Endoleak management after EVAS – Lessons learned

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Disclosure

• Speaker name: Dittmar Böckler
• I have the following potential conflicts of interest to report:
  • Consulting
  • Employment in industry
  • Stockholder of a healthcare company
  • Owner of a healthcare company
  • Research Grant
• I do not have any potential conflict of interest
Consequences and Implications of Endoelaks

- Continued sac expansion
- Persistent pressurization
- Neck dilatation
- Loss of sealing
- Migration
- Late Type I Endoleak
- Rupture
- Death
**Factors associated with rupture**

<table>
<thead>
<tr>
<th>Covariate</th>
<th>adjusted hazard ratio</th>
<th>p-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>top neck diameter (cm)</td>
<td>2.07</td>
<td>0.253</td>
</tr>
<tr>
<td></td>
<td>[0.59 – 7.20]</td>
<td></td>
</tr>
<tr>
<td>neck length (cm)</td>
<td>0.82</td>
<td>0.711</td>
</tr>
<tr>
<td></td>
<td>[0.28 – 2.38]</td>
<td></td>
</tr>
<tr>
<td>maximum common iliac diameter (cm)</td>
<td>0.97</td>
<td>0.956</td>
</tr>
<tr>
<td></td>
<td>[0.30 – 3.17]</td>
<td></td>
</tr>
</tbody>
</table>

**complications:**
- endoleaks type 1, 2 with sac growth, 3 and migration or kinking
  - 8.83
  - [3.76 – 20.76]
  - < 0.0001
EndoVascular Aneurysm Sealing (EVAS)

- seals the entire aneurysm
- designed to overcome EVAR issues
“Early Learning Curve” Cases

171 consecutive patients treated at 7 centers between Oct 2012 – March 2014

Results (5 mo follow-up)

- 8% endoleak
- 5% limb occlusion
- 9% reintervention
- No rupture
- No conversions

Results: During a 17-month period, 172 procedures were performed in 171 patients with the Nellix device and 77 procedures in 77 patients with the Talent device. Median age of patients was 74 ± 15 years with mean age of 74 ± 15 mm and infrarenal neck length of 19 ± 10 mm. Eighteen patients had a type 1b neck (25%), 24 patients had a type 1c neck (35%), and 24 patients had a type 1a neck (35%). There were eight limb occlusions with five related reinterventions.
Early Techniques and Learning Curve

Attempted Complex AAA

Juxtarenal AAA; Hostile Necks

Procedure Was Early in its Maturity

Nellix Stent Misalignment

Low Stent Placement
Early Techniques and Learning Curve

- Insufficient correction for parallax
- Didn’t use contrast in prefill
- Didn’t leave balloons up or maintain nominal inflation pressure during polymer fill and curing
Increasing Clinical Evidence

2009: 1
2010: 1
2011: 2
2012: 2
2013: 2
2014: 7
2015: 33
2016: 37
Global Registry: patients with more complex morphologies

- Neck Length <10mm: 17% (EVAS), 2% (ENGAGE)
- Neck Angle >60°: 8% (EVAS), 6% (ENGAGE)
- Chimney Procedure: 5% (EVAS), 0.1% (ENGAGE)
- Iliac diameters >25mm: 13% (EVAS), 0.6% (ENGAGE)
- EVAR Revision: 2.3% (EVAS), 0% (ENGAGE)
- Rupture: 2% (EVAS), 0% (ENGAGE)

EVAS Global Registry (n=300) vs. ENGAGE Registry (n=1262)

- 98% freedom from persistent endoleaks
- No secondary interventions for Type II endoleaks
- 97% freedom from aneurysm-related mortality
- 99% freedom from cardiovascular mortality
Global Registry: Freedom from Type II EL

Spontaneous Resolution of Type II Endoleak

99.2% Incidence
97.0% Persistence

Low Volume 0.1 – 0.4 mL
1 Yr

No secondary interventions for Type II Endoleak
Global Registry: Freedom from Type Ia EL On- and Off- IFU

Complex Proximal Neck Anatomy

Large proximal necks >28mm
Thrombus-laden necks

On-IFU
Off-IFU

96.9%
85.6%

p-value = 0.0008
Lesson #1: Prevent Endoleak - Stay on IFU

Proper Patient Selection: Large, Patent Lumbars / IMA
Asymmetric aneurysms ("stomach shaped") are potential candidates for stent displacement during pre-fill and/or polymer fill >>> Endoleak type 1a
Lesson #2: Establish Seal during EVAS Procedure

- Optimal seal requires precise management of *Pressure* AND *Volume*
- Inflate Nellix balloons to nominal pressure (7 Atm) for 30 seconds
- Leave balloons up during polymer fill
Proximal Neck Utilization Reduces Reintervention Risk

<table>
<thead>
<tr>
<th></th>
<th>Odds Ratio</th>
<th>95% CI</th>
<th>P-Value</th>
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</thead>
<tbody>
<tr>
<td>Proximal Endoleak</td>
<td>0.946</td>
<td>0.884, 1.013</td>
<td>0.1121</td>
</tr>
<tr>
<td>Proximal Reintervention</td>
<td>0.939</td>
<td>0.891, 0.990</td>
<td>0.0195</td>
</tr>
</tbody>
</table>
Increasing Neck Utilization reduces Migration Risk

**Early Technique:**
Less neck utilization in Global Registry

**Key Learning:**
Greater neck utilization in IDE

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**Global Registry**
- Non-Migration

**IDE**
- Non-Migration
Complex AAA: Better Suited for ChEVAS?
Lesson # 3: Know Your Imaging

EVAS appearances different from EVAR

Differentiating endoleak from adjacent, precipitated contrast in endobag or calcified plaque

Holden et al. J Endovasc Ther 2015
Diagnosing Type Ia Endoleak

- Cresenteric-shaped contrast rim between endobag and thrombus or aortic wall
- May not resolve and grow over time
- Diagnose and treat early

Holden et al. *J Endovasc Ther* 2015
Lesson # 4: Treat Type Ia Endoleak Early

Intraoperative Type Ia Endoleak

- Secondary fill with contrast
- Staged repair if persisting

Secondary Type Ia endoleak

- Scaffolding with liquid embolization
- Proximal extension with parallel grafts
Lesson # 4: Treat Type Ia Endoleak Early

6 mo CT

Angiogram Type Ia

Harvey et al. *JVIR* 2016
Option 1: Transcatheter Embolisation of Type Ia EL

Harvey et al. JVIR 2016
Transcatheter Embolisation of Type Ia EL

1 month post Secondary Intervention

Harvey et al. JVIR 2016
Successful Repair of Type 1a EL after EVAS

99.6% Freedom from Persistent Type 1A Endoleaks, demonstrated by successful secondary repair

Transcatheter Embolization
Option 2: Nellix-in-Nellix for Migration and Proximal Loss of Seal

Migration at 1 year

Migration at 2 Years with Loss of Proximal Seal
Nellix-in-Nellix plus Chimney for Proximal Repair

Post Polymer Fill with Nellix and Chimney Balloons Inflated

Completion Angio

1 mo CTA

Donselaar et al, *J Endovasc Ther* 2016
Option 4: Surgical conversion
EVAS for Endoleak after EVAR Repair

Use of the Nellix EVAS system to treat post-EVAR complications and to treat challenging infrarenal necks

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Aim. Current commercially available modular stent-grafts are associated with relevant reintervention rates during follow-up. The Nellix Endovascular Aneurysm Sealing (EVAS) System is a potential device to overcome these limitations of EVAR. Device implantations outside of manufacturer instructions for use due to challenging neck anatomies are very common. This article presents very early experience in the treatment of patients with post EVAR complications and challenging neck anatomies.

Methods. EVAS with the Nellix System consists of bilateral PTFE-covered stent grafts surrounded by endobags which are filled with bioabsorbable polymer which cures after 3–5 minutes. The device and concept is designed to seal the entire aneurysm lumen, to withstand lateral displacement forces and effectively seal lumbar or inferior mesenteric arteries. Potentially, device migration, type II endoleak, and subacute reinterventions will be reduced in the long-term. Single case experience in four European vascular centers is reported using Nellix off-IFU (instructions for use), addressing technical aspects as well as patient selection criteria.

Results. Recent preliminary clinical experience using Nellix outside of the IFU in challenging neck anatomies proves early feasibility and efficacy in patients being excluded for open repair (OR) and also for EVAR and FEVAR within OR. Short-term results are promising. Migration, renal artery occlusions or type II endoleaks were not observed. One type Ia endoleak was observed but was temporary and resolved. We also found that the chimney technique is feasible with Nellix, where secondary target vessel loss nor gutters were observed. The EVAS concept is a potential tool to treat post EVAR complications such as secondary type I endoleak or type IV material fatigue. Feasibility has been proven in single cases.

Conclusion. EVAS is an innovative, intriguing concept in the treatment of abdominal aortic aneurysm (AAA). Short-term outcomes of the Nellix system is promising. Early experience of Nellix out of IFU when treating patients with challenging proximal infrarenal necks, with post EVAR complications, short necks and chimney techniques show technical feasibility and promising short-term results. Mid- and long-term data are needed to validate device and procedure durability.

Key Words: Aorta - Endovascular procedures - Neck.

Over the past two decades, endovascular aortic aneurysm repair (EVAR) became the first line treatment in abdominal aortic aneurysm (AAA) repair. Short- and long-term results from randomized controlled trials such as EVAR1, DREAM and OVER not only demonstrated significant reduction in perioperative morbidity and mortality but also late catch up of aneurysm-related mortality compared to open repair (OR) during follow-up. 3,4 Comorbid elderly patients benefit from this minimally invasive approach in AAA repair. On the other hand, the “Achilles heel” of EVAR is

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Excluder

Courtesy of Francesco Torella, MD
Liverpool, UK

Anaconda

Courtesy of JP de Vries, MD, PhD
Nieuwegein, NL
Summary and Conclusion

- EVAS procedure has matured since launch 2013 and shows excellent outcomes adopting procedural best practices.
- Type II EL after EVAS essentially do not exist.
- Type I EL rate 3.1% in Global Registry (complex morphologies).
  - Avoid short neck, hostile neck; consider f-EVAR or chimneys.
- Transcatheter embolisation first line Tx for Type Ia EL.
- Further Options: chimney, Nellix in Nellix, conversion.
- EVAS maintains an important role for endovascular AAA therapy.
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