Iliac branch device indication in consideration of guidelines and clinical data

Jan MM Heyligers, MD, PhD, FEBVS
Consultant Vascular Surgeon
ETZ Tilburg, The Netherlands

Disclosures

Speaker name:

JMM Heyligers

I have the following potential conflicts of interest to report:

- [x] Consulting
- [ ] Employment in industry
- [ ] Stockholder of a healthcare company
- [ ] Owner of a healthcare company
- [x] Other(s)
- [ ] I do not have any potential conflict of interest

Common iliac artery aneurysms (CIAA)

- Isolated common iliac artery aneurysms are a rare condition
- Common iliac artery aneurysms are more common in conjunction with abdominal aneurysms: >20%: Aorto Iliac Aneurysms (AIA
- Often bilateral occurrence

Sandu RS, et al. Semin Vasc Surg 2005 Dec;18(4):209-15
Brunkwall, J. , et al. Vasc Surg 1989 Oct;10(4):381-4
Armon MP, et al. Eur J Vasc Endovasc Surg. 1998 Mar;15(3):255-7

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	up to 3%
Spinal ischemia	<1%

Verzini F, et al. J Vasc Surg 2009;49(5):1154-61
Farahmand et al. Eur J Vasc Endovasc Surg 2008;35(4):429-35
Lin PH, et al. Semin Vasc Surg 2009;22:193
Rayt HS, et al. Cardiovasc Intervent Radiol 2008;31:728–34

Iliac Branched Devices on the market

Iliac Branched Devices on the market

Cook®

20 Fr OD

BE Atrium Advanta V12

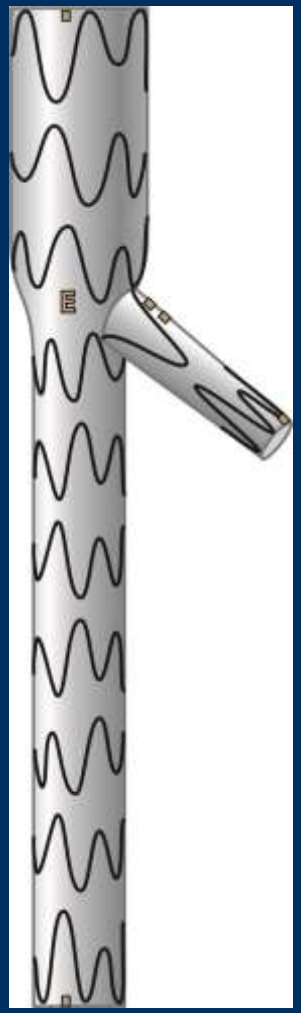
SE Fluency Bard

Iliac Branched Devices on the market

Jotec®

18 Fr OD

E-ventus covered stent



Iliac Branched Devices on the market

GORE® Iliac Branched Endoprosthesis

16 Fr OD

Dedicated GORE® internal iliac compoment HGB

The only FDA Approved IB-device since 2016

European and American Recommendations

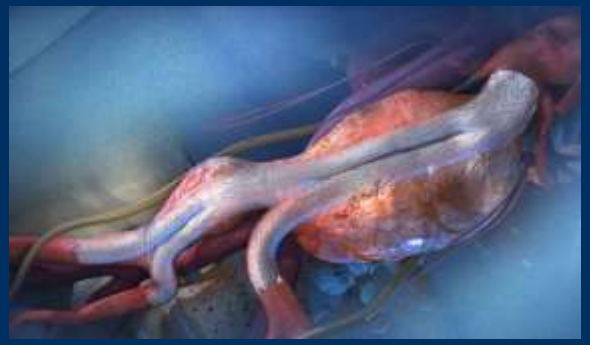
ESVS : Preserve at least one internal iliac artery (IIA); mandatory to avoid early complications

SVS 2017 update guideline: strongly recommends use of an FDA iliac branched endograft to maintain IIA perfusion

Clinical Studies with Gore® IBE®

Dutch Retrospective Cohort	JVS 2016 Jun 64(6):1451-7
Global Retrospective study on Bilateral IBE	JVS 2018 Jul 68(1):100-108
IDE study vs GREAT data	JVS 2019 Feb 69(2):367-77
ICEBERG Registry	clinicaltrials.gov

Dutch retrospective cohort



13 sites in the Netherlands

51 CIA aneurysms in 46 patients

Age	70.2 ± 8.5 year
Male gender	45/46 (98%)

van Sterkenburg SM, Heyligers JM, van Bladel M, Verhagen HJ, Eefting D, van Sambeek MR, Zeebregts CJ, Reijnen MM, for the Dutch IBE collaboration. Early experience with the GORE® EXCLUDER® Iliac Branch Endoprosthesis for common iliac artery aneurysms in the Netherlands. J Vasc Surg, i

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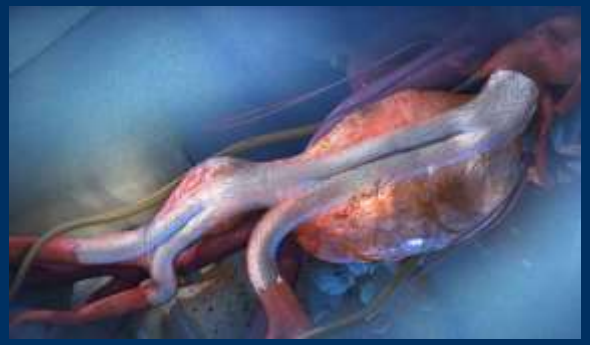

Primary patency IIA limb at six months is 94%

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

van Sterkenburg SM, Heyligers JM, van Bladel M, Verhagen HJ, Eefting D, van Sambeek MR, Zeebregts CJ, Reijnen MM, for the Dutch IBE collaboration. Early experience with the GORE® EXCLUDER® Iliac Branch Endoprosthesis for common iliac artery aneurysms in the Netherlands. J Vasc Surg, i

From the Vascular and Endovascular Surgery Society

Gore Iliac Branch Endoprosthesis for treatment of bilateral common iliac artery aneurysms

Thomas S. Maldonado, MD,[a] Nilo J. Mosquera, MD,[b] Peter Lin, MD,[c] Raffaello Bellosta, MD,[d] Michael Barfield, MD,[a] Albeir Moussa, MD,[e] Robert Rhee, MD,[f] Marc Schermerhorn, MD,[g] Jeffrey Weinberger, MD,[h] Marald Wikkeling, MD,[i] Jan Heyligers, MD,[j] Frank J. Veith, MD,[a] Ross Milner, MD,[k] *and* Michel P. J. Reijnen, MD,[l] on behalf of the Gore Bilateral IBE Study Group,* *New York and Brooklyn, NY; Ourense, Spain; Los Angeles, Calif; Brescia, Italy; Charleston, WVa; Boston, Mass; Indianapolis, Ind; Drachten, Tilburg, and Arnhem, The Netherlands; and Chicago, Ill*

ABSTRACT

Objective: The Gore Iliac Branch Endoprosthesis (IBE; W. L. Gore & Associates, Flagstaff, Ariz) has recently been approved by the Food and Drug Administration for treatment of common iliac artery (CIA) aneurysms. Despite early excellent results in clinical trial, none of 63 patients were treated for bilateral iliac aneurysms. The goal of this study was to examine real-world experience using the Gore IBE for bilateral CIA aneurysms.

Methods: A retrospective review of an international multicenter (16 U.S., 8 European) experience using the Gore IBE to treat bilateral CIA aneurysms was performed. Cases were limited to those occurring after Food and Drug Administration

International Multicenter Experience Review

24 Centers (16 US, 8 European), 47 patients

NYU Langone MEDICAL CENTER

Division of Vascular and Endovascular Surgery

Global Retrospective Study on Bilateral IBE

47 patients
45 male
Mean age 68 Yrs (range 41-84)

Global Retrospective Study on Bilateral IBE

Technical success 46 pts (97.9%)
No type 1 or 3 Endoleak detected
IIA branch Adjunctive stenting in 4 pts

Global Retrospective Study on Bilateral IBE

FU imaging available in 40 pts (85.1%)
Mean FU 6.5 Mo (range 1-36)
No type 1 or 3 Endoleaks
2 of 80 branches (2.5%) occluded; 1 suffered buttock claudication

In conclusion:
Bilateral preservation of IIA in bilateral Iliac aneurysms safe
Excellent technical success and short term patency

The GORE IBE® IDE trial

Prospective, multicenter, single arm study

Safety and effectiveness of the GORE EXCLUDER® IBE® as concomitant treatment with the GORE EXCLUDER® in patients with CIAA and AIA

Pivotal enrollment completed 2015

Continued access completed 2016

Bilateral treatment was only allowed in the continued access arm

GREAT Registry

GORE® initiated

To monitor ‘real world data’

IBE® IDE trial vs GREAT data

From the Society for Vascular Surgery

Outcomes of the GORE Iliac Branch Endoprosthesis in clinical trial and real-world registry settings

Darren B. Schneider, MD,[a] Ross Milner, MD,[b] Jan M. M. Heyligers, MD, PhD,[c] Nabil Chakfé, MD, PhD,[d] *and* Jon Matsumura, MD,[e] *New York, NY; Chicago, Ill; Tilburg, The Netherlands; Strasbourg, France; and Madison, Wisc*

ABSTRACT

Background: We report midterm outcomes with the GORE Iliac Branch Endoprosthesis (IBE; W. L. Gore & Associates, Flagstaff, Ariz) in the U.S. investigational device exemption (IDE) trial and comparatively assess outcomes in the IDE trial with outcomes in a real-world population of patients treated in the Gore Global Registry for Endovascular Aortic Treatment (GREAT).

Methods: From 2013 to 2016, the IDE trial enrolled 99 patients treated with the IBE for common iliac artery (CIA) aneurysms or aortoiliac aneurysms. Bilateral IBE treatment was allowed only in the continued access phase. From 2013 to

Baseline data IDE and GREAT

Table I. Baseline demographic characteristics for 99 pivotal phase and continued access subjects enrolled in the Investigational Device Exemption (IDE) trial of the Gore Iliac Branch Endoprosthesis (IBE) and 92 subjects treated with the IBE in the Gore Registry for Endovascular Aortic Treatment (GREAT)

Variable	IDE N=99	GREAT N=92	P value
Male	98/99 (99)	85/92 (92)	.02
Age	69.0 ± 9.3	72.2 ± 7.7	.01
Weight	99.9 ± 20.1	89.2 ± 19.0	< .001
BMI > 30	53 (54)	34 (37)	.02
Height	179.5 ± 6.7	174.7 ± 7.2	< .001
CHF	16/99 (16)	6/92 (7)	.04
CABG	12/99 (12)	7/92 (8)	.30
Hypercholesterolemia	69/99 (70)	46/91 (51)	.007
Hypertension	82/99 (83)	66/92 (72)	.07
COPD	20/98 (20)	19/92 (21)	.97
Diabetes	24/98 (24)	18/92 (20)	.41
Renal insufficiency	7/99 (7)	10/92 (11)	.36
PVD	37/99 (37)	13/91 (14)	< .001
ED	12/71 (17)	8/47 (17)	.99
Smoking	57/99 (58)	38/84 (45)	.10
Cancer	26/97 (27)	23/92 (25)	.78
Myocardial infarction	18/98 (18)	--	--

BMI, body mass index; *CABG*, coronary artery bypass graft; *CHF*, congestive heart failure; *COPD*, chronic obstructive pulmonary disorder; *ED*, erectile dysfunction; *PVD*, peripheral vascular disorder.

Continuous data are expressed as mean ± standard deviation. Categorical data are expressed as numerator/denominator (percentage). *P* values are derived from unpaired t test and χ^2 test.

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Bilateral Disease in IDE and GREAT

IDE: 30 patients had bilateral disease

- 26 staged procedure; 4 bilateral IBE implants

8 cases of buttock claudication in the total IDE cohort

- **1** pt buttock claudication ipsilateral with patent endograft
- **7** contralateral to the IBE device in 26 staged procedures = 27% = like in literature

Conclusions IDE and GREAT

Continued excellent outcomes for iliac aneurysm treatment using the GORE® IBE® through 2 years

> 50% of cases was outside IFU within GREAT

Sack expansion of CIAA was not observed

@ 2 Yrs 45% sack decrease of 5 mm or more

ICEBERG Registry

recent update by Michel Reijnen

- Prospective multi-centre, observational, post-market, real-world registry
- 101 included patients in 8 international sites
- Follow-up scheduled up to 5 years
- Inclusion ended in 2018

Inclusion criteria

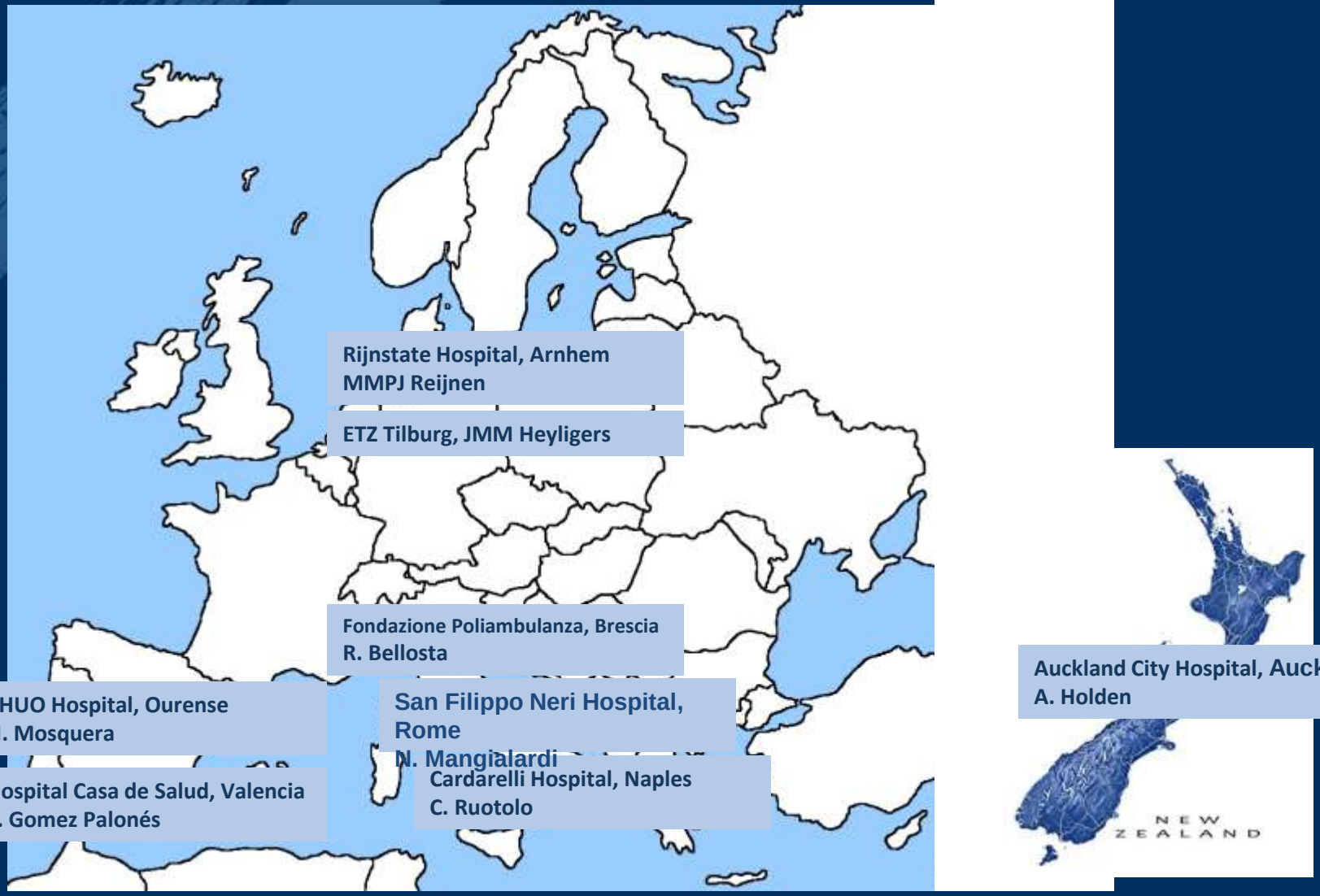
- Age 18 years or older
- Written informed consent
- Elective procedure
- Indication for aorto-iliac endovascular stent graft repair

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

Participating sites



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)	70.0 (IQR 64.5-75.5)
Male gender	97 (97%)
BMI (kg/m^2)	26.1 (IQR 24.1-29.0)
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	14/91
AAA present	60 (60%)
CIA aneurysm	95 (95%)
Left	17 (17%)
Right	33 (33%)
bilateral	45 (45%)
IIA aneurysm	17 (17.1%)
Other concomitant aneurysm	18 (18%)
Previous EVAR	4 (4%)

Interim analysis; data are subjected to changes

Iceberg registry

Procedural data

- Bilateral IBE in 20 cases and isolated IBE in 5 cases
- Procedural time 151 min (IQR 117-193 min)
- Contrast 130 mL (IQR 100-180 mL)
- Contralateral IIA
  - Patent and not overstented 60%
  - Bilateral IBE 20%
  - Patent and overstented 13%
  - Not patent before procedure 5%

Interim analysis; data are subjected to changes

Iceberg registry

Procedural data

- Procedural complications in 4 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

- Endoleaks at completion angiography
  - Ia N=2
  - Ib N=1
  - II N=15
  - III N=0

Interim analysis; data are subjected to changes

Iceberg registry

30-day outcome

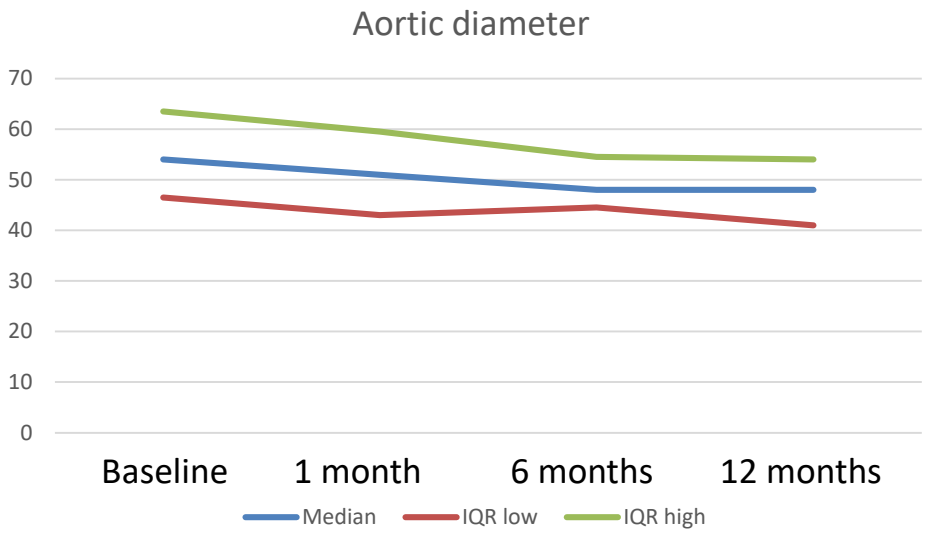
- Hospitalization 4 (IQR 3-5) days
- One re-intervention: angioplasty of iliac stenosis
- Failures:
  - 5 early occlusions of hypogastric branch
  - 2 endoleak's (1 type 1a and 1 type 3)
- Endoleaks;
  - Type Ia n=1*
  - Type II n=17
  - Type III n=1*
- No 30-day mortality

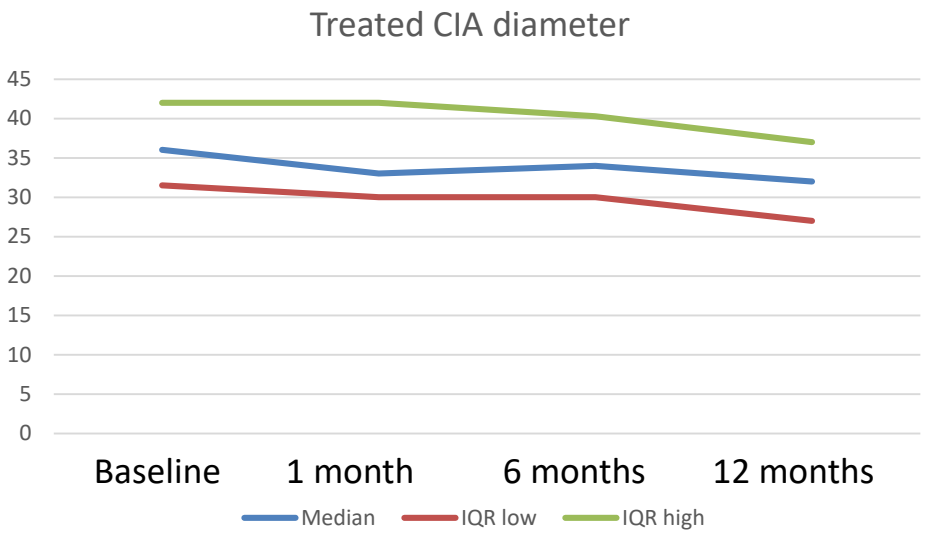
** Reintervention performed after 30 days*

Interim analysis; data are subjected to changes

Iceberg registry

1-year outcome



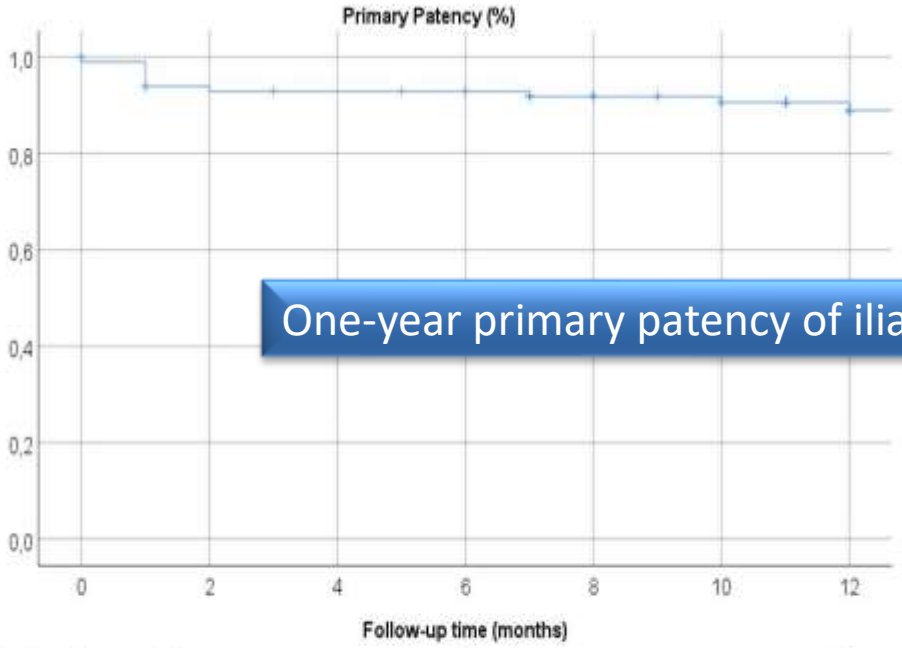


- Survival 95%
- No AAA-related mortality
- Four reinterventions performed for endoleaks
- 15 remaining type II endoleaks

Interim analysis; data are subjected to changes

Iceberg registry

1-year outcome



Primary Patency	0	1	6	12
No. At Risk	100	99	90	53
Patency (%)	100	99.0	92.9	88.9
SE		0.010	0.026	0.034

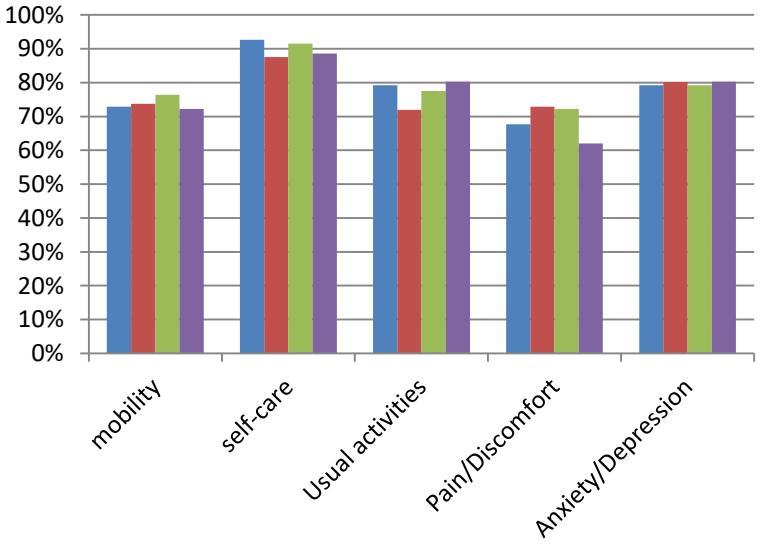
One-year primary patency of iliac component 89%

Interim analysis; data are subjected to changes

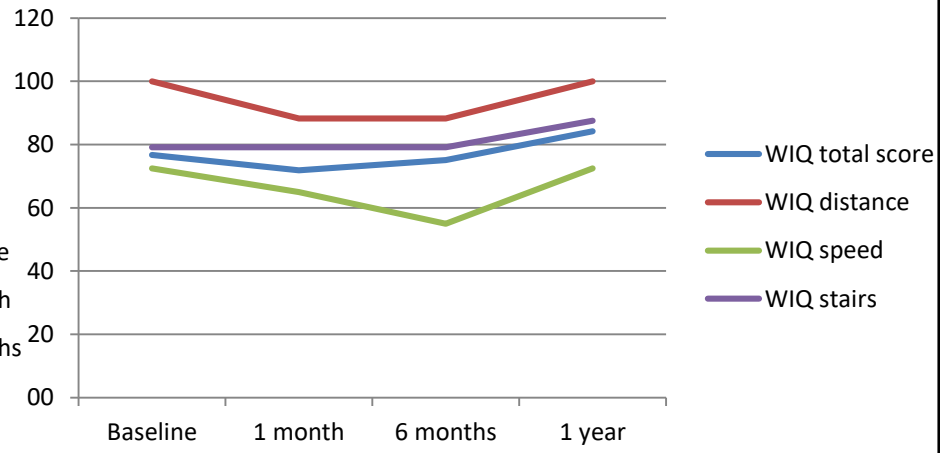
Iceberg registry

Clinical outcome

EQ5D % of patients that reported no problems



Walking Impairment Questionnaire

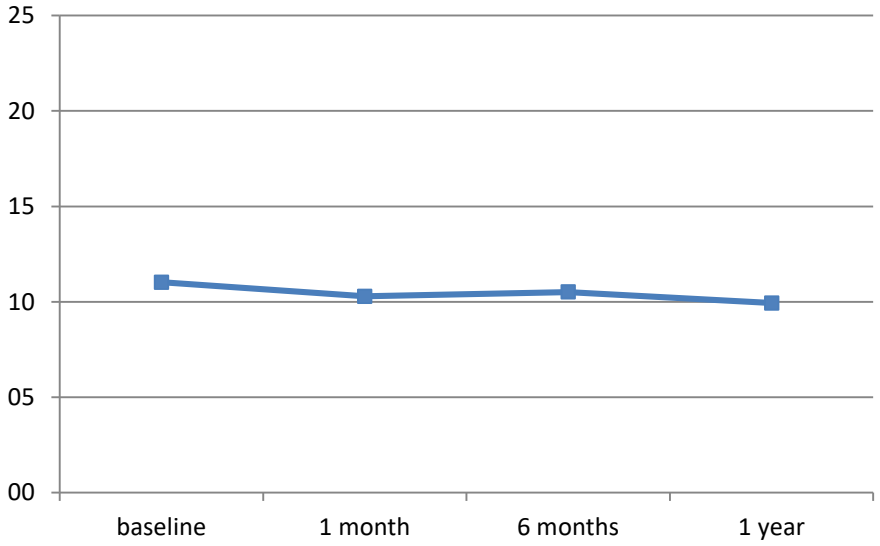


Interim analysis; data are subjected to changes

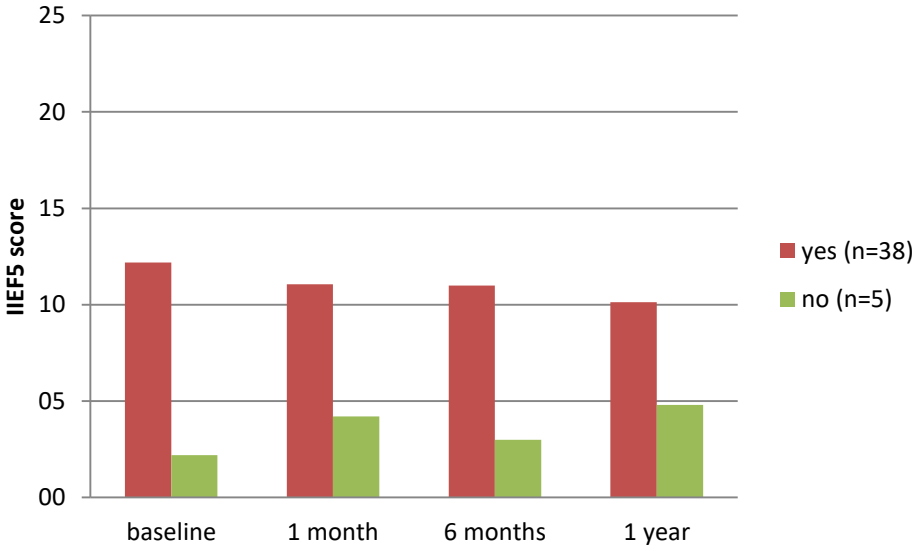
Iceberg registry

Clinical outcome

International Index of Erectile Function (n=43)



International Index of Erectile Function; contralateral patency



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

Interim analysis; data are subjected to changes

Summary ICEBERG

- The ICEBERG registry shows a favorable 1-year outcome of the GORE IBE device, with good clinical results
- Erectile dysfunction is prevalent, underestimated and related to contralateral occlusions

Iliac branch device indication in consideration of guidelines and clinical data: conclusions

- Iliac Branched Technology is a feasible technique and offers Endovascular Specialists a solid tool to preserve the IIA with good clinical results
- Double iliac aneurysms can be safely treated with this technique
- Guidelines recommend to preserve at least one IIA
- Sacrificing AII leads to buttock claudication and erectile dysfunction

I propose to update guidelines and preserve both IIA if feasible

Please feel welcome at
our 2 day Tilburg
IBE workshop

IBEworkshop@etz.nl

Iliac branch device indication in consideration of guidelines and clinical data

Jan MM Heyligers, MD, PhD, FEBVS
Consultant Vascular Surgeon
ETZ Tilburg, The Netherlands