Drug eluting devices in treating femoro-popliteal occlusion lesions: new evidence from China

Wei Guo, MD
Chief, Professor
Vascular and Endovascular Department
Chinese PLA General Hospital, Beijing, China

Disclosure
None

### DCB trials in China

<table>
<thead>
<tr>
<th>Manufacturer</th>
<th>DCB</th>
<th>Study design</th>
<th>Pts #</th>
<th>Primary Endpoint</th>
<th>Status</th>
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### DES trials in China

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<th>Primary Endpoint</th>
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- COOK Zilver PTX trial - Prospective, Multi-center, Single Arm
- ArcoTech AcoArt I Trial - Prospective, Multi-center, RCT
- Medtronic IN.PACT SFA China - Prospective, Multi-center, Single Arm
- Microport Re-warm-PTX trial - Prospective, Multi-center, RCT

### Zilver PTX China Trial

#### Baseline data

| Patients | 178 |
| Age (years) | 67 ± 9 |
| Male | 79% |
| Diabetes | 56% |
| High cholesterol | 19% |
| Hypertension | 76% |
| Rutherford Classification | 2:22% | 3:70% | 4:8% |

| Lesions | 178 |
| Lesion length (mm) | 79 ± 49 |
| Diameter stenosis (%) | 89 ± 15 |
| Total occlusions | 50% |
| Lesion calcification | None:24% | Mild:35% | Moderate:32% | Severe:10% |

1 Angiographic core lab assessment

#### Primary Patency

High primary patency rate through 12 months, similar to previous studies

<table>
<thead>
<tr>
<th>Months</th>
<th>Patency</th>
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<tr>
<td>0</td>
<td>100%</td>
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<tr>
<td>3</td>
<td>98.2%</td>
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<tr>
<td>6</td>
<td>95.9%</td>
</tr>
<tr>
<td>9</td>
<td>91.5%</td>
</tr>
<tr>
<td>12</td>
<td>81.9%</td>
</tr>
</tbody>
</table>
Freedom from TLR

High freedom from TLR rate through 12 months, similar to previous studies.

No deaths, amputations, or worsening Rutherford scores.

ABI/Walking and Clinical Outcomes

Pre-procedure | 6 months | 12 months
---|---|---
ABI | 0.6 ± 0.2 | 0.9 ± 0.2 | 0.9 ± 0.2
Walking distance | 22.9 ± 20.5 | 74.3 ± 33.8 | 77.9 ± 32.3
Walking speed | 27.8 ± 22.8 | 52.0 ± 32.3 | 52.5 ± 32.2
Stair climb | 48.5 ± 33.8 | 75.0 ± 33.5 | 75.3 ± 35.3

ABI and walking impairment significantly improved (p<0.001) through 12 months.

AcoArt I Trial

Prospective, Multi-center, RCT

DCB (n=100) | PTA (n=100) | P
---|---|---
Diabetes (%) | 54/100 (54%) | 57/100 (57%) | 0.67
Rutherford | 2 | 3 | 4 | 5
14% | 16% | 24% | 14%
12% | 27% | 44% | 17%
0.94
Lesion length (mm) | 147.26±109.52 | 151.59±108.94 | 0.78
Oclusion | 57% (57/100) | 52% (52/100) | 0.48
ISR | 29% (29/100) | 29% (29/100) | 0.55

6-month LLL shows Orchid DCB’s superiority

LLL (mm) | DCB 0.05±0.73 | PTA 1.15±0.89 | P-value < 0.001
---|---|---|---

Primary patency through 24 months

DCB | PTA
---|---
84.1% | 64.6%
46.5% | 31.4%

Freedom from CD-TLR through 24 months

DCB | PTA
---|---
92.8% | 86.5%

Patients Number | 96 | 95
Cumulative TLR events | 15 | 49
Arterial events | 9 | 9
Peri-procedure | 9 | 8
Chinese PLA General Hospital, Beijing, China

**ISR subgroup: Freedom from CD-TLR**

<table>
<thead>
<tr>
<th>Number</th>
<th>DCB</th>
<th>PTA</th>
</tr>
</thead>
<tbody>
<tr>
<td>27</td>
<td>26</td>
<td>25</td>
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</table>

**ISR subgroup: primary patency**

<table>
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<tr>
<th>24-mon FU</th>
<th>TLR</th>
</tr>
</thead>
<tbody>
<tr>
<td>24/27</td>
<td>3/24</td>
</tr>
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</table>

**Lesion Characteristics**

- N=143 Subjects
- N=143 Lesions

**Lesion Type**

- [1] De novo: 99.3% (142/143)
- [2] Restenotic (non-stented): 0.7% (1/143)

**Lesion length (cm ± SD)**

- 10.40 ± 6.51

**Total occlusions, % (n)**

- 52.4% (75/143)

**Severe calcification, % (n)**

- 11.9% (17/143)

**Procedural Characteristics**

- N=143 Subjects
- N=143 Lesions

**Pre-Dilatation (%)**

- 100% (143/143)

**Post-dilatation (%)**

- 14.0% (20/143)

**Dissections (%)**

- A 18.9% (27/143)
- B-C 0.0% (0/143)
- D 55.3% (79/143)
- E-F 25.9% (37/143)
- G 0.0% (0/143)

**Provisional Stenting (%)**

- 4.2% (6/143)

**Device Success (%)**

- 97.6% (206/211)

**Procedural Success (%)**

- 91.5% (130/142)

**Clinical Success (%)**

- 89.4% (127/142)

**Patient Characteristics**

- N=143 Subjects

**Age, Y ± SD**

- 66.8 ± 7.7

**Male Gender (%)**

- 74.8% (107/143)

**Diabetes Mellitus (%)**

- 46.2% (66/143)

**Current Smoker (%)**

- 36.4% (52/143)

**Lesion Length (mm)**

- 237.38 ± 243.46

**LLL (mm)**

- -0.04 ± 1.69

**24-mon FU**

- 24/27

**TLR**

- 3/24

**Average Time to first TLR, day**

- 392 ± 173

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**Reewarm PTX trial**

**Prospective, Multi-center, RCT**

**Device Success: Successful delivery, inflation, deflation and retrieval of the intact study balloon without burst < RBP**

**Procedural success: Residual stenosis ≤ 50% for non-stented subjects or ≤ 30% for stented subjects**

**Clinical success: Procedural success without procedural complications (death, major target limb amputation, thrombosis of target lesion or TVR) prior to discharge**

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**IN.PACT SFA China Study**

- 12-Month Patency (ITT)
- Rate of Clinically-driven TLR: 2.9% (4/139)

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**Consistent Patencies Across IN.PACT Studies**

- Iida, O. IN.PACT Japan 12 Month Results. LINC 2017

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**IN.PACT SFA China Study**

**Consistent Patencies Across IN.PACT Studies**

- 89.9% (90.9%)
- 90.9%

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**Reewarm PTX trial**

**Consistent, Multi-center, RCT**

**Device Success: Successful delivery, inflation, deflation and retrieval of the intact study balloon without burst < RBP**

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**IN.PACT SFA China Study**

**Consistent Patencies Across IN.PACT Studies**

- Iida, O. IN.PACT Japan 12 Month Results. LINC 2017
Conclusion

- Zilver PTX trial results suggest Zilver PTX is safe and effective in Chinese patients
- ArcoArt and Reewarm PTX trial demonstrated the safety and efficacy of Orchid and Reewarm DCB in treating femoropopliteal artery disease.
- IN.PACT SFA China results demonstrated remarkable performance of the IN.PACT admiral DCB in a Chinese population.

Thanks for your attention

Wei Guo, MD
pla301dm@vip.sina.com  guowei@301hospital.com.cn
Department of Endovascular and Vascular Surgery
Chinese PLA General Hospital, Beijing, China