New Long-term Information on PTX Coated DCB 5-year Results from the AcoArt I Study

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on behalf of the AcoArt I Investigators
Disclosure

Speaker name: Xin Jia

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
AcoArt I Study Design

AcoArt I was initially designed to be a 2 Year FU study

200 Pts
(10 sites)

DCB
N=100

6-month
Clinical: 99(99%)
Angio: 89(89%)

12-month
Clinical: 97(97%)

24-month
Clinical: 96(96%)

PTA
N=100

6-month
Clinical: 98(98%)
Angio: 89(89%)

12-month
Clinical: 96(96%)

24-month
Clinical: 95(95%)

Now study was extended to 5 years

AcoArt I
200 pts

DCB
5 Year
Clinical: 89(89%)

PTA
5 Year
Clinical: 91(91%)
AcoArt DCB

• produced by Acotec Scientific Co., Ltd, Beijing, China
• Paclitaxel dose:
  – 3.3µg/mm²
• Excipient: Mg-stearate
  – Minimize drug loss (<10%) during delivery
  – Less volume enables lower profile (6F compatible in most of sizes)
• Balloon sizes
  – Diameter(mm): 3.0-12.0, with half sizes (4.5, 5.5) design, match vessel precisely
  – Length(mm): 20, 30, 40, 60, 80, 100, 120, 150, 200, 250, 300, treat long lesion easily
• GW Compatible
  – AcoArt Orchid 0.035” GW compatible
  – AcoArt Tulip 0.018” GW compatible
  – AcoArt Litos 0.014” GW compatible
## Major Baseline Characteristics

<table>
<thead>
<tr>
<th></th>
<th>DCB</th>
<th>PTA</th>
<th>P</th>
</tr>
</thead>
<tbody>
<tr>
<td>Diabetes (%)</td>
<td>54/100 (54%)</td>
<td>57/100 (57%)</td>
<td>0.67</td>
</tr>
<tr>
<td>Rutherford</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>2</td>
<td>14%</td>
<td>12%</td>
<td>0.94</td>
</tr>
<tr>
<td>3</td>
<td>46%</td>
<td>44%</td>
<td></td>
</tr>
<tr>
<td>4</td>
<td>24%</td>
<td>27%</td>
<td></td>
</tr>
<tr>
<td>5</td>
<td>16%</td>
<td>17%</td>
<td></td>
</tr>
<tr>
<td>Lesion Length (mm)</td>
<td>147.26±109.52</td>
<td>151.59±108.94</td>
<td>0.78</td>
</tr>
<tr>
<td>Total Occlusions</td>
<td>57% (57/100)</td>
<td>52% (52/100)</td>
<td>0.48</td>
</tr>
<tr>
<td>ISR</td>
<td>27% (27/100)</td>
<td>23% (23/100)</td>
<td>0.51</td>
</tr>
</tbody>
</table>
Freedom from CD-TLR through 5 years

Less CD-TLR in DCB group through 5 years, compare to PTA group (p<0.001).

<table>
<thead>
<tr>
<th>CD-TLR</th>
<th>1yr</th>
<th>2yrs</th>
<th>5yrs</th>
</tr>
</thead>
<tbody>
<tr>
<td>DCB</td>
<td>7</td>
<td>13</td>
<td>21</td>
</tr>
<tr>
<td>PTA</td>
<td>38</td>
<td>39</td>
<td>40</td>
</tr>
</tbody>
</table>
Comparable results with previous Studies

Mean Lesion Length (cm)

- Zilver PTX: 6.6
- IN.PACT: 8.9
- Acotec: 14.7

5 years Freedom from CD-TLR

- Zilver PTX: 6.6
- IN.PACT: 8.8
- Acotec: 15.1

AcoArt I enrolled >50% CTO lesions

- Acotec DCB improve most FTLR in 5 years, compare to PTA

+18.4%

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- Zilver PTX: 6.6
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AcoArt I enrolled >50% CTO lesions

- Acotec DCB improve most FTLR in 5 years, compare to PTA

+18.4%
Freedom from All-cause Death through 5 years

No significant statistical difference on mortality between DCB and PTA within 5-year follow up

<table>
<thead>
<tr>
<th>Nr of Death</th>
<th>1 yr</th>
<th>2 yrs</th>
<th>5 yrs</th>
</tr>
</thead>
<tbody>
<tr>
<td>DCB</td>
<td>2</td>
<td>8</td>
<td>17</td>
</tr>
<tr>
<td>PTA</td>
<td>3</td>
<td>6</td>
<td>24</td>
</tr>
</tbody>
</table>

P value of Log-rank (Mantel-Cox) = 0.262
No significant statistical difference in Cause of Death between DCB and PTA within 5-year follow up.
# Death vs Survival Analysis

## Overall Cohort - Death vs Survival

<table>
<thead>
<tr>
<th>Patient / Lesion Characteristics</th>
<th>Death (N=41)</th>
<th>Survival (N=138)</th>
<th>p-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age</td>
<td>68.90 ± 7.65</td>
<td>65.03 ± 8.65</td>
<td>0.011</td>
</tr>
<tr>
<td>CHD</td>
<td>16 (39.02%)</td>
<td>32 (23.02%)</td>
<td>0.042</td>
</tr>
<tr>
<td>Bail-out stent</td>
<td>14 (34.15%)</td>
<td>23 (16.55%)</td>
<td>0.014</td>
</tr>
<tr>
<td>Lesion length (mm)</td>
<td>178.11 ± 108.13</td>
<td>139.29 ± 109.47</td>
<td>0.047</td>
</tr>
</tbody>
</table>

## DCB Cohort - Death vs Survival

<table>
<thead>
<tr>
<th>Patient / Lesion Characteristics</th>
<th>Death (N=17)</th>
<th>Survival (N=172)</th>
<th>p-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>CHD</td>
<td>8 (47.06%)</td>
<td>13 (18.06%)</td>
<td>0.011</td>
</tr>
<tr>
<td>Bail-out stent</td>
<td>8 (47.06%)</td>
<td>10 (13.89%)</td>
<td>0.002</td>
</tr>
<tr>
<td>Paclitaxel Dose (mg)</td>
<td>13.77 ± 6.96</td>
<td>12.52 ± 9.12</td>
<td>0.597</td>
</tr>
</tbody>
</table>
Meta-analysis of mortality at 5 years

Results when AcoArt I study is included.

*Deaths After Paclitaxel Interventions in the Leg Katsanos et al, DOI: 10.1161/JAHA.118.011245 Journal of the American Heart Association
Conclusions

• The efficacy of AcoArt Orchid drug coated balloon maintained over 5 years, even in complex lesions.
• No paclitaxel-related safety event observed during AcoArt I 5ys follow up.
• No different in cause of death between DCB and PTA arms.
• It is noticeable that no different in paclitaxel dose between death and survival group.
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