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 varying 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, 5 (1.7%) suffered a myocardial infarction, 14 (5.2%) were diagnosed with target vessel failure and 5 (2.8%) target lesion revascularizations (TLR) had become necessary because of in-scaffold restenosis. No scaffold thrombosis occurred. The 12-month MACE incidence of 5.0% was in the same range as in previous BVS studies (4.2% in ABSORB Cohort B; 6.9% in ABSORB EXTEND preliminary data from 450 patients) and in everolimus eluting metallic stent trials (4.1% in SPIRIT IV). At 12 months, angina pectoris was less frequent (17.3% versus 56.8%), as was unstable angina pectoris (1.7% versus 21.3%).

Conclusions: 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Abstract Withdrawn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 3 years (3.4%) and no scaffold thrombosis. Non-invasive MSCT imaging at 5 years confirmed the safety of the scaffolds in patients with a low risk profile. De novo lesions at the end of the trial 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. The ABSORB Cohort B trial, a continuation of that assessment with a larger 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.

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, 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 angle with CCS classification of III or IV. Patients without unstable angina: 28%, 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. Qualitative 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 vasomotion 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 varying 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.

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