Effectiveness of the Zilver PTX drug-eluting stent in patients with no tibial runoff vessels: 2-year results from the Zilver PTX Post-Market Surveillance Study in Japan

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Disclosures

I have no conflict of interest related to this presentation
Zilver PTX Global Clinical Program

More than 2400 patients to be included in current Zilver PTX clinical program
Japan Post-Market Study

• Japan PMS included a challenging patient population with complex lesions
  – 7% of lesions had no continuous runoff vessels

• 3-year Japan PMS results are positive and continue to support the long-term benefit of the Zilver PTX
Tibial runoff and SFA revascularization

• Poor tibial runoff is a known negative prognostic factor affecting the long-term patency following revascularization of the SFA

• No specific guidelines for the management of patients with poor runoff

• SVS recommends “caution [...] in the use of interventions for IC in anatomic settings where durability is limited ([...] poor runoff).”
Does poor runoff affect the long-term effectiveness of the Zilver PTX for the SFA?
Subgroup Analysis of No Patent Runoff Vessels in Patients from the Japan PMS

Japan PMS
n = 905
missing data for 5 patients

No runoff vessels
n = 54

≥ 1 runoff vessel
n = 846

n = 32

2-year data available

n = 627
Patient Demographics and Comorbidities

<table>
<thead>
<tr>
<th></th>
<th>No-Runoff</th>
<th>Runoff</th>
</tr>
</thead>
<tbody>
<tr>
<td>Patients (n)</td>
<td>54</td>
<td>846</td>
</tr>
<tr>
<td>Age (years)</td>
<td>74 ± 9</td>
<td>73 ± 9</td>
</tr>
<tr>
<td>Male</td>
<td>69%</td>
<td>70%</td>
</tr>
<tr>
<td>Diabetes</td>
<td>70%</td>
<td>58%</td>
</tr>
<tr>
<td>High cholesterol</td>
<td>61%</td>
<td>61%</td>
</tr>
<tr>
<td>Hypertension</td>
<td>89%</td>
<td>85%</td>
</tr>
<tr>
<td>Pulmonary disease</td>
<td>7%</td>
<td>8%</td>
</tr>
<tr>
<td>Critical limb ischemia</td>
<td><strong>44.8%</strong></td>
<td><strong>19.7%</strong></td>
</tr>
</tbody>
</table>

No statistically significant differences except higher proportion of CLI
Baseline Lesion Characteristics

<table>
<thead>
<tr>
<th></th>
<th>No-Runoff</th>
<th>Runoff</th>
</tr>
</thead>
<tbody>
<tr>
<td>Lesions (n)</td>
<td>71</td>
<td>1003</td>
</tr>
<tr>
<td>Lesion length (mm)</td>
<td>138 ± 96</td>
<td>147 ± 96</td>
</tr>
<tr>
<td>Diameter stenosis (%)</td>
<td>93 ± 9</td>
<td>92 ± 11</td>
</tr>
<tr>
<td>Total occlusions</td>
<td>44%</td>
<td>41%</td>
</tr>
<tr>
<td>In-stent restenosis</td>
<td>17%</td>
<td>19%</td>
</tr>
<tr>
<td>Patent runoff vessels</td>
<td></td>
<td></td>
</tr>
<tr>
<td>0</td>
<td>100%</td>
<td>N/A</td>
</tr>
<tr>
<td>1</td>
<td></td>
<td>34%</td>
</tr>
<tr>
<td>2</td>
<td>N/A</td>
<td>35%</td>
</tr>
<tr>
<td>≥3</td>
<td></td>
<td>31%</td>
</tr>
</tbody>
</table>

No statistically significant differences between the two groups
Safety

• No device or procedure related deaths

• Stent integrity through 1 year
  – 0.0% fracture rate in no runoff group
  – 2.5% fracture rate in runoff group

• Low rate of thrombosis through 2 years

• Three patients in the no runoff group and seven patients in the runoff group had an amputation through 2 years
  – All three amputations in the no runoff group occurred within 2 months of the initial procedure likely reflecting a more advanced stage of PAD
Freedom from TLR

- No Patent Runoff Vessels
- Patent Runoff Vessels

- 91.0% at 0 months
- 89.5% at 6 months
- 83.8% at 12 months
- 81.3% at 18 months
Clinical Benefit

89.2%
82.0%
80.0%
73.7%

Defined as freedom from persistent or worsening claudication, rest pain, ulcer, or tissue loss.
Primary Patency

- 86.3%
- 76.8%
- 70.7%
- 68.4%
Limitations

• Relatively limited number of patients with no runoff vessels and 2-year f/u data available

• No internal control group for other treatments
Conclusions

• First comparative analysis of Zilver PTX in patients with or without runoff vessels

• 2-year results indicate that Zilver PTX is safe and effective in patients with no runoff vessels

• Outcomes for this patient group are favorable compared to other studies on different treatment modalities
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