Key considerations of DCB in PAD treatment: Thrombosis and Embolization

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Disclosure

I do not have any potential conflict of interest
The incidence of PAD becomes popular

- **Adults**: 4.3%
- **>70yrs**: 14.5%

**Aorta-Iliac**: 30%
**CFA, SFA, POPA**: 80-90%
**BTK**: 40-50%

*Harrison’s Principles of Int Med*  
*Lancet, 2013*
More complicated than before

JVS. 2000; 31(1) Part 2: S106
JVS. 2007; 45(1): S51A
DCB becomes the first choice to treat complicated PAD

- Balloon + Paclitaxel

- Excipient:
  - iopromide
  - Urea
  - polymers
  - nanoparticles

Excipient: Carry & Release drug
DCB Clinic Trials

7 Trials/ 6 DCBs SFA-POP 6M LLL

# DCB Clinic Trials for ISR

## AcoArt I Study-All

<table>
<thead>
<tr>
<th></th>
<th>DCB</th>
<th>PTA</th>
<th>P value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Number</td>
<td>26</td>
<td>20</td>
<td></td>
</tr>
<tr>
<td>Total occlusion (%)</td>
<td>17/26 (65 %)</td>
<td>9/20 (45 %)</td>
<td>0.17</td>
</tr>
<tr>
<td>Lesion length (mm)</td>
<td>237.38 ± 100.28</td>
<td>243.46 ± 113.88</td>
<td>0.85</td>
</tr>
<tr>
<td>Late lumen loss (mm)</td>
<td>-0.04 ± 0.69</td>
<td>1.69 ± 0.71</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>6mon Restenosis</td>
<td>6/26 (23%)</td>
<td>18/20 (90%)</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>6mon TLR (%)</td>
<td>0/26 (0%)</td>
<td>15/20 (75%)</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>12mon Restenosis</td>
<td>6/26 (23%)</td>
<td>18/19 (95%)</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>12mon Cumulative TLR (%)</td>
<td>0/26 (0%)</td>
<td>18/19* (95%)</td>
<td>&lt;0.001</td>
</tr>
</tbody>
</table>

*3 patients had re-revascularization
Is DCB perfect?
Case-1

- Female, 78yrs
- R SFA-POP stent for 1 Y
- R foot pain for 3M
- Risk Factors: HP, DM
Case-1

L CFA access, Cross-over, Angiography
Case-1

Recanalization  R ATA, PTA  (2.5-100)
Case-1

SFA-POP POBA PTA (4,5-120)
Case-1

R POP-ATA stent（Pulsar-18 4-40）
Case-1

After DCB:
SFA-POP-ATA thrombosis
Case-1

After 24H CDT (UK15000U)
Case-2

- Male, 75yrs
- L SFA stent for 3 Y
- L foot rest pain for 3M
- Risk Factor: HP
Case-2

R CFA access, cross-over, Angiography
Case-2

POBA PTA (4,5mm-120)
Case-2

Embolization in TP trunk - PA

DCB 4.5-300
Case-2

After 24H POP A

After 24H TP trunk A

After 24H proximal PA

After 24H distal PA
Case-3

- Female, 80 yrs
- R SFA stent for 1 Y
- Right foot rest pain for 1M
- Risk factors: HP, DM

• POBA 5-120
• DCB 5-300
  5-80
Case-3

Immediately after DCB

7 min after DCB
DCB is not perfect

DCB

Thrombosis

Embolization
Complication- 1. Thrombosis

1. Re-endothelialization
2. Resolution of inflammation
3. Thrombus reorganisation
4. Smooth muscle cell proliferation
5. Smooth muscle cell matrix synthesis
6. Return of vasomotor regulation

+ Foreign body reaction due to polymers or other material causes giant cell inflammation

DCB Inhibition
Complication-2. Particulate Embolization

After DCB deploying:

- 25-35% into the wall
- 10% residual on catheter
- 60% wash-out to distal artery

Invest Radiol 2011
Complication-2.
Particulate Embolization

DCB: Different drug level with different embolization
Different drug level with same anti-restenosis effect

<table>
<thead>
<tr>
<th>TABLE 1</th>
<th>Angiographic Data at All Time Points</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Control Group</td>
</tr>
<tr>
<td>Injury, Day 0</td>
<td></td>
</tr>
<tr>
<td>RVD, mm</td>
<td>4.42 ± 0.82</td>
</tr>
<tr>
<td>MLD, mm</td>
<td>4.12 ± 0.79</td>
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<tr>
<td>BAR</td>
<td>1.23 ± 0.04</td>
</tr>
<tr>
<td>SAR</td>
<td>1.14 ± 0.19</td>
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<tr>
<td>Treatment, Day 14</td>
<td></td>
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<tr>
<td>MLD, mm</td>
<td>3.28 ± 0.73</td>
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<tr>
<td>%DS</td>
<td>19 ± 11</td>
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<tr>
<td>MLD post, mm</td>
<td>4.06 ± 0.62</td>
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<tr>
<td>Termination, Day 42</td>
<td></td>
</tr>
<tr>
<td>RVD, mm</td>
<td>4.59 ± 0.79</td>
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<tr>
<td>MLD, mm</td>
<td>0.99 ± 0.52</td>
</tr>
<tr>
<td>%DS</td>
<td>79 ± 12</td>
</tr>
<tr>
<td>Late loss, mm</td>
<td>3.07 ± 0.37</td>
</tr>
</tbody>
</table>

JACC: CARDIOVASCULAR INTERVENTIONS 2015
Why not lower the drug level for DCB?
Complication-2.
Particulate Embolization

Particulate Embolization & Accumulations with no clinic significance

Pictures courtesy of Bob Melder, Medtronic
Will you still use DCB if it is only one small run-off vessel?
Conclusions

- DCB is becoming a reasonable device to treat PAD
- Run-off vessel should be consider before DCB using
- Anticoagulation & Antiplatelet are important during and after the procedure
- Not all the DCB are the same
- Better DCB is always needed.
Thank You
Better DCB, Better Endo, Better Life
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