Interventional options for treatment of pelvic vein congestion syndrome

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Not the easiest diagnosis......

• I am quoting extensively from two European experts

Miguel Angel de Gregorio

Tony Lopez
Their experiences are subtly different....

- Lopez et al mainly performed PVE in the context of abolishing supply to primary or recurrent lower extremity varicose veins and vulval varices

- De Gregorio et al mainly describe PVE for PVCS

- J Vasc Interventional Radiology Volume 29, Issue 1, Pages 45-53 (January 2018) de GREGORIO
A Randomized Trial of Endovascular Embolization Treatment in Pelvic Congestion Syndrome: Fibered Platinum Coils versus Vascular Plugs with 1-Year Clinical Outcomes

Jose A. Guirola, MD, Maria Sánchez-Ballestin, MD, Sergio Sierre, MD, Celia Lahuerta, MSc, Victoria Mayoral, MD, PhD, Miguel A. De Gregorio, MD, PhD

Journal of Vascular and Interventional Radiology
Volume 29, Issue 1, Pages 45-53 (January 2018)
DOI: 10.1016/j.jvir.2017.09.011
Patients in follow up or treatment for lower limb varices
(performed by angiologist & vascular surgeon)

Screening questionnaire for PCS
Abdominal or chronic pelvic pain for more than 6 months?
Increased dysmenorrhea?
Dyspareunia?
Low back pain?
Visible varices in vulvar area and/or the groin?

If 3 or more answers positive

Ultrasound study

- Patient in supine position
- Transabdominal US (2-4 MHz convex transducer)
  - Internal diameter of left and right ovarian veins: > 6 mm
  - Flow direction of the ovarian veins (Color and duplex US): presence of reverse caudal flow
- Transvaginal US (5-9 MHz transducer)
  - Pelvic plexus: Measurement of maximal diameters and velocities (> 6mm, <3 cm/s)
  - Midline examination: Dilated tortuous arcuate veins in the myometrium that communicate with bilateral pelvic varicose veins
  - Valsalva maneuver: Change of the Duplex waveform, reverse caudal flow
  - Ovarian examination: Presence of polycystic changes
  - Vulva and groin examination: Presence of communicating veins

If veins of more than 6 mm in diameter
AND /OR
Venous reflux or dilated midline communicating veins

Randomization Process

- Computer software generated a block randomization allocation sequence of 4 patients in each block.
- The referred patients from the vascular surgeon were listed in the order of referral and were only randomized patients if:
  - US findings were positive (6 mm in diameter and/or venous reflux).
  - Signed and accepted informed consent to participate in the study.

Endovascular Treatment

- All Patients systematically were targeted for embolization procedure of the four main venous axes

The recruitment stopped when 100 patients were treated
Assuming their symptoms fit and the imaging agrees what are the interventional options?

• Surgery/Laparoscopic ligation of varices
• Hysterectomy
• Pelvic Vein Embolisation
Technique:

- R IJV access
- Based on prior imaging: selective catheterisation and embolization of:
  - Left ovarian V
  - Right Ovarian V
  - Left Internal Iliac Vein
  - Right Internal Iliac Vein
My (amateur) technique

- 2 x 5 F sheaths
- Catheterisation of L Ovarian Vein
- “Loop the loop” into Right Ovarian Vein
  - (Tony Lopez showed me this)
- (If you cannot get catheter all the way to the top of the Right Ovarian Vein, refluxing contrast into it from below will enable catheterisation of R Ov V from above through 2\textsuperscript{nd} 5 F sheath)
- Coils to all proximal veins; foam to all distal
Use of an occlusion balloon for Descending venography and Embolisation is very useful in my opinion.
What did recent JVIR paper show

- 100 patients:
  - 50 with fibred platinum coils (FPCs)
  - 50 with plugs
- Treatment of veins identified on pre-op US
- 1 year follow up
- Efficacy similar between two groups at over 90%
- Fluoroscopy time and radiation dose significantly less in plug group
- Cost slightly higher in Plug group
<table>
<thead>
<tr>
<th>Variable</th>
<th>FPC (n = 50)</th>
<th>VP (n = 50)</th>
<th>P</th>
</tr>
</thead>
<tbody>
<tr>
<td>Embolization devices, median; range</td>
<td>18.0; 15–21</td>
<td>4.0; 4–7</td>
<td>.000*</td>
</tr>
<tr>
<td>Cost of embolization devices, €, median; range</td>
<td>2,915.90; 2,430.00–3,401.93</td>
<td>3,520.00; 3,520.00–6,160.00</td>
<td>.000*</td>
</tr>
<tr>
<td>Total procedure time, min, mean ± SD</td>
<td>44.5 ± 4.09</td>
<td>29.0 ± 5.95</td>
<td>.000††</td>
</tr>
<tr>
<td>Fluoroscopy time, min, mean ± SD</td>
<td>33.4 ± 4.68</td>
<td>19.5 ± 6.14</td>
<td>.000††</td>
</tr>
<tr>
<td>DAP, mGy·cm², median; range</td>
<td>384,957.0; 118,125.0–632,758.0</td>
<td>144,287.5; 879,90.0–451,817.0</td>
<td>.000*</td>
</tr>
<tr>
<td>Total air kerma, mGy, median; range</td>
<td>975.9; 233.98–2,132.40</td>
<td>296.0; 189.37–986.49</td>
<td>.000*</td>
</tr>
</tbody>
</table>
Different embolic agents

• Each company has an offering in this arena
• Plugs or plug like devices:
  – Amplatzer (St. Jude)
  – “Hourglass” (Emba Medical)
  – Caterpillar (Bard)
• Glue-
• Foam – Sclerovein 1%; 3%
• Coils:
  – Detachable
  – Non-detachable
# BARD CATERPILLAR™ Vascular Embolization Device Development Pipeline

<table>
<thead>
<tr>
<th>Device</th>
<th>Target Vessel Diameter</th>
<th>Unconstrained Device Length</th>
<th>Catheter ID</th>
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</thead>
<tbody>
<tr>
<td>Caterpillar 027*</td>
<td>1.5 – 4 mm</td>
<td>15 mm</td>
<td>0.027”</td>
</tr>
<tr>
<td>Caterpillar 038*</td>
<td>3 – 6 mm</td>
<td>20 mm</td>
<td>0.038”</td>
</tr>
<tr>
<td>Caterpillar 070*</td>
<td>5 – 7 mm (arteries) 5 – 11 mm (veins)</td>
<td>30 mm 100 mm 150 mm</td>
<td>0.070”</td>
</tr>
</tbody>
</table>

*Product still under development, dimensions/product offering may be subject to change
BSCI
St. Jude- Amplatzer family
Cook Medical
• **EMBA Hourglass Embolization Plug**
  
  – CE Mark Granted
  
  – 510(k) Clearance Received 2017
  
  – Established Reimbursement

*EMBA Medical and Hourglass are trademarks of EMBA Medical, Inc.*
Hourglass™: One Device Treats Majority of Vessels

54 SKUs replaced by Hourglass™

3 Total SKUs needed when Hourglass™ sub-3mm and +8mm launch

Sub 3mm Vessels

3mm to 8 mm Vessels

Over 8mm Vessels

Neuro

Peripheral
Medtronic

Onyx™ liquid embolic system

Concerto™ detachable coils system

MVP™ Microvascular Plug System

Access products, e.g. Micro catheters

Pictures are property of Medtronic
Glue does not last for life. It is only for few years!!

Pelvic congestion Syndrome treated by Glue and Lipiodol
Curtesy of Dr Jamal Alkoteesh
Chief of Interventional Radiology/AAH/SEHA/UAE
A little taster of the different products available

- Pelvic Vein Embolisation will grow
- Treatment is rewarding for the patient; and personally satisfying for you
- Become familiar with the literature and the different devices
- In recent paper plugs were faster and required less radiation, with minimal difference in costs
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