

Drug-Eluting vs. Bare-Metal Stents: Is it a Matter of Vessel Size?

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Abstract

Background: Although drug-eluting stents (DES) for percutaneous coronary intervention have dramatically reduced the incidence of in-stent restenosis, their deployment for large-size coronary lesions is still controversial because of problems such as prolonged dual antiplatelet therapy, late in-stent thrombosis and costs.

Aim: This study sought to evaluate the safety and effectiveness of drug-eluting stents (DES) compared to bare-metal stents (BMS) for patients with large coronary vessels ≥ 3.5 mm.

Methods: This is a retrospective case-control comparative study conducted in the cardiology A department of the university hospital Fattouma Bourguiba in Monastir. A total of 77 consecutive patients (80 lesions) who underwent, between October 2003 and March 2014, successfully DES implantation were compared to 73 consecutive patients (84 lesions) who were treated with BMS in large coronary vessels ≥ 3.5 mm.

Results: The average age in our population was 59.7 ± 11.3 years with a male majority without any significant difference between the two groups. The DES group contained significantly more patients with diabetes (67.5% vs. 38.1%; $p < 0.0001$) and a history of coronary heart disease (40% vs. 16.7%; $p = 0.001$). The BMS group had significantly more procedures in the aftermath of MI (18.8% vs. 40.5%; $p = 0.002$) including more primary angioplasty (6.7% against 47.1%; $p = 0.006$). About two-thirds of the study patients had multi-vessel disease with equal distribution in both groups. The average duration of dual antiplatelet therapy was significantly prolonged in the DES group: 13.01 ± 8.31 months vs. 7.59 ± 8.19 months; $p < 0.0001$. A mean follow of 27.87 ± 14.82 months was obtained. At 12 months, DES led to a significant reduction in the combined rate of major cardiac events by about 70% (OR=0.32; 95% CI: 0.119 to 0.858; $p = 0.019$) without allowing a significant reduction in the rates of in-stent restenosis, in-stent thrombosis, target vessel revascularization or non-combined major cardiac events. During long-term follow-up, the benefit of DES in terms of MACE was maintained by allowing a 60% reduction in the combined rate of major cardiac events (OR=0.406; 95% CI: 0.172 to 0.955; $p = 0.035$). Multivariate analysis identified the BMS as an independent predictor of major cardiac events and death. However, the type of stent does not appear as a factor influencing the ISR and target lesion revascularization rates.

Conclusion: The results of our study demonstrate a clear clinical benefit of drug-eluting stents during angioplasty of large coronary arteries in reducing major cardiac events and death without having any effect on in-stent restenosis, in-stent thrombosis nor target lesion revascularization.

Keywords: Large coronary arteries; Drug-eluting stent; Bare-metal stent; MACE

Abbreviations: BMS: Bare-Metal Stent; DES: Drug-Eluting Stent; PCI: Percutaneous Coronary Intervention; CABG: Coronary Artery Bypass Grafting; STEMI: ST Elevation Myocardial Infarction; NSTEMI: Non ST Elevation Myocardial Infarction; LM: Left Main; LAD: Left Anterior Descending Artery; LCX: Left Circumflex Artery; RCA: Right Coronary Artery; SES: Sirolimus-Eluting Stent; PES: Paclitaxel-Eluting Stent; EES: Everolimus-Eluting Stent; ZES: Zotarolimus-Eluting Stent; BES: Biolimus-Eluting Stent; DAPT: Dual Antiplatelet Therapy; ACE: Angiotensin-Converting Enzyme; ARB: Angiotensin Receptor Blocker; CA: Calcium Antagonist; ISR: In-Stent Restenosis; ST: Stent Thrombosis; MACE: Major Adverse Cardiac Events; MI: Myocardial Infarction; TLR: Target Lesion Revascularization; OR: Odds Ratio; CI: Confidence Interval.

Introduction

It has been clearly demonstrated through randomized trials that drug-eluting stents (DES) have dramatically reduced the rate of restenosis as compared with bare-metal stents (BMS) in percutaneous coronary intervention (PCI) [1-4]. Previous studies in patients receiving BMS's have shown an inverse relationship between vessel diameter and the likelihood of in-stent restenosis [5-7]. Thus the larger the artery diameter the lower is the rate of restenosis. Under these conditions, the advantage of DES in small-size coronary arteries has been shown in several studies [8-10]. However, for patients with stenoses in large coronary arteries ≥ 3.5 mm in diameter, the benefit of the use of DES remains controversial, because the DES still has unsolved problems such as late and very late stent thrombosis phenomenon [11-14]. Furthermore, many DES trials excluded patients with larger arteries. So far, there have been a few retrospective subgroup analyses or registries of large vessel stenting (≥ 3.5 mm) and only some studies have analyzed the clinical outcome of DES and BMS

in large-size coronary arteries [15-19]. These studies didn't seem to conclusively address the problem. Although recent studies demonstrate that clinical outcomes were not significantly different between BMS and DES in large-vessel lesions [20,21], few data exist regarding the impact of stent type on clinical outcomes in terms of both short and long-term prognoses, and whether DES are superior to BMS for larger coronary arteries in the setting of routine clinical practice still remains unknown. Therefore, the aim of this study was to analyze the clinical data of patients who underwent PCI in large size coronary lesions greater than or equal to 3.5 mm diameter using DES or BMS, and to investigate the clinical outcomes over short and long-term follow-up.

Methods

Patients and treatments

Data collection for this study and the study protocol was approved by the local medical ethics committee of the hospital.

Consecutive patients who underwent PCI in the cardiology A department in Monastir, Tunisia with large stents for lesions $\geq 70\%$ of diameter stenosis in the epicardial coronary arteries or their major branches with reference vessel diameter ≥ 3.5 mm by visual estimation on angiogram by the operator were enrolled from October 2003 to March 2014. Indications for PCI included silent ischemia, heart failure, stable angina or acute coronary syndrome with elective or emergent procedures. Among them, we analyzed patients whose outcome was followed up for at least 1 year after intervention. Patients with unavailable data were excluded from the study. The angiographic and/or clinical failure of angioplasty was also considered as a criterion of exclusion. Experienced interventional cardiologists performed coronary angiography through the femoral or radial approach with 6F catheters. Device selection of guide wires, balloon catheters, and coronary stents was made at the discretion of the PCI operator. During PCI with DES or BMS, a bolus infusion of heparin (1 mg/kg) was administered to maintain an activated clotting time of more than 200 s. As a standard, dual antiplatelet therapy with aspirin 250 mg and clopidogrel 75–300 mg was employed [22]. As a standard of care at discharge, the duration of dual antiplatelet therapy was at least 12 months to all patients treated with DES, whereas clopidogrel was prescribed for at least 1 month to patients treated with BMS. However, this duration was left to the discretion of the interventional cardiologist according to the clinical presentation, the risk of stent thrombosis as well as the hemorrhagic risk.

Clinical follow-up, definitions, and outcome

Patients were evaluated clinically during the follow-up period by visits to outpatient clinics. In patients who did not show up at the outpatient clinic, we called them to inquire about any post-PCI events, medications, and other relevant information. At the beginning of our experience, and up to 2006, a coronary angiography was systematically performed on average 9 months after angioplasty by DES. After this period, in stable patients, myocardial ischemic as well as angiographic follow-up were not routinely performed in asymptomatic patients. The follow-up coronary angiography was commonly performed when patients had chest pain, or when the attending cardiologists recommended it as needed for the particular lesion type or clinical background of the patient. Procedural success was defined as an optimal coronary flow defined as a Thrombolysis in Myocardial Infarction (TIMI) flow grade of 3 and residual stenosis of $<20\%$. Binary restenosis was defined as stenosis of $>50\%$ [5,23]. Data on baseline

demographics, clinical, and angiographic [24] and procedural characteristics during the index PCI were collected. Clinical endpoints were defined as the occurrence of in-stent restenosis (ISR), stent thrombosis (ST) which was defined according to the criteria of the Academic Research Consortium definitions [25], and major adverse cardiac events (MACE). MACE were defined as all-cause death, nonfatal myocardial infarction or any need for revascularization of the target lesion (TLR). TLR was defined as clinically driven TLR performed when the patient had ischemic symptoms, ischemic electrocardiographic changes at rest, or positive stress test results [25]. In addition, even in the absence of clear ischemia, revascularization for stenosis of $\geq 70\%$ which the operator clinically judged an indication of PCI was also considered clinically driven TLR.

Statistical analysis

Continuous variables are presented as mean \pm standard deviation (SD) and categorical variables as percentages. Categorical variables were compared between groups using the χ^2 test or Fisher's exact test when appropriate, whereas continuous variables were compared with an unpaired t-test. Event-free survival curves for cardiac events were constructed using the Kaplan–Meier method, and statistical differences between curves were assessed by the log-rank test. Because the patients were not randomly assigned to stent placement, a logistic regression analyses were used to investigate the univariate and multivariate predictors of events during follow-up, adjusting for the differences in baseline patient epidemiological, clinical, anatomical and procedural characteristics. Multivariate models included the important variables with $p < 0.2$ after univariate analysis. Data are presented as hazard ratios and 95% confidence intervals (CI). The p values were two sided, and a $p < 0.05$ was considered statistically significant. All data analyses were performed using SPSS software, version 18.0 for Windows.

Results

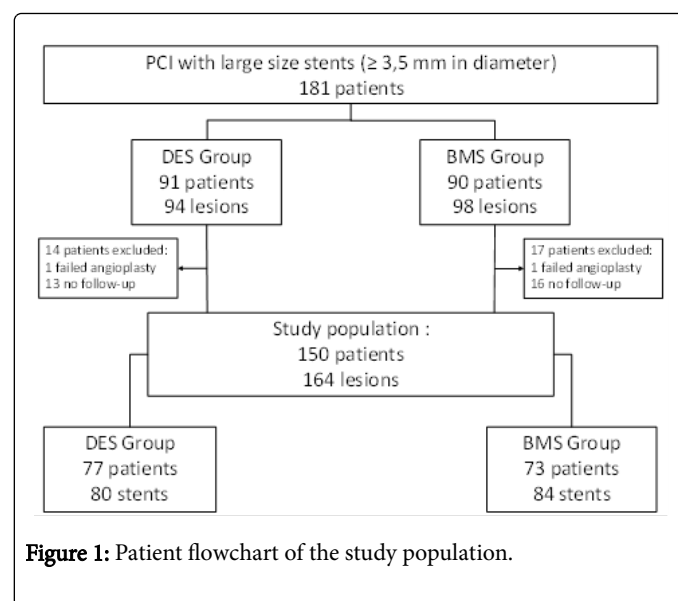


Figure 1: Patient flowchart of the study population.

Among consecutive 181 patients who underwent PCI with large stents, 150 patients and 164 lesions were eligible to enter our study (Figure 1). The mean age of patients was 59.7 ± 11.3 years, and 131 (80%) patients were men.

Baseline characteristics

The baseline characteristics of the enrolled patients are shown in Table 1. The DES group contained significantly more patients with diabetes (67.5% vs. 38.1%; $p < 0.0001$) and a history of coronary heart disease (40% vs. 16.7%; $p = 0.001$). There were no significant differences between the 2 groups in the presence of hypertension, dyslipidemia, current smoking, and chronic kidney failure. The frequency of NSTEMI and stable angina was significantly higher in the DES group than in the BMS group. On the other hand, the BMS group had significantly more procedures in the aftermath of STEMI (18.8% vs. 40.5%; $p = 0.002$) including more primary angioplasty (6.7% vs. 47.1%; $p = 0.006$). The lesions and stent characteristics are shown in Table 2. About two-thirds of the study patients had multi-vessel disease with equal distribution in both groups. There were no significant differences in lesion types between the 2 groups. The mean diameter of BMS was greater than that of DES; however DES had significantly longer average length than BMS.

	DES (N=80)	BMS (N=84)	p value
Age, years ± SD	58.4 ± 9.7	60.9 ± 12.5	0.161
Male, %	85	75	0.11
Diabetes mellitus, n (%)	54 (67.5%)	32 (38.1%)	<0.0001
Insulin treated, n (%)	19 (35.2%)	17 (53.1%)	0.1
Hypertension, n (%)	31 (38.1%)	34 (40.5%)	0.821
Dyslipidemia, n (%)	14 (16.7%)	14 (16.7%)	0.25
Current smoker, n (%)	48 (60%)	55 (65.5%)	0.468
Chronic kidney failure, n (%)	16 (23.2%)	31 (36.9%)	0.067
History of coronary heart disease, n (%)	32 (40%)	14 (16.7%)	0.001
Prior myocardial revascularization, n (%)	25 (31.3%)	12 (14.3%)	0.009
Prior angioplasty, n (%)	22 (27.5%)	10 (11.9%)	0.012
Prior CABG, n (%)	6 (7.5%)	4 (4.8%)	0.464
STEMI, n (%)	15 (18.8%)	34 (40.5%)	0.002
Thrombolysis, n (%)	5 (33.3%)	15 (44.1%)	0.476
Primary angioplasty, n (%)	1 (6.7%)	16 (47.1%)	0.006
Differed angioplasty, n (%)	14 (93.3%)	18 (52.9%)	0.006
NSTEMI, n (%)	47 (58.8%)	35 (41.7%)	0.029
Stable angina, n (%)	12 (15%)	4 (4.8%)	0.027

Table 1: Baseline patient characteristics.

	DES N=80	BMS N=84	p value
Multivessel disease, n (%)	56 (66.7%)	50 (62.5%)	0.577
Culprit artery			
LM, n (%)	11 (13.8%)	4 (4.8%)	0.046
LAD, n (%)	40 (50%)	25 (29.8%)	0.008
LCx, n (%)	11 (13.8%)	18 (21.4%)	0.198
RCA, n (%)	15 (18.8%)	35 (41.7%)	0.001
Graft, n (%)	3 (3.8%)	2 (2.4%)	0.676
AHA/ACC type, n (%)			
A, n (%)	9 (11.3%)	15 (17.9%)	0.231
B1, n (%)	28 (35%)	31 (36.9%)	0.799
B2, n (%)	32 (40%)	23 (27.4%)	0.087
C, n (%)	11 (13.8%)	15 (17.9%)	0.472
Ostial lesion, n (%)	16 (20%)	5 (6%)	0.007
Proximal lesion, n (%)	28 (35%)	35 (41.7%)	0.380
Medium and distal lesion, n (%)	36 (45%)	44 (52.4%)	0.345
Calcified lesion, n (%)	5 (6.3%)	0 (0%)	0.026
Thrombotic lesion, n (%)	7 (8.8%)	23 (27.4%)	0.002
ISR lesion, n (%)	9 (11.3%)	1 (1.2%)	0.008
Bifurcation lesion, n (%)	27 (33.8%)	14 (16.7%)	0.012
Mean lesion length, mm ± SD	14.48 ± 6.03	13.18 ± 4.78	0.131
Mean stent length, mm ± SD	18.69 ± 6.31	16.36 ± 5.24	0.011
Mean stent diameter, mm ± SD	3.54 ± 0.13	3.63 ± 0.26	0.004
1st generation DES			
SES, n (%)	10 (6.1%)	0	-
PES, n (%)	29 (17.7%)	0	-
2nd generation DES			
EES, n (%)	21 (12.8%)	0	-
ZES, n (%)	17 (10.3%)	0	-
BES, n (%)	3 (1.8%)	0	-
Predilatation, n (%)	32 (40.5%)	16 (19%)	0.003
Postdilatation, n (%)	32 (40.5%)	13 (15.5%)	<0.0001
Kissing, n (%)	20 (25%)	2 (2.4%)	<0.0001
Medication after admission			
DAPT, n (%)	80 (100%)	84 (100%)	1
Beta blocker, n (%)	72 (90%)	67 (79.8%)	0.068
ACE inhibitors, n (%)	57 (71.3%)	61 (72.6%)	0.845

ARB, n (%)	8 (9.5%)	8 (10%)	0.918
CA, n (%)	11 (13.8%)	7 (8.3%)	0.267
Statin, n (%)	77 (96.3%)	83 (98.8%)	0.358

Table 2: Lesion and stent characteristics.

Short and long-term clinical outcomes

The mean follow-up period was 27.87 ± 14.82 months with a significantly longer follow-up in the BMS group: 24.01 ± 13.51 vs. 31.55 ± 15.16 ; $p=0.001$. Angiographic control of treated lesions involved 62 (37.8%) stents. This control was significantly higher in the DES group (47.5% vs. 28.6%, $p=0.012$) with significantly more systematic control (27.5% vs. 3.6%, $p<0.0001$).

Administration of dual antiplatelet therapy with aspirin and clopidogrel was confirmed in all patients. The average duration of dual antiplatelet therapy was significantly prolonged in the DES group: 13.01 ± 8.31 months vs. 7.59 ± 8.19 months; $p<0.0001$.

At the end of the first 30 days of follow-up, there was no significant difference between the two groups in terms of primary and secondary endpoints.

At 12 months, cumulative incidence of MACE was significantly lower in the DES group than the BMS group (7.5% vs. 20.2%; OR=0.32; 95% CI: 0.119 to 0.858; $p=0.019$); however, the analysis of the separate cardiac events does not show statistically significant difference between the two groups. In addition, DES did not reduce significantly the rates of ISR, ST and TLR.

During long-term follow-up, 16 cases of ISR were observed including 6 (7.5%) in the DES group vs. 10 (11.9%) in the BMS group without reaching the significance threshold (OR=0.6, 95% CI: 0.207-1.736, $p=0.342$). The mean time to onset of ISR was later in the DES group but not significant (9.4 ± 10.17 months compared to 16.33 ± 11.57 months, $p=0.254$).

Kaplan–Meier ISR-free survival curves show early deflection during the first few months in the BMS group and then the two curves meet and remain parallel ($p=0.429$) (Figure 2).

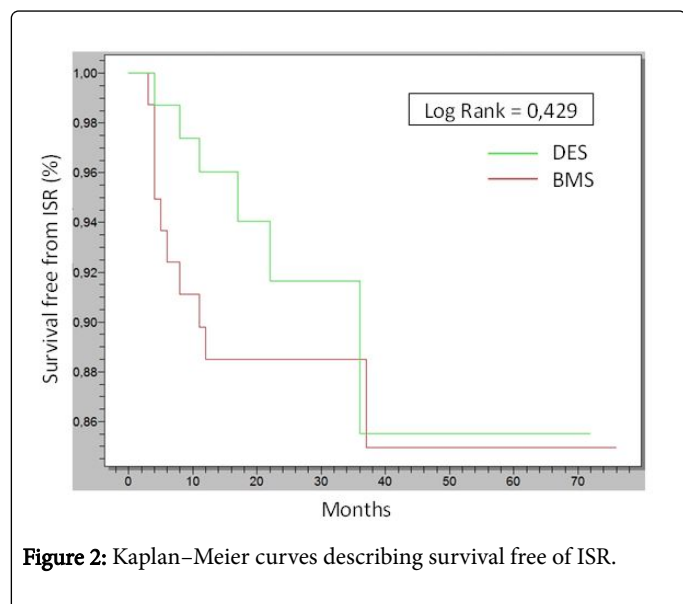


Figure 2: Kaplan–Meier curves describing survival free of ISR.

Two cases of probable sub-acute stent thrombosis occurred: the first was manifested by a sudden death on the 5th day following an angioplasty of the ostial LAD by a Taxus® stent. The second case was a NSTEMI rapidly complicated by a refractory cardiogenic shock, one month after a left main coronary artery stenting by a Resolute® in a patient who stopped clopidogrel. In addition to these two cases, a third case of possible late stent thrombosis has been documented in the DES group. This is a case of sudden death occurring one year after the implantation of a Taxus® stent on an ostial lesion of the circumflex. The incidence of stent thrombosis was not significantly different between the two groups although there were no patients with such events in the BMS group, $p=0.114$.

The benefit of DES in terms of MACE was maintained by allowing a 60% reduction in the combined rate of major cardiac events (OR=0.406; 95% CI: 0.172 to 0.955; $p=0.035$). The Kaplan–Meier curves describing survival free of MACE show a very early deflection in the first months in the BMS group ($p=0.067$) (Figure 3). As observed at one year, the analysis of separate cardiac events did not show statistically significant differences between the two groups. Kaplan–Meier analysis showed no significant difference between the two groups in survival free of TLR ($p=0.266$) or death ($p=0.135$).

During the long-term follow-up, 10 cases (6.1%) of hemorrhagic complications were noted. Only one case of gastrointestinal hemorrhage requiring blood transfusion in a patient implanted with a BMS has been reported. There was no significant difference between the DES group and the BMS group in terms of hemorrhagic complications (3.8% vs. 8.3%, OR=0.429, 95% CI: 0.107-1.719, $p=0.33$).

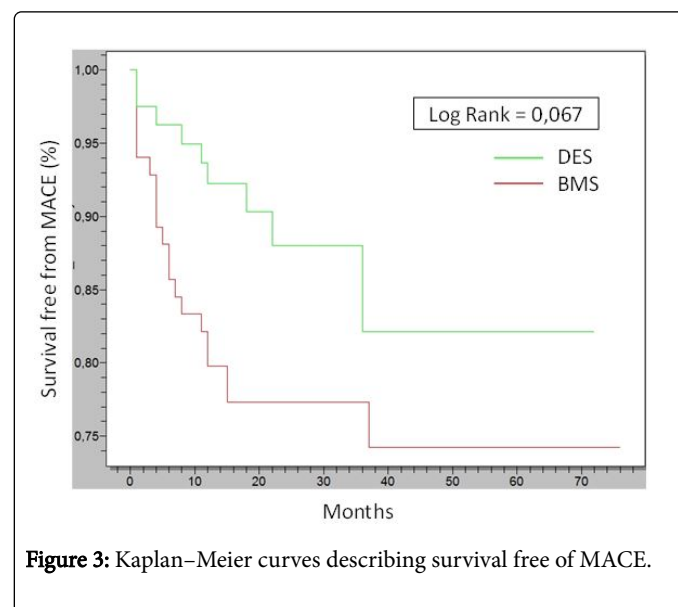


Figure 3: Kaplan–Meier curves describing survival free of MACE.

	DES (N=80)	BMS (N=84)	p value
ISR, n (%)	6 (7.5%)	10 (11.9%)	0.342
ST, n (%)	3 (3.8%)	0	0.114
MACE, n (%)	9 (11.3%)	20 (23.8%)	0.035
All-cause death, n (%)	4 (5%)	10 (11.9%)	0.114
MI, n (%)	1 (1.3%)	2 (2.4%)	1

TLR, n (%)	5 (6.3%)	10 (11.9%)	0.209
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Table 3: Long term clinical outcomes.

Predictive factors of endpoints

We performed a logistic regression analysis to determine the predictive factors for the outcome of our study's endpoints during follow-up. Due to the longitudinal nature of our study and the differences found between the two groups thus resulting in some bias for the results, we opted for the Cox model. Adjustments were made to account for differences in epidemiological, clinical, anatomical and procedural characteristics between the two groups of the study as well

as data from the literature. The covariates used in the regression model were: diabetes, history of coronary disease, renal failure, hospitalization for STEMI, bifurcation lesions and long lesions ≥ 20 mm.

Compared with patients who underwent PCI with DES, those who underwent PCI with BMS had significantly increased risk of MACE (OR=0.406; 95% CI: 0.172 to 0.955; p=0.035) in univariate analysis. As shown in Table 3, after adjusting for the above mentioned factors, the DES emerges as an independent protective factor against MACE by allowing about 70% reduction in their occurrence (HR=0.3, 95% CI: 0.126-0.718, p=0.0068). On the other hand, a history of coronary artery disease is an independent factor in the occurrence of MACE (HR=3.25, 95% CI: 1.357-7.806, p=0.0082).

Independent predictors of MACE	OR	95% CI	p value
DES	0.301	0.126-0.718	0.0068
Diabetes mellitus	1.699	0.748-3.861	0.205
History of coronary heart disease	3.255	1.357-7.806	0.0082
Chronic kidney failure	1.235	0.623-2.447	0.544
STEMI	1.188	0.459-3.075	0.721
Bifurcation lesion	1.261	0.542-2.934	0.59
Lesion length ≥ 20 mm	0.147	0.019-1.091	0.06

Table 4: Cox logistic regression for factors related to MACE.

	Before adjustment			After adjustment		
	OR	95% CI	p value	OR	95% CI	p value
MACE	0.406	0.172-0.955	0.035	0.301	0.126-0.718	0.0068
Death	0.389	0.117-1.297	0.114	0.209	0.056-0.774	0.019
TLR	0.493	0.161-1.513	0.209	0.382	0.119-1.224	0.105
ISR	0.6	0.207-1.736	0.342	0.412	0.134-1.262	0.120

Table 5: Relation between stent type (DES versus BMS) and clinical outcomes before and after adjustment

In the same way, we performed a regression for the following criteria: death, ISR and TLR (Table 4). Given the rare occurrence of ST and MI, we were unable to include them in the regression model. After adjustment, DES seems to be an independent protective factor against the occurrence of MACE and death. However, it has no effect on the occurrence of ISR and TLR (Table 5).

Discussion

The main finding of the present study of patients requiring large coronary stents (≥ 3.5 mm) was that during the median follow-up period over more than 2 years, ISR, ST, all-cause death, MI, and TLR were not significantly different between patients receiving BMS and those receiving DES. However, DES might have a benefit for preventing MACE. Interestingly, BMS was identified as an independent

predictor of major cardiac events and death; however, the type of stent does not appear as a factor influencing the ISR and target lesion revascularization rates. These results demonstrate that we should choose DES even in a large-size coronary artery ≥ 3.5 mm in diameter. Theoretically, with increasing vessel size, the benefits of DES over BMS will diminish. The inverse relationship between vessel size and restenosis rate following BMS implantation [26] may explain the equal efficacy between BMS and DES implants as reported in previous studies on large coronary artery lesions. A series of previous studies showed no significant differences in the rate of TLR and MACE between BMS and DES in patients requiring large coronary stents [15,17-19]. However, follow-up periods in these studies seemed to be relatively short to support their conclusions, because the late catch-up phenomenon and very late stent thrombosis could occur more than 1 year after stent implantation. In this study, the mean follow-up period in all patients was 27.87 ± 14.82 months. Under these conditions, the MACE rates were higher in BMS than in DES in the initial 12 months of follow-up, thus yielding overall higher MACE in BMS implanted lesions. Recent studies reported that there was no difference in TLR between BMS and DES in large coronary lesions [20,21]. However, in their study, Yoshida et al. found over 2 years of follow-up, that TLR rates were significantly higher in the BMS group than in the DES group, although there were no significant differences in the incidence of MACE between the two groups in lesions requiring large coronary stents >3.5 mm in diameter [27]. Especially in diabetic patients, TLR might be even higher in BMS than in DES as reported by a previous study [4]. Importantly, three patients suffered from stent thrombosis in the DES group. Generally, BMS is superior to DES in terms of stent thrombosis. A previous study reported that the rate of stent thrombosis was 0.34% at 30 days, 0.54% at 1 year, and 0.77% at 2 years after DES

implantation in a Japanese cohort [14]. Another study reported that an increase in inflammatory cytokines in the late phase after implantation of DES was shown and this might result in abnormal wound healing [28], although the use of DES could suppress the excessive intimal proliferation in accordance with out-stent plaque suppression [29]. Under these conditions, the likelihood of a benefit from DES may be relatively small in patients with occlusions in large coronary arteries because the rate of restenosis is low and the risk of adverse cardiac events due to late stent thrombosis may be greater than the risk among patients with small-vessel stents [30-32]. Steinberg et al. reported that implantation of DES in large coronary arteries confers no additional benefit compared with BMS, and the two approaches are associated with equally favorable clinical outcomes at 1 year [15]. Nonetheless, late or very late stent thrombosis may occur in the BMS group in case of large coronary arteries [27,33]. Positive remodelling and rupture of neoatherosclerosis in-stent segment might have been associated with late or very late BMS thrombosis [34]. In the present study, MACE was higher in BMS than in DES for simple lesions as well as in complicated lesions in large coronary arteries, suggesting BMS implantation in large coronary arteries might be inferior to DES in every type of lesion. Furthermore, we previously reported that in terms of PCI for the left main coronary, which should be the largest vessel in the coronary tree, the incidence of TLR was much greater with BMS for complex lesions than that with DES for simple lesions [35]. A previous study had shown that atherosclerotic progression of neointimal proliferation inside a BMS was observed with intravascular ultrasound over the long term, and this would be the potential for adverse clinical events [36]. A higher inflation pressure and/or greater balloon size for post-dilatation may be responsible for excessive neointimal proliferation, possibly contributing to higher incidence of TLR in BMS in the larger coronary arteries. Therefore, DES may be superior to BMS in terms of neointimal suppression even in large coronary lesions.

There remain several limitations in the present study. First, the number of patients enrolled in this study was relatively small. However, clearly significant differences were observed in the overall MACE rates between BMS and DES in the early phase after implantation into large coronary artery lesions. Second, the retrospective and non-randomized study design implies some degree of selection bias, especially since the two groups are not perfectly comparable. In fact, in observational studies, outcomes may reflect a lack of comparability in treatment groups rather than the effects of treatment. However, it should be noted that the outcome was demonstrated in consecutive patients in our hospital, and so these results might reflect a real-world population; in addition, we tried to overcome this problem by using a logistic regression. A future large-scale trial will be necessary to confirm any definitive conclusions on this subject. Third, the present study included patients treated with first-generation stents. However, the present results provide an important clinical implication regarding the selection of the next-generation stents.

Conclusion

The present study demonstrates that even in coronary lesions requiring large-size stents, the rate of MACE and death in DES was significantly reduced compared with BMS, and that there was an increased risk of unfavorable prognosis associated with BMS during the follow-up period beyond 2 years. However, the type of stent does not appear as a factor influencing the ISR, ST and TLR rates. We would suggest that DES might be encouraged in the treatment of even large-

size coronary lesions, if patients do not have any associated diseases that would preclude the use of these stents.

Conflict of Interest

The authors declare no conflict of interests.

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