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Implantation of Thin-Strut Sirolimus-Eluting Bioresorbable Vascular Scaffold in Patients With De Novo Coronary Artery Lesions: 2-Year Clinical and 6-Month Imaging Outcomes of the MeRes-1 Extend Trial

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BACKGROUND The development of bioresorbable vascular scaffold (BRS) offers a new treatment strategy for coronary artery lesion by replacement of a permanent metallic scaffold with a temporary scaffold and eradicating a nidus for very late adverse events. The first-in-human MeRes-1 trial reported favorable safety and efficacy of thin-strut (100 μm) MeRes100 sirolimus-eluting BRS (Meril Life Sciences Pvt. Ltd., India) in patients with de novo coronary artery lesions. Hence, to reaffirm the outcomes of the MeRes-1 trial, the MeRes-1 Extend trial sought to evaluate the safety and efficacy of the MeRes100 BRS in diverse patient population in Europe, Brazil, South Africa, and Asia Pacific.

METHODS The MeRes-1 Extend was a multicenter, prospective, single-arm study of MeRes100 BRS in 64 patients from Spain, Macedonia, Brazil, South Africa, Malaysia, and Indonesia. The safety endpoint was major adverse cardiac events (MACE), which composed of cardiac death, myocardial infarction (MI), and ischemia-driven target lesion revascularization (ID-TLR). Quantitative coronary angiography and optical coherence tomography (OCT) imaging was performed at baseline and 6-month follow-up.

RESULTS Among 64 enrolled patients (mean age: 58.30 ± 9.02 years), 26.56% had diabetes mellitus and 68.75% patients presented with stable angina. Of 69 target lesions, 71.01% were classified as type B2/C; average lesion length was 14.37 ± 5.89 mm and mean reference vessel diameter was 3.03 ± 0.35 mm. Procedural and device success was achieved in 64 and 62 patients, respectively. MACE was reported in 1 patient (1.61%) at 24-month follow-up in the form of ID-TLR with absence of MI, cardiac death, or scaffold thrombosis. At 6-month angiographic follow-up in a subset of 32 patients, mean in-scaffold LLL was 0.18 ± 0.31 mm. OCT analysis (n = 21) reported 97.95 ± 3.69% strut coverage with mean scaffold area of 7.56 ± 1.79 mm^2 and no evidence of strut malapposition.

CONCLUSION Based on 2-year clinical and 6-month imaging outcomes, the MeRes-1 Extend trial established favorable safety and efficacy of MeRes100 sirolimus-eluting BRS in patients with de novo coronary artery lesions.

CATEGORIES CORONARY: Stents: Bioresorbable Vascular Scaffolds