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Serial Analysis of the Malapposed and Uncovered Struts of the New Generation of Everolimus-Eluting Bioresorbable Scaffold With Optical Coherence Tomography

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Objectives The aim of this study is to assess the serial changes in strut apposition and coverage of the bioresorbable vascular scaffolds (BVS) and to relate this with the presence of intraluminal masses at 6 months with optical coherence tomography (OCT).

Background Incomplete strut/scaffold apposition (ISA) and uncovered struts are related to a higher risk of scaffold thrombosis. Bioresorbable vascular scaffolds can potentially avoid the risk of scaffold thrombosis because of its complete resorption. However, during the resorption period, the risk of scaffold thrombosis is unknown.

Methods OCT was performed in 25 patients at baseline and 6 months. Struts were classified according to apposition, coverage, and presence of intraluminal masses. Persistent ISA was defined as malapposed struts present at baseline and follow-up, and late acquired ISA as ISA developing at follow-up, and scaffold pattern irregularities when the strut distribution suggested scaffold fracture.

Results At baseline, 3,686 struts were analyzed: 128 (4%) were ISA, and 53 (1%) were located over side-branches (SB). At 6 months, 3,905 struts were analyzed: 32 (1%) ISA, and 35 (1%) at the SB. Persistent ISA was observed more frequently than late acquired-ISA (81% vs. 16%, respectively; 3% were unmatchable). Late acquired ISA was associated with scaffold pattern irregularities, which were related to overstretching of the scaffold. Uncovered struts (63 struts, 2%) were more frequently observed in ISA and SB struts, compared with apposed struts (29% vs. 1%; $p < 0.01$). Intraluminal masses (14 cross-sections, 3%; in 6 patients, 24%) were more frequently located at the site of ISA and/or uncovered struts (39% vs. 2% and 13% vs. 2%, respectively; $p < 0.01$).

Conclusions The lack of strut apposition at baseline is related to the presence of uncovered struts and intraluminal masses at 6 month. An appropriate balloon/artery ratio respecting the actual vessel size and avoiding the overstretching of the scaffold can potentially decrease the risk of scaffold thrombosis. (ABSORB Clinical Investigation, Cohort B [ABSORB B]; NCT00856856) (J Am Coll Cardiol Intv 2011;4:992–1001) © 2011 by the American College of Cardiology Foundation

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Serial intravascular ultrasound (IVUS) imaging of metallic drug-eluting stents (DES) has shown that incomplete stent/strut apposition (ISA) at follow-up can be caused by the persistence of ISA observed at baseline or by the new appearance of late acquired incomplete scaffold/strut apposition (LAISA) (1,2). Recent reports suggest that strut apposition is important for the development of strut coverage, because malapposed struts are more frequently uncovered at follow-up, as compared with apposed struts (3,4). Furthermore, the absence of neointimal coverage as well as the presence of malapposed struts have been related to late stent thrombosis, even in patients treated with dual antiplatelet therapy (5,6).

The novel everolimus-eluting bioresorbable vascular scaffolds (BVS) are promising intravascular devices that can potentially circumvent the risk of malapposed and uncovered struts at follow-up. Notably, at 2 years after implantation, the polymeric material has been shown to be resorbed with the disappearance of struts that were initially malapposed or at side branches (SBs) (7). The first-generation BVS (version 1.0) demonstrated a high rate of malapposed struts before complete resorption, with a rate of malapposed struts at 6 months higher than at baseline (6% vs. 5%, respectively; $p < 0.01$). This uncommon phenomenon was caused by a low rate of resolved malapposed struts and by the occurrence of LAISA at 6-month follow-up (8). The late scaffold area reduction (shrinkage) observed at 6 months was the most plausible explanation for the higher rate of ISA observed at follow-up compared with baseline. Despite this, only 1% of struts remained uncovered at 6-month follow-up (8).

The new-generation BVS (version 1.1) uses a new platform design and a different processing of the polymer, as compared with the previous generation of BVS (version 1.0), resulting in an increased radial force and longer retention of mechanical integrity (9). Consequently, there is now no detectable loss in scaffold area at 6 months (10,11). Nevertheless, ISA and uncovered struts can still be detected with the new generation of BVS, but the fate of these struts is unknown.

The aim of our study is to describe the serial changes of ISA and uncovered struts at baseline and at 6-month follow-up of the new generation of BVS (version 1.1), as assessed by optical coherence tomography (OCT).

Methods

Population. The ABSORB Cohort B (A Clinical Evaluation of the Bioabsorbable Everolimus Eluting Coronary Stent System [BVS EECSS] in the Treatment of Patients With de Novo Native Coronary Artery Lesions) trial is a nonrandomized, multicenter, single-arm, efficacy-safety study (12). The study included 101 patients that were allocated to 6-month angiographic and intravascular imaging control (cohort B1) or 12-month angiographic and intravascular imaging control (cohort B2). All lesions were treated with a single-size device (3 × 18 mm) of the new generation of BVS (version 1.1). The OCT imaging was an optional investigation performed in selected participating centers. In brief, the common inclusion criteria were patients 18 years of age or older, with a diagnosis of stable, unstable, or silent ischemia that presented with a de novo lesion in a native coronary artery between 50% and 99% of the luminal diameter and a Thrombolysis In Myocardial Infarction flow grade of 1 or more. Exclusion criteria included patients with an evolving myocardial infarction, stenosis of the left main or ostial right coronary artery, presence of intracoronary thrombus, or heavy calcification.

The present study is a post hoc analysis of those patients included in the ABSORB cohort B1 that were serially imaged with OCT at baseline and at 6-month follow-up.

Abbreviations and Acronyms

BVS = bioresorbable vascular scaffolds
DES = drug-eluting stents
ISA = incomplete scaffold/strut apposition
IVUS = intravascular ultrasound
LAISA = late acquired incomplete scaffold/strut apposition
OCT = optical coherence tomography
SB = side branch

BVS. The BVS version 1.1 revision is a balloon-expandable device, consisting of a polymer backbone of poly-L-lactide coated with a thin layer of a 1:1 mixture of an amorphous matrix of poly-D,L-lactide polymer containing 100 $\mu g/cm^2$ of the antiproliferative drug everolimus. The implant is radiolucent but has 2 platinum markers at each edge, which allows visualization on angiography and other imaging modalities. Physically, the scaffold has struts with an approximate thickness of 150 μm arranged as in-phase zigzag hoops linked together by 3 longitudinal bridges.

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