Temporal reverse flow by proximal femoral artery occlusion during drug-coated balloon dilatation

A significant technique to minimize downstream particle embolization

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Disclosure

Speaker name: Masayoshi Kimura, MD

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
Drug-coated Balloon
Paclitaxel-coated balloon

- Improve patency
- Stent-less

- Mortality?
- Downstream particle embolization
In my opinion, we should consider this possible adverse effect for critical limb ischemia patient at least.
Risk of Death and Amputation with Use of Paclitaxel-Coated Balloons in the Infrapopliteal Arteries for Treatment of Critical Limb Ischemia

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<table>
<thead>
<tr>
<th>Study</th>
<th>Paclitaxel Events</th>
<th>Paclitaxel Total</th>
<th>Control Events</th>
<th>Control Total</th>
<th>Odds Ratio</th>
<th>OR</th>
<th>95%-CI</th>
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<tbody>
<tr>
<td>DEBATE-BTK</td>
<td>0</td>
<td>65</td>
<td>1</td>
<td>67</td>
<td>0.34</td>
<td>0.34</td>
<td>[0.01; 8.46]</td>
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<tr>
<td>Haddad SE</td>
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<td>48</td>
<td>2</td>
<td>45</td>
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<td>[0.04; 5.23]</td>
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<tr>
<td>BIOLUX PII</td>
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<td>36</td>
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<td>0.49</td>
<td>[0.04; 5.61]</td>
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<tr>
<td>LUTONIX BTK</td>
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<td>3</td>
<td>155</td>
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<td>0.72</td>
<td>[0.16; 3.24]</td>
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<tr>
<td>ACOART II/BTK</td>
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<td>102</td>
<td>1</td>
<td>103</td>
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<td>1.01</td>
<td>[0.06; 16.37]</td>
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<tr>
<td>IN.PACT DEEP</td>
<td>20</td>
<td>227</td>
<td>4</td>
<td>111</td>
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<td>2.58</td>
<td>[0.86; 7.75]</td>
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<tr>
<td>SINGA-PACLI</td>
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<td>70</td>
<td>4</td>
<td>68</td>
<td>3.65</td>
<td>3.65</td>
<td>[1.13; 11.83]</td>
</tr>
</tbody>
</table>

GLM model
Heterogeneity: \(I^2 = 0\%\), \(\tau^2 = 0\), \(p = 0.53\)
Test for overall effect: \(z = 1.67 (p = 0.09)\)

0.02 0.1 0.5 1 2 10 50
What Can We Do?

- One is **to clarify the clinical results** of these downstream particle embolization and systemic effect.

- The other is **to seek the new method** to prevent downstream embolization and extract paclitaxel-rich blood in the target vessels.


- **In this presentation, we described the novel method to reduce these risks mentioned above in SFA intervention.**
Try to extract the paclitaxel particles as much as we can during the intervention.
Background Before showing my technique

- The basic knowledge of the blood flow during arteriotomy.
- It is consensus for vascular surgeons that the blood flow in the SFA was reversed during arteriotomy on the CFA.
Balloon-Assisted Guiding Catheter
OPTIMO PPI (Tokai Medical, Japan)

Sheath-less system
Outer diameter = 6.5Fr sheath
Scheme of the proximal balloon occlusion

A
CFA
Target lesion
SFA

B
Optimo PPI

C
Guidewire

D
0.035 inch compatible OTW balloon
pre-dilatation
Scheme of the proximal balloon occlusion

- **E**: Optimo balloon inflation
- **F**: Residual antegrade flow due to collaterals
- **G**: External compression
- **H**: 
- **I**: 

Arrow symbols indicate flow directions.
After deflating temporary occlusion balloon of the b-GC, the final angiogram was performed.
Paclitaxel crystal in the extracted blood
Conclusion: Proximal balloon occlusion can reduce adverse effect during DCB angioplasty.
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