2-year result of the REAL PTX - randomized clinical trial comparing Zilver PTX vs. DCB treatment in femoropoliteal lesions

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Disclosure
Speaker’s name: Dierk Scheinert
I have the following potential conflicts of interest to report:
Advisory Board /Consultant: Abbott, Biotronik, Boston Scientific, Cook Medical, Cordis, CR Bard, Gardia Medical/Allium, Medtronic, Trimeme Medical, Trivascular, Upstream Peripheral Technologies

Study Design
• Prospective, multicenter (5 centers in Europe), randomized, controlled trial
• Zilver PTX drug eluting stent vs drug coated balloon (1:1) in native femoropopliteal disease
• Investigator initiated: PI Prof. D. Scheinert, Germany
• N= 150 patients, 75 in each group
• Stratification for lesion length for both groups (1:1:1)
  short: ≤ 10 cm
  middle: > 10 and ≤ 20 cm
  long: > 20 and ≤ 30 cm
• Mean lesion length: 152.6 ± 88.2 mm
• Independent core-lab assessment for angio and duplex

Follow up: 3 Years
Endpoints
• Primary: Primary Patency @ 12 Month (Duplex)
• Secondary: Procedural sucess
Mayor Adverse Event (Mayor Amputation; Death or TLR within 30 days)
Primary Patency @ 24, 36 Month
Clinically driven target lesion revascularisation (TLR)
ABI, Improvement in Rutherford Categories, Assessment of walking capacity (WIQ)
Mortality

Patient Characteristics

<table>
<thead>
<tr>
<th></th>
<th>DCB (n=75)</th>
<th>Zilver PTX (n=75)</th>
<th>*p-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age in years (± SD)</td>
<td>68.2 ± 9.6</td>
<td>69.5 ± 9.5</td>
<td>0.422</td>
</tr>
<tr>
<td>Gender (male %)</td>
<td>40.0</td>
<td>76.0</td>
<td>0.004</td>
</tr>
<tr>
<td>BMI, mean (± SD)</td>
<td>26.5 ± 6.3</td>
<td>27.5 ± 4.9</td>
<td>0.156</td>
</tr>
<tr>
<td>Major arterial infections, n (%)</td>
<td>11(14.7)</td>
<td>9(12)</td>
<td>0.629</td>
</tr>
<tr>
<td>Mean failure ≤ 10 (%)</td>
<td>0.9 (%)</td>
<td>1.3 (1)</td>
<td>0.346</td>
</tr>
<tr>
<td>Hemodialysis, n (%)</td>
<td>12(16.0)</td>
<td>15(20.0)</td>
<td>0.508</td>
</tr>
<tr>
<td>Hyperlipidemia, n (%)</td>
<td>58(78.7)</td>
<td>61(81.3)</td>
<td>0.302</td>
</tr>
<tr>
<td>Renin-angiotensin, n (%)</td>
<td>34(45.3)</td>
<td>38(50.6)</td>
<td>0.309</td>
</tr>
<tr>
<td>Smoking, n (%)</td>
<td>0.447</td>
<td></td>
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</tr>
<tr>
<td>Current, n (%)</td>
<td>32(42.7)</td>
<td>29(38.7)</td>
<td></td>
</tr>
<tr>
<td>Previous, n (%)</td>
<td>22(29.3)</td>
<td>12(16.0)</td>
<td></td>
</tr>
<tr>
<td>Diabetes, n (%)</td>
<td>25(33.3)</td>
<td>21(28.0)</td>
<td>0.728</td>
</tr>
<tr>
<td>Type 1 (%)</td>
<td>3(4.0)</td>
<td>2(2.7)</td>
<td></td>
</tr>
<tr>
<td>Type 2 (%)</td>
<td>22(29.3)</td>
<td>19(25.3)</td>
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</tbody>
</table>

*For categorical data, Fisher’s exact test is performed in general

Lesion Characteristics

<table>
<thead>
<tr>
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<tbody>
<tr>
<td>Claudication (RC 2-3), n (%)</td>
<td>67(89.3)</td>
<td>63(84.0)</td>
<td></td>
</tr>
<tr>
<td>Critical limb ischemia (RC 4-5), n (%)</td>
<td>8 (10.7)</td>
<td>12 (16.0)</td>
<td>0.472</td>
</tr>
<tr>
<td>Lesion length (mm) ± SD*</td>
<td>144.8 ± 92.1</td>
<td>159.6 ± 97.3</td>
<td>0.341</td>
</tr>
<tr>
<td>Lesion location, n (%)***</td>
<td>SFA</td>
<td>60 (80.0)</td>
<td>62 (84.0)</td>
</tr>
<tr>
<td>Occlusion, n (%)***</td>
<td>40 (53.3)</td>
<td>39 (52.0)</td>
<td>0.870</td>
</tr>
<tr>
<td>MLD in lesion, mm ± SD**</td>
<td>0.57 ± 0.77</td>
<td>0.46 ± 0.77</td>
<td>0.076***</td>
</tr>
<tr>
<td>Percent diameter stenosis, n (%)</td>
<td>87.4 ± 16.0</td>
<td>86.0 ± 15.2</td>
<td>0.660**</td>
</tr>
<tr>
<td>Lesion calcification, n (%)</td>
<td>0.561</td>
<td></td>
<td></td>
</tr>
<tr>
<td>None</td>
<td>33 (43.7)</td>
<td>39 (52.0)</td>
<td></td>
</tr>
<tr>
<td>Mild</td>
<td>22 (29.3)</td>
<td>19 (25.3)</td>
<td></td>
</tr>
<tr>
<td>Moderate</td>
<td>24 (32.0)</td>
<td>24 (32.0)</td>
<td></td>
</tr>
<tr>
<td>Severe</td>
<td>17 (22.7)</td>
<td>26 (34.6)</td>
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</table>

*Fisher’s exact test is performed in general, ** non-parametric test (Mann-Whitney-Wilcoxon-U using t approximation) *** Satterthwaite approximation should be generally used (no deviations in all other variables)
**Acute Outcome**

| Group | Bailout Stent CoreLab, n (%) | Residual Stenosis,
visual estimate ≥ 30%, n (%) | CoreLab > 30%, n (%) | MLD post-procedure, mean ± SD | Dissection, n (%) | Type A/B, n (%) | Type C-D, n (%) | Embolic event, n (%) | AV Fistel (local), n (%) | Target Vessel Perforation, n (%) | *p-value*
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<tr>
<td>DCB</td>
<td>19 (25.3)</td>
<td>NA</td>
<td>2 (2.7)</td>
<td>14 (18.7)</td>
<td>6.5 ± 0.7</td>
<td>54 (72.0)</td>
<td>35 (46.7)</td>
<td>4 (5.3)</td>
<td>6 (8.0)</td>
<td>1 (1.3)</td>
<td>NA</td>
</tr>
<tr>
<td>Zilver PTX</td>
<td>1 (1.3)</td>
<td>1 (1.3)</td>
<td>30 (40.0)</td>
<td>4.1 ± 0.7</td>
<td>29 (38.7)</td>
<td>14 (18.7)</td>
<td>29 (38.7)</td>
<td>1 (1.3)</td>
<td>2 (2.7)</td>
<td>0 (0.0)</td>
<td>&lt; 0.001*</td>
</tr>
</tbody>
</table>

* For comparison Fisher’s exact test is performed in general

**1° Patency @ 12 and 24 month**

- **Primary Patency**
  - DCB: 87.6 ± 1.00
  - DES: 76.2 ± 0.96

- **Primary Patency @ 24 Month (%)**
  - DCB: 87.6 ± 1.00
  - DES: 76.2 ± 0.96

**Significant decrease in 1° Patency in Long Lesions!**

- Total of 16 patency events before 12 months
- 11/16 (68%) occurred in lesions >20cm
- 11/16 (68%) were restenotic lesions
- 9/16 (56%) had severe or moderate calcification
- Only 1 early stent thrombosis (<30 days)
- 4 patients with stent occlusions (partially thrombotic lesions - Rotarex treatment)
- 11 lesions were stenotic (restenosis or residual stenosis) with no thrombotic component
- 7/16 (44%) never needed a TLR

**Primary Endpoint**

**1° Patency @ 12 month**

- **Primary Patency**
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- **Primary Patency @ 24 Month (%)**
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REAL PTX – Case 003 - 021

stratified C: >20 cm and ≤ 30 cm
Total Occlusion of Stent (%) after 6 weeks

- Lesion Length: 27 cm
- Calcification: 1°
- Zilver PTX: 6x100 / 6x100 / 7x100 mm

- Core Lab: Residual stenosis 47%! (focal severe calcification, stent distal not completely expanded)

- TLR 6 weeks after index procedure: Instent re-occlusion (thrombolysis)

Residual Stenosis ≥ 30%

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<tr>
<td>Residual Stenosis, visual estimate ≥ 30%, n (%)</td>
<td>2 (2.7)</td>
<td>1 (1.3)</td>
<td></td>
</tr>
<tr>
<td>CoreLab &gt; 30%, n (%)</td>
<td>14 (18.7)</td>
<td>30 (40.0)</td>
<td>&lt;0.001*</td>
</tr>
</tbody>
</table>

Optimize acute outcome with consistent vessel preparation → will potentially lead to better long-term patency

1° Patency @ 24 Month
Stratification for Lesion Length – ITT

Primary Patency @ 24 Month
Long Lesion Group
Zilver PTX vs DCB only

Decreased patency for „DCB only“ in long lesions!

Conclusion

- No significant difference between DCB and DES in Primary Patency @ 12 months
- Trend showing better durability of DES treatment at 24 months
- Significantly better outcome for short lesions in both groups
- Increased benefit of DES in longer lesions in comparison to DCB only treatment
- Vessel preparation is mandatory for both DCB and DES – particularly in complex lesions!
- Pilot trial – not powered to show statistical significance
- 3 year follow-up is ongoing → LINC 2018
2-year result of the REAL PTX – randomized clinical trial comparing Zilver PTX vs. DCB treatment in femoropopliteal lesions

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