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Bioresorbable Vascular Scaffolds Versus Metallic Stents in Patients With Coronary Artery Disease

ABSORB China Trial

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ABSTRACT

BACKGROUND The everolimus-eluting bioresorbable vascular scaffold (BVS) is designed to achieve results comparable to metallic drug-eluting stents at 1 year, with improved long-term outcomes. Whether the 1-year clinical and angiographic results of BVS are noninferior to current-generation drug-eluting stents has not been established.

OBJECTIVES This study sought to evaluate the angiographic efficacy and clinical safety and effectiveness of BVS in a randomized trial designed to enable approval of the BVS in China.

METHODS Eligible patients with 1 or 2 de novo native coronary artery lesions were randomized to BVS or cobalt-chromium everolimus-eluting stents (CoCr-EES) in a 1:1 ratio stratified by diabetes and the number of lesions treated. Angiographic and clinical follow-up were planned at 1 year in all patients. The primary endpoint was angiographic in-segment late loss (LL), powered for noninferiority with a margin of 0.15 mm.

RESULTS A total of 480 patients were randomized (241 BVS vs. 239 CoCr-EES) at 24 sites. Acute clinical device success (98.0% vs. 99.6%; $p = 0.22$) and procedural success (97.0% and 98.3%; $p = 0.37$) were comparable in BVS- and CoCr-EES–treated patients, respectively. The primary endpoint of in-segment LL at 1 year was 0.19 ± 0.38 mm for BVS versus 0.13 ± 0.38 mm for CoCr-EES; the 1-sided 97.5% upper confidence limit of the difference was 0.14 mm, achieving noninferiority of BVS compared with CoCr-EES ($p_{noninferiority} = 0.01$). BVS and CoCr-EES also had similar 1-year rates of target lesion failure (cardiac death, target vessel myocardial infarction, or ischemia-driven target lesion revascularization; 3.4% vs. 4.2%, respectively; $p = 0.62$) and definite/probable scaffold/stent thrombosis (0.4% vs. 0.0%, respectively; $p = 1.00$).

CONCLUSIONS In the present multicenter randomized trial, BVS was noninferior to CoCr-EES for the primary endpoint of in-segment LL at 1 year. (A Clinical Evaluation of Absorb Bioresorbable Vascular Scaffold [Absorb BVS] System in Chinese Population—ABSORB CHINA Randomized Controlled Trial [RCT]; NCT01923740)
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Cardiovascular disease is the leading cause of death in China, accounting for 41% of all deaths (1,2). Exponential increases in percutaneous coronary intervention (PCI) in China have been observed over the last 10 years (2), with approximately 450,000 PCI cases performed in 2013 (3). The everolimus-eluting bioresorbable vascular scaffold (BVS) (Absorb, Abbott Vascular, Santa Clara, California) offers a new PCI option for this growing patient population.

The BVS is constructed from a poly L-lactide backbone coated with a bioresorbable polymeric poly (D,L-lactide) layer containing everolimus, and it was designed to provide comparable radial strength and antirestenotic efficacy to metallic drug-eluting stents (DES) in the first year. The degradation of poly L-lactide in vivo is governed by bulk erosion beginning with a decline in molecular weight, followed by mass loss via hydrolysis upon exposure to water over time (4,5). Complete bioresorption at approximately 3 years may then provide unique long-term benefits not possible with a permanent metallic stent, including restoration of physiological vasomotion and late adaptive remodeling. Real-world registries have shown favorable outcomes of BVS in simple and complex coronary anatomy with proper implantation technique (6,7).

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Whether BVS is noninferior to current-generation DES within 1 year and whether BVS has late clinical advantages to metallic DES can only be answered by adequately powered randomized trials. The ABSORB II randomized trial suggested comparable clinical outcomes between BVS and cobalt-chromium everolimus-eluting stents (CoCr-EES) (Xience V, Abbott Vascular) in 501 randomized patients at 1 year (8), although routine angiographic follow-up was not performed in this study. The pivotal, randomized ABSORB China trial sought to establish comparable angiographic efficacy and clinical safety and effectiveness between BVS and CoCr-EES to enable regulatory approval of BVS in China. The present report describes the 1-year principal outcomes from the ABSORB China randomized trial.

METHODS

STUDY DESIGN AND PATIENT POPULATION. ABSORB China is a prospective, randomized, active-controlled, open-label, multicenter trial designed to evaluate the safety and efficacy of BVS compared with CoCr-EES. The study was performed in compliance with the Declaration of Helsinki and Good Clinical Practice guidelines of the China Food and Drug Administration. All patients signed written informed consent before randomization.

Eligible patients were age ≥18 years with evidence of myocardial ischemia and suitability for elective (nonemergent) PCI, with a maximum of 2 de novo coronary artery lesions with reference vessel diameter 2.5 to 3.75 mm and length ≤24 mm as assessed by online quantitative coronary angiography (QCA) or visual estimation. In the case of multiple target lesions, each needed to be in a different epicardial vessel and each must meet eligibility criteria. In addition, 1 nontarget lesion in a nontarget vessel was allowed to be treated during the index procedure. Treatment of the nontarget lesion was required before randomization, and had to be successful and uncomplicated for randomization to proceed. Patients with recent myocardial infarction (MI) without biomarker return to normal, unstable cardiac arrhythmias and left ventricular ejection fraction <30% were excluded. Patients were also excluded for prior PCI in the target vessel within the past 12 months or in a nontarget vessel within the previous 30 days, or if future staged PCI either in a target vessel or nontarget vessel was planned. Left main stenoses, bifurcation lesions with a side branch ≥2.0 mm diameter or ≥50% diameter stenosis (DS) or requiring guidewire protection, ostial lesions, lesions with moderate or heavy calcification, myocardial bridges, and thrombus were also not eligible. Additional inclusion and exclusion criteria are detailed in the Online Appendix.

RANDOMIZATION AND ENROLLMENT. A total of 480 eligible patients who provided written informed consent were randomized in a 1:1 ratio to receive BVS or CoCr-EES at 24 sites in China. Randomization was stratified by diabetes status and the planned number of treated lesions, which included 3 options: single-target lesion, dual-target lesion, and 1 target lesion and 1 nontarget lesion. Randomization was performed via an interactive voice response system or an interactive web response system. Patients were considered enrolled in the trial at the time of randomization.

TREATMENT STRATEGY, MEDICATIONS, AND FOLLOW-UP. Pre-dilation was required, with post-dilation per investigator discretion. Each target lesion had to be covered by a single study stent, although use of a second device as randomized was allowed for edge dissection or other procedural issues. A loading dose of aspirin (≥300 mg) and either clopidogrel (≥300 mg) or ticagrelor (180 mg) 6 to 24 h before the

ABBREVIATIONS AND ACRONYMS

ABR = angiographic binary restenosis

BVS = bioresorbable vascular scaffold(s)

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

DS = diameter stenosis

LL = late loss

MI = myocardial infarction

MLD = minimum lumen diameter

PoCE = patient-oriented composite endpoint