Technical Tips And Multicenter Results With The Use Of Bilateral Gore IBDs In Patients With Bilateral Common Iliac Aneurysms

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New York University Langone Health

Disclosures

• Consultant for:
  • Cook
  • Endologix
  • Gore
  • Medtronic

Background

• Hypogastric occlusion is required in up to 20% of EVAR

• Sequelae not so benign*
  • Buttock claudication in up to 55%
  • Erectile Dysfunction (10-46%)
  • Colonic / Spinal Cord ischemia (less common but catastrophic)

Table 6. Outcomes for comparison of unilateral versus bilateral IIA treatment by summary of findings.

<table>
<thead>
<tr>
<th>Procedure</th>
<th>No. of studies</th>
<th>No. of patients</th>
<th>A-priori estimate</th>
<th>Effect estimate 2006 IIA</th>
<th>Overall effect IIA</th>
</tr>
</thead>
<tbody>
<tr>
<td>Buttock claudication</td>
<td>1 (2001)</td>
<td>146 (51)</td>
<td>.3</td>
<td>-.07 (.04, .04)</td>
<td>2.07</td>
</tr>
<tr>
<td>Erectile dysfunction</td>
<td>2 (2005, 2006)</td>
<td>118 (11)</td>
<td>.67</td>
<td>-.02 (.03, .23)</td>
<td>.70</td>
</tr>
</tbody>
</table>

Rayt et al. Cardiovasc Intervent Radiol 2008;31:728-34

Buttock Claudication
26% in unilateral IIA
26% in bilateral IIA

Erectile Dysfunction
9% in unilateral IIA
9% in bilateral IIA
Should we be doing BILATERAL IBE CASES? …

- Increased case complexity
  - Longer operative time?
  - More radiation?
  - Increased contrast required?
- Anatomic Limitations
- Cost?

International Multicenter Experience Review
24 Centers (18 US, 6 European, 47 patients)

Bilateral Gore IBE International Study Group

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Jeff Weinberger, MD  Community Heart Vascular Hospital, Fort Pierce, FL

Results: Anatomic characteristics

Aortic Diameters

<table>
<thead>
<tr>
<th>Diameters</th>
<th># of patients</th>
</tr>
</thead>
<tbody>
<tr>
<td>&lt;20</td>
<td>31 (65%)</td>
</tr>
<tr>
<td>20-30</td>
<td>11 (23%)</td>
</tr>
<tr>
<td>31-40</td>
<td>5 (10%)</td>
</tr>
<tr>
<td>41-50</td>
<td>2 (4%)</td>
</tr>
<tr>
<td>&gt;50</td>
<td>1 (2%)</td>
</tr>
</tbody>
</table>

11 (23%) of patients treated exclusively for CIA aneurysm (absence of AAA).

Results: Anatomic characteristics

Diameters

<table>
<thead>
<tr>
<th>Diameters</th>
<th># of patients</th>
</tr>
</thead>
<tbody>
<tr>
<td>Aortic Diam</td>
<td>47 patients</td>
</tr>
<tr>
<td>CIA Diam</td>
<td>46.5mm (21-97)</td>
</tr>
<tr>
<td>IIA Diam</td>
<td>40.3mm (25-97)</td>
</tr>
<tr>
<td>IIA Diam</td>
<td>10.9mm (5.41mm)*</td>
</tr>
</tbody>
</table>

* 4 patients had aneurysmal/ectatic IIA

From the Vascular and Endovascular Surgery Society

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

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47 patients
- IRB approved retrospective review
- Bilateral Gore IBE implanted,
  - In US post-FDA approval (2/2016)
  - In Europe post-CE mark (11/2013)
- Demographics
- Anatomic Characteristics
- Procedural detail
- Clinical and radiographic Follow-up: Mean 6.5 months, range 1-36
Internal Iliac artery aneurysm/ectasia
Coil embolization of branches to seal in largest 1st order branch

RESULTS: Lengths from Renal to IIA
195mm (range 148-230mm)
194mm (range 163-248mm)

ANATOMIC LIMITATIONS?
IFU: Lengths pose special challenges for Bilateral IBE

Tips and tricks to accommodate shorter lengths:
Maximize overlap

Tips and tricks to accommodate shorter lengths:
Closing the gap
**Tips and tricks to accommodate shorter lengths:**

*Intrinsic tortuosity can eat up distance…*

**Tips and tricks to accommodate shorter lengths:**

*Recreating Flow Divider*

**Tips and tricks to accommodate shorter lengths:**

*Using alternative Shorter Bridges (n=3)*

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### Results: Procedural Outcomes

- Technical Success (97.9%)
- No type 1 or 3 endoleaks
- Adjunctive Stenting required in 4 patients at time of index procedure
  - Distal IIA dissection (n=1)
  - Kinking (n=3)

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One technical failure: Failure to access tight IIA stenosis requiring coil and extension

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Severe left IIA stenosis and calcification

Unable to access
Results: Complications at 30 days

<table>
<thead>
<tr>
<th>Complication</th>
<th>n=47</th>
</tr>
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<tbody>
<tr>
<td>Rupture</td>
<td>0</td>
</tr>
<tr>
<td>Groin hematoma</td>
<td>0</td>
</tr>
<tr>
<td>Infection (groin)</td>
<td>1</td>
</tr>
<tr>
<td>Pelvic ischemia</td>
<td>0</td>
</tr>
<tr>
<td>Distal Embolization</td>
<td>0</td>
</tr>
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</table>

Results: Clinical and Radiographic Outcome

Follow-up: Mean 6.5 months, range 1-36 months

New Buttock Claudication:
1/47 patients (2.1%): 2 IIA occlusions on imaging

No Aneurysm related death
2 non-aneurysm related death at 1 year (cardiac)

Radiographic imaging available for 40/47 patients

<table>
<thead>
<tr>
<th>Radiographic Follow-up</th>
<th>n=40/47 (85.1%)</th>
<th>Time of occlusion</th>
<th>Presentation</th>
<th>Intervention</th>
</tr>
</thead>
<tbody>
<tr>
<td>EIA occlusion (n=3 patients)</td>
<td>3/80 (3.8%) vessels</td>
<td>POD#1 loss of pedal signal</td>
<td>Thrombectomy I/EIA stent</td>
<td></td>
</tr>
<tr>
<td>EIA stent deployed high above flow divider of IBE, partially occluding EIA limb, IIA limb sacrificed</td>
<td>POD#1* Rest pain</td>
<td>EIA stent**</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Buttock claudication at 6 month f/u</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>IIA stent remained patent on side of EIA occlusion</td>
<td></td>
<td></td>
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Results: Limb Occlusions: (External Iliac Limb)

Follow-up: Mean 6.5 months, range 1-36 months

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<th>Intervention</th>
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<tbody>
<tr>
<td>EIA occlusion (n=2)</td>
<td>2/80 (2.5%) vessels</td>
<td>POD#2* Buttock Claudication</td>
<td>None**</td>
<td></td>
</tr>
<tr>
<td>6 Months Asymptomatic</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
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</table>

• IIA branch occlusion: iatrogenic
  IIA stent inadvertently deployed high above flow divider of IBE
  Partially occluding EIA limb
  IIA stent deployed / IIA limb sacrificed
  Buttock claudication at 6 month f/u

Results: Limb Occlusions: (Internal Iliac Limb)

Follow-up: Mean 6.5 months, range 1-36 months

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* IIA stent deployed high above flow divider of IBE, partially occluding EIA limb, IIA limb sacrificed
**Conclusion**

- Preservation of bilateral IIA with Gore IBE can be performed safely with excellent technical success and short term patency rates.

- Only 1 new onset buttock claudication (2.1%)

**Cost?**

Main Body $11,275
Contra limb (bridge) #1 $4,623
Contra limb (bridge) #2 $4,623
Iliac Branch Component #1 $10,750
Iliac Branch Component #2 $10,750
Internal Iliac Component #1 $3,000
Internal Iliac Component #2 $3,000

TOTAL: $42,027

**NEW PROCEDURE CODES: for GORE IBE**

As of October 1, 2016, cases involving the IBE when used with the GORE® EXCLUDER® Device are eligible for new technology add-on payment when identified by ICD-10-PCS procedure codes:

<table>
<thead>
<tr>
<th>Procedure Code</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>04VC09Z</td>
<td>04VC09Z</td>
</tr>
<tr>
<td>04VC19Z</td>
<td>04VC19Z</td>
</tr>
<tr>
<td>04VC29Z</td>
<td>04VC29Z</td>
</tr>
<tr>
<td>04VC39Z</td>
<td>04VC39Z</td>
</tr>
<tr>
<td>04VC49Z</td>
<td>04VC49Z</td>
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</tbody>
</table>

The maximum new technology add-on payment for a case involving the use of the IBE is $5,250 for FY 2017.

**Conclusion**

- Preservation of bilateral IIA with Gore IBE can be performed safely with excellent technical success and short term patency rates.

- Only 1 new onset buttock claudication (2.1%)

- Limb and branch occlusions are rare can be treated successfully with stenting most of the time
Conclusion

- Preservation of bilateral IIA with Gore IBE can be performed safely with excellent technical success and short term patency rates.
- Only 1 new onset buttock claudication (2.1%)
- Limb and branch occlusions are rare can be treated successfully with stenting most of the time
- While anatomic limitations exist a number of maneuvers can permit technical success even in shorter length aorto-iliac segments.

Conclusion

- Preservation of bilateral IIA with Gore IBE can be performed safely with excellent technical success and short term patency rates.
- Only 1 new onset buttock claudication (2.1%)
- Limb and branch occlusions are rare can be treated successfully with stenting most of the time
- While anatomic limitations exist a number of maneuvers can permit technical success even in shorter length aorto-iliac segments.
- Contrast used, fluroscopy time and length of case do not appear prohibitive, however, cost remains an issue.

Thank you....