Welcome to LINC

Symposium: Treatment strategies for complex disease in the SFA/Pop supported with an educational grant from Abbott Vascular

Moderator: D. Scheinert

Introduction by the moderator and overview of complex SFA disease: calcium, long lesions, reintervention

D. Scheinert
Peripheral Artery Disease (PAD) TREATMENT is Still a Large Unmet Need

Diagnosis and Treatment of PAD Is Underpenetrated

GLOBAL TREATMENT MAP OF PAD

>200MM Prevalence

<5MM Treated annually

20MM Diagnosed

Treating PAD Reduces Burden of Disease and Increases Quality of Life

GLOBAL TREATMENT MAP OF PAD

5 YEAR MORTALITY RATE (%)

- Lung Cancer: 84%
- Colon Rectal Cancer: 36%
- PAD: 33%
- Breast Cancer: 10%
- Hodgkin’s Disease: 5%

2. Kovach, Richard. PAD Diagnosis and Noninvasive Testing, NCVH 2014
3. Leerink Swann Analysis, Sep 5, 2012. US intervention rate of 28% (700/2,500 diagnosed). WW: 28% of 20MM is 5.6MM but actual treated rates would be lower outside the US
5. American Cancer Society: Cancer Facts and Figures 2012, p. 11, 12, 13, 16
Importance of fempop treatment

• Estimated 300,000 endovascular fempop procedures in Europe
  – Stent rate around 50%
  – SNS, DES, DCB usage all growing
  – Endo expansion trend into TASC C/D

• LINC 2016 live case statistics
  – 91 live cases
  – 32 of which are fempop
Variables affecting outcome of femoropopliteal interventions

• Lesion length
  → Patency rates decrease in longer lesions

• Lesion location
  → distal locations in SFA and popliteal artery are more challenging

• Stenosis vs. Occlusion
  → CTOs more challenging to cross, higher plaque burden

• Calcification
There is an Unmet Need in Severely Calcified Lesions

• The presence of calcium represents a significant challenge to current endovascular device strategies

• Calcification is a predictor of lower procedural success and reduction in long-term outcomes.
  ✓ Currently most clinical trials often exclude severely calcified lesions

• Severe calcification may be associated with increased device and/or procedure related adverse events
  ✓ Severe dissections
  ✓ Vessel perforations
  ✓ Atheroembolization


Image courtesy of Dr. Andrej Schmidt
Supera Has Strong Clinical Outcomes in Calcification

% of Lesions with Severe Calcification (SUPERB Trial) | 45% (n=118)

Patency (VIVA 12 months) | 89%

Freedom from TLR % Over Time in Severe Calcium

- 12 months: 95%
- 24 months: 92%
- 36 months: 88%
### Published Results in SFA/Pop - TASC C & D Lesions

<table>
<thead>
<tr>
<th>Study/Device</th>
<th>Number of Patients</th>
<th>Mean Lesion Length</th>
<th>12 Month Primary Patency</th>
<th>12 Month Stent Fracture</th>
</tr>
</thead>
<tbody>
<tr>
<td>DURABILITY-200¹ Protégé Everflex</td>
<td>100</td>
<td>242 mm</td>
<td>64.8%</td>
<td>6.0%</td>
</tr>
<tr>
<td>STELLA Registry² LifeStent</td>
<td>58</td>
<td>220 mm</td>
<td>66.0%</td>
<td>17.7%</td>
</tr>
<tr>
<td>Zilver PTX Global Registry Zilver PTX³</td>
<td>135</td>
<td>226 mm</td>
<td>77.6%</td>
<td>2.1%</td>
</tr>
<tr>
<td>STELLA PTX Zilver PTX⁴</td>
<td>45</td>
<td>252 mm</td>
<td>52.5%</td>
<td>9.0%</td>
</tr>
<tr>
<td>Viabahn TASC C&amp;D Viabahn⁵</td>
<td>71</td>
<td>265 mm</td>
<td>67.0%</td>
<td>0.0%</td>
</tr>
<tr>
<td>SUPERB 500 Supera⁶</td>
<td>172</td>
<td>223 mm</td>
<td>80.5%</td>
<td>0.0%</td>
</tr>
<tr>
<td>St. Louis University Supera⁷</td>
<td>42</td>
<td>279 mm</td>
<td>80.1%</td>
<td>0.0%</td>
</tr>
</tbody>
</table>

Data differences depicted between these trials may not be statistically significant or clinically meaningful and different clinical trials may include differences in the demographics of the patient populations.

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Selection of available techniques for long femoropopliteal lesions

• Biomimetic stents (Supera)
• Drug-coated balloons
• Drug-eluting stents
• Stent-Grafts/ covered stents
• Conventional nitinol stents
• Atherectomy/ Laser
  ...
• Bypass-Surgery
The interventionalists dilemma

• Which tool in which lesion?
• What treatment leads to the best outcome?
  – Certainly not only one answer for all patients
  – Identify best strategy for each situation
• Are cost – benefit ratios respected?
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