Iliac Branch Grafts (IBD):
What is the Best Way to Utilize this Device?
Disclosures

Abbott - medical advisory board; consulting
Bard- contracted research funding
Boston Scientific - contracted research funding
Cook – contracted research funding
Medtronic - medical advisory board
W.L. Gore – contracted research funding; consulting; medical advisory board
Common iliac artery aneurysms are common!

Endovascular Repair of Abdominal Aortic Aneurysms With Concomitant Common Iliac Artery Aneurysm: Outcome Analysis of the EUROSTAR Experience

Roel Hobo, MSc; Johannes E.M. Sybrandy, MD; Peter L. Harris, MD, FRCS; and Jacob Buth, MD, PhD on Behalf of the EUROSTAR Collaborators

1EUROSTAR Data Registry Centre, Catharina Hospital, Eindhoven, The Netherlands. 2EUROSTAR Secretary, Royal University Hospital, Liverpool, United Kingdom.

- 28% of 6,286 EVAR patients
- CIAA patients had more complications:
  - Iliac occlusions
  - Type Ib and II endoleaks
  - Secondary re-interventions
  - Aneurysm ruptures

Hobo et al. J Endovasc Ther 2008
Iliac branch technology for EVAR is becoming widely available

Cook IBD

Gore IBE
What is the current standard of care?

“Coil and Cover”

or

Iliac Branch Device
Hypogastric Embolization Is **NOT** Benign

- Approximately 20-30% of patients develop buttock claudication (higher after bilateral sacrifice)
- BC persists in about 50%
- Sexual dysfunction occurs in approximately 10-20%
- Hypogastric artery embolization during EVAR is associated with higher risk of ischemic complications and death

Kouvelos et al. Eur J Vasc Endovasc Surg 2016
Farivar et al. J Vasc Surg 2017
Farahmand et al. Eur J Vasc Endovasc Surg 2008
For patients with persistent buttock claudication due to embolization, there is usually no effective treatment.
Quality of Life After EVAR

MOTHER GOOSE & GRIMM BY MIKE PETERS

NOW THAT I'VE BEEN TAKING THOSE PILLS, WHY HAVE WE BEEN BATHING IN SEPARATE TUBS ON THE BEACH?

Prospective, multicenter study of endovascular repair of aortoiliac and iliac aneurysms using the Gore Iliac Branch Endoprosthesis

Darren B. Schneider, MD,¹ Jon S. Matsumura, MD,¹ Jason T. Lee, MD,¹ Brian G. Peterson, MD,¹ Rabih A. Char, MD,² and Gustavo S. Oderich, MD,¹ New York, NY; Madison, Wisc; Stanford, Calif; St Louis, Mo; Pittsburgh, Pa; and Rochester, Minn

Gore IBE 12-04 Trial – 6 Month Primary Endpoint (N = 63)

- 0% Aneurysm-related mortality
- 95.2% Technical success
- 95.2% IBE device patency
- 0 type 1 or 3 endoleaks
- 98.4% Freedom from reintervention

Schneider et al. J Vasc Surg 2017
100% freedom from new-onset buttock claudication on IBE side

21 patients with bilateral CIAAs underwent embolization of one internal iliac artery

- The incidence of buttock claudication on the side opposite the IBE was 28.6% (6/21)
## Results of EVAR with IBDs

<table>
<thead>
<tr>
<th>Author (Year)</th>
<th>n</th>
<th>Branches</th>
<th>Mortality</th>
<th>Technical success</th>
<th>Mean FU (months)</th>
<th>Branch occlusion</th>
</tr>
</thead>
<tbody>
<tr>
<td>Haulon (2006)</td>
<td>52</td>
<td>53</td>
<td>0%</td>
<td>94%</td>
<td>14</td>
<td>11%</td>
</tr>
<tr>
<td>Dias (2008)</td>
<td>22</td>
<td>23</td>
<td>0%</td>
<td>91%</td>
<td>20</td>
<td>13%</td>
</tr>
<tr>
<td>Ferreira (2010)</td>
<td>37</td>
<td>54</td>
<td>0%</td>
<td>97%</td>
<td>22</td>
<td>11%</td>
</tr>
<tr>
<td>Parlani (2012)</td>
<td>100</td>
<td>100</td>
<td>0%</td>
<td>95%</td>
<td>17</td>
<td>7%</td>
</tr>
<tr>
<td>Wong (2013)</td>
<td>130</td>
<td>138</td>
<td>0%</td>
<td>94%</td>
<td>20</td>
<td>15%</td>
</tr>
<tr>
<td>Bisdas (2014)</td>
<td>18</td>
<td>22</td>
<td>0%</td>
<td>100%</td>
<td>-</td>
<td>0%</td>
</tr>
<tr>
<td>Pratesi (2014)</td>
<td>81</td>
<td>85</td>
<td>0%</td>
<td>99%</td>
<td>20</td>
<td>2%</td>
</tr>
<tr>
<td>Torsello (2015)</td>
<td>178</td>
<td>188</td>
<td>0.3%</td>
<td>99%</td>
<td>20</td>
<td>8%</td>
</tr>
<tr>
<td>GORE 12-04 (2017)</td>
<td>96</td>
<td>100</td>
<td>0%</td>
<td>98%</td>
<td>6</td>
<td>5%</td>
</tr>
<tr>
<td>Cook PRESERVE (2016)</td>
<td>52</td>
<td>52</td>
<td>0%</td>
<td>100%</td>
<td>7</td>
<td>0%</td>
</tr>
</tbody>
</table>
Outcomes of the Gore IBE in Clinical Trial and Real-World Registry settings

IBE 12-04 Multicenter Trial

N = 98
63 Pivotal Arm
35 Continued Access Arm
4 Bilateral IBE

GREAT Registry

N = 92
13 Bilateral IBE

190 Patients
207 IBE devices

Up to 3-years F/U
Mean Follow-up:
IBE 12-04: 605 days
GREAT: 315 days

## Outcomes

<table>
<thead>
<tr>
<th></th>
<th>IBE 12-04 (N=98) No. (%)</th>
<th>GREAT (N=92) No. (%)</th>
<th>P Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mean F/U (days)</td>
<td>650</td>
<td>315</td>
<td></td>
</tr>
<tr>
<td>Aneurysm-Related Mortality</td>
<td>0 (0)</td>
<td>0(0)</td>
<td>NA</td>
</tr>
<tr>
<td>All Cause Mortality</td>
<td>7 (7.1)</td>
<td>6 (6.5)</td>
<td>0.87</td>
</tr>
<tr>
<td>New-Onset Ipsilateral Buttock Claudication</td>
<td>0 (0)</td>
<td>-</td>
<td>NA</td>
</tr>
<tr>
<td>Reinterventions thru 6 mos</td>
<td>5 (5.1)</td>
<td>5 (5.4)</td>
<td>0.92</td>
</tr>
</tbody>
</table>

IBE Internal Iliac Limb Patency: Pivotal US Trial

All internal iliac limb occlusions occurred early

93.6% (95% CI, 86.4% - 97.1%) @ 12 and 24 months

Freedom from Reintervention: IBE Pivotal US Trial

Most reinterventions were for type II endoleaks

90.4% through 2 years (95% CI 81.3% - 95.2%)
Which EVAR Patients Should Be Treated with an IBD in 2018?

Any EVAR patient with:

- common iliac artery aneurysm
- and
- appropriate anatomy for treatment with an IBD
Anatomic Requirements – Gore IBE Instructions for Use (IFU)

- Minimum renal artery to internal iliac artery distance ≥ 165mm
- And adequate anatomy to receive EXCLUDER stent graft
Anatomic Suitability for IBD

- 51 pts/66 target IIAs analyzed
- 62% had at least one anatomical limitation by current IFU
Outcomes of a novel technique of endovascular repair of aneurysmal internal iliac arteries using iliac branch devices

Martin Austermann, MD, a Theodosios Bisdas, MD, a Giovanni Torsello, MD, a Michel J. Bosiers, MD, a Konstantinos Lazaridis, PhD, a and Konstantinos P. Donas, MD, PhD, a Münster, Germany; and Athens, Greece

IBD - Extension to Posterior Branch

Coils in Anterior Branches
Absolute Indication for IBD!
Multifocal or extensive aneurysmal disease to prevent spinal cord ischemia (SCI)
Indications for use of an IBD

**Absolute Indications**
- Multifocal aneurysms
- Extensive aortic coverage

**Strong Indications**
- Younger/Active patients
- Bilateral CIAA
- Type 1b endoleak

**Gray Area**
- CIA diameter 2.0-2.5 cm
- Candidate for flared limb
- Bilateral IBD vs. unilateral IBD
Iliac Branch Devices

**Cook IBD**
- 12mm
- 8mm
- 45/61mm
- 41/58mm

**Gore IBE**
- 23mm
- 25mm
- 5.5 cm
- 10cm
- 10/12/14.5 mm
Tortuous Anatomy

- 23mm
- 5.5 cm
- 25mm
- 10/12/14.5 mm
- Gore IBE
Short CIA

23mm

5.5 cm

25mm

10cm

10/12/14.5 mm

Gore IBE
Saccular/Distal CIAA

12mm

45/61mm

41/58mm

10/12mm

Cook IBD
Type 1b Endoleak
Failure of distal landing zone after EVAR – Type 1b Endoleak

Late failure of EVAR distal landing zone can result in type Ib endoleak

EVAR using flared limbs for CIA > 20mm is associated with a significantly higher risk of type Ib endoleak

Type Ib endoleak can be corrected with an IBD

Oderich ed. Endovascular Aortic Repair 2017
Gray et al. Eur J Vasc Endovasc Surg 2017
Hobo et al. J Endovasc Ther 2008
<table>
<thead>
<tr>
<th>Device</th>
<th>Iliac limb diameter</th>
<th>Distal landing zone length</th>
<th>Distal iliac diameter</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cook Zenith®</td>
<td>8 - 24</td>
<td>&gt;10</td>
<td>7-21</td>
</tr>
<tr>
<td>Gore Excluder®</td>
<td>10 - 27</td>
<td>&gt;10</td>
<td>8-25</td>
</tr>
<tr>
<td>Medtronic Endurant®</td>
<td>8 - 28</td>
<td>&gt;15</td>
<td>7-26</td>
</tr>
<tr>
<td>Endologix Powerlink®</td>
<td>16 - 25</td>
<td>&gt;15</td>
<td>10-23</td>
</tr>
</tbody>
</table>

* Based on *Information for Use* recommendations

Appropriate when used on IFU for patients who don’t have ideal anatomy for IBD
Iliac preservation whenever possible is the new standard of care!

• CIAAs are common and traditional treatment with hypogastric artery sacrifice is associated with increased morbidity and mortality

• Iliac preservation using iliac branch devices is:
  ➢ Safe and effective
  ➢ Associated with high technical success rates
  ➢ Durable with low branch occlusion rates

• Unresolved issues
  ➢ Cost/reimbursement
  ➢ Bilateral vs. unilateral IBD for B CIAAs
  ➢ Off-label indications