Long DCB in Long Lesion-Benefits for lesions beyond 150mm

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Disclosure

Speaker name: Weiwei Wu

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
Long SFA-pop Lesion

- lesion >15 cm in length, TASC C&D
- Ostial SFA and popliteal are usually involved
- Always occluded, need sub-intimal recanalization
- Time-consuming, costly
- Poor prognosis compared to short lesions
Improvement of long lesion treatment outcomes relies on innovation of devices.

Comparison of outcomes in long lesion treated with various devices:

- BMS
- DES
- Stent graft
- SUPERA stent
- DCB

References:
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- SUPERA 500. Werner M. Euroint 2014;10:861-868;
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- STELLA PTX Davaine JM. EJVES 2015;50:631-7;
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- VIPER. Saxon RR. JVIR 2013;24:165-173;
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Current data of DCB in long lesion

**IN.PACT Global**
(D.Scheinert, EuroPCR 2015)

- N=157
- Bail-out stent: 40.7%
- 91.1% Patency @ 1Y
- 6.0% TLR @ 1Y

**IN.PACT Long Study**
(Micari,A, PCR 2015)

- N=105
- Bail-out stent: 10.5%
- 89.3% Patency @ 1Y
- 4.0% TLR @ 1Y

**Leipzig complex lesion**
(Schmidt et al. JACC Intervent 2016)

- N=288 limbs
- Bail-out stent: 23.3%
- 79.2 % Patency @ 1Y
- 55.4 % Patency @ 2Y

Lesion length:
- IN.PACT Global: 26.40 ± 8.61 cm
- IN.PACT Long Study: 25.17 ± 7.9 cm
- Leipzig complex lesion: 24.0 ± 10.1 cm
Orchid DCB: the longest one in the world

- Mg-stearate excipient for optimized drug delivery
- Diameter (mm) 3.0 - 12.0, with half size design from 3-6mm
- Length (mm) 20, 30, 40, 60, 80, 100, 120, 150, **200, 250, 300**

Orchid, up to 300mm length

others, less than 150mm length
Benefits of long DCB
1 long balloon (300mm) = 3 short balloons (120mm)

<table>
<thead>
<tr>
<th>Homogenous dilatation</th>
<th>Less procedure time</th>
<th>Less radiation exposure</th>
<th>Cost saving</th>
</tr>
</thead>
<tbody>
<tr>
<td>• Better results</td>
<td>• Reduce 2/3 inflation times</td>
<td>• Avoid 2/3 radiation exposure</td>
<td>• Provide dramatic economic value by</td>
</tr>
<tr>
<td>• Less dissection in overlapping</td>
<td>• approx. 12 mins saved per procedure</td>
<td>• Good for both physicians and patients</td>
<td>saving 2/3 device cost</td>
</tr>
<tr>
<td>segments</td>
<td></td>
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</tr>
</tbody>
</table>

**Diagram:**
- 1 long balloon (300mm)
- 3 short balloons (120mm)
- 1 long balloon (360mm)
Orchid DCB in Chinese long lesions
Long Lesion Subgroup Analysis AcoArt I

<table>
<thead>
<tr>
<th>Average lesion length</th>
<th>DCB</th>
<th>PTA</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>27.8 ± 5.5 cm</td>
<td>28.7 ± 6.2 cm</td>
</tr>
</tbody>
</table>

AcoArt I Long Lesion Cohort

Late Lumen Loss (mm)

- DCB: 0.23 ± 0.84
- PTA: 1.35 ± 0.93
Long DCB in long lesion - Single center experience

For all lesion >15cm (N=20)

<table>
<thead>
<tr>
<th>Rutherford Category</th>
<th>2</th>
<th>10%(2/20)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>3</td>
<td>55%(11/20)</td>
</tr>
<tr>
<td></td>
<td>4</td>
<td>25%(5/20)</td>
</tr>
<tr>
<td></td>
<td>5</td>
<td>10%(2/20)</td>
</tr>
<tr>
<td>CTO</td>
<td></td>
<td>70%(14/20)</td>
</tr>
<tr>
<td>Mean lesion length(cm)</td>
<td>27.75 ± 7.68</td>
<td></td>
</tr>
</tbody>
</table>

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### Procedural data

<table>
<thead>
<tr>
<th></th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Bail-out stent</td>
<td>10% (2/20)</td>
</tr>
<tr>
<td>Average orchid DCB used in each case</td>
<td>1.74 ± 0.47</td>
</tr>
<tr>
<td>Average other DCB should be used in each case*</td>
<td>2.68 ± 0.52</td>
</tr>
<tr>
<td>Average DCB saved*</td>
<td>0.94</td>
</tr>
<tr>
<td>Average dilation time saved* (minute)</td>
<td>3.76</td>
</tr>
<tr>
<td>Radiation exposure time reduced*(minute)</td>
<td>1</td>
</tr>
</tbody>
</table>

*Based on the following assumption:

Non-orchid DCB has a max length of 150mm.
1 cm of overlapping area if multiple DCB used
Dilation and delivery cost average 4 minutes for each DCB, and 30% of the time need to be under radiation exposure.
Long DCB in long lesion - Single center experience

<table>
<thead>
<tr>
<th>Result &amp; follow up</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>ABI improvement post procedure</td>
<td>0.43±0.17</td>
</tr>
<tr>
<td>Clinical follow up</td>
<td>100%(20/20)</td>
</tr>
<tr>
<td>ABI follow up at 3 month (N)</td>
<td>7</td>
</tr>
<tr>
<td>ABI follow up at 6 month (N)</td>
<td>1</td>
</tr>
<tr>
<td>ABI improvement at 3rd month</td>
<td>0.39±0.12(n=9)</td>
</tr>
<tr>
<td>Recurred symptom case 1</td>
<td>Within 1 week</td>
</tr>
<tr>
<td>TLR case 1</td>
<td>At 4th month</td>
</tr>
</tbody>
</table>

One patient recurred with claudication but did not re-vascularized yet, ABI improved, with comorbidity of lumbar degeneration disease.
Long DCB in long lesion – Case share 1

- 84, female
- Intermittent claudication for 3 yr and rest pain for 1 mon
- Preoperative ABI: 0.7
- CTA: Long lesion of femoropopliteal arteries (stenosis and occlusion)
Case 1 - Long DCB

Baseline

3mm/4mm POBA, 4.5-300mm DCB dilation
Case1-Post procedural angiography

Follow up after 1 month: ABI:0.8, good flow from ultrasound
Long DCB in long lesion – Case share2

- 73, female
- Intermittent claudication of both lower limbs for 1 yr and rest pain of right foot for 1 mon
- Preoperative ABI: 0.53(right); 0.69(left)
- CTA: occlusive lesion of femoropopliteal arteries
Case2-Long DCB

Baseline

3mm/4mm POBA, 4.0-300mm/4.5-200mm DCB dilation
Case 2 - Post procedural angiography

Follow up after 1 month: ABI:1, good flow from ultrasound
Long DCB in long lesion – Case share3

- 71, male
- Restenosis after stenting in right SFA
- Preoperative ABI: 0.88
- CTA: intrastent occlusive lesion of right femoropopliteal artery
Case 3 - Long DCB

Baseline

Angiojet debulking, 3mm/4mm POBA, 4.5-300mm/4.5-150mm DCB dilation
Case 3 - Post procedural angiography

Follow up after 1 month: ABI:1.04, good flow from ultrasound
Conclusion

• Current data demonstrates remarkable overall outcomes for long lesions treated with drug coated balloon

• Long DCB provides more homogenous dilatation, while reducing procedure time, avoiding unnecessary radiation exposure, providing dramatic economic value as well

• Orchid DCB performs well in real world long lesions, according to single center experience

• Optimal vessel preparation is key to DCB’s outcomes in long lesion
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