Sirolimus eluting coronary self expanding system for the treatment of iliofemoral disease

Eugenio Stabile, MD, PhD

Professor of Cardiovascular Diseases
Department of Advanced Biomedical Sciences
University “Federico II”, Napoli, Italy
Disclosure

Speaker name: Eugenio Stabile

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)

☐ do not have any potential conflict of interest
STENTYS Self-Apposing® stent

- The nitinol self apposing stents
  **STENTYS** is coated with a drug with a durable polymer formulation including Sirolimus and a polymer blend carrier (composed of Polysulfone (PSU) and soluble Poly-vinyl-pyrrolidone (PVP) as excipient). The stent is loaded with 1.4 μg of Sirolimus per mm².

- The **Xposition delivery system** consists of a balloon catheter with a nominal sized delivery balloon, covered with a distal splittable 0.0032-inch-thick sheath assembly that keeps the stent in a compressed condition.

- The expansion of the balloon causes the sheath to split, allowing stent deployment. The jailed sheath with the delivery balloon is retracted after stent deployment.
STENTYS Self-Apposing® stent

• The rationale for the self-apposing nitinol platform is to achieve optimal stent strut apposition in arterial segments with varying lumen diameters or stressed by different mechanical forces (i.e. bending)

• The device has never been tested in the treatment of iliofemoral disease.
The Stentys PAD Fed II registry

• All procedures have been executed at University of Napoli “Federico II”.
• From January 2017 to October 2018, 7 claudicant patients, due LEAD at the iliofemoral locations, underwent PTA with the implant of self expandable drug eluting stent (Xposition, Stentys, France).
• Follow-up to 12 months by clinical assessment and duplex ultrasound.
Primary endpoint

Primary patency at 12 months, which is defined by the absence hemodynamically significant target lesion stenosis on duplex ultrasound (>50%, Peak systolic velocity ratio no greater than 2.4).

Secondary endpoint

Freedom from Target Lesion Revascularization (TLR) at 12 months.
## Baseline characteristics

<p>| | |</p>
<table>
<thead>
<tr>
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<tbody>
<tr>
<td>Male</td>
<td>71.4%</td>
</tr>
<tr>
<td>Age</td>
<td>66 ± 7.07</td>
</tr>
<tr>
<td>Diabetes</td>
<td>14.3%</td>
</tr>
<tr>
<td>Hypertension</td>
<td>71.4%</td>
</tr>
<tr>
<td>Hypercholesterolaemia</td>
<td>71.4%</td>
</tr>
<tr>
<td>Smoking history</td>
<td>85.7%</td>
</tr>
<tr>
<td>CLI (RC ≥4)</td>
<td>0 %</td>
</tr>
<tr>
<td>Rutherford Class</td>
<td>1.7 ± 2.82</td>
</tr>
</tbody>
</table>

| Mean lesion Length (mm) | 19 ± 4.4     |
| de novo lesions         | 100%         |
| External iliac artery   | 71.4%         |
| Common iliac artery     | 14.3%         |
| Isolating lesions       | 42.8%         |
| Outflow lesions         | 42.8%         |
| Inflow lesions          | 14.3%         |
Example case

Stentys  3.5 – 4.5 / 27 mm
Results - In hospital

- Technical success
- MACCE
- MALE
- Clinical success
Example case 12-months Follow up
Results up to one year

- Primary endpoint
- Secondary endpoint
- MACCE
- MALE
Conclusions

Drug eluting self expandable stents are a safe and effective therapeutic strategy for the treatment of patients with LEAD at the iliofemoral location.

These data should be considered hypothesis generators to design large scale registries.
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