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Drug-Eluting Stents versus Bare-Metal Stents in Large Coronary Arteries: 8 years follow up

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Abstract

Background: Drug-eluting stents (DESs) have been shown to reduce the risk of restenosis and other adverse cardiac events after percutaneous coronary intervention (PCI) as compared with bare-metal stents (BMSs). However, the superiority of DES over BMS has been questioned in large vessels. We evaluated the risks and benefits of the use of DES versus BMS in patients who undergo stenting of large coronary arteries (≥3.5 mm) up to 8 year follow-up.

Materials and Methods: This was a prospective study carried out in all-comer patients enrolled between January 2015 and December 2015. The patients with the variable indication for PCI, multi vessel involvement, prior revascularization, and adjuvant drugs such as GP IIb–IIIa inhibitors were included in the study. However, patients who did not provide written informed consent and received both DES and BMS were excluded from the study. The clinical outcomes were evaluated at 1year. We now report clinical outcomes of the patients who were followed up for eight years.

Results: A total of 266 lesions (240 patients) in the large coronary arteries were stented, of

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which 130 lesions were treated with BMS and 136 lesions were treated with DES. At 8-year follow-up, there were 2% patients lost to follow up. Target lesion revascularization/target vessel revascularization (TLR/TVR) (P = 0.7685) and all-cause death (P = 0.8790) did not differ significantly between the two groups. In addition, no significant difference was found in patients with effort angina as well as number of asymptomatic patients..

Conclusion: At 8-year follow-up, BMSs and DESs showed similar clinical outcomes in large coronary arteries. Hence, the use of BMS in large coronary arteries (≥3.5 mm) should not be discouraged unless clinically indicated.

KEYWORDS: Bare metal stent, druge luting stent, large coronary artery, percutaneous coronary intervention

Introduction

Bare-metalstents (BMSs) provide the endo luminal scaffold to seal vessel dissection and resist recoil and thereby overcome shortcomings of plain old balloon angioplasty. Still, the in-stent restenosis rate is 20%–30% and is proved to be a major limitation for BMS.[1,2]Itis well established that neointimal hyperplasia is a mechanism behind restenosis and hence for late lumenloss (LLL). Drug-eluting stents (DESs) were introduced with capability of local delivery of anti-proliferative drugs and thereby decrease neointimal hyperplasia. Studies have shown a 75% reduction in restenosis and target lesion revascularization (TLR) rate in the DES-treated patients compared to the BMS.[3-5] However, the main limitation of DES is stent thrombosis (ST) which, in turn, led to cardiac death and non fatal myocardial infarction (MI). Although the superiority of DES in the small coronary vessel is well established, its superiority in the large coronary artery is uncertain. This may be due to the fact that the rate of restenosis might *per se* be low and ST in these vessels, although less common, usually leads to sudden death or MI.[6,7] However, only a few real-world studies or registries of large coronary artery stenting are available.[8-10]

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The BASKET trial followed up patients with large coronary artery stenosis for 18 months. It showed that the rate of target vessel revascularization (TVR) was insignificantly different in patients who received DESs, as compared with patients receiving bare-metal stents (BMSs). Moreover, the rate of death or MI was higher in the DES-treated group.[11,12] Kaiser *et al*. in patients with large coronary artery (3.0 mm) stenting showed an insignificant difference in the rates of death and MI among patients treated with DES and BMS.[13] The present real-world study was to compare the clinical outcomes of DES versus BMS upto 8-year follow-up in patients who undergo stenting of large coronary arteries (≥3.5 mm).

Materials and Methods

This prospective study was carried out in all-comer patients, enrolled between January 2015 and December2015. The study was conducted as per the Declaration of Helsinki, and before study initiation, ethical approval was obtained from the Institutional Ethics Committee. A total of 240 patients underwent percutaneous coronary intervention (PCI), with at least one stent being deployed having a diameter ≥3.5 mm. The patients were included in the study irrespective of the indication for PCI, number of stents used, multivessel involvement, prior revascularization, and use of adjuvant drugs such as GP IIb–IIIa inhibitors. However, patients who did not provide written informed consent and received both DES and BMS were excluded from the study. Hospital course, outcome, and complications were studied from the case records and direct observation of the patients till discharge and during follow-up at 1 year. Basic demographic data, clinical data at the time of presentation, detailed history, relevant investigations, peri-procedural complications, angiographic details, antiplatelet, echo-cardiographic data for left ventricular function, and regional wall were collected.

All patients were prescribed with dual anti platelet therapy (DAPT) as per prevailing

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guidelines. After discharge, patients were followed up on a regular interval as per institutional policy and re-evaluated at 1 year. Patients were also examined during unscheduled visits when they presented with symptoms at the emergency department or cardiology outpatient department. During scheduled or unscheduled visits, patients were assessed for symptoms, drug compliance, electrocardiographic changes, new regional wall motion abnormalities, treadmill exercise electrocardiographic testing, and/or check angiography was advised, when needed. The patients who did not come for follow-up at 1 year were considered as lost to follow-up. All patients who remained in follow up till completion of 8 years were included in this analysis.

Definitions and Endpoints

We defined the large coronary artery as the one with adiameter of 3.5 mm and above. LLL was defined as the difference between minimal luminal diameter (MLD) after the index procedure and MLD at the follow-up angiography. Binary restenosis was defined as more than 50% diameter stenosis at follow-up coronary angiography in the treated coronary artery. Acute gain after index procedure was defined as a difference between MLD before and after the index procedure. Clinical endpoints included ACS, symptomatic status, effort angina, heart failure, bleeding, death and TLR/TVR at 8 years follow-up.

Statistical Analysis

The data analysis was done with “IBM SPSS” (IBM CORP, New York, USA). Quantitative variables were expressed as the mean ± standard deviation. Categorical variables were expressed as percentage (%). Continuous variables were compared between the DES and BMS groups with the use of the Student’s *t* test or Mann–Whitney test. The Chi-square test was used to analyze the association of categorical variables with the primary outcome. A nominal significance was taken as a two-tailed $P < 0.05$.

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Results

Of 240 patients enrolled, 122 patients were in the BMS group (males: 101) and 118 in the DES group (males:105). A total of 266 lesions were treated, of which 130 lesions were treated with BMS and the remaining 136 lesions were treated with DES. There was no significant intergroup difference in the demographic and the clinical characteristics of the patients, as shown in Table 1. The angiographic data showed the distribution of lesions all over the epicardial arteries. Patients treated with BMS with single-vessel disease (SVD), two-vessel disease (DVD), and three-vessel disease (TVD)were 66 (54.1%), 40(32.8%), and16 (13.1%),whereas in DES with SVD, DVD, and TVD were 49 (41.5%), 54(45.8%), and 15 (12.7%), respectively. In the patients with left anterior descending coronary artery (LAD), the DES was used more likely than BMS and the significant difference was observed for patients involving proximal LAD (P = 0.005). However, BMS was more commonly used in non-LAD lesions, and the difference was significant (P = 0.019) for the distal right coronary artery [Table 2]. In the BMS-treated patients, the maximum number of patients (47.69%) had a stent length of less than 18 mm (average stent length= 21.48 mm, P=0.040). In the DES- treated patients, the maximum number of patients (42.65%) had a stent length between1 8 and 28 mm (average stent length = 24.16, P = 0.7538) [Table 3]. All stents were the US Food and Drug Administration approved. BMS had cobalt-chromium platform. Among DES used, 13.7%, 32.6%, and 53.7% were paclitaxel-, zotarolimus-, and everolimus-eluting stents, respectively. The first, second, and third generation DES was used in19 (13.7%), 111 (81.6%), and 6 (4.42%) patients, respectively.

The average number of stents used per patient was 1.07 in the BMS and 1.15 in the DES; the difference was statistically insignificant. The distribution of antiplatelet drugs prescribed to both BMS-and DES-treated patients is shown in Table 4.

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One year follow up data of the study is published elsewhere. [14] At 8-year follow-up, 3 patients in the BMS group and 2 patients in the DES group were lost to follow up. A total of 119 patients in BMS group and 116 patients in the DES group were studied. Clinical outcomes such as symptomatic status, ACS, heart failure, Target lesion revascularization / target vessel revascularization (TLR/TVR), effort angina, bleeding and death were analyzed. 90 patients in the BMS group and84 patients in the DES group (P = 0.6738) were asymptomatic. Clinical outcomes such as ACS, heart failure, bleeding, death, and effort angina did not differ significantly between the two groups [Table 5].

Discussion

After a 8 year follow up, the major findings of the study shows that no significant difference was found in number of asymptomatic patients, the rate of revascularization (TLR/TVR), patients requiring medical management in both the groups. The death rate was similar in both the groups. These findings demonstrated that most of the patients with binary restenosis were asymptomatic, and the BMS and the DES had similarclinical outcomes in large coronary arteries at 8-year follow-up.

In most of the previous studies, the follow-up duration varied from 6 months to 6 years, and all the patients were scheduled to undergo repeat angiography irrespective of their clinical status which probably could have picked up clinically insignificant lumen loss and binary restenosis cases. [10,13-19] We have followed up the patients for 8 year after the index procedure, and repeat angiography was offered only when clinically indicated reducing the number of patients undergoing unnecessary angiography.

Patients included in our study were younger than previous studies (62–66 years), which is consistent with the fact that coronary artery disease(CAD)occurred at an earlier age in the Indian subcontinent people.[16,17,19,20] Patients recruited in this study had a high extent (58.5%and45.9%)in the DES and BMS groups, respectively) of a multi-vessel CAD,

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which implies that patients had profound coronary artery disease. Furthermore, in the current study, the number of stents used per patient was1.15and1.07and the mean length was 24.16 mm and 21.48 mm in the DES-and BMS-treated groups, respectively. Both the parameters, number of stents and stent length, used were similar to most of the previous studies. In addition, the mean stent length was higher in the DES-treated patients in the current and also in few previously reported studies, which reveals the current trend of DES use in the treatment of longer lesions and preference of medical practitioners towards DES.[17,19,20] DAPT compliance is equally important in patients implanted with DES as they are exposed to the more imminent risk of ST. Eisenstein *et al*., in an observational study of long-term use of clopidogrel after DES implantation, demonstrated that clopidogrel might reduce the risk of adverse events such as death or MI.[21]

In the study conducted by Na *et al*.[17] comparing DES with BMS after implantation in large (≥3.5mm) coronary artery, the LLL was 0.62 mm and 1.44mm (*P*=0.009), MLD was 0.8 mm and 0.92 mm (*P*=0.426), acute gain was 3.11 mm and 3.15 mm, and binary restenosis was 4.1 % and 7.8 %[19] in the DES and BMS groups, respectively. The possible reason for statistical non significance in our setting may be due to a very small number of patients who underwent repeat angiography. The incidence of binary restenosis was higher in Na *et al*. Study that may be due to repeat angiography of all the enrolled patients irrespective of clinical status. The LLL and MLD were comparable in both the studies. However, a higher acute gain was reported by Na *et al*. This may be due to reflective intravascular ultrasound (IVUS) guided more aggressive post dilation which was not used in our study.

The rate of TLR/TVR was 9.48% in the DES treated group and 8.4% in the BMS treated group in our study. The National Heart Blood Lung Institute (NHBL) Dynamic Registry compared DES with BMS in real world patients undergoing stenting of large (≥3.5 mm) coronary arteries. After 3 years of follow up, the rate of TVR was 4.4% and 3.7% (P =

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0.62), the rate of repeat revascularization was 15.5% versus 11.7%, and the rate mortality was 8.6% versus 9% (0.76) in the DES and BMS treated groups, respectively.[19] These clinical outcomes of previous studies were consistent with the clinical outcomes of our study. However, the higher rate of TLR/TVR in BMS treated patients compared to DES treated patients and a less rate of mortality reported in most of the previous studies may be due to varying duration of follow up, shorter stent length, less advanced lesions, and different study design. Although all the studies were conducted in large coronary arteries, the reference vessel diameter was different, as there is no cutoff for large coronary artery size; it affected the end results of PCI.[8,15,17,18,20,22,23]

In addition, we have observed the higher incidences of ACS (5 vs.2, *P* =0.0823) in the DES group compared to the BMS group. The reason may be that the large vessel stents are less prone to restenosis, but the risk of adverse cardiac events is more in case of ST. This finding is also in accordance with previous studies such as the Basket–Prove Study.[13] Mortality rates found in this study were 5.17% and 4.20% in the DES and BMS groups, respectively,whichwascomparabletomortalityratesfound in ICAS registry,[14] the study conducted by Chan *et al*.,[19] and also NORSTENT study.[19] None of the studies irrespective of their duration of follow up reported any significant mortality difference between DES and BMS, thus firmly establishing the fact that the use of DES does not provide mortality benefit over BMS in the large coronary artery.

Study Limitations

The study has a set of limitations. First, the type of stent, procedure technique, use of GP IIb/IIIa inhibitors, and treatment after discharge was at the operator's discretion, and the nonrandomized study design introduced the variation in the study. Second, lack of IVUS-guided estimation of lesions for accurate vessel dimensions, atheroma burden, and lesion characteristics. Third, the repeat angiography was done on only a symptom-driven basis;

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hence, the true incidence of binary restenosis and extent of LLL cannot be accurately calculated.

Conclusion

At 8-year of follow-up, BMS and DES had similar clinical outcomes in large coronary arteries. The study raises questions to superiority of DES over BMS in the large coronary artery and warrants further larger studies. Therefore, the use of BMS in large coronary arteries (≥3.5mm) should be evaluated further for any potential clinical or economic benefit.

Conflict of Interest

There are no conflicts of interest.

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Table1: Demographic profile and clinical parameters of Enrolled patients

Parameter	BMS(*n*=122)	DES(*n*=118)	*P*
Male	101	105	0.9456
BMI	26.79±5.16	26.15±5.48	0.3524
Hypertension	51 (41.8)	64 (54.2)	0.0721
Diabetes	19 (15.6)	25 (21.2)	0.3388
Known CAD	9 (7.4)	6 (5.1)	0.6407
CVA	2 (1.6)	4 (3.4)	0.6492
PreviousPTCA	4 (3.3)	4 (3.4)	0.7553
PreviousCABG	0	2 (1.7)	0.4630
PAOD	2 (1.6)	1 (0.85)	0.9768
Smoking	35 (28.7)	25 (21.2)	0.2330
Tobacco	29 (23.8)	36 (30.5)	0.3035
Effortangina	22 (18)	18 (15.3)	0.9049
NSTEMI	7 (5.7)	14 (11.9)	0.1468
STEMI	80 (65.7)	69 (58.5)	0.3172
Unstable angina	6 (4.9)	11(6.3)	0.2811

BMI = Body mass index, CAD = Coronary artery disease, CVA = Cerebrovascular accident, PTCA = Percutaneous transluminal coronary angioplasty, CABG = Coronary

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artery bypass graft, PAOD=Peripheral artery occlusive disease, STEMI=ST-elevation myocardial infarction, NSTEMI = Non-STEMI, BMS = Bare-metal stent, DES = Drug-eluting stent

Table 2: Distribution of lesions treated according to the vessel segment

Vessel segments	BMS (*n*=130)	DES (*n*=136)	*P*
LAD-P	15 (11.54)	35 (25.74)	0.0050
LAD-M	22 (16.92)	12 (8.82)	0.0728
LAD-D	4 (3.08)	2 (1.47)	0.6391
LCX-P	9 (6.92)	8 (5.88)	0.9234
LCX-M	10 (7.69)	6 (4.41)	0.4395
LCX-D	1 (0.77)	4 (2.94)	0.3941
RCA-P	38 (29.23)	29 (21.32)	0.1790
RCA-M	21 (16.15)	35 (25.74)	0.0775
RCA-D	9 (6.92)	1 (0.74)	0.0198
LMCA	1 (0.77)	4 (2.94)	0.3941

LAD-P = Left anterior descending-proximal, LAD-M=Left anterior descending- mid, LAD-D=Left anterior descending- distal, LCX-P=Left circumflex artery proximal, LCX M=Left circumflex artery mid, LCX-D=Left circumflex artery-distal, RCA-P=Right coronary artery-proximal, RCA-M=Right coronary artery- mid, RCA-D=Right coronary artery-distal, LMCA=Left main coronary artery, BMS=Bare-metal stent, DES=Drug-eluting stent

Table 3: Length of stents used versus the number of patients using the stents

Length	BMS(*n*=130)	DES(*n*=136)	*P*
≤18	62 (47.69)	47 (34.56)	0.0401
18≤28	52 (40.00)	58 (42.65)	0.7538

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>28	16 (12.31)	31 (22.79)	0.0375

BMS=Bare-metal stent, DES=Drug-eluting stent

Table 4: Number of patients using anti-platelet therapy

Anti-platelet	BMS (*n*=122)	DES (*n*=118)	*P*
Clopidogrel	93 (76.2)	61 (51.7)	0.0001
Prasugrel	28 (23)	40 (33.9)	0.0822
Ticagrelor	1 (0.8)	17 (14.4)	0.0002

BMS=Bare-metal stent, DES=Drug-eluting stent

Table 5: Clinical status of patients after 8 years of follow-up

Current clinical status	BMS (*n*=119)	DES (*n*=116)	*P*
Asymptomatic	90 (75.6)	84 (72.4)	0.6738
ACS	2 (1.68)	5 (4.31)	0.0823
Heart failure	4 (3.36)	6 (5.17)	0.8653
Bleeding	2 (1.68)	3 (2.58)	0.4930
Death	5 (4.2)	6 (5.17)	0.8790
TLR/TVR	10 (8.4)	11 (9.48)	0.7685
Effort angina	20(16.8)	22 (18.9)	0.8485

ACS=Acute coronary syndrome, BMS=Bare-metal stent, DES=Drug-eluting stent, TLR= Target lesion revascularization, TVR= Target vessel revascularization