Prestige Pilot: Phoenix atherectomy and Stellarex DCB in BTK interventions

Michael K. W. Lichtenberg MD, FESC
Within the past 12 months, I or my spouse/partner have had a financial interest/arrangement or affiliation with the organization(s) listed below.

<table>
<thead>
<tr>
<th>Affiliation/Financial Relationship</th>
<th>Company</th>
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<tbody>
<tr>
<td>1. Honoraria for lectures: CR Bard, Veniti, AB Medica,</td>
<td>Volcano, Optemed GmbH, Straub Medical,</td>
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<td>Terumo, Biotronik, Veryan</td>
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<td>2. Honoraria for advisory board activities: Veniti,</td>
<td>Optemed GmbH, Straub Medical, Biotronik,</td>
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<td>Veryan, Boston Scientific</td>
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<td>3. Participation in clinical trials: Biotronik, CR</td>
<td>Veryan, Straub Medical, Veniti, TVA Medical,</td>
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<td>Bard, Veryan, Straub Medical, Veniti, TVA Medical,</td>
<td>Boston Scientific, LimFlow, Terumo</td>
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<tr>
<td>4. Research funding: Biotronik, Boston Scientific,</td>
<td>Veryan, Veniti, AB Medica</td>
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Different world BTK

Technical challenges:
- Calcium burden: Media sclerosis > Intimal calcium: how to reach it
- Dissection: Probably underestimated BTK
- Visualization: Angio vs IVUS
- Lumen gain: How to achieve enough/stable lumen with media sclerosis
- Outflow: No outflow – no wound healing
- DCB: Need to avoid downstream embolisation

General challenges for studies
- Life expectancy: in CLI patients in general bad
- Amputation: Wound situation can change very quickly
- Wound care: Differently at different sites
- Definition of wounds: Not including the wrong ones
- ....
- ....
- ....
Post-PTA Dissections Below the Knee

More challenging to identify dissections due to smaller vessel size, overlapping bone
Question: Diagnostic modality?

**IVUS has advantages analysing...**

- distribution of calcium (> 180°?)
- localization of calcium
- correct vessel diameter
- complexity of dissections post PTA
- residual stenosis
- post PTA thrombus

**ANGIO has limitations analysing...**

- severity of calcium
- thrombus vs calcium
- correct vessel diameter
- number and severity of dissections
- post-PTA narrowing
- ....
Dissection matters

Dissection after PTA

• DEBELLUM
  – 15.0% PTA
  – 30.7% DCB
• IN.PACT™ DEEP
  – 12.3% PTA
  – 19.2% DCB

Fanelli JEV 2012
Zeller JACC 2014
Is it thrombus? Dissection?...
Question: Recanalization modality?

Based on diagnostic analysis

POBA vs DCB
Phoenix atherectomy system

- Cutting: Helical blades
- Collecting
- Capturing
Phoenix atherectomy catheter

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

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

**Phoenix 1.8mm (5F non-deflecting)**
- Minimum vessel diameter 2.5 mm
- 130 and 149 cm lengths
Ideally Suited for Below the Knee Treatment

- Designed to treat broad range of disease types
- Potentially Minimize Risk of Distal Embolization
PRESTIGE Pilot – Phoenix Atherectomy and Stellarex DCB clinical investigation in infrapopliteal interventions

PI Prof. T. Zeller and Dr. M. Lichtenberg

Lesion preparation strategy with Phoenix atherectomy before DCB IVUS guided
Study Design

- Prospective, single-arm, multi-center study
- Follow-up:
  - 30 days (phone-call)
  - 6 months
  - 12 months
  - 24 months
- Up to 75 subjects
- 5 sites in Germany (Dr. Lichtenberg, Prof. Zeller, Prof. Torsello, Prof. Korosoglu, Prof. Blessing)

- Devices: Phoenix atherectomy & Stellarex 0.014

Objective:
- Investigate if a lesion preparation strategy with Phoenix atherectomy before DCB usage in patients with PAD Rutherford Stage 4-5 and moderate/severe calcium can improve outcomes including patency and limb salvage and evaluate safety and performance of the combination therapy.
## Core Lab Adjudication

<table>
<thead>
<tr>
<th></th>
<th>Baseline</th>
<th>Post-Phoenix atherectomy</th>
<th>Post-DCB Procedure</th>
<th>6mo</th>
<th>12mo</th>
<th>24mo</th>
</tr>
</thead>
<tbody>
<tr>
<td>Angio</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>IVUS</td>
<td>X</td>
<td>X</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>DUS</td>
<td>X (prior to discharge)</td>
<td></td>
<td></td>
<td>X</td>
<td>X</td>
<td>X</td>
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## Primary Endpoints

<table>
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<tr>
<th>Primary Efficacy Endpoint</th>
<th>Patency at 6 months. Patency defined as freedom from occluded target lesions (flow) verified by duplex ultrasound without re-intervention</th>
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<td>Primary Safety Endpoint</td>
<td>Composite Safety: Freedom from BTK major adverse limb events (MALE) and/or perioperative death (POD) at 30-days</td>
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<td>Major Adverse Limb Event is defined as the composite of either major amputation or major re-intervention through 30 days of the index procedure. Major re-intervention is defined as creation of a new surgical bypass graft, the use of thrombectomy or thrombolysis or a major surgical graft revision such as a jump graft or an interposition graft</td>
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Secondary Endpoints

- **Procedural success** = achievement of a $\leq 30\%$ DS at the end of the procedure without MAEs as determined by angiographic core lab (irrespective of any pre- or post-adjunctive therapy, incl. stents)
- **Technical Success** = achievement of a $\leq 30\%$ DS following Phoenix and DCB as determined by angiographic core lab (without pre-dilatation and without any adjunctive therapy including stents).
- **Device Success** = achievement of a $\leq 50\%$ DS post-Phoenix without pre-dilatation and before any adjunctive therapy as determined by angiographic core lab

**IVUS specific:**
- Persisting stenosis $< 50\%$ on IVUS examination of the target lesion after treatment with atherectomy plus DCB either caused by dissection or remaining stenosis due to calcium
- Core lab assessed correlation between IVUS metrics of true luminal diameter, actual $\%$ area stenosis, change in plaque area and luminal gain pre- and post-therapy, plaque shape and angiographic core lab assessment of pre- and post-percent diameter stenosis ($\%$DS) and the extent of vascular calcification will be determined
- Final lumen gain based on IVUS core lab measurements
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TOBA: Dissection Repair Clinical Trials

**Tack® Implant**
- *Adaptive Sizing™* adapts to tapering ATK and BTK anatomy
  - ATK: 2.5 – 6.0mm
  - BTK: 1.5 – 4.5mm
- Nitinol with gold RO markers for visibility
- Unique anchoring system prevents migration
- 6mm deployed length

**Delivery System**
- ATK: 6F/0.035” - 6 implants pre-loaded on a single catheter
- BTK: 4F/0.014” - 4 implants pre-loaded on a single catheter
- Designed for highly accurate (≤1mm) deployment

| BTK        | TOBA BTK (N=35)       | Catheterization and Cardiovascular Intervention
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<td>Prospective, single arm</td>
<td>• 93.5% K-M freedom from CD- TLR</td>
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<td></td>
<td>6 Europe/New Zealand sites</td>
<td>• 84.5% Amputation-free survival</td>
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<td></td>
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<td>• 78.4% K-M patency rate</td>
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<tr>
<td>TOBA II BTK (N=232)</td>
<td>Prospective, single arm 60 US and international sites</td>
<td>Nearing full enrollment in US, Europe and New Zealand</td>
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</tbody>
</table>
Final Angiogram: No Dissection (core lab)
Conclusion

• For BTK interventions there is a need to find...
  • appropriate diagnostic modality (IVUS vs Angio)
  • optimal revascularisation strategy based on diagnostic modality (intraluminal calcium vs media sclerosis vs thrombus)
    • ...to achieve optimal lumen gain
    • ...to maintain lumen patency until wound healing
1st National Interdisciplinary CLI Congress

June 13th – 14th, 2019
Düsseldorf, Germany

Course Directors

Dr. med. Michael Lichtenberg
Prof. Dr. med. Giovanni Torsello
Prof. Dr. med. Markus Steinbauer
Prof. Dr. med. Thomas Zeller

„CLI congress is an interdisciplinary live course which provides an update on endovascular and operative therapy strategies for the most challenging vascular disease.“

www.cli-kongress.de
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