Nellix-in-Nellix proximal extensions for late failures

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Disclosures

Consultancy and/or Research Funding:

• Medtronic
• Bentley InnoMed GmbH
• Terumo Aortic
• Endologix Inc.
• W.L. Gore and associates
• Vascular Insights LLC
Endovascular Aneurysm Sealing

- Steep initial learning curve on the procedure to 2016
- Promising 1-year clinical results in challenging patient cohorts with low endoleak rates
- Failure modes apparent at 2y (migration and sac expansion)
- Root cause analysis and refinement of IFU
- Excellent expected clinical outcomes but reduced applicability
- Need for alternative treatment options for late failures; migration and proximal endoleak
Management of type Ia after EVAS

*Embolization with coils and glue/Onyx*

Brownrigg et al. *Eur J Vasc Endovasc Surg* 2015: 50, 157-64.

Suitable only in patients with gutter endoleaks without migration
Management of type Ia after EVAS

Proximal extension with secondary Nellix

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; chimney’s often indicated
- Flaring of initial stent (12 mm)
- **Stents as long as possible**; increase rigidity
- Unfurling of endobags prior to stent deployment
- Nellix balloons deflated during fill
- Low volume
  - Steep volume-pressure curve
  - Contrast (contrast polymer ration <10%)

Management of type Ia after EVAS

*Proximal extension with secondary Nellix*

- Retrospective observational cohort study
- 12 international sites (>50 EVAS procedures)
  - Elective cases: N=32
  - Ruptures: N=9
- 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
### Anatomical characteristics at time of first EVAS

<table>
<thead>
<tr>
<th>Characteristic</th>
<th>Elective cases (n=32)</th>
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<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>
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<tr>
<td>Maximum infrarenal neck diameter (mm)</td>
<td>25 (IQR 23-31)</td>
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<td><strong>Infrarenal neck length (mm)</strong></td>
<td><strong>17 (IQR 7-26)</strong></td>
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<tr>
<td>Infrarenal neck angulation (degrees)</td>
<td>20 (IQR 10-46)</td>
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<tr>
<td>Maximum diameter left CIA (mm)</td>
<td>16 (IQR 13-20)</td>
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<tr>
<td>Maximum diameter right CIA (mm)</td>
<td>17 (IQR 13-24)</td>
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</tbody>
</table>

5/32 electively cases were primary treated with Chimney-EVAS
Management of type Ia after EVAS

*Proximal extension with secondary Nellix*

- Procedural time: 208 min (IQR 164-256)
- Used Nellix stents: 100mm (100-120 mm)
- Chimney’s: n=21 (65%)
- Polymer volume: 15 mL (IQR 11-30 mL)
- Polymer pressure: 200 mmHg (190-240 mmHg)
- Technical success*: 93.8%
- Postprocedural 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.
Management of type Ia after EVAS
Proximal extension with secondary Nellix

- 30-day outcome in elective cases;
  - Mortality rate n=1 (3.1%)
  - Reintervention rate n=7 (22%)
    - Embolization type Ia endoleak n=1
    - Thrombus aspiration chimney n=1
    - Conversion for endobag rupture n=1
    - Access related re-interventions n=2
    - Compartment syndrome n=2
Management of type Ia after EVAS

Proximal extension with secondary Nellix

Latest FU in elective cases (median 3 months (IQR 1-11));

- Overall mortality n=6 (18.0%)
- AAA-related death n=1 (3.1%)
- Re-migration n=2 (6.2%)
- Re-interventions n=2 (6.3%)
  - PTA stenosis n=1
  - Embolization type Ia endoleak n=1
Management of type Ia after EVAS

Conversion

• 42 conversions (4.2%) in 8 international high volume sites
  • 67% elective procedures
  • 33% acute procedures (rupture or impending rupture)
• Mean time to conversion 20 months
• Indications for conversion
  • Migration
  • Type Ia endoleak
  • Infection
• Overall mortality 19% (8/42)
  • Elective conversion 7% (2/28)
  • Emergency conversion 42% (6/14)

Presented by Dittmar Böckler at 2017 Veith Symposium
Summary

• Type Ia and migration are the most common late complications after EVAS

• The Nellix-in-Nellix technique differs significantly from primary EVAS

• Nellix-in-Nellix is feasible with a low 30-day mortality, but related to a significant early re-intervention rate

• Conversion to open repair remains to be preferred in the fit patients
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