DESs vs. DEBs: Which Is Best In What Setting?

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Faculty Disclosure

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DCB or DES in Femoro-Popliteal Lesions?

Scheme

Predilatation of the SFA-lesion with an undersized balloon
(Usual treatment-path before DCB)

In case of severe dissection
Good result

- Zilver-PTX-Stent
- DCB according to the RVD
- Additional BMS if necessary

DEB the Preferred Solution for the SFA in Every Case?

Baseline Lesion Characteristics

<table>
<thead>
<tr>
<th>Zilver PTX RCT</th>
<th>PTA</th>
<th>Normal-to-normal lesion length (mm)</th>
<th>61 ± 43</th>
<th>66 ± 39</th>
<th>0.36</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td>Stenosed lesion length (mm)²</td>
<td>53 ± 46</td>
<td>55 ± 41</td>
<td>0.71</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Diameter stenosis (%)¹</td>
<td>78 ± 17</td>
<td>80 ± 17</td>
<td>0.38</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Total occlusions</td>
<td>27%</td>
<td>35%</td>
<td>0.20</td>
</tr>
<tr>
<td></td>
<td></td>
<td>De novo lesions</td>
<td>94%</td>
<td>95%</td>
<td>0.69</td>
</tr>
</tbody>
</table>

Baseline Angiographic & Procedural Characteristics

IN.PACT SFA vs. LEVANT 2

<table>
<thead>
<tr>
<th>IN.PACT DCB</th>
<th>PTA</th>
<th>Lutonix DCB</th>
<th>PTA</th>
</tr>
</thead>
<tbody>
<tr>
<td>Lesion Length (cm)</td>
<td>8.94 ± 4.89</td>
<td>8.81 ± 5.12</td>
<td>6.27±4.34</td>
</tr>
<tr>
<td>Total Occlusions (%)</td>
<td>26.8% (57)</td>
<td>19.5% (22)</td>
<td>20.6 (65)</td>
</tr>
<tr>
<td>Severe Calcification (%)</td>
<td>8.1% (18)</td>
<td>6.2% (7)</td>
<td>10.4 (33)</td>
</tr>
<tr>
<td>Diameter Stenosis pre (%)</td>
<td>81.3 ± 15.5</td>
<td>81.3 ± 13.7</td>
<td>80.8±14.8</td>
</tr>
<tr>
<td>Pre-dilatation (%)</td>
<td>96.4%</td>
<td>85.6%</td>
<td>100%</td>
</tr>
<tr>
<td>Provisional Stenting (%)</td>
<td>2.3%</td>
<td>12.6%</td>
<td>2.5%</td>
</tr>
</tbody>
</table>

*Angiographic core lab assessment
¹Region with > 20% diameter stenosis
²Statistically significant
Kaplan Meier Analysis - 12-month Primary Patency
INPACT SFA vs. LEVANT 2 vs. Zilver PTX

2-Year Freedom from TLR
Interims Analysis Zilver PTX RCT vs. INPACT SFA

Target Lesion Revascularization (TLR) defined as:
- Clinically driven re-intervention for ≥ 50% DS within treated segment (including +/- 5 mm)
- Surgical bypass of target vessel

IN.PACT SFA DCB

Propensity Score Analysis DES vs. DEB

Characteristics

<table>
<thead>
<tr>
<th>Characteristic</th>
<th>DES</th>
<th>P</th>
</tr>
</thead>
<tbody>
<tr>
<td>Location</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Proximal SFA</td>
<td>50.4% (86/171)</td>
<td>52.6% (61/117)</td>
</tr>
<tr>
<td>Mid SFA</td>
<td>70.2% (92/131)</td>
<td>79.4% (77/97)</td>
</tr>
<tr>
<td>Distal SFA</td>
<td>76.6% (100/131)</td>
<td>86.6% (84/97)</td>
</tr>
<tr>
<td>P1</td>
<td>26.0% (24/93)</td>
<td>17.5% (17/97)</td>
</tr>
<tr>
<td>P2</td>
<td>10.7% (14/131)</td>
<td>0.0% (0/97)</td>
</tr>
<tr>
<td>P3</td>
<td>7.6% (10/131)</td>
<td>0.0% (0/97)</td>
</tr>
<tr>
<td>Mean Length (mm)</td>
<td>154.4 ± 86.3</td>
<td>150.1 ± 64.5</td>
</tr>
<tr>
<td>Length Min/Max (mm)</td>
<td>100, 450</td>
<td>100, 390</td>
</tr>
<tr>
<td>Restenotic lesions</td>
<td>51.9% (68/131)</td>
<td>44.3% (43/97)</td>
</tr>
<tr>
<td>% Diameter Stenosis</td>
<td>93.5 ± 8.6</td>
<td>95.4 ± 7.6</td>
</tr>
<tr>
<td>Calcification</td>
<td>none</td>
<td>slight</td>
</tr>
<tr>
<td>none</td>
<td>31.3% (41/131)</td>
<td>23.7% (31/131)</td>
</tr>
<tr>
<td>slight</td>
<td>25.2% (33/131)</td>
<td>7.6% (10/131)</td>
</tr>
<tr>
<td>moderate</td>
<td>48.5% (47/97)</td>
<td>21.6% (21/97)</td>
</tr>
<tr>
<td>severe</td>
<td>9.3% (9/97)</td>
<td>9.3% (9/97)</td>
</tr>
</tbody>
</table>

IN.PACT DCB vs. DES in long SFA lesions

Zeller T. et al. JEVT 2014

Zilver Stent Clinical Program

12-Month Primary Patency (PSVR < 2.0)

in Longer Lesions

86.1%
Zilver PTX
70.5%
Zilver Flex

Lesion length (mm) 189.3 ± 91.1
IN.PACT Global Study Patient Cohorts
1538 patients enrolled

Clinical Cohort
- 1538 pts

Imaging Subsets
- ≥ 100 pts, DCB 100mm
- ≤ 100 pts

IN.PACT Global Long Lesion Imaging Cohort: Kaplan-Meier Estimate of Primary Patency

Lesion Length 26–60 g 8.01 cm
- Primary Patency
- Provisional Stent
  - LL 15–25 cm: 40.6% (63/156)
  - LL > 25 cm: 33.3% (33/99)
- DCB 150mm
  - ≥ 150 pts, Long Lesion (≥ 15 cm): 52.6% (30/57)
  - ≥ 100 pts, Long Lesion (≥ 15 cm): 52.6% (30/57)

IN.PACT Global Long Lesion Imaging Cohort: Primary Patency in Non-stented Subgroup

Primary Patency in Non-stented Subgroup
- DCB 150mm
  - LL 15–25 cm: 92.5%
  - LL > 25 cm: 91.1%
- Provisional Stent
  - LL 15–25 cm: 80.7%
  - LL > 25 cm: 77.9%

Reason why DEB might be preferred
- Occluded nitinol-stents
- GW-passage into stent failed

Calcium results in HIGHER LLL and LOWER patency at 12 months

Calcium may present a challenge for DCBs
- Calcium is a barrier to optimal drug absorption
- Calcium may present a challenge for DCBs
- Calcium results in HIGHER LLL and LOWER patency at 12 months

Summary
DEB vs. Zilver PTX DES in SFA-Revascularization
- Depending on the operators preference – leaving nothing behind or stent believer - DEB angioplasty and DES represent a first line strategy for TASC A & B de novo lesions (Level 1 of evidence)
- For TASC C & D femoro-popliteal lesions DEB & provisional BMS stent placement seem to be at least as good as DES
- Calcified lesions still remain a challenge and might more likely be treated with a DES (or upfront vessel preparation)