Distal Embolization after DCB: True or false?

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Disclosure

Speaker name:

.................................................................

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
Let’s begin with a case

- Male, 75y
- Intermittent Claudication

in right leg
peroneal and posterior tibial artery patent
4 mm pre-dilation  5*300 mm DCB (Acotec)  SFA patent without dissection
Distal embolization in PT

PT is patent, peroneal with high resistance
What's the cause of "distal embolization" after DCB?

Is it caused by the drug particles?
Study: Embolic Protection Device + DCB

- Capture the embolus
- Drug solution test
- Paclitaxel detection

DCB (Acotec) Spider (80-210 µm) (Medtronic)
Drug Solution Test

Drug particles from a real balloon

Drug particles soluble in organic solvent
Case 1: DCB for SFA

Thin piece material in filter net: big drug particles?

Typical plaque
Drug Solution Test

• Filter in solvent for 2 min
• Thin piece material: insoluble !
• It is not drug !
Paclitaxel Detection

Paclitaxel in the filter: 3.65% of total amount of 5*300mm DCB
Case 2: TurboHawk + DCB

- Tissue from Hawk atherectomy
- Thin piece material in filter net
Case 3: TurboHawk + DCB

Tissue from Hawk atherectomy

Thin piece material
Case 4: TurboHawk (without DCB)

Tissue from Hawk atherectomy

Thin piece material
## Results 1

<table>
<thead>
<tr>
<th>CASE</th>
<th>Hawk</th>
<th>DCB</th>
<th>Filter bottom</th>
<th>Filter net</th>
<th>Solution test</th>
<th>Paclitaxel content</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>/</td>
<td>5*300</td>
<td>Typical plaque</td>
<td>Thin piece material</td>
<td>insoluble</td>
<td>3.65%</td>
</tr>
<tr>
<td>2</td>
<td>Yes</td>
<td>5*300</td>
<td></td>
<td>Thin piece material</td>
<td>insoluble</td>
<td>0.9%</td>
</tr>
<tr>
<td>3</td>
<td>Yes</td>
<td>5*200</td>
<td></td>
<td>Thin piece material</td>
<td>insoluble</td>
<td>0.39%</td>
</tr>
<tr>
<td>4</td>
<td>Yes</td>
<td>4.5*150</td>
<td></td>
<td>Thin piece material</td>
<td>insoluble</td>
<td>0.29%</td>
</tr>
<tr>
<td>5</td>
<td>Yes</td>
<td>/</td>
<td></td>
<td>Thin piece material</td>
<td>/</td>
<td>/</td>
</tr>
</tbody>
</table>
Conclusion 1

- **Distal embolization in filter**: plaque, thin piece material
- **Thin piece material**: undefined, not drug particles
- **Drug particles rushed away**: partly captured by filter, paclitaxel content 0.29%-3.65%
Question 2

What is the “thin piece material”? Where does it come from?
Study 2: pathological examination

Thin piece material: hyaline degeneration and calcification (arteriosclerosis)
Question 3

What’s the size of drug particles rushed down? Will it cause below the knee artery embolization?
Study 3: particle size

<table>
<thead>
<tr>
<th>DCB</th>
<th>Total amount</th>
<th>Amount of particles with different size (μm)/ml</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td>5 ≤ φ ≤ 10</td>
</tr>
<tr>
<td>Acotec 4*40mm</td>
<td>6006</td>
<td>3855.3 (64.19%)</td>
</tr>
<tr>
<td>SeQuent Please</td>
<td>9248</td>
<td>3222.7 (34.85%)</td>
</tr>
</tbody>
</table>

Experiments to gather the particles and measure the size
Size of BTK artery

- Peroneal: 2–3mm
- Anterior tibial: 2–3mm
- Posterior tibial: 2–3mm
- Dorsal pedis: 1.5–2.5mm
- Plantar: 1.5–2.5mm
- PPL: 1–2mm
Size of small branches in foot

Small artery: 10 μm-1mm
Capillary: 6-8 μm
## Plaque v.s. Drug particles

<table>
<thead>
<tr>
<th></th>
<th>Plaque</th>
<th>Drug particles</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Diameter</strong></td>
<td>90µm-2mm, or larger</td>
<td>&lt;10µm, 64.2%</td>
</tr>
<tr>
<td></td>
<td></td>
<td>10-25µm, 35.1%</td>
</tr>
<tr>
<td></td>
<td></td>
<td>&lt;50µm, 0.61%</td>
</tr>
<tr>
<td><strong>Main artery</strong></td>
<td><strong>Embolization</strong></td>
<td>no</td>
</tr>
<tr>
<td><strong>Small branches</strong></td>
<td></td>
<td><strong>Hyper-resistance</strong></td>
</tr>
<tr>
<td><strong>Effect on the patency</strong></td>
<td>No flow</td>
<td>Patent with hyper-resistance</td>
</tr>
<tr>
<td><strong>Self-cure</strong></td>
<td>no</td>
<td>Yes it is soluble</td>
</tr>
</tbody>
</table>

**Embolization v.s. Hyper-resistance**
Conclusions

• **Distal embolization in main artery**: by different forms of plaque

• **Drug particles rushed down**: do exist, will not cause typical embolization in main artery, but hyper-resistance in small branches

• **Future studies**: decrease particles rushed down, hydrophilic or lipophilic, ...
THANK YOU