Type Ia endoleak after Nellix EVAS
Incidence, mechanism, and treatment options; What we’ve learned

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Disclosure

Speaker name:
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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
Endoleak is the Achilles heel of EVAR

• Endoleaks are the main indication for re-interventions after EVAR
• Predictive for conversion and secondary rupture
• Re-interventions are still common and costly
• Type 1a is high pressure endoleak and could be related to
  • Technique and planning
  • Device selection
  • Disease progression
EVAR versus EVAS

Alternative concept:

Fixation & Seal

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Diagnosis of type Ia endoleak

- Detection mostly by CTA;
  Both contrast-enhanced and blanco CT scan!

- Early detection is crucial as they tend to enlarge

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3 months  9 months  18 months

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Early type Ia endoleak after EVAS

**potential causes**

1. Low stent deployment
2. Stent malalignment

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Early type Ia endoleak after EVAS

potential causes

3. Underfilling of the endobags

Nosecone angiography

Pigtail angiography after removal 1st device

Pigtail angiography after Secondary fill

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Late type Ia endoleak after EVAS

potential causes

Mostly related to caudal migration of one or both stents
### Incidence of type Ia endoleak after EVAS

<table>
<thead>
<tr>
<th>EVAS</th>
<th>Incident % (n)</th>
<th>Persistent % (n)</th>
<th>Detail</th>
</tr>
</thead>
<tbody>
<tr>
<td>EVAS FORWARD Global Registry</td>
<td>4.3% (12)</td>
<td>0.4% (1)</td>
<td>N=300, 30 centers, 1 year</td>
</tr>
<tr>
<td>Holden, Veith 2015</td>
<td></td>
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</tr>
<tr>
<td>EVAS FORWARD IDE</td>
<td>0.7% (1)</td>
<td>0%</td>
<td>N=150, 15 centers, 30d</td>
</tr>
<tr>
<td>Carpenter, JVS 2015</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Boeckler, JVS 2015</td>
<td>2.3% (3)</td>
<td>0%</td>
<td>Early Commercial Learnings N=171, 7 centers, 5 mo</td>
</tr>
<tr>
<td>Brownrigg, EJVES 2015</td>
<td>3.8% (4)</td>
<td>0%</td>
<td>St. George’s (UK) N=105, 30d</td>
</tr>
<tr>
<td>Holden, JCVS 2015</td>
<td>1.7% (2)</td>
<td>0%</td>
<td>New Zealand Single Center N=120, 14m</td>
</tr>
<tr>
<td>Gossetti, JCVS 2015</td>
<td>0%</td>
<td>0%</td>
<td>Italian Single Center N=24, 30d-1yr</td>
</tr>
<tr>
<td>Szopinski, EJVES 2015</td>
<td>0%</td>
<td>0%</td>
<td>Polish Single Center N=50, 30d–1yr</td>
</tr>
<tr>
<td>Zerwes, Vascular 2015</td>
<td>2% (1)</td>
<td>0%</td>
<td>German Single Center N=50, 3 mo</td>
</tr>
<tr>
<td>Alsac, Annals 2015</td>
<td>0%</td>
<td>0%</td>
<td>French Prospective Study, Single Center, n=20, 30d-1yr</td>
</tr>
<tr>
<td><strong>EVAR</strong></td>
<td><strong>5%</strong></td>
<td><strong>0.4%</strong></td>
<td><em><em>11 studies</em> (IDE, post-mkt, meta-analyses) N=12716, 1 year</em>*</td>
</tr>
</tbody>
</table>

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Freedom From Type IA Endoleak: 
On- and off-IFU

85.6% Off-IFU*
96.4% On-IFU*

P-value = 0.0011

86% of off-label cases due to:
• Neck anatomy (short, angulated, wide)
• Large flow lumen
• Distal anatomy (large CIA, small access vessel)

* The original IFU for the Nellix EndoVascular Aneurysm Sealing System

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Retrospective analysis

- 15 participating Nellix experienced centers (>50 patients);
  - Site specific data
  - Individual patient CRF’s
  - All relevant imaging data analyzed (CTA, angiography, DEUS)
- 1851 EVAS treated patients Q2 2016
  (± ⅓ of all treated patients worldwide)
- Imaging assessed by Core Lab (Syntactx) and subsequent consensus meeting
- ISRB approval

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Retrospective analysis

- 58 cases detected with a type Ia endoleak
  - Incidence early endoleak 1.7%
  - Incidence late endoleak 1.5%
- 74% male, aged 79 ± 8 year
- Mean follow-up 501 ± 285 days
- Days to discovery 267 ± 280 days
- Elective treatment 53 (91%)

Baseline anatomy;

- AAA diameter 65.0 ± 13.2 mm
- Flow lumen diameter 43.6 ± 11.0 mm
- Infrarenal neck diameter 24.7 ± 3.5 mm
- Infrarenal neck length 14.9 ± 10.1 mm
- Neck angulation 41 ± 18 degrees
- Neck thrombus 47 ± 70 degrees

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Baseline imaging
Analysis of 55 patients

Outside Original IFU (46/55 patients) 84%
- Neck length (<10 mm*) 10 (18%)
- Neck diameter (<18 mm, >32 mm) 2 (4%)
- Neck angulation (>60 degrees) 7 (13%)
- Sac lumen (>60 mm) 3 (6%)
- Iliac artery diameter (<9 mm, >35 mm) 42 (76%)

Outside New IFU (53/55 patients) 96%
- Neck length (<10 mm*) 20 (36%)
- Neck diameter (<18 mm, >28 mm) 10 (18%)
- Neck angulation (>60 degrees) 7 (13%)
- Sac lumen (>60 mm) 3 (6%)
- AAA/lumen ratio (≥1.4) 31 (56%)
- Iliac artery diameter (<9 mm, >20 mm) 48 (87%)

*Definition for location of distal end of neck changed from 10% increase from the diameter of the lowest renal in the old IFU to 20% in the new IFU.

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Effect of EVAS on the infrarenal neck
Consensus meeting

- Images of all included patients with type IA endoleak were anonymously judged by three EVAS-experienced radiologists
- Early signs of endoleak were observed in 30% of cases
- Every endoleak but one had one of the following:
  - hostile anatomy (short and/or angulated necks, stomach shaped AAA) (16.1%)
  - low and/or mal-aligned stents (44.6%)
  - both (33.9%)
- There is a need for a novel classification system

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Novel Classification System of Post-EVAS Endoleaks

I S1
Contrast in infra-renal neck between endobag and aortic wall, not reaching aneurysm sac

I S2
Contrast in aneurysmal sac between endobag and thrombus or aneurysmal wall

I S3
Contrast between endobags

I S4
Secondary signs of endoleak without proof of endoleak

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Novel Classification System of Post-EVAS Endoleaks

Corelab analysis on 56 patients with a type Ia endoleak and available imaging

<table>
<thead>
<tr>
<th>Type</th>
<th>First EL (%)</th>
<th>1S1</th>
<th>1S2</th>
<th>1S3</th>
<th>1S4</th>
</tr>
</thead>
<tbody>
<tr>
<td>1S1</td>
<td>21 (39%)</td>
<td>6</td>
<td>3</td>
<td></td>
<td></td>
</tr>
<tr>
<td>1S2</td>
<td>23 (41%)</td>
<td>4</td>
<td>1</td>
<td></td>
<td></td>
</tr>
<tr>
<td>1S3</td>
<td>8 (14%)</td>
<td>1</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>1S4</td>
<td>4 (7%)</td>
<td></td>
<td></td>
<td>1</td>
<td></td>
</tr>
</tbody>
</table>

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Management of type Ia after EVAS

- 40 Re-interventions performed (69%);
  - Coil embolization                    n=5
  - Onyx/Glue with coil embolization    n=12
  - Nellix-in-Nellix proximal extensions n=10
    (7 in combination with chimneys)
  - Converted to open surgery           n=13

- Technical success;                   97%
- One re-intervention; conversion after Onyx treatment
- One patient died 19 days after conversion to open surgery due to cerebral hemorrhage

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Management of type Ia after EVAS

- In 19 patients no re-intervention performed (to date);
  - 3 endoleaks resolved spontaneously
  - 1 patient was not treated due to malignancy
  - 2 patients are scheduled for re-intervention
  - 3 patients presented with rupture and died (42 days, 204 days and 393 days after EVAS)
  - 1 patient died unrelated to AAA before re-intervention
  - 2 patients were too frail for conversion and died
  - 7 still in follow-up
Management of type la after EVAS

*Embolization with coils and glue/Onyx*


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Management of type Ia after EVAS

Proximal extension with secondary Nellix

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EVAS best practice

- Proper patient selection -> Within the IFU
- Technical aspects;
  - Use the entire seal length!!!
  - Remove parallax using sheath marker bands
  - Always perform pre-fill
  - Leaving Nellix balloons up during pre-fill and polymer fill to maintain stent position
  - Reposition stents before polymer fill to correct stent position
  - Angiography in multiple views through pigtail catheter after one Nellix device is removed
  - Do NOT remove both Nellix devices until full seal confirmed

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