How to optimize acute success and drug effect of DCB in BTK vessels

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.

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<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, Volcano, Optimed GmbH, Straub Medical, Terumo, Biotronik, Veryan</td>
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<td>2. Honoraria for advisory board activities: Veniti, Optimed GmbH, Straub Medical, Biotronik, Veryan, Boston Scientific</td>
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<td>3. Participation in clinical trials: Biotronik, CR Bard, Veryan, Straub Medical, Veniti, TVA Medical, Boston Scientific, LimFlow, Terumo</td>
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<td>4. Research funding: Biotronik, Boston Scientific, 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
1st 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 after PTA

- **DEBELLUM**
  - 15.0% PTA
  - 30.7% DCB

- **IN.PACT™ DEEP**
  - 12.3% PTA
  - 19.2% DCB

Fanelli JEVTV 2012
Zeller JACC 2014
Is it thrombus? Dissection?...
2nd Question: Recanalization modality?

Based on diagnostic analysis

POBA vs DCB
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

Lesion preparation = better lumen = better outcome?
Efficacy/safety difference intima vs. media calcification?
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PRESTIGE Pilot – Phoenix Atherectomy and Stellarex DCB clinical investigation in infrapopliteal interventions
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3rd Question: Maintain Lumen?

AVOIDING DISSECTIONS
Low atmosphere balloon inflations
Long duration of balloon angioplasty
Long balloons

(DES) Stent Implantation

Tack Implantation
# 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

## TOBA BTK
- **TOBA BTK**
  - (N=35)
  - Prospective, single arm
  - 6 Europe/New Zealand sites

## TOBA II BTK
- **TOBA II BTK**
  - (N=232)
  - Prospective, single arm
  - 60 US and international sites

### Catheterization and Cardiovascular Intervention
- 93.5% K-M freedom from CD-TLR
- 84.5% Amputation-free survival
- 78.4% K-M patency rate

### Enrollment
- Nearing full enrollment in US, Europe and New Zealand
Final Angiogram: No Dissection (core lab)
4th Question: How to maintain patency?

Is DCB technology back on stage?

Secondary Endpoint
(KM 6 Month Primary Patency – Total Occlusion / CD-TLR)

86.3% DCB
72.2% PTA
14.0% Δ (p = <0.001)

LUTONIX® DCB Interim 24 Month registry data
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
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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

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