Results of the multicenter pELVIS registry for isolated common iliac aneurysms treated by the iliac branch device

G Pratesi, MD

Vascular Surgery
IRCCS Policlinico San Martino, University of Genoa
Policlinico Tor Vergata, University of Rome “Tor Vergata”
Disclosure

Speaker name:
Giovanni Pratesi

I have the following potential conflicts of interest to report:

☑ Consulting: Abbott, Cook, Cordis, Medtronic, WL Gore & Associates
☐ Employment in industry
☐ Stockholder of a healthcare company
☐ Owner of a healthcare company
☐ Other(s)

☐ I do not have any potential conflict of interest
Iliac branch device has reached a state of maturity

- Learning curves in the selection of patients and performance of the procedure
- Dedicated endograft
- High technical success
- Low risk of graft-related reintervention rate
- Improved clinical outcomes and quality of life
General Review

Iliac Aneurysms Treated with Endovascular Iliac Branch Device: A Systematic Review and Meta-analysis

Iliac preservation with IBD: 22 articles with 1064 patients

• 93% pooled technical success
• 30-day outcomes:
  – mortality 2%
  – patency 93%
• Follow-up outcomes:
  – patency 86%
  – endoleak 12%
  – buttock claudication 6%
  – reintervention 11%

Li Y et al., Ann Vasc Surg 2019 in press
Iliac branch device: standard of care unilateral, bilateral, isolated
Isolated iliac artery aneurysms

- 2% to 7% of all intra-abdominal aneurysms (0.03 prevalence in the general population)
- CIA is the most commonly involved (70% to 90% of cases)
- Isolated IIA aneurysms are rare (10% to 30% of cases)
The Treatment of Isolated Iliac Artery Aneurysm in Patients with Non-aneurysmal Aorta

W. Dorigo,* R. Pulli, N. Troisi, A. Alessi Innocenti, G. Pratesi, L. Azas and C. Pratesi

Surgical treatment of IAAs provides good early and mid-term results. During mid-term follow-up the diameter of abdominal aorta remains stable, suggesting IAA may be a localized aneurysmal disease.
When an iliac branch device to treat isolated iliac artery aneurysms?

- Presence of an adequate proximal common iliac neck (diameter, length and angulation)
- Feasibility for IBD (outside IFU)
- Potential need for proximal extension (cuff, covered stent)
Iliac branch device
to treat isolated iliac artery aneurysms
Iliac branch device to treat isolated iliac artery aneurysms
Results of iliac branch device to treat isolated common iliac aneurysm

- December 2006 to June 2016
- 44 isolated CIAAs in 41 patients (3 bilateral) treated solely with an IBD at 7 vascular Italian centers
- 32 pts (2 bilat) received Cook ZBIS and 9 pts (1 bilat) were treated with Gore IBE
- 30-day mortality and the IBD occlusion rate were 2.4% and 2.3%,
- Mean follow-up: 40.2±33.9 months
Iliac branch device to treat isolated iliac artery aneurysms

Pre-op

3 yrs follow-up
Secondary Procedures Following Iliac Branch Device Treatment of Aneurysms Involving the Iliac Bifurcation: The pELVIS Registry

Konstantinos P. Donas, MD\textsuperscript{1,2}, Mirjam Inchingolo, MD\textsuperscript{1,2}, Piergiorgio Cao, MD\textsuperscript{3}, Carlo Pratesi, MD\textsuperscript{4}, Giovanni Pratesi, MD\textsuperscript{5}, Giovanni Torsello, MD\textsuperscript{1,2}, Georgios A. Pitoulias, MD, PhD\textsuperscript{6}, Ciro Ferrer, MD\textsuperscript{3}, Gianbattista Parlani, MD\textsuperscript{7}, and Fabio Verzini, MD\textsuperscript{7}, on behalf of the pELVIS Registry collaborators

650 iliac branch in 575 pts between 2005 and 2015; mean follow-up 32.6±9.9

- 621 Cook ZBIS, 29 Gore IBE
- 8.9% overall postoperative reintervention rate
- 4.6% IBD occlusion
- 4.3% type I EL IBD-related
AIM OF THE STUDY:

To evaluate short- and long-term results of off-label use of IBDs in isolated common iliac artery aneurysms compared with IBD and concomitant bifurcated aortic stent-graft based on the pELVIS Registry (pERformance of iLiac branch devIces for aneurysmS involving the iliac bifurcation).

J Vasc Surg 2018
Study group

Pelvis Registry
• 910 IBDs in 804 patients underwent EVAR for aorto-iliac aneurysm
• 9 high-volume European vascular centers
• January 2005 and April 2017

231 IBDs were implanted in 207 patients to treat an isolated common iliac aneurysm

91 ISOLATED IBDS (GROUP 1)

140 IBDS+BIFURCATED EG (GROUP 2)
## Demographics

<table>
<thead>
<tr>
<th></th>
<th>Group 1 (91 isolated IBDs)</th>
<th>Group 2 (140 IBDs+bif EG)</th>
<th>( \rho )</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Age</strong></td>
<td>70.4 ±8.8</td>
<td>71.1 ±8.9</td>
<td>.58</td>
</tr>
<tr>
<td><strong>Men</strong></td>
<td>84 (92.3%)</td>
<td>134 (95.7%)</td>
<td>.27</td>
</tr>
<tr>
<td><strong>Comorbidities</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Diabetes mellitus</td>
<td>12 (13.2%)</td>
<td>26 (18.6%)</td>
<td>.29</td>
</tr>
<tr>
<td>Hyperlipidemia</td>
<td>46 (50.5%)</td>
<td>82 (58.6%)</td>
<td>.26</td>
</tr>
<tr>
<td>Hypertension</td>
<td>72 (79.1%)</td>
<td>119 (85%)</td>
<td>.32</td>
</tr>
<tr>
<td>Cardiac Insufficiency</td>
<td>31 (34.1%)</td>
<td>60 (42.9%)</td>
<td>.20</td>
</tr>
<tr>
<td>COPD</td>
<td>20 (22%)</td>
<td>24 (17.1%)</td>
<td>.64</td>
</tr>
<tr>
<td>Smoking History</td>
<td>39 (42.6%)</td>
<td>67 (47.9%)</td>
<td>.50</td>
</tr>
<tr>
<td>CKD</td>
<td>6 (6.6%)</td>
<td>19 (13.6%)</td>
<td>.09</td>
</tr>
</tbody>
</table>
## Aneurysm morphology

<table>
<thead>
<tr>
<th>(mean diameter, mm)</th>
<th>Group 1 (91 isolated IBDs)</th>
<th>Group 2 (140 IBDs+bif EG)</th>
<th>$p$</th>
</tr>
</thead>
<tbody>
<tr>
<td>Abdominal aorta</td>
<td>30.2 ±11.5</td>
<td>32.2 ±9.8</td>
<td>.47</td>
</tr>
<tr>
<td>CIA on treated site</td>
<td>35.2 ±10.4</td>
<td>37.2 ±11.7</td>
<td>.19</td>
</tr>
<tr>
<td>IIA on treated site</td>
<td>19.9 ±15</td>
<td>16.5 ±10.4</td>
<td>.08</td>
</tr>
<tr>
<td></td>
<td>Group 1 (91 isolated IBDs)</td>
<td>Group 2 (140 IBDs+bif EG)</td>
<td>p</td>
</tr>
<tr>
<td>-----------------------------------</td>
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<td>---------------------------</td>
<td>------</td>
</tr>
<tr>
<td>Technical success</td>
<td>90 (98.9%)</td>
<td>137 (97.8%)</td>
<td>.55</td>
</tr>
<tr>
<td>Mortality</td>
<td>1 (1.1%)</td>
<td>-</td>
<td>.21</td>
</tr>
<tr>
<td>Type 1 A-B endoleak</td>
<td>1 (1.1%)</td>
<td>2 (1.4%)</td>
<td>.83</td>
</tr>
<tr>
<td>Type III endoleak</td>
<td>1 (1.1%)</td>
<td>1 (0.7%)</td>
<td>.77</td>
</tr>
<tr>
<td>IBD occlusions</td>
<td>2 (2.2%)</td>
<td>2 (1.4%)</td>
<td>.65</td>
</tr>
<tr>
<td>Procedure-related reinterventions</td>
<td>4 (4.4%)</td>
<td>3 (2.1%)</td>
<td>.33</td>
</tr>
</tbody>
</table>
### Long-term outcomes

<table>
<thead>
<tr>
<th>Event</th>
<th>Group 1 (91 isolated IBDs)</th>
<th>Group 2 (140 IBDs+bif EG)</th>
<th>( p )</th>
</tr>
</thead>
<tbody>
<tr>
<td>Overall mortality</td>
<td>13 (14.3%)</td>
<td>14 (10%)</td>
<td>.31</td>
</tr>
<tr>
<td>Aneurysm-related mortality</td>
<td>1 (1.1%)</td>
<td>1 (0.7%)</td>
<td>.77</td>
</tr>
<tr>
<td>Type 1 A-B endoleak</td>
<td>4 (4.4%)</td>
<td>8 (6.1%)</td>
<td>.66</td>
</tr>
<tr>
<td>Type III endoleak</td>
<td>2 (2.2%)</td>
<td>2 (1.4%)</td>
<td>.65</td>
</tr>
<tr>
<td>IBD occlusions</td>
<td>5 (5.5%)</td>
<td>8 (5.7%)</td>
<td>.96</td>
</tr>
<tr>
<td>Isolated target IIA occlusions</td>
<td>2 (2.2%)</td>
<td>2 (1.4%)</td>
<td>.65</td>
</tr>
<tr>
<td>Isolated EIA occlusions</td>
<td>-</td>
<td>4 (2.8%)</td>
<td>.11</td>
</tr>
<tr>
<td>All-cause reinterventions</td>
<td>14 (15.8%)</td>
<td>26 (18.6%)</td>
<td>.53</td>
</tr>
<tr>
<td>Conversion to OSR</td>
<td>1 (1.1%)</td>
<td>2 (1.4%)</td>
<td>.83</td>
</tr>
</tbody>
</table>
Long-term results
Long-term results

Graph showing freedom from type I/II and IBD occlusion for two groups.

Graph showing freedom from all-cause reintervention for two groups.
Conclusions

• IBDs represent the main option to preserve antegrade flow to IIAs, when anatomically feasible, during endovascular aneurysm repair involving the iliac bifurcation
• Isolated IBD implants seems to be a safe and effective treatment option when a proper anatomic patient selection is provided, with similar results to standard implants, allowing to avoid coverage of healthy aorta
• The absence of endoleak or migration when using isolated IBD suggest the optimal stability and seal even in absence of an aortic stent-graft
IBDs To Treat Isolated Iliac Artery Aneurysm: a safe and effective treatment option
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