Impact of Post Dilation on the Acute and One-Year Clinical Outcomes of a Large Cohort of Patients Treated Solely with the Absorb Bioresorbable Vascular Scaffold

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Background: Although bioresorbable scaffolds (BRS) may have important benefits, their deployment requires more aggressive lesion preparation compared to the best metallic DES due to different radial force and custom profile. In addition, the benefits of post-dilation (PD) have not been systematically studied, with reports of failure if the BRS expansion limits are exceeded by excessive PD. We sought to determine the impact of PD on clinical outcomes in a large cohort of patients treated with the Absorb Scaffold.

Methods: We evaluated all consecutive patients enrolled in the multicenter, single-arm ABSORB EXTEND Study through June 2013. The study allowed treatment of up to 2 coronaries (diameter 2.0 to 3.8mm) and the use of overlapping (lesion length ≤ 20mm). Patients with severe lesion calcification/birotteny were excluded. Aggressive lesion pre-dilation (balloon to artery ratio of 0.9-1.0) was mandatory and PD was left to the operator’s discretion (if performed, non-compliant balloons up to 0.5mm larger than the Absorb had to be used). Patients were grouped according to whether PD was performed or not, and the one-year incidence of TLF and scaffold thrombosis were compared.

Results: 768 patients were enrolled in the study and PD was performed in 526 (68.4%). There were no significant differences between the PD group and no-PD group in baseline characteristics, moderate calcification (13.7% vs.12.7%, p=0.7) and incidence of II/III lesions (43.9% vs. 41.8%), as well as mean length (12.5mm vs.12.1mm (p=0.6) and RVD (2.6mm for both groups, p=0.2). Residual in-scaffold stenosis (15.4 ± 6.5% with PD, 14.9 ± 6.1% without PD, p=0.3) and the need for bailout scaffold/stent (4.2% with PD, 4.5% without PD, p=0.8) were also comparable. At 1 year, there was no difference in TLF (5.4% in the PD vs. 2.6% in the non-PD group; p=0.13); all individual components of TLR, death, and MI were also similar. There were no significant differences in MACE and death/probable stent thrombosis between the two groups.

Conclusion: These results reflect very similar final angiographic and clinical results achieved with or without post-dilation in the treatment of how to moderately complex lesions.

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Conclusions: DREAMS shows excellent safety and efficacy data with no death and no scaffold thrombosis on 3- year follow-up. Multi-modality imaging documented the absorption process and the unaging aspect of this device already at 6 months.

TCT-626
Expanding Indications of Bioresorbable Scaffolds: Single Center Procedural and In-Hospital Outcomes with the first 300 Implanted Devices in a Diversified, All-Comer Patient Population
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Background: Bioresorbable stents have not been evaluated in a wide range of clinical settings including ACS, STEMI, stent restenosis, SVG, and CTO. As of April 1st 2013, ABSORB BVS (BVS) became our default drug eluting device for patients at our institution. The aim of this study is to evaluate the safety and efficacy of this new technology in a real-world setting.

Methods: Detailed patient characteristics and peri-procedural data are collected for both patients receiving and not receiving a BVS and systematically entered in a registry. In-hospital outcomes include MACE and bleeding complications and are independently assessed by dedicated personnel.

Results: We will report on our first year experience with BVS. Results are compared to those in a group of patients treated concomitantly with other stent types. As of March 2013, 3,044 BVS have been implanted in 335 patients. Unadjusted MACE (death, MI, Urgent PCI) rates were 5.1% and 4.5% in patients treated with BVS and DES, respectively.

Conclusions: Conclusions will be supported by the presented data and will reflect our main findings. Preliminary results suggest comparable clinical outcomes with BVS and DES in patients without contraindication to drug-eluting devices.

TCT-627
Comparison of Procedural Feasibility Between Bioresorbable Vascular Scaffold and New-Generation Drug Eluting Stent in an All-Comer Population
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Background: The strut thickness and deliverability of BVS may increase procedural time, contrast volume and fluoroscopy time, especially in complex lesions.

Methods: In this study, 205 consecutive patients treated with either BVS (n=99) or drug eluting stent (DES) (n=106) between May 2010 and May 2014 were enrolled.

Results: The number of complex lesions (ACC/AHA lesion classification type B2 and C) between BVS and DES group (84.7% vs. 90.6%, p=0.01) was similar. Pre and post-balloon dilation were performed more frequently in the BVS group compared to the DES group (97.1% vs. 79.4%, p<0.01; 99.2% vs. 71.7%, p<0.01, respectively). Maximum post-dilation balloon size was larger and maximum inflation pressure was higher in the BVS compared to the DES group (3.1±0.4 mm vs. 3.0±0.1 mm, p=0.01; 21.1±5.1 atm vs. 19.2±5.0 atm, p<0.01, respectively), despite similar quantitative coronary angiography (QCA) results. Procedure time, amount of contrast and fluoroscopy time in BVS group were increased significantly compared to those in the DES group (Table). In multivariable analysis, after adjustment for SYNTAX score, chronic total occlusion and lesion length by QCA BVS use was identified as an independent predictor of long procedure time (>120 min.) (odds ratio: 4.9, 95% confidence interval: 2.67-9.36, p<0.001).

Conclusions: Treating complex lesions with BVS requires longer procedural fluoroscopy times and larger volumes of contrast as compared to DES implantation to achieve similar procedural success rates and results. Improvements in scaffold design may reduce the need for meticulous lesion predilatation with dedicated devices and increase the spectrum of lesions amenable to treatment with BVS.

TCT-628
Safety and Efficacy of Everolimus-Eluting Bioresorbable Vascular Scaffolds in Complex Coronary Lesions
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Background: Everolimus-eluting bioresorbable vascular scaffolds (BVS) are increasingly used in patients with complex coronary anatomies. However, data on BVS in such indications are scarce. This study sought to evaluate the safety and efficacy of ABSORB BVS in patients with complex coronary lesions.

Methods: Consecutive patients (n=150) undergoing BVS implantation at a tertiary care center entered a prospective registry. All patients underwent a detailed assessment of clinical and procedural data. Clinical follow-up was performed 7±5 months after the index procedure and was completed in all patients. Major adverse cardiac events (MACE) included the occurrence of death, myocardial infarction, stent thrombosis and target lesion revascularization. Complex coronary artery disease was defined as type B2 or C lesions. Device success was defined as attainment of <30% residual stenosis. Procedural success was defined as device success without periprocedural complications. Clinical success was defined as procedural success and absence of MACE within follow-up.

Results: Complex coronary lesions were present in 45.3% (n=68) of patients. The number of complex lesions (1.6±0.6 vs. 1.1±0.3, p<0.001 /3.2±1.3 vs. 1.9±0.8, p<0.001). Device success rate was high in both groups (97.1% vs. 97.6%, p=1.00). At a relatively low rate of periprocedural complications (death dissection n=7, side branch occlusion n=2) procedural success did not differ significantly in patients with complex lesions in comparison to patients with non-complex lesions (91.2 vs. 95.1%, p=0.51). The majority of patients remained free of angina within follow-up (85.3 vs. 92.7%, p=0.19). MACE occurred in 1.5% (n=1) of patients with type B2/C lesions versus 7.3% (n=6) with type A/B1 lesions (p=0.13). Finally, clinical success was comparable in both groups (89.7% vs. 97.9%, p=0.48).

Conclusions: BVS in complex coronary lesions appear to be promising in terms of safety and efficacy.

TCT-629
Effect of the Absorb Bioresorbable Vascular Scaffold (BVS) on Coronary Plaque Regression in a Familial Hypercholesterolemia Swine: 1-Year Follow-Up
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Background: One of the hypothesized long-term clinical benefits of Absorb BVS is plaque regression (reduction in plaque volume) and stabilization (reduction in necrotic and lipid composition). This study evaluates the effect of Absorb BVS on plaque size and composition in a familial hypercholesterolemia (FH) swine model. We present here the IVUS results at 1-year follow-up.

Methods: Ten-month-old female FH swine were fed an atherogenic diet for 21 weeks. One week into the feeding, coronary arteries were balloon injured. Twenty weeks post injury, intervened segments were imaged by IVUS for lesion progression and randomly implanted with either Absorb BVS or metallic drug-eluting stents (DES, XIENCE™V) at a 2:1 ratio. All animals were imaged by angiography, IVUS and OCT post implant and at an interim 1-year follow-up.

Results: Plaque area (PA), %PA (as percentage of EEL area) and plaque tissue composition were statistically similar for both device groups at pre and post implant (baseline) demonstrating a good randomization of the study. At 1-year follow-up, the implanted vessel (Absorb = 23, DES = 11) sizes remained unchanged. Change in the mean PA from baseline to 1 year was -0.2±2.6±11mm2 for BVS and 1.5±1±3.6mm2 for DES (p=0.05). Changes of mean %PA were 1±12% and 7±6% for BVS and DES respectively (p=0.07), respectively. There was a significant decrease of %PA at MLD (minimal lumen diameter) in BVS (+8±12%) compared to metallic DES (4±8%) (p=0.01). Plaque tissue characterization (MaP-IVUS, Boston Scientific) revealed that percentage changes of each plaque component were the same between the two device groups with a decrease of fibrotic and increase of lipid and necrotic components.

Conclusions: At 1 year, plaque size trended towards reduction in Absorb but not in metallic DES implanted vessels. Plaque tissue characterization suggests that plaque stabilization has not occurred at 1 year; however, plaque stabilization is hypothesized to be related to tissue replacement of polymeric struts and as such expected during later stages of resorption. This hypothesis will be examined with repeat in vivo imaging follow-up and histological evaluation in these animals at 2, 3, and 4 years.