more often presented with prior percutaneous or surgical revascularization (46.0% vs. 35.6%, p = 0.006) and with a history of prior MI (50.0% vs. 31.8%, p = 0.001) compared to NITDM. At 12-months follow-up, the cumulative incidence of cardiac death, TLR and MI in patients with diabetes was comparable to that of non-diabetics (3.7% vs. 5.0%, p = 0.417). The ITDM patients demonstrated a higher, but non-significant, incidence of the composite end-point compared to NITDM (4.4% vs. 3.4%, p = 0.70). The incidence of definite/probable stent thrombosis was similar between diabetics (2/365, 0.5%) and non diabetics (5/851; 0.6%).

Conclusions: In this multicenter registry of patients suitable for PCI, the R-ZES resulted as safe and effective in diabetic and non-diabetic patients at 1-year follow-up. Among diabetics, patients with ITDM are associated with a higher, but not significant, incidence of adverse events than patients with NITDM.

TCT-211
Stenting and Delivery of Paclitaxel via Iopromide-Based Balloon Coating versus Durable Polymeric Matrix for De-Novo Coronary Lesions: Clinical and Angiographic Results from the Prospective Randomized Trial.
Aleksander Zurakowski1, Piotr P. Buszman1, Krzysztof Milewski1, Bogdan Gorycki2, Angelaonic Results from the Prospective Randomized Trial. Stenting and Delivery of Paclitaxel via Iopromide-Based Balloon Coating versus
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Aleksander Zurakowski1, Piotr P. Buszman1, Krzysztof Milewski1, Bogdan Gorycki2, Adam Janas1, Marek Kondys1, Marek Krol1, Janusz Prokopczak1, Anna Turek1, Juan Granadu1, Buszman P. Eawell1
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Background: The safety and efficacy of stenting followed by delivery of paclitaxel via balloon coating in comparison with stent-polymer matrix was not established. Therefore we compared clinical and angiographic results of paclitaxel eluting stenting (PES) with bare metal stenting and paclitaxel coated balloon post-dilation (BMS+PCB) for de novo coronary lesions.

Methods: In this multicenter, prospective, non-inferiority trial 202 patients with stable or unstable angina and at least one significant coronary artery lesion (>50% diameter stenosis, type A, B1 and B2) were randomized in 1:1 ratio to PCI with PES (Coroflex Please, B.Braun) or BMS+PCB (Coroflex + Sequent Please, B.Braun). Clinical follow-up was obtained at 9 months in all patients, whereas angiographic in a subset of 94.

Results: Patients baseline characteristics were well balanced between groups. At 9 months, in-stent late lumen loss in PCB+BMS were comparable and non-inferior to PES (0.21±0.5 vs. 0.30±0.7mm respectively, pnon-inf<0.05). Clinically, the incidence of MACCE (7.0 vs. 6.9%, HR=1.90 vs. 3.28; p=0.99), comprising of occurrence of myocardial infarction (4.9 vs. 3.0% HR=1.62 (95%CI:0.4-6.5; p=0.32), target lesion revascularization (6.9 vs. 5.0%, HR=1.42 (95%CI:0.4-4.4; p=0.54) and stent thrombosis (ST: 5.9 vs. 3.8% HR=2.01 (95%CI:0.5; 7.4) was similar between PCB+BMS and PES respectively. In PCB+BMS when compared to PES most ST occurred early (<0.1% vs. 0.10), whereas in PES - late (0.9 vs. 2.8% p=0.18). There were no deaths or cerebro-vascular accidents in both groups.

Conclusions: Revascularization strategy with PCB+BMS is an alternative to PES with regard to neointimal hyperplasia, however the incidence of early ST raises safety concerns.

TCT-212
Efficacy of the Novel BioMime Sirolimus-Eluting Stents with a Biodegradable Polymer in the Treatment of De Novo Coronary Lesions: An Angiographic Subanalysis of the Combined meriT-1 and merIT-2 Prospective Clinical Trials
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7Fortis Hospital, Mumbai, India
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13Fortis Escorts Heart Institute, Okhla Road, New Delhi 110025 (India), New Delhi, India

Background: The novel BioMime drug-eluting stent (Meril Life Sciences Pvt. Ltd., Gujarat, India) incorporates a L605 cobalt-chromium metallic platform that combines ultra-thin struts (65μm) with hybrid cell design and a bioabsorbable co-polymer (P LLA/PLGA) which carries and releases sirolimus in a dosage of 1.25g/mg2 of stent surface area. Our objective was to report the angiographic findings of the BioMime sirolimus-eluting stents (SES) tested in the merIT-1 and -2 clinical trials.

Methods: 280 pts with 385 de novo lesions located in native vessels were prospectively enrolled in 2 non-randomized studies in India, including the first-in-man, single center merIT-1 trial (30 patients/lesions) and the subsequent multicenter merIT-2 trial (250 pts/355 lesions). Angiographic follow-up was assigned at 8 months. QCA analysis was performed at an independent angiographic core lab.

Results: LAD was the target vessel in 47%, 16.4% had significant calcium, 78.4% were eccentric, 4.9% had ulcer and pre-TIMI flow 3 was found in 87.5%. Most lesions were classified as highly complex (type B2/C in 74.8%). Predilatation was performed in 91%, the study stent was implanted in 100%, an additional stent stent was implanted in 6%, and 60% had postdilatation; also, final TIMI 3 flow was achieved in 99.5%. QCA results are shown in the Table. Binary restenosis was found in 5.7% (4.5% in-stent) including focal pattern (type-I) in most cases (4.8%).

<table>
<thead>
<tr>
<th>Variable</th>
<th>N=385</th>
</tr>
</thead>
<tbody>
<tr>
<td>Preprocedure</td>
<td></td>
</tr>
<tr>
<td>- Lesion length, mm</td>
<td>13.17 (8.97, 18.73)</td>
</tr>
<tr>
<td>- Reference diameter, mm</td>
<td>2.73 (2.43, 2.99)</td>
</tr>
<tr>
<td>- MLD, mm</td>
<td>0.74 (0.44, 1.02)</td>
</tr>
<tr>
<td>- %DS</td>
<td>72.2 (61.8, 83.8)</td>
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<tr>
<td>Postprocedure (in-stent analysis)</td>
<td></td>
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<tr>
<td>- MLD, mm</td>
<td>2.60 (2.31, 2.88)</td>
</tr>
<tr>
<td>- %DS</td>
<td>7.4 (4.7, 11.6)</td>
</tr>
<tr>
<td>- Acute gain, mm</td>
<td>1.88 (1.49, 2.24)</td>
</tr>
<tr>
<td>Follow-up at 8 months (in-stent analysis)</td>
<td>N=385 (87%)</td>
</tr>
<tr>
<td>- MLD, mm</td>
<td>2.40 (2.05, 2.71)</td>
</tr>
<tr>
<td>- %DS</td>
<td>11.8 (7.4, 19.2)</td>
</tr>
<tr>
<td>- Late lumen loss, mm</td>
<td>0.12 (0.05, 0.30)</td>
</tr>
</tbody>
</table>

Conclusions: In this subanalysis of the combined merIT-1 and -2 trials, the novel BioMime SES demonstrated efficacy in the treatment of complex de novo coronary lesions, as demonstrated by the relatively low median in-stent late lumen loss (a surrogate of neointimal hyperplasia) at 8-month angiographic follow-up (87%). In addition, in-stent binary restenosis was low (<5%) and associated with focal pattern in the majority of cases.