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ORIGINAL ARTICLE

Full-metal jacket technique using second-generation drug-eluting stent: clinical and angiographic follow-up in 2 years

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Abstract

The aims of this study are to evaluate the efficacy of percutaneous coronary intervention (PCI) using full-metal jacket (FMJ) with second-generation drug-eluting stents (DES). A single-center, non-randomized, retrospective study was performed from May 2005 to February 2014 at Miyazaki Medical Association Hospital, Japan. PCI using FMJ with DES was performed to treat 240 very long lesions (> 60 mm) in 240 patients. Subjects were divided into a first-generation or second-generation DES group. The primary endpoint was the incidence of major adverse cardiac events (MACE) at 2 years. MACE included all-cause death, myocardial infarction (MI), cerebrovascular event, and target vessel revascularization. The secondary endpoint was binary restenosis (> 50% stenosis) assessed by angiography at 1 year of follow-up. Second-generation DES were implanted to treat 121 lesions, and the first-generation DES were implanted to treat 119 lesions. Since 35 patients were lost to follow-up, the final analysis included 102 patients with second-generation DES and 103 with first-generation DES. At the 2-year follow-up, the incidence of MACE was significantly less in the second-generation DES group (9.8% vs. 20.4%, $p = 0.03$). The incidence of binary restenosis at 1 year was also significantly lower in the second-generation DES group (6.7% vs 29.1%, $p < 0.01$). When PCI was performed using FMJ with DES to treat very long lesion, the angiographic and clinical outcomes were better with second-generation than first-generation DES.

Keywords Stable angina · Diffuse disease · Drug-eluting stent

Introduction

Long stents or multiple stents may play an important role in PCI for the treatment of long lesions. However, in a bare-metal stent era, longer stented segment was an independent predictor of restenosis [1]. After introducing the drug-eluting stent (DES), DES reduced the restenosis and was widely used to complex lesions. DES was also effective in the treatment of long, complex coronary artery lesions [2]. Small- or single-center registries have suggested that DES implantation to the long lesion like FMJ is safe and get acceptable immediate and late clinical outcomes [3–5]. However, there are some fears for stent thrombosis, difficulty of revascularization to future restenosis, and long-term patency [6–10]. On the contrary, incomplete lesion coverage is an independent risk factor for the restenosis and stent thrombosis [11]. Second-generation DES is thinner strut and more flexible than the first-generation DES and some has anti-thrombotic or biocompatible polymer. Second-generation DES has potential to overcome this embarrassment when treating long lesions. However, there are a few reports on follow-up in patients who undergo PCI using FMJ with second-generation DES [12–14]. Therefore, we sought to evaluate the efficacy of FMJ with second-generation DES.

Methods

Patient population

The present study was a single-center, non-randomized, retrospective study in Miyazaki Medical Association Hospital, Japan. We examined consecutive patients who underwent PCI using FMJ for de novo coronary stenosis (Fig. 1). FMJ

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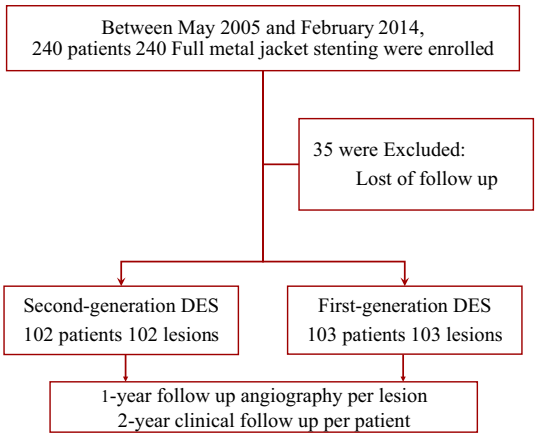

Fig. 1 Study flow diagram

was defined as a continuous segment of stenting measured that > 60 mm in a native coronary artery. A total of 7339 cases were treated by PCI from May 2005 to February 2014 in this single center. Among them, FMJ with DES for de novo coronary stenosis was performed in 240 patients to treat 240 lesions. Those were divided into 121 patients treated with second-generation DES and 119 treated with first-generation DES. Since 35 patients were lost to follow-up, the final analysis included 102 patients with 102 lesions treated with second-generation DES, and 103 patients with 103 lesions treated with first-generation DES. The second-generation DES group included everolimus-eluting stents, biolimus-eluting stents, and zotarolimus-eluting stents. The first-generation DES group included sirolimus-eluting stents and paclitaxel-eluting stents. The primary endpoint was the incidence of major adverse cardiac events (MACE) at 2 years. MACE included all-cause death, myocardial infarction (MI), cerebrovascular event, and target vessel revascularization. The secondary endpoint was binary restenosis (> 50% stenosis) at follow-up angiography. All patients provided informed consent for both the procedure and subsequent data collection and analysis for research purposes. Ethics approval was obtained from the Institution Review Board of Miyazaki Medical Association Hospital.

Stenting procedure

All PCI procedures were performed using the standard techniques. The choice of treatment strategy, DES selection, and the need for post-implant dilatation were left to the operator´s discretion. Protection of side branches was encouraged, with "jailing" of wires as required. A degree of overlap between stents was required, but the degree of overlap was intentionally minimized. A chronic total occlusion was defined as an artery occluded for > 3 months with Thrombolysis in Myocardial Infarction grade 0 flow at the start of the procedure [15]. The duration of dual antiplatelet therapy ranged from a minimum of 12 months to long-term (defined as extending beyond 12 months).

Quantitative coronary angiography (QCA)

Angiographic measurements were made during diastole using a guiding catheter to calibrate magnification. A QCA analysis system (CAAS 5.7, Pie Medical Imaging, Maastricht, The Netherlands) was used to analyze baseline coronary angiograms using the single projection showing the most severe stenosis. The percentage diameter stenosis, minimal lumen diameter, and reference vessel diameter were measured before dilatation, after stenting, and at 1-year follow-up.

Follow-up

Clinical follow-up was achieved through clinic visits, telephone calls, and records from hospital admissions at 1 and 2 years. Angiographic follow-up was performed in all patients at 1 year after PCI. The measured endpoints during follow-up were the incidence of MACE at 2 years. Out-of-hospital MI was defined as a creatine kinase level of two times the upper limit of normal with a positive creatine kinase-MB level and appropriate history of symptoms or electrocardiographic changes.

When out-of-hospital MI was diagnosed clinically, it was coded as FMJ-related MI unless coronary angiography demonstrated an acute occlusion in a non-FMJ vessel during the same hospital admission. Target vessel revascularization included repeat PCI or surgical intervention in a previously treated vessel.

Angiographic restenosis (binary restenosis) was defined as a luminal stenosis of > 50% at the site of PCI, or within 5 mm of the treated segment, and was calculated by a dedicated team of researchers using computer-assisted QCA.

A cerebrovascular event was defined as an ischemic or hemorrhagic event with clinical and neurological symptoms due to acute damage of the brain.

Statistics

For continuous variables, normally distributed data are reported as the mean ± the standard deviation; nonparametric data are reported as the median and interquartile range. For categorical variables, data are presented as counts and percentages. The cumulative incidence of adverse events was calculated according to the Kaplan–Meier method, and Kaplan–Meier curves for endpoints were censored at the time of the first event or at 2 years, whichever occurred first. A 2-sided p value of < 0.05 was considered statistically

significant. All statistical analysis was performed using SPSS version 22.0 (SPSS, Inc, Chicago, IL).

Results

Patient characteristics

There were 240 patients who underwent PCI using FMJ with DES to treat native coronary lesions. The mean age of patients was 68.7 ± 10.5 years, and 78.8% were males. The demographic and clinical characteristics of patients are provided in Table 1. There were no significant differences between the two groups.

Lesion and procedural characteristics

There were 240 native coronary lesions that were treated using FMJ with DES. The lesion characteristics and procedural details are provided in Table 2. The most commonly treated vessel was the right coronary artery followed by the left anterior descending artery and the left circumflex artery. Rotational atherectomy was performed in 17.1% of the cases. Chronic total occlusion was present in 10.0% of the lesions. The use of imaging devices (intravascular ultrasound or optical coherence tomography) was not significantly different between the two groups. The mean length of all the stents that covered the vessel was 74.4 ± 13.6 mm, and the frequency of ≧3 stents implanted per vessel was 60.4%. In the first-generation DES group, most of the cases were treated using sirolimus-eluting stents (sirolimus-eluting stents 79.8%; paclitaxel-eluting stents 20.1%). In the second-generation DES group, everolimus-eluting stents were used in the majority of lesions (everolimus-eluting stents 84.3%; biolimus-eluting stents 11.6%; zotarolimus-eluting stents 4.1%).

Quantitative coronary angiography findings

There were 205 lesions that had angiographic follow-up at 1 year (12 ± 2 months) (Table 3). The pre- and post- PCI reference diameters and percent diameter stenosis were similar between the two groups. The pre-PCI minimum lumen diameter was smaller in the second-generation DES group than the first-generation DES group (0.42 ± 0.35 vs 0.60 ± 0.42 mm, $p = 0.03$). Despite a lower pre-PCI minimum lumen diameter in the second-generation DES group, the post-PCI minimum lumen diameter was not significantly different between the second-generation and first-generation DES groups (2.64 ± 0.39 vs 2.69 ± 0.40 mm, $p = 0.77$).

At 1 year of follow-up, binary restenosis was seen in 37 lesions (18.0%). There was significantly less binary restenosis in the second-generation DES group (6.7% vs. 29.1%, $p < 0.01$). In the second-generation DES group, the minimum lumen diameter was significantly larger (2.18 ± 0.60 vs 1.75 ± 0.77 mm, $p < 0.01$), and the percent diameter stenosis was significantly lower (22.0 ± 20.0 vs 37.1 ± 26.3%, $p < 0.01$).

Table 1 Patient characteristics

	Total $n = 240$	Second DES $n = 121$	First DES $n = 119$	p value
Male, *n* (%)	189 (78.8)	96 (79.3)	93 (78.2)	0.82
Age (years)	68.7 ± 10.5	69.6 ± 10.2	68.0 ± 10.7	0.24
Risk factors, *n* (%)				
Hypertension	189 (78.8)	102 (84.3)	87 (73.1)	0.06
Dyslipidemia	164 (68.3)	85 (70.2)	79 (66.4)	0.52
Diabetes mellitus	106 (44.2)	55 (45.5)	51 (42.9)	0.69
Smoking	102 (42.5)	49 (40.5)	53 (44.5)	0.13
Family history	20 (8.3)	10 (8.3)	10 (8.4)	0.97
Hemodialysis	7 (2.9)	5 (4.1)	2 (1.7)	0.26
Clinical presentation, *n* (%)				
Previous CABG	11 (4.6)	5 (4.1)	6 (5.0)	0.74
Old myocardial infarction	79 (32.9)	36 (29.8)	43 (36.1)	0.29
Acute coronary syndrome	10 (4.1)	7 (5.7)	3 (2.5)	0.38
Renal failure (eGFR < 60)	93 (38.8)	48 (39.7)	45 (48.4)	0.77
eGFR	61.4 ± 19.6	59.4 ± 19.6	63.4 ± 19.6	0.14
LDL cholesterol (mg/dl)	110.0 ± 68.2	104.2 ± 90.8	115.7 ± 32.8	0.23

CABG coronary artery bypass grafting, *eGFR* estimated glomerular filtration rate (ml/min/1.73 m^2), *LDL* low density lipoprotein

Table 2 Lesion and procedural characteristics

	Total $n = 240$	2nd DES $n = 121$	1st DES $n = 119$	p value
Target vessel, *n* (%)				
LAD	110 (45.8)	53 (43.8)	57 (47.9)	
LCX	18 (7.5)	7 (5.8)	11 (9.2)	0.39
RCA	112 (46.7)	61 (50.4)	51 (42.9)	
Chronic total occlusion, *n* (%)	24 (10.0)	15 (12.4)	9 (7.6)	0.21
Imaging device, *n* (%)	225 (93.7)	116 (95.9)	109 (91.6)	0.15
Rotablator, *n* (%)	41 (17.1)	16 (13.2)	25 (21.0)	0.11
Stent length, mm	74.4 ± 13.6	73.6 ± 13.5	75.6 ± 14.2	0.29
Mean stent diameter, mm	2.74 ± 0.33	2.67 ± 0.37	2.81 ± 0.29	0.15
Number of stent ≧ 3, *n* (%)	145 (60.4)	65 (53.7)	80 (67.2)	0.03
Drug eluting stent, *n* (%)				
Sirolimus eluting stent			95 (79.8)	
Paclitaxel eluting stent			24 (20.1)	
Everolimus eluting stent		102 (84.3)		
Biolimus eluting stent		14 (11.6)		
Zotarolimus eluting stent		5 (4.1)		

LAD left descending artery, *LCX* left circumflex artery, *RCA* right coronary artery

Table 3 Quantitative coronary angiography findings

	Total $n = 205$	Second DES $n = 102$	First DES $n = 103$	p value
Quantitative coronary angiography (pre)				
Reference diameter (mm)	2.49 ± 0.62	2.38 ± 0.57	2.57 ± 0.65	0.51
Minimum lumen diameter (mm)	0.52 ± 0.40	0.42 ± 0.35	0.60 ± 0.42	0.03
Percent diameter stenosis (%)	79.7 ± 15.0	83.3 ± 14.0	77.0 ± 15.3	0.16
Quantitative coronary angiography (post)				
Reference diameter (mm)	2.79 ± 0.40	2.76 ± 0.42	2.83 ± 0.37	0.29
Minimum lumen diameter (mm)	2.67 ± 0.40	2.64 ± 0.39	2.69 ± 0.40	0.77
Percent diameter stenosis (%)	4.0 ± 9.1	3.8 ± 7.5	4.3 ± 10.4	0.05
Quantitative coronary angiography (1 year)				
Reference diameter (mm)	2.81 ± 0.45	2.80 ± 0.41	2.82 ± 0.47	0.26
Minimum lumen diameter (mm)	1.96 ± 0.73	2.18 ± 0.60	1.75 ± 0.77	< 0.01
Percent diameter stenosis (%)	29.8 ± 24.6	22.0 ± 20.0	37.1 ± 26.3	< 0.01
Binary restenosis (1 year), *n* (%)	37 (18.0)	7 (6.7)	30 (29.1)	< 0.01

MACE at 2 years of follow-up

At the 2-year follow-up, there were five deaths (2.4%, two from cardiovascular causes), there were no case of non-procedure related MI and stent thrombosis, and 25 patients (12.2%) had undergone target vessel revascularization. MACE occurred in 31 patients (15.1%) (Table 4). The incidence of MACE was significantly lower in the second-generation DES group (9.8% vs. 20.4%, $p = 0.03$). Freedom from MACE is shown in Fig. 2.

At the 2-year follow-up, the incidence of target vessel revascularization was significantly less in the second-generation DES group (Fig. 2, 5.9% vs. 18.4%, $p < 0.01$).

Table 4 Major adverse cardiac event at 2 years

	Total $n=205$	Second DES $n=102$	First DES $n=103$	p value
2-year MACE, n (%)	31 (15.1)	10 (9.8)	21 (20.4)	0.03
All-cause death, n (%)	5 (2.4)	3 (2.9)	2 (1.9)	0.25
Myocardial infarction, n (%)	0	0	0	
Cerebrovascular event, n (%)	1 (0.5)	1 (1.0)	0	
Target vessel revascularization, n (%)	25 (12.2)	6 (5.9)	19 (18.4)	<0.01

MACE major adverse cardiac events

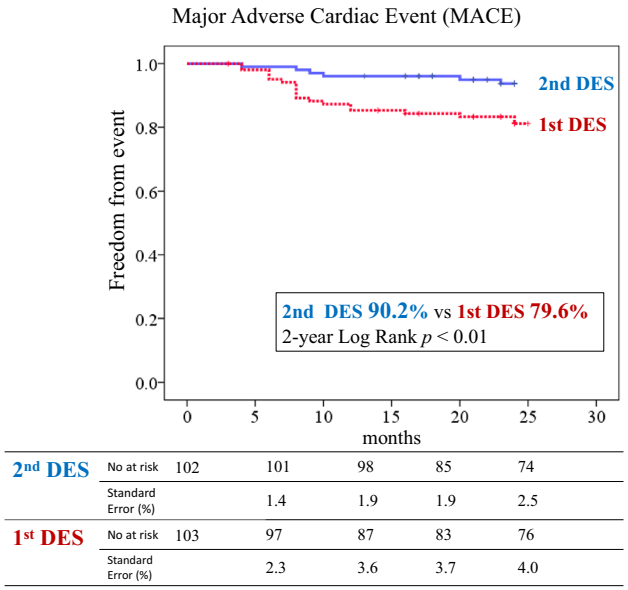

Fig. 2 Kaplan–Meier curves that show survival free from major adverse cardiac events for the second-generation and first-generation DES groups. A log-rank test was used to compare the 2 curves

Discussion

In the present study, we evaluated the efficacy of FMJ with second-generation DES. The efficacy of FMJ with second-generation DES was better than that of FMJ with first-generation DES. Non-procedure-related MI and stent thrombosis were not observed during follow-up in either group. The acceptable short-term incident of MACE suggests that FMJ with second-generation DES is effective for the treatment of diffuse coronary lesions.

Diffuse coronary lesions often pose technical challenges for the operator and are often associated with disappointing clinical outcomes [6–10]. Longer stent length is generally associated with an increased risk of restenosis and stent thrombosis [1]. Although medical therapy and surgical revascularization are alternative treatment options, PCI is expected to achieve effective revascularization due to recent improvements in stent technology, procedural techniques, and antiplatelet pharmacotherapy.

There are several differences between second-generation and first-generation DES. First, second-generation DES have a new stent platform that consists of a thinner cobalt–chromium or platinum–chromium alloy, and which makes the deliverability easier than first-generation DES. Thinner struts also help to preserve the lumen area at sites of strut overlap. Second, second-generation DES are more biocompatible than first-generation DES. They may result in less inflammation and more rapid vessel endothelialization or healing. Third, second-generation DES have longer length of struts than first-generation DES (maximum stent length 38 mm vs 33 mm). Therefore, second-generation DES reduce the number of stents and overlap sites needed to cover long lesions [16].

Furthermore, in the second-generation DES era, dual antiplatelet therapy (aspirin plus platelet P2Y12 receptor blocker) was established based on the prevention of post-PCI ischemic events. Especially, patients with complex lesions tend to be treated with more prolonged dual antiplatelet therapy for the prevention of ischemic events [17].

Due to these changes, randomized trials in patients with simple coronary lesions have shown second-generation DES to be superior to first-generation DES for composite outcomes that include death, MI, stent thrombosis, and revascularization [18–20]. For more complex lesions, second-generation DES have also been shown to be superior. Second-generation DES implantation for unprotected left main coronary disease, bifurcation lesions, and ostial lesions is associated with a reduced incidence of adverse events compared with first-generation DES implantation [21–23]. DES have been reported to be superior to bare-metal stents for the treatment of long coronary lesions [3]. However, there is little clinical evidence on the treatment of coronary lesions with second-generation DES.

Our study demonstrated the advantage of second-generation DES, over first-generation DES in terms of efficacy when PCI was performed using FMJ. In the first-generation DES group, the incidence of MACE was more frequent, and the majority of events were target vessel revascularization for restenosis. Restenosis sites with first-generation

DES tended to occur at sites of stent overlap site. Development of dedicated devices, drug and polymer coatings, and especially thinner struts may have decreased the restenosis rate with second-generation DES. In addition, a longer stent length reduced number of stents that need to be implanted and the restenosis rate at the site of stent overlaps with second-generation DES. Because of disappointing results of FMJ using first-generation DES, we were hesitant in the past to treat diffused coronary lesions. First-generation DES are no longer used in daily practice. It is time to reconsider FMJ using second-generation DES.

Fortunately, there were no cases of stent thrombosis resulting in out-of-hospital MI. This might have been due to the short duration of follow-up and small sample size.

Study limitations

This study has several limitations. First, this was a non-randomized, retrospective observational study between May 2005 and February 2014. Second-generation DES was mainly used in the latter years with several potential advantages over the early years as follows: (1) more antiplatelet therapies became available in the latter years, (2) the strategy and technique for chronic total occlusion lesions improved over time, and (3) some imaging devices were introduced or improved. Ideally, a study should be performed in which patients to FMJ with either first- or second-generation DES. Second, this study was conducted at a single center. However, PCI in this study was performed with a standard strategy, so our results should be similar to those at other institutions. Third, follow-up was not continued beyond 2 years in this study. Longer term follow-up is required to describe the long-term superiority of second-generation DES to treat long lesions. Fourth, in the first-generation DES group, there was no information regarding the presence of ischemic symptoms or signs, such as chest pain, myocardial perfusion imaging with radioisotopes, or fractional flow reserve. Therefore, we could not identify clinically driven events.

Conclusion

The results of FMJ with second-generation DES were better than the results with first-generation DES. Second-generation DES are more effective than first-generation DES to treat diffuse coronary lesions when the FMJ approach is used.

Compliance with ethical standards

Conflict of interest The authors have no conflicts of interest to declare.

Human rights statements and ethical standards All procedures followed were in accordance with the ethical standards of the responsible committee on human experimentation (institutional and national) and with the Helsinki Declaration of 1964 and later revisions. Informed consent was obtained from all patients who were included in the study.

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