The “IceBERG” Study – Preserving the internal iliac artery

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Disclosure

Speaker name:
MMPJ 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
Common iliac artery aneurysms

- Isolated common iliac artery aneurysms are a rare condition
- Postmortem study showed an incidence of <1%
- Common iliac artery aneurysms are more common in conjunction with abdominal aneurysms: >20%
- Often bilateral occurrence

Endovascular treatment options

- Coil-and-coverage of the internal iliac artery
- Preservation of the internal iliac artery:
  - Bell-bottom limb
  - Off-label endovascular 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%

Iliac Branched Devices

Cook® Zenith® Branch Iliac Endovascular Graft

- First branched endoprosthesis for the treatment of common iliac aneurysm (CE mark October 2006)
- Single component – no dedicated internal iliac component
- Requires additional covered stent (Other platform)
  - ATRIUM® ADVANTA V12 Covered Stent
  - BARD® FLUENCY® PLUS Stent Graft
- Complications include:
  - Endoleak rate 3% – 30%
  - Occlusion rate 12%

Gore Excluder Iliac Branch Endoprosthesis

Aim:
- To provide an endovascular treatment of common iliac artery or aorto-iliac aneurysms with a dedicated device designed to be used in conjunction with the Excluder endoprosthesis.
- Simple, easy-to-use, accurate, low-profile device
- 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
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%)

### 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
- Fluoroscopy time 41 ± 14 min
- Hospitalization time 3.5 ± 1.5 days
- Immediate endoleak n=6 (13%)
  - Type Ib n=2 (4%)
  - Type II n=3 (7%)
  - Unknown n=1 (2%)
- Procedural success 94% (one implant failure)

Retrospective cohort study of patients treated in the Netherlands

30-day outcome (n=40)

<table>
<thead>
<tr>
<th>Condition</th>
<th>Count/Total (Percentage)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Re-interventions</td>
<td>0/37 (0%)</td>
</tr>
<tr>
<td>External Iliac limb stenosis</td>
<td>1/40 (3%)</td>
</tr>
<tr>
<td>Internal Iliac limb occlusion</td>
<td>1/40 (3%)</td>
</tr>
<tr>
<td>Endoleak</td>
<td>6/40 (15%)</td>
</tr>
<tr>
<td>• Type I</td>
<td>0/40 (0%)</td>
</tr>
<tr>
<td>• Type II</td>
<td>5/40 (13%)</td>
</tr>
<tr>
<td>• Unknown</td>
<td>1/40 (3%)</td>
</tr>
<tr>
<td>Buttock claudication</td>
<td>3/40 (8%)</td>
</tr>
<tr>
<td>• Ipsilateral site</td>
<td>2/40 (5%)</td>
</tr>
<tr>
<td>Erectile dysfunction</td>
<td>1/21 (3%)</td>
</tr>
<tr>
<td>Spinal or colonic ischemia</td>
<td>0/40 (0%)</td>
</tr>
</tbody>
</table>

Retrospective cohort study of patients treated in the Netherlands

Latest follow-up (n=29, 32 IBE devices): mean 6 months

- One patient died 4 months after the procedure
- External Iliac limb stenosis 1/29 (3%)
- Internal iliac limb occlusion 2/29 (7%)
- Endoleak 5/29 (18%)
  - Type Ib 1/29 (4%)
  - Type II 4/29 (14%)
- Buttock claudication 1/29 (4%)
- Erectile dysfunction 2/18 (7%)
- Spinal or colonic ischemia 0/26 (0%)

Retrospective cohort study of patients treated in the Netherlands

Latest follow-up (n=29, 32 IBE devices): mean 6 months

- Primary patency IIA limb at six months is 94%

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

- Re-interventions preformed in 2 patients (7%):
  - BE stent external iliac limb stenosis
  - Type 1b endoleak

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

- Rijnstate Hospital, Arnhem
  SMM van Sterkenburg
  MMPJ Reijnen
- St Elizabeth Hospital, Tilburg
  J Heyligers
- Krankenhaus Pasing, Munich
  P Heider
- Isaar Klinik, Munich
  R Ghotbi
- CHUO Hospital, Ourense
  Dr. Mosquera
- Hospital Casa de Salud, Valencia
  G Palones
- Fondazione Poliambulanza, Brescia
  R Bellosta
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 Q1/Q2 2017
- 12/100 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

• 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
  • 83% within Instructions for Use and learning curve

• Results of the prospective ICEBERG registry have to be awaited
The “IceBERG” Study – Preserving the internal iliac artery

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