Iliac branch device indication in consideration of guidelines and clinical data

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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

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%

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 component 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  
Global Retrospective study on Bilateral IBE  
IDE study vs GREAT data  
ICEBERG Registry  

JVS 2016 Jun 64(6):1451-7  
JVS 2018 Jul 68(1):100-108  
JVS 2019 Feb 69(2):367-77  
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%)

Dutch retrospective cohort

Primary patency IIA limb at six months is 94%
Significant decrease in CIA aneurysm diameter:
  - Baseline: $42.4 \pm 7.2$ mm
  - 6 months: $38.4 \pm 7.5$ mm
Re-interventions preformed in 2 patients (7%):
  - BE stent external iliac limb stenosis
  - Type 1b endoleak

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, WV; 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
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’
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)

<table>
<thead>
<tr>
<th>Variable</th>
<th>IDE N=99</th>
<th>GREAT N=92</th>
<th>P value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Male</td>
<td>98/99 (99)</td>
<td>85/92 (92)</td>
<td>.02</td>
</tr>
<tr>
<td>Age</td>
<td>69.0 ± 9.3</td>
<td>72.2 ± 7.7</td>
<td>.01</td>
</tr>
<tr>
<td>Weight</td>
<td>99.9 ± 20.1</td>
<td>89.2 ± 19.0</td>
<td>&lt; .001</td>
</tr>
<tr>
<td>BMI &gt; 30</td>
<td>53 (54)</td>
<td>34 (37)</td>
<td>.02</td>
</tr>
<tr>
<td>Height</td>
<td>179.5 ± 6.7</td>
<td>174.7 ± 7.2</td>
<td>&lt; .001</td>
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<tr>
<td>CHF</td>
<td>16/99 (16)</td>
<td>6/92 (7)</td>
<td>.04</td>
</tr>
<tr>
<td>CABG</td>
<td>12/99 (12)</td>
<td>7/92 (8)</td>
<td>.30</td>
</tr>
<tr>
<td>Hypercholesterolemia</td>
<td>69/99 (70)</td>
<td>46/91 (51)</td>
<td>.007</td>
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<td>Hypertension</td>
<td>82/99 (83)</td>
<td>66/92 (72)</td>
<td>.07</td>
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<tr>
<td>COPD</td>
<td>20/98 (20)</td>
<td>19/92 (21)</td>
<td>.97</td>
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<tr>
<td>Diabetes</td>
<td>24/98 (24)</td>
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<td>Renal insufficiency</td>
<td>7/99 (7)</td>
<td>10/92 (11)</td>
<td>.36</td>
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<tr>
<td>PVD</td>
<td>37/99 (37)</td>
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<td>12/71 (17)</td>
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<td>26/97 (27)</td>
<td>23/92 (25)</td>
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<tr>
<td>Myocardial infarction</td>
<td>18/98 (18)</td>
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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 \( \chi^2 \) test.

\( BMI \), body mass index; \( CABG \), coronary artery bypass graft; \( CHF \), congestive heart failure; \( COPD \), chronic obstructive pulmonary disorder; \( ED \), erectile dysfunction; \( PVD \), peripheral vascular disorder.
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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 χ² test.
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
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

Rijnstate Hospital, Arnhem
MMPJ Reijnen

ETZ Tilburg, JMM Heyligers

CHUO Hospital, Ourense
N. Mosquera

Hospital Casa de Salud, Valencia
F. Gomez Palonés

Fondazione Poliambulanza, Brescia
R. Bellosta

San Filippo Neri Hospital, Rome
N. Mangialardi
Cardarelli Hospital, Naples
C. Ruotolo

Auckland City Hospital, Auckland
A. Holden
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
## Baseline characteristics

<table>
<thead>
<tr>
<th>Characteristic</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age (years)</td>
<td>70.0 (IQR 64.5-75.5)</td>
</tr>
<tr>
<td>Male gender</td>
<td>97 (97%)</td>
</tr>
<tr>
<td>BMI (kg/m$^2$)</td>
<td>26.1 (IQR 24.1-29.0)</td>
</tr>
<tr>
<td>Hypertension</td>
<td>66 (66%)</td>
</tr>
<tr>
<td>Diabetes mellitus</td>
<td>11 (11%)</td>
</tr>
<tr>
<td>Hyperlipidemia</td>
<td>60 (60%)</td>
</tr>
<tr>
<td>Current smoking</td>
<td>27 (27%)</td>
</tr>
<tr>
<td>Cardiac disease</td>
<td>27 (27%)</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>14/91</td>
</tr>
<tr>
<td>AAA present</td>
<td>60 (60%)</td>
</tr>
<tr>
<td>CIA aneurysm</td>
<td>95 (95%)</td>
</tr>
<tr>
<td>Left</td>
<td>17 (17%)</td>
</tr>
<tr>
<td>Right</td>
<td>33 (33%)</td>
</tr>
<tr>
<td>bilateral</td>
<td>45 (45%)</td>
</tr>
<tr>
<td>IIA aneurysm</td>
<td>17 (17.1%)</td>
</tr>
<tr>
<td>Other concomitant aneurysm</td>
<td>18 (18%)</td>
</tr>
<tr>
<td>Previous EVAR</td>
<td>4 (4%)</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 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
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

Interim analysis; data are subjected to changes

One-year primary patency of iliac component 89%
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)**

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