Endovascular Treatment of a CLI-Patient with BTK-Disease

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Disclosure of Interest

Speaker 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
Case-Presentation

- 52 years male patient
- Diabetes mellitus type 2
- Heavy smoker
- Severe restpain dig I left and gangrene since 4 weeks
Rutherford 5 left

Pedal arch occluded
Typical disease-pattern for DM?
Buerger’s disease?
Recanalization Treatment

Endo / bypass ? (long lesion)

Peroneal or anterior / posterior tib. ?

POBA, atherectomy, stenting ?

Reconstruction of forefoot-arteries ?
Endovascular Treatment

- Slow healing
- Restpain resolves slowly during healing-process
- At 6 weeks toe still ischemic
- Repeat angio?

PTA with a low profile 2.5/150 balloon
Re-Occlusion at 6 Weeks

- Repeat PTA?

- Peroneal bypass?

- Conservative treatment?
  (toe-amputation not necessary)

- Endo: some different technique?
Re-Occlusion at 6 Weeks

Re-occlusion

Second treatment with POBA
Second Re-occlusion after 4 Months

- Recurrence of ischemia at toes, but no ulcer / gangrene

- Continues to smoke

- Bypass ?
- Endo ?
- Different techniques ?
Second Re-occlusion after 4 Months

Second re-occlusion 3 x 4/80mm self-expanding BMS
Result after 3. PTA and Stent-Implantation
Third Re-Occlusion (in Stent) after 5 Months

- Recurrence of ischemia forefoot
  Swelling, restpain, discoloration

- Endo / Bypass still possible?
Third Re-Occlusion (in Stent) after 5 Months

Third re-occlusion

Fourth treatment with POBA
Fourth Re-Occlusion at 6 Mo, Recurrence of Disease

Fourth Re-occlusion

5. Intervention (DCB)
6 Months Angiography after DCB, no Symptoms
6 months after DCB

3.5 years after DCB
Angio during treatment right
DCB-treatment in the first step would have prevented recurrence of disease and 4 TLRs?
### 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><em>35.5%</em></td>
<td>0.609</td>
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</tbody>
</table>

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

*Zeller et al. JACC 2014*
Leipzig Experience With DCBs 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 ± 92 mm
• Occlusion 142 (69.3%)
• De-novo 133 (64.9%)
Leipzig Experience With IN.PACT Deep BTK

Limb Salvage

Cumulative Survival

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

POBA  8.3% [2.8 – 23.7]
DRB  0.0% [0.0 – 0.0]
p-value : 0.239
(Fisher’s exact)

Zeller et al. JACC Intervent 2015
TL Primary Patency at 6 months

POBA  75.9% [61.4 – 85.6]

DEB  82.4% [66.5 – 91.2]

p*-value : 0.452 (Log Rank)

Zeller et al. JACC Intervent 2015
Summary

- So far no good data to prove that DCB work BTK but cases give hints that they can be effective