Treatment options of late failures of EVAS

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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
Endovascular Aneurysm Sealing

- Commercially introduced in 2013 to reduce the incidence of re-intervention and late complications
- Multiple manuscripts have been published on the short-term outcome
- Maturation in indications for treatment, instructions for use, procedural practice and the device itself
- Complications including migration, AAA growth and proximal endoleak have been recognized
Freedom From Type IA Endoleak: *On- and off-IFU*

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
EVAS FORWARD IDE trial

At one year:
- AAA-related mortality 1.3%
- Incidence of Endoleak 3.1%
- Incidence of migration 2.3%
- Reinterventions 3.7%

However; a higher incidence of late failures than anticipated was observed at 24 months:
1. Aneurysm growth
2. Migration

-> Refinements of the IFU based on statistical modeling

Contrast in aneurysmal sac between endobag and thrombus or aneurysmal wall

Contrast between endobags

Secondary signs of endoleak without proof of endoleak

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.

Clinical relevance of type 1S1

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>
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</tbody>
</table>

At least 40% of cases with a 1S1 leak will evolve into more severe types in time

Management of type Ia after EVAS

*Embolization with coils and glue/Onyx*


Suitable in patients with 1S1 leak and 1S2 leak without migration
Management of type Ia after EVAS

Proximal extension with secondary Nellix

Completion 12 months FU Proximal Nellix-in Nellix extension with chimney

Suitable in patients with migration with or without an endoleak
Management of type Ia after EVAS

*Proximal extension with secondary Nellix*

- At least 2-3 cm protrusion
- Flaring of initial stent (12 mm)
- Stents as long as possible; stiffness
- Unfurling of endobags prior to stent deployment
- Nellix balloons deflated during fill
- Low volume
  - Steep volume-pressure curve
  - Prefill vs. dilution
  - Contrast (contrast polymer ration <10%)

Management of type la after EVAS

Proximal extension with secondary Nellix

• Retrospective observational cohort study
• 12 international sites (>50 EVAS procedures)
  • Elective cases: N=32 (of which primary 5 CHEVAS cases)
  • Ruptures: N=9
• IRB approval
• Median FU 3 months (IQR 1-11)
• Time from first procedure was 18.5 months (IQR 12.3-35.3)
• Indication for NINA in elective cases
  • Type Ia endoleak \(n=7\)
  • Migration without endoleak \(n=5\)
  • Migration with endoleak/growth \(n=16\)
  • Other \(n=4\)

Interim analysis; data subjected to changes
Management of type Ia after EVAS  
*Proximal extension with secondary Nellix*

### Baseline characteristics

<table>
<thead>
<tr>
<th>Condition</th>
<th>Elective cases (n=32)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Male</td>
<td>25 (78.1%)</td>
</tr>
<tr>
<td>Age at NINA procedure*</td>
<td>75 ± 7.2</td>
</tr>
<tr>
<td>ASA class 2</td>
<td>8 (25.0%)</td>
</tr>
<tr>
<td>ASA class ≥3</td>
<td>24 (75.0%)</td>
</tr>
<tr>
<td>Hypertension</td>
<td>29 (90.6%)</td>
</tr>
<tr>
<td>Hyperlipidemia</td>
<td>22 (68.8%)</td>
</tr>
<tr>
<td>Smoking, or history of smoking in last 10 years</td>
<td>19 (59.4%)</td>
</tr>
<tr>
<td>Cardiac disease</td>
<td>21 (65.6%)</td>
</tr>
<tr>
<td>Pulmonary disease</td>
<td>15 (18.8%)</td>
</tr>
<tr>
<td>Renal disease</td>
<td>10 (31.2%)</td>
</tr>
<tr>
<td>Diabetes mellitus</td>
<td>4 (12.5%)</td>
</tr>
</tbody>
</table>

### Anatomical characteristics at time of first EVAS

<table>
<thead>
<tr>
<th>Measurement</th>
<th>Elective cases (n=32)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Maximum AAA sac diameter (mm)</td>
<td>63 (IQR 58-65)</td>
</tr>
<tr>
<td>Maximum AAA lumen diameter (mm)</td>
<td>38 (IQR 30-43)</td>
</tr>
<tr>
<td>Maximum infrarenal neck diameter (mm)</td>
<td>25 (IQR 23-31)</td>
</tr>
<tr>
<td>Infrarenal neck length (mm)</td>
<td>17 (IQR 7-26)</td>
</tr>
<tr>
<td>Infrarenal neck angulation (degrees)</td>
<td>20 (IQR 10-46)</td>
</tr>
<tr>
<td>Maximum diameter left CIA (mm)</td>
<td>16 (IQR 13-20)</td>
</tr>
<tr>
<td>Maximum diameter right CIA (mm)</td>
<td>17 (IQR 13-24)</td>
</tr>
</tbody>
</table>

*Interim analysis; data subjected to changes*
Management of type Ia after EVAS

*Proximal extension with secondary Nellix*

- Procedural time: 208 min (IQR 164-256)
- Proximal extension: n=54 (92%)
- Used Nellix stents: 100mm (100-120 mm)
- Singe NINA extension: n=5 (16%)
- Chimney’s: n=21 (65%)
- Polymer volume: 15 mL (IQR 11-30 mL)
- Polymer pressure: 200 mmHg (190-240 mmHg)
- Technical success*: 93.8%
- Postoperative endoleak: n=2 (6.3%)
  - Type Ia: n=1
  - Type II: n=1

* = defined as successful introduction and deployment of the device without conversion, death, type I or II endoleak, or graft limb occlusion within 24 hours after the procedure.

Interim analysis; data subjected to changes
Management of type Ia after EVAS

Proximal extension with secondary Nellix

• 30 day outcome;
  • Morbidity rate 28%
  • Mortality rate 3.1%
  • Reintervention rate 22%
    • Embolization type Ia endoleak n=1
    • Thrombus aspiration chimney n=1
    • Conversion for endobag rupture n=1

• Latest FU;
  • Reinterventions n= 2 (6.3%)
    • Stenosis n=1
    • Type Ia endoleak n=1
  • Migration n= 2 (6.2%)
  • Type Ia endoleak n= 1 (3.1%)
  • AAA growth n= 0 (0%)
  • Rupture n= 0 (0%)

Interim analysis; data subjected to changes
Management of type Ia after EVAS Conversion

- Retrospective physician initiated study (Dittmar Böckler)
- 8 international high volume sites (986 EVAS procedures)
- 42 conversions (4.2%)
  - 67% elective procedures
  - 33% acute procedures (rupture or impending rupture)
- Treated inside the original IFU 55%
- Mean time to conversion 20 months
- Indications for conversion
  1. Migration
  2. Type Ia endoleak
  3. Infection

Presented at 2017 Veith Symposium
Management of type Ia after EVAS

Conversion

- Clamping infrarenal: 39%
- Suprarenal clamping time: 10.2±14.8 min
- Procedural time: 182±97 min
- Blood loss: 1500±1300 mL
- ICU stay: 4.4±8.5 days
- Overall mortality: 19% (8/42)
  - Elective conversion: 7.1% (2/28)
  - Emergency conversion: 42% (6/14)

Presented at 2017 Veith Symposium
### Management of type Ia after EVAS Conversion

Comparison EVAR vs EVAS

<table>
<thead>
<tr>
<th></th>
<th>EVAR¹</th>
<th>EVAS*</th>
</tr>
</thead>
<tbody>
<tr>
<td>Conversion rate</td>
<td>3.7%</td>
<td>4.3%</td>
</tr>
<tr>
<td>30 day mortality</td>
<td>9.1%</td>
<td>7.1%</td>
</tr>
<tr>
<td>Leading indication</td>
<td>Endoleak Rupture</td>
<td>Endoleak Rupture</td>
</tr>
<tr>
<td>Post-proc. Rupture Rate</td>
<td>0.9%</td>
<td>1.5%</td>
</tr>
</tbody>
</table>

¹ EVAR 1, DREAM, Kouvelos Böckler, J Endovasc Ther 2002 - * unpublished data
Conclusions

• Type Ia and migration are the most common complications after EVAS
• In similarity to EVAR the proximal endoleaks do require treatment, including those not reaching the aneurysmal sac
• Endovascular treatment options are available but long-term durability remains to be shown
• The use of a Nellix-in-Nellix procedure after failed EVAS seems to be a feasible treatment option
• Conversion after EVAS is not more complicated compared to conversion post-EVAR
Treatment options of late failures of EVAS

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