Orchid DCB in Leipzig – real world experience

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Disclosures

Speaker’s name: Dierk Scheinert

I have the following potential conflicts of interest to report:

Advisory Board /Consultant:
- Abbott, Biotronik, Boston Scientific, Cook Medical, Cordis,
- CR Bard, Gardia Medical/Allium, Medtronic, TriReme Medical, Trivascular, Upstream Peripheral Technologies
Orchid Drug Coated Balloon

- Retrospective, non-randomized monocenter cohort study
- Symptomatic PAD patients undergoing femoropopliteal intervention
- Inclusion from 01.8.2015 up to 01.05.2016
Orchid Drug Coated Balloon

- Pre-scheduled follow-up visits at 6 and 12 months, yearly thereafter
- Telephone contact for assessment of clinical and vital status

Clinical follow up:
- Deaths
- Target lesion revascularization
# Baseline patient characteristics

<table>
<thead>
<tr>
<th>Number of Patients</th>
<th>104</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age, years</td>
<td>69 ± 10*</td>
</tr>
<tr>
<td>Female</td>
<td>38 (37%)</td>
</tr>
<tr>
<td>Rutherford stage, Median</td>
<td>3</td>
</tr>
<tr>
<td>Hypertension</td>
<td>103 (99%)</td>
</tr>
<tr>
<td>Hyperlipidemia</td>
<td>82 (79%)</td>
</tr>
<tr>
<td>Obesity (BMI&gt;30 kg/m2)</td>
<td>26 (25%)</td>
</tr>
<tr>
<td>Diabetes: NIDDM</td>
<td>21 (20%)</td>
</tr>
<tr>
<td></td>
<td>IDDM 25 (24%)</td>
</tr>
<tr>
<td>Current/former smoking</td>
<td>58 (56%)</td>
</tr>
<tr>
<td>Coronary heart disease</td>
<td>35 (34%)</td>
</tr>
<tr>
<td>Cerebrovascular disease</td>
<td>15 (14%)</td>
</tr>
</tbody>
</table>

*Data are given as mean±std.*
Lesion and interventional characteristics

<table>
<thead>
<tr>
<th>Number of treated legs</th>
<th>115</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cumulative device length (mm)</td>
<td>277 ± 121*</td>
</tr>
<tr>
<td>Diameter of devices (mm)</td>
<td>5.2 ± 0.5*</td>
</tr>
<tr>
<td>Run-off vessels</td>
<td>2.2 ± 1.1*</td>
</tr>
<tr>
<td>In-stent restenosis</td>
<td>26 (24%)</td>
</tr>
<tr>
<td>Treatment of vessel occlusion</td>
<td>53 (46%)</td>
</tr>
<tr>
<td>Dissection post PTA</td>
<td>47 (41%)</td>
</tr>
<tr>
<td>Stent implantation</td>
<td>66 (57%)</td>
</tr>
<tr>
<td>Inflow intervention</td>
<td>4 (4%)</td>
</tr>
<tr>
<td>Atherectomy/thrombectomy</td>
<td>32 (28%)</td>
</tr>
<tr>
<td>Popliteal artery treated</td>
<td>38 (33%)</td>
</tr>
</tbody>
</table>

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Follow-up

- Mean follow up: 8.9±3.2 months
- 2 deaths, 7 lost to follow up
- Survival analysis for target lesion revascularization
Target lesion revascularization

Kaplan-Meier curves

KM-estimate ± SE

<table>
<thead>
<tr>
<th></th>
<th>6 mo</th>
<th>12 mo</th>
</tr>
</thead>
<tbody>
<tr>
<td>Orchid</td>
<td>95.8 ± 2.0</td>
<td>94.0 ± 2.7</td>
</tr>
</tbody>
</table>
Real world comparison of IN.PACT vs. Lutonix DCB in complex SFA lesions

Sabine Steiner
Division of Interventional Angiology
University Hospital Leipzig, Germany
# Lesion and interventional characteristics

<table>
<thead>
<tr>
<th></th>
<th>In.Pact DCB (n=366)</th>
<th>Lutonix DCB (n=168)</th>
<th>Orchid (n=115)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cumulative device length (mm)</td>
<td>291 ± 124*</td>
<td>280 ± 116*</td>
<td>277 ± 121*</td>
</tr>
<tr>
<td>Diameter of devices (mm)</td>
<td>5.2±0.5*</td>
<td>5.2±0.6*</td>
<td>5.2 ± 0.5*</td>
</tr>
<tr>
<td>Run-off vessels</td>
<td>2.2±0.9*</td>
<td>2.0±0.9*</td>
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</tr>
<tr>
<td>In-stent Restenosis</td>
<td>17 %</td>
<td>18 %</td>
<td>24 %</td>
</tr>
<tr>
<td>Treatment of vessel Occlusion</td>
<td>46 %</td>
<td>40 %</td>
<td>46 %</td>
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<tr>
<td>Dissection post PTA</td>
<td>45 %</td>
<td>39 %</td>
<td>41 %</td>
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<tr>
<td>Stent Implantation</td>
<td>52 %</td>
<td>47 %</td>
<td>57 %</td>
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<tr>
<td>Inflow intervention</td>
<td>6 %</td>
<td>7 %</td>
<td>4 %</td>
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<tr>
<td>Atherectomy/thrombectomy</td>
<td>37 %</td>
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<td>28 %</td>
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<tr>
<td>Popliteal artery treated</td>
<td>31 %</td>
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Target lesion revascularization

Kaplan-Meier curves

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<tr>
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<td>94.7 ± 1.2</td>
<td>89.0 ± 2.0</td>
</tr>
<tr>
<td>Lutonix DCB</td>
<td>93.9 ± 1.9</td>
<td>82.9 ± 3.0</td>
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No. at risk
### Target lesion revascularization

#### Kaplan-Meier curves

*KM-estimate ± SE*

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**Admiral**

| 357 | 164 | 108 | 158 | 128 | 35 |

**Lutonix**

| 266 | 164 | 91  |  |

**Orchid**

| 108 |  |

Logrank p = 0.4165

No. at risk
Summary

- Promising results after use of the new generation orchid DCB in a group of real world patients
- Comparison with two established DCBs with proven efficacy shows comparable results
- Necessity of further evaluation in a larger patient cohort
- Head-to-head comparisons in RCT preferred but not available
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