Background: Previous ABSORB studies proved safety and efficacy of bioresorbable vascular scaffolds (BVS; Abbott Vascular Inc., Santa Clara, CA) under clinical study conditions. However, in a real world setting including patients with a worse health status, a higher proportion of complex lesions and lacking obligatory IVUS or OCT guidance, BVS treatment has not been evaluated. For this purpose, we set up the ASSURE registry over a period of 3 years.

Methods: Unselected, consecutive patients with de novo native coronary artery disease were enrolled at 6 German centers in the prospective, observational registry. Outcomes were procedural success and occurrence of cardiovascular death, myocardial infarction, ischemia driven target lesion revascularization, and target vessel failure or revascularization. Angiographic parameters including independent quantitative coronary angiography were assessed pre and post procedure. One-year experience is being reported.

Results: A total of 183 patients (198 lesions) were treated with BVS. In 128 (64.7%) lesions a complex ACC/AHA morphology (B2 or C) was present. Procedural success was achieved in all patients. Acute gain of minimal lumen diameter was 1.54±0.51 mm. Through 12 months, 1 patient (0.5%) died from gastrointestinal bleeding, 3 (1.7%) non-cardiac death occurred (after target vessel revascularization of TLR), and 5 (2.8%) target lesion revascularizations (TLR) had become necessary because of insufficient patency.

Conclusion: One-year ASSURE results suggest that BVS for de novo coronary artery disease are associated with favorable clinical and functional outcomes in all day clinical practice without mandatory IVUS or OCT guidance (ClinicalTrials.gov: NCT01583608).

TCT-618
Abstract Withdrawn

TCT-619
ABSORB Cohort B Trial: Five Year Angiographic Results Of The ABSORB Everolimus Eluting Bioresorbable Vascular Scaffold
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Background: The ABSORB Cohort A trial results demonstrated the safety of Absorb BRS (Abbott Vascular, Santa Clara, CA, USA) in 30 patients with single de novo native coronary artery lesions, with a low long-term MACE rate at 5 years (3.4%) and no scaffold thrombosis. Non-invasive MSCT imaging at 5 years confirmed the patency of the vessels with a non-significant decrease in plaque area. The ABSORB Cohort B trial, a continuation of that assessment with a modified Absorb BRS, enrolled 101 patients at 12 sites in Europe and Asia Pacific.

Methods: The patients of the ABSORB Cohort B trial were divided into 2 groups, Cohort B1 (45 patients) having imaging follow-up performed at 180 days, 2 years and 5 years and Cohort B2 (56 patients) having imaging follow-up performed at 1 year and 3 years and 5 years. Five-year data for Cohort B1 are currently being collected.

Results: In the ABSORB Cohort B trial, the mean age was 62 years. Patients with diabetes: 17%, hypertension: 66%, hypercholesterolemia: 85%, family history of CAD: 55%, stable angina: 68%, of which 15% having stable angiography with CCS classification of III or IV. Patients with unstable angina: 15%, 2% with unstable angina of Braunwald Class III. Lesion location was RCA (33%), LAD (43%), LCX (22%) and Ramus (1%), with ACC/AHA lesion classification of B1 for 55%, B2 for 40% and C for 4%. In Group B2, late loss at 3 years was 0.29±0.43mm, unchanged from 1 year (0.27±0.34mm) and vasomotion, as a response to nitroglycerine injection, was demonstrated. Quantitative IVUS results revealed mean scaffold area and mean lumen area enlargement between baseline and 3 years. The scaffold enlargement at 3 years was confirmed by OCT. At 3 years, the strut cores were still visible on OCT, which is in line with earlier pre-clinical data showing that the scaffold is biodegraded and replaced by provisional matrix at 3 years. Hypothetically, due to the integration process after bioresorption, further lumen enlargement as well as wall thinning could be expected at later time points. Clinical data up to 4 years showed an ID-MACE rate of 10.1% with no events of scaffold thrombosis.

Conclusions: The long-term 5-year QCA and vasoemotion results for Cohort B1 will be presented.

TCT-620
Twelve-Month Clinical Results After Bioresorbable Scaffolds – The ASSURE Registry
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Background: Previous ABSORB studies proved safety and efficacy of bioresorbable vascular scaffolds (BVS; Abbott Vascular Inc., Santa Clara, CA) under clinical study conditions. However, in a real world setting including patients with a worse health status, a higher proportion of complex lesions and lacking obligatory IVUS or OCT guidance, BVS treatment has not been evaluated. For this purpose, we set up the ASSURE registry over a period of 3 years.

Methods: Unselected, consecutive patients with de novo native coronary artery disease were enrolled at 6 German centers in the prospective, observational registry. Outcomes were procedural success and occurrence of cardiovascular death, myocardial infarction, ischemia driven target lesion revascularization, and target vessel failure or revascularization. Angiographic parameters including independent quantitative coronary angiography were assessed pre and post procedure. One-year experience is being reported.

Results: A total of 183 patients (198 lesions) were treated with BVS. In 128 (64.7%) lesions a complex ACC/AHA morphology (B2 or C) was present. Procedural success was achieved in all patients. Acute gain of minimal lumen diameter was 1.54±0.51 mm. Through 12 months, 1 patient (0.5%) died from gastrointestinal bleeding, 3 (1.7%) non-cardiac death occurred (after target vessel revascularization of TLR), and 5 (2.8%) target lesion revascularizations (TLR) had become necessary because of insufficient patency.

Conclusion: One-year ASSURE results suggest that BVS for de novo coronary artery disease are associated with favorable clinical and functional outcomes in all day clinical practice without mandatory IVUS or OCT guidance (ClinicalTrials.gov: NCT01583608).

TCT-621
ABSORB Everolimus-Eluting Bioresorbable Scaffold In Coronary Interventions: 12-Months Results Of a Single Center Registry
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Background: There is limited outcome data on the use of the ABSORB bioresorbable vascular scaffold (BVS) in daily clinical practice, in particular in acute coronary syndrome (ACS) patients and more complex lesions. The aim of this study was to evaluate the clinical outcome after BVS implantation in both simple and complex lesions in stable patients and acute coronary syndrome patients, similar to a more "real world" population.

Methods: All patients assigned to treatment with BVS between August 2012 and August 2013 were included in this single center registry. 12-month clinical outcomes assessed were cardiac death, myocardial infarction (MI), stent thrombosis (ST), target lesion revascularization (TLR), target vessel revascularization (TVR) and target vessel failure (TVF). TVF was defined as a composite of the device oriented endpoints of all-cause mortality, any MI or TVR.

Results: A total of 135 patients (59 ± 11 years, 73% male, 20% diabetic) were enrolled and 159 lesions were treated. Stable angina was the indication for PCI in 47%, and ST-segment elevation myocardial infarction (STEMI) in 13%. The majority of the lesions (67%) were lesion type B2 or C (AHA/ACC classification), including 2 left main, 13 chronic total occlusions and 24 bifurcation lesions. Median follow-up duration was 378 days (Q1-Q3: 201-435). At 12 months the individual clinical endpoints of cardiac death occurred in one patient (12-month cumulative event rate 0.8%), MI in 5 (4.3%), TLR in 11 (9.8%) and TVR in 14 (12.0%). ST occurred in 4 patients (12-month cumulative definitive ST rate of 3.0%). All cases of ST were angiographic defined as definite, including three sub-acute and one late-ST. In summary, the composite endpoint of TVF occurred in 15 patients resulting in a 12-month cumulative event rate of 13.2%.

Conclusions: Based on the results of the current study we believe that implantation of the ABSORB BVS in a "real world" patient population is applicable and associated with acceptable clinical outcomes at 12 months. Complete 12-month follow-up results will be available at TCT 2014.