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Long-Term Clinical Outcomes For Primary Angioplasty with Resolute Zotarolimus Eluting Stent in ST-Segment Elevation Acute Myocardial Infarction

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Background: Historically bare metal stents were considered standard of care for ST-segment elevation acute myocardial infarction (STEMI). There is limited data on STEMI patients treated for primary angioplasty with ResoluteTM zotarolimus-eluting stent (R-ZES) and the everolimus-eluting stent (EES).

Methods: The global RESOLUTE program enrolled STEMI patients in 4 trials: RESOLUTE-All Comers (RAC), RESOLUTE International, RESOLUTE China, and RESOLUTE China Registry. The multicenter R-AC trial randomized patients to R-ZES vs. EES. STEMI was a prespecified subset analysis. Target Lesion Failure (TLF) was defined as a composite of death from cardiac causes (CD), target vessel myocardial infarction (TV-MI), and target lesion revascularization (TLR). Stent thrombosis (ST) was defined as ARC definite/probable ST.

Results: Among 7618 patients who received R-ZES in the pooled RESOLUTE clinical program, 854 had STEMI. Mean age was 59+12 years, 81% of patients were men, 23% had diabetes mellitus, and patients had on average 1.4±0.7 lesions treated. The 4-year Kaplan-Meier incidence of TLF was 11.5%, TLR 4.8%, CD/TV-MI 8.2%, CD 5.5%, TV-MI 2.7%, and ST 1.9%. Among the 2292 patients randomized in R-AC, 122 STEMI patients were treated with R-ZES and 158 with EES. There were no significant differences at 5 years in TLF, TLR, CD, TV-MI, or ST, but there was a significant reduction in all cause death / TV-MI with R-ZES (5.1% vs 9.0%, p=0.036) (Table). Conclusion: A pooled analysis of complex STEMI patients treated with R-ZES found R-ZES to be associated with excellent and sustained clinical outcomes. Additionally, long-term outcomes with R-ZES in STEMI patients were numerically lower than or similar to EES; however, R-ZES had a significant reduction in all cause death / TV-MI as compared to EES at 5 years. Submitted on behalf of the RESOLUTE Global Clinical Program.

<table>
<thead>
<tr>
<th>Events at 5 years</th>
<th>EES (n=240)</th>
<th>PES (n=212)</th>
<th>Relative Risk (95% CI)</th>
<th>p-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Death</td>
<td>6.7% (16)</td>
<td>8.5% (18)</td>
<td>0.79 [0.41-1.50]</td>
<td>0.46</td>
</tr>
<tr>
<td>Myocardial Infarction</td>
<td>6.7% (16)</td>
<td>10.8% (23)</td>
<td>0.61 [0.33-1.13]</td>
<td>0.11</td>
</tr>
<tr>
<td>Target Vessel Revascularization</td>
<td>5.8% (14)</td>
<td>11.3% (24)</td>
<td>0.51 [0.27-0.97]</td>
<td>0.04</td>
</tr>
<tr>
<td>Target Lesion Revascularization</td>
<td>5.4% (13)</td>
<td>9.4% (20)</td>
<td>0.57 [0.29-1.12]</td>
<td>0.10</td>
</tr>
<tr>
<td>Def./Prob. Stent Thrombosis</td>
<td>3.8% (9)</td>
<td>4.7% (10)</td>
<td>0.80 [0.33-1.92]</td>
<td>0.61</td>
</tr>
<tr>
<td>MACE (Primary Endpoint)</td>
<td>14.6% (35)</td>
<td>23.1% (49)</td>
<td>0.63 [0.42-0.93]</td>
<td>0.02</td>
</tr>
</tbody>
</table>

Conclusions: At 5-years EES reduced significantly MACE in patients treated with primary PCI for STEMI compared to PES which was mainly driven by lower rates of TLR.

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A Real-World Single Centre Experience Using The Self-Expanding Coronary Stent

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Background: A coronary self-expanding stent (Stentys S.A., Paris, France) may be used to overcome the drawback of difficult stent sizing and avoid stent malapposition with very flexible, and highly deliverable third-generation DES, investigated in the randomized, multicenter, all-comer DUCHEX (TWENTE II) trial. Of the 1,811 eligible all-comer patients of DUCHEX, 817 (45%) were treated in the setting of acute MI. Method: We assessed the one-year safety and efficacy of the Resolute Integrity zotarolimus-eluting stent (ZES) (Medtronic, Santa Rosa, CA, USA) and Promus Element everolimus-eluting stent (EES) (Boston Scientific, Natick, MA, USA) in 817 DUCHEX PEERS patients who were treated for acute MI. One-year follow-up data of

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Comparison of everolimus-eluting and paclitaxel-eluting coronary stents in patients undergoing primary percutaneous coronary intervention: 5 year follow-up from the COMPARE I trial

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Background: Long-term all-comers data of the current generation everolimus-eluting stent (Xience V, Abbott Vascular, Santa Clara, CA, USA) compared to the first generation paclitaxel-eluting stent (Taxus Liberté, Boston Scientific, Natick, MA, USA; PES) in patients undergoing primary percutaneous coronary intervention (PCI) for ST-elevating myocardial infarction (STEMI) are scarce.

Methods: The COMPARE I trial randomized, single-center, all-comers trial randomly allocating patients to receive either EES or PES (1:1). It is to date the only randomized trial comparing EES to PES in a true all-comers population with an independent adjudicated 5-year follow-up. We performed a post-hoc sub-analysis in patients treated with primary PCI. The pre-specified endpoint was major adverse cardiovascular events (MACE) defined as the composite of the safety endpoints death or myocardial infarction (MI) and the efficacy endpoint target vessel revascularization (TVR).

Results: Of the 1800 study patients, 432 patients underwent primary PCI for STEMI for whom 240 were treated with EES and 212 with PES. At 5 years EES was superior to the PES with a significant lower incidence of the endpoints MACE and TVR. Moreover, EES showed a trend for reduction in MI and target lesion revascularization. No significant differences were found in rates of death and definite/probable stent thrombosis. The 5-year outcomes are tabulated.