Sirolimus vs Everolimus stents for bifurcated lesions

FRANCESCO BURZOTTA
Conflicts of interest

Within the past 12 months, I or my spouse/partner have had a financial interest/arrangement or affiliation with the organization(s) listed below.

<table>
<thead>
<tr>
<th>Affiliation/Financial Relationship</th>
<th>Company</th>
</tr>
</thead>
<tbody>
<tr>
<td>Consulting Fees/ Speaker Fees</td>
<td>Medtronic</td>
</tr>
</tbody>
</table>
SEA-CORP BC:
SEAside and CORpal Bifurcation trials
Cooperative study

PIs: BURZOTTA F.¹, PAN M.²,

Co-Investigators: TRANI C. ¹, MEDINA A. ³, SUÀREZ DE LEZO J. ², NICCOLI G. ¹, ROMERO M. ², PORTO I. ¹, MAZUELOS F. ², LEONE A.M. ¹, MARTIN P. ³, COLUCCIA V. ¹, SUÀREZ DE LEZO J. ², OJEDA S. ², CREA F.

From:
1. Catholic University of the Sacred Heart, ROME, ITALY
2. University of Cordoba, CORDOBA, SPAIN
3. University of Las Palmas, LAS PALMAS DE GRAN CANARIA, SPAIN

Final results presented at TCT 2012, in press on Rev Esp Card
BACKGROUND

- Different drug-eluting stents (DES) have different clinical efficacy in unselected coronary lesions (EES vs SES?)

Mean FU duration 13 months...

De Waha et al. Clin Res Cardiol 2012
Different stent platforms have different performance during PCI on bifurcated lesions (Xience V better than Cypher !)

Burzotta, Mortier, Trani (submitted)
BACKGROUND

• Two independent studies with similar design have compared the acute results of PCI using sirolimus-eluting stent (SES) and everolimus-eluting stent (EES) in bifurcated lesions: SEASIDE trial* and CORPAL trial**

• Prospective randomized trials assessing the long term clinical outcome of patients with bifurcated lesions undergoing PCI with SES or EES are lacking

* Burzotta et al. JACC Intv 2011
** Pan et al. CCI 2012
SEACORP BC STUDY POPULATION: 443 patients undergoing PCI with Provisional approach and randomized 1:1 to:

STUDY FLOW - CHART

SEASIDE TRIAL: 150 patients with bifurcated lesion undergoing DES implantation

CORPAL TRIAL: 293 patients with bifurcated lesion undergoing DES implantation

SEACORP BC STUDY POPULATION: 443 patients undergoing PCI with Provisional approach and randomized 1:1 to:

SES* EES**

* Cypher stent
** Xience V stent

clinical follow-up to assess the incidence of major adverse events: death or myocardial infarction or target vessel revascularization @ 3 years
<table>
<thead>
<tr>
<th></th>
<th>SES</th>
<th>EES</th>
<th>P</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pts</td>
<td>220</td>
<td>223</td>
<td>ns</td>
</tr>
<tr>
<td>Age (mean±SD)</td>
<td>64±10</td>
<td>63±10</td>
<td>ns</td>
</tr>
<tr>
<td>Diabetes Mellitus (%)</td>
<td>69 (31.4)</td>
<td>69 (30.9)</td>
<td>ns</td>
</tr>
<tr>
<td>Target Bifurcation:</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>- Distal Left Main (%)</td>
<td>25 (11.4)</td>
<td>28 (12.6)</td>
<td>ns</td>
</tr>
<tr>
<td>- LAD/Diag (%)</td>
<td>132 (60.0)</td>
<td>128 (57.4)</td>
<td>ns</td>
</tr>
<tr>
<td>- Circumflex or Right (%)</td>
<td>63 (28.6)</td>
<td>67 (30)</td>
<td></td>
</tr>
<tr>
<td>Clinical Presentation:</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>- Acute Coronary Syndrome (%)</td>
<td>133 (60.5)</td>
<td>137 (61.4)</td>
<td>ns</td>
</tr>
<tr>
<td>-- Stable Angina /Silent ischemia (%)</td>
<td>87 (39.5)</td>
<td>86 (38.6)</td>
<td>ns</td>
</tr>
<tr>
<td>Bifurcation type:</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>- 1,1,1 (%)</td>
<td>69 (31.4)</td>
<td>96 (43.0)</td>
<td>ns</td>
</tr>
<tr>
<td>- 1,0,1 or 0,1,1 (%)</td>
<td>28 (12.7)</td>
<td>20 (9.0)</td>
<td></td>
</tr>
<tr>
<td>- other types (%)</td>
<td>123 (55.9)</td>
<td>107 (48.0)</td>
<td></td>
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</table>
## PCI DETAILS

### PROVISIONAL STENTING

<table>
<thead>
<tr>
<th></th>
<th>SES</th>
<th>EES</th>
<th>P</th>
</tr>
</thead>
<tbody>
<tr>
<td>MV Stent according to randomization (%)</td>
<td>220 (100)</td>
<td>223 (100)</td>
<td>ns</td>
</tr>
<tr>
<td>MV stent length (mm, mean)</td>
<td>24±13</td>
<td>25±11</td>
<td>ns</td>
</tr>
<tr>
<td>MV stent diameter (mm, mean)</td>
<td>3.0±0.5</td>
<td>3.1±0.5</td>
<td>ns</td>
</tr>
<tr>
<td>Kissing balloon inflation (%)</td>
<td>116 (52.7)</td>
<td>109 (48.9)</td>
<td>ns</td>
</tr>
<tr>
<td>SB stenting (TAP or T) followed by kissing (%)</td>
<td>11 (5.0)</td>
<td>12 (5.4)</td>
<td>ns</td>
</tr>
<tr>
<td>SB stent length (mm, mean)</td>
<td>17±9</td>
<td>17±5</td>
<td>ns</td>
</tr>
<tr>
<td>SB stent diameter (mm, mean)</td>
<td>3.0±0.4</td>
<td>2.8±0.2</td>
<td>ns</td>
</tr>
</tbody>
</table>

*Note: ns = not significant*
Clinical follow-up at 3 years available in 439 out of 443 pts (99.1%)
3-YEAR MACE BY DES TYPE

- **all-cause death**
  - SES: 9 (4.1%)
  - EES: 4 (1.8%)
  - P = 0.14

- **myocardial infarction**
  - SES: 3 (1.4%)
  - EES: 3 (1.3%)
  - P = 0.98

- **target vessel revascularization**
  - SES: 14 (6.4%)
  - EES: 11 (4.9%)
  - P = 0.51

- **any major adverse event**
  - SES: 23 (10.6%)
  - EES: 15 (6.7%)
  - P = 0.15

9th European Bifurcation Club meeting - London, UK - 18th & 19th October 2013
3-YEAR MACE BY DES TYPE

3-year major adverse events

Freedom from MACE

Time in months

p=0.16

EES

SES
LANDMARK ANALYSIS:
LATE (>12 MO.) MACE BY DES TYPE

Late (>12 months) events

Freedom from MACE after 12 months

Time in months

p=0.025

9th European Bifurcation Club meeting - London, UK - 18th & 19th October 2013
LANDMARK ANALYSIS:
LATE (>12 MO.) MACE BY DES TYPE

- **SES** (N=217)
- **EES** (N=222)

<table>
<thead>
<tr>
<th>Event</th>
<th>SES</th>
<th>EES</th>
<th>p-value</th>
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</thead>
<tbody>
<tr>
<td>All-cause death</td>
<td>3 (1.5%)</td>
<td>1 (0.5%)</td>
<td>0.30</td>
</tr>
<tr>
<td>Myocardial infarction</td>
<td>0%</td>
<td>0%</td>
<td>1.00</td>
</tr>
<tr>
<td>Target vessel revascularization</td>
<td>8 (3.9%)</td>
<td>2 (1%)</td>
<td>0.03</td>
</tr>
<tr>
<td>Any major adverse event</td>
<td>11 (5.4%)</td>
<td>3 (1.4%)</td>
<td>0.02</td>
</tr>
</tbody>
</table>
CONCLUSIONS

The results of this pooled analysis of two trials comparing SES and EES in patients with bifurcated lesions undergoing DES implantation show that

- adopting the provisional stenting technique (with a very low rate of side-branch stent implantation according to T/TAP), the 3-year outcome is characterized by very low rates of major adverse events

- patients randomized to EES, as compared with SES, exhibited a numerically lower incidence of adverse events during the 3-year follow-up and a significantly lower rate of late (beyond 1 year) adverse events
This work has been realized thanks to the cooperative spirit of
Thank you for your attention