IceBERG registry: improving patient health care with hypogastric preservation

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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
Iliac Branched Devices
Gore Excluder Iliac Branch Endoprosthesis

• CE mark November 2013
• 16 Fr introducer sheath
• SE Iliac component based on the same platform
• Option for repositioning
• IFU;
  a. Adequate iliac / femoral access
  b. Minimum common iliac diameter of 17 mm at the proximal implantation zone of the IBE
  c. External Iliac artery treatment diameter range of 6.5 – 25 mm and seal zone length of at least 10 mm
  d. 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

• IDE trial – 6 month primary endpoint
  • 95.2% technical success
  • 0% aneurysm related mortality
  • Internal iliac limb patency 95.1%
  • No type 1 or 3 endoleaks

• Dutch experience – mean FU of 6 months
  • 93.5% Technical success
  • 0% aneurysm related mortality
  • Internal iliac limb patency 94.0%
  • Re-intervention rate 7% (n=2)
  • 1 type 1b endoleak

ICEBERG Registry

- Prospective multi-centre, observational, post-market, real-world registry
- 100 included patients in 8 international sites
- Follow-up scheduled 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**
- Life expectancy <2 years
- Psychiatric or other condition that may interfere with the study
- Allergy to any device component
- 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
Primary endpoints:
- Successful exclusion of the aneurysm without type I/III endoleak at 1 year
- Primary patency of hypogastric side branch 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; WIQ
- Freedom from Erectile dysfunction; IIEF-5
### Iceberg registry

**Baseline characteristics**

<table>
<thead>
<tr>
<th>Characteristic</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age (years)</td>
<td>69.6 ± 8.4</td>
</tr>
<tr>
<td>Male gender</td>
<td>97 (97%)</td>
</tr>
<tr>
<td>BMI (kg/m²)</td>
<td>26.9 ± 4.1</td>
</tr>
<tr>
<td>Hypertension</td>
<td>66 (66%)</td>
</tr>
<tr>
<td>Diabetes mellitus</td>
<td>11 (11%)</td>
</tr>
<tr>
<td>Hyperlipidemia</td>
<td>60 (60%)</td>
</tr>
<tr>
<td>Current smoking</td>
<td>27 (27%)</td>
</tr>
<tr>
<td>Cardiac disease</td>
<td>27 (27%)</td>
</tr>
<tr>
<td>Renal impairment</td>
<td>14 (14%)</td>
</tr>
<tr>
<td>Pulmonary disease</td>
<td>26 (26%)</td>
</tr>
<tr>
<td>Buttock claudication</td>
<td>6 (6%)</td>
</tr>
<tr>
<td>Erectile dysfunction</td>
<td>14 (15%)</td>
</tr>
<tr>
<td>AAA present (&gt;30 mm)*</td>
<td>75 (75%)</td>
</tr>
<tr>
<td>CIA aneurysm</td>
<td>95 (95%)</td>
</tr>
<tr>
<td>Left</td>
<td>17 (17%)</td>
</tr>
<tr>
<td>Right</td>
<td>33 (33%)</td>
</tr>
<tr>
<td>Bilateral</td>
<td>45 (45%)</td>
</tr>
<tr>
<td>IIA aneurysm</td>
<td>17 (17%)</td>
</tr>
<tr>
<td>Other concomitant aneurysm</td>
<td>18 (18%)</td>
</tr>
<tr>
<td>Previous EVAR</td>
<td>4 (4%)</td>
</tr>
</tbody>
</table>

* AAA with diameter above the threshold for treatment n=32
### Iceberg registry

**Baseline characteristics**

<table>
<thead>
<tr>
<th>Measurement</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Aortic proximal neck diameter (mm)</td>
<td>23 (IQR 21-25)</td>
</tr>
<tr>
<td>Aortic neck length (mm)</td>
<td>26.5 (IQR 18-37)</td>
</tr>
<tr>
<td>AAA diameter (mm) (when applicable)</td>
<td>51 (IQR 42-61)</td>
</tr>
<tr>
<td>Diameter above aortic bifurcation (mm)</td>
<td>33 (IQR 28-42)</td>
</tr>
<tr>
<td>Proximal CIA diameter IBE treated side (mm)</td>
<td>20 (IQR 17-28)</td>
</tr>
<tr>
<td>Maximum Proximal CIA diameter IBE treated side (mm)</td>
<td>36 (IQR 31-41)</td>
</tr>
</tbody>
</table>
Iceberg registry

Procedural data

- Isolated IBE in 7 cases and bilateral IBE in 22 cases
- Procedural time 151 min (IQR 117-193 min)
- Contrast 130 mL (IQR 100-180 mL)
- Landing in main IIA branch in 85/100 patients
- Contralateral IIA;
  - Patent and preserved 60%
  - Second IBE 22%
  - Patent and overstented 13%
  - Not patent before procedure 5%
Iceberg registry
Early outcomes

• Procedural complications in 5 patients;
  • Bleeding IIA; embolization and overstenting
  • Dislodgement of bridging stent; additional stent
  • Partial coverage of a renal artery; stenting of renal artery
  • Failure of closure device
  • Thrombosis of the CFA

• Endoleaks at completion angiography
  • Type Ia  N=2
  • Type Ib  N=1
  • Type II  N=15

• Assisted primary technical success; 99%
• No 30-day mortality
Iceberg registry
1-year technical outcomes

- 15 remaining type II endoleaks
- Freedom from secondary interventions 97%
- Freedom from all-cause mortality 95%
- Freedom from AAA-related mortality 100%
Primary patency for patients inside and outside the anatomical requirements of the IFU was 91.8% and 85.7%, respectively, p=0.059

One-year primary patency of iliac component 91.3%
**Iceberg registry**

*1-year clinical outcomes*

**EQ5D**

% of patients that reported no problems

<table>
<thead>
<tr>
<th></th>
<th>Mobility</th>
<th>Self-Care</th>
<th>Usual Activities</th>
<th>Pain/Discomfort</th>
<th>Anxiety/Depression</th>
</tr>
</thead>
<tbody>
<tr>
<td>Baseline</td>
<td>77%</td>
<td>72%</td>
<td>75%</td>
<td>65%</td>
<td>73%</td>
</tr>
<tr>
<td>1 month</td>
<td>79%</td>
<td>88%</td>
<td>73%</td>
<td>65%</td>
<td>79%</td>
</tr>
<tr>
<td>6 months</td>
<td>79%</td>
<td>88%</td>
<td>79%</td>
<td>65%</td>
<td>88%</td>
</tr>
<tr>
<td>1 year</td>
<td>100%</td>
<td>100%</td>
<td>100%</td>
<td>100%</td>
<td>100%</td>
</tr>
</tbody>
</table>

**Walking Impairment Questionnaire**

Iceberg registry 1-year clinical outcomes

- **EQ5D**
  - % of patients that reported no problems

- **Walking Impairment Questionnaire**
  - Iceberg registry 1-year clinical outcomes

- **Baseline**
  - mobility: 77%, self-care: 72%, usual activities: 75%, pain/discomfort: 65%, anxiety/depression: 73%

- **1 month**
  - mobility: 79%, self-care: 88%, usual activities: 73%, pain/discomfort: 65%, anxiety/depression: 79%

- **6 months**

- **1 year**
  - mobility: 100%, self-care: 100%, usual activities: 100%, pain/discomfort: 100%, anxiety/depression: 100%

Iceberg registry 1-year clinical outcomes

- **Baseline**
  - mobility: 77%, self-care: 72%, usual activities: 75%, pain/discomfort: 65%, anxiety/depression: 73%

- **1 month**
  - mobility: 79%, self-care: 88%, usual activities: 73%, pain/discomfort: 65%, anxiety/depression: 79%

- **6 months**

- **1 year**
  - mobility: 100%, self-care: 100%, usual activities: 100%, pain/discomfort: 100%, anxiety/depression: 100%
A contralateral occlusion of the IIA at baseline had a significant negative impact on the erectile function at all time points.

**International Index of Erectile Function**

<table>
<thead>
<tr>
<th>Score Range</th>
<th>Erectile Dysfunction Severity</th>
</tr>
</thead>
<tbody>
<tr>
<td>1 to 7</td>
<td>Severe erectile dysfunction</td>
</tr>
<tr>
<td>8 to 11</td>
<td>Moderate erectile dysfunction</td>
</tr>
<tr>
<td>12 to 16</td>
<td>Mild-moderate erectile dysfunction</td>
</tr>
<tr>
<td>17 to 21</td>
<td>Mild erectile dysfunction</td>
</tr>
<tr>
<td>22 to 25</td>
<td>No erectile dysfunction</td>
</tr>
</tbody>
</table>

**Iceberg registry**

1-year clinical outcomes
Summary

• IIA preservation is indicated when treating iliac artery aneurysms, especially in young patients.

• The ICEBERG registry shows a favorable 1-year results of the Gore Excluder Iliac Branch Endoprosthesis, with regard to both technical and clinical outcome parameters.

• Erectile dysfunction is prevalent, underestimated and related to contralateral occlusions.
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