Atherectomy: Is Vessel Preparation for Drug Coated Balloons the Breakthrough Indication?

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Disclosure

Speaker name: Ehrin J. Armstrong MD

I have the following potential conflicts of interest to report:

- Consulting: Abbott Vascular, Boston Scientific, Cardiovascular Systems, Medtronic, Philips
- Employment in industry
- Stockholder of a healthcare company
- Owner of a healthcare company
- Other(s)

I do not have any potential conflict of interest
Limitations of Drug Coated Balloons

DCB outcomes are predicated on adequate vessel preparation.

Lower patency rates of DCBs in severely calcified lesions.

Possible late catch-up of DCBs along the 3-5 year timeframe.
Improving Vessel Preparation

Goals:

<30% residual stenosis
No significant dissection

Use of atherectomy optimizes the likelihood of adequate vessel preparation, especially in anatomically complex disease.
Laser Atherectomy
Laser Atherectomy
DCBs and Calcium

- Concentric calcium is associated with lower primary patency and higher rates of TLR, even with DCBs.

DCBs and Calcium

- Bilateral angiographic calcium is associated with increased late lumen loss.

Tepe, J Endovasc Ther 2015; 22:727-733
Jetstream Atherectomy
Jetstream Atherectomy
Orbital Atherectomy
Orbital Atherectomy
DEFINITIVE AR

102 patients with claudication or rest pain.

Randomized to directional atherectomy + DCB or DCB alone.

Superior technical success with DA + DCB (89.6%) vs. DCB alone (64.2%)

Lower flow limiting dissection rates with DA + DCB (2% vs. 19%)

Similar patency and TLR rates at one year.

Zeller et al, Circ Cardiovasc Interv 2017
139 SFA or popliteal lesions treated with DCBs.
  - 40 (29%) treated with DCB + OA

Moderate to severe calcification in 83% of OA+DCB, vs. 42% of DCB alone.
Intraprocedural Outcomes

**TABLE IV. Intraprocedural Treatment and Outcomes**

<table>
<thead>
<tr>
<th>Variable</th>
<th>Orbital atherectomy + drug-coated balloon (N = 40)</th>
<th>Drug-coated balloon only (N = 99)</th>
<th>P value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Stent placed</td>
<td>7 (18)</td>
<td>39 (39)</td>
<td>0.01</td>
</tr>
<tr>
<td>Scoring balloon</td>
<td>35 (88)</td>
<td>35 (35)</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Embolization</td>
<td>0 (0)</td>
<td>2 (2)</td>
<td>0.4</td>
</tr>
<tr>
<td>Dissection</td>
<td>5 (13)</td>
<td>14 (14)</td>
<td>0.8</td>
</tr>
<tr>
<td>Perforation</td>
<td>0 (0)</td>
<td>0 (0)</td>
<td>1.0</td>
</tr>
<tr>
<td>Procedural success</td>
<td>39 (98)</td>
<td>98 (99)</td>
<td>0.8</td>
</tr>
<tr>
<td>Access site complication (hematoma)</td>
<td>3 (3)</td>
<td>0 (0)</td>
<td>0.360</td>
</tr>
</tbody>
</table>

Values are n (%).

- Significantly lower bailout stent rate when OA + DCB used.
Freedom From TLR

- Similar TLR rates despite significantly more calcification in OAS group.

82% freedom from TLR

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Number at risk
No Orbital Atherectomy 99 77 49 20 4
Orbital Atherectomy 40 35 24 14 1

Follow-Up (Days)
Ongoing Trials

REALITY Study
Directional atherectomy + DCB for treatment of moderately to severely calcified femoropopliteal lesions.

JET-RANGER Study
Randomized study of Jetstream + DCB vs. DCB alone for treatment of complex femoropopliteal disease.
Conclusions

• Calcium remains a challenge for long-term patency among patients with PAD.
  – Poor drug penetration, higher rates of TLR.

• Atherectomy may improve acute procedural outcomes with DCB.
  – Lower bailout stent rates.

• Further studies necessary to understand drug penetration, effect of atherectomy on patency rates.
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