Bilateral use of the Gore IBE device for bilateral CIA aneurysms and a first interim analysis of the prospective Iceberg registry

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• Medtronic
• Bentley InnoMed GmbH
• Terumo Aortic
• Endologix Inc.
• W.L. Gore and associates
• Vascular Insights LLC
Common iliac artery aneurysms

- CIA aneurysms mostly present in conjunction with an AAA and are often bilateral

- Patients with CIA aneurysms have been related to more type Ib endoleaks, secondary interventions and ruptures

- Coil and coverage strategy is related to ischemic complications, including buttock claudication and erectile dysfunction

- Applicability of bell-bottom limbs is limited and seems to be related to late complications
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 balloon expandable)

**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**
GORE® EXCLUDER® Iliac Branch Endoprosthesis

**IDE trial – 6 month primary endpoint (n=63)**
- 95.2% technical success
- 0% aneurysm related mortality
- Internal iliac limb patency 95.1%
- Re-intervention rate 1.6%
- 0 type 1 or 3 endoleaks

**Dutch experience – mean FU of 6 months (n=46)**
- 93.5% Technical success
- 0% aneurysm related mortality
- Internal iliac limb patency 94.0%
- Reintervention rate 7% (n=2)
- 1 type 1b endoleak

ICEBERG Registry

- Prospective multi-centre, observational, post-market, real-world registry
- 101 included patients in 8 international sites
- Inclusion ended in 2018
- Follow-up scheduled 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**
# Iceberg registry

## Baseline characteristics

<table>
<thead>
<tr>
<th>Characteristic</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age (years)</td>
<td>70.0 (IQR 65.0-75.0)</td>
</tr>
<tr>
<td>Male gender</td>
<td>98 (97%)</td>
</tr>
<tr>
<td>BMI (kg/m$^2$)</td>
<td>26.0 (IQR 24.1-28.7)</td>
</tr>
<tr>
<td>Hypertension</td>
<td>67 (66%)</td>
</tr>
<tr>
<td>Diabetes mellitus</td>
<td>11 (11%)</td>
</tr>
<tr>
<td>Hyperlipidemia</td>
<td>61 (60%)</td>
</tr>
<tr>
<td>Current smoking</td>
<td>28 (28%)</td>
</tr>
<tr>
<td>Cardiac disease</td>
<td>28 (28%)</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 (14%)</td>
</tr>
<tr>
<td>AAA present</td>
<td>69 (68%)</td>
</tr>
<tr>
<td>AAA present &gt;50mm</td>
<td>32 (32%)</td>
</tr>
<tr>
<td>CIA aneurysm</td>
<td>96 (95%)</td>
</tr>
<tr>
<td>CIA aneurysm Left</td>
<td>17 (17%)</td>
</tr>
<tr>
<td>CIA aneurysm Right</td>
<td>34 (34%)</td>
</tr>
<tr>
<td>CIA aneurysm bilateral</td>
<td>45 (44%)</td>
</tr>
<tr>
<td>IIA aneurysm</td>
<td>16 (16%)</td>
</tr>
<tr>
<td>Other concomitant aneurysm</td>
<td>18 (18%)</td>
</tr>
<tr>
<td>Previous EVAR</td>
<td>2 (2%)</td>
</tr>
</tbody>
</table>

*Interim analysis; data are subjected to changes*
## Iceberg registry
### Baseline characteristics

<table>
<thead>
<tr>
<th>Measurement</th>
<th>Value</th>
</tr>
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<tbody>
<tr>
<td>Aortic proximal neck diameter (mm)</td>
<td>23  (IQR 21-25)</td>
</tr>
<tr>
<td>Aortic neck length (mm)</td>
<td>29  (IQR 20-38)</td>
</tr>
<tr>
<td>AAA diameter (mm) (when applicable)</td>
<td>50  (IQR 40-61)</td>
</tr>
<tr>
<td>Diameter above aortic bifurcation (mm)</td>
<td>30  (IQR 24-39)</td>
</tr>
<tr>
<td>Right CIA diameter; max. (mm)</td>
<td>35  (IQR 24-42)</td>
</tr>
<tr>
<td>Left CIA diameter; max. (mm)</td>
<td>28  (IQR 21-37)</td>
</tr>
<tr>
<td>Max. diameter IBE treated CIA (mm)</td>
<td>35  (IQR 30-42)</td>
</tr>
<tr>
<td>Right IIA landing zone diameter (mm)</td>
<td>9   (IQR 8-11)</td>
</tr>
<tr>
<td>Right IIA landing zone length (mm)</td>
<td>30  (IQR 20-40)</td>
</tr>
<tr>
<td>Left IIA landing zone diameter (mm)</td>
<td>10  (IQR 9-11)</td>
</tr>
<tr>
<td>Left IIA landing zone length (mm)</td>
<td>30  (IQR 20-35)</td>
</tr>
</tbody>
</table>

*Interim analysis; data are subjected to changes*
Iceberg registry

Procedural data

- Bilateral IBE in 20 cases and isolated IBE in 5 cases
- Procedural time 152 min (IQR 117-193 min)
- Contrast 130 mL (IQR 100-180 mL)
- Contralateral IIA
  - Patent and not overstented  N=61
  - Second IBE  N=20
  - Patent and overstented  N=13
  - Not patent before procedure  N=5

Interim analysis; data are subjected to changes
Iceberg registry

Procedural data

• Procedural complications
  • 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

• Endoleaks at completion angiography
  • Ia N=1
  • Ib N=0
  • II N=15
  • III N=0

Interim analysis; data are subjected to changes
Hospitalization 4 (IQR 3-5) days
Serious adverse events N=9 with 1 re-intervention: angioplasty of stenosis iliac bifurcation
Endoleaks Ia N=1
   Ib N=0
   II N=16
   III N=0
4 early occlusions of hypogastric branch
No 30-day mortality

Interim analysis; data are subjected to changes
Iceberg registry

Clinical outcome

Interim analysis; data are subjected to changes
Meta-analysis of 1084 patients in 22 studies; 5 devices
Follow-up ranged between 1 and 44 months
Patency 86% (95%CI; 84-88%)
- IIA occlusion; 27 patients
- EIA occlusion; 23 patients
IBD related reintervention rate 11% (95%CI; 8-14)
Buttock claudication in 6% (95%CI; 5-8%)
Erectile dysfunction in 2 patients

The main reason of buttock claudication was contralateral embolization of the IIA
47 patients, aged 68 ± 9 years

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 and procedural details

Mean follow-up 6.5 months (range 1-36)
Results; procedural details

<table>
<thead>
<tr>
<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 fluoroscopy time, minutes</strong></td>
<td></td>
</tr>
<tr>
<td>Mean (SD)</td>
<td>40.4 (15.8)</td>
</tr>
<tr>
<td>Median</td>
<td>37</td>
</tr>
<tr>
<td>Range</td>
<td>16.2 (7.0)</td>
</tr>
<tr>
<td><strong>Contrast material used, mL</strong></td>
<td></td>
</tr>
<tr>
<td>Mean (SD)</td>
<td>1181 (53.5)</td>
</tr>
<tr>
<td>Median</td>
<td>107</td>
</tr>
<tr>
<td>Range</td>
<td>16 (290)</td>
</tr>
<tr>
<td><strong>Procedure duration, minutes</strong></td>
<td></td>
</tr>
<tr>
<td>Mean (SD)</td>
<td>153.1 (50.8)</td>
</tr>
<tr>
<td>Median</td>
<td>145</td>
</tr>
<tr>
<td>Range</td>
<td>66 (156)</td>
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</table>

<table>
<thead>
<tr>
<th>Access</th>
<th>Percutaneous</th>
<th>Open cutdown</th>
<th>Anesthesia</th>
</tr>
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<tbody>
<tr>
<td>CETA</td>
<td>Spinal</td>
<td>Local</td>
<td></td>
</tr>
<tr>
<td>55 (87.3)</td>
<td>0 (0)</td>
<td>8 (12.7)</td>
<td>38 (80.9)</td>
</tr>
<tr>
<td>32 (51)</td>
<td>7 (14.9)</td>
<td>2 (4.3)</td>
<td></td>
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*CEA: General endotracheal anesthesia. SD: standard deviation.*
*Represents data from Core IBE 12-04 study. All of these cases are unilateral.*

(9.8 min fluoro, Δ24.3%, p=0.004)
(26 cc contrast, Δ22%, p=0.032)
(44.6 min procedure, Δ29.1%, p<0.001)
Results; procedural details

• Technical Success (98%)
  – One technical failure: failure to access tight IIA
• No procedural type I or III endoleaks
• Adjunctive stenting was 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

- Two deaths, both not AAA-related
- New Buttock Claudication: 1/47 patients (2.1%)
- Radiographic imaging available for 40/47 patients
  - Type 1/3 endoleak: n=0
  - Migration: n=0
  - Sac enlargement: n=0
  - EIA occlusion: n=3
  - IIA occlusion: n=2

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<th>Radiographic Follow-up</th>
<th>n=40/47 (85.1%)</th>
<th>Time of occlusion</th>
<th>Sequelae/Presentation</th>
<th>Intervention</th>
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<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>
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<td></td>
<td></td>
<td>6 Months</td>
<td>Asymptomatic</td>
<td>None</td>
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- New Buttock Claudication: 1/47 patients (2.1%)
- Radiographic imaging available for 40/47 patients

Preservation of bilateral IIAs in repair of bilateral CI aneurysms can be performed safely with excellent technical success and short term patency

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Summary

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

• The prospective ICEBERG registry shows a favorable early outcome of the GORE IBE device but 1-year outcome needs to be awaited

• When technically feasible a bilateral preservation of the IIA should be considered and can be performed safely
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