The role of vessel preparation – insights from the Heidelberg PANTHER registry

Changing paradigms and future concepts in peripheral interventions

Erwin Blessing
SRH Klinikum Karlsbad-Langensteinbach
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) Research Grants, Speakers honoraria

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

Predictors:

– Lesion length\textsuperscript{1}
– Diabetes\textsuperscript{2}
– Occlusions\textsuperscript{3}
– Calcification

DCB use in calcified lesions

12-month Results

Fanelli, Cardiovasc Intervent Radiol 2014
DCB use 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?
DCB use 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

AngioSculpt® PTA

Nylon Balloon
Angiosculpt plus DCB

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

<table>
<thead>
<tr>
<th>Age (years)</th>
<th>71.9 ± 9.3</th>
</tr>
</thead>
<tbody>
<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>
PANTHER Evaluation of treatment of femoro Popliteal lesions with ANgiosculpT PTA Scoring Balloons – HEidelberg Registry

Real world registry
Angiosculpt PTA in calcified femoropopliteal lesions

<table>
<thead>
<tr>
<th>Occlusions (%)</th>
<th>20 (16.1)</th>
</tr>
</thead>
<tbody>
<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>
</tbody>
</table>

Lesion Localization:
- iliacal, (%) 2.5
- femoral (%) 78.6
- popliteal (%) 18.9
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!!!
PANTHER Evaluation of treatment of femoro Popliteal lesions with ANgiosculpT PTA Scoring Balloons – HEidelberg Registry

Real world registry
Angiosculpt PTA in calcified femoropopliteal lesions

Overall cohort
124 lesions

![Graph showing primary and secondary patency rates over 12 months.]

- Primary Patency: 91.8%
- Secondary Patency: 81.2%
PANTHER Evaluation of treatment of femoro Popliteal lesions with ANgiosculpT PTA Scoring Balloons – HEidelberg Registry

Real world registry
Angiosculpt PTA in calcified femoropopliteal lesions

Calcification

124 lesions

81.8%
81.3%
78.9%
PANTHER Evaluation of treatment of femoro Popliteal lesions with ANgiosculpT PTA Scoring Balloons – HEidelberg Registry

Real world registry
Angiosculpt PTA in calcified femoropopliteal lesions

<table>
<thead>
<tr>
<th></th>
<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>
<td>10.1</td>
</tr>
<tr>
<td>Occlusions (%)</td>
<td>2.2</td>
<td>17.5</td>
<td>31.6</td>
</tr>
</tbody>
</table>

124 lesions

Primary Patency (%)

0  10  20  30  40  50

0  6  12  Months

77.8%
Real world registry
Angiosculpt PTA in calcified femoropopliteal lesions
Clinical outcome
101 patients
6 Months
12 Months

- **RBC Baseline**
- **RBC FollowUp**

- *** **p<0.0001

- **ABI Baseline**
- **ABI FollowUp**

- * **p<0.01
- *** **p<0.0001
PANTHER Evaluation of treatment of femoro Popliteal lesions with ANgiosculpT PTA Scoring Balloons – HEidelberg Registry
Conclusions

- DCBs seem to 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
- Calcification was no predictor for loss of 12-month patency as long as lesion preparation was performed
- Results of PANTHER have to be confirmed in a RCT, comparing scoring balloons plus DCB vs. POBA plus DCB
- Role for drug eluting scoring balloons?
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