The Value of DEBs in Infrapopliteal Arteries Is Promising: Why In.Pact Deep Failed To Show A Benefit And What is Being Done To Make DEBs Work Better In Leg Arteries

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Potential conflicts of interest

Speaker's name: Andrej Schmidt
✓ I have the following potential conflicts of interest to report:
Consulting:
- Medtronic, Abbott, Boston Scientific, Cook, Cordis, C.R.Bard, Intactvascular, ReFlow Medical, Spectranetics, Upstream Peripheral

IN.PACT DEEP Study

- Multicentric. randomized. controlled
  - In.Pact Amphirion PTX-eluting balloon vs.
  - Uncoated Amphirion Deep (Medtronic)

- Endpoints:
  - 12-months LLL and clinically driven TLR
  - Composite endpoint
    - Death, TLR, major-amputation

- 358 patients included 2:1

IN.PACT DEEP Study-Design

358 patients
DEB = 239; PTA = 119

Angio at 12 mo (LLL)
(lesions ≤ 10 cm)
DEB = 113; PTA = 54

FU without Angio
DEB = 126; PTA = 65

clinical FU
(lesion-length 5.9 / 8.0 cm)
(lesion-length 10.2 / 12.9 cm)

IN.PACT DEEP: 12 Months Results

<table>
<thead>
<tr>
<th></th>
<th>DEB</th>
<th>POBA</th>
<th>P</th>
</tr>
</thead>
<tbody>
<tr>
<td>LLL (mm)</td>
<td>0.61</td>
<td>0.62</td>
<td>0.950</td>
</tr>
<tr>
<td>Binary restenosis rate</td>
<td>41.0 %</td>
<td>35.5 %</td>
<td>0.609</td>
</tr>
</tbody>
</table>

In.Pact Deep Study: Results from the POBA-Angio-Group

<table>
<thead>
<tr>
<th>Lesion-length (mm)</th>
<th>12-mo angi-restenosis-rate</th>
<th>CTOs</th>
</tr>
</thead>
<tbody>
<tr>
<td>Iida EJVES</td>
<td>140</td>
<td>82 %</td>
</tr>
<tr>
<td>DEBATE-BTK</td>
<td>131</td>
<td>74 %</td>
</tr>
<tr>
<td>In.Pact Deep</td>
<td>80</td>
<td>36 %</td>
</tr>
<tr>
<td>Achilles</td>
<td>27</td>
<td>45 %</td>
</tr>
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IN.PACT DEEP: 12 Months Results

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<tr>
<td>Major amputation</td>
<td>8.8 %</td>
<td>3.6 %</td>
<td>0.080</td>
</tr>
</tbody>
</table>

Twice as many patients were treated in the DCB-arm as in the POBA arm.

Zeller et al. JACC 2014

Leipzig Experience With DEBs BTK

1/2009 – 5/2012:
- IN.PACT DCBs were used in Apop / BTK
- 195 CLI patients (Ruth 4-6); 205 limbs
- Rutherford 4: 52 (25.4%)
- Rutherford 5: 140 (68.3%)
- Rutherford 6: 13 (6.3%)
- Mean lesion length: $148 \pm 92$ mm
- Occlusion 142 (69.3%)
- De-novo 133 (64.9%)

Leipzig Experience With IN.PACT Deep BTK

Limb Salvage

1-year major amputations 3.9% (n=8)
1-year TLR 20.1%

Follow-up in days

BIOLUX P-II: RCT Passeo 18-Lux vs. POBA BTK

Major Adverse Events at 30 days
- Passeo-Lux DCB 31 patients
- Passeo-control 31 patients

Primary safety endpoint:
- composite of all-cause-mortality, major amputation, TL-thrombosis and TLR at 30 days

TL Primary Patency at 6 months

DCBs are not all the same

Technology of the In.Pact Deep Balloon:
- first folded and then coated

Zeller et al. JACC Intervent 2015
Coating Integrity

- DCBs were delivered in a peripheral track model with fluid recirculation
- Particulates lost downstream were collected with a 5 µm polycarbonate filter and are shown as green dots

Ongoing: Lutonix BTK Clinical Trial

- 320 patients at 55 global sites,
- Rutherford 4 and 5; randomized 2:1
- Clinical FU and Duplex up to 36 months
- Angiography in a subset of patients at 12 months
- Primary endpoint:
  - Safety at 30 days (Major amputation / major re-intervention)
  - Limb salvage & primary patency at 12 months

Status of Lutonix 014 BTK IDE Study

- 49 Active Sites
- 255 Enrolled Subjects
  - 179 have completed 6 month follow-up
  - 121 have completed 12 month follow-up
- The Safety Data Monitoring Committee has met 7 times (quarterly) and deemed the study safe to continue.

Summary

- To show a potential clinical benefit for DCBs BTK in CLI-patients larger trials with better DCB-technology are needed.