Gore Excluder Iliac Branched Endograft device for hypogastric revascularization: the initial Dutch experience

Michel M.P.J. Reijnen
Rijnstate Hospital, Arnhem, The Netherlands

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
    - Bilateral 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%

Disclosures

Consultancy and/or Research Funding:
- Atrium Maquet Getinge Group
- Endologix, Inc.
- W.L. Gore and associates
- Vascular Insights LLC
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

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%)

Maximal Diameter:
- Right CIA (mm): 38.5 (12.0-90.0)
- Left CIA (mm): 31.0 (12.0-73.0)
- Right IIA (mm): 10.0 (3.0-18.0)
- Left IIA (mm): 10.0 (6.0-21.0)
- Right EIA (mm): 12.0 (9.0-17.0)
- Left EIA (mm): 12.0 (7.0-15.0)
- Infrarenal aortic neck (mm): 22.0 (16.0-30.0)
- Maximal diameter infrarenal aorta (mm): 44.5 (19.0-80.0)

Procedural data:
- General anesthesia 44/46 (96%)
- Surgical cut down 43/46 (94%)
- 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%)

30-day outcome (n=40)
- Re-interventions 0/37 (0%)
- External iliac limb stenosis/occlusion 1/40 (3%)
- Internal iliac limb stenosis/occlusion 1/40 (3%)
- Endoleak
  - Type I 0/40 (0%)
  - Type II 5/40 (13%)
  - Unknown 1/40 (3%)
- Buttock claudication 3/40 (8%)
- Ipsilateral ischemia 2/40 (5%)
- Erectile dysfunction 1/21 (3%)
- Spinal or colonic ischemia 0/40 (0%)
Retrospective cohort study of patients treated in the Netherlands
Latest follow-up (n=29, 32 IBE devices): mean 5.8 months

- One patient died 4 months after the procedure
- External Iliac limb stenosis/occlusion: 1/29 (3%)
- Internal iliac limb stenosis/occlusion: 2/29 (7%)
- Endoleak: 5/29 (17%)
  - 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%)

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

Iceberg registry
**Participating sites**

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 resolve 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
- 6 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

Iceberg 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 interventional endovascular stent graft repair

Exclusion criteria
- Patient 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
- Tuberculosis or other prior infection
- Other stents placed in CIA or hypogastric arteries than the Gore® EXCLUDER® iliac branch Endoprosthesis
Conclusions

- Hypogastric artery preservation seems to be 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 ICEBERG registry have to be awaited

Acknowledgments

ICEBERG Registry participants

Gore Excluder Iliac Branched Endograft device for hypogastric revascularization: the initial Dutch experience

Michel M.P.J. Reijnen
Rijnstate Hospital, Arnhem, The Netherlands