Real-world clinical performance of the sirolimus-eluting coronary stent system in Saudi patients: Results from the multicentre Supralimus CORE- Saudi (SCORES) registry

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Potential conflicts of interest

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☑️ I do not have any potential conflict of interest
Device Description

**Coronnium®**
Cobalt Chromium Coronary Stent System

Two Different Layers of Biodegradable Polymers

100% Drug - Base Layer (Programmed for Biphasic Drug Release)

0% Drug - Top Protective Layer (Protects from Light, Moisture & Premature Drug Release)

Sirolimus
Drug Release Kinetics

Supralimus-Core® stent contains Sirolimus drug at the dose of 1.4 µg/mm$^2$

Unique Biodegradable Polymeric Matrix-PLLA, PLGA and PVP

Drug release is designed to occur in two phases

**Initial burst**

- Right after the stent implantation, smooth muscle cell (SMC) proliferation initiates which is one of the major contributing factor of restenosis. The initial high level of drug release prevents excess cell growth

**Sustained release up to 48 days**

- To maintain the sufficient amount of drug level in the arterial tissues, SMT stents are designed to deliver drug at sustained rate up to about 7 weeks after implantation.
DES Drug and Polymer Weight

- Coating Weight (µg, 16 mm Stent)
  - Contributes to less coating thickness, no significant increase in overall profile
  - Lower polymer load, minimizes the risk of adverse events like stent thrombosis
Supralimus Core OCT Study

Complete coverage at 3 to 5 months

Good healing in calcified vessel

Optical Coherence Tomography Evaluation (cont.)

Comparison of uncovered struts between various stents

- Supralimus-Core: 2.79%
- Xience V: 3.40%
- Endeavor Resolute: 4.40%
- Cypher: 10.20%

Early strut coverage » Less chances of stent thrombosis

Objective

- The **SCORES registry** is designed to collect clinical outcome data from real-world Saudi patients receiving Supralimus-Core® Sirolimus-Eluting Stent (SES) in daily practice.
Methods

• This was a multicentre, observational, non-randomized and post-marketing surveillance registry, which included 482 daily practice patients, exclusively treated with biodegradable polymer-coated SES (Sahajanand Medical Technologies Pvt. Ltd., Surat, India) were enrolled.

• Primary end-point was: clinical incidence of major adverse cardiac events (MACE) up to four year.
Baseline demographics characteristics

- Previous MI: 68.7%
- Hypercholesterolemia: 57.7%
- Diabetes Mellitus: 53.3%
- Hypertension: 51.7%
- Smoker: 38.4%
- Unstable angina: 35.9%
- Stable angina: 15.6%
- Family History of CAD: 6.2%
Lesion and procedural characteristics

**Target Coronary Artery**
- LAD: 24.9%
- LIMA: 24.6%
- SVG: 0.3%
- RCA: 0.3%
- LCX: 49.9%

**ACC/AHA Lesion Classification**
- A: 19.2%
- B1: 39.0%
- B2: 15.1%
- C: 25.9%

*ACC: American College of Cardiology; AHA: American Heart Association*
Lesion complexity

- Calcified (moderate/severe): 14.0
- Total occlusion: 13.9
- Bifurcation lesion: 10.1
- Long (≥30 mm) lesion: 8.1
- Restenotic lesion: 5.6
Results

- A total of 993 Supralimus-Core® stents were implanted at index procedure (2.06 stents per patient) with an average diameter and total stent length of $2.93 \pm 0.39$ mm and $22.66 \pm 6.93$ mm, respectively.

- Primary events developed in 30 patients (6.2%) up to four years consisting of 4 (0.8%) cardiac deaths, 19 (3.9%) target lesion revascularization, 6 (1.2%) target vessel revascularization and 1 (0.2%) stent thrombosis.
# Clinical outcomes up to 4-years

<table>
<thead>
<tr>
<th>4-years outcomes (n=482)</th>
<th>0-1 year</th>
<th>&gt;1-year</th>
<th>0-4 years</th>
</tr>
</thead>
<tbody>
<tr>
<td>Death, n (%)</td>
<td>9 (1.9%)</td>
<td>5 (1.0%)</td>
<td>14 (2.9%)</td>
</tr>
<tr>
<td>Cardiac Death, n (%)</td>
<td>3 (0.6%)</td>
<td>1 (0.2%)</td>
<td>4 (0.8%)</td>
</tr>
<tr>
<td>Non-cardiac Death, n (%)</td>
<td>6 (1.2%)</td>
<td>4 (0.8%)</td>
<td>10 (2.1)</td>
</tr>
<tr>
<td>Target lesion revascularisation, n (%)</td>
<td>16 (3.3%)</td>
<td>3 (0.6%)</td>
<td>19 (3.9%)</td>
</tr>
<tr>
<td>Target vessel revascularisation, n (%)</td>
<td>3 (0.6%)</td>
<td>3 (0.6%)</td>
<td>6 (1.2%)</td>
</tr>
<tr>
<td>Stent thrombosis, n (%)</td>
<td>1 (0.2%)</td>
<td>0</td>
<td>1 (0.2%)</td>
</tr>
<tr>
<td>MACE, n (%)</td>
<td>23 (4.8%)</td>
<td>7 (1.5%)</td>
<td>30 (6.2%)</td>
</tr>
</tbody>
</table>
MACC free survival curve at four years
Comparative Data of Supralimus-Core® vs. Xience V EES *

MAXIMUS: Indian Heart J. 2012 Nov-Dec;64(6):547-52.

SPIRIT I: EuroIntervention - Volume 1 - Number 1 - May 2005 - page 58 to 65

SPIRIT II: EuroIntervention 2006;2:286-294

SPIRIT III: JAMA, April 23/30, 2008—Vol 299, No. 16
MAXIMUS: Indian Heart J. 2012 Nov-Dec;64(6):547-52.

Endeavor II: Circulation. 2006;114:798-806

Endeavor III: J. Am. Coll. Cardiol, 2006;48:2440-2447

Conclusion

- The present registry demonstrates satisfactory and sustained up to four-year clinical safety and efficacy profiles as evidenced by the low rates of MACE for the Supralimus-Core® SES, in unrestricted Saudi patients.
Thank You