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Acute Gain in Minimal Lumen Area Following Implantation of Everolimus-Eluting ABSORB Biodegradable Vascular Scaffolds or Xience Metallic Stents

Intravascular Ultrasound Assessment From the ABSORB II Trial

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ABSTRACT

OBJECTIVES The study compared, by intravascular ultrasound (IVUS), acute gain (AG) at the site of the pre-procedural minimal lumen area (MLA) achieved by either the Absorb (Abbott Vascular, Santa Clara, California) scaffold or the Xience stent and identified the factors contributing to the acute performance of these devices.

BACKGROUND It is warranted that the acute performance of Absorb matches that of metallic stents; however, concern exists about acute expansion and lumen gain with the use of Absorb.

METHODS Of a total of 501 patients (546 lesions) in the ABSORB II (ABSORB II Randomized Controlled Trial) randomized trial, 445 patients with 480 lesions were investigated by IVUS pre- and post-procedure. Comparison of MLA pre- and post-procedure was performed at the MLA site by matching pre- and post-procedural IVUS pullbacks.

RESULTS Lower AG on IVUS (lowest tertile) occurred more frequently in the Absorb arm than in the Xience arm (3.46 mm^2 vs. 4.27 mm^2, respectively; $p < 0.001$; risk ratio: 3.04; 95% confidence interval: 1.94 to 4.76). The plaque morphology at the MLA cross-section was not independently associated with IVUS acute gain. The main difference in AG in MLD by angiography was observed at the time of device implantation (Xience vs. Absorb, Δ+1.50 mm vs. Δ+1.23 mm, respectively), whereas the gain from post-dilation was similar between the 2 arms (Δ+0.16 mm vs. Δ+0.16 mm) when patients underwent post-dilation, although expected balloon diameter was smaller in the Absorb arm than in the Xience arm ($p = 0.003$) during post-dilation.

CONCLUSIONS At the site of the pre-procedural MLA, the increase of the lumen post-procedure was smaller in the Absorb-arm than in the Xience arm. To achieve equivalent AG to Xience, the implantation of Absorb may require more aggressive strategies at implantation, pre- and post-dilation than the technique used in the ABSORB II trial. (ABSORB II Randomized Controlled Trial [ABSORB II]; NCT01425281) (J Am Coll Cardiol Intv 2016;9:1216–27)

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The fully bioresorbable scaffold is a novel device to treat coronary artery stenosis, potentially minimizing the long-term complications seen with metallic drug-eluting stents. The everolimus-eluting Absorb bioresorbable vascular scaffold (Absorb, Abbott Vascular, Santa Clara, California) made of poly-L-lactide (PLLA) provides a temporary coronary scaffolding for at least 6 months and becomes fully resorbed by approximately 3 years (1). The first-in-humans trial using the Absorb showed excellent safety results with potential late benefits such as late lumen enlargement and restoration of vasomotion (2). The ABSORB II (ABSORB II Randomized Controlled Trial; NCT01425281) study is the first randomized trial between the Absorb scaffold and Xience metallic stents in patients with up to 2 de novo native coronary lesions (3,4).

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It is warranted that the acute performance of Absorb matches that of metallic stents; however, concern exists about acute expansion and lumen gain with the use of a polymeric device. In the ABSORB first-in-humans trial, post-procedural intravascular ultrasound (IVUS) imaging demonstrated that implantation of an Absorb scaffold resulted in a more eccentric lumen with nonhomogeneous scaffold expansion compared with metallic stents (5). Furthermore, nonrandomized matched population from the ABSORB and SPIRIT trials demonstrated that angiographic acute gain in lumen diameter tends to be smaller in the Absorb than in the Xience (6). This trend was also observed in the randomized Japanese ABSORB trial (7-9). In the ABSORB II randomized trial, pre-procedural and post-procedural documentary IVUS imaging were mandatory and provided a unique opportunity to evaluate the scaffold/stent expansion at the precise site of pre-procedural minimal lumen area (MLA) and to relate the degree of expansion to the mechanical performance of both devices, procedural parameters of implantation and tissue composition derived from IVUS analyses (4).

Therefore, the purpose of this study was to investigate the IVUS acute gain at the site of minimal lumen area between the Absorb scaffold and the Xience stent and to identify the factors contributing to the acute performance of these devices.

ABBREVIATIONS AND ACRONYMS

IVUS = intravascular ultrasound

MLA = minimal lumen area

MLD = minimal lumen diameter

QCA = quantitative coronary angiography

METHODS

STUDY DESIGN AND POPULATION. The ABSORB II study was a randomized controlled trial comparing the safety and efficacy of the Absorb everolimus-eluting bioresorbable vascular scaffold and the Xience everolimus-eluting metallic stent in patients with up to 2 de novo native coronary lesions. Details of the study are available elsewhere (3). After successful pre-dilation of the target lesion, 2:1 randomization was performed. Of a total of 501 patients (546 lesions), 335 patients (364 lesions) were randomly assigned to receive Absorb device, and 166 patients (182 lesions) were assigned to receive the Xience device. Grayscale IVUS and IVUS-virtual histology (VH) imaging pre-procedure and post-implantation was mandatory but documentary. No treatment recommendation on the basis of IVUS imaging was made in the protocol.

STUDY DEVICE. The Absorb device has an amorphous poly-DL-lactide (PDLLA) coating that contains and controls the release of the antiproliferative drug everolimus. The scaffold is made of semicrystalline PLLA. PLLA is completely biodegraded by hydrolysis into water and CO_2 via the Krebs cycle. Physically, the scaffold has struts with an approximate thickness of 150 μm. The Xience device is an everolimus-eluting, cobalt chromium alloy device with a platform consisting of serpentine rings connected by links fabricated from a single piece. The overall strut thickness including the drug coating is approximately 90 μm.

PROCEDURE AND IVUS ACQUISITION. Pre-procedural IVUS was mandatory before dilation of the target lesion. If it was not technically feasible (e.g., the IVUS catheter could not cross the lesion), pre-dilation with a small balloon was allowed to facilitate the IVUS catheter insertion.

IVUS images were obtained with a rotational 45-MHz IVUS catheter (Revolution, Volcano Corp.,

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