CONCLUSION The data support clinical feasibility of thin-strut scaffolds without compromising radial strength and fracture resistance and with virtually stable arterial responses up to 2 years.

CATEGORIES CORONARY: Stents: Bioresorbable Vascular Scaffolds

TCT CONNECT-270

FANTOM II Trial: Safety and Performance Study of the Fantom Sirolimus-Eluting Bioresorbable Coronary Scaffold—First Report: 4-Year Clinical Outcomes

Matthias Lutz,[1] Jeffrey Anderson,[2] Alexandre Abizaid,[3] Didier Carrie,[4] Norbert Frey,[5] Bernard Chevalier[6]
[1]Department of Cardiology and Angiology, Universitätsklinikum Schleswig-Holstein, Campus Kiel, Kiel, Germany; [2]REVA Medical, San Diego, California; [3]Instituto Dante Pazzanese de Cardiologia, São Paulo, Brazil; [4]Rangueil Hospital Toulouse, Toulouse, France; [5]Department of Internal Medicine III, Cardiology and Angiology, University Hospital Schleswig-Holstein, Campus Kiel, Kiel, Germany, Kiel, Germany; [6]Institut Cardiovasculaire Paris Sud, Massy, France

BACKGROUND The primary objective of the FANTOM II (Safety and Performance Study of the Fantom Sirolimus-Eluting Bioresorbable Coronary Scaffold) was to evaluate the safety and performance of native coronary artery stenting using the Fantom Sirolimus-Eluting Bioresorbable Coronary Scaffold by assessing the incidence of major adverse cardiac events and late lumen loss. The Fantom scaffold is a fully resorbable scaffold (Tyrocore, REVA Medical) that is composed mainly of an iodinated, polycarbonate copolymer of tyrosine analogs. Fantom is completely radiopaque and is composed of thin struts (125 μm) that facilitate device delivery and precise target lesion treatment.

METHODS The FANTOM II study is a prospective, multicenter trial that enrolled 240 patients with single de novo coronary stenosis with reference vessel diameter 2.5 to 3.5 mm and lesion length ≤20 mm. Major adverse cardiac events through 48-month follow-up were assessed. Angiographic follow-up was performed in consecutive patient cohorts at 6 months (n = 117) and 9 months (n = 123). Additional angiographic and optical coherence tomography serial imaging has been performed in a subset of patients at 24 months.

RESULTS Acute delivery success, acute technical success, acute procedural success, and clinical procedural success rates as defined in the clinical protocol were 97.9% (235 of 240), 95.8% (230 of 240), 99.1% (228 of 230), and 99.6% (227 of 228), respectively. The mean in-stent late lumen loss at 6 months and 9 months were 0.25 ± 0.40 mm and 0.33 ± 0.36 mm, respectively, and in-segment binary restenosis occurred in 2.0% and 7.6% of patients, respectively. Patient follow-up is now complete through 48 months. Adjudication of all events is in process, and final clinical outcomes through 48 months will be reported for the first time at the Transcatheter Cardiovascular Therapeutics 2020 annual meeting.

CONCLUSION The Fantom sirolimus-eluting bioresorbable coronary scaffold demonstrated favorable safety and effectiveness performance at 4 years of follow-up. Longer-term follow-up through 5 years is ongoing to examine the late outcomes with this novel device.

CATEGORIES CORONARY: Stents: Bioresorbable Vascular Scaffolds

TCT CONNECT-271

The MeRes-1 Extend Trial: 2-Year Clinical and 6-Month Imaging Outcomes of Thin-Strut Sirolimus-Eluting BRS in Patients With De Novo Coronary Artery Lesions

Alexandre Abizaid,[1] Sasko Kedev,[2] Rosli Bin Mohd Ali,[3] Teguh Santoso,[4] Angel Cequier,[5] R.J.M. van Geuns,[6] Bernard Chevalier,[7] Farrel Hellig,[8] Ricardo Costa,[1] Yoshinobu Onuma,[9] Jose Costa, Jr.,[10] Patrick Serruys,[9] Sripal Bangalore[11]
[1]Instituto Dante Pazzanese de Cardiologia, São Paulo, Brazil; [2]University Clinic of Cardiology, Skopje, Macedonia; [3]National Heart Institute, Kuala Lumpur, Malaysia; [4]Medistra Hospital, Jakarta, Indonesia; [5]Bellvitge University Hospital, Barcelona, Spain; [6]Erasmus Medical Center, Rotterdam, Netherlands; [7]Institut Cardiovasculaire Paris Sud, Massy, France; [8]Sunninghill Hospital, Johannesburg, South Africa; [9]National University of Ireland, Galway, Galway, Ireland; [10]Cardiovascular Research Center, São Paulo, Brazil; [11]New York University School of Medicine, New York, New York

BACKGROUND The long- term clinical outcomes of percutaneous coronary intervention can be improved by replacing metallic drug-eluting stents with bioresorbable vascular scaffolds. The MeRes-1 Extend trial was designed to assess the safety and efficacy of a novel thin-strut MeRes100 bioresorbable vascular scaffold (Meril Life Sciences) in a diverse patient population.

METHODS The MeRes-1 Extend was a prospective, multicenter, single-arm study that enrolled 64 patients in Spain, Macedonia, Brazil, South Africa, Malaysia, and Indonesia. Major adverse cardiac events, consisting of cardiac death, myocardial infarction, and ischemia-driven target lesion revascularisation, were the safety endpoint. At baseline and 6-month follow-up, quantitative coronary angiography and optical coherence tomography were performed.

RESULTS Of all patients enrolled (mean age: 58.30 ± 9.02 years), 76.56% had hypertension, 26.56% had diabetes mellitus, 48.44% had dyslipidemia, and 28.13% had a previous myocardial infarction; 68.75% of patients presented with stable angina, 9.38% with unstable angina, and 21.88% with silent ischemia. A total of 69 target lesions (mean length: 14.37 ± 5.89 mm) were detected of which 71.01% were type B2/C. Procedural and device success were achieved in 64 and 62 patients, respectively. Major adverse cardiac events rate was reported in 1 patient (1.61%) in the form of ischemia-driven target lesion revascularization; there were no cases of myocardial infarction, cardiac death, or scaffold thrombosis. At 6-month angiographic follow-up (n = 32), mean in-scaffold late lumen loss was 0.18 ± 0.31 mm. Optical coherence tomography analysis (n = 21) showed 97.95 ± 3.69% strut coverage and mean scaffold area of 7.56 ± 1.79 mm^2, with no strut malapposition. Updated data will be presented during Transcatheter Cardiovascular Therapeutics 2020 annual meeting.

CONCLUSION Two-year clinical and 6-month imaging outcomes of MeRes-1 Extend trial demonstrated favorable safety and efficacy of novel thin-strut MeRes100 sirolimus-eluting bioresorbable vascular scaffolds in patients with de novo coronary artery lesions.

CATEGORIES CORONARY: Stents: Bioresorbable Vascular Scaffolds

TCT CONNECT-272

Long-Term Comparison of Everolimus- vs. Novolimus-Eluting Bioresorbable Vascular Scaffolds

Beytullah Çakal,[1] Sinem Çakal,[2] Bilal Boztosun[1]
[1]Istanbul Medipol University, Istanbul, Turkey; [2]Haseki Training and Research Hospital, Istanbul, Turkey

BACKGROUND The vast majority of clinical trials regarding bioresorbable vascular scaffold (BVS) use came from comparison of everolimus-eluting scaffolds with metallic stents, and it remains unclear whether similar results would be true when a different type of BVS is used. This study sought to evaluate the long-term performance of novolimus-eluting bioresorbable vascular scaffolds (nBVSs) compared with everolimus-eluting bioresorbable vascular scaffolds (eBVS).

METHODS A total of 140 patients with nBVS (n = 202 before exclusion) and 98 patients with eBVS (n = 135 before exclusion) were included in current study. After propensity-score matching, 98 patients treated with 135 eBVSs were compared with 98 patients treated with 136 nBVSs. The primary outcome was the 3-year rate of major adverse cardiovascular events, defined as the composite of cardiac death, target vessel myocardial infarction, and target lesion revascularization.

RESULTS Baseline characteristics, clinical presentation, and lesion characteristics were comparable in both groups. The 3-year major adverse cardiovascular events rate was higher in the eBVS group (17.3% vs. 6.1%; p log-rank = 0.02). The occurrences of target lesion revascularization (16.3% vs. 5.1%; p log-rank = 0.02) and target vessel myocardial infarction (8.2% vs. 0%; p log-rank = 0.004) were also higher in the eBVS group except for cardiac deaths (1% vs. 2%; p log-rank = 0.98; eBVS vs. nBVS, respectively). Of note, definite device