The DEVASS study: Influence of patient selection on outcomes following EVAS with Nellix within the various IFU

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Disclosure

Speaker name: Michel Reijnen

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); Research funding

☐ 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
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

Anticipated results at 24 months:

- Freedom from AAA growth: 98.1%
- Freedom from Type Ia endoleak: 98.9%
- Freedom from migration: 97.5%

Keep in mind:

- Instructions for use is not only case selection; best practice!
- Second generation commercially available device has been introduced; distal endobag attachment
DEVASS study

*Dutch Endovascular Aneurysm Sealing Study*

- Retrospective observational cohort study
- 3 Dutch hospitals
  - IFU 2013: N=168
  - IFU 2016: N=48
- All imaging analyzed
- IRB approval
- Mean FU 23 months (12-29 months)
### Results: baseline characteristics

<table>
<thead>
<tr>
<th>Baseline characteristics</th>
<th>IFU 2013 (%, SD)</th>
<th>IFU 2016 (%, SD)</th>
<th>P value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Male</td>
<td>155 (92.3)</td>
<td>40 (83.3)</td>
<td>0.064</td>
</tr>
<tr>
<td>Female</td>
<td>13 (7.7)</td>
<td>8 (16.7)</td>
<td></td>
</tr>
<tr>
<td>Age at procedure*</td>
<td>74 (68-79)</td>
<td>75 (68.25-79)</td>
<td>0.702</td>
</tr>
<tr>
<td>ASA class</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>2</td>
<td>107 (63.7)</td>
<td>29 (60.4)</td>
<td>0.766</td>
</tr>
<tr>
<td>&gt;2 missing</td>
<td>60 (35.7)</td>
<td>18 (37.5)</td>
<td></td>
</tr>
<tr>
<td></td>
<td>1 (0.6)</td>
<td>1 (2.1)</td>
<td></td>
</tr>
<tr>
<td>Hypertension</td>
<td>112 (66.7)</td>
<td>33 (68.8)</td>
<td>0.786</td>
</tr>
<tr>
<td>Hyperlipidemia</td>
<td>126 (75.0)</td>
<td>38 (79.2)</td>
<td>0.552</td>
</tr>
<tr>
<td>Smoking, or history of smoking in last 10 years</td>
<td>78 (46.4)</td>
<td>20 (41.7)</td>
<td>0.559</td>
</tr>
<tr>
<td>Cardiac disease</td>
<td>72 (42.9)</td>
<td>27 (56.3)</td>
<td>0.117</td>
</tr>
<tr>
<td>Pulmonary disease</td>
<td>47 (28.0)</td>
<td>13 (27.1)</td>
<td>0.903</td>
</tr>
<tr>
<td>Renal disease</td>
<td>34 (20.2)</td>
<td>8 (16.7)</td>
<td>0.581</td>
</tr>
<tr>
<td>Diabetes mellitus</td>
<td>27 (16.1)</td>
<td>11 (22.9)</td>
<td>0.272</td>
</tr>
</tbody>
</table>
### Results; anatomical details

<table>
<thead>
<tr>
<th>Anatomical characteristics</th>
<th>IFU 2013</th>
<th>IFU 2016</th>
<th>P-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Infrarenal neck diameter</td>
<td>23.3 (21.8 – 25.5)</td>
<td>22.3 (20.9 – 24.3)</td>
<td>0.031</td>
</tr>
<tr>
<td>Infrarenal neck angle</td>
<td>21.9 (13.1 – 35.0)</td>
<td>25.2 (15.2 – 38.2)</td>
<td>0.234</td>
</tr>
<tr>
<td>Infrarenal neck length at</td>
<td>18.0 (12.0 – 31.0)</td>
<td>20.0 (15.0 – 30.8)</td>
<td>0.548</td>
</tr>
<tr>
<td>10% diameter increase</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>AAA lumen diameter</td>
<td>42.3 (37.9 – 48.1)</td>
<td>46.6 (41.3 – 50.8)</td>
<td>0.003</td>
</tr>
<tr>
<td>AAA outer diameter</td>
<td>57.9 (54.3 – 61.7)</td>
<td>56.4 (53.0 – 61.2)</td>
<td>0.141</td>
</tr>
<tr>
<td>Ratio AAA outer diameter to</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>AAA lumen diameter</td>
<td>1.35 (1.19 – 1.57)</td>
<td>1.27 (1.15 – 1.32)</td>
<td>0.000</td>
</tr>
<tr>
<td>Infrarenal lumen volume</td>
<td>80.3 (64.1 – 107.3)</td>
<td>93.6 (73.7 – 110.8)</td>
<td>0.128</td>
</tr>
<tr>
<td>Right CIA lumen diameter</td>
<td>10.5 (9.3 – 12.0)</td>
<td>10.0 (9.2 – 11.0)</td>
<td>0.054</td>
</tr>
<tr>
<td>Right CIA outer diameter</td>
<td>18.0 (15.0 – 21.4)</td>
<td>16.5 (14.1 – 18.2)</td>
<td>0.002</td>
</tr>
<tr>
<td>Left CIA lumen diameter</td>
<td>10.5 (9.3 – 12.0)</td>
<td>10.2 (9.1 – 11.0)</td>
<td>0.133</td>
</tr>
<tr>
<td>Left CIA outer diameter</td>
<td>17.2 (14.8 – 20.4)</td>
<td>16.0 (14.1 – 18.1)</td>
<td>0.019</td>
</tr>
<tr>
<td>Procedure Details</td>
<td>IFU 2013</td>
<td>IFU 2016</td>
<td></td>
</tr>
<tr>
<td>-----------------------------------------</td>
<td>------------------------------------</td>
<td>-----------------------------------</td>
<td></td>
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<tr>
<td>Procedural time</td>
<td>90 min (70-108)</td>
<td>90 min (74-106)</td>
<td></td>
</tr>
<tr>
<td>Technical success rate</td>
<td>98.2%</td>
<td>97.9%</td>
<td></td>
</tr>
<tr>
<td>Type Ia endoleak</td>
<td>n=3 (1.8%)</td>
<td>n=1 (2.1%)</td>
<td></td>
</tr>
<tr>
<td>Blood loss</td>
<td>130 mL (IQR 100-300)</td>
<td>150 mL (IQR 63-300)</td>
<td></td>
</tr>
<tr>
<td>Distal extensions</td>
<td>n=15 (8.3%)</td>
<td>n=7 (2.1%)</td>
<td></td>
</tr>
<tr>
<td>Scheduled</td>
<td>n=7 (4.2%)</td>
<td>n=0</td>
<td></td>
</tr>
<tr>
<td>Admission time</td>
<td>3 days (IQR 3-4)</td>
<td>3 days (IQR 3-4)</td>
<td></td>
</tr>
</tbody>
</table>
Results; 24 month outcome

- The freedom-from-reinterventions
  - IFU 2013: 94.4% (12 months), 89.7% (24 months)
  - IFU 2016: 95.7% (24 months)
- significantly more reinterventions in the first 45 cases ($p=.005$).

- The freedom from all endoleaks
  - IFU 2013: 97.4% (12 months), 92.7% (24 months)
  - IFU 2016: 97.8% (12 months), 90.1% (24 months)

- The freedom-from-migration
  - IFU 2013: 98.3% (12 months), 89.9% (24 months)
  - IFU 2016: 100% (24 months)

- Freedom from aneurysm growth
  - IFU 2013: 97.9% (12 months), 91.8% (24 months)
  - IFU 2016: 100% (24 months)

- Primary patency
  - IFU 2013: 96.4% (12 months), 94.0% (24 months)
  - IFU 2016: 100% (24 months)

- Overall survival
  - IFU 2013: 95.5% (12 months), 90.9% (24 months)
  - IFU 2016: 95.5% (24 months)
Results; AAA growth and insufficient distal seal
Occurrence of type Ia endoleak:

- < 1 year, N=4
- 1 year - 2 years, N=5

At two-year FU, 6 of 9 cases had received a reintervention:

- Conversions to open repair (n=4), one of them also had an aorto-enteral fistula
- Nellix-in-Nellix proximal extension (rAAA) (n=2)
- Embolization of the endoleak

Results; Type Ia endoleaks
2013 (n=9) 2016 (n=3)
Results; reinterventions
2013 (n=19) 2016 (n=4)

• **30 days (n=3, 1.8%)**
  – Fem-fem crossover (IFU 2016 cohort)
  – Thrombectomy with or without relining (n=2)

• **30 days - 1 year (n=6, 3.6%)**
  – Thrombectomy/thrombolysis with or without relining (n=4, 1x IFU 2016 cohort)
  – Relining for stenosis
  – Conversion for aorto-enteric fistula

• **1 year – 2 years (n=10, 5.9%)**
  – Relining for stenosis
  – Fem-fem crossover
  – Embolisation for Ia endoleak (IFU 2016 cohort)
  – NiNa for migration and Ia endoleak (N=2, 1x for rAAA)
  – Conversion (n=5) for Ia endoleak (n=3, 1x IFU 2016 cohort), AAA growth and para-aortitis
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 in patients with 1S1 leak and 1S2 leak without migration
Management of type Ia after EVAS

*Proximal extension with secondary Nellix*

Suitable in patients with migration with or without an endoleak
**DEVASS cohort; learning curve**

- First 15 cases of each site versus the later cases
- Significantly more re-interventions in early cases (13.3% vs. 7.3%); mostly reinterventions for stenosis/occlusion

<table>
<thead>
<tr>
<th></th>
<th>2013</th>
<th>2016</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Preoperative neck length</strong></td>
<td>18mm (IQR 12-31)</td>
<td>20mm (IQR 15-31)</td>
</tr>
<tr>
<td><strong>Seal length</strong></td>
<td>14mm (IQR 7-25)</td>
<td>14mm (IQR 11-24)</td>
</tr>
<tr>
<td><strong>Complicated</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Preoperative neck length</strong></td>
<td>16mm (IQR 13-23)</td>
<td>21mm (IQR 12-32)</td>
</tr>
<tr>
<td><strong>Seal length</strong></td>
<td>11mm (IQR 7-18)</td>
<td>14mm (IQR 6.5-27)</td>
</tr>
</tbody>
</table>
Conclusions

• EVAS used in patients inside the current IFU is related to good outcomes at 2 years follow-up
• The current IFU has significantly reduced the applicability of the technique
• IFU not only includes anatomical features but also best practice
• The positive impact of the distal endobag attachment of the new device on distal seal and subsequent AAA growth remains to be shown
• EVAS-Global-2 Registry will show the results of the latest generation device with the current best practice within the IFU
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