Use Of Nellix Device And Endovascular AAA Sealing (EVAS) For RAAA:
Advantages, Limitations And Results

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Endovascular treatment of acute aneurysms

- Randomized trial failed to prove a reduction in 30-day mortality over open repair:
  - IMPROVE 35% vs. 37%
  - AJAX 21% vs. 25%
  - ECAR 18% vs. 24%

- Nevertheless EVAR is progressively considered the preferred treatment for acute aneurysms:
  - Trend for lower mortality for EVAR after 1 year
  - Earlier recovery
  - Gains in health-economic outcomes at 1 year

Clinical significance of type II endoleak in rAAA

- Patent side branches in a ruptured AAA can be problematic post-EVAR
  - In cases of ruptured AAA, Type II endoleaks may cause ongoing bleeding, and a large retroperitoneal hematoma, in turn, may lead to paralytic bowel obstruction or abdominal compartment syndrome, with subsequent prolonged hospitalization

- Type II endoleak most common indication reason for reintervention following rEVAR

Theoretical (dis)advantages of EVAS in rAAA

- Implantation is rapid and straightforward
- No cannulation required of a contralateral limb
- Pre-fill provides a fast control of the bleeding
- Could be used in combination with chimney’s in ruptured juxtarenal AAA
- No persistent bleeding from an endoleak

- But: Pressure guided technique in already damaged aneurysm wall: is it safe?
Bulging of endobags

Retrospective, multi-center, observational study

- 8 EVAS experienced sites
- 58 patients with an acute aneurysm
- 28 ruptured aneurysms
- 30 symptomatic aneurysms
- Treated from February 2013 until April 2015
- Primary endpoint: 30-day mortality
- Secondary endpoints: 30-day morbidity, endoleaks and re-interventions
- Age: 74 ± 9 years
- Male: 46 (79%)

Global experience with the Nellix endosystem for ruptured and symptomatic abdominal aortic aneurysms

J Endovasc ther 2016;23:21-8

Retrospective, multi-center, observational study

Anatomical data

<table>
<thead>
<tr>
<th>Type of aneurysm</th>
<th>Symptomatic AAA</th>
<th>Ruptured AAA</th>
<th>p-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Fusiform</td>
<td>28 (93%)</td>
<td>24 (86%)</td>
<td>0.451</td>
</tr>
<tr>
<td>Pseudoaneurysm</td>
<td>2 (7%)</td>
<td>4 (14%)</td>
<td></td>
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<tr>
<td>Maximum AAA diameter (mm)</td>
<td>65.8 ± 13.0</td>
<td>74.7 ± 15.7</td>
<td>0.03</td>
</tr>
<tr>
<td>infra-renal neck length (mm)</td>
<td>19.2 ± 13.4</td>
<td>18.2 ± 12.9</td>
<td>0.734</td>
</tr>
<tr>
<td>infra-renal neck diameter (mm)</td>
<td>23.3 ± 5.2</td>
<td>26.2 ± 7.6</td>
<td>0.662</td>
</tr>
<tr>
<td>infra-renal neck angulation (degrees)</td>
<td>18±5.1</td>
<td>20 ± 6.5</td>
<td>0.911</td>
</tr>
<tr>
<td>Maximum blood lumen diameter (mm)</td>
<td>41.0 ± 11.1</td>
<td>49.0 ± 12.5</td>
<td>0.065</td>
</tr>
<tr>
<td>Maximum right iliac artery diameter (mm)</td>
<td>20.3 ± 12.5</td>
<td>17.9 ± 13.5</td>
<td>0.329</td>
</tr>
<tr>
<td>Maximum left iliac artery diameter (mm)</td>
<td>19.3 ± 11.1</td>
<td>16.5 ± 4.7</td>
<td>0.117</td>
</tr>
<tr>
<td>Within instructions for use</td>
<td>17 (57%)</td>
<td>11 (39%)</td>
<td>0.162</td>
</tr>
</tbody>
</table>

EVAS in ruptured aneurysms

68-year old male patient

History:
- Diabetes mellitus
- Duodenal perforation
- Aortic valve sclerosis

Ruptured AAA 60 mm

*Hemodynamic stable situation with a contained rupture

EVAS in ruptured aneurysms

71-year old male patient

Medical history:
- Tube graft for rAAA with suprarenal clamping 2008
- COPD
- Rheumatoid arthritis

62 cm ruptured pararenal aneurysm

Chimney-EVAS with two Advanta V12™ chimneys in the renal arteries
EVAS in ruptured aneurysms outside IFU

Consensus on procedure rEVAS

Consensus on procedural protocol is crucial:
- As close to elective procedure as possible
- Prefill with 10-15% contrast
- Intended endobag pressure of 180 mmHg
- Balloons up throughout the procedure
- Secondary fill at the discretion of the operator
- Remove one catheter first and replace it by a regular angiography catheter (high quality imaging)
- Control angiography in at least two directions

Global experience with the Nellix endosystem for ruptured and symptomatic abdominal aortic aneurysms / Published: the 2016/2/21
Conclusions

- Retrospective data show the feasibility of EVAS in ruptured aneurysms in experienced sites.
- 30-day mortality in ruptures in line with EVAR trials, but many patients were treated outside the IFU.
- More robust prospective data and standardization of the treatment protocol are required and should be provided in a prospective registry.