Technology

CRT-700.00

One-year Clinical Outcomes of Biodegradable Polymer Coated Sirolimus-Eluting Coronary Stent System in Patients With Coronary Artery Disease

Shridhar Kasturi
Interventional Cardiologist-Sunshine Heart Institute, Secunderabad, Hyderabad, India

BACKGROUND The biodegradable polymer-coated Sirolimus-eluting Coronary Stent (SES) System for the treatment of coronary artery diseases has resulted in substantial improvements in real-life scenario.

AIM To evaluate the safety and performance of Metafor Sirolimus-eluting Coronary Stent System (SES) in consecutive patients with coronary artery disease (CAD) in a real-life scenario.

METHODS This was a retrospective, observational, postmarketing study conducted in 251 patients with CAD who were implanted with Metafor SES (Meril Life Sciences, Pvt .Ltd., Gujarat, India) and followed clinically/telephonically at one-year. The primary endpoint was a major adverse cardiac event (MACE) defined as the aggregate of cardiac death, myocardial infarction (MI), and any target lesion revascularization (TLR) at one year. Also, stent thrombosis (ST) was observed at one-year patients follow-up.

RESULTS Out of them 251 participants, 191 (76.1%) were male, 95 (37.8%) patients had diabetes, 153 (61%) had MI, 161 (64.1%) had stable angina, and 134 (53.4%) had hypertension which is suggestive of a real-life scenario. Mean patient age was 56.35 ± 11.23 years and 17 patients underwent primary percutaneous coronary interventions (PCI). A total of 295 lesions were treated, out of which 13.6% of the lesions were long lesion of ≥ 40mm. At one-year, MACE occurred in 4 (1.6%) of 251 patients, consisting of 2 (0.8%) cardiac deaths, 2 (0.8%) MI, and 0 (0%) TLR. Stent thrombosis was reported in one patient (0.4%).

CONCLUSION This retrospective data demonstrated excellent safety and performance of Metafor SES in the "real-life" consecutive CAD patients, indicating low rates of MACE and ST at one-year follow-up.

CRT-700.01

Favourable Outcomes for Systemic Pharmacokinetic Study of Sirolimus-Eluting BioResorbable Vascular Scaffold System in Treating de novo Native Coronary Artery Lesion: A Sub Study of MeRes-1 Trial

Ashok Seth,[1] Praveen Chandra,[2] Vinay Kumar Bahl,[3] Manjunath Cholenahally Nanjappa,[4] Pratap Chandra Rath,[5] Mathew Samuel Kalarickal,[6] Gurpreet Singh Wander,[7] Anil Mishra,[8] Ajaykumar Umakant Mahajan,[9] Ajaykumar Umakant Mahajan,[9] Ajit Kumar Velaparambil Kumaran,[10] AGeorge Koshy,[11] Parvin Kumar Goel,[12] Gaurav Ganeshwala,[13] Viveka Kumar,[14] Upendra Kaul,[15] Vijay Kumar[16]
[1]Fortis Escorts Heart Institute, Department of Academics & Research, Room No - 23, Second Floor, RC Building, Residential Tower, Okhla Road, New Delhi, India; [2]Devision of Interventional Cardiology, Medanta - The Medcity, Sector - 38, Gurgaon, Haryana, India; [3]Department of Cardiology, All India Institute of Medical Sciences, Ansari Nagar, New Delhi, India; [4]3rd floor Next To Echo Room Sri Jayadeva Institute of Cardiovascular Sciences & Research, Bannerghatta road, Jayanagar 9th Block, Bengaluru, India; [5]AMIRS Building clinical trial unit 1st floor, Apollo Hospital, Jublee Hill, Haryana, India; [6]Apollo hospitals Educational & Research Foundation, Room no 16 & 17, 2nd floor, Krishnadeep Chambers, Apollo Annexe No - 1, Wallace Garden, Thousand Lights, Chennai, India; [7]Hero DMC Heart Institute, Dayanand Medical College & Hospital, Tagore nagar, Civil lines, Ludhiana, India; [8]Clinical Research Department, B.M.Birla Heart Research Centre, 1/1 National Library Avenue, Kolkata, India; [9]Department of Cardiology, Lokmanya Tilak Municipal Medical College and General Hospital, Sion, Mumbai, India; [10]Sree Chitra Tirunal Institute for Medical Sciences & Technology, Thiruvananthapuram, kerala, India; [11]Trivandrum Medical College, Medical College Ulloor Road, Thiruvananthapuram, kerala, India; [12]Department of Cardiology, C block, Sanjay Gandhi Postgraduate Institute of Medical Sciences, Rae Bareli Rd, lucknow, India; [13]Ruby Hall Clinic, Sassoon road, Pune, India; [14]Office of Research, Max Super Speciality Hospital, 2, Press Enclave Road, Saket, New Delhi, India; [15]Fortis Flt.Lt.Rajan Dhall Hospital, Sector B,Pocket 1, Aruna Asaf Ali Marg, Vasant kunj, New Delhi, India; [16]G.B. Pant, Hospital Jawaharlal Nehru Marg, New Delhi, India

BACKGROUND MeRes100 (Meril Life Science, Vapi, India) is a novel Sirolimus-Eluting BioResorbable Vascular Scaffold system (BRS). This sub study of MeRes-1 trial evaluated the systemic release of sirolimus from the MeRes100 BRS applied for the treatment of *de novo* native coronary artery lesions.

METHODS The MeRes-1 is a prospective, multicentre, first-in-human trial of MeRes100 Sirolimus-Eluting BRS. The pharmacokinetic sub study was conducted in 10 patients at 2 Indian sites who were implanted with the BRS with 1.25 μg per mm^2 dose of sirolimus. A total of 13 venous blood samples (each of 6 mL) were collected at multiple time points including pre-dose (-10min) and post-dose samples at 10min, 30min, 1hr, 3hrs, 6hrs, 12hrs, 24hrs, 7 days, 14 days, 30 days, 60 days, and 90 days. Sirolimus concentration in venous blood was successively analyzed using an ultra performance liquid chromatography-electro spray ionization-mass spectrometry/mass spectrometry (UPLC-ESI-MS/MS) method.

RESULTS A total of 12 scaffolds were implanted in 10 patients. Non-compartmental analysis demonstrated that the maximum blood concentration of sirolimus occurred between 1 hr and 3 hrs after scaffold implantation. After the initial peak, the mean concentration reduced uniformly and the last point, at which the whole blood concentration could be quantified, was at 60 days after the implantation of scaffold. The Lower Limit of Quantification (LLOQ) was 0.101ng/mL. The C_{max} was deduced to be 7.468 ± 2.6082ng/ml and the $t_{1/2}$ was observed at 98.589 ± 33.5798hours.

CONCLUSION The MeRes-1 pharmacokinetic sub study confirmed that the MeRes100 BRS causes a low dose systemic exposure of sirolimus drug which is safe and tolerable.

CRT-700.02

Clinical Outcomes After Implantation of Absorb BVS in a Real World Setting, with pre And post Dilatation, Guided By Intravascular Ultrasound And Optical Coherence Tomography

Costantino R. Costantini, Sergio G. Tarbine, Costantino O. Costantini, Marcelo de Freitas Santos, Daniel Anibal Zanuttini, Marco Antonio Denk
Hospital Cardiologico Costantini, Curitiba, Brazil

BACKGROUND The safety and performance of the Absorb Bioresorbable Vascular Scaffold (Absorb) has been previously demonstrated with clinical data. However, these trials included patients with simple lesions. Aiming to evaluate clinical outcomes, we analyzed the treatment of real world patients from a single center.

METHODS between 11/2014 and 10/2016, consecutive unselected pts. were treated with one or more Absorb BVS. Pre dilatation before stent deployment, and post dilatation, Intravascular Ultrasound (IVUS) and Optical Coherence Tomography (OCT) were used in 99% of cases.

RESULTS 100 pts (88% male, mean age 58.15±9.83 yo) were included in this analysis. Diabetes was present in 31% and multivessel ds. in 52%. 32% had stable angina. A total of 141 lesions were treated (LAD 74%), being B/C class in 60%. The median SYNTAX score was 14.23±8.88 The total number of Absorb BVS implanted was 190, with an average of 1.69 per patient. Further intervention following imaging and optimization with balloon was necessary in 31 Stents (16% of cases), regarding IVUS/OCT. With 100% procedure success rate, all patients completed 30 days. 7 months mean follow up MACE showed definite/probable scaffold thrombosis in 0%, with 4% TLR, and 3% TVR.

CONCLUSION The analysis of this cohort of patients, is showing no acute/subacute thrombosis so far, in a real world setting. Predilatation, the use of IVUS/OCT in all cases, and final balloon optimization might have impact on this outcome. 7 months mean follow up shows low MACE rate with 4% TLR and 3% TVR, caused by focal restenosis.