New Information and Longer Follow-Up From The Multicenter Trial Of The Gore IBD For Iliac Aneurysms:

Hypogastric Embolization Is NOT Benign

- Approximately 20-30% of patients develop buttock claudication (higher after bilateral sacrifice)
- BC persists in about 50%
- Sexual dysfunction occurs in approximately 10-20%
- Hypogastric artery embolization during EVAR is associated with higher risk of ischemic complications and death

Disclosures

Abbott - medical advisory board; consulting
Bard - contracted research funding
Boston Scientific - contracted research funding
Cook – contracted research funding
Meditronic - medical advisory board
W.L. Gore – contracted research funding; consulting; medical advisory board

"Coil and Cover" vs. Hypogastric Preservation

100% freedom from new-onset buttock claudication on IBE side

Gore IBE 12-04 Trial – 6 Month Primary Endpoint (N = 63)

0% Aneurysm-related mortality
95.2% Technical success
95.2% IBE device patency
0 type 1 or 3 endoleaks
98.4% Freedom from reintervention

Schneider et al. J Vasc Surg 2017

Kouvelos et al. Eur J Vasc Endovasc Surg 2016
Farivar et al. J Vasc Surg 2017
Farahmand et al. Eur J Vasc Endovasc Surg 2008

"Coil and Cover" or Iliac Branch Device

12 Tips To Drop That Stupid Fat Butt!
Results of EVAR with IBDs

<table>
<thead>
<tr>
<th>Author (Year)</th>
<th>n</th>
<th>Branches</th>
<th>Mortality</th>
<th>Technical success mean FU (months)</th>
<th>Branch occlusion</th>
</tr>
</thead>
<tbody>
<tr>
<td>Haulon (2006)</td>
<td>52</td>
<td>53</td>
<td>0%</td>
<td>94%</td>
<td>14</td>
</tr>
<tr>
<td>Dias (2008)</td>
<td>22</td>
<td>23</td>
<td>0%</td>
<td>91%</td>
<td>20</td>
</tr>
<tr>
<td>Ferreira (2010)</td>
<td>37</td>
<td>54</td>
<td>0%</td>
<td>97%</td>
<td>23</td>
</tr>
<tr>
<td>Parlani (2012)</td>
<td>100</td>
<td>100</td>
<td>0%</td>
<td>95%</td>
<td>17</td>
</tr>
<tr>
<td>Wong (2013)</td>
<td>130</td>
<td>138</td>
<td>0%</td>
<td>94%</td>
<td>20</td>
</tr>
<tr>
<td>Bots (2016)</td>
<td>18</td>
<td>22</td>
<td>0%</td>
<td>100%</td>
<td>-</td>
</tr>
<tr>
<td>Roeme (2016)</td>
<td>81</td>
<td>85</td>
<td>0%</td>
<td>99%</td>
<td>20</td>
</tr>
<tr>
<td>Tavolli (2015)</td>
<td>178</td>
<td>188</td>
<td>0.3%</td>
<td>99%</td>
<td>20</td>
</tr>
<tr>
<td>GORE 12-04 (2017)</td>
<td>96</td>
<td>100</td>
<td>0%</td>
<td>98%</td>
<td>6</td>
</tr>
<tr>
<td>Cook PRESERVE (2016)</td>
<td>52</td>
<td>52</td>
<td>0%</td>
<td>100%</td>
<td>7</td>
</tr>
</tbody>
</table>

Outcomes

<table>
<thead>
<tr>
<th></th>
<th>IBE 12-04 (N=98)</th>
<th>GREAT (N=92)</th>
<th>P Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mean F/U (days)</td>
<td>650</td>
<td>315</td>
<td>NA</td>
</tr>
<tr>
<td>Aneurysm-Related Mortality</td>
<td>0 (0)</td>
<td>0 (0)</td>
<td>NA</td>
</tr>
<tr>
<td>All Cause Mortality</td>
<td>7 (7.1)</td>
<td>6 (6.5)</td>
<td>0.87</td>
</tr>
<tr>
<td>New-Onset Ipsilateral Buttock Claudication</td>
<td>0 (0)</td>
<td>-</td>
<td>NA</td>
</tr>
<tr>
<td>Reinterventions thru 6 mos</td>
<td>5 (5.1)</td>
<td>5 (5.4)</td>
<td>0.92</td>
</tr>
</tbody>
</table>

Outcomes: Type II Endoleaks

- High incidence of type II endoleaks – 60% at 1 month and 35% at 2 years
- A total of five patients had reintervention for a type II endoleak through 2 years

Outcomes: Aneurysm Sac

- AAA sac expansion (>5mm) 2% and 9% @ 12 and 24 months
- CIAA sac expansion (>5mm) 0% @ 12 and 24 months
Freedom from Reintervention: IBE Pivotal US Trial

Most reinterventions were for type II endoleaks

90.4% through 2 years (95% CI 81.3% - 95.2%)

IBE Clinical Trial: Initial Pivotal Cohort 3 yr follow-up

- 40/61 patients with reported imaging @ 3 yr
- No additional events reported since 2 yr data
- 0 Type I/III Endoleaks
- 0 Ruptures
- 0 Migration

"We recommend preservation of flow to at least one internal iliac artery."
Grade analysis: 1A

"We recommend using Food and Drug Administration (FDA)-approved branch endograft devices in anatomically suitable patients to maintain perfusion to at least one internal iliac artery."
Grade analysis: 1A

Conclusions

Through 3-year follow-up, the Gore IBE device demonstrates durable preservation of internal iliac artery flow in the treatment of CIA and aortoiliac aneurysms.

Use of iliac branch devices for hypogastric artery preservation is:
- Safe and effective
- Associated with high technical success rates
- Durable with low branch occlusion rates