

**TCT-13****Clinical outcomes after implantation of Absorb BVS in small vessels: results from the Italian RAI multicenter registry**

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**BACKGROUND** Early experiences on PCI of small vessels (SV) with bioresorbable vascular scaffolds (BVS) have shown an increased risk of adverse clinical events. We aimed to assess the clinical outcomes of Absorb BVS implantation in the SV subset of the RAI multicenter registry.

**METHODS** The Italian RAI Registry is an ongoing, spontaneous, multicentre prospective data collection which evaluates all patients treated at participating centres with the second-generation everolimus-eluting Absorb BVS. Our analysis was restricted to patients who received Absorb BVS implantation in at least one small vessel, defined as pre-procedure reference vessel diameter (RVD)  $\leq 2.5$  mm at quantitative coronary analysis (QCA).

**RESULTS** Between March 2012 and June 2015, 1089 consecutive unselected patients were treated with one or more Absorb BVS in the RAI Registry. 123 patients (mean age 62 years, 77% males) were included in this analysis. A total of 149 lesions located on SVs were treated with Absorb BVS in this cohort. Seventy-six (62%) of these patients had an acute coronary syndrome. Diabetic patients were 30 (24%). Multi-vessel coronary artery disease was present in 67% of patients, and the median SYNTAX score was  $17 \pm 15$ . The majority (76%) of this patients received SV scaffolding alone, while the remaining 24% were treated also in larger segments ( $>2.5$ mm). Twenty-eight (23%) patients received also metallic stents on the same or different target vessel. The total number of Absorb BVS implanted in this population was 249, with an average of 1.9 per patient. Procedural success occurred in 96% of patients. At a median follow up of 21 months (interquartile range, 11 - 32 months) target lesion failure rate was 5.7%. More in detail, adverse events were: 1 cardiac death, 5 target vessel myocardial infarctions, 4 target lesion revascularizations due to three definite scaffold thrombosis (1 sub-acute, 1 late, 1 very-late).

**CONCLUSIONS** In the RAI registry, adverse event rates after treatment of small vessels with Absorb BVS were relatively low and comparable to previous results in less complex subsets of patients undergoing PCI with the Absorb BVS.

**CATEGORIES CORONARY:** Bioresorbable Vascular Scaffolds

**KEYWORDS** Bioresorbable scaffold, Percutaneous coronary intervention, Small Vessel Disease

**TCT-14****ABSORB FIRST: 1-year clinical outcomes from a prospective, multi-center, global, real-world registry**

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**BACKGROUND** The safety and performance of the Absorb Bioresorbable Vascular Scaffold (Absorb) (Abbott Vascular, Santa Clara, CA) has been previously demonstrated with clinical data up to 5 years. However, these trials treated patients with relatively simple lesions. ABSORB FIRST is designed to evaluate Absorb BVS in the treatment of patients with more complex lesions in a real-world setting.

**METHODS** ABSORB FIRST is a prospective, multi-center, global registry to evaluate the safety and effectiveness of Absorb during commercial use in an all-comer population. This study enrolled 1,801 patients between 01/2013 and 08/2014 at 87 sites worldwide. Treatment strategy was determined by physicians per the IFU and limited to lesions in vessels without prior intervention. The key clinical endpoints include scaffold thrombosis (ST), cardiac death, myocardial

infarction (MI), revascularization, target lesion failure (TLF), major adverse cardiac events (MACE) and target vessel failure (TVF). All reported adverse events are 100% monitored and clinical events are independently adjudicated.

**RESULTS** Baseline characteristics of this population reflect the typical PCI, all-comer population: dyslipidemia (64.7%), hypertension (63.7%), diabetics (24.0%), family history of premature CAD (38.5%), AMI (26.3%), multi-vessel disease (44.3%), and prior cardiac interventions (24.1%). There is also a high proportion of patients with Class B2/C lesions (47.2 %), moderate/severe calcified lesions (18.8%), bifurcations (12.9%), total occluded lesions (10.3%), ostial lesions (5.7%). The mean lesion length is  $18.5 \pm 9.3$  mm. The device success and procedure success rates are 97.3 % and 95.5 %, respectively, comparable to those observed in prior simple trials. The rate of definite/probable ST rate at 1-year based on interim data on  $\sim 950$  patients is 0.8%. The 1-year clinical outcomes from the entire population will be reported and subgroup analyses by patient and lesion complexities might also be presented.

**CONCLUSIONS** The 1-year results from this large, global registry demonstrate the safety and effectiveness of Absorb in real-world patients, indicating its applicability in daily PCI use.

**CATEGORIES CORONARY:** Bioresorbable Vascular Scaffolds

**TCT-15****Multislice computed tomography assessment of absorb bioresorbable vascular scaffold in comparison with metallic drug-eluting stents: data from the ABSORB Japan trial**

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**BACKGROUND** Noninvasive assessment of coronary stenosis by multislice computed tomography (MSCT) has been clinically applicable. However, the diagnostic accuracy in stented segments has been hampered by blooming artifacts caused by metallic stent struts. Everolimus-eluting bioresorbable vascular scaffold (BVS) is composed of radiolucent poly-lactide backbone which induces no image blooming artifacts, but, presence of platinum markers on scaffold edges may cause artifacts. The prospective pre-specified MSCT subgroup analysis of ABSORB Japan trial sought to assess the diagnostic capability of MSCT in BVS by compared to everolimus-eluting metallic stent (CoCr-EES).

**METHODS** ABSORB Japan was a single-blind, multicenter, randomized, Japanese trial. Eligible patients, with one or two de novo lesions in different epicardial vessels, were randomized in a 2:1 ratio to BVS or CoCr-EES treatment. The pre-specified subgroup of patients underwent MSCT at 13 months but prior to invasive coronary angiography. Angiography physician was blinded to MSCT findings. Quantitative coronary angiography (QCA) was performed at the angiographic core laboratory (Beth Israel Deaconess Medical Center, Boston, USA), while qualitative and quantitative MSCT analysis were performed at the independent MSCT core laboratory (Cardiocre Japan, Tokyo, Japan).

**RESULTS** The substudy enrolled 146 patients (97 patients with 102 lesions in BVS and 49 patients with 49 lesions in EES). There were no significant differences in baseline clinical characteristics between the 2 groups. MSCT was performed at 13 months in 83 patients (87 lesions) in BVS and 42 patients (42 lesions) in CoCr-EES, respectively. No stenosis was observed in either arm. The MSCT image quality was adequate for assessment in 82 lesions (94%) in BVS and 28 lesions in EES (67%), respectively ( $P < 0.0001$ ). Of the 5 lesions with poor image quality in BVS, 2 (2.3% of the total lesions) were due to image artifacts caused by the edge platinum markers and 4 were related to motion artifact of patients (multiple reasons). In contrast, of the 14 lesions with poor image quality in CoCr-EES, 13 (31.0% of the total lesions) were due to imaging artifacts caused by stent struts. Comparison with QCA data will be present at the time of presentation.

**CONCLUSIONS** Visualization and assessment of vascular implants by MSCT is more feasible for BVS compared to CoCr-EES.

**CATEGORIES CORONARY:** Bioresorbable Vascular Scaffolds