Expand the indication for iliac branching: key clinical and technical learning in the bilateral treatment.
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, 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
25 ~ 40% OF ALL AAA CASES

iliac


EVAR: concerns about pelvic circulation

Clinical Value of Preservation

<table>
<thead>
<tr>
<th></th>
<th>n</th>
<th>Complication</th>
<th>Conclusion</th>
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<tbody>
<tr>
<td>1. Mehta M, Veith FJ (J Vasc Surg 2001)</td>
<td></td>
<td>Unilateral internal iliac occlusion</td>
<td>Hypogastric preservation seems reasonable</td>
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<tr>
<td>5. Semmens JB, (J Endo- vasc Ther 2006)</td>
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<td>-spinal ischemia</td>
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<td></td>
<td></td>
<td>all</td>
<td>Hypogastric preservation seems reasonable</td>
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<tr>
<td>2. Dix FP, Tit M (Eur J Vasc Endovasc Surg)</td>
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|   |   | Unilateral internal iliac occlusion              | Hypogastric preservation is mandatory           |
|   |   | -buttock claudication                            |                                                 |
|   |   | -impotence                                       |                                                 |
|   |   | -colonic ischemia                                |                                                 |
|   |   | -spinal ischemia                                 |                                                 |
|   |   | all                                              |                                                 |

Colon and spinal ischemia are directly related to hypogastric patency
EVAR: concerns about pelvic circulation
Clinical Value of Preservation

"...the question of whether to preserve or sacrifice the hypogastric artery is fundamental with regard to a possible decrease of complications..."
—Schönhofer, 2015

<table>
<thead>
<tr>
<th>15–55%</th>
<th>5–45%</th>
<th>2–3%</th>
<th>Rare</th>
</tr>
</thead>
<tbody>
<tr>
<td>Significant Hip and / or Buttock Claudication</td>
<td>Erectile Dysfunction</td>
<td>Colonic Ischemia</td>
<td>Spinal Chord Ischemia</td>
</tr>
</tbody>
</table>

EVAR: concerns about pelvic circulation

Results for WL IBE

U.S. IDE Clinical Trial Data*

- Key research outcomes

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<table>
<thead>
<tr>
<th>External Iliac Artery</th>
<th>Internal Iliac Artery</th>
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</thead>
<tbody>
<tr>
<td>100% Patency 1 and 6 months</td>
<td>95% Patency 1 and 6 months</td>
</tr>
</tbody>
</table>

98.4% Freedom from Reintervention

0% Buttock Claudication

0% New Onset Erectile Dysfunction

0% Aneurysm Enlargement (> 5 mm) at 6 Months

152 Minutes Procedure Time

40 Minutes Fluoro Time

114 ml Contrast Used

95.2% Technical Success**

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Primary enrollment of 62 patients. Data through six-month follow-up.

* For additional clinical study information, please refer to the One-Year U.S. Results publication referenced in the appendix of this document.

** Defined as successful implantation with lack of endoleaks.
EVAR: concerns about pelvic circulation

Results for WL IBE

<table>
<thead>
<tr>
<th>100% Procedure Survival</th>
<th>0% Mortality</th>
<th>0% Aortic Rupture</th>
</tr>
</thead>
<tbody>
<tr>
<td>100% EIA Patency</td>
<td>98% FREEDOM from Reintervention</td>
<td></td>
</tr>
<tr>
<td>0% Conversion to Open Repair</td>
<td>0% Sexual Dysfunction Reported</td>
<td></td>
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<tr>
<td>0% Buttock Claudication Reported</td>
<td>0% Reintervention related to patency of IIA</td>
<td></td>
</tr>
</tbody>
</table>

Global Registry for Endovascular Aortic Treatment (GREAT) Data*

* 58 patients enrolled in Europe and Australia through March 2016. Data through six months follow-up shown unless otherwise noted. Technical success: no device issues were reported as Serious Adverse Events related to elements of technical success definition.
• Society Clinical Practice Guidelines support the value of preservation.
  – U.S. (SVS, 2009): It is recommended that blood flow be preserved to at least one hypogastric artery in the course of OSR or EVAR.¹
  – Europe (ESVS, 2011): Preservation of flow to at least one hypogastric artery is recommended in standard risk patients.²

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**EVAR:** concerns about pelvic circulation

Clearly preservation is strong Recommendation confirmed in current ESVS Guidelines

<table>
<thead>
<tr>
<th>Recommendation</th>
<th>Class</th>
<th>Level</th>
<th>References</th>
</tr>
</thead>
<tbody>
<tr>
<td>Recommendation 53</td>
<td>I</td>
<td>C</td>
<td>[49,65,66,443]</td>
</tr>
<tr>
<td>In open abdominal aortic aneurysm repair, it is recommended to preserve the blood flow to at least one internal iliac artery to reduce the risk of buttock claudication and colonic ischaemia.</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Recommendation 104</td>
<td>I</td>
<td>B</td>
<td>[302]</td>
</tr>
<tr>
<td>Preserving blood flow to at least one internal iliac artery during open surgical and endovascular repair of iliac artery aneurysms is recommended.</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Recommendation 105</td>
<td>I</td>
<td>C</td>
<td>[302]</td>
</tr>
<tr>
<td>In patients where internal iliac artery embolisation or ligation is necessary, occlusion of the proximal main stem of the vessel is recommended if technically feasible, to preserve distal collateral circulation to the pelvis.</td>
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</table>
EVAR: concerns about pelvic circulation
Do we have some clue in bilateral treatment?

**CONCLUSIONS**

This study represents the largest experience to date for endovascular treatment of bilateral CIA aneurysms using IBD. Preservation of bilateral IIAs in repair of bilateral CIA aneurysms can be performed safely with excellent technical success and short-term patency rates using the bilateral IBE technique and may provide some improvement in renal function over a unilateral approach. Extra fluoroscopy and procedural time as well as contrast material used for bilateral cases compared with unilateral cases appears to be minimal and should not be a deterrent to preserving flow to both IIAs in cases in which it is necessary.

Bilateral preservation with IBE can be achieved with excellent tech success and patency rates.
EVAR: concerns about pelvic circulation?

Do we have some clue in bilateral treatment?

The results of the present study are in line with those of Maldonado et al., and with those reported in the unilateral IBD studies for technical success, mortality, IBD patency, and re-intervention. EIA limb patency was also good, with only one (1.8%) occlusion registered during follow up. This suggests that adding a second IBD does not increase operative risks in anatomically suitable cases. Considering that all three patients with initial morbidity, the OF results in the unilateral IBD studies of 1-128

Adding a second iliac branch does not increase operative risk or affect FU result.

Technical success: 95%

Estimated IIA branch patency at one and three years was 97.8% and 88.5%.

Cook Medical ZBIS®
EVAR: concerns about pelvic circulation
Do we have some clue in bilateral treatment?

3 recent papers reporting good technical success and Patency at FU for Unilateral treatment.

12 bilateral patients reported from the E-Iliac collaborative group study by Mylonas et al.

No subgroup analysis so far for JOTEC E-Iliac branch graft in bilateral approach but global results suggest also good performance.
EVAR: concerns about pelvic circulation

Our Results for WL Gore® IBE

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EVAR: concerns about pelvic circulation

Our Results for WL IBE: series

Jan 2014-Dec 2018

60 patients treated (19 bilateral)

79 IBE implanted.

Age: 63 to 91 y (mean 76)

Gender: 58 Male / 2 female

5 years FU Mean FU 2 years
EVAR: concerns about pelvic circulation

Our Results for WL IBE

ITI evaluation

The iliac tortuosity index ($\tau$) 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 ($\phi$) 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 ($\phi$) between 160° and 180°; 1, $1.25 < \tau \leq 1.5$ or $\phi$ between 121° and 159°; 2, $1.5 < \tau \leq 1.6$ or $\phi$ between 90° and 120°; 3, $\tau > 1.6$ or $\phi < 90°$.

Identifying and grading factors that modify the outcome of endovascular aortic aneurysm repair.
Chaikof EL, Fillinger MF, Matsumura JS, Rutherford RB, White GH, Blankstein JD, Bernhard VM, Harris PL, Kent KC, May J, Veith FJ, Zarrin CK.
EVAR: concerns about pelvic circulation

Our Results for WL IBE
1 month FU results

Technical success: 97% (76/79)

- 1 case use off label use of 13mm Viabahn.
- 1 case use acute thrombosis internal iliac.
- 1 case off label use Endurant Limb as bridge extension and type III leak

Clinical success: 98.3% (1 case gluteal claudication)
EVAR: concerns about pelvic circulation

Our Results for WL IBE

3 year FU results

No Type Ia, Ib or III endoleak

32% type II endoleaks

96% freedom from reintervention

98.3 freedom from AAA mortality: 1 graft infection LLC patient

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

Freedom from sac expansion 98.3% (clinical success)/ IMA type II to be treated

+1 internal iliac component oclusion (asymptomatic) 96% patency
EVAR: concerns about pelvic circulation

Our Results for WL IBE

3 year FU results

2 cases gluteal claudication: both unilateral + contralateral embolization

No significative difference in patency or redo between uni and bilateral treatment

Difference in clinical success in favour to BILATERAL approach

Results comparable to those reported by Tom Maldonado for Bilateral IBE and Patency Rate superior to that reported by Eric Voerhoeven for bilateral ZBIS
EVAR: concerns about pelvic circulation

Clinical Value of Preservation

Is hypogastric preservation a real need from the clinical point of view?

Yes, it is!!!!
EVAR: concerns about pelvic circulation
A decalogue of 10 Key technical learnings

1. Tortuosity is not a contraindication

The graft will conform but it will be challenging.
EVAR: concerns about pelvic circulation
A decalog of 10 Key technical learnings

2. Use 0.035” hydrophilic cross over wire and Dry-Seal Flex Sheats

3. Use Short tip (1 cm) Amplatz superstiff wire to advance the internal ileac component

4. Use balloon technique to support advance and retrieve of components: make the procedure more stable
EVAR: concerns about pelvic circulation
A decalogue of 10 Key technical learnings

5. Do the “easiest” branch first and think about the crossing angle for the second one
6. Size the bridge extension without any stiff wire: mimic the anatomy.

7. Deploy the bridging components without stiff support, slow deployment to help the graft to conform.

8. Deploy the bridging components without stiff support: start the deployment below IBE marker: this is also useful in cases with short distance from renal to hypogastric.
EVAR: concerns about pelvic circulation
A decalog of 10 Key technical learnings

9. Mould with balloon and prepare for the final run without any stiff wire: mimic the anatomy
EVAR: concerns about pelvic circulation

A decalog of 10 Key technical learnings

10. As in all our complex cases final run without any stiff wire: prevent complications related to conformation
EVAR: concerns about pelvic circulation

Economic Value of Preservation

In my institution
EVAR: concerns about pelvic circulation

Economic Value of Preservation

Unilateral treatment IBE evaluation

8 unilateral patients treated

Always 3 pieces strategy + Iliac branch and internal component

All case in total 5 pieces: 16763 euros/case

Complication rate: 0%

Discharge 24h fast track protocol

Reintervention rate 0% at 1.5 y mean FU
EVAR: concerns about pelvic circulation

Economic Value of Preservation

Unilateral treatment coil and cover evaluation (historic cohort)

15 unilateral patients treated

Always 3 pieces strategy + 1 limb extension

Complication rate: 20 buttock claudication

Discharge 24h fast track protocol

Total cost per case: 15499 Euros

Mean 7.2 coils per case: 18631 euros/case

Hipogastric related Reintervention 7% at 3 y mean FU

just 1264 Euros/7.5% favours coil&cover
EVAR: concerns about pelvic circulation

Economic Value of Preservation

Unilateral treatment coil and cover evaluation (historic cohort): redo cost

Hipogastric related
Reintervention 7%
at 3 y mean FU

Redo procedure:
transgraft enembolization (more proximal) successful

Cost for this procedure including 2 days hospital care and OR cost: 16660 Euros

Total cost per case: 16660 Euros

Total cost for the coil and cover series: 249914 Euros

Equal than preservation if we include reintervention related to HYPOGASTRIC
EVAR: concerns about pelvic circulation

Economic Value of Preservation

Bilateral treatment IBE evaluation

9 patients treated (IFU)

Always 3 pieces strategy + 2 Iliac branch and 2 internal component

All case in total 7 pieces: 21863 euros/case

Complication rate: 0%

Discharge 24h fast track protocol

Reintervention rate 0% at 1.5 y mean FU
EVAR: concerns about pelvic circulation

Economic Value of Preservation

Bilateral sequential treatment coil and cover evaluation (historic cohort)

7 unilateral patients treated Always 3 pieces strategy + 2 limb extension to external

All cases in total 5 pieces: 15731 euros/case

Complication rate: 42% buttock claudication

No major complications Hipogastric related

Reintervention 0% at 4 y mean FU

2 Stages procedure:

4700 euros added for 1st stage embolization

Bilateral embolization could be even more expensive than bilateral preservation

Total cost calculation: Bilateral vs Unilateral vs coil and cover: 1639 euros extra cost (9%)

Total cost per case: 18218 Euros

just 3645 Euros/16% less than preservation
EVAR: concerns about pelvic circulation
Preservation vs Coil and cover

- Coil and cover can introduce additional complications compared to standard EVAR:
  - Increased complication rates
  - Increased reintervention rates
  - Increased aneurysm growth rates
  - This involves an adjunct procedure

Higher complication rate
Higher reintervention rate

Mean follow-up period of 42 months

EVAR: concerns about pelvic circulation

Economic Value of Preservation

Some thoughts

The difference between preservation and coil and cover is not major in economic value even with no immediate complications and cost increase is clearly related to material. Bilateral embolization is more complex and expensive than preservation: **Bilateral preservation is the way to go.**

The impact of the potentially higher complication rate or redo procedure for the coil and cover technique **can make even more expensive this particular technique.**
Conclusions

1. Hypogastric preservation is nowadays mandatory if technically possible.

2. The clinical value of preservation is clear to prevent complications and preserve function, even more in bilateral cases.

3. The preservation technique seems to be efficient from the economical point of view and the cost can be even lower than coil and cover taking care of mid and long term FU.
Status Update on Key Points & Beyond

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

www.sitesymposium.com
Expand the indication for iliac branching: key clinical and technical learning in the bilateral treatment

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