Multicentre (London/Nuremberg) clinical experience in BEVAR procedures – what do new devices offer me as a surgeon

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Disclosure

Speaker name: Said Abisi

I have the following potential conflicts of interest to report:

☑ Proctor/speaker: Gore, Cook, Bentley, Cryolife
☐ Employment in industry
☐ Stockholder of a healthcare company
☐ Owner of a healthcare company
☐ Other(s)

☐ I do not have any potential conflict of interest
BEVAR now

Increasing options...

CMD

Off-the-shelf solutions

No on-label Bridging stent graft yet..
What has been available

• Self-expandable BSG
  - Flexibility and conformability

• Balloon expandable BSG- stainless steel based - Smaller delivery system and precise deployment

• Different opinions, relining and reinforcement
What is new?

• BeGraft +: the latest balloon expandable BSG with double layers of Cobalt Chromium stents and ePTFE membranes.
What is different in B+

**Cobalt Chromium:**
1. radial force
2. kink resistance
3. Flexibility
4. Visibility
5. Struts can be thinned
   * (lower profile + better trackability)*

**ePTFE Membranes:**
sandwiched between 2 layers of stents without individually encapsulating the struts
London & Nuremberg

- Early Launch of BeGraft + 2017

- Collected data of high volume users of B+

- Sub group in depth analysis

- Evaluating common question about relining

Nuremberg data courtesy of Eric Verhoeven et al
2017-2020

• Combined experience of 295 branches in BEVAR for TAAA in 2 practices since May 2017

• Primary technical failure: 2/295
  – Disconnection due to advancement of sheath
  – Delivery balloon did not inflate

• Occlusion: 4/295 = 1.4%

Nuremberg data courtesy of Eric Verhoeven et al
Further analysis - London

minimum diameter for target vessels:

4.5 mm for the renal arteries

6.5 mm for superior mesenteric and coeliac arteries

10-20% oversize

15 mm -20 mm sealing in the target vessel

Approximate overlap of 15 mm between BSGs
• **Primary endpoint**
  - Target vessel patency.

• **Secondary endpoints**
  - Target vessel instability.
  - Adjunct interventions including extension and relining.
Target Vessel Patency

Month | 0  | 4  | 8  | 12 | 16 | 20 | 24 
Number at risk | 163 | 138 | 116 | 87 | 71 | 56 | 49 

Patency (%)

98%
Secondary endpoints

• Target vessel instability as a composite endpoint as any death or rupture related to side branch, late BSG related reinterventions due to stenosis, occlusions, kink, fracture, dislodgment or endoleak (type 1 or 3)

• 4 events (2.4%)
Branch related instability

[2 occlusions- outer branches and 2 in-stent restenosis- inner branches]
Differentiate relining from extension

<table>
<thead>
<tr>
<th>Treatment</th>
<th>Number</th>
</tr>
</thead>
<tbody>
<tr>
<td>Distal extension with BSG</td>
<td>27</td>
</tr>
<tr>
<td>Proximal extension with BSG</td>
<td>3</td>
</tr>
<tr>
<td>Distal extension with uncovered self-expanding stent for dissection</td>
<td>2</td>
</tr>
<tr>
<td>Distal extension with uncovered self-expanding stent for excessive angulation</td>
<td>3</td>
</tr>
</tbody>
</table>

3% distal extension with self-expanding uncovered stent

79% of the target vessels were treated with a single BSG
### Outer branches vs inner branches

<table>
<thead>
<tr>
<th></th>
<th>Not extended</th>
<th>Extended</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td>Inner</td>
<td>53</td>
<td>16</td>
<td>69</td>
</tr>
<tr>
<td>Outer</td>
<td>19</td>
<td>19</td>
<td>94</td>
</tr>
<tr>
<td>Total</td>
<td>128</td>
<td>35</td>
<td>163</td>
</tr>
</tbody>
</table>

*No difference*
Additional advantage
In summary

- Good outcomes for B+ as BSG in BEVAR
- No routine relining since introducing B+
- Clinical trial data awaited to prove the potential as on label BSG for BEVAR
Thank you