Treatment of challenging calcified lesions with the next generation PHOENIX ATERECTOMY SYSTEM

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Disclosure

Speaker name:

Michael Lichtenberg, M.D.

I have the following potential conflicts of interest to report:

- [x] Consulting
- [ ] Employment in industry
- [ ] Stockholder of a healthcare company
- [ ] Owner of a healthcare company
- [ ] Other(s)
Why debulking?

- Calcification removal before DCB usage
- Stent avoidance (leave nothing behind)
  - In long diffuse non-occlusive disease
  - In no stent zone (CFA, Popliteal artery)
  - BTK long DCB angioplasty
- Preserves bypass landing zones
- Low pressure balloon angioplasty possible
- Keeps options for future treatment
Effect of calcium on the efficacy of DEB (IN.PACT) during SFA revascularization

- Calcium is a barrier for drug absorption
- Circumferential distribution most influencing factor

Fanelli, LINC 2013

**Long and Severely Calcified Lesions**

DEFINITIVE AR suggests added patency benefit of using DA in long lesions and severely calcified lesions.

- **Lesions > 10 cm**
  - DUS Patency: 96.8%
  - Angiographic Patency: 85.9%
  - DAART: 90.9%
  - DCB: 68.8%

- **All Severely Calcified Lesions**
  - DUS Patency: 70.4%
  - Angiographic Patency: 62.5%
  - DAART: 58.3%
  - DCB: 42.9%

**≤ 30% Residual Stenosis**

DEFINITIVE AR suggests improved patency when a higher volume of plaque is removed with DA prior to DCB.

- **≤30% Residual Stenosis Post-DA**
  - DUS Patency: 90.0%
  - Angiographic Patency: 77.8%

- **>30% Residual Stenosis Post-DA**
  - DUS Patency: 94.1%
  - Angiographic Patency: 68.8%

N=20, N=18, N=17, N=16

**Per Core Lab assessment, “All severe CA++” group includes all patients treated with DAART or DCB therapy, including randomized and nonrandomized patients with severe calcium.**

Figure 2. Twelve-month patency outcomes in patients who received directional atherectomy followed by a DCB versus patients who received DCB only.
Debulking plus drug-coated balloon combination as revascularisation strategy for complex femoropopliteal lesions: A new standard technique?

M. Lichtenberg, J Endovasc Ther. 2016
## Comparison of debulking systems

<table>
<thead>
<tr>
<th></th>
<th>Phoenix</th>
<th>Jetstream</th>
<th>Directional (Phantheris, Hawk)</th>
<th>Laser</th>
</tr>
</thead>
<tbody>
<tr>
<td>Front cutting / Rotational device</td>
<td>+++</td>
<td>+++</td>
<td>----</td>
<td>Front „cutting“</td>
</tr>
<tr>
<td>Active aspiration</td>
<td>+++</td>
<td>+++</td>
<td>+</td>
<td>---</td>
</tr>
<tr>
<td>Concentric lumen</td>
<td>+++</td>
<td>+++</td>
<td>-/+</td>
<td>-/+</td>
</tr>
<tr>
<td>Excentric lesion</td>
<td>++</td>
<td>-</td>
<td>Pantheris (+)</td>
<td>-</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Hawk +</td>
<td></td>
</tr>
<tr>
<td>CTO</td>
<td>++</td>
<td>++</td>
<td>Ocelot +</td>
<td>+</td>
</tr>
<tr>
<td>Soft Plaque</td>
<td>++</td>
<td>++</td>
<td>+</td>
<td>++</td>
</tr>
<tr>
<td>Fibrotic plaque</td>
<td>+++</td>
<td>+++</td>
<td>+++</td>
<td>+++</td>
</tr>
<tr>
<td>Calcium</td>
<td>++</td>
<td>++</td>
<td>+</td>
<td>-</td>
</tr>
<tr>
<td>Thrombus</td>
<td>+</td>
<td>++</td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td>Embolisation risk</td>
<td>-/+ (no Filter!)</td>
<td>++ (Filter!)</td>
<td>++ (Filter!)</td>
<td>-/+</td>
</tr>
</tbody>
</table>
Phoenix atherectomy devices

Phoenix 2.4mm (7F deflecting)*
Minimum vessel diameter 3.0 mm
127 cm length

Phoenix 2.2mm (6F non-deflecting)
Minimum vessel diameter 3.0mm
130 and 149cm lengths

Phoenix 1.8mm (5F non-deflecting)
Minimum vessel diameter 2.5mm
130 and 149cm lengths

Posterior tibial
<table>
<thead>
<tr>
<th>Catheter Size</th>
<th>Introducer Size</th>
<th>Working Length</th>
<th>Guidewire Diameter</th>
<th>Minimum Vessel Size</th>
</tr>
</thead>
<tbody>
<tr>
<td>1.8 mm tracking</td>
<td>5 Fr</td>
<td>130 cm</td>
<td>.014”</td>
<td>2.0 mm</td>
</tr>
<tr>
<td>2.2 mm tracking</td>
<td>6 Fr</td>
<td>130 cm</td>
<td>.014”</td>
<td>3.0 mm</td>
</tr>
<tr>
<td>2.4 mm deflecting tip</td>
<td>7 Fr</td>
<td>130 cm</td>
<td>.014”</td>
<td>3.0 mm</td>
</tr>
</tbody>
</table>
Phoenix atherectomy system

Cutting: Helical blades

Collecting

Capturing
62 y, male, current smoker, art. hypertension. Rutherford III
Straight tip
Deflected tip
Passeo 18 – LUX DCB
6 x 100 mm
Atherectomy with Phoenix 2.2 mm catheter plus DEB angioplasty
Instent restenosis
Post – Ballooning with DCB 6 x 80 mm
Penetrating flash occlusions

Penetration with standard Terumo stiff wire and support catheter not possible
Blind (no guidewire at tip) poking on the proximal plaque with the 1.8 mm Phoenix atherectomy system

V 14 guidewire loaded
V14 wire passing the occlusion
Straight Tip vs Curved Tip
Effective Atherectomy plus DCB
BTK lesions

Front cutting device

in small vessels or tight lesions cutting device on distal tip of the systems helps to eliminate dottering

Pushability of the 1.8 mm catheter

good forward pressure. Very helpful in long BTK lesions > 40 cm
Phoenix 2.2 mm
<table>
<thead>
<tr>
<th>Variable</th>
<th>N=123</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pre-Treatment with PTA</td>
<td>1 (0.8%)</td>
</tr>
<tr>
<td>Distal Protection Used in Treatment of Target Lesions</td>
<td>0 (0%)</td>
</tr>
<tr>
<td>Bailout Stent Required</td>
<td>1 (0.8%)</td>
</tr>
<tr>
<td>Handle Run Time</td>
<td>5.9 + 4.7 mins (0.5, 4.6, 25.0)</td>
</tr>
</tbody>
</table>
## Safety aspects

<table>
<thead>
<tr>
<th>Clinical Concern</th>
<th>Phoenix Solution</th>
<th>Safety Data¹</th>
</tr>
</thead>
</table>
| Vessel Injury      | Front cutter clears tissue in a way that may help reduce potential trauma to the vessel | 1.9% Perforation  
                      |                                                                                   | 0.9% Dissection* |
| Distal Embolization** | Continuous capture and clearance of debulked material into the catheter       | <1% distal embolization  
                      |                                                                                   | 0% use of distal protection |

¹ Endovascular Atherectomy Safety and Effectiveness Study (EASE), ClinicalTrials.gov Identifier NCT01541774 (accessed 23Oct2015). Results presented at the Vascular Interventional Advances (VIVA) Conference in October of 2013 (Las Vegas, NV) by Stephen Williams, MD 600-0100.153/001
Conclusion

- Debulking plus DCB seems to become the treatment of choice especially in long calcified SFA and BTK lesions
- Phoenix Atherectomy is very simple to use with a quick set up
- Useful in calcified and fibrotic lesions (instent restenosis)
- WE NEED MORE AHERECTOMY PLUS DCB DATA FOR MORE EVIDENCE
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