Zilver PTX Japan 5-year Results for Paclitaxel-Eluting Stent Treatment of Femoropopliteal Artery Disease

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On behalf of the Investigators
Disclosure

Speaker name: Hiroyoshi Yokoi

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): COOK

☐ I do not have any potential conflict of interest
Global Clinical Program for Zilver PTX

More than 2400 patients included in current Zilver PTX clinical program
5-year Follow-up for Japan PMS

- 904 patients with 1080 lesions treated with 1877 Zilver PTX stents
  - 411 patients completed 5-year follow-up
  - 493 patients exited study through 5 years (~10% per year)
    - 226 lost to follow-up through 5 years (25%)
    - 82 withdrawals through 5 years (9%)
    - 185 deaths through 5 years (20%)
      - None adjudicated as device or procedure related
  - Follow-up and exit rates very similar to those observed in RCT
## Patient Demographics and Lesion Characteristics

<table>
<thead>
<tr>
<th>Patient Characteristics</th>
<th>Zilver PTX Japan PMS</th>
</tr>
</thead>
<tbody>
<tr>
<td>Patients</td>
<td>904</td>
</tr>
<tr>
<td>Age (years)</td>
<td>74 ± 9</td>
</tr>
<tr>
<td>Male</td>
<td>70%</td>
</tr>
<tr>
<td>Diabetes</td>
<td>59%</td>
</tr>
<tr>
<td>High cholesterol</td>
<td>61%</td>
</tr>
<tr>
<td>Hypertension</td>
<td>85%</td>
</tr>
<tr>
<td>Pulmonary disease</td>
<td>8%</td>
</tr>
<tr>
<td>Renal disease</td>
<td>44%</td>
</tr>
<tr>
<td>Renal failure (eGFR &lt; 60 and/or “on dialysis”)</td>
<td>36%</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Lesion Characteristics</th>
<th>Zilver PTX Japan PMS</th>
</tr>
</thead>
<tbody>
<tr>
<td>Lesions</td>
<td>1080</td>
</tr>
<tr>
<td>Lesion length (cm)</td>
<td>14.6 ± 9.6</td>
</tr>
<tr>
<td>Diameter stenosis (%)</td>
<td>92 ± 11</td>
</tr>
<tr>
<td>Total occlusions</td>
<td>42%</td>
</tr>
<tr>
<td>In-stent restenosis</td>
<td>19%</td>
</tr>
<tr>
<td>Rutherford 4-6 (CLI)</td>
<td>21%</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Patent runoff vessels</th>
<th>0</th>
<th>7%</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>1</td>
<td>32%</td>
</tr>
<tr>
<td></td>
<td>2</td>
<td>33%</td>
</tr>
<tr>
<td></td>
<td>3</td>
<td>29%</td>
</tr>
</tbody>
</table>
Consistently good results in challenging patient population including diabetics, renal failure, long lesions, ISR, no runoff, CLI
Japan PMS Subgroups Analyzed

Japan PMS
(n=904)

- Complex lesions (>14 cm, no runoff, ISR)
  - Diabetic patients
  - CLI patients
  - No runoff
  - Chronic renal failure patients
  - ISR lesions
  - Calcified lesions
Diabetic Subgroup

Japan PMS
(n=904)

- Complex lesions (>14 cm, no runoff, ISR)
- Diabetic patients
- CLI patients
- ISR lesions
- Chronic renal failure patients
- No runoff
- Calcified lesions

Japan PMS
(n=904)

Diabetics
(n=532)

Non-diabetics
(n=372)
Diabetic vs. Non-diabetic Patients

• Diabetic patients:
  – More hypercholesterolemia: 69% vs. 50%
  – More hypertension: 88% vs. 82%
  – More renal disease: 49% vs. 36%
    • More renal failure: 42% vs. 27%
  – More CLI: 26% vs. 14%
  – Fewer patent runoff vessels: 53% vs. 31%
  – Lower ABI: 0.61 vs. 0.65
  – Younger: 72 vs. 75
  – Fewer total occlusions: 39% vs. 46%
Diabetic patients have similar benefit with DES as non-diabetics
No Patent Runoff Vessel Subgroup

- Complex lesions (>14 cm, no runoff, ISR)
- Diabetic patients
- CLI patients
- No runoff
- Chronic renal failure patients
- ISR lesions
- Calcified lesions

Japan PMS (n=904)

- ≥1 runoff vessel (n=845)
- No runoff vessels (n=54)

Runoff status was not reported for 5 patients.

- In the no runoff group:
  - Higher incidence of CLI: 45% vs. 20%
Freedom from TLR

Similar outcomes for patients with and without patent runoff vessels

<table>
<thead>
<tr>
<th>Years</th>
<th>Freedom from TLR (n=patients)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Overall Japan PMS (n=903)</td>
</tr>
<tr>
<td>1</td>
<td>90.8%</td>
</tr>
<tr>
<td>2</td>
<td>83.3%</td>
</tr>
<tr>
<td>3</td>
<td>78.8%</td>
</tr>
<tr>
<td>4</td>
<td>77.4%</td>
</tr>
<tr>
<td>5</td>
<td>74.2%</td>
</tr>
</tbody>
</table>
In-Stent Restenosis Subgroup

Japan PMS (n=904)

- Complex lesions (>14 cm, no runoff, ISR)
- Diabetic patients
- CLI patients
- No runoff
- Chronic renal failure patients
- ISR lesions
- Calcified lesions

Japan PMS n=904

- ISR n=175
- Non-ISR n=729

- In the ISR group:
  - Higher incidence of hypercholesterolemia: 70% vs. 59%
  - Lower ABI: 0.59 vs. 0.64
  - Longer lesion length: 17.8 cm vs. 14.0 cm
Freedom from TLR

Positive outcomes for ISR patients

<table>
<thead>
<tr>
<th>Years</th>
<th>Overall Japan PMS (n=903)</th>
<th>JPMS ISR (n=175)</th>
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<tbody>
<tr>
<td>1</td>
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</table>
Conclusions

• The Japan PMS included challenging patient subgroups often excluded from clinical studies
• Results from the Japan PMS are consistently good through 5 years
  – Diabetic patients have similar benefit as non-diabetics
  – Similar outcomes for patients with and without patent runoff vessels
  – Positive results for patients with in-stent restenosis
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