How can we improve treatment of long femoropopliteal lesions with DCB?

Dr. Marc Bosiers
LINC 2018, Leipzig
Conflict of interest

☐ 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)

✔ I do not have any potential conflict of interest
DCB-treatment works... Proof of concepts

DCB

POBA

- PASSEO 18 LUX
  - PTX 3\(\mu\)g/mm\(^2\) + BTHC
  - P=0.033

- PACOCATH
  - PTX 3\(\mu\)g/mm\(^2\)
  - P=0.031

- IN.PACT
  - PTX 3,5\(\mu\)g/m\(^2\)
  - P=0.001

- CVI
  - PTX Excipient?

- THUNDER
  - PTX 3\(\mu\)g/mm\(^2\)
  - P<0.001

- LEVANT
  - PTX 3\(\mu\)g/mm\(^2\) + polysorbate & sorbitol
  - P=0.016

- ADVANCE
  - PTX 3\(\mu\)g/mm\(^2\)
  - No excipient
  - P=0.12

Lesion Length (mm)

Late Lumen Loss (mm)

PASSEO 18 LUX

FEMPAC

PACIFIER

CVI

THUNDER

LEVANT

ADVANCE

PTX
1-Year Patency Rates of DCB (in ideal circumstances)

<table>
<thead>
<tr>
<th>Primary Patency (%)</th>
<th>89.50</th>
<th>89.00</th>
<th>87.50</th>
<th>85.40</th>
<th>N.A.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Lesion Length (mm)</td>
<td>70</td>
<td>72</td>
<td>89.4</td>
<td>62.9</td>
<td>80.4</td>
</tr>
<tr>
<td>% Bail-out stenting</td>
<td>6</td>
<td>15.4</td>
<td>7.3</td>
<td>25.2</td>
<td>14.5</td>
</tr>
<tr>
<td>% CTO</td>
<td>9.4</td>
<td>19.2</td>
<td>25.8</td>
<td>31.2</td>
<td>22.1</td>
</tr>
<tr>
<td>% Severe Ca++</td>
<td>9.4</td>
<td>12.7</td>
<td>8.1</td>
<td>N.A.</td>
<td>11.7</td>
</tr>
</tbody>
</table>
However in “Real Life”

- LL > 10 cm
- CTO > 30%
- Severe Ca++ > 30%
REFLOW study

A study investigating the Efficacy of the LEGFLOW Paclitaxel-Eluting for the treatment of long femoropopliteal lesions (TASC C&D)
Legflow Drug Coated Balloon
Study design

- **Study Objective:**
  To evaluate the performance of the **LEGFLOW Paclitaxel-Eluting** Peripheral balloon catheter for the treatment of **long femoropopliteal lesions (TASC C&D)**.

- **Primary Endpoint:**
  **Primary Patency at 12 months**, defined as absence of a hemodynamically significant stenosis on duplex ultrasound (systolic velocity ratio ≤2.4) at the target lesion and without reintervention.
Participating centers

- **BELGIUM**
  - M. Bosiers, K. Deloose, J. Callaert - AZ Sint-Blasius, Dendermonde
  - P. Peeters, J. Verbist, W. Van den Eynde - Imelda Hospital, Bonheiden
  - L. Maene, R. Beelen - OLV, Aalst
  - K. Keirse - RZ Heilig Hart, Tienen
  - J. Hendriks, P. Lauwers – University Hospital Antwerp, Edegem

- **GERMANY**
  - G. Torsello – St. Franziskus-Hospital Münster
  - D. Scheinert – Universitätsklinikum Leipzig
Inclusion criteria

Main inclusion criteria

- Rutherford classification from 2 to 5
- *De novo lesion* in the femoropopliteal arteries, suitable for endovascular therapy
- Total target lesion length > 150mm

ReFlow

101 out of 120 patients enrolled (84%)
<table>
<thead>
<tr>
<th>Timeline</th>
<th>Baseline</th>
<th>disch</th>
<th>1 M</th>
<th>6 M</th>
<th>12 M</th>
</tr>
</thead>
<tbody>
<tr>
<td>Medication</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Physical examination</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Rutherford</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>ABI</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Core Lab Ultrasound</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
# Patient Demographics

<table>
<thead>
<tr>
<th>Condition</th>
<th>Count (Percentage)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Male (%)</strong></td>
<td>43 (66.15%)</td>
</tr>
<tr>
<td><strong>Age (min – max)</strong></td>
<td>70.01 (35.05 – 89.27) years</td>
</tr>
<tr>
<td><strong>Nicotine abuse (%)</strong></td>
<td>39 (60.00%)</td>
</tr>
<tr>
<td><strong>Hypertension (%)</strong></td>
<td>49 (75.38%)</td>
</tr>
<tr>
<td><strong>Diabetes mellitus (%)</strong></td>
<td>20 (30.77%)</td>
</tr>
<tr>
<td><strong>Renal insufficiency (%)</strong></td>
<td>9 (13.85%)</td>
</tr>
<tr>
<td><strong>Hypercholesterolemia (%)</strong></td>
<td>36 (55.38%)</td>
</tr>
<tr>
<td><strong>Obesity (%)</strong></td>
<td>13 (20.00%)</td>
</tr>
</tbody>
</table>

N = 65 out of 120

![Rutherford Classification Chart](chart.png)
### Procedural characteristics

<table>
<thead>
<tr>
<th></th>
<th>N = 65 out of 100</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Procedure time</strong> <em>(min–max)</em></td>
<td>49.06 <em>(20-115)</em> minutes</td>
</tr>
<tr>
<td>Scopy time <em>(min – max)</em></td>
<td>11.70 <em>(3 – 38.50)</em> minutes</td>
</tr>
<tr>
<td></td>
<td>*missing information for 1 patient</td>
</tr>
<tr>
<td><strong>Contrast</strong> <em>(min – max)</em></td>
<td>96.89 <em>(25 – 195)</em> mL</td>
</tr>
<tr>
<td><strong>Cross-over performed (%)</strong></td>
<td>37 <em>(56.92%)</em></td>
</tr>
<tr>
<td><strong>Inflow Lesion (%)</strong></td>
<td>5 <em>(7.69%)</em></td>
</tr>
<tr>
<td><strong>Outflow lesion (%)</strong></td>
<td>14 <em>(21.54%)</em></td>
</tr>
</tbody>
</table>
Lesion Characteristics

<table>
<thead>
<tr>
<th></th>
<th>N = 65 out of 100</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Lesion length</strong> <em>(min – max)</em></td>
<td><strong>218 (150 – 390) mm</strong></td>
</tr>
<tr>
<td><strong>Ref Vessel Diameter</strong> <em>(min – max)</em></td>
<td><strong>5.37 (4.5 – 6.0) mm</strong></td>
</tr>
<tr>
<td>Pre-dilatation (%)</td>
<td><strong>41 (63.08%)</strong></td>
</tr>
<tr>
<td>1 DCB (%)</td>
<td><strong>16 (24.62%)</strong></td>
</tr>
<tr>
<td>2 DCB’s (%)</td>
<td><strong>37 (56.92%)</strong></td>
</tr>
<tr>
<td>3 DCB’s (%)</td>
<td><strong>12 (18.46%)</strong></td>
</tr>
<tr>
<td>Post-dilatation (%)</td>
<td><strong>14 (21.54%)</strong></td>
</tr>
<tr>
<td><strong>Bail-out stenting (%)</strong></td>
<td><strong>13 (20.00%)</strong></td>
</tr>
<tr>
<td>Occlusion (%)</td>
<td><strong>25 (31.25%)</strong></td>
</tr>
<tr>
<td><strong>Calcified lesion (%)</strong></td>
<td><strong>43 (53.75%)</strong></td>
</tr>
</tbody>
</table>
6-month Primary Patency – 65 pts

Primary Patency - 65 pts - 6MFU

Cumulative Primary Patency Rate (%)

84.10%
6-month Freedom from TLR – 65 pts

Freedom from Target Lesion Revascularization - 65 pts - 6MFU

Cumulative freedom from TLR Rate (%)

- Time (days)
  - 0
  - 30
  - 60
  - 90
  - 120
  - 150
  - 180
  - 210

- Number at risk
  - 65
  - 64
  - 61
  - 61
  - 61
  - 58
  - 55
  - 26

- 88.90%
6-month Rutherford evolution – 65 pts
Conclusion

• Preliminary results suggest that the LEGFLOW DCB is a valid and effective alternative to treat “real-life” long, complex and calcified femoropopliteal lesions.

• Awaiting for the final 12-month results.
How can we improve treatment of long femoropopliteal lesions with DCB?

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