Treatment of challenging calcified lesions with the next generation Phoenix Atherectomy System

Michael K.W. Lichtenberg

Klinikum Arnsberg
Akademisches Lehrkrankenhaus
Westfälische Wilhelms-Universität Münster
Disclosures

Speaker name:

**Michael Lichtenberg**

I have the following potential conflicts of interest to report:

- **X** Consulting (CR Bard, Biotronik, COOK, Optimed, Straub Medical, Terumo, Volcano, Boston)
- Employment in industry
- Stockholder of a healthcare company
- Owner of a healthcare company
- Other(s)

- **X** I do not have any potential conflict of interest
Long and Severely Calcified Lesions

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

<table>
<thead>
<tr>
<th>Lesions &gt; 10 cm</th>
<th>All Severely Calcified Lesions**</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>DUS Patency</strong></td>
<td><strong>Angiographic Patency</strong></td>
</tr>
<tr>
<td>96.8%</td>
<td>90.9%</td>
</tr>
<tr>
<td>85.9%</td>
<td>68.8%</td>
</tr>
<tr>
<td>70.4%</td>
<td>62.5%</td>
</tr>
<tr>
<td>58.3%</td>
<td>42.9%</td>
</tr>
</tbody>
</table>

**< 30% Residual Stenosis

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

<table>
<thead>
<tr>
<th>&lt; 30% Residual Stenosis Post-DA</th>
<th>&gt; 30% Residual Stenosis Post-DA</th>
</tr>
</thead>
<tbody>
<tr>
<td>90.0%</td>
<td>77.8%</td>
</tr>
<tr>
<td>94.1%</td>
<td>68.8%</td>
</tr>
</tbody>
</table>

**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.
• 30 Patienten, single center
  – CLI 94 %
  – Diabetes 60 %
  – MLL 115 ± 35 mm
  – CTO 13 %

• TurboHawk + IN.PACT
  – Stenting 7 %
  – Prim. Pat. = 90 % 12 Monate
  – Sek. Pat. = 100 % 12 Monate
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
Phoenix atherectomy system

- **Phoenix 2.4mm (7F deflecting)**
  - 3.0 – 7.0 mm vessels

- **Phoenix 2.2mm (6F non-deflecting)**
  - 3.0 – 4.0 mm vessels

- **Phoenix 1.8mm (5F non-deflecting)**
  - 2.5 – 3.5 mm vessels
Phoenix atherectomy system

Collecting

Cutting: Helical blades

Capturing
Capture, Cut, Clear

- **Distal cutting element** rotates at 12,000 RPM (Cutting element made of stainless steel alloy with proprietary coating)
- **Battery-Powered Handle** (Powers rotation of cutting element, Handheld) Compatible with all catheter sizes
Advantages of the Phoenix catheter

- 5 F and 6 F profile atherectomy system
  - Turbohaw and SilverHawk: 6F systems
  - Jetstream: 7F systems
- Front cutting mechanism
- Good pushability and trackability
  - Without decrease in RPM of cutting blades
- BTK: low crossing profile with 1.8 mm system over an 0.014 inch wire
- Debulking of fibrotic and calcified lesions
Where to use the Phoenix catheter

Diffuse long segment calcification

(distal) SFA, APOP ! and BTK !

Restenotic disease morphology
Instent restenosis
Atherectomy with Phoenix 2.2 mm catheter plus DEB angioplasty
82 y, male, calcified subtotal stenosis of popliteal artery

Phoenix 2.2mm plus DEB PTA
Phoenix atherectomy BTK
BTK lesions

Front cutting device

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

Pushability

good forward pressure. Very helpful in long BTK lesions > 40 cm
EASE: Endovascular atherectomy safety and effectiveness study

- PI: Dr. Davis (Detroit) and Dr. McKinsey (Columbia)

<table>
<thead>
<tr>
<th>Variable</th>
<th>n = 123</th>
</tr>
</thead>
<tbody>
<tr>
<td>ATK</td>
<td></td>
</tr>
<tr>
<td>SFA</td>
<td>62 (50.4%)</td>
</tr>
<tr>
<td>Popliteal</td>
<td>36 (29.3%)</td>
</tr>
<tr>
<td></td>
<td>26 (21.1%)</td>
</tr>
<tr>
<td>BTK</td>
<td></td>
</tr>
<tr>
<td>AT</td>
<td>61 (49.6%)</td>
</tr>
<tr>
<td>TPT</td>
<td>20 (16.3%)</td>
</tr>
<tr>
<td>PT</td>
<td>20 (16.3%)</td>
</tr>
<tr>
<td>Per</td>
<td>13 (10.6%)</td>
</tr>
<tr>
<td></td>
<td>8 (6.5%)</td>
</tr>
<tr>
<td>Patent Tibial Vessels</td>
<td></td>
</tr>
<tr>
<td>Single or less</td>
<td>44 (42%)</td>
</tr>
</tbody>
</table>
## EASE Study

<table>
<thead>
<tr>
<th>Variable</th>
<th>N</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pre-Treatment with PTA</td>
<td>1</td>
</tr>
<tr>
<td>Distal Protection Used in Treatment of Target Lesions</td>
<td>0</td>
</tr>
<tr>
<td>Bailout Stent Required</td>
<td>1</td>
</tr>
<tr>
<td>Handle Run Time</td>
<td>5.9 + 4.7 mins</td>
</tr>
<tr>
<td></td>
<td>(0.5, 4.6, 25.0)</td>
</tr>
</tbody>
</table>
## EASE Study: Effectiveness endpoints

<table>
<thead>
<tr>
<th>Variable</th>
<th>30D (n=104)</th>
<th>6M (n=98)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Rutherford Class Change from Baseline at Visit</td>
<td></td>
<td></td>
</tr>
<tr>
<td>≥ -1</td>
<td>76/102 (74.5%)</td>
<td>78/97 (80%)</td>
</tr>
<tr>
<td>No Change</td>
<td>26/102 (25.5%)</td>
<td>16/97 (16%)</td>
</tr>
<tr>
<td>+ 1</td>
<td>0 (0.0%)</td>
<td>2/97 (2%)</td>
</tr>
<tr>
<td>+ 2</td>
<td>0 (0.0%)</td>
<td>1/97 (1%)</td>
</tr>
<tr>
<td>&gt; 2+</td>
<td>0 (0.0%)</td>
<td>0 (0.0%)</td>
</tr>
</tbody>
</table>

**Kaplan-Meier Patency Estimates at 6 months:**
- Freedom from TLR: 88.0%
- Freedom from TVR: 86.1%
Phoenix atherectomy for ISR Debulking
Morphology analysis with IVUS after ISR debulking
Conclusions

• Debulking plus DEB 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, also for instent restenosis

• WE NEED MORE AHERECTOMY PLUS DEB DATA FOR MORE EVIDENCE
Thank you for your attention
9TH HERDRINGER VASCULAR COURSE
April 24-25, 2015

9TH LIVE VASCULAR COURSE IN ARNSBERG – HERDRINGEN FOR VASCULAR SPECIALISTS
Live! Live! Live! in a historic scenic place. Up to date in vascular medicine.

Congress language:
German with simultaneous English translation

Live case centers:
- University Clinic Muenster, Angiology department and Vascular surgery Clinic, Muenster, Germany
- Herzzentrum Bad Krozingen, Bad Krozingen, Germany
- Vascular Center, Arnsberg Clinic, Arnsberg, Germany

Faculty:
Prof. Marianne Brodmann, Prof. Thomas Zeller
Dr. Michael Lichtenberg, Dr. Wilhelm Stahlhoff
PD Dr. Andrej Schmidt, Prof. Giovanni Torsello
Prof. Karl-Ludwig Schulte

Location:
Jagdschloss Herdringen
Zum Herdringer Schloss 7
59757 Arnsberg

Further Information:
www.klinikum-arnsberg.de/fb-termine

www.klinikum-arnsberg.de

Responsible for organisation:
Dr. Michael Lichtenberg
Dr. Wilhelm Stahlhoff
Klinikum Arnsberg, Karolinen-Hospital
Stolte Ley 5, D-59759 Arnsberg

Supported by: incathlab
the interactive cardiovascular channel
Treatment of challenging calcified lesions with the next generation Phoenix Atherectomy System

Michael K.W. Lichtenberg

Klinikum Arnsberg
Akademisches Lehrkrankenhaus
Westfälische Wilhelms-Universität Münster