The hypogastric artery preservation should be first line strategy in 2018

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Lisbon.
Disclosure

Speaker name:

Nilo J Mosquera, MD.

I have the following potential conflicts of interest to report:

☑ Consulting: Lombard Medical, Cook Medical, WL Gore, Bolton Medical, Cordis Cardinal Health, JOTEC

Employment in industry

Stockholder of a healthcare company

Owner of a healthcare company

☑ Other(s): Spanish National Health Service Employee

I do not have any potential conflict of interest
Index

1. Is hypogastric preservation a real need?

2. Can we go beyond the limits with Cook ZBIS platform?

3. New options in tortuous anatomies: Our experience with WL Gore IBE
EVAR : concerns about pelvic circulation

Up to 40% AAA have common iliac disease*.


<table>
<thead>
<tr>
<th>n</th>
<th>Complication</th>
<th>Conclusion</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Mehta M, Veith FJ (J Vasc Surg 2001)</td>
<td>Unilateral internal iliac occlusion</td>
<td>Hypogastric preservation seems reasonable</td>
</tr>
</tbody>
</table>

| 1. Arko FR, Lee WA (J Vasc Surg. 2004) | Bilateral occlusion | Hypogastric preservation is mandatory |
| 2. Dix FP, Titulaer JS (Eur J Vasc Endovasc Surg 2005) | Significative Increase in mortality and morbidity |

Colon and spinal ischemia are directly related to hypogastric patency.
1. Is hypogastric preservation a real need?

Yes, it is!!!
EVAR for aorto-iliac aneurysm: Iliac branch devices

IBD are regular therapy with great clinical success and good mid-term results

<table>
<thead>
<tr>
<th>Authors</th>
<th>n</th>
<th>Complication/technical success/Patency</th>
<th>FU</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Initial Experience</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Malina M, Dirven M (J Endovasc Ther. 2006)</td>
<td>10</td>
<td>10%/90%/90%</td>
<td>1-32 months</td>
</tr>
<tr>
<td>Serracino-Inglot F, Bray AE (J Vasc Surg, 2007)</td>
<td>8</td>
<td>0%/100%/100%</td>
<td>1-14 months</td>
</tr>
<tr>
<td><strong>Current experience</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Haulon S, Greenberg RK (Eur J Vasc Endovasc Surg, 2007)</td>
<td>53</td>
<td>6%/94%/89%</td>
<td>14.2 months (mean FU)</td>
</tr>
<tr>
<td>Donas KP, Torsello G (J Vasc Surg. 2011)</td>
<td>64</td>
<td>5.9%/98.4%/98.4%</td>
<td>60 months</td>
</tr>
</tbody>
</table>

Good results mid and longterm FU
...iliac branched endografts ARE a demonstrated powerful approach to many cases.
Cook Medical Z-BIS™ Technology development.

Gen V IBD

>10000 grafts implanted

Gen V device designed and implanted from 2009

(Same graft as CE-Marked Gen IV)

- Shorter Common Iliac Section to allow ‘over the bifurcation’ insertion of the bridging stent in a higher percentage of cases
- It has a nitinol Z stent that is designed to contract the Sidebranch to a diameter of 6mm
- It has two nitinol reinforcing rings on side branch
- Changed to curved catheter and improved Flexor sheath

2009
IBD: Cook Medical Z-BISTM after CE Mark, increasing clinical experience and evidence.

2009

Internal Iliac Artery Branch Following Previous Op.

J. Nair, P. D. Hayes, U. J. Tompkins
Regional Vascular Unit, and Dept. Hospitals NHS Trust, Box 201, A1B
To demonstrate the use of a commercially available (IAA) in common iliac artery (CIA) aneurysm surgery.


case 1

A 67-year-old man was referred with a found to have an incidental aneurysm. EC
history included elective AAA tube graft 1993 and 2004. A computed tomography showed an 8 cm right CIA, 3.7 cm left a 2.3 cm right IIA (Fig. 1A).


2008

Endovascular abd. aneurysm repair in patients with additional iliac
aneurysms – Initial results with the bifurcated iliac si.

征信 辛克洛夫, MD, MSc, and Paul Myers, MBA, MS, FRCS (Ed) (Vasc & Endovasc Surg)

Objective: To present our initial experience with endovascular repair of iliac aneurysms. Methods: Between November 2005 and October 2007, 36 patients underwent endovascular repair of 1 or more iliac aneurysms. 21 patients had 1 iliac aneurysm, and 15 had 2 or more iliac aneurysms.最有效的

2013

Long-term Results of Iliac Artery Branch Devices: A French Multicenter Study

Universite de Bourgogne, Hospices Civils de Beaune, Franche-Comte, France

Background: The purpose of this study was to evaluate long-term results of endovascular treatment of common iliac artery (CIA) aneurysms with a stent graft by using iliac branch devices (IBDs), which enables maintenance of antegrade perfusion to the internal iliac artery (IIA).

Methods: Our investigation was done in a prospective, multicenter, nonrandomized manner. IBDs were implanted to exclude CIA aneurysms with a diameter >20 mm in patients unfit for open repair. The stent grafts were designed on a preoperative anatomical study. A covered stent implantation between the IIA and the target CIA was performed during the same surgical procedure. Angio-CT was completed on the 30 days after the procedure. From January 2009 to April 2012, 39 patients were included in our study (38 men and 1 woman, mean age 73 years).

Results: The CIA aneurysm (mean diameter 23.2 mm) was isolated in 15 patients and associated with an iliac branch aneurysm (mean diameter 69 mm) in 24 patients. The IBD was systematically connected to a bifurcated aorto-iliac stent graft. The bifurcated stent graft was implanted during the same procedure in all patients, except for two who had a bifurcated stent graft history. Median surgical time, fluoroscopy time, and volume of contrast product were 192 (range 90–360) minutes, 32.3 (range 20–140) minutes, and 150 (range 95–262) ml, respectively. In 37 patients (95%), the internal iliac branch was patent at the end of the surgery. In two patients (5%), it was occluded, enabling a subselective coiled stent with embolus in one of them. To treat a type I endoleak, a proximal extension partially covering a renal artery was implanted during the same surgery. A type III endoleak was diagnosed on the postoperative angiography and CT. In three patients, a cross-over fenestrated stent graft was performed for an external

2007

After IBD: Cook Medical Z-BISTM after CE Mark, increasing clinical experience and evidence.
Surgical versus endovascular repair by iliac branch device of aneurysms involving the iliac bifurcation

Konstantinos P. Donas, MD, PhD,a Giovanni Torsello, MD, PhD,a Georgios A. Pitoulis, MD, PhD,b Martin Austermann, MD, PhD,a and Dimitrios K. Papadimitriou, MD, PhD,b Münster, Germany; and Thessaloniki, Greece

All results in favour IBD Group

### January 2004 – March 2010

#### Table II. Results

<table>
<thead>
<tr>
<th></th>
<th>Open (n = 54)</th>
<th>Endovascular (n = 64)</th>
<th>P</th>
</tr>
</thead>
<tbody>
<tr>
<td>30-day severe morbidity (n; %)</td>
<td>5; 9.3%</td>
<td>3; 4.6%</td>
<td>&lt;.001</td>
</tr>
<tr>
<td>30-day mortality (n; %)</td>
<td>3; 5.5%</td>
<td>0; 0%</td>
<td>&lt;.001</td>
</tr>
<tr>
<td>30-day vascular complications (n; %)</td>
<td>1; 2%</td>
<td>2; 3.1%</td>
<td>.698</td>
</tr>
<tr>
<td>30-day non-vascular complications (n; %)</td>
<td>9; 16.7%</td>
<td>3; 6.3%</td>
<td>.025</td>
</tr>
<tr>
<td>Intensive care unit stay (mean ± SD in days)</td>
<td>2.5 ± 1.2</td>
<td>1.2 ± 0.4</td>
<td>NP</td>
</tr>
<tr>
<td>Postoperative stay (mean ± SD in days)</td>
<td>9.7 ± 4.1</td>
<td>4.1 ± 1.5</td>
<td>&lt;.001</td>
</tr>
<tr>
<td>Operative blood loss (mean ± SD in mL)</td>
<td>669 ± 460</td>
<td>89 ± 30</td>
<td>&lt;.001</td>
</tr>
<tr>
<td>Transfusion (mean ± SD in units of packed red cells)&lt;sup&gt;a&lt;/sup&gt;</td>
<td>1.6 ± 2.0</td>
<td>—&lt;sup&gt;a&lt;/sup&gt;</td>
<td>NP&lt;sup&gt;b&lt;/sup&gt;</td>
</tr>
<tr>
<td>Operative duration (mean ± SD in min)</td>
<td>197 ± 23</td>
<td>89 ± 24</td>
<td>.234</td>
</tr>
<tr>
<td>Related death during follow-up&lt;sup&gt;c&lt;/sup&gt;</td>
<td>1; 2%&lt;sup&gt;d&lt;/sup&gt;</td>
<td>—</td>
<td>NP&lt;sup&gt;b&lt;/sup&gt;</td>
</tr>
<tr>
<td>Primary endoleak (n; %)</td>
<td>—</td>
<td>8; 12.5%</td>
<td>NP&lt;sup&gt;b&lt;/sup&gt;</td>
</tr>
<tr>
<td>Primary patency (n; %)</td>
<td>51; 100%&lt;sup&gt;d&lt;/sup&gt;</td>
<td>63; 98.4%</td>
<td>.358</td>
</tr>
<tr>
<td>Buttock claudication (n; %)</td>
<td>3; 5.9%&lt;sup&gt;d&lt;/sup&gt;</td>
<td>2; 3.1%</td>
<td>.473</td>
</tr>
<tr>
<td>Colonic ischemia (n; %)</td>
<td>1; 2%&lt;sup&gt;d&lt;/sup&gt;</td>
<td>0; 0%</td>
<td>.263</td>
</tr>
<tr>
<td>Postoperative hernia</td>
<td>16; 31.4%&lt;sup&gt;d&lt;/sup&gt;</td>
<td>—</td>
<td>NP&lt;sup&gt;b&lt;/sup&gt;</td>
</tr>
</tbody>
</table>

*Cook Medical Z-BIST<sup>TM</sup> after CE Mark, increasing clinical experience and evidence*
Despite good results limitations related to anatomy.

Table 2  Inclusion criteria for IBD series.

<table>
<thead>
<tr>
<th>Author, year</th>
<th>Morphological inclusion criteria</th>
</tr>
</thead>
</table>
| Dias/Malina et al 2008/2006<sup>23,25</sup> | IIA diameter <11 mm  
IIA length >10 mm  
None specified  
CIA diameter >24 mm  
Difficulty with: intimal flaps, severe EIA kinking, >500 IIA of any length  
IIA calcification  
IIA lesion  
IIA length >11 mm  
IIA lumen <10 mm  
IIA length >18 mm  
Interaluminal thrombus)  
Relieve contra-indications:  
- Sharp aortic bifurcation, iliac tortuosity  
- Non-aneurysmal IIA  
- IIA not heavily stenotic  
- CIA diameter >24 mm  
- Patent CIA lumen >20 mm  
- CIA length >40 mm  
- IIA length >10 mm  
- EIA length >15 mm  
- None specified |
| Haulon/Greenberg et al, 2007/2006<sup>21,24</sup> |  
Serracino-Ingiott et al, 2007<sup>26</sup> |  
Ziegler et al, 2007<sup>29</sup> |  
Tielli et al, 2009<sup>27</sup> |  
Verzini et al, 2009<sup>28</sup> |
there are clear LIMITATIONS to IBD:

1. Complex and tortuous iliac anatomies are real contraindications for ZBIS itself

2. Tortuous aorta is a real contraindication for Zenith™ graft

3. Most of the patients with indication for iliac branch have tortuous anatomy
…can we go beyond the IFU restrictions to deal with complex anatomy?

ZBIS™: opportunities to boldly go…

Yes, we can!!!
IFU and Limitations

1. Short common iliac landing or only one iliac patent: Braquial/Axilar Access

- Preloaded wire/catheter: brachial-femoral technique
- AUI Main body first deployment
- Long Flexor™ 8 or 9F sheath directly to hypogastric artery
- Same technique is useful for bilateral ZBIS™
2. Tortuous and angulated iliacs: Short ZBIS™ and SPIRAL-Z™

- Deal with angulation using Spiral Z limb extensions (bridging and distal)
- Self expandable flexible stents (covered or uncovered) to reline with external iliac angulations
- Use the shorter ZBIS™ possible (45-41)
3. Tortuous and angulated hypogastric: Nitinol covered stents

Use Covered self-expandable stents to bridge the hypogastric
4. Proximal Hypogastric disease: use distal or hypogastric branch as target vessel

- Use longer Covered self-expandable stents to bridge the hypogastric
- Use a hypogastric branch as distal landing if suitable.
- Coil secondary branch if necessary.

8 mm x 10 cm Viabahn™
IFU and Limitations

4. Proximal Hypogastric disease: use distal or hypogastric branch as target vessel

Image Courtesy of A Massman  Saarland University Medical Center
5. Narrow lumen: Area calculation concept

16 mm is the minimum (IFU) lumen inner-inner diameter required for the ZBIS™

Using entire area means 12 mm minimum diameter so 14 mm should be enough

Use self expandable stents for iliac branch to deal with compression

10 mm ZBIS™ (external iliac)
The Zenith fenestrated™ graft.

Combination with IBD technique to preserve collateral flow and prevent neurological damage.
The Zenith abdominal branched™ graft.

Combination with IBD technique to preserve collateral flow and prevent neurological damage.
Serious Clinical Problem:

Preserve the Hypogastric Artery
Treating tortuous aortic anatomy (contraindication for Zenith graft)
And
Tortuous Iliacs (contraindication for ZBIS)
Index

1. Can we go beyond the limits with Cook ZBIS platform?

2. New options in tortuous anatomies: Our experience with WL Gore IBE
Our initial experience & results

Jorge F Noya
CHUS Hospital
Santiago de Compostela. Spain

Nilo J Mosquera
CHUO Hospital
Ourense. Spain
The WL Gore IBE™: our experience

January 2014-Jun 2015

30 patients treated (13 bilateral)

43 IBE implanted.

Age: 67 to 85 y (mean 73)

Gender: 29 Male / 1 female
The WL Gore IBE™: comorbidities

- HTA 45%
- DM 35%
- Active Smokers 35%
- Renal Induficiency 0%
- COPD 10%
- Obese 40%
- Coronary disease 45%
- ASA III&IV 60%
The iliac tortuosity index (τ) is defined as $\tau = L_1/L_2$ where $L_1$ is the distance along the central lumen line between the common femoral artery and the aortic bifurcation and $L_2$ is the straight-line distance from the common femoral artery and the aortic bifurcation (Fig 1, A). The iliac angle (φ) is the most acute angle in the pathway between the common femoral artery and the aortic bifurcation. Ideally, both the iliac angle and iliac tortuosity index are measured from spatially-correct three-dimensional data. They are scored as follows: 0, $\tau \leq 1.25$ or an iliac angle (φ) between 160° and 180°; 1, $1.25 < \tau < 1.5$ or φ between 121° and 159°; 2, $1.5 < \tau \leq 1.6$ or φ between 90° and 120°; 3, $\tau > 1.6$ or φ < 90°.
The WL Gore IBE™: procedure

Percutaneous Approach: 91%

Bifurcated C3 graft all cases

C3 main body and IBE + internal iliac component implant in 97% cases (29/30)

C3 main body + Iliac Branch + 13 mm Viabahn 2% (1 IBE) Off label procedure

Hypogastric embolization 3% (1 case)

7 cases use of Viabahn extension to internal iliac (1 case sandwich approach to hypogastric branches)
January 2014-June 2015

Technical success: 94% (28/30)
- 1 case use off label use of 13mm Viabahn.
- 1 case use acute thrombosis internal iliac.

Clinical success: 97% (1 case gluteal claudication)

The WL Gore IBE™: 1m FU results
The WL Gore IBE™: 1y FU

- No Type Ia, Ib or III endoleak
- 23% type II endoleaks
- No reinterventions
- No other Major or Significant Adverse events

- 1 external iliac oclusion (long distal claudication, incidental finding)

- Freedom from sac expansion 100% (clinical success)

- +1 internal iliac component oclusion (asymptomatic) 96% patency
Some Conclusions

1. Hypogastic preservation is nowadays mandatory if technically possible no matter how far why need to go!

2. There are interesting tips an tricks we can use to reduce anatomical contraindication to ZBIS™

3. ZBIS™ is a powerful tool in combination with fenestrated/thoracoabdominal repair to prevent neurological complications

4. WL Gore IBE is a new approach to hypogastic preservation in challenging anatomies
Status Update on Key Points & Beyond

27th - 29th MARCH 2019
Barcelona – Spain, School of Medicine, University of Barcelona

www.sitesymposium.com