Drug-coated balloons in below-the-knee arteries – data from the Heidelberg registry

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Disclosure

Speaker name:
Felicitas Stoll

I have the following potential conflicts of interest to report:

- Consulting
- 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 in the past 12 months
Background – DCB below-the-knee (1)

DEBATE BTK

- Reduction of
  - 1-year restenosis
  - target lesion revascularization
  - target vessel occlusion compared to PTA in diabetic patients with critical limb ischemia

Background – DCB below-the-knee (2)

INPACT.DEEP

- IA-DEB had comparable efficacy to PTA
- However trend towards increased major amputation rate compared to PTA

# DCB BTK – Heidelberg

- **Age**: 73 yrs (SD 9)

<table>
<thead>
<tr>
<th>Condition</th>
<th>Percentage</th>
<th>Count (Total)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Male</td>
<td>60%</td>
<td>41/68</td>
</tr>
<tr>
<td>Diabetes mellitus</td>
<td>62%</td>
<td>42/68</td>
</tr>
<tr>
<td>Hypertension</td>
<td>91%</td>
<td>62/68</td>
</tr>
<tr>
<td>Hyperlipidemia</td>
<td>72%</td>
<td>49/68</td>
</tr>
<tr>
<td>Obesity</td>
<td>31%</td>
<td>21/68</td>
</tr>
<tr>
<td>Active Smoker</td>
<td>25%</td>
<td>17/68</td>
</tr>
<tr>
<td>Renal insufficiency</td>
<td></td>
<td></td>
</tr>
<tr>
<td>NI 4</td>
<td>6%</td>
<td>4/68</td>
</tr>
<tr>
<td>NI 5</td>
<td>9%</td>
<td>6/68</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Rutherford Category</th>
<th>Percentage</th>
<th>Count (Total)</th>
</tr>
</thead>
<tbody>
<tr>
<td>3</td>
<td>39%</td>
<td>29/75</td>
</tr>
<tr>
<td>4</td>
<td>13%</td>
<td>10/75</td>
</tr>
<tr>
<td>5</td>
<td>25%</td>
<td>19/75</td>
</tr>
<tr>
<td>6</td>
<td>23%</td>
<td>17/75</td>
</tr>
</tbody>
</table>

- **ABI**: 0.53 (SD 0.30)
- **ABI ≥1.3**: 20%

- **CLI in 61% of patients**

- **Retrospective study**
- **75 interventions in 68 patients between January 2013 and July 2014**
Heidelberg DCB BTK: Procedural and Angiographic Characteristics

- Average target lesion length: 14 cm
- Complete vessel occlusion: 60%
- Average calcification grade: 1.65 (mild to moderate)
- Additional treatment of inflow lesion in 69%
- One covered stent due to perforation, one stent due to dissection

<table>
<thead>
<tr>
<th>Artery</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td>Anterior tibial artery</td>
<td>61</td>
</tr>
<tr>
<td>Tibioperoneal tract</td>
<td>56</td>
</tr>
<tr>
<td>Posterior tibial artery</td>
<td>28</td>
</tr>
<tr>
<td>Peroneal artery</td>
<td>32</td>
</tr>
</tbody>
</table>

- DCB
  - Medtronic InPact
  - Amphirion
  - Bard Lutonix
  - (Sequent Please DEB)
Heidelberg DCB BTK: Target lesion revascularisation

Freedom from TLR after 1 year: 68%
Heidelberg DCB BTK: Primary and Secondary Patency Rates*  

*as defined by freedom from clinically driven TLR and/or DUS/angiography
Heidelberg DCB BTK: Primary Patency* after 12 months

<table>
<thead>
<tr>
<th>Patency (12 mo)</th>
<th>Count</th>
<th>% in Balloon</th>
<th>Balloon</th>
<th>InPact</th>
<th>Amphirion</th>
<th>Lutonix</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td>no</td>
<td>11</td>
<td>32,4%</td>
<td>InPact</td>
<td>11</td>
<td>9</td>
<td>20</td>
<td></td>
</tr>
<tr>
<td>yes</td>
<td>23</td>
<td>67,6%</td>
<td>Amphirion</td>
<td>23</td>
<td>3</td>
<td>26</td>
<td></td>
</tr>
<tr>
<td>Total</td>
<td>34</td>
<td>100%</td>
<td>Lutonix</td>
<td>12</td>
<td>46</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

(P = 0.01)

*as defined by freedom from clinically driven TLR and/or DUS/angiography
Heidelberg DCB BTK: Ulcer Healing

### Ulcer localisation

<table>
<thead>
<tr>
<th>Location</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td>Toes</td>
<td>61</td>
</tr>
<tr>
<td>Heel</td>
<td>17</td>
</tr>
<tr>
<td>Ankle</td>
<td>8</td>
</tr>
<tr>
<td>Calf</td>
<td>22</td>
</tr>
<tr>
<td>Foot</td>
<td>8</td>
</tr>
</tbody>
</table>

- In 68% angiosome-driven angioplasty

### Ulcer healing after 6 months

- 78% Improved
- 20% Unimproved

n = 25
Heidelberg DCB BTK: Amputation

Freedom from Major Amputation after 1 year: **92%**

- For CLI patients: **86%**

Freedom from Minor Amp: **88%** (CLI: 81%)
Heidelberg DCB BTK: Amputation and Death

Freedom from Major Amputation and Death after 1 year: **84%**

- For CLI patients: **74%**
Heidelberg DCB BTK - Limitations

- Single-center retrospective registry
- Limited number of patients
- Heterogenous patient cohort (Rutherford 3-6)
- Heterogenous lesion morphologies
  - high rate of occlusions compared to other studies
  - long lesion lengths
- No comparison to plain balloon angioplasty
Heidelberg DCB BTK - Conclusions

- DCB treatment could be safely performed (no device malfunctions)
- Low rate of major amputations and deaths in CLI patients
- Low rate of stent implantation
- No definite conclusion can be drawn regarding an increased patency rate after DCB treatment
- Large randomized controlled studies are needed to further analyze the benefit of DCB in BTK arteries
Thanks to

*Heidelberg University Hospital, Angiology:*
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Tanja Wobedo
Ira Weyer

Prof. Dr. med. Erwin Blessing, *Karlsbad-Langensteinbach*

Thank you for your attention!
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