Repositionable iliac branch endoprosthesis

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Disclosures

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• Atrium Maquet Getinge Group
• Endologix, Inc.
• W.L. Gore and associates
• Vascular Insights LLC
Common iliac artery aneurysms

- Isolated common iliac artery aneurysms are rare with incidence of <1%
- Common iliac artery aneurysms are more common in conjunction with AAA and then often bilateral
- 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

Hobo et al. J Endovasc Ther 2008
Endovascular treatment options

- Coil-and-coverage of the internal iliac artery

- Preservation of the internal iliac artery:
  - Bell-bottom limb
  - Off-label endovascular techniques
  - Sac anchoring techniques
  - Iliac branched devices
Coil and cover internal iliac artery

- Occlude internal iliac artery and cover with endograft with sealing in the external iliac artery
- 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%

Bell bottom iliac limbs

- An adequate sealing zone of at least 1.5 cm proximal of the origin of the IIA
- Does not imply a higher risk of reintervention or endoleak compared to regular EVAR
- Reinterventions and perioperative complications lower compared to coil and coverage strategy
- Maximum CIA diameter of 24-25 mm – limited applicability

Outside IFU techniques

- Parallel or chimney grafts
- Trifurcated endograft technique with a second bifurcated endoprosthesis
- AUI with cross-over and ‘banana’ graft EIA-IIA
- Upside-down Excluder limb
Iliac Branched Devices

*Cook® Zenith® Branch Iliac Endovascular Graft*

- First branched endoprosthesis for the treatment of common iliac aneurysms (CE mark October 2006)
- 20 Fr introducer sheath
- Single component – **no dedicated internal iliac component**
- Requires additional covered stent (Other platform, mostly BE)
  - ATRIUM® ADVANTA V12 Covered Stent
  - BARD® FLUENCY® PLUS Stent Graft
- Technical success rate 85-100%
- Initial results included:
  - Endoleak rate 3% – 30%
  - Patency 91%-96% at one year
    - 81% at three years

Iliac Branched Devices
Gore Excluder Iliac Branch Endoprosthesis

- CE mark November 2013
- Used in conjunction with the Excluder endoprosthesis
- 16 Fr introducer sheath
- Option for repositioning
- **SE Iliac component based on the same platform**

**Instructions for Use:**
- Minimum common Iliac diameter 17 mm at the proximal implantation zone of the IBE
- External Iliac artery treatment diameter range of 6.5–25 mm and seal zone length of at least 10 mm
- Internal Iliac artery treatment diameter range of 6.5–13.5 mm and seal zone length of at least 10 mm
Iliac Branched Devices
Gore Excluder Iliac Branch Endoprosthesis
Retrospective cohort study of patients treated in the Netherlands

- November 2013 - December 2014
- 13 sites in the Netherlands
- 51 CIA aneurysms in 46 patients
- Age 70.2 ± 8.5 year
- Male gender 45/46 (98%)
- Bilateral treatment 5/46 (11%)
- IBE only 7/46 (16%)
- Treated outside IFU 7/46 (16%)

Retrospective cohort study of patients treated in the Netherlands

**Anatomical characteristics**

<table>
<thead>
<tr>
<th>Parameter</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Maximum diameter right CIA (mm)</td>
<td>38.5 (12.0-90.0)</td>
</tr>
<tr>
<td>Maximum diameter left CIA (mm)</td>
<td>31.0 (12.0-73.0)</td>
</tr>
<tr>
<td>Length right CIA (mm)</td>
<td>70.0 (44.0-182.0)</td>
</tr>
<tr>
<td>Length left CIA (mm)</td>
<td>68.0 (40.0-155.0)</td>
</tr>
<tr>
<td>Maximum diameter right IIA (mm)</td>
<td>10.0 (3.0-18.0)</td>
</tr>
<tr>
<td>Maximum diameter left IIA (mm)</td>
<td>10.0 (6.0-21.0)</td>
</tr>
<tr>
<td>Maximum diameter right EIA (mm)</td>
<td>12.0 (9.0-17.0)</td>
</tr>
<tr>
<td>Maximum diameter left EIA (mm)</td>
<td>12.0 (7.0-15.0)</td>
</tr>
<tr>
<td>Diameter infrarenal aortic neck (mm)</td>
<td>22.0 (18.0-30.0)</td>
</tr>
<tr>
<td>Maximum diameter infrarenal aorta (mm)</td>
<td>44.5 (19.0-80.0)</td>
</tr>
</tbody>
</table>
Retrospective cohort study of patients treated in the Netherlands

Procedural data

- General anesthesia: 44/46 (96%)
- Contralateral IIA embolized: 9/44 (20%)
- Operation time: 198 ± 56 min
- Immediate endoleak: n=6 (13%)
  - Type Ib: n=2 (4%)
  - Type II: n=3 (7%)
  - Unknown: n=1 (2%)
- Technical success: 94% (one implant failure)
- Hospitalization time: 3.5 ± 1.5 days
# Results

<table>
<thead>
<tr>
<th>Follow-up</th>
<th>At 30-days (n=40)</th>
<th>At 6 months (n=28)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mortality</td>
<td>0 (0%)</td>
<td>1 (4%)</td>
</tr>
<tr>
<td>Re-interventions</td>
<td>0 (0%)</td>
<td>2 (7%)</td>
</tr>
<tr>
<td>External iliac limb stenosis/occlusion</td>
<td>1 (3%)</td>
<td>1 (4%)</td>
</tr>
<tr>
<td>Internal iliac limb stenosis/occlusion</td>
<td>1 (3%)</td>
<td>2 (7%)</td>
</tr>
<tr>
<td>Endoleak</td>
<td>6 (15%)</td>
<td>5 (18%)</td>
</tr>
<tr>
<td>Type Ib</td>
<td>0 (0%)</td>
<td>1 (4%)</td>
</tr>
<tr>
<td>Type II</td>
<td>5 (13%)</td>
<td>4 (14%)</td>
</tr>
<tr>
<td>Unknown</td>
<td>1 (3%)</td>
<td>0 (0%)</td>
</tr>
<tr>
<td>Intermittent buttock claudication</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Contralateral</td>
<td>2 (5%)</td>
<td>0 (0%)</td>
</tr>
<tr>
<td>Ipsilateral</td>
<td>2 (5%)</td>
<td>1 (4%)</td>
</tr>
<tr>
<td>Erectile dysfunction</td>
<td>1 (3%)</td>
<td>2 (7%)</td>
</tr>
</tbody>
</table>

Retrospective cohort study of patients treated in the Netherlands
Retrospective cohort study of patients treated in the Netherlands

*Latest follow-up (n=29, 32 IBE devices): mean 5.8 months*

- Primary patency IIA limb at six months is 94%

- Significant decrease in CIA aneurysm diameter:
  - Baseline: $42.4 \pm 7.2$ mm
  - 6 months: $38.4 \pm 7.5$ mm

- Re-interventions preformed in 2 patients (7%):
  - BE stent external iliac limb stenosis
  - Type 1b endoleak
Iliac Branched Devices
Gore Excluder Iliac Branch Endoprosthesis

Lessons learned:
• Use a 0.035” flexible throughwire in combination with a 12 Fr flexible sheath
• Take care to avoid wrapping of throughwire
• Change for 0.018” guidewire in case of resistance advancing internal component
• Use repositioning option to optimize position
• Device can be used for revision after EVAR
• Combination of the internal component with proximally flared BE stent in case of diameter discrepancy

Courtesy of Dr. Flett, Ninewells, Dundee
Iliac Branched Devices
Gore Excluder Iliac Branch Endoprosthesis

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Overview data on iliac branched devices

<table>
<thead>
<tr>
<th>Author (Year)</th>
<th>N</th>
<th>Branches</th>
<th>Mortality</th>
<th>Technical success</th>
<th>Mean FU (months)</th>
<th>Branch occlusion</th>
<th>Re-intervention</th>
</tr>
</thead>
<tbody>
<tr>
<td>Haulon (2006)</td>
<td>52</td>
<td>53</td>
<td>0%</td>
<td>94%</td>
<td>14</td>
<td>11%</td>
<td>-</td>
</tr>
<tr>
<td>Dias (2008)</td>
<td>22</td>
<td>23</td>
<td>0%</td>
<td>91%</td>
<td>20</td>
<td>13%</td>
<td>18%</td>
</tr>
<tr>
<td>Ferreira (2010)</td>
<td>37</td>
<td>54</td>
<td>0%</td>
<td>97%</td>
<td>22</td>
<td>11%</td>
<td>-</td>
</tr>
<tr>
<td>Parlani (2012)</td>
<td>100</td>
<td>100</td>
<td>0%</td>
<td>95%</td>
<td>17</td>
<td>7%</td>
<td>9%</td>
</tr>
<tr>
<td>Wong (2013)</td>
<td>130</td>
<td>138</td>
<td>0%</td>
<td>94%</td>
<td>20</td>
<td>15%</td>
<td>16%</td>
</tr>
<tr>
<td>Bisdas (2014)</td>
<td>18</td>
<td>22</td>
<td>0%</td>
<td>100%</td>
<td>-</td>
<td>0%</td>
<td>10%</td>
</tr>
<tr>
<td>Pratesi (2014)</td>
<td>81</td>
<td>85</td>
<td>0%</td>
<td>99%</td>
<td>20</td>
<td>2%</td>
<td>12%</td>
</tr>
<tr>
<td>Torsello (2015)</td>
<td>178</td>
<td>188</td>
<td>0.3%</td>
<td>99%</td>
<td>20</td>
<td>8%</td>
<td>23%</td>
</tr>
<tr>
<td>GORE Trial (2015)</td>
<td>75</td>
<td>78</td>
<td>0%</td>
<td>99%</td>
<td>6</td>
<td>3%</td>
<td>1%</td>
</tr>
<tr>
<td>Cook Trial (2015)</td>
<td>40</td>
<td>40</td>
<td>0%</td>
<td>100%</td>
<td>7</td>
<td>0%</td>
<td>8%</td>
</tr>
<tr>
<td>Lebas (2016)</td>
<td>25</td>
<td>26</td>
<td>0%</td>
<td>96%</td>
<td>6</td>
<td>4%</td>
<td>4%</td>
</tr>
<tr>
<td>Van Sterkenburg (2016)</td>
<td>40</td>
<td>51</td>
<td>0%</td>
<td>94%</td>
<td>6</td>
<td>6%</td>
<td>5%</td>
</tr>
</tbody>
</table>

Trend towards a lower rate of branch occlusions and re-interventions during time
Iliac Branch Excluder ReGistry – ICEBERG

- Multi-centre, observational, post-market, real world registry
- 10 European sites
- 100 Consecutive patients with follow-up to 5 years

**Inclusion criteria**
- Age 18 years or older
- Written informed consent
- Elective procedure
- Indication for aorto-iliac endovascular stent graft repair

**Exclusion criteria**
- Patient’s life expectancy <2 years
- Psychiatric or other condition that may interfere with the study
- Allergy to any device component
- Patient with a systemic infection
- Coagulopathy or uncontrolled bleeding disorder
- Acute or mycotic aneurysm
- CVA or MI within the prior three months
- Pregnancy
- Other stents placed in CIA or hypogastric arteries than the Gore® EXCLUDER® iliac branch Endoprothesis
Iceberg registry

Participating sites

- Addenbrook's Hospital, Cambridge
  P Hayes
- Royal Liverpool University Hospital
  R Fisher
- Rijnstate Hospital, Arnhem
  SMM van Sterkenburg
  MMPJ Reijnen
- St Elizabeth Hospital, Tilburg
  J Heyligers
- Krankenhaus Pasing, Munich
  P Heider
- Isar Klinik, Munich
  R Ghotbi
- CHUO Hospital, Ourense
  Dr. Mosquera
- Hospital Casa de Salud, Valencia
  G Palones
- Fondazione Poliambulanza, Brescia
  R Bellosta
- San Filippo Neri Hospital, Rome
  N Mangialardi
  S Ronchey
Iceberg registry
Endpoints

**Primary endpoints:**
- Primary patency of hypogastric side branch at 1 year
- Successful exclusion of the aneurysm without type I endoleak at 1 year

**Secondary endpoints:**
- 30 day morbidity
- Complications during follow-up including any endoleak, aneurysm sac expansion, migration, conversion to open repair
- Primary-assisted and secondary patency of hypogastric artery
- Secondary endovascular procedures
- Clinical success, defined as freedom from flow-limiting stenosis and from new onset of clinical ischemic symptoms (buttock claudication, erectile dysfunction, bowel ischemia)
- Freedom from buttock claudication; Walking impairment questionnaire (WIQ)
- Freedom from Erectile dysfunction; (International Index of Erectile Function (IIEF-5))
Iceberg registry

Design

- Enrollment anticipated in 2016 and 2017
- 19 patients included to date
- Scheduled analysis
  - 30-day outcome after inclusion of the target population
  - After completion of 1 year follow-up
  - After completion of 5 year follow-up
- Analysis on intention to treat base
Conclusions

• Hypogastric artery preservation is indicated when treating common iliac artery aneurysms, especially in young patients

• Iliac branched devices are the treatment of choice for CIA aneurysms with a diameter >25mm

• Initial results with the Gore IBE device are promising:
  • Low complication and re-intervention rates at short-term follow-up
  • Low incidence of ischemic complications
  • 17 % outside Instructions for Use and learning curve

• Results of the ICEBERG registry expected in Q4 2017