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Bioresorbable Scaffold for Treatment of Coronary Artery Lesions

Intravascular Ultrasound Results From the ABSORB Japan Trial

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ABSTRACT

OBJECTIVES The aim of this study was to characterize post-procedural intravascular ultrasound (IVUS) findings in the ABSORB Japan trial, specifically stratified by the size of target coronary arteries.

BACKGROUND Despite overall noninferiority confirmed in recent randomized trials comparing bioresorbable vascular scaffolds (BVS) (Absorb BVS) and cobalt-chromium everolimus-eluting metallic stents (CoCr-EES), higher event rates of Absorb BVS have been reported with suboptimal deployment, especially in small coronary arteries.

METHODS In the ABSORB Japan trial, 150 patients (2:1 randomization) were scheduled in the IVUS cohort. Small vessel was defined as mean reference lumen diameter <2.75 mm. Tapered-vessel lesions were defined as tapering index (proximal/distal reference lumen diameter) ≥1.2.

RESULTS Overall, IVUS revealed that the Absorb BVS arm had smaller device expansion than the CoCr-EES arm did, which was particularly prominent in small- and tapered-vessel lesions. Higher tapering index was also associated with higher rates of incomplete strut apposition in Absorb BVS, but not in CoCr-EES. With respect to procedural techniques, small-vessel lesions were treated more frequently with noncompliant balloons at post-dilatation but using significantly lower pressure in the Absorb BVS arm. In contrast, tapered-vessel lesions were post-dilated at equivalent pressure but with significantly smaller balloon catheters in the Absorb BVS arm, compared with the CoCr-EES arm.

CONCLUSIONS The significantly smaller device expansion especially in small vessels may account for the poorer outcomes of Absorb BVS in this lesion type. Appropriate optimization strategy, possibly different between polymeric and metallic devices, needs to be established for bioresorbable scaffold technology. (AVJ-301 Clinical Trial: A Clinical Evaluation of AVJ-301 Absorb™ BVS) in Japanese Population [ABSORB JAPAN]; NCT01844284) (J Am Coll Cardiol Intv 2018;11:648–61) © 2018 by the American College of Cardiology Foundation.

Recent randomized controlled trials have shown equivalent safety and efficacy outcomes at the midterm between everolimus-eluting bioresorbable vascular scaffold (BVS) (Absorb BVS) and cobalt-chromium everolimus-eluting stent (CoCr-EES) (both Abbott Vascular, Santa Clara, California) (1-4). However, a higher rate of scaffold thrombosis and its association with inadequate scaffold expansion have been reported in multicenter observational studies and recent meta-analyses (5-8).

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Previous studies have also reported that post-procedural nonuniform scaffold expansion, device-vessel mismatch, and the use of Absorb BVS in small vessels were associated with adverse clinical events (2,9,10). These data suggest that knowledge of acute device performance and deployment characteristics may be important to ensure favorable clinical outcomes and reduce adverse events.

SEE PAGE 662

The ABSORB Japan (AVJ-301 Clinical Trial: A Clinical Evaluation of AVJ-301 [Absorb^{TM} BVS] in Japanese Population) trial was a randomized, controlled trial comparing the Absorb BVS with the control CoCr-EES, designed to support regulatory approval of the Absorb BVS in Japan. It included an intravascular ultrasound (IVUS) cohort study (1), providing a unique opportunity to compare the acute results of polymeric scaffold and metallic stent implantation. In addition, there may be potential differences in angiographic measures between thicker radiolucent polymeric scaffold and thinner, more radiodense metallic stents. Therefore, the primary aim of this study was to systematically characterize post-procedural IVUS findings in the ABSORB Japan trial, focusing especially on acute device performance related to procedural factors and lesion characteristics. Additionally, the secondary aim was to compare differences between quantitative coronary angiography (QCA) and IVUS measurements, understanding of which is considered essential for image-guided BVS implantation and post-deployment optimization.

METHODS

STUDY DESIGN. The design of the ABSORB Japan trial has been described previously (1). In brief, the ABSORB Japan trial was a prospective, multicenter, randomized, single-blind, active-controlled clinical trial in which 400 patients undergoing percutaneous coronary intervention from 38 investigational sites in Japan were randomized in a 2:1 ratio to treatment with Absorb BVS or the XIENCE CoCr-EES. Among the study cohorts, 150 patients were scheduled in the IVUS cohort. The Institutional Review Board at each investigational site approved the clinical trial protocol. All patients provided written informed consent before enrollment.

STUDY POPULATION. Patients were eligible for enrollment if they were ≥20 years of age and had evidence of myocardial ischemia (stable angina, unstable angina, or silent ischemia). Patients with left ventricular ejection fraction <30%, estimated glomerular filtration rate <30 ml/min/1.73 m^2, recent myocardial infarction, and those at high bleeding risk were excluded. Key angiographic inclusion criteria were lesions with no more than 24 mm in length, reference lumen diameter (RLD) of ≥2.5 to ≤3.75 mm, and diameter stenosis (DS) of ≥50 to <100% on visual assessment. Key angiographic exclusion criteria were left main or ostial location; excessive vessel tortuosity; heavy calcification proximal to or within the target lesion; restenotic lesion; and bifurcation lesion with side branch ≥2 mm in diameter, requiring protection guidewire or dilation.

STUDY PROCEDURE. The study allowed treatment of up to 2 de novo lesions in separate epicardial coronary arteries. Successful predilation of the target lesion was mandatory. Device sizes available in the study were: 2.5, 3.0, and 3.5 mm in diameter and 8, 12, 18, and 28 mm in length. The target lesion had to be treated with a single study device and planned overlapping was not allowed. Post-dilatation of Absorb BVS was not mandatory but was allowed, using a low-profile, high-pressure, noncompliant balloon with diameter ≤0.5 mm larger than the nominal size. Post-dilatation of CoCr-EES was per standard of care.

QUANTITATIVE CORONARY ANGIOGRAPHY. QCA was performed at baseline and post-procedure, using MEDIS QAngio XA 7.3 (Medis Medical Imaging Systems, Leiden, the Netherlands) at Beth Israel Deaconess Medical Center. Quantitative measurements included lesion length; minimum lumen diameter (MLD); proximal, distal, and mean (average of proximal and distal) RLD; DS; acute gain (in-device MLD at post-procedure minus MLD at baseline); and tapering index (proximal/distal RLD). MLD and RLD were obtained by the average values of 2 different projections. Smaller MLD was used for comparison with IVUS-determined MLD at minimum lumen area (MLA) site. Procedure success was defined as residual in-device DS ≤30%. Device sizing was evaluated by nominal device diameter minus mean RLD and classified as undersized (≤−0.25 mm), properly sized (−0.25 to 0.25 mm), and oversized (>0.25 mm), respectively. Very small vessels were defined as vessels with mean RLD <2.25 mm (2). Angulated lesions were defined as lesions with bend angle ≥30°. To compare mean RLD with mean reference lumen and vessel diameters by IVUS, mean RLD was divided into 4 subgroups (<2.50, 2.50 to 3.00, 3.00 to 3.50, and >3.50 mm).

INTRAVASCULAR ULTRASOUND. IVUS was performed in a standard manner using an automated transducer

ABBREVIATIONS AND ACRONYMS

BVS = bioresorbable vascular scaffold

CoCr-EES = cobalt-chromium everolimus-eluting stent(s)

DS = diameter stenosis

ISA = incomplete strut apposition

IVUS = intravascular ultrasound

MLA = minimum lumen area

MLD = minimum lumen diameter

OCT = optical coherence tomography

QCA = quantitative coronary angiography

RLD = reference lumen diameter

RVD = reference vessel diameter