Relationship between lesion length and 1-year primary patency

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Disclosure

Speaker name:  Yoshimitsu Soga

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
Limitations of SFA Technologies

Performance Decreases as Lesion Get Longer

Current SFA Studies - 12 Month Results

DCB, drug-coated balloon; DES, drug-eluting stent; SES, self-expanding stent; SFA, superficial femoral artery.

Modified from Shroë H. Superficial femoral artery PTA or stenting? 5-Year results. CIRSE 2011; Munich, Germany.
CONCLUSION:
Based on the PTA performance efficacy rate of 33% derived from industry clinical trial data and the medical literature, and the requirement that the bare nitinol stent 12-month efficacy performance goal be set to equal twice this rate, the patency efficacy goal equals 66%. Additional information is provided on safety and other reporting standards and stent integrity evaluation for bare metal stents.
3471 limbs received primary EVT for chronic FP disease

- 951 Balloon angioplasty alone
- 72 non-nitinol stent (52 wall, 20 balloon-expandable stent)

2520 limbs received bare-metal nitinol stent implantation

- 99 Rutherford class I
- 495 Rutherford class V or VI (393 class V, 102 class VI)

1854 limbs received bare-metal nitinol stent implantation for R 2-4

- 55 death < 1Y
- 301 FU <1Y (window ±1M 330 to 400 days)
- 125 lack of data

1373 limbs (1073 patients) received bare-metal nitinol stent implantation for R 2-4 with 1Y FU data
Relationship between LL and 1YPP

1373 limbs (1073 patients)
bare-metal nitinol stent
R 2-4 with 1Y FU data

<table>
<thead>
<tr>
<th>LL (mm)</th>
<th>50</th>
<th>100</th>
<th>150</th>
<th>200</th>
<th>250</th>
<th>300</th>
<th>350</th>
</tr>
</thead>
<tbody>
<tr>
<td>1Y-PP (%)</td>
<td>87.3</td>
<td>82.9</td>
<td>78.3</td>
<td>73.8</td>
<td>69.9</td>
<td>66.4</td>
<td>63.3</td>
</tr>
<tr>
<td>Lower (%)</td>
<td>84.4</td>
<td>80.1</td>
<td>75.3</td>
<td>70.4</td>
<td>65.7</td>
<td>59.6</td>
<td>51.8</td>
</tr>
<tr>
<td>Upper (%)</td>
<td>89.7</td>
<td>85.4</td>
<td>81.0</td>
<td>77.0</td>
<td>73.8</td>
<td>72.6</td>
<td>73.5</td>
</tr>
</tbody>
</table>

Results from STOP-IC

Primary Endpoint (12 months angiographic restenosis)

(As provisional stenting, SMART stent was used in ALL cases)

- **Intention to treat**
  - Cilostazol: 21% (16 of 76)
  - Non-Cilostazol: 48% (36 of 75)
  - OR: 0.29 (95%CI: 0.14, 0.59)
  - P=0.0005

- **Per protocol analysis**
  - Cilostazol: 21% (15 of 71)
  - Non-Cilostazol: 49% (37 of 76)
  - OR: 0.28 (95%CI: 0.14, 0.58)
  - P=0.0005


Notes:
- SMART stent was used in all cases.
The longer, the worse.

Cilostazol is a good option for SFA EVT.

- 1373 limbs (1073 patients)
- bare-metal nitinol stent R 2-4 with 1Y FU data


1-year primary patency rate

Lesion length (mm)

Cilostazol (+)

Cilostazol (-)
Risk of 1-year restenosis after Zilver PTX implantation

Adjusted odds ratio

Lesion length (cm)

Q1 ≤ 7
Q2 8-15
Q3 16-24
Q4 ≥ 25

O. Iida et al. J Am Coll Cardiol Intv 2015; 8: 1105-12
Summary

• 1-Y primary patency is **linearly** decreasing depending on the extension of LL in even BNS era.
• The OPG after BNS placement is set to **66%** or more
• Up to **24cm** of LL seems to be acceptable.
• **Cilostazol** is still a good option for SFA intervention.
• We expect next generation drug-delivery technology to improve 1-y PP regardless of LL
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