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Original article

Comparison of angioscopic findings among second-generation drug-eluting stents

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ABSTRACT

Background: First-generation drug-eluting stents (DES) have reduced short-term stent failure as compared to bare-metal stents due to the inhibition of neointima hyperplasia, but instead increased the risk of very-late stent failure. Although better outcomes have been reported for second-generation DES than for first-generation DES, the difference in the angioscopic findings at 1-year follow-up has not been adequately elucidated among second-generation DES.
Methods: Consecutive 161 patients who received angioscopic examination at 1 year after implantation of second-generation DES, i.e. Nobori biolimus-eluting stents (Terumo, Tokyo, Japan) (N-BES, $n = 25$), Xience everolimus-eluting stents (Abbot Vascular, Santa Clara, CA, USA; X-EES, $n = 95$), or Resolute zotarolimus-eluting stents (Resolute Integrity; Medtronic, Minneapolis, MN, USA; R-ZES, $n = 41$), in de novo native coronary lesions were analyzed.
Results: Maximum neointima coverage grade (N-BES, 0.9 ± 0.3; X-EES, 1.2 ± 0.4; R-ZES, 1.5 ± 0.5; $p < 0.001$) was the highest in R-ZES and lowest in N-BES. Heterogeneity score was higher in R-ZES than in N-BES (N-BES, 0.8 ± 0.4; X-EES, 0.9 ± 0.4; R-ZES, 1.1 ± 0.5; $p = 0.007$). Maximum yellow color grade and prevalence of thrombus were not different. Multivariate analysis demonstrated that only stent type was associated with maximum neointima coverage grade; stent type and total stent length were associated with heterogeneity score; and stenting for acute coronary syndrome (ACS) and total stent length were associated with maximum yellow color grade.
Conclusions: Neointima coverage and heterogeneity were mainly determined by stent type even among second-generation DES, while yellow color was determined mainly by whether target lesion was of ACS.
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Introduction

First-generation drug-eluting stents (DES), i.e. Cypher sirolimus-eluting stents (C-SES) (Cordis, Bridgewater, NJ, USA) and Taxus paclitaxel-eluting stents (T-PES) (Boston Scientific, Natick, MA, USA), have reduced short-term stent failure as compared to bare-metal stents due to the inhibition of neointima hyperplasia, but instead increased the risk of stent thrombosis and target lesion revascularization (TLR), i.e. very-late stent failure (VLSF) [1,2]. Although better outcome has been reported for second-generation DES [3–13], the difference in the angioscopic findings at 1-year follow-up has not been adequately elucidated among second-generation DES.

Methods

Study design

This was a single-center observational study to compare the angioscopic findings of stented lesion at 1 year after implantation among Nobori biolimus-eluting stents (N-BES) (Nobori; Terumo, Tokyo, Japan), Xience everolimus-eluting stents (X-EES) (Xience V, PRIME and Xpedition; Abbot Vascular, Santa Clara, CA, USA), and Resolute zotarolimus-eluting stents (R-ZES) (Resolute Integrity; Medtronic, Minneapolis, MN, USA). Stents were selected mainly by

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the consideration of lesion length, location and morphology. N-BES was preferably selected for ostium lesions and R-ZES for tortuous lesions.

The 1-year follow-up catheterization was encouraged for all patients who received coronary intervention, but it was not performed when (1) the patient had renal dysfunction or (2) informed consent was not obtained. At the 1-year follow-up catheterization, angioscopy was encouraged for all patients who received DES implantation, but it was not performed when (1) an angioscopic specialist was not available; (2) there was not adequate time for the examination; or (3) informed consent was not obtained. We have a registry of all patients who undergo angioscopic examination. From this registry, we retrospectively analyzed for this study the consecutive patients who received implantation of N-BES (between June 2011 and December 2013), X-EES (between January 2011 and December 2013), or R-ZES (between September 2012 and December 2013) at de novo lesions of native coronary artery and had successful angioscopic examination at 1-year follow-up catheterization.

During these periods, N-BES was implanted in 114 lesions and follow-up angioscopy was performed in 26 patients; X-EES was implanted in 588 lesions and follow-up angioscopy was performed in 101 patients; and R-ZES was implanted in 198 lesions and follow-up angioscopy was performed in 46 patients without re-intervention before the follow-up. The patients who had in-stent restenosis at the follow-up (9 patients for N-BES, 38 patients for X-EES, and 8 patients for R-ZES) were not included, because we focused on clarifying the angioscopic characteristics of the stented lesion in the patients without early stent failure before 1-year follow-up. When we implanted several types of second-generation DES in the same vessel, we classified the patient according to the type of stent implanted in the most proximal lesion. Multiple vessels were not treated at the same time in the present study patients, and thus, only one stent was included for this study from a patient. Therefore, we included 25 patients with N-BES, 95 patients with X-EES, and 41 patients with R-ZES for the present analysis.

Catheterization was performed via the femoral, brachial, or radial artery approach using a 6-Fr or 7-Fr sheath and catheters. Coronary angiogram was recorded by the Innova Cardiovascular imaging system (GE Healthcare Japan, Tokyo, Japan). All patients were taking aspirin 100 mg/day and ticlopidine 200 mg/day or clopidogrel 75 mg/day (dual antiplatelet therapy) throughout the study period. GPIIb/IIIa inhibitors were not used for any patient, because they were not approved in Japan for clinical use. Hypertension was defined as blood pressure >140/90 mmHg or the use of anti-hypertensive drugs. Diabetes mellitus was defined as fasting blood glucose >126 mg/dl or the use of oral drugs for diabetes mellitus or insulin therapy. Hypercholesterolemia was defined as low-density lipoprotein cholesterol >140 mg/dl or the use of statins. Acute coronary syndrome (ACS) includes acute myocardial infarction with or without ST elevation defined by the Joint European Society of Cardiology/American College of Cardiology Committee and unstable angina defined according to the Braunwald classification. This study was approved by the Osaka Police Hospital Ethical Committee. Written informed consent was obtained from all enrolled patients.

Angioscopy

The non-obstructive coronary angioscope RX-3310A & MV-5010A (Machida, Tokyo, Japan) and optic fiber DAG-2218 LN (Machida) were used. Angioscopic observation of stented lesions was done while blood was cleared away from view by the injection of 3% dextran-40 as we have previously reported [14]. Yellow color was classified into 4 grades (0, white; 1, slight yellow; 2, yellow; and 3, intensive yellow) comparing with standard colors as we have previously reported [15,16]. Neointima coverage was classified into 3 grades (0, no coverage; 1, poor coverage; 2, complete coverage) as we have previously reported [17,18]. Thrombus was defined as white or red material that had cotton-like or ragged appearance or that presented fragmentation with or without protrusion into lumen or adherent to the luminal surface. Maximum and minimum neointima coverage grade, maximum yellow color grade, and presence or absence of thrombus was determined for each stented lesion. Presence of yellow plaque was defined as maximum yellow color grade $\geq$2. The heterogeneity score was defined as maximum–minimum neointima coverage grade to evaluate the heterogeneity of the coverage. Two specialists of angioscopy (Y.N. and K.M.) evaluated the angioscopic images. In the case of disagreement, a third reviewer (Y.U. or R.S.) served as an arbitrator. No observers had information of patient profile at the evaluation of angioscopic images. The inter- and intra-observer reproducibility for the interpretation of angioscopic images was 95% and 95% for stent coverage, 85% and 95% for plaque color, and 90% and 100% for thrombus, respectively [17].

Definition of neoatherosclerosis by angioscopy

Angioscopy cannot differentiate the yellow plaque inside the neointima and that under stent in the original vessel wall. We focused on the atherosclerosis including both, since both of the yellow plaques formed after stent implantation and those in the native coronary artery are similarly associated with thrombus formation. If a yellow plaque in the original vessel wall is covered by a thick neointima, it becomes white and stable. However, if the yellow plaque is covered by a thin neointima, it remains yellow and vulnerable. We would like to define angioscopic neoatherosclerosis as the yellow plaque formed or advanced in yellow color intensity after stent implantation, i.e. progression of atherosclerosis after stent implantation regardless of whether the yellow plaque exists in the neointima or in the original vessel wall.

Statistical analysis

Continuous data are expressed as mean $\pm$ SD. Comparison between groups was performed by one-way ANOVA with Tukey's multiple comparison test, Kruskal–Wallis test, or chi-square test. Multivariate logistic regression analysis was performed to determine the contributing factors for maximum neointima coverage grade $\geq$2, heterogeneity score $\geq$2, and maximum yellow color grade $\geq$2, including all available parameters that may theoretically have influence on, i.e. stent type, stenting for ACS, gender, diabetes mellitus, hypertension, current smoking, chronic kidney disease, statin use, eicosapentaenoic acid use, stent diameter, and total stent length as independent variables. A *p*-value <0.05 was regarded as statistically significant. All analysis was performed using SPSS (version 22.0 J for Windows, SPSS Inc., Chicago, IL, USA).

Results

Study patients

Included were 25 patients for N-BES, 95 patients for X-EES, and 41 patients for R-ZES. The interval between stent implantation and follow-up catheterization was 364 $\pm$ 78 days for N-BES, 392 $\pm$ 74 days for X-EES, and 393 $\pm$ 38 days for R-ZES. The patients, lesions, and procedural characteristics are presented in Tables 1 and 2. Representative cases of N-BES, X-EES, and R-ZES are shown in Fig. 1.

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