LINC 2015, Leipzig

Proven?
Combining DEB and Stent

Koen Deloose, MD
Disclosure slide

☐ I 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
Drug (PTX?) Delivery

Scaffolding devices
**DES : Zilver PTX RCT**

**Primary Patency**

- **84.4%** for Zilver PTX
- **66.4%** for Optimal PTA + BMS

**Optimal PTA + BMS**

<table>
<thead>
<tr>
<th>Years (LESIONS)</th>
<th>0</th>
<th>1</th>
<th>2</th>
<th>3</th>
<th>4</th>
<th>5</th>
</tr>
</thead>
<tbody>
<tr>
<td>Zilver PTX</td>
<td>318</td>
<td>246</td>
<td>199</td>
<td>163</td>
<td>137</td>
<td>109</td>
</tr>
<tr>
<td>Failed</td>
<td>1</td>
<td>48</td>
<td>71</td>
<td>83</td>
<td>92</td>
<td>94</td>
</tr>
<tr>
<td>Standard Care</td>
<td>183</td>
<td>108</td>
<td>64</td>
<td>52</td>
<td>44</td>
<td>38</td>
</tr>
<tr>
<td>Failed</td>
<td>0</td>
<td>57</td>
<td>73</td>
<td>79</td>
<td>84</td>
<td>86</td>
</tr>
</tbody>
</table>

$p < 0.01$ (log-rank)
DES : Zilver PTX RCT

- Economical considerations
- Short stent lengths available
- Multiple overlapping zones in long lesions
DCB

- Cheaper than DES
- Longer lengths available
- No permanent implant
- Fantastic results:
  - proof of concepts studies
  - available RCT’s
  - all comers registries
PROOF OF CONCEPTS
PIVOTAL RCT’S

LEVANT 2 Clinical Trial

- Primary patency 1 yr 73.5%
- Freedom TLR 1 yr 89.7%

IN.PACT SFA I-II Trial

- Primary patency 1 yr 89.9%
- Freedom TLR 1 yr 97.5%

Rosenfield K et al, presented @ VIVA2014, Las Vegas, US
Tepe et al, presented @ CX2014, London, UK
### 12-month Efficacy

- **Freedom from Clinically-driven TLR**: 91.3% (527/577)

### 12-month Safety

<table>
<thead>
<tr>
<th>Event</th>
<th>Percentage</th>
</tr>
</thead>
<tbody>
<tr>
<td>Primary Safety Endpoint [1]</td>
<td>89.6% (517/577)</td>
</tr>
<tr>
<td>Major Adverse Events [2]</td>
<td>13.5% (78/577)</td>
</tr>
<tr>
<td>Death (all-cause)</td>
<td>3.3% (19/577)</td>
</tr>
<tr>
<td>Major Target Limb Amputation</td>
<td>0.3% (2/577)</td>
</tr>
<tr>
<td>Any TLR</td>
<td>9.0% (52/577)</td>
</tr>
<tr>
<td>Any TVR</td>
<td>9.9% (57/577)</td>
</tr>
</tbody>
</table>

[1] Ref: DCB

DCB

- No good response to Ca++ lesions
- No solution for dissection
- No scaffolding
- No resistance to acute recoil

\[\text{high provisional stent rates}\]
Severe calcification % 10.4 8.1

"predilatation screening"

Ca distribution/severity affect LLL/primary patency Ca++ represents a barrier to optimal drug absorption

### DCB

#### Provisional stenting

<table>
<thead>
<tr>
<th>Length (cm)</th>
<th>Thunder</th>
<th>FemPac</th>
<th>Levant I</th>
<th>Italian Registry</th>
<th>Pacifier</th>
<th>Debellum</th>
<th>Leipzig Registry</th>
<th>Zeller Registry</th>
</tr>
</thead>
<tbody>
<tr>
<td>Stent-Rate %</td>
<td>4</td>
<td>9</td>
<td>24</td>
<td>12</td>
<td>21</td>
<td>57</td>
<td>23.3</td>
<td>18.3</td>
</tr>
</tbody>
</table>

#### IN.PACT GLOBAL Trial

- Single or multiple Lesions in full femoropopliteal tract
- *de novo* + restenotic (ISR or non-ISR) lesions
- Stenosis & Occlusions of all lengths
- Predilatation is @physicians’ discretion

<table>
<thead>
<tr>
<th>Lesion length (cm)</th>
<th>12.23 + 9.59</th>
</tr>
</thead>
<tbody>
<tr>
<td>Total occlusions (%)</td>
<td>35.8</td>
</tr>
<tr>
<td>Severe calcification (%)</td>
<td>10.4</td>
</tr>
<tr>
<td>Predilatation (%)</td>
<td>75.4</td>
</tr>
<tr>
<td>Provisional stenting (%)</td>
<td>24.7</td>
</tr>
</tbody>
</table>

“predilatation screening”
• Perfect “scaffolding” devices
• Cheaper than DES
• Longer lengths available
• Modern generation offers good results
### 20-25% recurrent disease @ 1 year

<table>
<thead>
<tr>
<th>Study</th>
<th>A.L.L</th>
<th>PEACE</th>
<th>TASC D</th>
<th>DURABILITY</th>
<th>DURABILITY II</th>
<th>DURABILITY Y 200</th>
<th>ZILVER PTX</th>
<th>ZILVER PTX Long</th>
<th>SUPERB</th>
<th>AURORAA</th>
<th>SUPERA 500</th>
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<tbody>
<tr>
<td>4EVER</td>
<td>71 mm</td>
<td></td>
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<td>PEACE</td>
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<tr>
<td>TASC D</td>
<td>245 mm</td>
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</tr>
<tr>
<td>DURABILITY</td>
<td>96 mm</td>
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<tr>
<td>DURABILITY II</td>
<td>89 mm</td>
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<td>DURABILITY Y 200</td>
<td>242 mm</td>
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<tr>
<td>ZILVER PTX</td>
<td>66 mm</td>
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<tr>
<td>ZILVER PTX Long</td>
<td>226 mm</td>
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<tr>
<td>SUPERB</td>
<td>78 mm</td>
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<tr>
<td>AURORAA</td>
<td>143 mm</td>
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<tr>
<td>SUPERA 500</td>
<td>126 mm</td>
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</table>
Why not combining the best of 2 worlds?

DEBATE-SFA

DEBAS I study

Zeller LL registry

DCB

BMS

Liistro et al. JACC 2013;6(12):1295-1302

Mwipatayi P. Presented @ VERVE 2014, Sydney, Australia

Why not combining the best of 2 worlds?

DEBATE-SFA

- Single center, randomized trial
- 110 lesions: 55 DCB + BMS vs 55 POBA + BMS
- Primary endpoint: 12 m binary restenosis
- MII: 94 ± 60 (DCB + BMS) vs 96 ± 69 (POBA + BMS)

![1-Year Restenosis and TLR](image)

Listro et al. JACC 2013;6(12):1295-1302
Why not combining the best of 2 worlds?

- Single center, prospective, single arm trial
- 65 lesions: Pulsar 18 BMS + Passeo 18 LUX post-dil
- Primary endpoint: 12/24 m ppr (PSVR<2,0)
- MII: 137.7 mm

DEBAS I study

35 patients results @ 1 yr

<table>
<thead>
<tr>
<th></th>
<th>FTLR</th>
<th>Freedom Maj.Amp.</th>
<th>PP</th>
<th>FMAE</th>
</tr>
</thead>
<tbody>
<tr>
<td>FtLR</td>
<td>94.3%</td>
<td>100.0%</td>
<td>91.4%</td>
<td>100.0%</td>
</tr>
</tbody>
</table>

Mwipatayi P. Presented @ VERVE 2014, Sydney, Australia
Why not combining the best of 2 worlds?

- Single center, retrospective study with propensity score stratification
- 228 lesions: **131 DCB** vs **97 DES**
- **MII**: 194 mm (DCB) vs 195 mm (DES)

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**Zeller LL registry**

**PPR @ 1 yr**
- 76.1% (DEB) vs. 69.6% (DES)
- p=0.1334

**F TLR @ 1 yr**
- p=0.7689

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**BIOLUX 4EVER study**

Physician-Initiated, prospective, multi-center (5), controlled trial investigating the Efficacy of Endovascular Treatment of Femoropopliteal Arterial Stenotic Disease with the **BIO**tronik Passeo-18 **LUX** Drug Releasing Balloon and the Biotronik Pulsar-18 Stent (comparing with the **4EVER** trial results)

120 patients – Target lesion < 19 cm

Primary endpoint: PPR @ 12 months DUS (PSVR < 2.5)
BIOLUX 4EVER study

Currently
44 patients enrolled

36.7%
BIOLUX 4EVER study - Conclusion
Drug elution & Scaffolding are key factors in endovascular success on the long run.

DES, DCB & BMS offer opportunities but each with their “own dark sides”

There is some evidence that combining DCB with scaffolding BMS create a win-win situation.

BIOLUX 4EVER study will add more clarity on this topic.

A lot of unanswered questions remain: DCB + BMS? BMS + DCB? Full length coverage or spot stenting?...
Proven?
Combining DEB and Stent

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