BACKGROUND For the treatment of chronic total occlusion (CTO), the efficacy and safety of the bioresorbable vascular scaffold is still considered limited. The aim of this study was to assess the feasibility and efficacy BVS implantation in percutaneous treatment of chronic total occlusion. Patient selection and study endpoints were based on a comprehensive literature review. The measurements were adjusted according to the ARC criteria. RESULTS All scaffolds were delivered and deployed successfully. The final OCT analysis not revealed any significant scaffold malapposition. 9.1% patients presented significant troponin elevations in the range associated with a non-Q periprocedural myocardial infarction. No other in-hospital adverse clinical events were recorded. After 12±1 months of follow-up, the events rate was 6%, due to 4 repeat revascularization (3 PCI and 1 CABG). Re-evaluation by angiography with OCT will be obtained in next 12 months follow-up after procedure. CONCLUSIONS In this study we demonstrated midterm safety and efficacy BVS implantation in percutaneous treatment of chronic total occlusion.

CATEGORIES CORONARY: Stents: Bioresorbable Vascular Scaffolds

LOCALIZATION: Stents: Bioresorbable Vascular Scaffolds

FIVE-YEAR TRUE SERIAL EVALUATION OF JAIRED SIDE BRANCHES BY ABSORB BIORESORBABLE VASCULAR SCAFFOLDS USING THREE-DIMENSIONAL OPTICAL COHERENCE TOMOGRAPHY

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BACKGROUND The fate of side branch (SB) ostia jailed by struts of the Absorb bioresorbable vascular scaffold (BVS, Abbott Vascular, Santa Clara, CA) has not yet been fully explored. METHODS We performed a 3D-OCT sub-analysis of the ABSORB Cohort B trial. In this trial, 101 patients were included, all treated with a 3.0x18mm BVS. According to study protocol, the first 45 patients (cohort B1; BVS) underwent repeat angiography with invasive imaging (IVUS; OCT was optional) at 6 months and 2 years; the other 56 patients (cohort B2; CB2) were examined at 1 and 3 years. According to an additional protocol amendment all patients were consented again to return for another repeat angiography at 5 years. We present 3D-OCT assessments of jailed SB ostia from patient with true serial follow-up from baseline to 5 years, using the validated ‘cut-plane’ analysis method of the new QAngioOCT 1.0 software (Medis Specials BV, Leiden, the Netherlands).

RESULTS A total of 27 patients (11 in CB1, 16 in CB2) with 100 jailed SB ostia from the Absorb bioresorbable vascular scaffold (BVS, Abbott Vascular, Santa Clara, CA) has not yet been fully explored. METHODS We performed a 3D-OCT sub-analysis of the ABSORB Cohort B trial. In this trial, 101 patients were included, all treated with a 3.0x18mm BVS. According to study protocol, the first 45 patients (cohort B1; BVS) underwent repeat angiography with invasive imaging (IVUS; OCT was optional) at 6 months and 2 years; the other 56 patients (cohort B2; CB2) were examined at 1 and 3 years. According to an additional protocol amendment all patients were consented again to return for another repeat angiography at 5 years. We present 3D-OCT assessments of jailed SB ostia from patient with true serial follow-up from baseline to 5 years, using the validated ‘cut-plane’ analysis method of the new QAngioOCT 1.0 software (Medis Specials BV, Leiden, the Netherlands).

RESULTS Patients suffered from an acute coronary syndrome in 44%, diabetes mellitus in 24%. Multiple scaffold implantations were performed in 24% (N=61/74 lesions) with a mean 2.2±0.5 scaffolds (range 2-4), resulting in a total mean scaffold length of 48mm (range 28-112mm). Minimal lumen diameter (MLD) pre PCI was 1.04±0.50mm in the single scaffold and 0.89±0.49 in the multiple scaffold group. Lesion length was 13.5±7.7mm in the single versus 30.0±15.9mm in the multiple scaffold group. Reference diameter and MLD in the scaffold and total segment were significantly smaller with multiple compared with single scaffold treatment. Mean length of scaffold per lesion was 20mm (8-28mm) with a single scaffold and 37mm ranging from 20 to 112mm with multiple scaffolds. Pre-dilatation was performed in all cases. Acute gain in the scaffold segment was 1.37±0.47mm, leading to a final minimal luminal diameter of 2.44±0.41mm in the single scaffold and 2.27±0.37mm in the multiple scaffold group. Reference diameter post PCI was 2.94±0.77mm in the single and 2.77±0.38mm in the multiple scaffold group. With our dual antiplatelet therapy there was no definite scaffold thrombosis. Within 12 months follow-up the device oriented composite endpoint was low with 2.2% (0.8% in the single versus 6.8% in the multiple scaffold group, p=0.009). CONCLUSIONS With careful predilatation and post dilation using high pressure balloons in long scaffold segments and dual antiplatelet therapy there was no scaffold thrombosis. Device oriented composite endpoint was low with a significantly higher rate with multiple scaffold implantation. Diabetes mellitus and length of scaffold segment were significant predictors for the occurrence of a device oriented endpoint.

CATEGORIES CORONARY: Stents: Bioresorbable Vascular Scaffolds

KEYWORDS Bioresorbable scaffold, Coronary interventions

TCT-508 BIOPREDEGRADABLE VASCULAR SCAFFOLD FOR THE TREATMENT OF CHRONIC TOTAL OCCLUSION LESIONS - CLINICAL OUTCOMES AND INTRACORONARY IMAGING FOLLOW-UP

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RESULTS Five-year true serial evaluation of jailed side branches by Absorb bioresorbable vascular scaffolds using three-dimensional optical coherence tomography

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BACKGROUND The fate of side branch (SB) ostia jailed by struts of the Absorb bioresorbable vascular scaffold (BVS, Abbott Vascular, Santa Clara, CA) has not yet been fully explored. METHODS We performed a 3D-OCT sub-analysis of the ABSORB Cohort B trial. In this trial, 101 patients were included, all treated with a 3.0x18mm BVS. According to study protocol, the first 45 patients (cohort B1; BVS) underwent repeat angiography with invasive imaging (IVUS; OCT was optional) at 6 months and 2 years; the other 56 patients (cohort B2; CB2) were examined at 1 and 3 years. According to an additional protocol amendment all patients were consented again to return for another repeat angiography at 5 years. We present 3D-OCT assessments of jailed SB ostia from patient with true serial follow-up from baseline to 5 years, using the validated ‘cut-plane’ analysis method of the new QAngioOCT 1.0 software (Medis Specials BV, Leiden, the Netherlands).

RESULTS A total of 27 patients (11 in CB1, 16 in CB2) with 100 jailed SB ostia (41 in CB1, 49 in CB2) were evaluated. A total of 12 jailed SB ostia could be truly serially assessed (3 from CB1, 9 from CB2). In CB1, the mean post-procedural ostial surface was 2.75±0.29mm2, which decreased to 1.98±1.85mm2 at 6 months, decreased a bit further to 1.24±0.66mm2 at 2 years, but increased to 2.83±0.82mm2 at 5 years (p-values not calculated due to too small number of cases). In Cohort B2, the mean post-procedural ostial surface was 0.73±0.87mm2, which decreased to 0.49±0.32mm2 at 1 year (p<0.30), remained stable (0.44±0.24mm2) at 3 years (p=0.45), but significantly increased to 0.80±0.48mm2 at 5 years (p=0.008). The total number of complications in the cohort was 5 patients (in 3 from CB1, 2 in CB2) and remained similar from 2/3 years to 5 years (see figure).
CONCLUSIONS This is the first study which systematically evaluated, in a truly serial fashion, the fate of jailed BVS side branch struts up to 5 years follow-up using a validated ‘cut-plane’ method. We showed that initially the total surface of the jailed ostia decreased due to closure of 1 or more compartments. However, after full bioresorption of the scaffold, the surface of the compartments which remained patent gradually increased from 2/3 years to 5 years. This information might have important implications for future bifurcation treatment using bioresorbable scaffolds.

CATEGORIES CORONARY: Stents: Bioresorbable Vascular Scaffolds

KEYWORDS Biodegradation polymer coating, DES, Endothelialization

TCT-512

Bioresorbable Vascular Scaffold Radial Expansion and Conformation Compared to a Metallic platform: Insights from In-vitro Expansion in a Coronary Artery Lesion Model

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BACKGROUND The aim of this study was to compare the acute expansion behavior of a polymer based Bioresorbable Scaffold and a second generation metallic DES platform in a coronary artery lesion model. Although there are significant differences in the material properties between currently available metallic stents and polymer based bioresorbable scaffolds, experimental data have shown so far little differences in their mechanical properties. Still, differences in acute results have been observed in clinical studies comparing BVS directly to metallic DES platforms.

METHODS We examined the expansion behavior of the Bioresorbable Vascular Scaffold (3.0x18mm Absorb BVS; Abbott Vascular, Santa Clara, CA) after expansion at 37°C in an identical coronary artery stenosis model (12 different experiments were performed in total). Devices expansions were compared during balloon inflation and after deflation using microscopy to allow assessment of plaque recoil. Minimal Lumen Diameter (MLD) and Stent eccentricity were quantified from Optical Coherence Tomography (OCT) imaging at nominal diameter and after post-dilation at 18 ATM.

RESULTS The MLA in the models with BVS deployed was 4.92 ± 0.17 mm (while in the metallic DES was 4.50 ± 0.13mm(±0.02) at Nominal Pressure (NP) and 5.41 ± 0.20 and 5.67 ± 0.15 mm2 (p<0.02) after expansion at 18 ATM respectively. Stent eccentricity index at the MLA was 0.71 ± 0.02 in BVS compared to 0.81 ± 0.02 in the metal stent at NP (p=0.003), and 0.73 ± 0.03 compared to 0.75 ± 0.02 at 18 ATM.

CONCLUSIONS Such in-vitro experiments provide insights to better understand the behavior of BVS scaffolds and to guide their optimal implantation in-vivo.

CATEGORIES CORONARY: Stents: Bioresorbable Vascular Scaffolds

KEYWORDS Bioabsorbable scaffolds, Conformability, Drug-eluting stents