New safety and effectiveness data of Luminor DCB: EffPac trial 3.5 years

Scheinert, Dierk MD
on behalf of the investigators
Head of Medical Department V - Angiology
University of Leipzig Medical Center, Germany
Disclosure

Advisory Board / Consultant:
Abbott, Acotec, Biotronik, Boston Scientific, Cook Medical, Cordis, CR Bard, Gardia Medical/Allium, Medtronic, TriReme Medical, Trivascular, Upstream Peripheral Technologies
luminor
Paclitaxel coated balloon
(3.0 µg/mm²)

Ultra low tip and crossing profiles

Innovative and UNIQUE nanotechnology coating

Fast deflation

Complete balloon range dimensions
Luminor 35: 5-7mm Ø and 20-150mm length
Luminor 18: 2-8 mm Ø and 20-200mm length
Luminor 14: 1.5-4mm Ø and 40-200mm length
Study Design & Participating Sites

Investigator initiated, prospective, multicenter, randomized controlled trial

01 Jena  PD Dr. R. Aschenbach  University Hospital Jena
02 Leipzig  Prof. Dr. Dierk Scheinert  University Hospital Leipzig
03 Bad Krozingen  Prof. Dr. Thomas Zeller  Heart Center
04 Hamburg  Dr. S. Sixt, Dr. S. Brucks  Angiologikum
05 München  PD Dr. M. Treitl  University Hospital
06 Berlin  Prof. Dr. K. Brechtel  „Ihre Radiologen“
07 Sonneberg  Dr. M. Thieme  Medinos Clinic
08 Karlsbad  Prof. Dr. E. Blessing  SRH-Clinic
09 Heidelberg  Dr. B. Vogel, Dr. C. Erbel  University Heidelberg
10 Arnsberg  Dr. M. Lichtenberg  Clinic Arnsberg
11 Kusel  Dr. P. von Flotow  Westpfalz Clinic
Study Endpoints

**Primary Endpoint**
- LLL at 6 months

**Secondary Endpoints**
- Binary restenosis
- Primary patency
- Freedom from TLR
- Freedom from TVR
- Rutherford category
- WIQ-score
- ABI
- EQ-5D score

- All-cause mortality
- Target limb amputation
Key Eligibility Criteria

Inclusion
- Rutherford category 2-4
- De-novo stenotic/restenotic or occluded (≥ 70%) SFA/prox. PA lesions
- Lesion length ≤ 150 mm
- 1 lesion/patient
- Successful pre-dilation

Exclusion
- Previous TV surgery
- Major amputation TL
- Severely calcified lesions (PTA resistant)
- In-stent restenosis
Enrollment
Sept 2015 – Dec 2016

Successful guidewire passage and **pre-dilation**

Randomization
n = 171

**DCB* Angioplasty**
n = 85 (84 received DCB)

- Discontinued
  n=29
  (Died: n=2)

**POBA**
n = 86

- Discontinued
  n=35
  (Died: n=7)

42-month Analysis (ITT)
Clinical n=56 (65.9%)
DUS n=45 (52.9%)

42-month Analysis (ITT)
Clinical n=51 (59.3%)
DUS n=46 (53.5%)
## Baseline Patient Characteristics

<table>
<thead>
<tr>
<th></th>
<th>DCB (n = 85)</th>
<th>POBA (n = 86)</th>
<th>P value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age, years</td>
<td>68.0 ± 7.5</td>
<td>68.1 ± 8.8</td>
<td>p = 0.979</td>
</tr>
<tr>
<td>Male, %</td>
<td>60.0</td>
<td>69.8</td>
<td>p = 0.239</td>
</tr>
<tr>
<td>Diabetes, %</td>
<td>36.5</td>
<td>40.4</td>
<td>p = 0.681</td>
</tr>
<tr>
<td>Hypertension, %</td>
<td>87.1</td>
<td>84.9</td>
<td>p = 0.850</td>
</tr>
<tr>
<td>Hyperlipidemia, %</td>
<td>70.7</td>
<td>68.6</td>
<td>p = 0.144</td>
</tr>
<tr>
<td>Current smoker, %</td>
<td>40.5</td>
<td>43.0</td>
<td>p = 0.856</td>
</tr>
<tr>
<td>Critical limb ischemia, %</td>
<td>3.6</td>
<td>1.2</td>
<td>p = 0.613</td>
</tr>
<tr>
<td>ABI</td>
<td>0.73 ± 0.23</td>
<td>0.74 ± 0.23</td>
<td>p = 0.929</td>
</tr>
<tr>
<td>Lesion and Procedure Characteristics</td>
<td>DCB (n = 85)</td>
<td>POBA (n = 86)</td>
<td>P value</td>
</tr>
<tr>
<td>-------------------------------------</td>
<td>-------------</td>
<td>--------------</td>
<td>---------</td>
</tr>
<tr>
<td>Lesion length, mm</td>
<td>59.1 ± 43.4</td>
<td>55.8 ± 39.1</td>
<td>p = 0.732</td>
</tr>
<tr>
<td>CTO, %</td>
<td>20.2</td>
<td>25.6</td>
<td>p = 0.492</td>
</tr>
<tr>
<td>Calcification, %</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Severe</td>
<td>3.6</td>
<td>11.6</td>
<td>p = 0.232</td>
</tr>
<tr>
<td>Moderate</td>
<td>42.2</td>
<td>44.2</td>
<td></td>
</tr>
<tr>
<td>Mid / dist. popliteal artery, %</td>
<td>18.8</td>
<td>14.0</td>
<td>p = 0.248</td>
</tr>
<tr>
<td>Pre-dilation, %</td>
<td>98.8</td>
<td>98.8</td>
<td>p = 0.993</td>
</tr>
<tr>
<td>Dissection, %</td>
<td>37.6</td>
<td>40.7</td>
<td>p = 0.801</td>
</tr>
<tr>
<td>Bailout stenting, %</td>
<td>15.3</td>
<td>18.8</td>
<td>p = 0.709</td>
</tr>
<tr>
<td>Residual DS, %</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>post-angioplasty</td>
<td>15.5 ± 16.7</td>
<td>14.9 ± 16.2</td>
<td>p = 0.807</td>
</tr>
<tr>
<td>post-treatment</td>
<td>7.5 ± 9.3</td>
<td>8.3 ± 10.1</td>
<td>p = 0.699</td>
</tr>
<tr>
<td>Study</td>
<td>DCB 6-month LLL</td>
<td>Control 6-month LLL</td>
<td>Difference DCB vs POBA (mm)</td>
</tr>
<tr>
<td>-------------------------</td>
<td>-----------------</td>
<td>---------------------</td>
<td>-----------------------------</td>
</tr>
<tr>
<td>THUNDER: Paccocath coating (Tepe et al. 2008)</td>
<td>0.4±1.2</td>
<td>1.7±1.8</td>
<td>-1.3</td>
</tr>
<tr>
<td>AcoArt I Trial: Orchard (Acotec) (Jia et al. 2016)</td>
<td>0.05±0.73</td>
<td>1.15±0.89</td>
<td>-1.1</td>
</tr>
<tr>
<td>EFFPAC: Luminor (iVascular) (2018)</td>
<td><strong>0.14</strong> [CI: -0.38; 0.67]</td>
<td><strong>1.06</strong> [CI: 0.54; 1.59]</td>
<td><strong>-0.92</strong> [CI: -1.364; -0.49] p &lt; 0.001</td>
</tr>
<tr>
<td>RANGER: Ranger DCB (Bausback et al. 2017)</td>
<td>-0.16±0.99</td>
<td>0.76±1.4</td>
<td>-0.92</td>
</tr>
<tr>
<td>LEVANT: Lutonix (Bard) (I Scheinert et al. 2014)</td>
<td>0.46±1.13</td>
<td>1.09±1.07</td>
<td>-0.63</td>
</tr>
<tr>
<td>BIOLUX P-I: Passeo-18 Lux (Biotronik) (Scheinert et al. 2015)</td>
<td>0.51±0.72</td>
<td>1.04±1.0</td>
<td>-0.53</td>
</tr>
<tr>
<td>FEMPAC: Paccocath DCB (Werk et al. 2008)</td>
<td>0.5±1.1</td>
<td>1.0±1.1</td>
<td>-0.5</td>
</tr>
<tr>
<td>CONSEQUENT: SeQuent Please (B. Braun) (2017)</td>
<td>0.35 [CI: 0.19; 0.79]</td>
<td>0.72 [CI: 0.68; 1.22]</td>
<td>-0.37</td>
</tr>
</tbody>
</table>
Clinical Improvement: Change of RBC - 42 mo

*P-value for difference in change from baseline to 42 months between DCB and POBA

*p = 0.188*
*p = 0.021*
*p = 0.740*
*p = 0.882*

n=85  n=85  n=74  n=74  n=74  n=70  n=59  n=56  n=52  n=51
Primary Patency: Freedom from restenosis (determined by duplex ultrasound PSVR < 2.5) and freedom from TLR.

Primary patency – 42 Months

p=0.010 (logrank test)

Primary patency after 42M (Kaplan Meier estimate with 95% CI)

DCB: 69.6% [95% CI: 55.0% to 80.3%]
POBA: 60.0% [95% CI: 47.3% to 70.6%]

Follow-up (Months)

DCB: 77 77 75 71 67 55 55 55 52 42 41 40 40 39 22 2 2 0
POBA: 77 77 70 54 47 39 38 37 30 29 29 29 17 1 1 0
Freedom From TLR – 42 Months

Freedom from TLR after 42M (Kaplan Meier estimate with 95% CI)

- **DCB**: 90.1% [95% CI: 79.1% to 95.4%]
- **POBA**: 78.1% [95% CI: 66.6% to 86.1%]

*p=0.018 (logrank test)*
<table>
<thead>
<tr>
<th></th>
<th>DCB</th>
<th>POBA</th>
<th>P value</th>
</tr>
</thead>
<tbody>
<tr>
<td>All-cause mortality*, %</td>
<td>2** (2.4)</td>
<td>7*** (8.3)</td>
<td>p = 0.168</td>
</tr>
<tr>
<td>Binary restenosis, %</td>
<td>34**** (54.8)</td>
<td>34**** (54.8)</td>
<td>p = 1.000</td>
</tr>
<tr>
<td>TLR, %</td>
<td>7**** (12.3)</td>
<td>16**** (29.1)</td>
<td>p = 0.036</td>
</tr>
<tr>
<td>Periprocedural complication, %</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Dissection</td>
<td>32 (37.6)</td>
<td>35 (40.7)</td>
<td>p = 0.801</td>
</tr>
<tr>
<td>False aneurysm</td>
<td>0</td>
<td>1 (1.2)</td>
<td>p = 1.000</td>
</tr>
<tr>
<td>Thromb. embolization</td>
<td>1 (1.2)</td>
<td>0</td>
<td>p = 1.000</td>
</tr>
</tbody>
</table>

* Survey of all randomized patients, DCB: n=82, POBA: n=84 (4 patients could not be reached, 1 patient has withdrawn informed consent)
** Two DCB patients died for unknown reason
*** Reasons: suicide, cardiac arrest (2x), cholangiocellular carcinoma, multiple organ failure, respiratory failure, unknown
**** including patients with an event (binary restenosis/TLR) at an earlier follow-up
Conclusions

At 3.5 years, DCB angioplasty (Luminor-35®) of medium length SFA/PA lesions resulted in

- A significant clinical and hemodynamic improvement from baseline with lower TLR rate
- All-cause mortality similar to POBA
- Significantly less need for TLR