Rijnstate

UNIVERSITY OF TWENTE.

5-Year Outcomes Of The ICEBERG Study Of The Gore IBD (IBE Device) For Revascularizing The Hypogastric Artery With Aortoiliac Aneurysms: Advantages And Limitations

Michel MPJ Reijnen, MD, PhD

Department of Vascular Surgery, Rijnstate, Arnhem

MultiModality Medical Imaging Group, University of Twente, Enschede

The Netherlands

Disclosures

- Consultancy and/or Research Funding:
  - W.L. Gore and Associates
  - Terumo Aortic
  - Medtronic
  - Artivion
- The IceBERG study was funded by an unrestricted grant from W.L. Gore and associates

Society guidelines

The Society for Vascular Surgery (SVS):

- Preservation of flow to **at least one internal iliac artery**.
  - Level of recommendation: **1 (Strong)**
  - Quality of evidence: **A (High)**
- Using a Food and Drug Administration (FDA) approved branch endograft in anatomically suitable patients to maintain perfusion to at least one internal iliac artery.
  - Level of recommendation: **1 (Strong)**
  - Quality of evidence: **A (High)**

European Society for Vascular Surgery (ESVS):

- The availabillity of iliac side branch stent grafts now **allows preservation of IIA flow in most cases.**
  - Level of recommandation: 1
  - Quality of evidence: B

Japanese Society for Vascular Surgery (JCS/JSCS/JATS/JSVS):

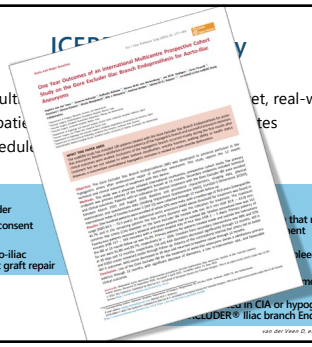
- We **recommend preservation of flow to at least on internal iliac artery**.
  - Level of recommendation: 2a
  - Quality of evidence: B

Iliac Branched Devices
Gore Excluder Iliac Branch Endoprosthesis

- Introduced in EU in November 2013
- 16 Fr introducer sheath
- Intended to be used in combination with the Excluder device
- Self-expanding Iliac component based on the Excluder platform
- Option for repositioning

ICE… …y

- Prospective mult… …et, real-world registry
- 100 included pati… …tes
- Follow-up schedul…



Inclusion criteria

- Age 18 years or older
- Written informed consent
- Elective procedure
- Indication for aorto-iliac endovascular stent graft repair

…that may interfere with the study …ent

…bleeding disorder

…months

…in CIA or hypogastric arteries than the …CLUDER® Iliac branch Endoprothesis

van der Veen D, et al. Eur J Vasc Endovasc Surg. 2021 Aug;62(2):177-185.

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%)
Concomitant aneurysm	18 (18%)
Previous EVAR	4 (4%)

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

van der Veen D, et al. Eur J Vasc Endovasc Surg. 2021 Aug;62(2):177-185.

Iceberg registry
Procedural data

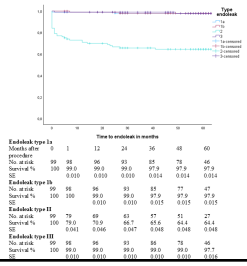
- Isolated IBE in 7 cases and bilateral IBE in 22 cases
- Procedural time 151 min (IQR 117-193 min)
- Contrast 130 mL (IQR 100-180 mL)
- Landing in main IIA branch in 85/100 patients
- Contralateral IIA;
  - Patent and preserved 60%
  - Second IBE 22%
  - Patent and overstented 13%
  - Not patent before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

van der Veen D, et al. Eur J Vasc Endovasc Surg. 2021 Aug;62(2):177-183.

Key one-year outcomes IceBERG, IDE, GREAT & GALICIAN trials

	Patients	Technical success	Bilateral IBE	Contralateral embolization	Procedural mortality	Re-interventions	Hypogastric patency
IceBERG trial	100	99%	20	13	0%	3%	91.3%
GREAT registry	92	98,1%	13	N.A.	0%	5,4%	100%
IDE trial	99	95,2%	4	26	0%	5,1%	93,6%
GALICIAN trial	81	99%	24	9	0%	6,2%	98.1%

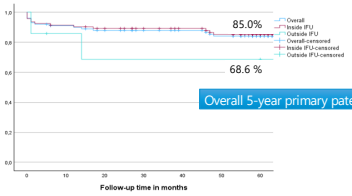
Iceberg registry update
5-year technical outcomes



At 5-year follow-up;
- Freedom from type Ia endoleak 97.9%
- Freedom from type Ib endoleak 97.9%
- Freedom from type II endoleak 64.4%
- Freedom from type IIII endoleak 97.7%

Interim analysis, subjected to changes

Iceberg registry update
5-year technical outcomes



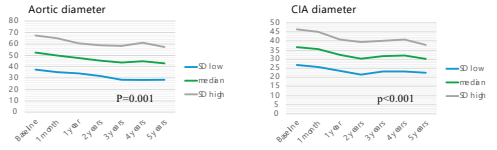
Overall 5-year primary patency of iliac component 84.0%

Primary patency for patients inside and outside the anatomical requirements of the IFU was **85.0% and 68.6%** (p=0.270)

Interim analysis, subjected to changes

Iceberg registry update
5-year technical outcomes

At 5-year follow-up;
- Freedom from all-cause mortality 82.9%
- Freedom from AAA rupture 95.8%
- Freedom from AAA-related mortality 96.0%
- Freedom from secondary interventions 92.2%



Interim analysis, subjected to changes

Iceberg registry update
5-year technical outcomes

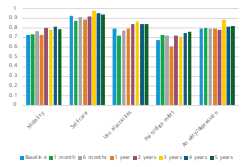
Eight reinterventions through 5-year follow-up of which 5/8 endovascular:

- Embolization of type II EL n=1
- Extension of hypogastric branch because loss of seal n=2
- Relining type III EL n=2
  - One for a ruptured aneurysm
- Femoro-femoral bypass for EIA occlusion n=1
- External to internal iliac artery bypass n=1
- Explantation of EVAR device, with preservation of IBE for sac enlargement n=1

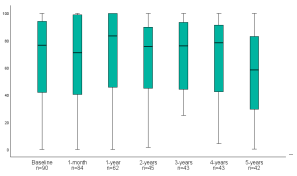
Interim analysis, subjected to changes

Iceberg registry update
5-year clinical outcomes

EQ5D
% of patients that reported no problems



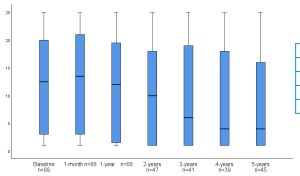
Walking Impairment Questionnaire



Interim analysis, subjected to changes

Iceberg registry update
5-year clinical outcomes

p=0.001



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 through the first 12 months

Interim analysis, subjected to changes

Summary

- IIA preservation is indicated when treating iliac artery aneurysms, especially in young patients
- The IceBERG study shows favorable 5-year results of the Gore Excluder Iliac Branch Endoprosthesis, both considering technical and clinical outcome parameters
- Erectile dysfunction is prevalent, underestimated and in the early phase 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

Rijnstate

UNIVERSITY OF TWENTE.

5-Year Outcomes Of The ICEBERG Study Of The Gore IBD (IBE Device) For Revascularizing The Hypogastric Artery With Aortoiliac Aneurysms: Advantages And Limitations

Michel MPJ Reijnen, MD, PhD

Department of Vascular Surgery, Rijnstate, Arnhem

MultiModality Medical Imaging Group, University of Twente, Enschede

The Netherlands