

1.06 ± 0.12; mean postdilation balloon diameter 3.26 ± 0.44mm; mean maximal postdilation pressure: 16.05 ± 4.24mmhg). Baseline clinical characteristics were similar between the PD and non-PD groups. The left anterior descending artery (47.8%) was the most commonly treated vessel in the study population. Lesion complexity and calcification were higher in the PD group (AHA B2/C lesion: 48.4% in PD vs 24.5% in non-PD, p < 0.001; Moderate/heavy calcification: 51.2% vs 29.6%, p<0.001). Treatment length was significantly longer in PD compared to non-PD (25.31 ±14.53 vs 20.06 ±10.13, p<0.001). Lesion preparation (percentage predilation performed and pre B:A ratio) was similar between the PD and non-PD groups. Acute lumen gain was significantly decreased in PD compared to non-PD (1.33 ±0.59 vs 1.53 ±0.63mm, p= 0.002). From QCA, PD resulted in a significant increase in reference vessel diameter (RVD, 0.16 ± 0.37, p< 0.001), minimal lumen diameter (MLD: 0.14 ± 0.32mm, p < 0.001) and non-significant decrease in diameter stenosis [%DS: (-)0.03 ± 12.39%, p= 0.976] after BRS implantation. Overall device success rates was 99.5% and all-cause mortality occurred in 2.7% of the study population with no differences between the PD and non-PD groups. Other clinical outcomes are currently being adjudicated and would be available on presentation.

CONCLUSIONS In our study, while PD resulted in a marginal increase in RVD and MLD after BRS implantation, acute lumen gain was smaller in the PD group and short term procedural outcome and mortality remained similar between the 2 groups.

CATEGORIES CORONARY: Bioresorbable Vascular Scaffolds

KEYWORDS Bioabsorbable scaffolds, Mortality, Quantitative coronary angiography

TCT-541

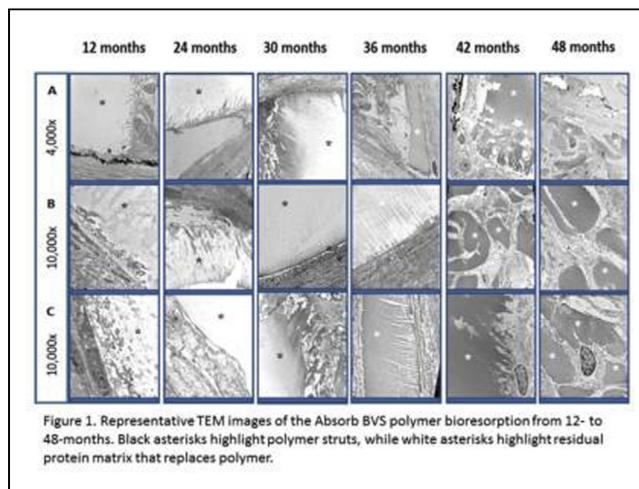
Absorb Bioresorbable Vascular Scaffold: ultrastructural changes assessed by transmission electron microscopy in the porcine coronary model

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BACKGROUND No reports have described the ultrastructural changes that occur over the course of bioresorption of the everolimus-eluting Absorb BVS (150 μm PLLA-strut thickness with 6 μm PDLLA-coating) [Abbott Vascular, Santa Clara, CA].

METHODS Eighteen Absorb BVS were implanted in main coronary arteries of healthy Yucatan mini Swine. Transmission electron microscopy was performed at seven time points from 28-days to 48-months. Ultrastructural changes of polymeric struts / resorption sites (RS, > 36 months) were morphologically characterized.

RESULTS Up to 12-months, struts were intact with surrounding macrophages and fibroblasts. The PDLLA polymer coating was observed as a black line of calcified material (A) as thinly separated from the strut polymer. Collagen deposition was seen along the surfaces with acellular cytoplasmic processes extending into the strut surface from the surrounding cellular area (B & C). At 24-months the acellular processes extended deeper into the strut surface. Collagen and smooth muscle cells bordered the strut. At 30-months, some strut surfaces remained intact with surrounding dense collagen and fibroblasts (B) while other areas shows superficial polymer micro-fragmentation (A & C). Internally, struts appeared sparsely granular. At 36-months RS were tightly surrounded by fibrous tissue (B). Cellular and collagen-proteoglycan ingrowth subdivided RS, which show more dense granularity than at 30 months (A & C). At 42- and 48-months, RS were reduced to multiple amorphous, densely granular particles subdivided and surrounded by collagen and proteoglycan rich matrix with myofibroblasts and interspersed calcified material.



CONCLUSIONS Our investigation reveals the nature of the changes seen within the polymeric struts. As polymer resorbs (30 - 36 months) it shows increasing granularity (nonfibrellar glycoprotein) with eventual replacement by a proteinaceous matrix with integrated collagen and myofibroblasts at 48-months.

CATEGORIES CORONARY: Bioresorbable Vascular Scaffolds

KEYWORDS Bioabsorbable scaffolds, Biocompatibility, Polymer

TCT-542

Stenting of Coronary Bifurcation Lesions with Bioresorbable Everolimus-Eluting Scaffolds. Poznan Bifurcation-Absorb Pilot Registry

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BACKGROUND The data concerning the use of bioresorbable vascular scaffolds (BVS) in coronary bifurcation lesions are limited. Given the complexity of the procedure and the potential risk of struts' damage it is imperative to evaluate the efficacy and long-term safety of BVS in such lesions. The aim of the study was to evaluate the early and long-term clinical outcomes of bifurcation stenting with BVS.

METHODS The study is a prospective, nonrandomized clinical registry of patients with coronary bifurcation lesion treated with everolimus-eluting BVS. Sixty consecutive patients, with stable coronary artery disease or acute coronary syndromes were enrolled. The study excluded patients with concomitant serious illnesses, those who were unable to receive prolonged dual antiplatelet therapy or required chronic oral anticoagulation therapy. Bifurcation lesion was defined and classified according to European Bifurcation Club definition and Medina classification. The main clinical study end point was a device-oriented target lesion failure (TLF), defined as the combination of cardiac death, target vessel myocardial infarction, or clinically driven target lesion revascularization.

RESULTS Sixty consecutive patients (male 71.7%, mean age 62.6±11.2 years) were included, 18 of them had diabetes mellitus (30%) and 10 chronic kidney disease (17%). True bifurcation lesion was found in 27 patients (45%). Nine lesions (15%) comprised the left main coronary artery. On QCA the mean proximal and distal main vessel reference diameters were 3.12 ± 0.36 mm and 2.65 ± 0.43 mm respectively, whereas the mean lesion length and diameter stenosis were 12.73 ± 9.53 mm and 69.72 ± 27.33 mm. The mean side branch (SB) reference diameter was 2.34 ± 0.36 mm, SB lesion length 5.66 ± 5.27 mm, and lesion diameter stenosis 44.58± 27.47%. A total of 71 BVS were implanted. Provisional T stenting was performed in 42 patients (70%), distal main vessel stenting in one patient, systematic T stenting in 6 (10%), and T with minimal protrusion (TAP) in 2 patients (2.2%). SB ostial stenting was performed in additional 9 patients (15%). The final

mini-kissing post-dilatation was performed in 18 patients (30%). The procedural success was achieved in 98.3%. At twelve months, the rate of cardiac death was 1.7% (1 patient), target vessel myocardial infarction was 1.7% and TLR was also 1.7%, giving the TLF of (3.3%). The cumulative incidence of definite/probable scaffold thrombosis was 3.4% (2 patients). Both events happened within 10 days after procedure.

CONCLUSIONS Stenting of coronary bifurcation lesions with bioresorbable everolimus-eluting scaffolds is feasible with excellent acute performance and satisfactory early and long-term clinical outcomes. The results of our study represent a major step forward towards more complete implementation of BVS to coronary interventions.

CATEGORIES CORONARY: Bioresorbable Vascular Scaffolds

KEYWORDS Bifurcation stenting, Bioabsorbable scaffolds, Clinical outcomes

TCT-543

Neointimal Coverage, Vessel Wall Healing and Major Evaginations after Everolimus-Eluting Absorb™ Bioresorbable Vascular Scaffold Implantation Assessed with Serial Optical Coherence Tomography

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BACKGROUND The illumination of the spontaneous vascular healing pattern following implantation of an everolimus-eluting Absorb™ bioresorbable vascular scaffold (BVS) remains sparse. Optical coherence tomography (OCT) allows accurate and detailed in vivo assessment of the arterial healing following BVS-implantation.

METHODS Serial OCT (after Absorb™ BVS implantation, 9- and 24-month follow-up) was performed in 20 patients with stable angina pectoris post implantation, at 9-month and after 24 months were available in 18 patients. Dynamic changes in scaffold strut coverage and major coronary evaginations were evaluated. Coronary evaginations were defined when the maximal depth of outward bulges of the luminal contour between scaffold struts were >150 μm. Major evaginations were defined as presence of evaginations in ≥3 consecutive analyzed frames, with a minimal evagination depth of 10% of the nominal scaffold diameter.

RESULTS The lesion length was 14.4 ± 3.4 mm and the scaffold length was 19.7 ± 4.2 mm. The scaffold size was 3.0 ± 0.3 mm, maximum balloon size was 3.3 ± 0.3 mm and maximum balloon pressure was 14.5 ± 2.6 atm. At baseline, 3,745 struts were analyzed. The median percentage of uncovered struts was 5.1% [25th-75th percentiles: 0.5-10.0%] after 9 months and 0.0% [0.0-0.0%] after 24 months. Completely covered scaffolds were seen in 3 patients (16.7%) after 9 months and in 17 patients (94.4%) after 24 months (p=0.001). The median neointimal thickness increased from 9-month: 100 μm [70-120 μm] to 24-month: 115 μm [98-133 μm] (p=0.013). The minimum lumen area decreased significantly from 5.2 mm² [4.8-5.7 mm²] at post-implantation to 4.4 mm² [3.7-4.8 mm²] at 9-month (p=0.003), while no significant change was observed from 9-month to 4.5 mm² [3.6-4.9 mm²] at 24 months, (p=ns). Major coronary evaginations were seen in 7 patients (38.9%) at 9-month follow-up and resolved in 6 out of these 7 patients (85.7%) after 24 months.

CONCLUSIONS Almost complete scaffold strut coverage was present at 24 months without causing long-term minimum lumen area reduction. Major coronary evaginations were relatively frequent morphological findings after 9 months and mainly resolved after 24 months.

CATEGORIES CORONARY: Bioresorbable Vascular Scaffolds

KEYWORDS OCT, Percutaneous coronary intervention, Vascular healing

TCT-544

Bioresorbable Coronary Devices in Clinical Practice: Immediate and 30-day Results of the Prospective REPARA Registry

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BACKGROUND Bioresorbable coronary devices are currently being used in selected lesions and patients. Routine use in daily clinical practice has not yet been established and few data exist about specific lesions and clinical scenarios.

METHODS REPARA is a multicenter, prospective registry, designed to evaluate the efficacy and safety of the bioresorbable coronary device Absorb (Abbott Vascular, Santa Clara, California) in daily clinical practice in more than 2400 patients undergoing elective coronary intervention in native coronary arteries in Spain and Portugal. The primary objective is a combined of MACE at 12 months, including cardiac death, myocardial infarction, TLR and stent thrombosis.

RESULTS Complete data will be available at the time of the meeting. By now, 1627 patients have been included (mean age 57±11 years, 81% male), 25% diabetics. Clinical indication was MI in 59% (STEMI in 32%, non-STEMI in 27%), unstable angina in 18%, stable angina or silent ischemia in 21% and others in 2%. Radial access was used in 83% of patients. A total of 2159 lesions were treated (type A 22%, B1 38%, B2 26%, C 14%), mean 1.35±0.7 for patient, 51% in LAD, 21% in Cx and 28% in RCA. Mean lesion length was 18.1±9.1 mm, 13% were bifurcations, 10% complete occlusions and 3% ostial location. Lesion predilatation was performed in 78% and 1.2±0.5 devices were implanted in each lesion. Mean device length was 23±13 mm and mean device diameter 3±0.4 mm. Overlapping rate was 14% (67% for total coverage of the lesion, 33% to treat proximal or distal dissection). Balloon postdilatation rate was 40% (mean balloon diameter 3.3±0.4 mm, mean length 12.8±4 mm, mean pressure 17.6±5 atm). Intracoronary imaging was performed in 12% of lesions (IVUS in 2.8% and OCT in 9.1%), and malapposition was detected only in 0.3%. Procedural success rate was 98.4%. In-hospital MACE were 1.6% (1.1% periprocedural MI, 0.3% acute stent thrombosis, 0.2% TLR and 0.2% cardiac deaths). At 30 days (1479 patients) total adverse events were 2.4% (1.6% MI, 0.9% stent thrombosis, 0.8% TLR and 0.3% cardiac deaths). At discharge, all patients were receiving double antiplatelet therapy (ASA 100%, clopidogrel 57%, ticagrelor 27%, prasugrel 16%). Subgroup analyses by patient and lesion complexities will be provided.

CONCLUSIONS Results from this large real-world registry with bioresorbable coronary devices show good immediate and 30-day outcomes in unselected lesions and with a high rate of ACS patients. Early stent thrombosis rates are comparable to those reported with drug-eluting stents.

CATEGORIES CORONARY: Bioresorbable Vascular Scaffolds

KEYWORDS Antiplatelet therapy, Bioresorbable scaffold, Stent thrombosis