Aortic Neck Enlargement after EVAR Differs with Self-Expanding and Balloon Expandable Endografts: Why the Difference is Important

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Disclosure Statement of Financial Interest

- None, related to presented topic

Aortic Neck Enlargement

- Neck enlargement after EVAR

<table>
<thead>
<tr>
<th></th>
<th>1 year</th>
<th>2 years</th>
<th>3 years</th>
<th>4 years</th>
<th>10 years</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>13%</td>
<td>28%</td>
<td>38%</td>
<td>69%</td>
<td>100%</td>
</tr>
<tr>
<td>2</td>
<td>13%</td>
<td>28%</td>
<td>38%</td>
<td>69%</td>
<td>100%</td>
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</tbody>
</table>

Endograft devices utilize self-expanding stent structures to provide proximal fixation and seal
- Neck enlargement can result in:
  - Loss of proximal seal - type 1 endoleak
  - Loss of proximal fixation - endograft migration
  - Device oversizing at time of implantation
  - Long-term durability concerns

Potential Causes of Neck Enlargement

- Device related: radial force, oversizing
- Disease progression

- Systematic review: PubMed, Embase, Cochrane databases
  - 23 relevant articles reporting on 8415 patients
  - No clear relationship between device oversizing and neck dilation
  - Oversizing up to 25% decreased risk of type 1 endoleaks
  - No clear relation of oversizing to migration
  - Conclusion: Neck dilation is most likely an expression of aneurysmal wall degeneration

Hypothesis

Radial forces applied to the aortic neck by self expanding endografts may induce aortic neck enlargement over time

Does neck enlargement occur in aneurysm patients treated with endografts which do not employ self-expanding stents?

Proximal Endograft Stent Structures

- Balloon expandable stents
  - Parodi device
  - MEGS device
  - Ovation
  - Nellix (EVAS)

- Self-expanding stents (EVAR)
  - Most-all commercially available devices
  - Various constructs
  - Suprarenal elements: bare stents, hooks and barbs
There was tendency to reduce number of Type 1 endoleaks, when graft been oversized by 25%
Administrator, 11/20/2015
**Objective**

To determine whether proximal stent structure plays a role in aortic neck enlargement after EVAR

**Method**

**Balloon expandable (BES): Nellix**
- Investigational device: IRB approved trial
- 49 consecutive patients, 2008-2010
- Dr. Dainis Krievins, Riga Latvia
- Dr. Andrew Holden, Auckland, New Zealand
- Max FU 4.8 years, mean 36 mo

**Self-expanding (SES): Endurant**
- 3rd generational commercial device
- 56 consecutive patients, 2008-2010
- Dr. Jean-Paul deVries, Nieuwegein, the Netherlands
- Max FU 4.4 years, mean 24 mo (ns)

Prospective CT based FU: pre, post, yearly (> 1 yr. FU in all)
- Quantitative CT analysis: 2 independent vascular radiologists blinded to outcome results

**Quantitative CT Image Analysis**
**Aortic Diameter Measurements**

**Treatment Related Change in Aortic Diameter**
**pre vs post implant CT diameter (mm)**

<table>
<thead>
<tr>
<th></th>
<th>BES</th>
<th>SES</th>
<th>P value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Suprarenal aorta</td>
<td>0.07</td>
<td>0.81</td>
<td>0.52</td>
</tr>
<tr>
<td>Infra renal aorta</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Level 1</td>
<td>0.48</td>
<td>1.80</td>
<td>0.008*</td>
</tr>
<tr>
<td>Level 2</td>
<td>0.89</td>
<td>2.04</td>
<td>0.037*</td>
</tr>
<tr>
<td>Level 3</td>
<td>1.13</td>
<td>2.63</td>
<td>0.074</td>
</tr>
</tbody>
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* P<0.05 compared to pre-op baseline

**Neck Diameter Change over Time**

<table>
<thead>
<tr>
<th></th>
<th>BES</th>
<th>SES</th>
<th>P value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Infrarenal aorta (Level 3)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Pre-op diameter</td>
<td>25.0</td>
<td>25.7</td>
<td>ns</td>
</tr>
<tr>
<td>Post-op change</td>
<td>+1.4</td>
<td>+2.7</td>
<td>&lt;0.05</td>
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<tr>
<td>3 year change</td>
<td>+1.9</td>
<td>+6.5</td>
<td>&lt;0.0001</td>
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At 3 years:
- BES no change in neck diameter
- Not different from expected age related change
- SES 25% increase in neck diameter

**Aortic Neck Diameter Change over Time**
**Representative examples**
Summary of Study Results

- Neck enlargement
  - Immediate enlargement in both
    - BES 1mm, (4%)
    - SES 2.5 mm (10%)
  - At 3 years
    - No enlargement in BES
    - No endoleak, no migration
    - 6.5 mm enlargement in SES, (13%)*
    - Continuous neck enlargement overtime
    - No migration, no new type I endoleak

Conclusion

- These data suggest that neck enlargement after EVAR with SES endografts is likely related to the radial force exerted by stent elements rather than disease progression in the infrarenal neck.

- Aortic neck enlargement may NOT occur when using devices that do not impart continuous outward forces on the aortic wall.

Thank You