The outcome of patients treated with bilateral iliac branched devices for CIA aneurysms

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Presented on behalf of the Bilateral Gore IBE International Study Group
Disclosure

Speaker name:
Michel Reijnen

I have the following potential conflicts of interest to report:

☐ Consulting
☐ Employment in industry
☐ Stockholder of a healthcare company
☐ Owner of a healthcare company
☐ Other(s)

✓ I do not have any potential conflict of interest with regard to this presentation
Common iliac artery aneurysms

- **Eurostar data:**
  - CIA in 28% of 6,286 EVAR patients
  - Patients with CIA had more:
    - Type Ib and II endoleaks
    - Secondary re-interventions
    - Aneurysm ruptures

- **Common iliac artery aneurysms mostly present in conjunction with an AAA and then are often bilateral**

*References*

Hobo et al. *J Endovasc Ther* 2008
Iliac branched devices

GORE® EXCLUDER® Iliac Branch Endoprosthesis

• IDE trial – 6 month primary endpoint
  • 95.2% technical success
  • 0% aneurysm related mortality
  • Internal iliac limb patency 95.1%
  • 0 type 1 or 3 endoleaks

• Dutch experience – mean FU of 5.8 months
  • 93.5% Technical success
  • 0% aneurysm related mortality
  • Internal iliac limb patency 94.0%
  • Reintervention rate 7% (n=2)
  • 1 type 1b endoleak

Total of 63 in clinical trial ... no patients treated with Bilateral IBE

Total of 46 in clinical trial ... Five patients treated with bilateral IBE

In 35% and 22% was contralateral side treated with coil embolization and coverage of the IIA
Coil and cover internal iliac artery

- Complications after IIA coil and coverage are not benign
  - Buttock claudication:
    - Unilateral 27% (range 14-50%)
    - Bilateral 32% (range 13-80%)
  - Erectile dysfunction:
    - Unilateral 14% (range 11-45%)
    - Bilateral 18% (range 11-50%)
  - Colonic ischemia  up to 3%
  - Spinal ischemia  <1%

International Multicenter Experience Review
24 Centers (16 US, 8 European), 47 patients
Multicenter (16 US, 8 European) Experience

- 47 patients
- IRB approved retrospective review
- Bilateral Gore IBE implanted;
  - In US post-FDA approval (2/2016)
  - In Europe post-CE mark (11/2013)
- Demographics
- Anatomic Characteristics
- Procedural detail
- Follow-up: Mean 6.5 months (range 1-36)
Results; patient characteristics

<table>
<thead>
<tr>
<th>Characteristic</th>
<th>Count (Percentage)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Gender (n=47)</td>
<td></td>
</tr>
<tr>
<td>Male</td>
<td>45 (97.5%)</td>
</tr>
<tr>
<td>Female</td>
<td>2 (2.5%)</td>
</tr>
<tr>
<td>Mean +/- SD Age (y)</td>
<td>68.2 +/- 8.9</td>
</tr>
<tr>
<td>Coronary Artery Disease (n=47)</td>
<td>16 (34%)</td>
</tr>
<tr>
<td>Smoker (n=47)</td>
<td>27 (57.4%)</td>
</tr>
<tr>
<td>Diabetes (n=47)</td>
<td>8 (17.0%)</td>
</tr>
<tr>
<td>Symptomatic (n=47)</td>
<td>6 (12.7%)</td>
</tr>
<tr>
<td>Buttock Claudication (n=47)</td>
<td>0 (0%)</td>
</tr>
<tr>
<td>Impotence (n=28)</td>
<td>3 (10.7%)</td>
</tr>
</tbody>
</table>
11 (23%) of patients treated exclusively for CIA aneurysm (absence of AAA)

Aortic Diameter: 46.5mm (21-97)
CIA Diameter: 40.3mm (25-97)
IIA Diameter: 10.9mm (5-41mm)*

*4 patients had aneurysmal/ectatic IIA
### IFU: Recommended Minimum Lengths

*From lowest renal to IIA origin*

<table>
<thead>
<tr>
<th>Main Body Diameter (mm)</th>
<th>Total IBE side length (mm) via Contralateral side</th>
<th>Total IBE side length (mm) via Ipsilateral side</th>
</tr>
</thead>
<tbody>
<tr>
<td>23, 26, 28.5</td>
<td>165</td>
<td>195</td>
</tr>
<tr>
<td>31</td>
<td>175</td>
<td>205</td>
</tr>
<tr>
<td>35</td>
<td>185</td>
<td>215</td>
</tr>
</tbody>
</table>

Larger Main Bodies require longer length anatomy from lowest renal to IIA

*Main Body Diameter (mm)*

- **89%**: 23, 26, 28.5
- **4%**: 31
- **7%**: 35

*One larger diameter case (36mm) was a zenith fenestrated case with bilateral Gore IBE*
Length from renal arteries to IIA:

- 195mm (range 148-230mm)
- 12 cm (range 13-14 cm)
- 5 cm, 6 cm
- 2.5 cm
- 194mm (range 163-248mm)
Maneuvers to accommodate shorter lengths

1. Crossing the limbs

Courtesy of Thomas Maldonado
Maneuvers to accommodate shorter lengths

2. Using alternative shorter bridges (n=3)

- Gore Excluder: 100mm Long
- Medtronic Endurant: 82mm Long
Maneuvers to accommodate shorter lengths

3. Recreating the flow-divider

Courtesy of Rabih Chaer
**Results; procedural details**

<table>
<thead>
<tr>
<th></th>
<th>Clinical Trial: Primary Enrollment (n=63) and Continued Access (n=31)</th>
<th>Global Experience with Bilateral IBE (n=47)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Total Fluoro Time (min)</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Mean (Std Dev)</td>
<td>40.4 (15.8)</td>
<td>50.2 (18.4)</td>
</tr>
<tr>
<td>Median</td>
<td>37</td>
<td>48</td>
</tr>
<tr>
<td>Range</td>
<td>(19,120)</td>
<td>(25,107)</td>
</tr>
<tr>
<td><strong>Contrast Used (ml)</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Mean (Std Dev)</td>
<td>118.1 (53.5)</td>
<td>144.1 (72.1)</td>
</tr>
<tr>
<td>Median</td>
<td>107</td>
<td>135</td>
</tr>
<tr>
<td>Range</td>
<td>(16,290)</td>
<td>(43,350)</td>
</tr>
<tr>
<td><strong>Procedure Duration (min)</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Mean (Std Dev)</td>
<td>153.1 (50.8)</td>
<td>197.7 (74.4)</td>
</tr>
<tr>
<td>Median</td>
<td>145</td>
<td>194</td>
</tr>
<tr>
<td>Range</td>
<td>(68,334)</td>
<td>(52,444)</td>
</tr>
<tr>
<td><strong>Access</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Percutaneous</td>
<td>*n=63</td>
<td></td>
</tr>
<tr>
<td>Open</td>
<td>31 (49%)</td>
<td>27 (57%)</td>
</tr>
<tr>
<td>Cutdown</td>
<td>32 (51%)</td>
<td>20 (43%)</td>
</tr>
<tr>
<td><strong>Anesthesia</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>GETA</td>
<td>55 (87.3%)</td>
<td>38 (80.9%)</td>
</tr>
<tr>
<td>Spinal</td>
<td>0 (0%)</td>
<td>7 (14.9%)</td>
</tr>
<tr>
<td>Local</td>
<td>8 (12.7%)</td>
<td>2 (4.3%)</td>
</tr>
</tbody>
</table>

(9.8min fluoro, ∆24.3%, p=0.004)

(26cc contrast, ∆22%, p=0.032)

(44.6min procedure, ∆29.1%, p<0.001)
Results; procedural details

- Technical Success (97.9%)
- One technical failure: failure to access tight IIA
- No procedural type I or III endoleaks
- Adjunctive stenting required in 4 patients at time of index procedure
  - Distal IIA dissection (n=1)
  - Kinking (n=3)
Results at latest follow-up

Mean 6.5 months, range 1-36 months

- No aneurysm related death
- Two non-aneurysm related death at 1 year (cardiac)
- New Buttock Claudication: 1/47 patients (2.1%)
- Radiographic imaging available for 40/47 patients

<table>
<thead>
<tr>
<th>Radiographic Follow-up</th>
<th>n=40/47 (85.1%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Endoleak</td>
<td>Type 1/3</td>
</tr>
<tr>
<td></td>
<td>0</td>
</tr>
<tr>
<td></td>
<td>Type 2</td>
</tr>
<tr>
<td></td>
<td>12 (25.5%)</td>
</tr>
<tr>
<td>Sac Enlargment</td>
<td>0</td>
</tr>
<tr>
<td>Device Migration</td>
<td>0</td>
</tr>
</tbody>
</table>
Results at latest follow-up
Mean 6.5 months, range 1-36 months

<table>
<thead>
<tr>
<th>Radiographic Follow-up</th>
<th>n=40/47 (85.1%)</th>
<th>Time of occlusion</th>
<th>Presentation</th>
<th>Intervention</th>
</tr>
</thead>
<tbody>
<tr>
<td>EIA occlusion (n=3 patients)</td>
<td>3/80 (3.8%) vessels</td>
<td>POD#1</td>
<td>loss of pedal signal</td>
<td>Thrombectomy/EIA stent</td>
</tr>
<tr>
<td></td>
<td></td>
<td>POD#1*</td>
<td>Rest pain</td>
<td>EIA stent*</td>
</tr>
<tr>
<td></td>
<td></td>
<td>POD 6 months</td>
<td>Leg Claudication</td>
<td>Fem-Fem bypass**</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Radiographic Follow-up</th>
<th>n=40/47 (85.1%)</th>
<th>Time of occlusion</th>
<th>Sequelae/Presentation</th>
<th>Intervention</th>
</tr>
</thead>
<tbody>
<tr>
<td>IIA occlusion (n=2)</td>
<td>2/80 (2.5%) vessels</td>
<td>POD#1*</td>
<td>Buttock Claudication</td>
<td>None*</td>
</tr>
<tr>
<td></td>
<td></td>
<td>6 Months</td>
<td>Asymptomatic</td>
<td>None</td>
</tr>
</tbody>
</table>

* IIA stent deployed high above flow divider of IBE, partially occluding EIA limb, IIA limb sacrificed
** IIA stent remained patent on side of EIA occlusion
Conclusions

• Preservation of bilateral IIA can be safely performed with Gore IBE with excellent technical success and short-term patency rates.

• Limb and branch occlusions are rare can be treated successfully with stenting most of the time

• While anatomic limitations exist a number of maneuvers can permit technical success even in shorter length aorto-iliac segments

• Contrast used, fluoroscopy time and length of case do not appear prohibitive, however, cost remains an issue.
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