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Original Research Article

Drug eluting stents versus bare metal stents in coronary artery disease patients: outcomes and complications

Veeraj V. Kalburgi*

Department of Cardiology, Khaja Bandanawaz Institute of Medical Sciences, Gulbarga, Karnataka, India

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***Correspondence:**
Dr. Veeraj V. Kalburgi,
E-mail: vrishi7@yahoo.co.in

ABSTRACT

Background: To date, data regarding the long-term safety and efficacy of BMS and DES implantation in a real-world population are limited. Thus, this study was designed to study the complications, early and late outcomes of drug-eluting stents (DES) versus bare metal stents (BMS) after implantation in coronary artery disease (CAD) patients up to 6months follow-up period.
Methods: This was a single-center, hospital-based, prospective study conducted at a tertiary care center in India. Records of 250 patients who underwent percutaneous coronary intervention (PCI) in the period of January to December 2007 were included in the study. Early outcomes were indications of coronary angioplasty, length of hospital stay, Killip's classification at presentation, type of coronary lesions, cath-lab outcomes and acute stent thrombosis (ST). Patients were clinically followed-up till hospital discharge, 30days and in 6months.
Results: Total 250 patients with an age range of 30-39years underwent PCI. Of the study population who underwent PCI 111 patients (44.4%) received DES, 104 patients (8%) received BMS, 20 patients received both DES and BMS and 15 patients underwent POBA, respectively. Complications like stroke and major bleeding were observed in 2 patients (0.8%) and 12 patients (4.8%) respectively. TIMI III flow and ST was observed in 215 patients (91.5%) and 6 patients (2.6%), respectively. Death was observed in 3 patients (1.2%) due to cardiogenic shock.
Conclusions: DES and BMS have good procedural success in achieving early revascularization with PCI. The incidence of ST was almost equal in DES compared to BMS.

Keywords: Bare metal stents, Coronary artery disease, Drug eluting stents, Percutaneous coronary intervention

INTRODUCTION

Cardiovascular disease (CVD) is the general term that involves the heart or the blood vessels leading cause of death and serious illness accounting for 30% of the deaths annually.[1] Forty years ago, coronary artery bypass surgery (CABG) was the most common treatment used in coronary artery diseases.[1] The era of interventional cardiology began with the pioneering work of Andres Gruentzig on plain balloon angioplasty.[2] In the late 1980s, coronary stents were developed with the goals of reducing the risk of restenosis and achieving a more predictable acute result of angioplasty, thus avoiding the dreaded abrupt closure to dissection.[1,3] Coronary stents were successful and the number of percutaneous coronary interventions (PCI) performed each year has expanded considerably.

The PCI was initially performed by inflating a distensible balloon which resulted in symptomatic re-narrowing of the artery.[4] This resulted in increased use of bare metal stents (BMS). As the years elapsed, the era budged from

the use of BMS to drug eluting stents (DES).[1] DESs are the milestone development in the field of interventional cardiology.[5] The clinical presentation of the restenosis process was most often associated with the recurrence of angina and doesn't lead to any cause of death or myocardial infarction.[6]

However, DES has been shown to reduce the neointimal proliferation and thereby lowering the need for in-stent restenosis as compared with BMS.[6,7] The new emerging problem with DES was stent thrombosis (ST) which was a multifactorial problem involving failure to adequately expand the stents, residual coronary dissection, stent length, medication compliance and possibly genetic factors predisposing to diminished responsiveness to aspirin and clopidogrel. There was a growing evidence that late thrombosis was a complication of DES.[8] However, delayed ST remains a significant problem in patients treated with DES implantations, particularly with the permanent polymer DES. Biodegradable polymers have been developed as an answer to this problem.[5]

An early invasive strategy by urgent re-PCI represents the most adopted strategy to manage patients presenting with ST. However, despite its evident clinical relevance, available data derived from sub-studies on the ST was still lacking. To date, data regarding the long-term safety and efficacy of BMS and DES implantation in a real-world population are limited. Author, therefore, performed this current study with the aim to study the complications, early and late outcomes of DES versus BMS.

METHODS

This is a single-center, hospital-based, prospective study conducted at a tertiary care center (Khaja Bandanawaz Institute of Medical Sciences, Gulbarga, Karnataka) in India. The present study included 250 patients who had undergone PCI. From January 2007 to December 2007, the patients who received either DES or BMS implantations were included in the study. In this study, all medical records were surveyed and age, gender, detailed history of the patients, major cardiovascular risk factors including diabetes, hypertension, obesity, cigarette smoking, tobacco chewing, family history of coronary artery disease (CAD) and other history includes history of congestive cardiac failure, anaemia, peripheral vascular disease (PVD), chronic renal failure (CRF) and chronic obstructive pulmonary disease (COPD) were included. History of prior Myocardial infarction (MI) and revascularization were also included in the study. The study was approved by the institutional ethics committee of the hospital. The PCI was performed according to standard techniques through femoral or radial artery in the cardiac catheter laboratory.

The type of stent implanted (BMS or DES), pre-dilation or post stent adjunctive balloon inflation and administration of drugs such as low molecular weight heparin/unfractionated heparin or glycoprotein IIb/IIIa (Abciximab, Eptifibatide, Tirofiban) inhibitors were chosen at the discretion of the operator. Before intervention dual antiplatelet treatment was prescribed, including aspirin (81-325mg) and clopidogrel (300-600mg) as a loading dose. After intervention same dosage of aspirin was continued and clopidogrel 75mg twice daily was administered for all the patients.

Intra-aortic balloon pump (IABP) insertion if required was again done in the cath-lab or intensive coronary care unit (ICCU) only. The post-procedure, femoral sheath was removed according to the standard protocol and the radial sheaths were removed in the cath-lab only. Later they were sent to the ICCU with tourniquet which was removed once the bleeding from the puncture site gets stopped. The patients were kept in the ICCU, as per the hemodynamics status, and then they were transferred to the ward and later discharged as per the operator's choice and the patient status.

The primary endpoints, early outcomes were studied in terms of indications of coronary angioplasty, length of hospital stay, Killip's classification at presentation, ejection fraction, type of coronary lesions, cath-lab outcomes (TIMI flow, perforation, dissection, no reflow, slow flow, periprocedural MI) and acute ST. These primary endpoints were again followed in 30days and 6months. The secondary endpoints included are ST, death, MI), target lesion re-vascularization (TLR) and stroke. Stent thrombosis was identified based on the Academic Research Consortium (ARC) definition.[9]

Stent thrombosis cases were categorized according to the timing of occurrence as follows acute (0-24hours post-stent implantation), sub-acute (from 24hrs to 30days/1-month), late (between 1-month to 12months) and very late (1year post-stent implantation). MI was diagnosed based on the development of new Q waves in two or more contiguous leads of the electrocardiogram with or without elevated cardiac enzymes or accompanied by significant elevation of creatine kinase greater than three times the upper limit of normal or without new Q waves in the electrocardiogram. TLR is defined as the re-stenosis inside the implanted stent or within 5mm proximally or distally to the stent. Patients were clinically followed-up till hospital discharge and in 30days.

The patients were again followed-up in 6months through outpatient visits or telephonic contact. Full follow-up of all the patients was available till hospital discharge and in 30days. At 6months 47 patients were lost to follow-up for varied reasons. Continuous variables were represented as mean±standard deviation. Categorical variables were expressed as frequencies and group percentages. The student's t-test and Pearson chi-square test was used to compare some continuous and categorical variables. A confidence level of more than 95% was considered statistically significant ($p<0.05$). Statistical analyses were performed using statistical package for social sciences

(SPSS). Analysis of variance (ANOVA) was used to compare three or more quantitative variables.

RESULTS

Total 250 patients with an age range of 30-39years underwent PCI. Of these, 198 (79.2%) were males, and 52 (20.8%) were females in which the most common age incidence of coronary artery diseases (CAD) was found to be 50-59years (37.2%). Unstable angina (203 patients, 81.2%) was the most common indication for PCI. The baseline demographic characteristics are shown in Table 1.

Table 1: Baseline demographic characteristics.

Characteristics	Patients (N=250)
Age (mean ± SD, years)	54 ± 6
Male, n (%)	198 (79.2%)
Cardiovascular risk	
Diabetes mellitus, n (%)	150 (60%)
Hypertension, n (%)	50 (20%)
Dyslipidemia, n (%)	200 (80%)
Smoker, n (%)	100 (40%)
Previous MI, n (%)	25 (10%)
Previous PCI, n (%)	12 (5%)
Clinical presentation	
Asymptomatic, n (%)	12 (4.8%)
Acute MI, n (%)	25 (10%)
Cardiogenic shock, n (%)	5 (2%)
Stable angina, n (%)	5 (2%)
Unstable angina, n (%)	203 (81.2%)

MI-Myocardial infarction, PCI-Percutaneous coronary intervention.

Lesions and procedural characteristics are displayed in Table 2 and 3. The femoral route was found to be the most commonly used route for angioplasty among the study population accounting for 165 patients (66%) followed by radial route in 85 patients (85%). In the Table, it indicates that the single vessel angioplasty was done in 198 patients (16.8%), followed by multi-vessel angioplasty in 52 patients (23.2%), CABG grafts revascularization and left main plasty were done in 2 patients (0.8%) and 1 patient (0.4%), respectively. Most of the culprit vessels were the left anterior descending (LAD) (107 patients, 42.8%) and right coronary artery (RCA) (47 patients, 18.8%).

Among the 250 patients B type lesions were more found in 138 patients (55.2%) followed by C type lesions in 112 patients (44.8%). Out of 250 patients GP IIb/IIIa inhibitors were used in 68 patients (27.2%) and direct thrombin inhibitor (bivaflo) were used in two patients (0.8%). Of these 68 patients, eptifibatide was used in 38 patients (63.3%). In this study, patients with cardiogenic shock and complex angioplasty had IABP during angioplasty. Of all the study population who underwent PCI 111 patients (44.4%) received DES, 104 patients (8%) received BMS, 20 patients had received both DES+BMS and the rest of the 15 patients had plain old balloon angioplasty (POBA), respectively. Among the 250 patients, complications like stroke and major bleeding was observed in 2 patients (0.8%) and 12 patients (4.8%), respectively. Procedural outcomes like TIMI III flow was observed in 215 patients (91.5%).

Of these 215 patients, TIMI III flow was achieved in 101 patients (91%) who received DES, 96 patients (92.3%) who received BMS and 18 patients (90%) who received both DES+BMS, respectively.

Table 2: Lesion characteristics of all the patients.

Characteristics	Patients (N=250)
Lesion location	
CABG graft, n (%)	1 (0.4%)
Diagonal, n (%)	3 (1.2%)
LAD, n (%)	107 (42.8%)
LAD/LCX, n (%)	17 (6.8%)
LAD/RCA, n (%)	14 (5.6%)
LAD/LCX/OM/RAMUS, n (%)	1 (0.4%)
LAD/LCX.RCA, n (%)	3 (1.2%)
LAD/LCX/RCA/RAMUS, n (%)	1 (0.4%)
LAD/Renal, n (%)	3 (1.2%)
LCX-OM, n (%)	2 (0.8%)
LCX, n (%)	38 (15.2%)
LCX/RCA, n (%)	6 (2.4%)
LCX/PD, n (%)	1 (0.4%)
LM, n (%)	1 (0.4%)
PDA, n (%)	1 (0.4%)
RAMUS, n (%)	2 (0.8%)
RCA, n (%)	47 (18.8%)
RCA/RAMUS, n (%)	1 (0.4%)
SVG graft, n (%)	1 (0.4%)
Lesion classification	
ACC/AHA B lesions, n (%)	138 (55.2%)
ACC/AHA C lesions, n (%)	112 (44.8%)
Bifurcation lesions, n (%)	25 (10%)
CTO, n (%)	47 (18.8%)
IRA, n (%)	60 (24%)
Ostial lesions, n (%)	70 (28%)
Multi vessel CAD, n (%)	52 (23%)

CABG-Coronary Artery Bypass Graft, LAD-Left Anterior Descending, LCX-Left Circumflex Artery; RCA-Right Coronary Artery, OM - Oblique Marginal Artery, RAMUS-Ramus Intermedius artery, LM-Left Main, PDA-Patent Ductus Arteriosus, SVG-Saphenous Vein Grafts, ACC/AHA-American College of Cardiology/American Heart Association, CTO-Chronic Total Occlusion.

The Pearson chi-square value did not show any significant difference between DES and BMS for achieving good TIMI III flow. Peri-procedural complications like perforation was found to be the most common complication among the study population, accounting for 3 patients (1.2%) followed by dissection

in 2 patients (0.8%). The ST was observed in 6 patients, of which 2, 3, 1 patient had acute, sub-acute and late ST, respectively. Of these 2 patients who had acute ST 1 patient (0.5%) belong to DES group and 1 patient (0.7%) belongs to BMS group.

Table 3: Procedural characteristics of all the patients.

Characteristics	Patients (N=250)
Balloon to artery ratio (mean±SD)	1.25±0.13
Stents per lesion (mean±SD)	1.59±0.72
Stents length per lesion (mean±SD)	24.8 ± 19.3
Pre-intervention	
MLD (mean ± SD)	0.82 ± 0.49
RVD (mean ± SD)	70.3 ± 14.6
Route of angioplasty	
Femoral, n (%)	165 (66%)
Radial, n (%)	85 (34%)
GP IIb/IIIa inhibitor	
Eptifibatide, n (%)	38 (15.2%)
Abciximab, n (%)	22 (8.8%)
Tirofiban, n (%)	8 (3.2%)
Bivaflo, n (%)	2 (0.8%)
Type of stents	
Total stents, n (%)	235 (94%)
DES	111 (47.2%)
BMS	104 (44.3%)
BMS+DES	20 (8.5%)
POBA, n (%)	15 (6%)
Use of IABP, n (%)	27 (28%)
Post procedural TIMI flow	
I, n (%)	1 (0.4%)
II, n (%)	19 (8.1%)
III, n (%)	215 (91.5%)

MLD - Minimum Lumen Diameter; RVD - Reference Vessel Diameter; DES - Drug Eluting Stents; BM - Bare Metal Stents; IABP- Intra aortic Balloon Pump; TIMI - Thrombolysis in myocardial infarction.

Table 4: Complications and clinical outcomes of all the patients after 6months.

Characteristics	Patients (N=250)
Stroke, n (%)	2 (0.8%)
Bleeding complications	
Major, n (%)	12 (4.8%)
Minor, n (%)	3 (1.2%)
Peri-procedural complications- 0 (0%)	
No reflow	8 (3.2%)
Perforation, n (%)	3 (1.2%)
Dissection, n (%)	2 (0.8%)
Stent thrombosis, n (%)	6 (2.6%)
In-stent restenosis, n (%)	10 (4.3%)
Death, n (%)	3 (1.2%)

Of these 3 patients who had sub-acute ST 2 patients (1%) belong to DES group and 1 patient (0.7%) belongs to BMS group. One patient (0.5%) who had late ST belongs to the DES group. Of all the study population, in-stent restenosis (ISR) was observed in 10 patients (4.3%). Death was observed in 3 patients (1.2%) due to cardiogenic shock. It indicates that cardiogenic shock had a significant higher incidence of mortality (60%) and it was also statistically significant. Complications and clinical outcomes are demonstrated in Table 4 and 5.

Table 5: Stent thrombosis and in-stent thrombosis of all the patients after 6months.

Characteristics	DES N = 111	BMS N = 104	BMS+DES N=20
Stent thrombosis			
Acute, n (%)	1 (0.9%)	1 (1%)	0 (0%)
Sub-acute, n (%)	2 (1.8%)	1 (1%)	0 (0%)
Late, n (%)	1 (0.9%)	0 (0%)	0 (0%)
In-stent restenosis	4 (3.6%)	3 (2.8%)	3 (15%)

DISCUSSION

The present study included 250 patients who underwent PCI. All patients were followed-up to hospital discharge and again in 30days. However, 47 patients lost to follow-up in 6-months for varied reasons.

Recently, DES has resulted in decrease of restenosis across a wide range of world population. In an unselected daily practice population, DES implantation has been proved to markedly reduce the incidence of repeat revascularization and restenosis.[8,10] In this study, most of the culprit vessels were the LAD and Ostial lesions. In a previous study conducted on a population treated with PCI demonstrated that the location of the lesion in LAD was not an independent predictor for MACE.[8,11] According to the results of a recent study by Lee CW et al, reported that post-intervention MLD and lesion length were the predictors of restenosis.[12] In this study LMWH was used in 54.4% patients, which was superior to UFH (the dose adjusted according to age, weight and renal function). Women derive a significant benefit from adjusted therapy with LMWH (enoxaparin) compared with UFH, that was similar to the magnitude of the benefit seen in men.

Ortolani P et al, reported that early administration of glycoprotein IIb/IIIa agents may provide long-term clinical benefits in patients treated by PPCI.[13] Angiographically early group patients are more often achieved pre-PPCI TIMI grade II and III flow, reduction in mortality and non-fatal reinfarction which was similar and can be compared with this study.

In this study 70 patients (28%) received glycoprotein IIb/IIIa inhibitor in which abciximab was mostly commonly used in acute MI group. There was no difference in angiographic successful epicardial reperfusion or left ventricular recovery between

Eptifibatide and Tirofiban. Early administration of GP IIb/IIIa agents provided good TIMI III flow, reduction in mortality and non-fatal reinfarction. In this study, IABP was used in more complex angioplasty, LM plasty, cardiogenic shock and hypotension in 27 patients (28%). IABP increases the efficacy of thrombolytic therapy by increasing coronary perfusion in STEMI patients with cardiogenic shock.[14,15] IABP therapy as an adjunct to thrombolysis would support the rationale for myocardial and organ recovery.[16] The ESC guideline also strongly recommends IABP treatment in STEMI with cardiogenic shock patients.[17] This can be compared with the Sjauw KD et al, study shows that STEMI patients with cardiogenic shock treated with thrombolysis and IABP therapy was associated with an 18% decrease in 30days mortality compared to patients without IABP support.[14]

According to ARC definition, most of the ST occurred in the time range of immediate to 12hrs of period. The risk factor for ST was a multi-factorial problem involving stent under expansion, residual coronary dissection, stent number or length, drug compliance and possible genetic factors as that predisposing diminished responsiveness to aspirin and clopidogrel respectively. Out of 6 patients, 3 patients underwent repeat TLR, 2 patients underwent TLR with DES and 1 patient underwent POBA.

Three patients expired despite attempted revascularization inotropes, GP-IIb/IIIa agents. Most of the cases with ST occurred within a month.[18] Only 2 out of 23 cases presented as late ST in a study conducted by de Man FH et al, and showed that it occurred due to incorrect use of antiplatelet agents. This in accordance with other studies that have showed that withdrawal of antiplatelet agents was associated with a 90-fold increase in risk of ST.[19] In a study conducted by Spaulding C et al, enrolled 1748 patients and evaluated the safety of sirolimus-eluting stents as compared with BMS and shows that the incidence of sub-acute ST was 0.5% in each DES and BMS groups which was similar to this study showing that the incidence of sub-acute ST was found to be 1% versus 0.7% between DES and BMS groups respectively.[20]

A series of observations from studies with different designs strongly suggest that discontinuation of premature antiplatelet therapy may play a key role in DES thrombosis and that late and very late STs were more observed in DES groups than in BMS groups respectively.[18,21] This can be compared with this study showing that late ST was seen in 1 patient (0.5%) due to antiplatelet withdrawal and was considered as the strongest risk factor for late Burzotta F et al, showed that residual uncovered dissection leads to a four-fold increase in risk of ST.[21] In this study, dissection was noted in case of acute ST group. Three patients had evidence of antiplatelet resistance and can be compared with the Müller I et al, study.[22] The present study showed that restenosis was shown in 10 patients (4.3%) it can be compared with the M-heart trial and also reported that LAD lesion were more prone to restenosis than lesions in LCX and RCA.[23,24] A greater number of patients and a longer follow-up period could allow the observation of long-term changes in clinical outcomes of DES and BMS groups. After PCI with DES or BMS the patients will have long-term favourable outcomes, unless there was occurrence of ST or peri-procedural complications.

Early and judicious use of dual uninterrupted long-term antiplatelet therapy, LMWH and GP IIb/IIIa should be done when appropriate in achieving a good TIMI-III flow and great revascularization. The incidence of peri-procedural complications was low but proper care should be given to prevent this complication as this may lead to catastrophic events and death. The incidence of ST was almost equal in DES compared to BMS.

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