Journal of Cardiology 60 (2012) 270–276

Contents lists available at SciVerse ScienceDirect

Journal of Cardiology

journal homepage: www.elsevier.com/locate/jjcc

Original article

Serial change and its determinants of residual plaque characteristics under sirolimus-eluting stent: A coronary angioscopic study

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ARTICLE INFO

Article history:
Received 15 January 2012
Received in revised form 16 May 2012
Accepted 18 May 2012
Available online 21 July 2012

Keywords:
Angioscopy
Cardiovascular disease
Prevention
Cholesterol-lowering drugs
Stent

ABSTRACT

Objectives: To examine serial change in the residual plaque behind the sirolimus-eluting stent (SES) using coronary angioscopy in patients with SES implantation and to identify its baseline determinants.
Background: Previous coronary angioscopic studies have demonstrated that SES enhances the yellow grade of residual plaque during follow-up period.
Methods: A total of 42 patients with stable angina pectoris or silent ischemic heart disease, who had a successful SES implantation were examined by coronary angioscopy both at the baseline (SES implantation) and the follow-up period (9–14 month follow-up). The patients were divided into three groups as: worsened group (WS: yellow color grade of coronary plaque at the follow-up period was worsened compared to the baseline period, $n = 15$), no change group (NP: no change compared to the baseline, $n = 16$), and improved group (IP: improved compared to the baseline, $n = 11$). Then, the determinants of the nominal change of yellow color grade were examined by multiple regression analysis.
Results: The low-density lipoprotein cholesterol (LDL-C) level in IP group at the follow-up was significantly decreased compared to baseline (from 120.0 ± 29.8 mg/dl to 74.3 ± 16.7 mg/dl, $p = 0.0005$), and was the lowest among three groups (WS: 103.5 ± 16.4 mg/dl, NC: 105.7 ± 18.7 mg/dl, and IP: 74.3 ± 16.7 mg/dl). Multiple regression analysis revealed that family history, statin administration, baseline serum creatinine, baseline 'in-stent' thrombus, and follow-up LDL-C were significant determinants to the nominal change of yellow color grade after the SES implantation ($p < 0.0001$).
Conclusions: Serial change in tissue characteristics within residual plaque under SES is determined by several factors, especially LDL-C level as well as statin administration. Adequate management of LDL-C by statins might be crucial for stabilizing residual plaque after SES implantation.
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Introduction

Drug-eluting stents such as sirolimus-eluting stent (SES) are well known to prevent the proliferation of smooth muscle cells; however, absent or poorly formed neointima appears to increase the risk of stent thrombosis, especially when there is a yellow plaque under the stent [1]. More coronary yellow plaques have been reported to be associated with a higher risk of stenosis progression within seven months [2]. Moreover, SES implantation has been reported to increase the yellow color grade of residual plaque behind the struts [3], which might be unfavorable. Previous coronary angioscopic studies have demonstrated that lowering of low-density lipoprotein-cholesterol (LDL-C) with 3-hydroxy-3-methylglutaryl-coenzymeA reductase inhibitor (statin) therapy stabilizes yellow color grade of coronary plaques [4]. However, the effect of statins on residual plaque under implanted SES is unknown.

The purpose of the present study was to examine serial changes in the residual plaque behind the SES using coronary angioscopy in patients with SES implantation and to identify its baseline determinants. The effect of statin on this change was also assessed.

Methods

Study design

A total of 42 patients who met the following criteria were enrolled in this retrospective observational study from January 2005 through December 2010 in Nihon University Hospital. The

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http://dx.doi.org/10.1016/j.jjcc.2012.06.002

entry criteria were as follows: (1) patients with stable angina pectoris or silent ischemic heart disease were enrolled; (2) SES were successfully implanted on a new coronary lesion due to significant angiographic stenosis without using any additional interventional devices; (3) coronary angiography and angioscopy were performed in the baseline period just after SES implantation as well as at the follow-up periods (9–14 months: an average of 11.2 ± 2.3 months after the implantation). The exclusion criteria were: (1) patients with acute coronary syndrome; (2) coronary arteries in which lesions were not suitable for angioscopic examination such as left main coronary artery; (3) patients with heart failure, uncontrolled hypertension, uncontrolled severe diabetes mellitus, liver or kidney dysfunction, hemodialysis, or secondary dyslipidemia. All patients had provided written informed consent, and this study was approved by the ethical committee at the Nihon University Hospital.

At baseline, coronary risk factors for each patient were identified such as smoking, hypertension, diabetes mellitus, hyperuremia, dyslipidemia, and family history. At baseline and follow-up, body mass index (BMI), serum concentration of LDL-C, high-density lipoprotein cholesterol (HDL-C), LDL-C/HDL-C ratio (L/H ratio), serum creatinine (sCr), triglyceride, serum uremic acid, hemoglobin A1c (HbA1c), and high-sensitivity C-reactive protein (hsCRP) were measured. The level of LDL-C was measured directly using a LDL-C kit (Cholestest® LDL, Sekisui Medical Co. Ltd., Tokyo, Japan), which uses differences in affinities of detergents to lipoproteins. Then, management of LDL-C level and the control of other types of coronary risk factor were undertaken following the Japan Atherosclerosis Society (JAS) guidelines [5] for coronary artery disease. The type of statin used for each patient was determined by the doctor who treated the patient. Some patients did not take statin because of side effects or decisions by the doctor during the observation period.

Coronary angiography and percutaneous coronary intervention

All coronary angiograms and interventions were performed in Nihon University Itabashi Hospital. Catheterization was performed by the brachial or femoral artery approach, using a 6 or 7Fr sheath and catheter. For the coronary segment with more than 75% angiographic stenosis with ischemic symptoms of coronary artery disease, SES implantation was performed.

Angioscopic procedure and evaluation

A non-occlusion type of coronary angioscopic system (Machida Endoscope Co. Ltd., Tokyo, Japan) was used in all patients. Before the angioscopic observation, the white balance was adjusted for color correction. Angioscopic studies were performed while the blood was cleared away by the injection of 3% dextran-40, as previously reported [6]. During the observation, an experienced assistant adjusted the light power to keep a regular degree of brightness on the target plaque as well as to avoid excessive reflection. The angioscopic images were recorded by hard disk recorder. The yellow color grade of targeted lesion was evaluated after the stent implantation in all patients of this study. The degree of yellowness of the culprit plaques behind the stent was graded as 0 (white), 1 (light yellow), 2 (yellow), or 3 (intense yellow) as previously reported [6], and the maximal yellow color grade of the coronary plaque behind the stent was determined, and regarded as the yellow color grade in this study. The observer variability for assessing the yellow color grade was already validated in the previous study [4,7]. This grade

Table 1a
Patient characteristics.

	Profiles				*p*-Value			
	All	Worse (WS)	No change (NC)	Improved (IP)	Overall	Tukey–Kramer		
N	42	15	16	11	(ANOVA)	WS vs. NC	WS vs. IP	NC vs. IP
Age	66.7 ± 9.2	61.8 ± 8.0	70.0 ± 9.6	68.6 ± 7.8	0.0286*	0.030*	0.1246	0.9137
Male	26 (61.9%)	9 (60.0%)	8 (50.0%)	9 (81.8%)	0.2424	–	–	–
Smoking	21 (50.0%)	9 (60.0%)	7 (43.8%)	5 (45.5%)	0.6247	–	–	–
Hypertension	32 (76.2%)	14 (93.3%)	12 (75.0%)	6 (54.5%)	0.0712	–	–	–
Diabetes mellitus	19 (45.2%)	8 (53.3%)	7 (43.8%)	4 (36.4%)	0.6836	–	–	–
Hyperuremia	5 (11.9%)	2 (13.3%)	1 (6.3%)	2 (18.2%)	0.6280	–	–	–
Dyslipidemia	34 (81.0%)	13 (86.7%)	11 (68.8%)	10 (90.9%)	0.2767	–	–	–
Family history	12 (28.6%)	7 (46.7%)	3 (18.8%)	2 (18.2%)	0.1538	–	–	–
Patients coronary profile								
Target lesion LAD	23 (54.8%)	7 (46.7%)	10 (62.5%)	6 (54.5%)		–	–	–
LCX	8 (19.0%)	1 (66.7%)	4 (25.0%)	3 (27.3%)	0.1943	–	–	–
RCA	11 (26.2%)	7 (46.7%)	3 (18.8%)	2 (18.2%)		–	–	–
Medicine profile								
Statin (%)	33 (78.6%)	11 (73.3%)	11 (68.9%)	11 (100%)	0.1249	–	–	–
ARB	19 (45.2%)	8 (53.3%)	4 (25.0%)	7 (63.6%)	0.1030	–	–	–
Ca blocker	19 (45.2%)	8 (53.3%)	8 (50.0%)	2 (27.3%)	0.3723	–	–	–
α-Blocker	1 (2.4%)	0 (0.0%)	0 (0.0%)	1 (9.1%)	0.2361	–	–	–
β-Blocker	19 (45.2%)	8 (53.3%)	7 (43.8%)	4 (36.4%)	0.6836	–	–	–
Allopurinol	4 (9.5%)	2 (13.3%)	1 (6.3%)	1 (90.1%)	0.7969	–	–	–
Diuretics	3 (7.1%)	0 (0.0%)	2 (12.5%)	1 (9.1%)	0.3850	–	–	–
Nitroglyceride	9 (21.4%)	3 (20.0%)	2 (12.5%)	4 (36.4%)	0.3274	–	–	–
Nicorandil	27 (64.3%)	8 (53.3%)	10 (62.5%)	9 (81.8%)	0.3200	–	–	–
Sulfonylurea	9 (21.4%)	3 (20.0%)	3 (18.8%)	3 (27.3%)	0.8566	–	–	–
Pioglitazone hydrochloride	4 (9.5%)	1 (6.7%)	2 (12.5%)	1 (9.1%)	0.8569	–	–	–
Warfarin	2 (4.8%)	1 (6.7%)	0 (0.0%)	1 (9.1%)	0.5029	–	–	–

This table shows the clinical characteristics of all patients. Among the patients examined, the yellow grade of residual plaque behind SES was divided into three groups, which were worsened in 15 patients (WS group), unchanged in 16 patients (NC group), and improved in 11 patients (IP group).
Continuous variables are expressed as mean ± SD. Comparisons of continuous variables among three groups were performed using one-way ANOVA and Tukey–Kramer's HSD analysis. Comparisons of the categorical variables presented as numbers (percentage) were performed by either the chi-square test or Fisher's exact test.
WS, worsen group (yellow color grade of coronary plaque at the follow-up period was worsened compared to the baseline period); NC, no change group (no change compared to the baseline); IP, improved group (improved compared to the baseline); LAD, left anterior descending coronary artery; LCX, left circumflex coronary artery; RCA, right coronary artery; ARB, angiotensin receptor blocker.
* $p < 0.05$ was considered to significant.

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