Nellix endografts can be used effectively to treat RAAA's: Tips, Tricks, Advantages and Limitations

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Endovascular treatment of acute aneurysms

- Randomized trial failed to prove reduction in 30-day mortality:
  - IMPROVE 35% vs. 37% (36% vs. 41%)
  - AJAX 21% vs. 25%

- 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

Endoleaks after EVAR for rAAA

Theoretical (dis)advantages of EVAS in rAAA

- Implantation is fast and easy
- No cannulation required of a contralateral limb
- Pre-fill provides a fast control of the bleeding
- Ability to treat a broad range of anatomies within IFU
- No persistent bleeding from endoleak
- Can be used in combination with chimney’s in ruptured juxtarenal AAA

- But: Pressure guided technique in already damaged aneurysm wall: is it safe?
Retrospective, multi-center, observational study

Anatomical data

<table>
<thead>
<tr>
<th></th>
<th>Symptomatic AAA (n=30)</th>
<th>Ruptured AAA (n=28)</th>
<th>p-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Type of aneurysm</td>
<td>Fusiorm</td>
<td>28 (93%)</td>
<td>24 (86%)</td>
</tr>
<tr>
<td></td>
<td>Pseudoaneurysm</td>
<td>2 (7%)</td>
<td>4 (14%)</td>
</tr>
<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>cTAA-neck length (mm)</td>
<td>19.2 ± 13.4</td>
<td>20.2 ± 12.3</td>
<td>0.76</td>
</tr>
<tr>
<td>cTAA-neck diameter (mm)</td>
<td>21.5 ± 5.2</td>
<td>26.6 ± 7.6</td>
<td>0.662</td>
</tr>
<tr>
<td>cTAA-neck angulation (deg)</td>
<td>36.5 ± 20.5</td>
<td>38.2 ± 33.0</td>
<td>0.913</td>
</tr>
<tr>
<td>Maximum blood lumen</td>
<td>41.2 ± 9.1</td>
<td>45.6 ± 12.5</td>
<td>0.404</td>
</tr>
<tr>
<td>Maximum right iliac artery diameter (mm)</td>
<td>20.3 ± 12.5</td>
<td>17.5 ± 13.8</td>
<td>0.329</td>
</tr>
<tr>
<td>Maximum left iliac artery diameter (mm)</td>
<td>19.3 ± 11.1</td>
<td>16.9 ± 6.7</td>
<td>0.117</td>
</tr>
<tr>
<td>Within instructions for use</td>
<td>17 (57%)</td>
<td>11 (39%)</td>
<td>0.186</td>
</tr>
</tbody>
</table>

EVAS in ruptured aneurysms
within IFU

68-year old male patient

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

Ruptured AAA 60 mm

• Hemodynamic stable situation with a contained rupture

EVAS in ruptured aneurysms
outside IFU

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
within IFU

2x 10-170 Nellix™ device
115 cc Polymer
(230 mm Hg)

EVAS in ruptured aneurysms
outside IFU

Prefill with saline solution
Optional addition of contrast
Pressure 180 mm Hg
Prefill of endobags with contrast

EVAS in ruptured aneurysms outside IFU

EVAS in ruptured aneurysms outside IFU

Retrospective, multi-center, observational study

Procedural data

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<th>Ruptured (n=28)</th>
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</tr>
</thead>
<tbody>
<tr>
<td>Procedural time (min)</td>
<td>100 ± 46</td>
<td>95 ± 31</td>
<td>0.943</td>
</tr>
<tr>
<td>Local anesthesia</td>
<td>4 (14%)</td>
<td>18 (64%)</td>
<td>0.000</td>
</tr>
<tr>
<td>Hemoglobin at start procedure (mmol/L)</td>
<td>8.1 ± 1.3</td>
<td>7.3 ± 1.1</td>
<td>0.013</td>
</tr>
<tr>
<td>Creatinin at start procedure (mmol/L)</td>
<td>107.5 ± 48.3</td>
<td>151.9 ± 103.4</td>
<td>0.012</td>
</tr>
<tr>
<td>Prefill done</td>
<td>30 (100%)</td>
<td>21 (75%)</td>
<td>0.004</td>
</tr>
<tr>
<td>Polymer volume</td>
<td>95 ± 49</td>
<td>136 ± 93</td>
<td>0.087</td>
</tr>
<tr>
<td>Fill pressure (mmHg)</td>
<td>205 ± 26</td>
<td>185 ± 16</td>
<td>0.002</td>
</tr>
<tr>
<td>Concomitant procedures</td>
<td>13%</td>
<td>18%</td>
<td>1.000</td>
</tr>
</tbody>
</table>

3 chimney procedures, 2 distal extensions, 4 access related procedures

Retrospective, multi-center, observational study

post-procedural data

<table>
<thead>
<tr>
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<th>Ruptured (n=28)</th>
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</tr>
</thead>
<tbody>
<tr>
<td>Admission (days)</td>
<td>7.4 ± 4.7</td>
<td>12.4 ± 5.7</td>
<td>0.680</td>
</tr>
<tr>
<td>ICU (days)</td>
<td>0.8 ± 0.9</td>
<td>4.0 ± 9.6</td>
<td>0.002</td>
</tr>
<tr>
<td>30-day mortality (%)</td>
<td>5 (17%)</td>
<td>16 (57%)</td>
<td>0.001</td>
</tr>
<tr>
<td>30-day mortality (%)</td>
<td>2 (7%)</td>
<td>9 (32%)</td>
<td>0.011</td>
</tr>
</tbody>
</table>

One related to conversion for persistent instability e.g.i.
Six cardiac, two pulmonary causes of death, two related to MODS and one to ischemic colon

Retrospective, multi-center, observational study

30-day data

<table>
<thead>
<tr>
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<th>Ruptured (n=28)</th>
<th>P-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Type Ia endoleak</td>
<td>N=1</td>
<td>N=1</td>
<td>NA</td>
</tr>
<tr>
<td>Type Ib endoleak</td>
<td>N=0</td>
<td>N=0</td>
<td>NA</td>
</tr>
<tr>
<td>Type II endoleak</td>
<td>N=0</td>
<td>N=0</td>
<td>NA</td>
</tr>
<tr>
<td>Limb stenosis/occlusion</td>
<td>N=0</td>
<td>N=0</td>
<td>NA</td>
</tr>
<tr>
<td>Stent #</td>
<td>N=0</td>
<td>N=0</td>
<td>NA</td>
</tr>
<tr>
<td>Re-intervention</td>
<td>N=1*</td>
<td>N=8**</td>
<td>0.0051</td>
</tr>
</tbody>
</table>

*One end only for small Type Ia endoleak
** 3 conversions: 2x due to instability and one to mycotic origin(bridge to surgery)
2 laparostomies and 2 bowel resections
Retrospective, multi-center, observational study

Latest available follow-up

- Mean follow up
  - Ruptured group 280 ± 94 days
  - Symptomatic group 372 ± 163 days
- Stable aneurysm diameters
- Three re-interventions performed:
  - One type-1a in conjunction with a distal migration of the stents (ruptured group)
  - One type-1b endoleak treated with SE covered stent (symptomatic group)
  - One renal artery stenosis stented (previously treated with Onyx)
- No other endoleaks

Conclusions

- Data show the feasibility of EVAS in both ruptured and symptomatic aneurysms in experienced sites
- 30-day mortality in ruptures in line with EVAR trials, but many patients outside the IFU
- More robust prospective data are required
- Treatment protocols and bail-out strategies are still in development

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