TCT-508

Bioresorbable Vascular Sccafold For The Treatment Of Chronic Total Occlusion Lesions - Clinical Outcomes And Intracoronary Imaging Follow-Up

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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 of BVS for the CTO percutaneous treatment, analyze clinical outcomes and intracoronary imaging at one year follow-up. The reabsorption of the BVS could provide some advantages at long-term follow-up as compared with metallic drug-eluting stents.

METHODS Between October 2013 and January 2015, percutaneous treatment of CTO with BVS implantation were performed in 66 patients (66 lesions). The mean patient age was 62±11 years and 63% patients were male, 45.1% suffered from hypertension and 30.3% from diabetes. The decision of an antegrade or retrograde approach was taken by the operator after a thorough study of the CTO anatomy. An antegrade approach was the strategy used to cross 42% CTO, 33% a retrograde approach, while in 25% antegrade and dissection technique was needed. The most frequently treated vessel was the LAD (45%). Estimate the size of the BVS was made on the basis of the IVUS examination just after first balloon predilatation. The total scaffold length implanted per lesion was 55.8±18.9 mm. Post-dilatation was undertaken in 93%. All scaffolds were successfully delivered and deployed. Optical coherence tomography (OCT) was performed after BVS implantation. Primary endpoints were procedural success of deployment of the BVS at the target lesion and absence of in-hospital major adverse events (death, Q-wave myocardial infarction, stroke or any repeat target lesion revascularization). After 6 month of BVS implantation clinical evaluation was made, all included patients will have control angiography with OCT in 12 months follow-up.

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 6.0% 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

TCT-509

Clinical follow-up after implantation of bioresorbable drug-eluting scaffolds - a prospective single center experience up to 3 years

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BACKGROUND In the Absorb II study the use of the scaffold was associated with similar results compared with the everolimus eluting stent. Lesion complexity in Absorb II as well as follow-up (12 months) was limited. We evaluated clinical results in our prospective registry including a real world population with dual antiplatelet therapy for 6 months (stable angina) or 12 months (acute coronary syndrome).

METHODS In this prospective registry (clinicaltrials.gov NCT01583608) 236 patients were enrolled and treated with the bioresorbable scaffold (Absorb). Patients had stable or unstable coronary artery disease. Pre-dilation was mandatory and post-dilation with a high-pressure balloon was performed in patients with a scaffold length >12mm. Quantitative coronary angiography pre and post scaffold implantation was done. Patients received dual antiplatelet therapy for 6 months (aspirin and clopidogrel) for stable angina pectoris and 12 months for acute coronary syndrome. Mean follow-up was 382 days. Primary outcome measure was a device oriented composite endpoint defined as cardiac death, myocardial infarction not clearly related to a non-target vessel and target lesion revascularization. Scaffold thrombosis were defined according to the ARC criteria.

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±5.7mm in the single versus 30.0±15.5mm 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 segment 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 strategy 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=0.003).

CONCLUSIONS With careful predilation 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

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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; CB1) 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±0.2.96mm2, 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 low 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 compartments per jailed ostium decreased from baseline to 2 years (CB1) and 3 years (CB2), and remained similar from 2/3 years to 5 years (see figure).