Combination Lesion Treatment with Passeo-18 Lux DCB & Pulsar-18 Uncoated stent: Advantages and good results

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Disclosure slide
Speaker name: Koen Deloose, MD

I have the following potential conflicts of interest to report:

- Consulting: Medtronic, Biotronik, Abbott, Bard, Vascular, Bentley, Cook, GE, Healthcare, Terumo, Boston Scientific, Contego Medical
- Employment in industry
- Stockholder of a healthcare company
- Owner of a healthcare company
- Other(s)

I do not have any potential conflict of interest

The reality of BMS anno 2018

Lesion length seems to be an issue for BMS

Durability seems to be an issue for BMS

The reality of DCB anno 2018

Evidence supports use in simple & complex lesions
Performance of DCBs seems to be lesion complexity

Durability seems to be improved with DCB
The reality of DCB anno 2018

Let’s evaluate this daily “combination therapy” in a prospective multicentric way...

**First Stent, then DCB**

**DEBAS STUDY**

- Direct scaffolding
- No DCB only possibility
- Loosing PTX-wall contact

Single center, single arm prospective study
65 lesions
Pulsar 18 + Passeo-18 Lux (Biotronik)
Mean lesion length: 18.7 cm

**First DCB, then Stent**

**BIOLUX 4EVER**

- Maximum contact PTX
- DCB only possibility
- Distal embolization?

Multicenter, single arm prospective study
120 lesions
Passeo-18 Lux + Pulsar 18 (Biotronik)
Mean lesion length: 8.1 cm

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**Patient demographics**

- **N = 120 out of 120**
  - Male (%): 79 (65.83%)
  - Age (min – max; ±SD): 70.87 years (43.73 – 92.41; ±10.52)
  - Nicotine abuse (%): 73 (60.83%)
  - Hypertension (%): 76 (63.33%)
  - Diabetes mellitus (%): 23 (18.78%)
  - Renal insufficiency (%): 15 (12.50%)
  - Hypercholesterolaemia (%): 66 (55.00%)
  - Obesity (%): 28 (23.33%)

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**Lesion length (min – max; ±SD)**: 83.33 mm (6.0 – 280.0; ±49.49)

**Reference Vessel Diameter**: 5.26 mm (4.0 – 6.0; ±0.59)

**Mean DCB diameter (min – max; ±SD)**: 5.15 mm (4.0 – 6.0; ±0.57)

**Mean STENT diameter (min – max; ±SD)**: 5.78 mm (5.0 – 7.0; ±0.53)

**Occlusion (%)**: 40 (33.33%)

**Calcified lesion (%)**: 60 (50.00%)
**12 Month results**

**PRIMARY PATENCY**

<table>
<thead>
<tr>
<th>Month</th>
<th>% Patency</th>
</tr>
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<tbody>
<tr>
<td>12</td>
<td>83.5%</td>
</tr>
</tbody>
</table>

**FREEDOM FROM TLR**

<table>
<thead>
<tr>
<th>Month</th>
<th>% Freedom</th>
</tr>
</thead>
<tbody>
<tr>
<td>12</td>
<td>86.1%</td>
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</tbody>
</table>

**Is it comparable to DES data?**

**Benchmarking in the DES world @ 2 yr**

<table>
<thead>
<tr>
<th>Criteria</th>
<th>12M DES</th>
<th>12M BIOLUX 4EVER</th>
</tr>
</thead>
<tbody>
<tr>
<td>TVR</td>
<td>7.0</td>
<td>5.5</td>
</tr>
<tr>
<td>PVR</td>
<td>2.5</td>
<td>2.0</td>
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</tbody>
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**...but with the potential of “leaving less metal behind”**

**As Less As Reasonably Achievable Stenting...**

**Morphological – Anatomical criteria**

- Angiography
- IVUS
- OCT

**Functional – Flow-dynamical criteria**

- DUS intra-operative
- Pressure gradient/flow measurements (FFR)
Adding Paclitaxel to BMS is definitely improving patency & TLR

Implanting Pulsar-18® stent, postdilated with Passeo-18 Lux® creates a win-win situation as shown in the full 12 months & 24 months data of DEBAS.

Prepping with Passeo-18 Lux® & scaffolding afterwards with Pulsar-18® stent creates a win-win situation as shown in the full 12 months & 24 months data of BIOLUX 4EVER.

The combination of Passeo-18 Lux® & Pulsar-18® offers similar efficacy outcomes compared to DES data.