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Diagnostic Accuracy of Coronary CT Angiography for the Evaluation of Bioresorbable Vascular Scaffolds

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ABSTRACT

OBJECTIVES The purpose of this study was to assess the diagnostic accuracy of coronary computed tomography angiography (CTA) for bioresorbable vascular scaffold (BVS) evaluation.

BACKGROUND Coronary CTA has emerged as a noninvasive method to evaluate patients with suspected or established coronary artery disease. The diagnostic accuracy of coronary CTA to evaluate angiographic outcomes after BVS implantation has not been well established.

METHODS In the ABSORB II (A Bioresorbable Everolimus-Eluting Scaffold Versus a Metallic Everolimus-Eluting Stent II) study, patients were randomized either to receive treatment with the BVS or everolimus-eluting metallic stent. At the 3-year follow-up, 238 patients (258 lesions) treated with BVS underwent coronary angiography with intravascular ultrasound (IVUS) evaluation and coronary CTA. The diagnostic accuracy of coronary CTA was assessed by the area under the receiver-operating characteristic curve with coronary angiography and IVUS as references.

RESULTS The mean difference in coronary CTA-derived minimal luminal diameter was −0.14 mm (limits of agreement −0.88 to 0.60) with quantitative coronary angiography as reference, whereas the mean difference in minimal lumen area was 0.73 mm^2 (limits of agreement −1.85 to 3.30) with IVUS as reference. The per-scaffold diagnostic accuracy of coronary CTA for detecting stenosis based on coronary angiography diameter stenosis of ≥50% revealed an area under the receiver-operating characteristic curve of 0.88 (95% confidence interval [CI]: 0.82 to 0.92) with a sensitivity of 80% (95% CI: 28% to 99%) and a specificity of 100% (95% CI: 98% to 100%), whereas diagnostic accuracy based on IVUS minimal lumen area ≤2.5 mm^2 showed an area under the receiver-operating characteristic curve of 0.83 (95% CI: 0.77 to 0.88) with a sensitivity of 71% (95% CI: 44% to 90%) and a specificity of 82% (95% CI: 75% to 87%). The diagnostic accuracy of coronary CTA was similar to coronary angiography in its ability to identify patients with a significant lesion based on the IVUS criteria ($p = 0.75$).

CONCLUSIONS Coronary CTA has good diagnostic accuracy to detect in-scaffold luminal obstruction and to assess luminal dimensions after BVS implantation. Coronary angiography and coronary CTA yielded similar diagnostic accuracy to identify the presence and severity of obstructive disease. Coronary CTA might become the method of choice for the evaluation of patients treated with BVS. (J Am Coll Cardiol Img 2018;11:722–32) © 2018 by the American College of Cardiology Foundation.

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Coronary computed tomography angiography (CTA) has emerged as a noninvasive method to evaluate patients with suspected or established coronary artery disease (CAD). The luminal angiographic evaluation combined with atherosclerotic plaque characterization has been shown to provide diagnostic and prognostic information (1,2). Furthermore, the adoption of coronary CTA into the work-up of patients with suspected CAD has been shown to improve the prescription of guideline-directed medical treatment (i.e., statins) (3,4).

Nonetheless, in patients with known CAD who had undergone percutaneous coronary revascularization with metallic stents, a lower diagnostic performance of coronary CTA has been reported compared with patients with de novo lesions, mainly due to the artifact created by the metal in the coronary lumen (5,6). The radiolucency of the polymeric backbone in the Absorb everolimus-eluting bioresorbable vascular scaffold (BVS) allows for coronary CTA imaging without beam-hardening artifacts. In the first-in-human study, coronary CTA was performed at 18 and 72 months after the implantation of the BVS. Qualitative and quantitative coronary luminal evaluation was found to be feasible in more than 80% of the patients at both follow-up periods (7). However, the absence of concurrent invasive imaging precluded validation of the noninvasive findings.

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In the ABSORB II (A Bioresorbable Everolimus-Eluting Scaffold Versus a Metallic Everolimus-Eluting Stent II; NCT01425281) study, systematic invasive and coronary CTA evaluations were performed in all patients treated with BVS at the 3-year follow-up (8). We sought to investigate the diagnostic accuracy of coronary CTA to evaluate angiographic outcomes after BVS implantation with coronary angiography and intravascular ultrasound (IVUS) examination as references.

METHODS

STUDY DESIGN. The ABSORB II trial was a prospective, randomized, active-controlled, single-blind, parallel 2-arm, multicenter clinical trial. A total of 501 subjects were randomized either to treatment with the everolimus-eluting BVS (Abbott Vascular, Santa Clara, California) or the everolimus-eluting metallic stent (Xience, Abbott Vascular) in a 2:1 ratio at 46 sites in Europe and New Zealand. The trial protocol allowed the treatment of up to 2 de novo noncomplex native coronary artery lesions (9). All patients provided informed consent before being included in the trial and all participating sites received medical ethics committee approval for the study. Subjects had clinical follow-up at 30 and 180 days and 1, 2, and 3 years. Invasive (i.e., coronary angiography and IVUS) and noninvasive (i.e., coronary CTA) evaluation was scheduled at the 3-year follow-up. Abbott Vascular funded the study.

ABBREVIATIONS AND ACRONYMS

AUC = area under the curve

BVS = bioresorbable vascular scaffold

CAD = coronary artery disease

CTA = computed tomography angiography

IVUS = intravascular ultrasound

MLA = minimal lumen area

MLD = minimal lumen diameter

QCA = quantitative coronary angiography

STUDY DEVICE AND BIORESORPTION. The BVS 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 poly(L-lactide-co-D, L-lactide) polymer and the antiproliferative drug everolimus containing 100 μg everolimus/cm^2 scaffold (10). The scaffold is radiolucent, but has 2 radiopaque platinum markers of 244 μm at each end that allows for easy visualization on computed tomography (CT) and other imaging modalities. At 3 years, both poly-L-lactide and poly(L-lactide-co-D, L-lactide) are resorbed.

CORONARY CTA ACQUISITION AND ANALYSIS. Images were acquired from CT scanners of 64-slice and beyond (Online Table 1). Standard acquisition techniques were used, which included nitrates before image acquisition and beta-blockers in patients with a heart rate >65 beats/min, tube settings depending on patient body mass index (80 to 140 kV), and axial scan protocols for patients with lower heart rates to reduce radiation doses, all at the discretion of the sites. Images were reconstructed using thin slices (range 0.50 to 0.67 mm) and medium smooth reconstruction filters in different phases. All data were stored on a DVD for core laboratory evaluation.

Data from the coronary CTA was analyzed off-line by an independent core laboratory (Cardialysis BV, Rotterdam, the Netherlands) using a validated cardiovascular analysis package (Aquarius iNtuition software version 4.4, Terarecon, Inc., Foster City, California). Vessel cross-sections were reconstructed

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