Orchid DCB brings new life to a ISR patient
Story behind 31 months patency

Baixi Zhuang, MD, PhD
Xiyuan Hospital, Beijing
Disclosure

Speaker name: Zhuang Baixi

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
ISR - Achilles heel of SFA stenting!

- 30% to 40% of patients will present with initial ISR within 2 years of stent implantation, and 65% will return with recurrent ISR posttreatment \[1\]

- In the past 10 years, there is no efficient therapy to treat ISR patients in China.

- DCB era just arrived in China, will it change our strategy to treat ISR patients?

DCB seems to be the best for ISR

Comparison of outcomes treating FP ISR with different devices

12 months patency %

ISR lesion length (mm)

## AcoArt I Trail-ISR Cohort

<table>
<thead>
<tr>
<th></th>
<th>DCB</th>
<th>PTA</th>
<th><em>P value</em></th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Number</strong></td>
<td>26</td>
<td>20</td>
<td></td>
</tr>
<tr>
<td>Total occlusion (%)</td>
<td>17/26 (65 %)</td>
<td>9/20 (45 %)</td>
<td>0.17</td>
</tr>
<tr>
<td>Lesion length (mm)</td>
<td>237.38 ± 100.28</td>
<td>243.46 ± 113.88</td>
<td>0.85</td>
</tr>
<tr>
<td>Late lumen loss (mm)</td>
<td>-0.04 ± 0.69</td>
<td>1.69 ± 0.71</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>6mon Restenosis</td>
<td>6/26 (23%)</td>
<td>18/20 (90%)</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>6month TLR (%)</td>
<td>0/26 (0%)</td>
<td>15/20 (75%)</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>12month Restenosis</td>
<td>6/26 (23%)</td>
<td>18/19 (95%)</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>12month Cumulative TLR (%)</td>
<td>0/26 (0%)</td>
<td>18/19[1] (95%)</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>24 month Cumulative TLR(%)</td>
<td>3/24 (12.5%)</td>
<td>20/20[2] (100%)</td>
<td>&lt;0.001</td>
</tr>
</tbody>
</table>

1.3 patients had re-revascularization
2.5 patients had 2 re-revascularizations. 10 patients had 1 re-vascularization.
# DCB in ISR – Single Center Experience

<table>
<thead>
<tr>
<th></th>
<th>DCB</th>
<th>PTA(History)</th>
<th>P value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Number</td>
<td>36</td>
<td>40</td>
<td></td>
</tr>
<tr>
<td>Total occlusion (%)</td>
<td>27/36 (75 %)</td>
<td>29/40 (72.5 %)</td>
<td>0.22</td>
</tr>
<tr>
<td>Lesion length (mm)</td>
<td>202.97 ± 110.44</td>
<td>192.40 ± 103.08</td>
<td>0.64</td>
</tr>
<tr>
<td>3mon Restenosis*</td>
<td>3/36 (8.3%)</td>
<td>14/40 (35%)</td>
<td>&lt;0.01</td>
</tr>
<tr>
<td>6mon TLR (%)</td>
<td>0/36 (0%)</td>
<td>11/40 (27.5%)</td>
<td>&lt;0.01</td>
</tr>
</tbody>
</table>

*PSVR > 2.4 = Restenosis

- Bai-xi ZHUANG, Vascular Surgery Department, Xiyuan Hospital, China Academy of Chinese Medical Sciences, Beijing, China.  E-mail: zhuangbaixi@163.com
Case Presentation

- 64-year-old male was admitted to my center due to right IC in 2009
- His left cuff has been amputated because of severe ischemia lead to gangrene in 2008
- Risk factors: smoking history for 30 years, HTN
- His right leg underwent 6 interventions before enrolled by AcoArt I study in 2013
- Kept patent for 31 months after DCB treatment
6 Interventions Before DCB!

- April 2009: Aspirin 0.1 mg/qd, Clopidogrel 75mg qd
- May 2010: Aspirin 0.1 mg/qd, Clopidogrel 75mg qd
- October 2010: Aspirin 0.1 mg/qd, Clopidogrel 75mg qd, Simvastatin 20mg qn
- January 2011: Aspirin 0.1 mg/qd, Clopidogrel 75mg qd, Simvastatin 20mg qn, Cilostazol 100mg bid, Warfarin INR Control 2.0
- March 2011: Aspirin 0.1 mg/qd, Clopidogrel 75mg qd, Simvastatin 20mg qn, Cilostazol 100mg bid, Warfarin INR Control 2.0
- September 2011: Aspirin 0.1 mg/qd, Clopidogrel 75mg qd, Simvastatin 20mg qn, Cilostazol 100mg bid, Warfarin INR Control 2.0
Treated with DCB in 2013

Pre Procedure

Post Procedure
Angiographic Follow Up at 2014 April (6Ms After DCB)
Before DCB

<table>
<thead>
<tr>
<th></th>
<th>After DCB</th>
<th>3 month</th>
<th>6 month</th>
<th>12 month</th>
</tr>
</thead>
<tbody>
<tr>
<td>Before DCB</td>
<td>0.37</td>
<td>0.75</td>
<td>1.01</td>
<td>0.83</td>
</tr>
<tr>
<td>6 month</td>
<td>0.77</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>3 month</td>
<td></td>
<td>1.01</td>
<td></td>
<td>0.83</td>
</tr>
<tr>
<td>12 month</td>
<td></td>
<td></td>
<td>0.83</td>
<td>0.77</td>
</tr>
</tbody>
</table>
18 Month Follow-up

0.80

Strong stent echo was observed in SFA Vessel stenosis <50%
Symptom recurred
Walking capacity 100 m

31 Month Follow-up......
31 Month Follow-up
Dilatation: Pre-dilatation & DCB
Follow up after 5 month

Vessel stenosis < 50%
Conclusions

- In-stent-restenosis in femo-popliteal artery remains a challenging problem, while DCB seems to be the best solution at the moment.
- Orchid DCB’s performance has been demonstrated in Chinese ISR patients, by providing 0% TLR and 12.5% TLR at 12 month and 24 month follow up respectively, as shown in AcoArt I study.
- Single center experience from Xiyuan hospital indicating a very good outcome for DCB in real world ISR patients.
- Outstanding results of this special case demonstrates remarkable efficacy for Orchid DCB to treat complex ISR patients.
Orchid DCB brings new life to a ISR patient
Story behind 31 months patency

Baixi Zhuang, MD, PhD
Xiyuan Hospital, Beijing