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3-Year Clinical Outcomes With Everolimus-Eluting Bioresorbable Coronary Scaffolds

The ABSORB III Trial

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ABSTRACT

BACKGROUND The Absorb everolimus-eluting poly-L-lactic acid–based bioresorbable vascular scaffold (BVS) provides early drug delivery and mechanical support functions similar to metallic drug-eluting stents (DES), followed by complete bioresorption in approximately 3 years with recovery of vascular structure and function. The ABSORB III trial demonstrated noninferior rates of target lesion failure (cardiac death, target vessel myocardial infarction [TVMI], or ischemia-driven target lesion revascularization) at 1 year in 2,008 patients with coronary artery disease randomized to BVS versus cobalt-chromium everolimus-eluting stents (EES).

OBJECTIVES This study sought to assess clinical outcomes through 3 years following BVS implantation.

METHODS Clinical outcomes from the ABSORB III trial were analyzed by randomized treatment assignment cumulative through 3 years, and between 1 and 3 years.

RESULTS The primary composite endpoint of target lesion failure through 3 years occurred in 13.4% of BVS patients and 10.4% of EES patients ($p = 0.06$), and between 1 and 3 years in 7.0% versus 6.0% of patients, respectively ($p = 0.39$). TVMI through 3 years was increased with BVS (8.6% vs. 5.9%; $p = 0.03$), as was device thrombosis (2.3% vs. 0.7%; $p = 0.01$). In BVS-assigned patients, treatment of very small vessels (those with quantitatively determined reference vessel diameter <2.25 mm) was an independent predictor of 3-year TLF and scaffold thrombosis.

CONCLUSIONS In the ABSORB III trial, 3-year adverse event rates were higher with BVS than EES, particularly TVMI and device thrombosis. Longer-term clinical follow-up is required to determine whether bioresorption of the polymeric scaffold will influence patient prognosis. (ABSORB III Randomized Controlled Trial [RCT] [ABSORB-III]; NCT01751906) (J Am Coll Cardiol 2017;■:■–■) © 2017 by the American College of Cardiology Foundation.

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ABBREVIATIONS AND ACRONYMS

BVS = bioresorbable vascular scaffold(s)

DES = drug-eluting stent(s)

EES = everolimus-eluting stent(s)

ID-TLR = ischemia-driven target lesion revascularization

MI = myocardial infarction

PCI = percutaneous coronary intervention

QCA = quantitative coronary angiography

RVD = reference vessel diameter

TLF = target lesion failure

TVMI = target vessel myocardial infarction

Despite improvements in clinical and angiographic measures of restenosis with the evolution in percutaneous coronary intervention (PCI) from balloon angioplasty to bare-metal stents and subsequently to drug-eluting stents (DES) (1), there remains a 2% to 3% per year incidence of stent-related events beyond 1 year following implantation regardless of stent type; this ongoing annual risk lasts at least 15 years (2–4). The pathogenesis of these events may relate to the common presence of a metallic frame, which distorts and constrains the vessel; limits vasomotion and adaptive vascular remodeling; and serves as nidus for chronic inflammation, neoatherosclerosis, thrombosis, and strut fracture (5). With the specific intent of improving very late clinical outcomes, fully bioresorbable vascular scaffolds (BVS) were developed that completely resorb within several years after PCI, restoring more normal vascular structure and function. In the ABSORB III randomized trial, the everolimus-eluting poly-L-lactic acid-based Absorb BVS was demonstrated to be noninferior to the everolimus-eluting fluoropolymer-based cobalt-chromium Xience stent (EES) for the occurrence of target lesion failure (TLF) (composite of cardiac death, target vessel myocardial infarction [TVMI], or ischemia-driven target lesion revascularization [ID-TLR]) at 1 year following PCI, resulting in U.S. regulatory approval of Absorb (6). Recent reports from smaller randomized trials and observational studies have suggested an incremental increase in device thrombosis and MI with Absorb beyond 1 year after implantation (7–11), in part due to scaffold dismantling during the bulk erosion process (12,13). Characterizing the true frequency of these very late adverse events has been limited by the modest size of prior randomized trials and reported follow-up through only 2 years in many studies. In this context, we analyzed the 3-year clinical outcomes following treatment with Absorb BVS and Xience EES in the ABSORB III trial.

METHODS

The ABSORB III trial study design, major inclusion and exclusion criteria, endpoints, definitions, and 1-year results have been previously described in detail (6,14). Patients undergoing PCI of 1 or 2 de novo native coronary artery lesions in separate epicardial coronary vessels were eligible for enrollment. Target lesions were required to be no more than 24 mm in length, with reference vessel diameters of 2.5 to 3.75 mm by visual assessment. Patients with acute MI and specific complex lesion features were excluded.

All patients received a loading dose (≥300 mg) of aspirin within 24 h prior to PCI and a loading dose of a $P2Y_{12}$ receptor antagonist either prior to or within 1 h of PCI completion. Successful pre-dilation of the target lesion was required before randomized assignment in a single-blind fashion (2:1 ratio) to treatment with BVS or EES, respectively. Randomization was stratified by the presence of diabetes status, the number of target lesions, and clinical site. After device implant, high-pressure post-dilation with an appropriately sized noncompliant balloon (≤0.5 mm larger than nominal scaffold diameter) was recommended. By protocol, dual antiplatelet therapy was prescribed for at least 1 year post-PCI, and aspirin (≥81 mg daily) was continued indefinitely.

Independent study monitors verified all data from case report forms. An independent clinical events committee unaware of treatment assignment adjudicated all major adverse cardiac events, and quantitative coronary angiographic (QCA) analyses were performed at a central core laboratory. An independent data and safety monitoring committee periodically reviewed outcomes data and recommended study continuation without modification.

Clinical endpoints have previously been described and included the primary study endpoint of TLF at 1 year (powered for noninferiority), with pre-specified and powered major secondary endpoints including 1-year rates of angina, all revascularization, and ischemia-driven target vessel revascularization (6,14). Follow-up is ongoing annually through 5 years, and is currently complete through 3 years.

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