

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 Endoprosthesis

Iceberg registry

Endpoints

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

Age (years)	69.6 ± 8.4
Male gender	97 (97%)
BMI (kg/m ²)	26.9 ± 4.1
Hypertension	66 (66%)
Diabetes mellitus	11 (11%)
Hyperlipidemia	60 (60%)
Current smoking	27 (27%)
Cardiac disease	27 (27%)
Renal impairment	14 (14%)
Pulmonary disease	26 (26%)

Buttock claudication	6 (6%)
Erectile dysfunction	14 (15%)
AAA present (>30 mm)*	75 (75%)
CIA aneurysm	95 (95%)
Left	17 (17%)
Right	33 (33%)
bilateral	45 (45%)
IIA aneurysm	17 (17%)
Other concomitant aneurysm	18 (18%)
Previous EVAR	4 (4%)

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

Iceberg registry

Baseline characteristics

Aortic proximal neck diameter (mm)	23 (IQR 21-25)
Aortic neck length (mm)	26.5 (IQR 18-37)
AAA diameter (mm) (when applicable)	51 (IQR 42-61)
Diameter above aortic bifurcation (mm)	33 (IQR 28-42)
Proximal CIA diameter IBE treated side (mm)	20 (IQR 17-28)
Maximum Proximal CIA diameter IBE treated side (mm)	36 (IQR 31-41)

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%

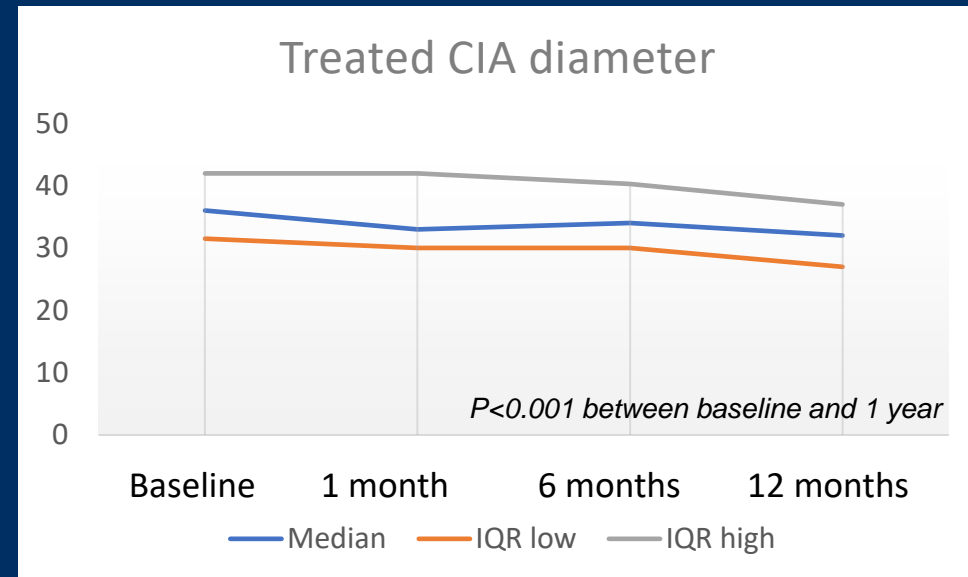
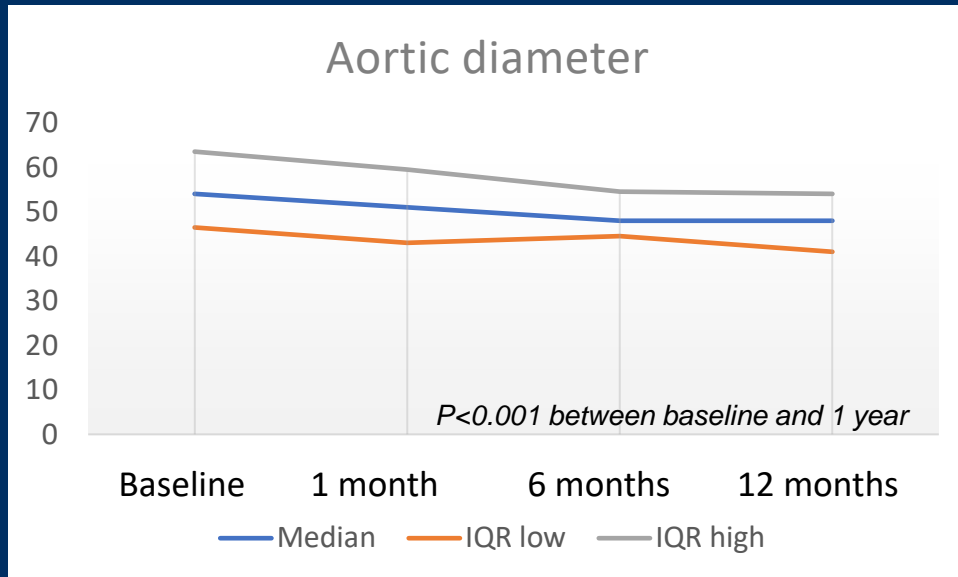
Iceberg registry

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

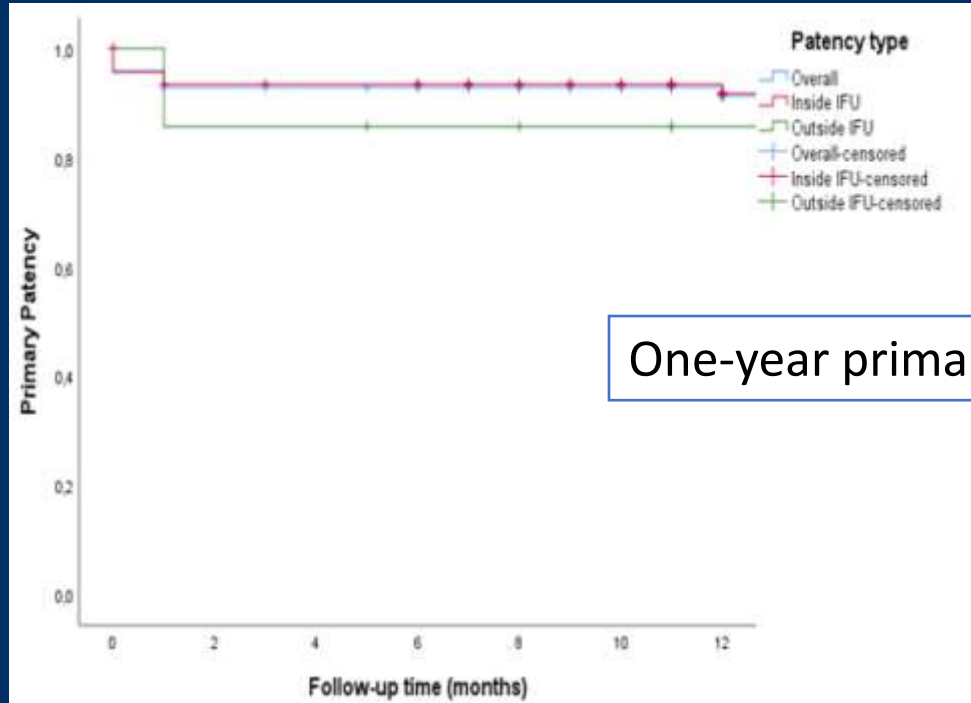
1-year technical outcomes



- 15 remaining type II endoleaks
- Freedom from secondary interventions 97%
- Freedom from all-cause mortality 95%
- Freedom from AAA-related mortality 100%

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1-year technical outcomes



One-year primary patency of iliac component 91.3%

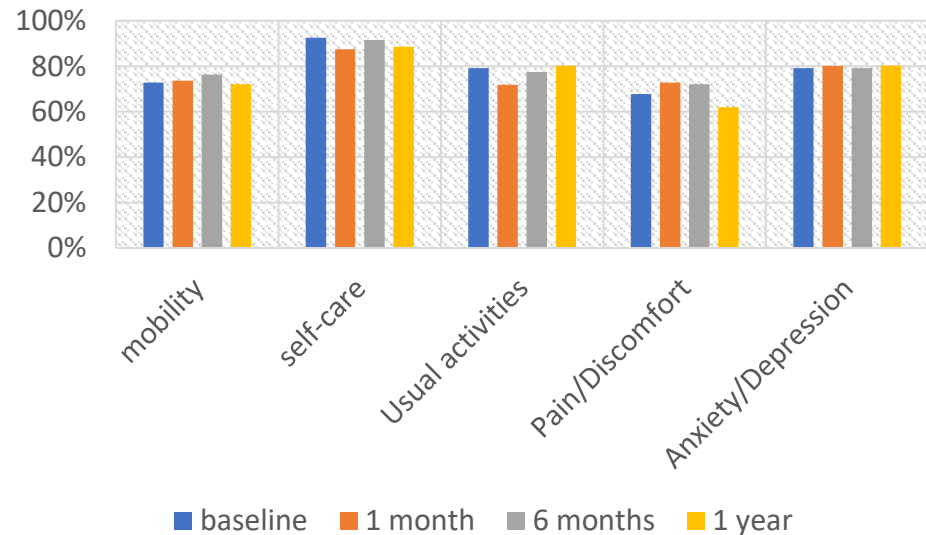
Primary patency for patients inside and outside the anatomical requirements of the IFU was 91.8% and 85.7%, respectively, $p=0.059$

Iceberg registry

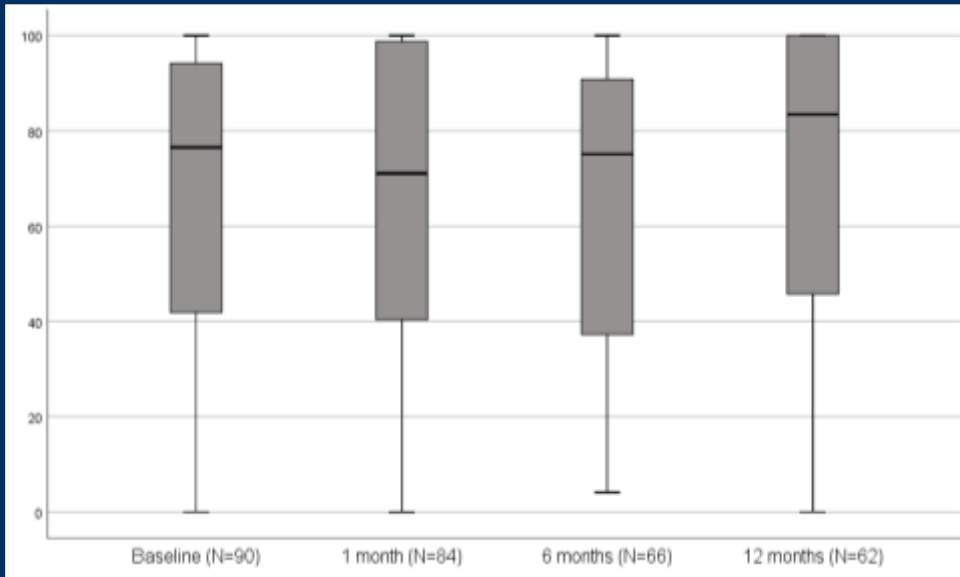
1-year clinical outcomes

EQ5D

% of patients that reported no problems

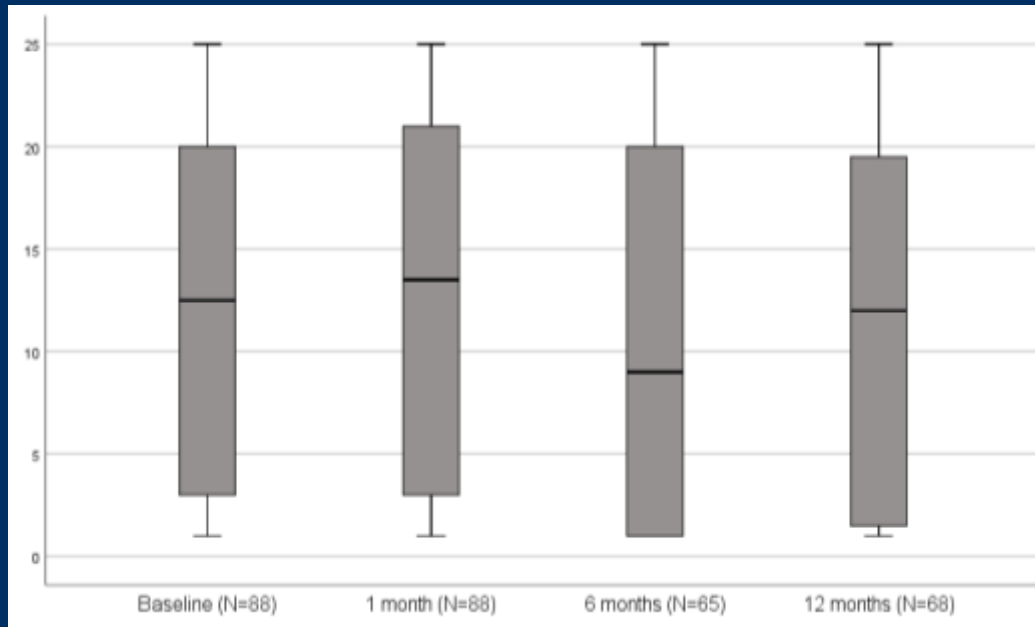


Walking Impairment Questionnaire



Iceberg registry

1-year clinical outcomes



International Index of Erectile Function

1 to 7	Severe erectile dysfunction
8 to 11	Moderate erectile dysfunction
12 to 16	Mild-moderate erectile dysfunction
17 to 21	Mild erectile dysfunction
22 to 25	No erectile dysfunction

A contralateral occlusion of the IIA at baseline had a significant negative impact on the erectile function at all time points

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

Acknowledgements



- Daphne van der Veen
- Suzanne Holewijn
- Raffaello Bellosta
- Steven van Sterkenburg
- Jan Heyligers
- Ilaria Ficarelli
- Francisco Gómez Palonés
- Nicola Mangialardi
- Nilo Mosquera
- Andrew Holden
- The IceBERG Study collaboration

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