How effective is preservation when viewed through a clinical and economic lens?

Nilo J Mosquera, MD.

Head of Department
Angiology and Vascular Surgery Department.
Complexo Hospitalario Universitario de Ourense.
CHUO. Spain

Disclosure

Speaker name:

Nilo J Mosquera, MD.

I have the following potential conflicts of interest to report:

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

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
ANEURYSMAL DISEASE
extends into the common iliac arteries

25 ~ 40% OF ALL AAA CASES\textsuperscript{1-2}


EVAR: concerns about pelvic circulation

Clinical Value of Preservation

- 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

<table>
<thead>
<tr>
<th>n</th>
<th>Complication</th>
<th>Conclusion</th>
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Unilateral internal ilac occlusion -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..."
—Schönofer, 2015

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

EVAR: concerns about pelvic circulation

Results for WL IBE

### U.S. IDE Clinical Trial Data*

- Key research outcomes

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

<table>
<thead>
<tr>
<th>98.4% Freedom from Reintervention</th>
</tr>
</thead>
<tbody>
<tr>
<td>0% Buttock Claudication</td>
</tr>
<tr>
<td>0% New Onset Erectile Dysfunction</td>
</tr>
<tr>
<td>0% Aneurysm Enlargement (&gt; 5 mm) at 6 Months</td>
</tr>
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<table>
<thead>
<tr>
<th>152 Minutes Procedure Time</th>
</tr>
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<tr>
<td>40 Minutes Fluoro Time</td>
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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>
</tr>
</thead>
<tbody>
<tr>
<td><strong>0% Mortality</strong></td>
</tr>
</tbody>
</table>

| 100% EIA Patency | **at 6 months** |
|------------------|
| **0% Conversion** | **98% FREEDOM from Reintervention** |
| to Open Repair | |

<table>
<thead>
<tr>
<th>0% Buttock Claudication Reported</th>
<th><strong>0% Sexual Dysfunction Reported</strong></th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>0% Reintervention related to patency of IIA</strong></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.
EVAR: concerns about pelvic circulation
Results for WL IBE

Jorge F Noya
CHUS Hospital
Santiago de Compostela.
Spain

Nilo J Mosquera
CHUO Hospital
Ourense. Spain
EVAR: concerns about pelvic circulation

Our Results for WL IBE: series

January 2014-Jun 2015

30 patients treated (13 bilateral)

43 IBE implanted.

Age: 67 to 85 y (mean 73)

Gender: 29 Male / 1 female
EVAR: concerns about pelvic circulation

Our Results for WL IBE: comorbidities

<table>
<thead>
<tr>
<th>Condition</th>
<th>Percentage</th>
</tr>
</thead>
<tbody>
<tr>
<td>HTA</td>
<td>45%</td>
</tr>
<tr>
<td>DM</td>
<td>35%</td>
</tr>
<tr>
<td>Active Smokers</td>
<td>35%</td>
</tr>
<tr>
<td>Renal Insuficiency</td>
<td>0%</td>
</tr>
<tr>
<td>COPD</td>
<td>10%</td>
</tr>
<tr>
<td>Obese</td>
<td>40%</td>
</tr>
<tr>
<td>Coronary disease</td>
<td>45%</td>
</tr>
<tr>
<td>ASA III&amp;IV</td>
<td>60%</td>
</tr>
</tbody>
</table>
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 1A). 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 < $\tau$ < 1.5 or $\phi$ between 121° and 159°; 2, 1.5 < $\tau$ < 1.6 or $\phi$ between 90° and 120°; 3, $\tau$ > 1.6 or $\phi$ < 90°.

1.1 to 1.8

Mean 1.4


Identifying and grading factors that modify the outcome of endovascular aortic aneurysm repair.

Chaiken EL, Fillinger MF, Matsumura JS, Rutherford RB, White GH, Blankensteijn JD, Bernhard VM, Harris PL, Kent KC, May JS, Veith FJ, Zarins CK.
EVAR: concerns about pelvic circulation

Our Results for WL IBE: procedure

Percutaneous Approach: 91%

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*

Bifurcated C3 graft all cases

Hypogastric embolization 3% (1 case)

7 cases use of Viabahn extension to internal iliac (1 case sandwich approach to hypogastric branches)
EVAR: concerns about pelvic circulation

Our Results for WL IBE
1 month FU results

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)
EVAR: concerns about pelvic circulation

Our Results for WL IBE

1 year FU results

- No Type Ia, Ib or III endoleak
- 23% type II endoleaks
- No reinterventions
- No other Major or Significant Adverse events
- 1 external iliac occlusion (long distal claudication, incidental finding)
- Freedom from sac expansion 100% (clinical success)
- +1 internal iliac component occlusion (asymptomatic) 96% patency
EVAR: concerns about pelvic circulation preservation vs Coil and cover

- Coil and cover can introduce additional complications compared to standard EVAR\(^1\)
  - Increased complication rates
  - Increased reintervention rates
  - Increased aneurysm growth
  - This involves an adjunct procedure

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

Yes, it is!!!!
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

Total cost per case: 15499 Euros

just 1264 Euros/7.5% plus than preservation

13631 euros/case

Complication rate: 20 buttoc claudication%

Discharge 24h fast track protocol

Hipogastric related Reintervention 7% at 3 y mean FU
EVAR: concerns about pelvic circulation

Economic Value of Preservation

Unilateral treatment coil and cover evaluation (historic cohort)

- Hipogastric related Reintervention 7% at 3 y mean FU
- Redo procedure: transgraft reenbolization (more proximal)

Cost for this procedure including 2 days hospital care and OR costs: 21700 Euros

Total cost per case: 16660 Euros

Total cost for the coil and cover series: 249914 Euros

Equal than preservation
EVAR: concerns about pelvic circulation
Preservation vs Coil and cover

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

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 (7.5% of procedure value) and cost increase is clearly related to material.

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.

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.

4. WL Gore IBE is a new approach to hypogastric preservation in all kind of anatomies.
ACTUALIDAD DE LOS TEMAS CLAVE Y MÁS ALLÁ
STATUS UPDATE ON KEY POINTS & BEYOND

12 Simposio Internacional sobre Terapéutica Endovascular
International Symposium on Endovascular Therapeutics

29 al 31 de Marzo de 2017
29th to 31st March 2017

Barcelona - España - Spain
Facultat de Medicina, Universitat de Barcelona
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