

TCT-513**ABSORB III PK: Pharmacokinetics of Everolimus Eluted from the Absorb Bioresorbable Vascular Scaffold (BVS)**

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BACKGROUND The ABSORB III Pharmacokinetic (PK) study is a prospective, open-label, non-randomized sub-study of the ABSORB III randomized trial designed to determine the PK of everolimus delivered by the Absorb bioresorbable vascular scaffold (BVS) in subjects who only receive Absorb BVS with a maximum treatment of two de novo coronary artery lesions. The pharmacokinetic profile of Absorb BVS has not previously been described.

METHODS Twelve subjects were enrolled at two sites in the United States. Subjects received one (n=8) or two (n=4) Absorb BVS with diameters of 2.5-, 3.0 or 3.5 mm and lengths of 8, 12, 18 or 28 mm. The total everolimus dose received ranged from 181 to 443 µg. Blood samples (arterial or venous) were collected from the subjects pre-procedure and at fifteen time points post-procedure (10 and 30 minutes, 1, 2, 4, 6, 12, 24, 48, 72, 96, 120 (day 5), 168 (day 7), 336 (day 14), and 720 hours (day 30) after the last scaffold implantation). The concentration of everolimus in the blood was determined by Liquid Chromatography-Mass Spectrometry/Mass Spectrometry assay. The lower limit of quantification was 0.1 ng/mL. The blood concentration-time data were subjected to non-compartmental methods to determine PK parameters (C_{max}, t_{max}, AUC, t_{1/2}).

RESULTS Everolimus blood concentrations increased rapidly after Absorb BVS deployment, reaching maximum concentration between 0.17 and 2.37 hours (t_{max}), declining thereafter with a terminal half-life ranging between 45.9 and 115 hours. By 4 hours, everolimus blood concentrations were below 3 ng/ml (the chronic therapeutic level necessary to prevent organ rejection in transplant patients) in all subjects. Everolimus blood concentrations were low but measurable for up to 168 hours (7 days) after last scaffold deployment. The maximum observed everolimus concentration (C_{max}) increased with dose and ranged from 1.085 to 4.460 ng/ml across the dose range studied. Similarly, individual AUC (AUC_{24h}: 12.09 to 44.22 ng*h/mL; AUC_{last}: 25.37 to 104.6 ng*h/mL; AUC_{0-∞}: 33.15 to 120.8 ng*h/mL) increased proportionally with total scaffold dose.

CONCLUSIONS The local arterial delivery of everolimus and systemic exposure increased proportionally with dose and rapidly declined thereafter. The everolimus PK profiles seen with Absorb BVS are safe, and are similar to previously reported profiles for the cobalt chromium everolimus-eluting XIENCE stent.

CATEGORIES CORONARY: Bioresorbable Vascular Scaffolds

KEYWORDS Bioabsorbable scaffolds, Everolimus, Safety

TCT-514**Absorb Vs DESolve: an optical coherence tomography comparison of acute mechanical performances**

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BACKGROUND The bioresorbable scaffold (BRS) is a novel approach to treat coronary artery lesions. The mechanical properties of the polymer-based Absorb scaffold (Abbott Vascular, Santa Clara, California, USA) have already been compared to those of second-generation metallic DES. Lately, the novolimus-eluting DESolve (Elixir Medical Corporation, Sunnyvale, California, USA) gained permission for clinical use in Europe. We aimed to compare with OCT the acute performance of the Absorb scaffold vs the DESolve scaffold.

METHODS Very final post deployment OCT pullbacks of consecutive patients treated with either Absorb or DESolve were reviewed. The following parameters were calculated: mean and minimal lumen area (MLA), residual in-scaffold area stenosis (RAS), incomplete strut apposition (ISA), tissue prolapse area, eccentricity index, symmetry index, strut fracture and edge dissection.

RESULTS A total of 72 patients were included. The Absorb group consisted out of 35 patients treated with 63 Absorb scaffolds, which were compared to a well-matched group of 37 patients treated with 50 DESolve scaffolds. Baseline characteristics did not differ significantly between the two groups. Procedural characteristics were different with respect to maximal balloon inflation pressure (Absorb vs DESolve: 21.5±0.4atm vs 16.8±3.8atm; p<0.01) and mean NC balloon diameter used for post-dilatation (Absorb vs DESolve 3.3±0.4mm vs 3.5±0.4mm; p<0.01). OCT analysis showed similar MLA (Absorb vs DESolve: 5.8±1.9 mm² vs 6.1±2.6 mm²; p=0.43) and mean luminal area (Absorb vs DESolve: 7.1±2.2 mm² vs 7.2±1.9 mm²; 0.77). The DESolve group showed a larger maximum scaffold diameter (Absorb vs DESolve: 3.2±0.5mm vs 3.5±0.4mm, p=0.01), a higher minimal scaffold diameter (2.7±0.4mm vs 2.9±0.4mm; p<0.01) with a lower degree of RAS (Absorb vs DESolve: 20 ± 7.4% vs 14.9±10.8%, p=0.16). The mean eccentricity index was 0.85± 0.05 with Absorb and 0.80± 0.05 with DESolve, p<0.01. A lower frequency of distal edge ISA (Absorb vs DESolve: n=5 [8.2%] vs 16 [32.0%]; p<0.01) and smaller prolapse area (Absorb vs DESolve : 1.0±1.1mm² vs 3.6±6.2; p<0.01) was found with Absorb.

CONCLUSIONS The two scaffolds showed similar MLA while there was a trend toward a lower RAS and a larger maximum and minimum scaffold diameter with DESolve. DESolve scaffold was more eccentric as compared to Absorb. These results might be related to the DESolve peculiar expansion properties.

CATEGORIES CORONARY: Bioresorbable Vascular Scaffolds

KEYWORDS Bioabsorbable, Bioabsorbable scaffolds

TCT-515**Multi-Center, Post-marketing Evaluation of the Elixir DESolve® Novolimus Eluting Bioresorbable Coronary Stent System: 6-month Results from the DESolve PMCF Study**

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BACKGROUND A post marketing clinical follow-up study was conducted evaluating the continued safety and effectiveness of the CE-mark approved DESolve® Novolimus Eluting Bioresorbable Coronary Scaffold System (NEBCSS) (Elixir Medical, Sunnyvale, CA), a drug-eluting bioresorbable scaffold combining a PLLA-based scaffold coated with a biodegradable polylactide-based polymer and Novolimus, a macrocyclic lactone mTOR inhibitor. The drug dose is 5 µg per mm of scaffold length and the device is available in multiple diameters (2.5, 3.0, 3.25 and 3.5) and lengths (14, 18 and 28 mm).

METHODS A total of 100 patients were treated with the DESolve NEBCSS in de novo lesion coronary artery lesions with a reference vessel diameter between 2.25 and 3.5 mm and treatable with a single scaffold between 14 and 28 mm in length. Patient data for the clinical endpoints of major adverse cardiac events (MACE) defined as: cardiac death, target vessel MI, clinically-indicated target lesion revascularization (TLR); target vessel revascularization and stent thrombosis are to be analyzed at 1, 6, 12 months and annually through 5 years. The study was approved the local Ethics Committees and all patients provided informed consent.

RESULTS Patients were enrolled over a one year period at 10 sites in Germany, and Italy. After the index procedure, patients were contacted at 30 days and 6 months either via an office visit or telephonically. Patient demographic, lesion characteristics and clinical results though 6 months will be presented.

CONCLUSIONS The DESolve NEBCSS post-marketing clinical follow-up study demographics and lesion characteristics overview and clinical results through 6 months will be presented.

CATEGORIES CORONARY: Bioresorbable Vascular Scaffolds

KEYWORDS Bioabsorbable scaffolds, Drug-eluting stent, bioabsorbable, Novolimus