Plaque scoring in calcified lesions

Advancing DCB therapy in complex SFA lesions

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Disclosure

Speaker name: Erwin Blessing

I have the following potential conflicts of interest to report:

☐ Consulting
☐ Employment in industry
☐ Stockholder of a healthcare company
☐ Owner of a healthcare company

X Other(s): speakers honoraria (Spectranetics, Medtronic, Abbott)

☐ I do not have any potential conflict of interest
Restenosis following interventions

Predictors:

- Lesion length¹
- Diabetes²
- Occlusions³
- Calcification

¹ Norgren et al. Eur J Vas Endovasc Surg 33, S1-S75: 2007
³ Lida et al Cath and Cardiovasc Interven 2011 Oct 1;78(4):611-7
DCB use in calcified lesions

12-month Results

Fanelli, Cardiovasc Intervent Radiol 2014
Scoring balloons in calcified lesions

- Inadequate penetration of the drug into the media/adventitia and therefore poorer outcome?

- Does a lesion preparation prior DCB improve penetration of the drug and therefore patency?
Scoring balloons in calcified lesions

- Inadequate penetration of the drug into the media/adventitia and therefore poorer outcome?

- Does a lesion preparation prior DCB improve penetration of the drug and therefore patency?
Scoring Balloon Catheter

VascuTrak (Bard)

**MECHANISM OF ACTION**

- Two external wires deliver Focused Force along the length of the balloon, for dilatation at low inflation pressures
- Low inflation pressure angioplasty reduces the potential for balloon-induced over-dilation of the vessel and offers controlled plaque modification, even in calcified lesions
- Focused Force is applied in two parallel planes, unlike standard balloons with unconcentrated circumferential dilatation forces
Scoring Balloon Catheter

Flextome Cutting Balloon
(Boston Scientific)
Scoring Balloon Catheter

Chocolate (TriReme Medical)
Scoring Balloon Catheter

AngioSculpt (Spectranetics)

**Semi-compliant** nylon balloon with an external **nitinol** shape memory helical scoring edge
90 year old female patient
Claudicant (walking capacity 50 m)
CVRF: Art. HTN, HLP
PANTHER Evaluation of treatment of femoro Popliteal lesions with ANgiosculpT PTA Scoring Balloons – HEidelberg Registry

Real world registry
Angiosculpt PTA in calcified femoropopliteal lesions

101 patients

<p>| | |</p>
<table>
<thead>
<tr>
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</thead>
<tbody>
<tr>
<td>Age (years)</td>
<td>71.9 ± 9.3</td>
</tr>
<tr>
<td>Gender (m/f)</td>
<td>76/25</td>
</tr>
<tr>
<td>Arterial hypertension, n (%)</td>
<td>94 (93.1)</td>
</tr>
<tr>
<td>Diabetes, n (%)</td>
<td>45 (44.6)</td>
</tr>
<tr>
<td>Aktive smoking, n (%)</td>
<td>25 (24.7)</td>
</tr>
<tr>
<td>Hyperlipidemia, n (%)</td>
<td>74 (93.1)</td>
</tr>
<tr>
<td>BMI (kg/m²)</td>
<td>26.9 ± 4.5</td>
</tr>
<tr>
<td>Ankle Brachial Index</td>
<td>0.63 ± 0.22</td>
</tr>
<tr>
<td>Claudicants, n (%)</td>
<td>66 (65.3)</td>
</tr>
<tr>
<td>Critical Limb Ischemia, n (%)</td>
<td>35 (34.7)</td>
</tr>
</tbody>
</table>

JEVT, submitted
PANTHER Evaluation of treatment of femoro Popliteal lesions with ANgiosculpT PTA Scoring Balloons – HEidelberg Registry

Real world registry
Angiosculpt PTA in calcified femoropopliteal lesions

124 lesions

<p>| | |</p>
<table>
<thead>
<tr>
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</thead>
<tbody>
<tr>
<td>Occlusions (%)</td>
<td>20 (16.1)</td>
</tr>
<tr>
<td>Lesion length (cm)</td>
<td>7.4±5.9</td>
</tr>
<tr>
<td>Degree of Stenosis (%)</td>
<td>85.5</td>
</tr>
<tr>
<td>Degree of Calcification, n (%)</td>
<td></td>
</tr>
<tr>
<td>1 (mild)</td>
<td>27 (21.8)</td>
</tr>
<tr>
<td>2 (moderate)</td>
<td>43 (34.7)</td>
</tr>
<tr>
<td>3 (severe)</td>
<td>54 (43.5)</td>
</tr>
<tr>
<td>Lesion Localization:</td>
<td></td>
</tr>
<tr>
<td>- iliacal, (%)</td>
<td>2.5</td>
</tr>
<tr>
<td>- femoral (%)</td>
<td>78.6</td>
</tr>
<tr>
<td>- popliteal (%)</td>
<td>18.9</td>
</tr>
</tbody>
</table>

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PANTHER Evaluation of treatment of femoro Popliteal lesions with ANgiosculpT PTA Scoring Balloons – HEidelberg Registry

Real world registry
Angiosculpt PTA in calcified femoropopliteal lesions

Treatment strategy

124 lesions
Non randomized – by discretion of the interventionalist!!!

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Real world registry
Angiosculpt PTA in calcified femoropopliteal lesions

Overall cohort
124 lesions

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Real world registry
Angiosculpt PTA in calcified femoropopliteal lesions

Lesion length
124 lesions

![Graph showing primary patency over months for lesion lengths of < 5 cm, 5-10 cm, and > 10 cm.]

- < 5 cm: 86.5%
- 5-10 cm: 85.7%
- > 10 cm: 53.8%

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Real world registry
Angiosculpt PTA in calcified femoropopliteal lesions

<table>
<thead>
<tr>
<th>Angiosculpt</th>
<th>Angiosculpt + DCB</th>
<th>Angiosculpt + Supera Stent</th>
</tr>
</thead>
<tbody>
<tr>
<td>Lesion length (cm)</td>
<td>6.1</td>
<td>5.9</td>
</tr>
<tr>
<td>Occlusions (%)</td>
<td>2.2</td>
<td>17.5</td>
</tr>
</tbody>
</table>

124 lesions

Primary Patency (%)

Months

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Real world registry
Angiosculpt PTA in calcified femoropopliteal lesions

Calcification

124 lesions

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Calcification
124 lesions

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Calcification

124 lesions

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Real-world registry

Angiosculpt PTA in calcified femoropopliteal lesions

Clinical outcome

101 patients

6 Months

12 Months

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PANTHER Evaluation of treatment of femoro Popliteal lesions with ANgiosculpT PTA Scoring Balloons – HEidelberg Registry
Scoring balloons in long lesions?

pre 2 atm 4 atm 8 atm
Scoring balloons in long lesions?
Scoring balloons in ISR?
Scoring balloons in ISR?

Angiosculpt 5x200 mm

4 atm  
6 atm  
12 atm
Scoring balloons in ISR?

Post
Angiosculpt 5x200 mm
Scoring balloons in ISR?

Final result after DCB
Conclusions

- DCBs work less well in heavily calcified lesions
- Improved penetration of drug after lesion preparation?
- Encouraging register data for scoring balloons in short and moderate long calcified femoropopliteal lesions (hypothesis generating)
- Calcification was no predictor for loss of 12-month patency as long as lesion preparation was performed
- Scoring balloons might be a (less expensive) alternative to debulking devices in calcified lesions
Plaque scoring in calcified lesions

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