The impact of drug-coated balloon on wound healing in patients with critical limb ischemia

Kansai Rosai Hospital Cardiovascular Center

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Disclosure

Speaker name:

Takuya Tsujimura

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
IN.PACT SFA trial

Downstream effect??

Downstream Panniculitis Secondary to Drug-Eluting Balloon Angioplasty

Vasculitis resulting from a superficial femoral artery angioplasty with a paclitaxel-eluting balloon
Case 1: 60-year-old man

➢ **Chief complaint**
   Ulcer in the left lower limb

➢ **History of present illness**
   He underwent endovascular therapy (EVT) and transmetatarsal amputation for left lower limb because of gangrene of toes 6 month ago. However, he referred to our hospital because of the recurrence of rest pain and ulcer in the left lower limb.

➢ **Past history**
   Hypertension, dyslipidemia, coronary artery disease
   chronic kidney disease (dialysis)
Initial angiography

SFA

Pop

Below knee
EVT for ATA

Rapid Cross 2.0/2.5*210 mm

SAVERX 3.0*300 mm
EVT for SFA-Pop.A (Pre-dilatation)
Angiography after POBA

SFA

Pop
EVT for SFA-Pop.A
(POBA with DCB)

IN.PACT 4.0*150 mm × 3
Angiography after DCB

SFA

Pop

Below ankle
Clinical course of wound

Pre EVT

Day 3

Day 6

Day 17
Case 2: 76-year-old woman

- **Chief complaint**
  Gangrene of left third, fourth and fifth toe

- **History of present illness**
  She underwent plain balloon angioplasty for left SFA and peroneal artery because of CLI 3 month ago in other hospital. However, she was admitted to our hospital for EVT of left lower limb because of refractory gangrene of left third, fourth and fifth toe.

- **Past history**
  Hypertension, dyslipidemia, diabetes mellitus, chronic kidney disease
Initial angiography
EVT for TPT~Pero. A

Initial

DES

Final

Xience 3.0*28 mm
Additional EVT for Pero. A 1 month after EVT

Initial

DES

Final

Xience 2.25*38 mm
Additional EVT for SFA 1 month after EVT

Initial

DCB

IN.PACT 5.0*120 mm

Final
Clinical course of wound

- pre DCB
- Day 4
- Day 10
- Day 110
EVT for TPT~Pero. A

UA crystal ⇒ Distal embolism
## CLI patient characteristics in our hospital

<table>
<thead>
<tr>
<th></th>
<th>EVT with DCB N=45</th>
<th>EVT without DCB N=735</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age, years</td>
<td>75 ± 10</td>
<td>74 ± 10</td>
</tr>
<tr>
<td>Male, n (%)</td>
<td>26 (58)</td>
<td>450 (61)</td>
</tr>
<tr>
<td>Body mass index, kg/m²</td>
<td>22.6 ± 4.5</td>
<td>21.4 ± 3.7</td>
</tr>
<tr>
<td>Non-ambulatory status, n (%)</td>
<td>15 (34)</td>
<td>324 (44)</td>
</tr>
<tr>
<td>Hypertension, n (%)</td>
<td>29 (67)</td>
<td>482 (66)</td>
</tr>
<tr>
<td>Dyslipidemia, n (%)</td>
<td>14 (33)</td>
<td>130 (18)</td>
</tr>
<tr>
<td>Diabetes mellitus, n (%)</td>
<td>27 (63)</td>
<td>491 (67)</td>
</tr>
<tr>
<td>Hemodialysis, n (%)</td>
<td>23 (51)</td>
<td>398 (54)</td>
</tr>
<tr>
<td>Current/past smoker, n (%)</td>
<td>19 (44)</td>
<td>184 (25)</td>
</tr>
<tr>
<td>Coronary artery disease, n (%)</td>
<td>31 (69)</td>
<td>325 (44)</td>
</tr>
<tr>
<td>Chronic heart failure, n (%)</td>
<td>9 (20)</td>
<td>84 (19)</td>
</tr>
<tr>
<td>Rutherford classification</td>
<td></td>
<td></td>
</tr>
<tr>
<td>R5, n (%)</td>
<td>36 (80)</td>
<td>573 (78)</td>
</tr>
<tr>
<td>R6, n (%)</td>
<td>9 (20)</td>
<td>162 (22)</td>
</tr>
</tbody>
</table>
Wound healing rate

Follow-up period (month)

EVT with DCB
EVT without DCB

Log rank
P=0.14
Previous reports demonstrated that DCB was superior to standard PTA, with significantly higher primary patency.

Although extremely rare, downstream effect can occur in using DCB.

In our initial experience of IN.PACT DCB, downstream effect doesn't impact on wound healing process in CLI patients.
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