Systematic review and meta-analysis on DCB vs. POBA for de-novo femoropopliteal PVD: DOND (NCT02927574)

Christof Tobias Klumb
Disclosure

Speaker name:
Christof Tobias Klumb

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
<table>
<thead>
<tr>
<th>Manufacturer</th>
<th>Name</th>
<th>Trial</th>
<th>Paclitaxel dose</th>
<th>Excipient</th>
</tr>
</thead>
<tbody>
<tr>
<td>Acotec Scientific</td>
<td>Orchid DCB</td>
<td>AcoArt I</td>
<td>3,0 µg/mm²</td>
<td>magnesium stearate</td>
</tr>
<tr>
<td>Bayer</td>
<td>PACCOCATH / Cotavance</td>
<td>FemPac THUNDER</td>
<td>3,0 µg/mm²</td>
<td>PACCOCATH (iopromide coated matrix)</td>
</tr>
<tr>
<td>BBraun</td>
<td>SeQuent Please OTW</td>
<td>ConSeQuent</td>
<td>3,0 µg/mm²</td>
<td>Resveratrol</td>
</tr>
<tr>
<td>Biotronik</td>
<td>Passeo-18 LUX</td>
<td>Biolux P-I</td>
<td>3,0 µg/mm²</td>
<td>Butyryl-tri-hexylcitrat (BTHC)</td>
</tr>
<tr>
<td>Boston Scientific</td>
<td>Ranger</td>
<td>RANGER-SFA</td>
<td>2,0 µg/mm²</td>
<td>Citrate ester</td>
</tr>
<tr>
<td>Cardionovum</td>
<td>Legflow</td>
<td>MAGNIFICENT</td>
<td>3,0 µg/mm²</td>
<td>&quot;SAFEPAX&quot;</td>
</tr>
<tr>
<td>Cook</td>
<td>Advance 18 PTX</td>
<td>Advance 18 PTX</td>
<td>3,0 µg/mm²</td>
<td>&quot;none&quot;</td>
</tr>
<tr>
<td>CR BARD</td>
<td>Lutonix 035</td>
<td>LEVANT I LEVANT II</td>
<td>2,0 µg/mm²</td>
<td>polysorbate, sorbitol</td>
</tr>
<tr>
<td>Eurocor</td>
<td>Freeway DCB</td>
<td>FREERIDE</td>
<td>3,0 µg/mm²</td>
<td>Shellac</td>
</tr>
<tr>
<td>iVascular</td>
<td>Luminor</td>
<td>EffPac</td>
<td>3,0 µg/mm²</td>
<td>Organic ester</td>
</tr>
<tr>
<td>Medtronic</td>
<td>IN.PACT Admiral</td>
<td>IN.PACT SFA DEBATE-SFA PACIFIER</td>
<td>3,5 µg/mm²</td>
<td>Urea</td>
</tr>
<tr>
<td>Spectranetics Corporation</td>
<td>Stellarex DCB</td>
<td>ILLUMENATE-FIH</td>
<td>2,0 µg/mm²</td>
<td>Polyethylene Glycol</td>
</tr>
</tbody>
</table>
What is DOND?

Drug Or No Drug?

- systematic review and meta-analysis
- including RCTs → comparing DCB vs. POBA for fem-pop PVD
- exclusion: focus on CLI, focus on BTK, focus on ISR-treatment
- 9 trials with 5 study devices
- 1,552 patients (DCB 905 vs. POBA 647), 2 trials did recruit >50% of patients
- 6 of 9 trials are industry-sponsored
- LLL at 6mo is most common primary endpoint (6 of 9)
Risk of Bias

- randomisation
- blinding of physician
- blinding of follow-up
- missing data
- selective reporting
- groups unmatched
- different treatment
LLL at 6 months

= Late Lumen Loss

PACIFIER (IN.PACT Admiral): LLL at 6 months (median) = -0.01mm (DCB) vs. 0.65mm (POBA); p < 0.01

> all tested DCB can reduce neointimal proliferation!
FfTLR at 12 months

= Freedom from Target Lesion Revascularisation

- not all results statistically significant
- NNTs range from 3 to 33
Clinical outcome, Safety

No statistical significant outcome differences found in terms of

- ABI,
- Rutherford classification,
- functional outcome (e.g. walking tests),
- Quality of Life (e.g. EQ-5D) and
- safety (major amputation, thrombosis, all-cause death)

at 12 months.
How about long-term results?

4 of 9 trials did report 24 months results
- 2x PACCOCATH
- 1x IN.PACT Admiral, Lutonix DCB

1 of 9 trials (THUNDER trial, PACCOCATH DCB) has results (post-hoc analysis) at 56 months (n = 66)

late catch-up?

results presented at LINC 2017:
- AcoArt I 24 months
- IN.PACT SFA 36 months
How about long-term results?

4 of 9 trials did report 24 months results
- 2x PACCOCATH
- 1x IN.PACT Admiral, Lutonix DCB

1 of 9 trials (THUNDER trial, PACCOCATH DCB) has results at 56 months (n = 66, post-hoc analysis)

late catch-up?

results presented at LINC 2017:
- AcoArt I 24 months
- IN.PACT SFA 36 months
Conclusion

- all tested DCB can reduce neointimal proliferation at 6 months
- most tested DCB could show significant higher FfTLR at 12 months
  => NNTs range from 3 to 33 – NO class effect!
- no significant differences in clinical and safety outcome
- many DCB don’t have published results yet!
- missing long-term data
- high risk of bias in included studies
Systematic review and meta-analysis on DCB vs. POBA for de-novo femoropopliteal PVD: DOND (NCT02927574)

Christof Tobias Klumb