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Impact of out-stent plaque characteristics on vascular response after second generation drug-eluting stent implantation: iMAP-intravascular ultrasound and angioscopic study

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ABSTRACT

Purpose: The purpose of this study is to elucidate the impact of out-stent plaque characteristics on vascular response after implantation of second generation drug-eluting stent (G2-DES).
Methods: Enrolled were 37 patients with 39 coronary artery lesions into which three types of G2-DES were successfully implanted (9 Nobori biolimus-, BES; 15 Xience everolimus-, EES; 15 Resolute zotarolimus-eluting stents; R-ZES). Immediately after (baseline) and one year after the implantation (follow-up), iMAP-intravascular ultrasound (IVUS) was performed to measure out-stent plaque volume (OSPV) and its components. Percent OSPV and vulnerable plaque index (VPI) were defined as percentile of OSPV to vessel volume and as percentile of lipidic plus necrotic volume to OSPV. Coronary angioscopy at follow-up rated the degree of arterial repair by neointimal stent coverage (NSC).
Results: Poor NSC was found in approximately 60% of each G2-DES. In BES, % OSPV at baseline was significantly greater in poor NSC than in good NSC (36.2 ± 3.9 vs. 27.3 ± 4.0%, P = 0.01). In EES, %OSPV was significantly greater in poor NSC than in good NSC (41.0 ± 4.1 vs. 32.6 ± 2.7%, P < 0.01). In R-ZES implantation, there was no significant difference with regards to %OSPV between poor and good NSC. In BES, VPI at baseline was significantly greater in poor NSC than good NSC (54.0 ± 5.8 vs. 42.2 ± 5.1%, P = 0.02). There was no significant difference with regards to VPI between poor and good NCS in EES and R-ZES.
Conclusions: Impact of out-stent plaque characteristics on vascular response was different among the three types of G2-DES.

1. Introduction

Although arterial repair after intracoronary implantation of drug-eluting stents (DES) depends not only on bio-suppressive drug elution from stent struts but also on solvent polymer [1], impact of out-stent plaque characteristics on arterial repair has been controversial [2]. Pathology revealed the delayed arterial repair after implantation of the first generation drug-eluting stents (G1-DES) in comparison with bare metal stents [3]. This delay was angioscopically characterized by poor neointimal stent coverage (NSC) and in-stent yellow plaque [4,5]. Autopsy revealed that NSC after G1-DES implantation delayed in cadavers with acute myocardial infarction in comparison with those with stable angina pectoris [6]. The delayed arterial repair might cause very late stent thrombosis, a serious complication of DES implantation.

In this study, we performed one-year followed up of arterial repair after implantation of the second generation drug-eluting stents (G2-DES) into patients with coronary artery disease. We employed coronary angioscopy as well as iMAP™-intravascular ultrasound (IVUS) to assess plaque characteristics [7]. The purpose of this study was to elucidate the impact of out-stent plaque volume (OSPV) and plaque vulnerability on vascular response after implantation of three types of G2-DES.

2. Methods

2.1. Study population

From July 2012 to July 2013, enrolled were consecutive 40 patients with coronary artery diseases who received successful implantation of G2-DES at their culprit lesions. For this period, we did not fail to implant G2-DES. Implanted stents were composed of Xience everolimus-eluting stents (EES, Xience®, Abbott-vascular Co., Abbott Park, IL, USA), Resolute zotarolimus-eluting stents (R-ZES, Resolute Integrity®, Medtronic Co., Minneapolis, MN, USA), and biolimus-eluting stents (BES, Nobori®, Terumo Co., Tokyo, Japan). Selection of G2-DES depended on operator's preference. Immediately after the stent implantation, iMAP-IVUS were performed (baseline). When a patient received two stents, we implanted the same G2-DES as the first one. In other words, cases with hybrid stenting (bare-metal stent/DES and different types of G2-DES) were excluded from the enrollment. Dual antiplatelet therapy, 75 mg clopidogrel and 100 mg aspirin, had been continued at least for one year until follow-up coronary angiography (CAG). Two patients were withdrawn from the follow-up because of stroke and non-cardiac death.

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Follow-up CAG was performed at one year after the stent implantation, revealing in-stent restenosis in a patient who was withdrawn from further intracoronary imaging analyses. Subsequently, 39 stents in 37 patients, i.e. 18 acute coronary syndrome (ACS) and 19 stable angina pectoris (SAP), were subjected to iMAP™-IVUS and coronary angioscopy (follow-up). The study protocol was approved by our institutional review board. A written informed consent was obtained from each patient before his or her participation.

2.2. iMAP-IVUS analyses

IVUS was performed by iMAP™-system (Boston Scientific Corp, Fremont, CA, USA). A 3.6 Fr 40 MHz IVUS catheter (Atrantis SR Pro 2; Boston Scientific Corporation, Minneapolis, MN) was introduced into a coronary artery. First, gray-scale IVUS provided planimetric data throughout stent length at every 0.5 mm interval. Vessel area was defined as inner area within outer border of sonolucent zone. Vessel volume and stent volume were calculated by integral from distal to proximal edge of each stent (Fig. 1). Out-stent plaque volume (OSPV) was defined as subtraction of stent volume from vessel volume. Percent OSPV (%OSPV), a representative parameter for plaque burden, was calculated as ratio of OSPV to vessel volume.

Second, iMAP system provided the tissue characterization of out-stent plaques [7]. On the cross section images, iMAP coded the out-stent plaques as light-green (fibrotic), yellow (lipidic), pink (necrotic), light-blue (calcified), and artifact area. Artifact area was caused by interference of guide wires (ignored area). Employing EchoPlaque Analysis software (INDEC Medical Systems, Santa Clara, CA), fractions of each component in out-stent plaques were calculated by integral throughout stent length at every 0.5 mm interval (Fig. 1). To assess out-stent plaque vulnerability, we tentatively defined vulnerable plaque index (VPI) as ratio of lipidic plus necrotic volume to total OSPV.

2.3. Coronary angioscopy

Coronary angioscopy (Visible™, Fiber-tech, Tokyo) was performed through a 6 Fr sheath under continuous flush of 3% dextran 40 as described previously [8,9]. It visualized in-stent appearance, i.e. grade of neointimal stent coverage (NSC), presence of yellow plaque, and mural thrombus. NSC was classified into two grades, poor or good coverage [10]. Poor NSC was corresponded to grade 0–1, and good NSC was corresponded to grade 2–3 according to previous report methods [2,5]. When both grades were observed in a stent, dominant grade of NSC was assigned to the grade of the entire stented segment. All angioscopic data were evaluated by 2 angioscopic specialists blinded to the patient characteristics.

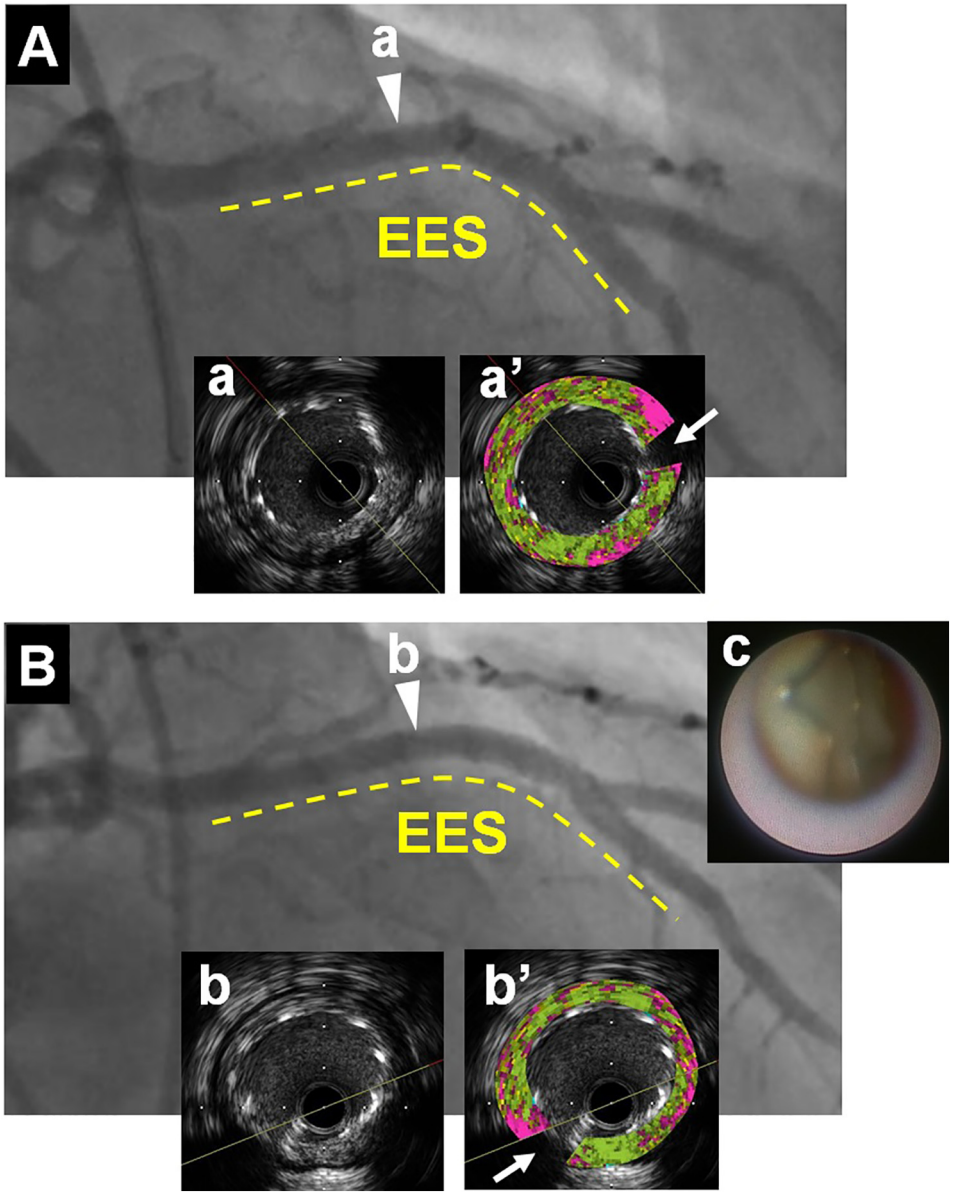

Fig. 1. A representative case. At baseline (A), EES (dotted line) was successfully implanted into proximal LAD, a culprit lesion of anterior acute myocardial infarction, in a 70-year-old male. At the center of EES (arrowhead), cross sectional images of gray-scale IVUS (a) and iMAP-IVUS (a') were shown. Planimetry of out-stent plaque was done in the former. The out-stent plaque was colorized on the basis of tissue characteristics (a'). Artifact area caused by guide wire interference was excluded for iMAP analysis (arrow). Integral of each area throughout the stent gave each volume. At follow-up (B), cross sectional images of gray-scale IVUS (b) and iMAP-IVUS (b') were shown. From baseline to follow-up, %OSPV reduced from 55.7 to 42.8%. VPI reduced from 61 to 56%. Coronary angioscopy was performed only at follow-up, showing yellow plaque and stent struts covered with thin transparent neointima (poor coverage) (c).