What Is New in Endovascular Treatment of Iliac Artery Aneurysmal Disease

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Disclosures

Consultant:

• Medtronic
• Gore & Associates
Iliac Artery Aneurysms
Iliac Artery Aneurysms

- ~11% CIAA in isolation
- 2% of intra-abdominal aneurysms\textsuperscript{1-2}

- 20 – 30% of AAA extend into iliac arteries\textsuperscript{3-4}

Treatment Considerations

- Indications for treatment
  - $\geq 3$ cm in isolation
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  - $\geq$ 3 cm in isolation

- CIA assessment as adequate distal landing zone (DLZ) for EVAR
  - $\geq$ 10 mm length parallel wall artery

- Bell-bottom iliac limbs (up to 28mm)
  - Problematic in ectatic iliac arteries
  - ↑ diameter of DLZ
  - ↑ Type Ib endoleak
Traditional Options

- Limb extension to EIA
  - Internal iliac artery occlusion w/ embolization coils/plugs

- Significant adverse side effects

  - 15–55% Significant Hip and/or Buttock Claudication
  - 2–3% Colon Ischemia
  - 5–45% Erectile Dysfunction
  - Rare Spinal Cord Ischemia

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Risks of Hypogastric Embolization

- **EVAR (n=82)**
- **EVAR with IIA Embolization (n=24)**

**106 total patients; Mean follow-up 42 months**

<table>
<thead>
<tr>
<th>Category</th>
<th>EVAR (n=82)</th>
<th>EVAR with IIA Embolization (n=24)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Complications</td>
<td>2.4%</td>
<td>12.5%</td>
</tr>
<tr>
<td>Reinterventions</td>
<td>12.8%</td>
<td>22.7%</td>
</tr>
<tr>
<td>Aneurysm Growth</td>
<td>9.4%</td>
<td>27.8%</td>
</tr>
</tbody>
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Associated with:
- Worse peri-operative outcomes
- Increased rates of mid- to late failure (including rupture)

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Alternate Preservation Options

Axillary/brachial access

Limitations of OSR


In Development

- Multiple devices available OUS to maintain antegrade hypogastric flow

Excluder Iliac Branch Endoprosthesis (IBE)

- Indicated for the treatment of:
  - Isolated common iliac artery aneurysm
  - Aortoiliac aneurysm
  - Preservation of flow into the external and internal iliac arteries

- Suitable anatomy
  - ≥17mm CIA diameter
  - 6.5 – 13.5mm IIA diameter with 10mm seal zone
  - 6.5 – 25mm EIA diameter with 10mm seal zone
  - Adequate length from lowest renal artery to IIA
  - Use with Gore Excluder AAA Endoprosthesis
IBE Design

Internal Iliac Component
- 12 French compatible
- 6.5 – 13.5mm treatment range
- Deploys hub to tip

Iliac Branch Component
- 16 French compatible
- 6.5 – 25mm EIA treatment range (with Excluder Iliac Extenders)
IBE Design
Technique
Technique
Technique
Technique
Technique
Technique
**U.S. IDE Clinical Trial Data**

- Primary enrollment of 63 patients @ 50 centers
  - Mean CIA diameter 3.9 cm ± 1.0 cm
  - Continued enrollment of 28 additional patients (data not included)

<table>
<thead>
<tr>
<th>Procedure Time</th>
<th>Technical Success*</th>
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<tbody>
<tr>
<td>152 Minutes</td>
<td>95.2%</td>
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<table>
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<tr>
<th>Fluoro Time</th>
<th>Contrast Volume</th>
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<tr>
<td>40 Minutes</td>
<td>114 mL</td>
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*Defined as successful implantation without endoleak
U.S. IDE Clinical Trial Data

• Primary enrollment of 63 patients @ 50 centers
  • Mean CIA diameter 3.9 cm ± 1.0 cm

<table>
<thead>
<tr>
<th>US IBE Clinical Trial Preliminary Data</th>
<th>1-month &amp; 6-month Follow-up</th>
</tr>
</thead>
<tbody>
<tr>
<td>External iliac artery Patency</td>
<td>100%</td>
</tr>
<tr>
<td>Internal iliac artery Patency</td>
<td>95%</td>
</tr>
<tr>
<td>Freedom from Re-intervention</td>
<td>98.4%</td>
</tr>
<tr>
<td>Aneurysm Enlargement (&gt; 5mm at 6 mo)</td>
<td>0%</td>
</tr>
<tr>
<td>Type I or III Endoleak</td>
<td>0%</td>
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<tr>
<td>Buttock Claudication</td>
<td>0%</td>
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<tr>
<td>New-Onset Erectile Dysfunction</td>
<td>0%</td>
</tr>
</tbody>
</table>
Supplemental Data

• European commercial data\textsuperscript{1-2}
  • EIA patency 98%
  • IIA patency 95%
  • Freedom from reintervention 98%
  • No buttock claudication
  • No erectile dysfunction

• Durable solution compared to parallel stent grafts
  • Improved patency (IIA: 95\% v. 88\% at 6-mo)
  • Greater freedom from re-intervention (98\% v. 87\% at 6-mo)

Summary

• Off-the-shelf solution for internal iliac artery preservation

• Wide component selection for varying anatomy

• Initial results promising, more follow-up needed
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