



ORIGINAL ARTICLE

Bare-metal stents versus drug-eluting stents in large (≥ 3.5 mm) single coronary artery: Angiographic and clinical outcomes at 6 months

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KEYWORDS

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Summary

Background: Although drug-eluting stents (DES) have been shown to dramatically reduce restenosis and improve the rate of event-free survival in large randomized trials, the benefit of DES appears to be limited to restenosis. In large arteries, it is not clear which type of stent is more superior in angiographic and clinical outcomes between DES and bare-metal stents (BMS). We compared the angiographic and clinical outcomes of DES versus BMS in large arteries (≥ 3.5 mm).

Method: Two hundred and forty patients from March 2002 to March 2007 received stents; 196 patients were treated with DES (44.9% sirolimus-eluting stents; 43.9% paclitaxel-eluting stents; 11.2% zotarolimus-eluting stents) and 44 with cobalt–chromium BMS for single de novo lesions in a large vessel. All subjects received aspirin, clopidogrel, and/or cilostazol as the standard antiplatelet regimen. The angiographic and clinical outcomes were evaluated at 6 months.

Results: For the baseline characteristics, there were no significant differences between the DES and BMS groups. In addition, for the initially implanted stent there was no difference in the length, stent diameter, and lesion site between the two groups. After 6 months, the follow-up angiogram showed that in-stent diameter restenosis and late loss was more common with BMS than DES ($39 \pm 21\%$ vs. $19 \pm 17\%$, $p=0.007$; 1.44 ± 0.83 mm vs. 0.62 ± 0.58 mm, $p=0.009$, respectively). However, the target-lesion revascularization/target-vessel

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revascularization, and total major adverse cardiac events showed no significant differences between the groups (5.3% vs. 3.6%, $p=0.62$; 5.3% vs. 4.6%, $p=0.86$, respectively).

Conclusion: The DES and cobalt–chromium BMS placed in large coronary arteries showed equally favorable 6-month clinical outcomes, although the 6-month angiographic results appeared more favorable in the DES group than in the BMS group.

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Introduction

Since sirolimus-eluting (Cypher; Cordis Corporation, Miami, FL, USA) and paclitaxel-eluting (Taxus; Boston Scientific Corporation, San Diego, CA, USA) stents were introduced and approved by the US Food and Drug Administration (FDA) in 2003–2004, bare-metal stents (BMS) have been rapidly replaced by drug-eluting stents (DES). Many large randomized trials have demonstrated that DES markedly reduce restenosis and improve the rate of event-free survival [1–3]. However, the frequency of myocardial infarction and survival rates has not decreased with DES [4,5]. Furthermore, the advantages of DES over BMS have not been confirmed for larger coronary arteries; larger coronary arteries can adapt to intimal hyperplasia, and the need for repeat target-lesion revascularization is decreased [6–8]. Nevertheless, the utilization of DES has been widespread, regardless of the vessel size, and concerns with regard to their long-term safety and cost have been raised [9].

We investigated three types of DES and a type of cobalt–chromium BMS (Driver; Medtronic, Minneapolis, MN, USA) with regard to the 6-month clinical and angiographic outcomes for single large (≥ 3.5 mm) vessel interventions.

Methods

Study group

From March 2002 to March 2007, a database of patients was collected at the Cardiovascular Center of Guro Hospital (Seoul, Korea). Patients who were treated for large (≥ 3.5 mm) single de novo lesions located in a native coronary vessel resulting in stenosis of 70–99% of the luminal diameter were enrolled in the study. Subjects had a history of stable or unstable angina and all received percutaneous coronary intervention (PCI). The types of DES were: sirolimus-eluting stent, paclitaxel-eluting stent and zotarolimus-eluting stent (Endeavor; Medtronic) and the type of BMS was the cobalt–chromium stent (Driver;

Medtronic). The major exclusion criteria were acute ST segment elevation myocardial infarction or acute non-ST segment elevation myocardial infarction, cardiogenic shock, underlying structural heart disease including hypertrophic cardiomyopathy, previous bypass graft surgery, a serum creatinine level of more than 2.0 mg/dl, age under 18 years, contraindication or allergy to antiplatelet agents or contrast medium, life expectancy of less than 1 year, and other serious medical conditions. A total of 240 patients were selected for the study; 196 patients were treated with DES and 44 patients were treated with a BMS.

Procedures

All patients received oral aspirin (200 mg for a loading dose) and oral clopidogrel (300–600 mg for a loading dose) as the standard antiplatelet regimen. During the PCI, intravenous heparin boluses were given every hour to maintain an activated clotting time of 250–300 s. Additional use of intravenous glycoprotein IIb/IIIa inhibitors was administered at the physician's discretion. After successfully wiring to the target lesion, predilation was performed using 2.0–2.5 mm diameter balloons and then the stent was deployed until the nominal pressure (or plus 2–4 atm.) was achieved. Additional ballooning was performed if angiographically needed. After finishing the procedure, all patients were treated with aspirin (100 mg/day; indefinitely) and clopidogrel (75 mg/day; 1 month for BMS, 6–12 months for DES). Cilostazol (100 mg/day; maximum for 2 weeks) was added in 4% of DES patients and in none of BMS cases.

Pre- and postprocedural 12-lead electrocardiography was routinely performed and creatine kinase-MB levels assessed at 4 h, 12 h, and 24 h after the PCI to detect postprocedural ischemic events.

Definitions and end points

We defined a large coronary artery as one that was more than 3.5 mm in diameter. Procedural success was defined as residual stenosis $<30\%$ of the diameter with a Thrombolysis In Myocardial Infarction

(TIMI) flow grade 3, and no evidence of complications (dissection, death, and Q-wave myocardial infarction) of the PCI. Major adverse cardiac events (MACEs) included death, a Q-wave/non-Q-wave myocardial infarction, target-lesion revascularization (TLR), and target-vessel revascularization (TVR). Binary restenosis was defined as a stenosis of more than 50% of the luminal diameter in the target lesion. Late loss was defined as the difference in minimal luminal diameter between the index procedure and the follow-up angiography.

The clinical end point was a survival free of death, myocardial infarction, TLR/TVR after 6 months in the BMS versus DES groups. The angiographic outcomes compared with binary restenosis, minimal luminal diameter (MLD), and late lumen loss (LL).

Statistical analysis

All statistical analyses were done with Statistical Package for Social Science (SPSS) software (version 13.0, SPSS Inc., Chicago, IL, USA). The results are presented as means \pm standard deviation. The Student's *t*-test was used to compare differences in the continuous variables, and the Chi-square analysis was used to compare proportions in the categorical variables. The cumulative incidence of adverse events was estimated using the Kaplan–Meier method. Differences between the event-free survival curves for the two groups were compared by log-rank test. A two-sided probability value of $p < 0.05$ was considered statistically significant.

Results

Two hundred and forty patients from March 2002 to March 2007 underwent stent procedures: 196 received DES (44.9% sirolimus-eluting stents; 43.9% paclitaxel-eluting stents; 11.2% zotarolimus-eluting stents) and 44 cobalt–chromium BMS for single de novo lesions in a large vessel. The baseline characteristics are shown in Table 1. There were no significant differences in the baseline characteristics between two groups.

The procedural characteristics are displayed in Table 2. Most of the culprit vessels were the left anterior descending artery (41.7% in BMS group and 54.5% in DES group) and right coronary artery (44.4% in BMS group and 31.4% in DES group). A left main coronary artery lesion was found in 2.8% of the BMS group and 5.8% of the DES group. However, there was no lesion site difference between the BMS and DES groups. There was a tendency for the mean stent length to be longer in the DES group than in the BMS group; but this difference was not statistically significant ($p = 0.38$). In addition, there was no difference in mean stent diameter (4.01 mm in BMS and 3.96 mm in DES group, $p = 0.61$).

A coronary angiogram was performed 6 months after the initial procedure in 38 out of 44 patients in the BMS group and all 196 patients in the DES group. The 6-month clinical outcomes are shown in Fig. 1. There were no significant differences between the groups in the target-vessel and target-lesion revascularization rate (5.3% in BMS group and 3.6% in DES group, $p = 0.62$). There were two cases of MACEs that developed in the BMS group (5.3%) and nine cases in the DES group (4.6%); these differences were not statistically significant ($p = 0.86$).

Table 1 Baseline characteristics.

	DES group (N = 196)	BMS group (N = 44)	p-Value
Age, years	66.2 \pm 9.7	69.0 \pm 8.8	0.103
Sex (male, %)	61.2	63.2	0.77
Stent type (%)			
Cypher	44.9		
Taxus	43.9		
Endeavor	11.2		
Underlying disease (%)			
Hypertension	44.9	40.9	0.60
Diabetes	27.0	43.2	0.081
Smoking	32.1	31.8	0.97
Obesity (BMI > 25 kg/m ²)	35.2	29.5	0.67
Hyperlipidemia	42.3	40.9	0.86
Family history for CVD	20.9	18.2	0.68
Previous CVD	11.2	9.1	0.68

DES, drug-eluting stent; BMS, bare-metal stent; CVD, cardiovascular disease; BMI, body mass index.

Table 2 Procedural characteristics and 6-month outcomes.

	BMS group	DES group	p-Value
Target vessel			
Left main (%)	2.8	5.8	0.091
Left anterior descending (%)	41.7	54.5	0.62
Left circumflex (%)	11.1	9.3	0.57
Right coronary (%)	44.4	31.4	0.66
Type C lesion (%)	11.4	21.9	0.11
Minimal luminal diameter (mm)			
Preprocedure	0.92 ± 0.53	0.80 ± 0.66	0.426
Postprocedure	4.07 ± 0.53	3.91 ± 0.40	0.092
Six months after procedure	2.65 ± 0.79	3.24 ± 0.92	0.004
Final balloon pressure (atm)	13.4 ± 3.2	14.4 ± 3.9	0.17
Stent length (mm)	19.7.6	24.6 ± 5.9	0.38
Stent diameter (mm)	4.01 ± 0.41	3.96 ± 0.47	0.61
TLR/TVR (6 months) (%)	2/38 (5.3)	7/196 (3.6)	0.62
MACE (6 months) (%)	2/38 (5.3)	9/196 (4.6) [†]	0.86
Diameter stenosis in-stent (%)	38.9 ± 20.8	18.5 ± 17.1	0.007
Late loss (mm)	1.44 ± 0.83	0.62 ± 0.58	0.009
Binary restenosis (%)	3/38 (7.8)	8/196 (4.1)	0.28

DES, drug-eluting stent; BMS, bare-metal stent; TLR/TVR, target-lesion revascularization/target-vessel revascularization; MACE, major adverse cardiac events.

[†] In-hospital mortality 1; 6-month mortality 1; myocardial infarction 1.

Of the two cardiac deaths in the DES group, one was due to sudden cardiac death while in the hospital but autopsy was not done, and the other one was due to a myocardial infarction after discharge (94 days after percutaneous intervention). The 6-month angiographic outcomes showed that in the BMS group, more late loss (1.44 ± 0.83 mm vs. 0.62 ± 0.58 mm, $p = 0.009$) developed and there was a higher frequency of in-stent diameter stenosis ($38.9 \pm 20.8\%$ vs. $18.5 \pm 17.1\%$, $p = 0.007$) than in

the DES group (Fig. 2A). However, there were no significant differences between the two groups for the frequency of binary restenosis (7.8% in BMS group and 4.1% in DES group, $p = 0.28$) (Fig. 2B). Also the same clinical and angiographic results were seen in comparison between each type of DES group and the BMS group. Although the late loss was significantly higher in BMS group than each type of DES groups, no significant differences were seen in the binary restenosis, TLR/TVR, and MACEs (Table 3).

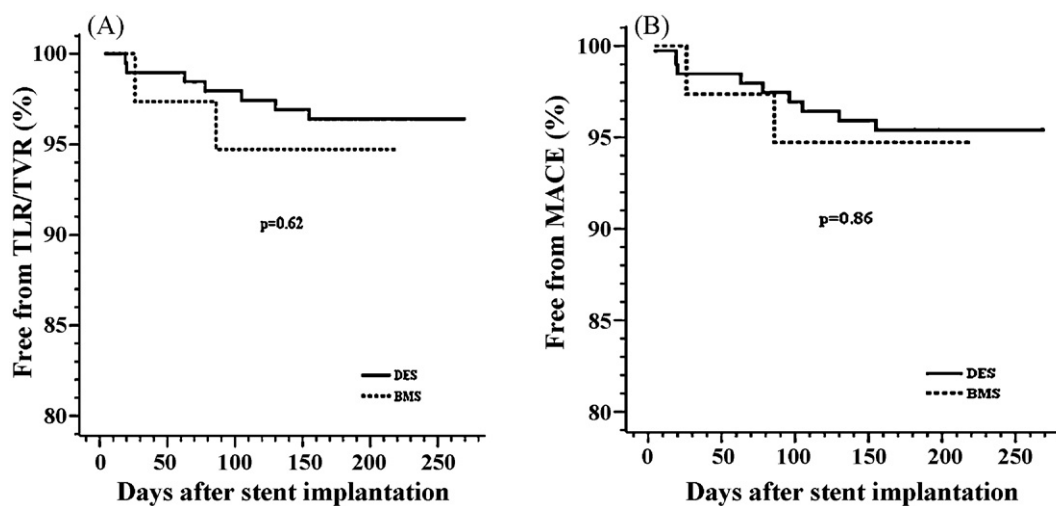


Figure 1 Six-month event-free incidences of target-lesion/vessel revascularization (A) and composite MACE (B). The cumulative 6-month incidence free from target-lesion and target-vessel revascularization, and MACE curves were comparable between the groups. TLR, target-lesion revascularization; TVR, target-vessel revascularization; MACE, major adverse cardiac events.

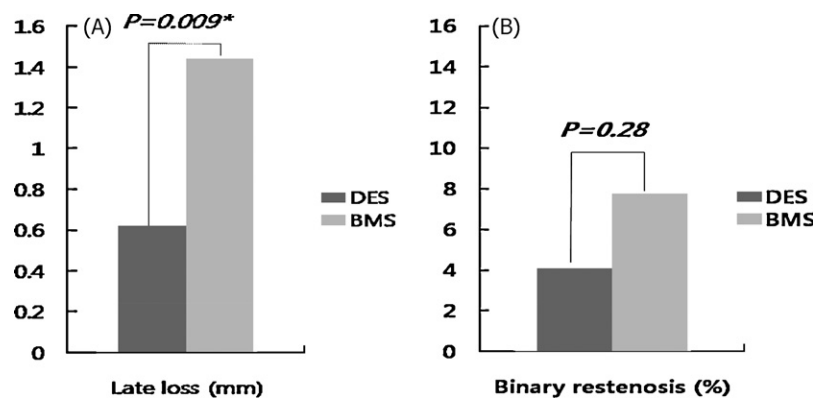


Figure 2 Six-month angiographic outcomes. Although late loss of bare-metal stents (BMS) was higher than that of drug-eluting stents (DES) (A), binary restenosis did not substantially differ between the groups (B).

Discussion

The results of this study showed that the 6-month clinical outcomes, after PCI of large single de novo coronary arteries, were excellent in both the BMS and DES groups. For cases with a coronary artery diameter of more than 3.5 mm, the BMS had a favorable 6-month outcome with a low frequency of cardiac events and was not inferior to the DES.

Our findings are also consistent with previous studies [6,7]. Many prior studies have reported an inverse relationship between the restenosis risk and the vessel diameter after BMS implantation. For the SIRRollUS-coated stent in the treatment of patients with de novo coronary artery lesions (SIRIUS) trial, they reported that a smaller vessel size increased the risk of restenosis by multivariate

analysis [1]. In addition, according to the TAXUS-IV subgroup analysis, confirmation of DES's superiority over BMS, in large coronary arteries (>3.0 mm) failed to show a benefit, but demonstrated superiority of DES for smaller arteries (<3.0 mm) [2]. In the TAXUS-V study, the 9-month adverse cardiac events in the 4.0-mm BMS (Express2, Boston Scientific Corporation) subgroup were not significantly higher than in the Taxus stent subgroup [5]. In addition, in the BeStent 2, a randomized study that compared the Cypher and thin strut BMS, although the general restenosis rate of the DES was lower than that of BMS by 67%, there was no significant difference in angiographic and clinical restenosis in cases with a vessel size greater than 2.8 mm [10].

There are several reasons for similar outcomes for the BMS and DES in large coronary arter-

Table 3 Clinical and angiographic outcomes comparison between each type of DES and BMS.

	Cypher group	BMS group	p-Value
Late loss (mm)	0.59 ± 0.60	1.44 ± 0.83	<0.01
Binary restenosis (%)	3/88 (3.4)	3/38 (7.9)	0.29
TLR/TVR (6 months) (%)	2/88 (2.3)	2/38 (5.3)	0.40
MACE (6 months) (%)	4/88 (4.5)	2/38 (5.3)	0.88
	Taxus group	BMS group	p-Value
Late loss (mm)	0.52 ± 0.48	1.44 ± 0.83	<0.01
Binary restenosis (%)	4/86 (4.7)	3/38 (7.9)	0.45
TLR/TVR (6 months) (%)	4/86 (4.7)	2/38 (5.3)	0.86
MACE (6 months) (%)	4/86 (4.7)	2/38 (5.3)	0.86
	Endeavor group	BMS group	p-Value
Late loss (mm)	0.86 ± 0.59	1.44 ± 0.83	<0.01
Binary restenosis (%)	1/22 (4.5)	3/38 (7.9)	0.62
TLR/TVR (6 months) (%)	1/22 (4.5)	2/38 (5.3)	0.92
MACE (6 months) (%)	1/22 (4.5)	2/38 (5.3)	0.92

DES, drug-eluting stent; BMS, bare-metal stent; TLR/TVR, target-lesion revascularization/target-vessel revascularization; MACE, major adverse cardiac events.

ies. DES have been shown to be superior to BMS in the inhibition of neointimal hyperplasia [11,12]. As intravascular ultrasound studies have suggested, small vessels cannot accommodate well to neointimal hyperplasia after BMS implantation [13,14]. However, for large arteries, the superiority of the DES is diminished because the same degree of neointimal hyperplasia develops, and the large arteries can more easily accommodate intimal hyperplasia than the small arteries [8]. This explains why although neointimal hyperplasia develops in large vessels, clinically or angiographically significant restenosis is not likely to occur. For example, for the late loss of 1 mm, binary restenosis is under 50%, and there is adequate patency without the development of hemodynamic compromise and the need for further intervention. In addition, it is important to recognize that the restenosis rate depends on other clinical variables such as diabetes and lesion complexity as well as vessel size [15,16]. The patients in this study did not differ based on their clinical characteristics.

There have been numerous studies that have shown the relative superiority of DES compared to BMS with regard to in-stent restenosis; however, there has not been a study that has shown superiority with regard to mortality. Furthermore, although it is evident that DES treatment can reduce restenosis or clinically relevant events during the first year compared to the BMS, rate catch-up phenomenon of DESs was reported and repeat target revascularization or stent thrombosis has been increasing [17,18]. We thought that the one case of in-hospital sudden cardiac death in the present study might have occurred due to acute thrombosis. So the long-term overall clinical benefits are controversial. This is especially true for late events related to very late stent thrombosis and large native vessel stenting can be more dangerous.

The concerns raised with regard to the DES include the following. First, DES might be associated with delayed wound healing due to the effects of sirolimus, paclitaxel or zotarolimus. Therefore, long-term dual antiplatelet agents are needed, which increase the danger of bleeding as well as cost. Second, the risk for late restenosis and late stent thrombosis after discontinuing antiplatelet agents might be increased. Third, DES are much more expensive than BMS.

Considering the outcomes found in this study, it is important to determine which patient group has the same outcome, with both the DES and BMS. The results of this study showed that the outcomes for both the BMS and DES were the same for the vessels with a diameter over 3.5 mm, after adjustments for other factors. The proportion of diabetes

in the BMS group was 42%, but it was only 27% in the DES group – even though not statistically significant – we thought it a possible factor that affected the outcomes. And to conclude, BMS can be recommended as an option in cases with large vessel de novo single lesions after excluding high-risk conditions such as chronic total occlusion, a diffuse long lesion, in-stent restenosis, and a bifurcation lesion.

The limitations of this study include the following. The retrospective and non-randomized study design implies some degree of selection bias. In addition, the follow-up period was short because of our policy for angiography follow-up, which is 6 months after the initial PCI. Furthermore, there were fewer subjects in the BMS group than in the DES group. And there were three types of DES, but only one type of BMS; each of the DES types had a similar number of patients as the BMS group except for the Endeavor type.

Conclusion

The findings from the present study showed that the DES and the cobalt–chromium BMS when placed in a large single coronary artery, showed equally favorable 6-month clinical outcomes, although the 6-month angiographic results were more favorable in the DES group than in the BMS group.

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