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First-in-human Evaluation of a Novel Poly-L-lactide Based Sirolimus-eluting Bioresorbable Vascular Scaffold for the Treatment of De Novo Native Coronary Artery Lesions: MeRes-1 Trial

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BACKGROUND The life-long presence of the metallic prosthesis interferes with the restoration of vasomotion and restricts quality lesion imaging during repeat surgical or percutaneous treatment. As a solution to this, we assessed safety and efficacy of a novel Poly-L-Lactide based Sirolimus-eluting BioResorbable Vascular Scaffold (BRS) MeRes100 in patients with *de novo* native coronary artery lesions.

METHODS The MeRes-1 is a prospective, multicentre, first-in-human trial of MeRes100 Sirolimus-eluting BRS (Meril Life Science, Vapi, India). A total of 108 patients with 116 lesions were enrolled at 13 Indian centers. The primary endpoint was major adverse cardiac events (MACE) at six months defined as a composite of cardiac death, myocardial infarction, and ischemia driven-target vessel revascularization (TVR). The secondary endpoints were MACE, scaffold thrombosis (ST), in-scaffold late lumen loss (LLL) and device related serious adverse events at subsequent follow-ups. Clinical follow-ups were scheduled at 1, 6, 12, 24 and 36 months. Angiographic, optical coherence tomography (OCT) and intravascular ultrasound (IVUS) follow-ups were scheduled at 6 and 24 months.

RESULTS Overall device success per lesion was 100%. No MACE, TVR, and ST were noted at 6-month follow-up in 108 (100%) patients. The Quantitative Coronary Angiography (QCA) results at six months showed LLL of 0.15 $\pm$ 0.23mm. Around 99.3% of the struts analyzed with OCT at six months follow-up demonstrated complete coverage. The IVUS subset analyses at six months showed limited in-scaffold neo-intimal hyperplasia (NIH) area (0.14mm^2). No malapposition or late-acquired ISA (Incomplete strut apposition) was observed till six months. Follow-up at one year was available in 21 (19.4%) patients. No MACE and ST were observed at one-year follow-up.

CONCLUSION The preliminary data reflects device feasibility in treating *de novo* native coronary artery lesions. The interim results for safety and efficacy of MeRes100 BRS are encouraging. Long-term data to assess scaffold safety and efficacy are awaited.

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Early Clinical Outcomes Following "Off-" Versus "On-label" Indications of Bioresorbable Vascular Scaffolds for the Treatment of 1505 Patients with Coronary Artery Disease: Results from the Prospective "Registro Absorb Italiano" (RAI Registry)

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BACKGROUND ABSORB (BVS) is a bioresorbable, everolimus-eluting scaffold intended for coronary use, whose data on real-world patients with complex lesions are limited. Short-term follow-up from recent studies points to a higher rate of 30-day BVS thrombosis than the one observed with current-generation drug-eluting stents.

METHODS RAI (Clinical Trials. gov Identifier: NCT02298413) is an Italian, prospective, multicentre registry not funded by the manufacturer, whose aim is to investigate BVS performance through a 5-year follow-up of all consecutive patients who have undergone successful implantation of 1 or more BVS in different lesions subsets. Co-primary endpoints were target lesion revascularization (TLR) and BVS definite/probable thrombosis. The secondary endpoint was the occurrence of device-oriented cardiac events (DOCE). The registry was started in October 2012 and the last patient was enrolled in December 2015. We here report the 30-day outcomes of the whole population of the registry according to the "on-" versus "off-label" indications for BVS implantation established by the manufacturer's instructions for use.

RESULTS We enrolled 1505 consecutive patients (1,969 lesions) of whom 873 (58%) treated for an "off-label" indication (1,161 lesions). Most of the patients (1,235, 82%) were male while 337(22.4%) diabetics. At presentation, 891 (59.2%) of the patients had an acute coronary syndrome, including 317 (21%) ST-elevation myocardial infarctions. No significant differences were reported in baseline clinical characteristics between the "on-" versus "off-label" groups while more complex lesions were treated in the "off-label" group (i.e. bifurcations and in-stent restenosis, both $p<0.001$). All lesions were pre-dilated and in 96.8% of the cases BVS was post-dilated. At 30 days, the co-primary study endpoint TLR occurred in 9 patients (0.6%) while definite/probable BVS thrombosis in 12 (0.8%) in the whole population. No significant differences were reported between the "on-" versus "off-label" groups in terms of TLR (0.6% vs. 0.6%, $p=0.8$) while a trend for higher early BVS thrombosis rate was reported in the "off-label" group (1.1% vs. 0.3%, $p=0.07$). There were 2 cases (0.13%) of death (both cardiac and in the "off-label" group) while DOCE occurred in 15 patients (1%) of the whole cohort without differences between the groups (0.8% vs. 1.1%, $p=0.5$).

CONCLUSION Our data from a population of consecutive patients with a wide spectrum of coronary lesions and clinical settings suggest that use of current BVS following a meticulous implantation approach is associated with good clinical outcomes in both "on-" and "off-label" groups. Longer follow-up is awaited to confirm these early findings.