METHODS A prospective, randomized single center study including consecutive patients in stable clinical condition and with lesions amenable to be treated with the BVS stent according to predefined criteria. Patients were randomized to either treatment with BVS or Synergy™. The procedure was performed according to operators discretion. Full details of the procedure were collected including use of resources, devices, radiation, contrast and myocaridal enzymes and creatinine before and after procedure.

RESULTS A total of 100 patients (124 lesions) were included with no significant differences in baseline characteristics and only a trend to have more lesions treated in the Synergy™ group. Pre-dilatation was more frequent with BVS (97% vs. 24%;p<0.001). Implanted stents had similar diameter (3±0.4 mm in BVS and 3±0.5 mm in Synergy™) and length (19±6 mm in BVS and 20±8 mm in Synergy™). Post-dilatation was more frequently done with BVS (58% vs. 42%;p=0.1) using very similar balloons (3.3 mm diameter in both groups) and peak pressure (16 atm and 15 atm respectively). The number of wires and catheters was equivalent. The BVS group showed an increase in use of contrast volume of 10%, increase in radiation of 28% and an increase in the 24 h post-PCI TnI value a 53% higher in comparison with the Synergy™ group. No cases of contrast-induced nephropathy were noted.

CONCLUSIONS The use of current generation of BVS in comparison with Synergy™ showed more frequent treated lesions, a smaller in diameter (3 mm in Synergy vs. 3.3 mm in BVS) and a similar change in target vessel failure, suggesting a higher use of resources in the procedure, more radiation and a more than TnI release post-PCI.

CATEGORIES CORONARY: Stents: Bioresorbable Vascular Scaffolds

KEYWORDS Bioresorbable scaffold, Drug-eluting stent, Procedure difficulty

TCT-506 Two-year Outcomes After Bioresorbable Scaffold Implantation – The Multicenter ASSURE Registry

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BACKGROUND In the ASSURE registry, the treatment of de-novo coronary artery lesions in a real world setting with everolimus-eluting bioresorbable scaffolds (Absorb, Abbott Vascular, Santa Clara, CA, USA) was associated with favorable clinical 1-year outcomes. The current investigation aimed to assess efficacy and safety over a longer period of time. Here we report on clinical outcomes and angiographic findings at 2 years.

METHODS In the prospective, multicenter registry, 183 consecutive patients received bioresorbable scaffolds at 6 German sites. Two-year outcomes of equal weight were angina status and freedom from major adverse cardiac vascular events (MACE) and target vessel failure or revascularization. Quantitative angiography was conducted at follow-up and in the event of ischemia driven revascularization.

RESULTS Two-year clinical follow-up was completed in 170 (92.9%) patients. Three (1.8%) patients died for cardiovascular reasons, one from gastrointestinal bleeding, one from sudden cardiac death, and one from cardiopulmonary insufficiency. Five (2.9%) myocardial infarctions due to non-target lesions occurred, and 9 (5.3%) ischemia driven target lesion revascularizations had become necessary because of in-scaffold restenosis. One of the participating centers with a 82.1% (46/56 patients) angiographic follow-up reported on a 20.4% (10/49) rate of >70% diameter restenosis through 2 years, half of which associated with symptoms of ischemia. No scaffold thrombosis was observed. Freedom from MACE was 91.6% ± 2.1% (95% CI [87.4% - 95.8%]). Ten patients (5.9%) experienced a target vessel failure or revascularization. Clinical improvement was sustained over two years, with no substantial change in the rate of angina pectoris since the 6- and 12-month follow up (16.8% versus 16.9% and 17.3%, respectively). Quantitative angiographic core lab results from 71 patients (38.8%) will be available by August 2015.

CONCLUSIONS Two-year ASSURE results suggest that bioresorbable scaffolds for de-novo coronary artery lesions in daily clinical practice are safe and effective in the mid term. No scaffold thrombosis was observed. A considerable number of asymptomatic in-scaffold restenoses may have remained undetected. (ClinicalTrials.gov: NCT01983608)

CATEGORIES CORONARY: Bioresorbable Vascular Scaffolds

KEYWORDS Bioresorbable scaffold, Optical coherence tomography