Approaches for fem-pop complex disease: What is the best option?

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Disclosure

Speaker name:
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I have the following potential conflicts of interest to report:

☒ Consulting: unpaid consultant, W.L. Gore, RELINE MAX Global PI
☐ Employment in industry
☐ Stockholder of a healthcare company
☐ Owner of a healthcare company
☐ Other(s)

☐ I do not have any potential conflict of interest
Session Highlights

- Viastar- VB vs. BMS
- SuperB- VB vs. bypass
- Reline- VB vs. PTA for ISR
- Viper- VB for complex SFA disease
- Japan IDE- VB for complex SFA disease
VIPER Clinical Study

- Prospective, multi-center, 12 US sites
- 119 limbs
- Independent core lab vessel sizing
- Primary patency (PSVR <2.5)
- Average lesion length 19 cm
- 56% CTOs

Core lab: significant stent oversizing in 30%

Saxon et al, J Vasc Inter Radiol 2013;24(2):165-73
VIPER: Lessons Learned

• Patency improved when device not oversized by >20% proximally
• Patency independent of device diameter (5, 6, 7 cm devices utilized, p=0.22)
• Primary patency independent of lesion length (lesion length >20 cm vs. ≤ 20 cm, p=0.51)

Saxon et al, J Vasc Inter Radiol 2013;24(2):165-73
Gore Japan IDE Clinical Study

- RC 2-5
- Surgical bypass candidate
- Lesion length ≥ 10 starting at least 1 cm below SFA origin, ending 1 cm above intercondylar notch
- Patent distal popliteal
- At least one patent tibial artery
- Ref diameter 4.0-7.5mm
- **QA or IVUS (70%) mandated for proper sizing**

**Mean lesion length 21.8±5.8 cm**

| Mean target lesions length (cm) ± SD | 21.8 ± 5.8 |
| Total occlusions                   | 67 (65.7%) |

<table>
<thead>
<tr>
<th>TASC classification</th>
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<tbody>
<tr>
<td>TASC II A</td>
<td>0 (0.0%)</td>
</tr>
<tr>
<td>TASC II B</td>
<td>16 (15.5%)</td>
</tr>
<tr>
<td>TASC II C</td>
<td>75 (72.8%)</td>
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<tr>
<td>TASC II D</td>
<td>12 (11.7%)</td>
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<thead>
<tr>
<th>SFA lesion location (lesion may cross over)</th>
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<tbody>
<tr>
<td>Proximal</td>
<td>72 (69.9%)</td>
</tr>
<tr>
<td>Mid</td>
<td>99 (96.1%)</td>
</tr>
<tr>
<td>Distal</td>
<td>77 (74.8%)</td>
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65.7% CTOs

Ohki, J Vasc Surg 2017;66/130-42
Japan IDE Study: 24M Results

PP 88.1% @ 12M

Ohki, J Vasc Surg 2017;66/130-42
REAL PTX: RCT of DES vs. DCB

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<tr>
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<th>PP</th>
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<tbody>
<tr>
<td>DCB</td>
<td>21%</td>
</tr>
<tr>
<td>Zilver PTX*</td>
<td>45%</td>
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Follow up @ KM estimates ±SE

- ZilverPTX: 0.74±0.07 at 1 year, 0.56±0.08 at 2 years, 0.45±0.08 at 3 years
- DCB only: 0.75±0.08 at 1 year, 0.32±0.09 at 2 years, 0.21±0.09 at 3 years

Mean lesion length 152.6 ±88.2mm

* 40% had >30% residual stenosis

Scheinert, LINC 2018
RCT of VB vs. Prosthetic BPG

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<tr>
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<th>VB (n=50)</th>
<th>BPG (n=50)</th>
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<tr>
<td>Diameter</td>
<td>5.7 mm</td>
<td>7.4 mm</td>
</tr>
<tr>
<td>Mean stent length</td>
<td>25.6 cm</td>
<td>-</td>
</tr>
<tr>
<td>TASC II A &amp; B</td>
<td>N= 39</td>
<td>N=35</td>
</tr>
<tr>
<td>TASC II C &amp; D</td>
<td>M=11 (27%)</td>
<td>N=15 (30%)</td>
</tr>
</tbody>
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All p = ns

McQuade et al, J Vasc Surg 2010;52:584-591
Primary Patency in SFA Stenting: 
Relation of Primary Patency to Lesion Length

[Graph showing the relation between one-year primary patency and lesion length, with markers for Zilver PTX, Resilient, Supera, Zilver FAST, FACT, Absolute, VIBRANT BMS, and VIBRANT (VIABAHN).]
Panel Discussion Questions

• Best practices:
  – Role of IVUS: Yes or No, if yes, when?
  – Duration of DAPT?
  – Frequency of surveillance?
  – Adjunctive Rx, e.g atherectomy, IVL, etc.

• Your treatment algorithm for BMS ISR: DCB or Viabhan?
Session Summary:
Viabhan remains a relevant and important treatment for long, complex SFA disease and ISR!

• There is level 1 evidence (Viastar, Reline) that covered stents are *SUPERIOR* to BMS and PTA in the treatment of long complex SFA disease and ISR, respectively

• The SuperB RCT showed no difference in patency between covered stents and the traditional gold standard of fem-pop bypass surgery, with less morbidity and shorter length of stay

• Optimal sizing and technique, vessel diameter $\geq 5$ mm, and surveillance are critical for best outcomes
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