more often presented with prior percutaneous or surgical revascularization (46.0% vs. 37%, p=0.003). Of the 365 diabetics, 101 (27.6%) were ITDM. ITDM patients were more often female (35.6% vs. 21.6, 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.

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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 95%CI:0.3-2.8; 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 to 7,4) was similar between PCB+BMS and PES respectively. In PCB+BMS when compared to PES most ST occurred early (5.0 vs. 1.0%; p=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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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 (PLLA/PLGA) formulation (2µm thickness) which carries and releases sirolimus in a dosage of 1.25µg per mm2 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 study 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%).

Variable	N=385
Preprocedure	
- Lesion length, mm	13.17 [8.97, 18.73]
- Reference diameter, mm	2.73 [2.43, 2.99]
- MLD, mm	0.74 [0.44, 1.02]
- %DS	72.2 [61.8, 83.8]
Postprocedure (in-stent analysis)	
- MLD, mm	2.60 [2.31, 2.88]
- %DS	7.4 [4.7, 11.6]
- Acute gain, mm	1.88 [1.49, 2.24]
Follow-up at 8 months (in-stent analysis)	N=335 (87%)
- MLD, mm	2.40 [2.05, 2.71]
- %DS	11.8 [7.4, 19.2]
- Late lumen loss, mm	0.12 [0.05, 0.30]

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.

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