Japan update
Optimal Strategies for Vessel Preparation and DCB usage

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Disclosure

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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
Provisional Stents rate in Real World DCB trials

Provisional Stenting

Results from different trials are not directly comparable. Information provided for educational purposes.
Provisional stenting after failed DCB is not reimbursed in Japan

Instruction For Use of DCB in Japan

DCB

- <50% stenosis
- Non severe dissection (0-C) After Prep
- Non severe calcification

High expectation of DCB Performance

No recommend DCB

- ≥50% residual stenosis
- Severe dissection (≥D) After Prep
- Severe calcification

No expectation of DCB Performance
**Effort of Japanese Doctors to Minimize Dissection after Preparation**

**Long Balloon**

**Slow & Long inflation**

**Scoring Balloon**


Sugihara M, et al. Circulation reports

Horie K, et al. J Endovasc Ther. 2020
Fate or Result

Benign dissection

Malignant dissection

Fujihara et al. J Endovasc Ther. 2017
Dissection D (Spiral type)
Dissection E & F
(Filling Defects, Total Obstruction)

Severe recoil of Organized Thrombus
Dissection 0, A, B, C (Intimal Thickness)
Highly expectation of DCB Performance

- Stenosis (Intimal Thickness)
- CTO (Thrombus relate)
- Calc

Images depict various conditions and their impact on DCB performance.
Total **725** EVT for FP lesion; 2018.2-2020.9 (32 months)

**DCB treatment for 357** FP lesion

Exclusion
- Death; 47 cases
- Major amputation within 12 M; 10 cases
- CFA lesion; 15 cases
- ISR; 57 cases
- Lost follow up; 34 cases
- Within 12M after EVT; 94 cases

**100** Cases (LUTONIX DCB 56, IN.PACT DCB 44);
Complete follow up by Duplex echo examination at 12 month after EVT
Our Preparation Methods

**NO Special Preparation**

- **Conventional balloon** enough to cover the lesion
- **Inflation time 30 seconds**
- **Direct DCB (17%)** for non severe calcified stenotic lesion without PreP.
<table>
<thead>
<tr>
<th>Patients &amp; Clinical characteristics</th>
<th>DCB (n=100)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Age, yrs</strong></td>
<td>71.6 ± 9.2</td>
</tr>
<tr>
<td><strong>Male, %</strong></td>
<td>67</td>
</tr>
<tr>
<td><strong>Diabetes Mellitus, %</strong></td>
<td>61</td>
</tr>
<tr>
<td><strong>Hemodialysis, %</strong></td>
<td>33</td>
</tr>
<tr>
<td><strong>Rutherford 4-6, %</strong></td>
<td>31</td>
</tr>
<tr>
<td><strong>Baseline ABI</strong></td>
<td>0.64 ± 0.15</td>
</tr>
<tr>
<td><strong>Lesion length, mm</strong></td>
<td>159 ± 82</td>
</tr>
<tr>
<td><strong>TASC II C/D</strong></td>
<td>52</td>
</tr>
<tr>
<td><strong>Diameter Stenosis, %</strong></td>
<td>93.0 ± 7.2</td>
</tr>
<tr>
<td><strong>CTO, %</strong></td>
<td>35</td>
</tr>
<tr>
<td><strong>PACCS 4 calcification, %</strong></td>
<td>20</td>
</tr>
<tr>
<td><strong>Vessel Diameter, mm</strong></td>
<td>4.9 ± 0.8</td>
</tr>
<tr>
<td><strong>Numbers of BTK runoff vessel</strong></td>
<td>1.53 ± 0.87</td>
</tr>
<tr>
<td>Procedural characteristics</td>
<td>DCB (n=100)</td>
</tr>
<tr>
<td>--------------------------------------------</td>
<td>-------------</td>
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<tr>
<td>DCB Length, mm</td>
<td>152 ± 53</td>
</tr>
<tr>
<td>DCB Number</td>
<td>1.0 ± 0.4</td>
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<tr>
<td>DCB Diameter, mm</td>
<td>5.4 ± 0.6</td>
</tr>
<tr>
<td>Residual Stenosis, %</td>
<td>23.9 ± 4.0</td>
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<tr>
<td>Dissections, %</td>
<td></td>
</tr>
<tr>
<td>0-C (Benign)</td>
<td>100</td>
</tr>
<tr>
<td>D-F (Malignant)</td>
<td>0</td>
</tr>
<tr>
<td>Provisional Stent, %</td>
<td>0</td>
</tr>
</tbody>
</table>
1 year Primary patency (PSVR<2.5)

Patency rate

Follow up periods (month)

81.6%
1 year Freedom from CD-TLR

93.8%
Summary

• We need to identify the lesions for which DCB is effective

• Malignant dissection is caused by organized thrombus related lesion

• Preparations for vessels with thicker intima do not need to be nervous

• Our results of DCB treatment were acceptable compare to other DCB data