulation during endovascular aneurysm repair?

There are actually quite a few useful tips and tricks for this. We have to realize, however, that treating severe angulation of the neck is usually still considered to be outside of the Instructions for Use for many devices. Furthermore, severe angulation of the proximal neck may not be particularly difficult to manage during open repair. If one decides to treat severely angulated proximal anatomy with endovascular aneurysm repair (EVAR), there are still rules to obey. For instance, the greater the angulation, the longer the neck length should be. In general, most endografts end up being positioned perpendicular to the patient rather than perpendicular to the aorta. Therefore, the essential sealing length is not achieved, so more length to start with is essential.

In case of heavy angulation proximally, using a flexible and conformable stent graft seems to be advantageous and further modification will leave us with a treatment that has a completely unknown durability.

In a study of predictors of procedure-related stroke after endovascular repair of ruptured thoracic aortic aneurysms, your group found that there is a considerable risk of stroke; however, this risk decreased significantly over time. To what do you attribute this change? Do you still view stroke as a considerable risk?

Stroke is, and will always be, a considerable risk during thoracic endovascular aneurysm repair (TEVAR). Its exact cause is multifactorial, with wire/catheter manipulation, hemodynamic instability, local anatomy, age, etc., as clear risk factors. Some of the risk factors may become less important in the future with more experienced teams performing this procedure. Unfortunately, the risk will never vanish.

Are there any factors (aside from arrhythmia) that you might hypothesize as causing late catch-up in mortality rates between endovascular treatment and open repair?
What new EVAR technologies in the pipeline are you excited about? What is on your wish list?

It is good to see that, after a quiet period, new players wish to be involved in the EVAR arena. Especially revolutionary new concepts (like sac filling, for example) have my full attention. My wish list contains two major issues: (1) to finally have endografts for which the follow-up scheme resembles the surveillance program after open repair, and (2) to gain further insight into the genetic background of aneurysm disease to either prevent it from the start or to make sure patients are found and treated in time.
What new EVAR technologies in the pipeline are you excited about? What is on your wish list?

Especially revolutionary new concepts (like sac filling, for example) have my full attention.
Conclusions

- Hostile neck anatomy is not well treated by conventional EVAR devices
- EVAR polymer technologies provide a relatively simple method to treat many of these cases
- THAT IS A HUGE ADVANTAGE!