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Incidence and Imaging Outcomes of Acute Scaffold Disruption and Late Structural Discontinuity After Implantation of the Absorb Everolimus-Eluting Fully Bioresorbable Vascular Scaffold

Optical Coherence Tomography Assessment in the ABSORB Cohort B Trial (A Clinical Evaluation of the Bioabsorbable Everolimus Eluting Coronary Stent System in the Treatment of Patients With De Novo Native Coronary Artery Lesions)

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ABSTRACT

OBJECTIVES This study sought to describe the frequency and clinical impact of acute scaffold disruption and late strut discontinuity of the second-generation Absorb bioresorbable polymeric vascular scaffolds (Absorb BVS, Abbott Vascular, Santa Clara, California) in the ABSORB (A Clinical Evaluation of the Bioabsorbable Everolimus Eluting Coronary Stent System in the Treatment of Patients With De Novo Native Coronary Artery Lesions) cohort B study by optical coherence tomography (OCT) post-procedure and at 6, 12, 24, and 36 months.

BACKGROUND Fully bioresorbable scaffolds are a novel approach to treatment for coronary narrowing that provides transient vessel support with drug delivery capability without the long-term limitations of metallic drug-eluting stents. However, a potential drawback of the bioresorbable scaffold is the potential for disruption of the strut network when over-expanded. Conversely, the structural discontinuity of the polymeric struts at a late stage is a biologically programmed fate of the scaffold during the course of bioresorption.

METHODS The ABSORB cohort B trial is a multicenter single-arm trial assessing the safety and performance of the Absorb BVS in the treatment of 101 patients with de novo native coronary artery lesions. The current analysis included 51 patients with 143 OCT pullbacks who underwent OCT at baseline and follow-up. The presence of acute disruption or late discontinuities was diagnosed by the presence on OCT of stacked, overhung struts or isolated intraluminal struts disconnected from the expected circularity of the device.

RESULTS Of 51 patients with OCT imaging post-procedure, acute scaffold disruption was observed in 2 patients (3.9%), which could be related to overexpansion of the scaffold at the time of implantation. One patient had a target lesion revascularization that was presumably related to the disruption. Of 49 patients without acute disruption, late discontinuities were observed in 21 patients. There were no major adverse cardiac events associated with this finding except for 1 patient who had a non-ischemia-driven target lesion revascularization.

CONCLUSIONS Acute scaffold disruption is a rare iatrogenic phenomenon that has been anecdotally associated with anginal symptoms, whereas late strut discontinuity is observed in approximately 40% of patients and could be viewed as a serendipitous OCT finding of a normal bioresorption process without clinical implications. (ABSORB Clinical Investigation, Cohort B [ABSORB B]; NCT00856856) (J Am Coll Cardiol Intv 2014;7:1400–11) © 2014 by the American College of Cardiology Foundation.

Fully bioresorbable scaffolds are a novel approach for treatment of coronary narrowing that provides transient vessel support with drug delivery capability without the long-term limitations of metallic drug-eluting stents, such as permanent caging with either outward bulging (evagination) of the luminal wall outside of the "cage," or intracage neoatherosclerosis (1,2). By freeing the coronary artery from metallic caging, the vessel thereby recovers its pulsatility, and vasomotion becomes again responsive without any constraint to the biochemical milieu, the endothelial shear stress, and the physiological cyclic strain (3,4). The technology has the potential to overcome many of the safety concerns associated with metallic drug-eluting stents and could possibly even provide further clinical benefit (5).

In the ABSORB (A Clinical Evaluation of the Bioabsorbable Everolimus Eluting Coronary Stent System in the Treatment of Patients With De Novo Native Coronary Artery Lesions) cohort A trial, the first generation of the Absorb everolimus-eluting fully bioresorbable polymeric vascular scaffolds (Absorb BVS, Abbott Vascular, Santa Clara, California) showed a low event rate with a late lumen enlargement from 6 months to 2 years. At 5 years, the absence of metallic material allowed the noninvasive anatomical as well as functional assessment by multislice computed tomography of arteries previously treated with a bioresorbable scaffold (4,6,7). In the subsequent ABSORB cohort B trial, the second generation of the Absorb BVS showed a low late loss of 0.19 mm without any reduction of the scaffold area at 6 months by intravascular ultrasound (IVUS) and optical coherence tomography (OCT) (8,9). At 12-month follow-up, the angiographic late loss was 0.27 ± 0.32 mm, with an unchanged scaffold area. In addition, vasomotion induced by ergonovine and acetylcholine followed by intracoronary nitrate became detectable again, suggesting that the scaffolds mechanical integrity had subsided. At 24-month follow-up, the angiographic late loss remained stable (0.27 ± 0.20 mm) with a late enlargement of the scaffold that compensated for the neointimal growth as detected by OCT (10–12).

However, a potential drawback of this new technology is the risk for disruption of the strut network when it is overexpanded. Historically, the phenomenon was documented for the first time in an anecdotal case from the ABSORB cohort A trial. A 3.0-mm scaffold was overexpanded with a 3.5-mm balloon, resulting in scaffold disruption as documented by OCT (7). Due to the recurrence of anginal symptoms at 40 days, this patient underwent repeat revascularization despite an angiographically nonsignificant stenosis by quantitative coronary angiography (QCA) (diameter stenosis of 42%) (13). It is important that this acute mechanical disruption, is distinguished from the structural discontinuity of the polymeric struts at a later stage, a biologically programmed process during the course of bioresorption (13–15).

ABBREVIATIONS AND ACRONYMS

BVS = bioresorbable polymeric vascular scaffolds

Dmax = maximum diameter

IVUS = intravascular ultrasound

OCT = optical coherence tomography

QCA = quantitative coronary angiography

TLR = target lesion revascularization

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