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A study to compare Major Adverse Cardiac Event in patient undergoing PCI with Drug Eluting Stents Vs Bare Metal Stents

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ABSTRACT

This study compared Major Adverse Cardiac Event in patient with Acute Coronary Syndromes undergoing PCI with Drug Eluting Stents Vs Bare Metal Stents. A retrospective, observational study was carried out in an inpatient setting of the private tertiary care hospital. Patients with >18 years, diagnosed for Acute Coronary Syndromes (ACS), required intervention in coronary artery with implantation of Drug Eluting Stents (DES) or Bare Metal Stents (BMS) were recruited in the study. The data had been collected from file or database of the hospital. All subjects were followed for major adverse cardiac event. A total of 202 patients who underwent Percutaneous Coronary Intervention (PCI) were enrolled into DES group (N=101) and BMS group (N=101). All patients were followed up at 1 month, 3 months, 6 months & 12 months for Major Adverse Cardiac Events (MACE). Clinical outcomes during 12 months were compared between DES group & BMS group. There was no significant difference in baseline parameters including demographic, risk factors of ACS, diagnosis, angiographic parameters between both groups. Overall MACE rates were reported non-significantly high in BMS group patients (14.85%) compare to DES group patients (8.91%) (P=0.458). However, DES group had lower rates of death (0.99% vs 1.98%, P=0.57), rate of MI (3.96% vs 4.95% P=0.73), rate of revascularization (1.98% vs 3.96% p=0.42) & rate of sub acute thrombosis (1.98% vs 3.96% P=0.42) and higher rate of bleeding (1.98% vs 0.99% p=0.57) compare to cohort-II. The use of DES in the setting of Acute Coronary Syndrome is associated with lower Major Adverse Cardiac Event (MACE) rate compared to BMS without compromising the overall safety over the course of one-year follow-up. The long-term safety of drug-eluting stents needs to be ascertained in large, randomized trials.

Key Words: *Drug Eluting Stent (DES), Bare Metal Stent (BMS), Major Adverse Cardiac Event (MACE), Acute Coronary Syndrome (ACS).*

INTRODUCTION

Coronary artery disease (CAD) is the leading cause of mortality and morbidity in the world and acute coronary syndromes (ACS), which encompass unstable angina (UA), non-ST-segment elevation myocardial infarction (NSTEMI) and ST-segment elevation myocardial infarction (STEMI), are the commonest causes of mortality in patients with CAD. India has the highest burden of acute coronary syndromes in the world, yet little is known about the treatments and outcomes of these diseases. There will be required to document the characteristics, treatments, and outcomes of patients with acute coronary syndromes who were admitted to hospitals in India [2].

Prospective, randomized clinical trials have shown that in-stent restenosis is reduced by the use of drug-eluting stents, as compared with bare-metal stents. However, the use of drug-eluting stents has rapidly been expanded to all types of patients, including those with more complicated coronary lesions and in acute settings. Recently metaanalyses of randomized trials [3-4] and registries [5] have raised concern about incomplete neointimal coverage with a subsequent increase in late stent thromboses in patients with drug-eluting stents [6-7]. One randomized trial indicated that the implantation of drug-eluting stents was associated with an early reduction in death and myocardial infarction - an improvement that was lost during the subsequent 6 to 18 months by a late increase in the same events [8]. We determined that the evaluation of large clinical registries might provide useful information concerning the long-term efficacy and safety of drug-eluting stents. Therefore, we evaluated the long-term outcome in all patients who underwent stent implantation.

MATERIAL AND METHODS

A retrospective, open label, observational study carried out in an inpatient setting of the private tertiary care hospital. The patients recruited in the study as per the criteria given below.

Inclusion criteria:

1. Patients were >18 years old.
2. Patients were diagnosed for Acute Coronary Syndromes (ACS).
3. Patients were required intervention with implantation of Drug Eluting Stents (DES) or Bare Metal Stents (BMS).

Exclusion criteria:

1. Planned elective surgery necessitating discontinuation of clopidogrel within the regular planned period of clopidogrel administration
2. Previous implantation of a Drug Eluting Stent (DES) or Bare Metal Stent (BMS).
3. Patients in whom anti-platelet and/or anticoagulation therapy was contraindicated.
4. Patients were participated in another randomized trial that clinically interferes with the present trial, or requires coronary angiography or other coronary artery imaging procedures.
5. Incomplete information regarding patient

The data had been collected from file or database of the hospital. All subjects were followed for major adverse cardiac event (MACE) including death, Myocardial infarction, Urgent revascularization, sub acute thrombosis & bleeding at 1 month, 3 months, 6 months & 12 months after PCI. All collected data was analyzed in its group for clinical outcomes. All variables were analyzed using percentage, mean & standard deviation. Statistical difference between both cohorts was calculated by applying independent t-test & odds ratio.

RESULT AND DISCUSSION

There were 202 patients who underwent PCI between December 2008 and July 2009 was enrolled in retrospective, observational study. All these subjects were divided in two Cohorts.

Cohort-1: Patients implanted Drug Eluting Stent (DES) (N=101)
Cohort-2: Patients implanted Bare Metal stent (BMS) (N=101)

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Out of the 202 patients, 87.13% (N=88) and 89.11% (N=90) were male patients in Cohort-1 & Cohort-2 respectively. The average age of the patients were 56.34 & 55.46 in Cohort-1 & Cohort-2 respectively (Table 1). Risk of acute coronary syndrome was increase with increasing age (**Fig. 1**). Average BMI in cohort 1 & cohort 2 were 25.25 Kg/m^2 & 28.87 Kg/m^2 respectively. There was no significant difference in baseline demographic parameters between both groups (**Table 1**).

There were no significant difference in hypertension (46.53% Vs 33.66% P=0.74), diabetes Mellitus-II (30.69% Vs 21.78% P=0.15), family history of CAD (22.77% Vs 24.75% P=0.06), prior history of CAD (15.84% Vs 11.88% P=0.42), smoker (14.85% Vs 22.77% P=0.15), tobacco chewer (15.84% Vs 8.91% P=0.15), hyperlipidemia (1.98% Vs 1.98% P=1.00) in cohort-I & cohort-II respectively (**Fig. 2**).

There were high number of subjects were reported as STEMI in both groups. STEMI was reported 35.64% (36) Vs 34.66% (35), p=0.88 in Cohort-1 & Cohort-2 respectively. NSTEMI was reported 27.73% (28) Vs 31.68% (32), p=0.54 in Cohort-1 & Cohort-2 respectively. Unstable angina was reported 29.7% (30) Vs 30.69% (31), p=0.88 in Cohort-1 & Cohort-2 respectively. Stable angina was reported 6.93% (7) Vs 2.97% (3), p=0.21 in Cohort-1 & Cohort-2 respectively (**Fig. 3**).

During coronary angiography (CAG), It was found that the main culprit vessel in coronary artery disease was LAD (66.34% & 54.45% in Cohort-1 & Cohort-2 respectively) followed by RCA (21.78% & 23.76% in Cohort-1 & Cohort-2 respectively). There were high numbers of subjects having coronary stenosis >90% in both cohorts (49.5% & 52.47% in Cohort-1 & Cohort-2 respectively). Detail coronary angiographic findings were shown in **Table 2**.

Overall MACE rates were reported non-significantly high in Cohort-I (8.91%) compare to Cohort-II (14.85%) (P = 0.458). However, Cohort-I had lower rates of death (0.99% vs 1.98%, P=0.57), rate of MI (3.96% vs 4.95% P=0.73), rate of revascularization (1.98% vs 3.96% p=0.42) & rate of sub acute thrombosis (1.98% vs 3.96% P=0.42) compare to cohort II (Table 3).

Over all MACE rate reported for both of the groups was 0.99% Vs 0.99% (P=1) at one month, 0.99% Vs 2.97% (P=0.34) at three months, 2.97% Vs 3.96% (P=0.7) at six months and 3.96% Vs 6.93% (P=0.36) at twelve months in Cohort-1 & Cohort-2 respectively (**Fig. 4**).

Safety and efficacy study result demonstrated that over all MACE and mortality rate appears lower in DES group compare to BMS group. However, it was not significant statistically. Further long term study is required to get more viable results with larger population.

Table No. 1: Demographic parameters

Parameters	Cohort-I	Cohort-II	P-value
Age	56.34 ± 10.93	55.46 ± 12.47	0.59
Gender-Male	87.13% (88)	89.11% (90)	0.66
Weight	68.02 ± 11.33	69.8 ± 0.29	0.29
Height	164.2 ± 9.55	164 ± 7.08	0.88
BMI	25.25 ± 3.81	28.87 ± 3.74	0.24
BSA	1.74 ± 0.17	1.76 ±0.17	0.48

Table No. 2: Angiographic findings

Parameters	Cohort-I	Cohort-II	P Value
Type of Vessel			
LAD	66.34% (67)	54.45% (55)	0.09
RCA	21.78% (22)	23.76% (24)	0.74
LAD & RCA	4.95% (5)	3.96% (4)	0.73
LCX	3.96% (4)	10.89% (11)	0.07
RAMUS	1.98% (2)	0% (0)	0.29
SVG Graft	0.99% (1)	0% (0)	0.5
OM-2	0% (0)	3.96% (4)	0.14
LCX &LAD	0% (0)	0.99% (1)	0.5
LMCA	0% (0)	0.99% (1)	0.5
RCA & LCX	0% (0)	0.99% (1)	0.5
Lesion Class			
A	13.86% (14)	14.85% (15)	0.84
B1	20.79% (21)	22.77% (23)	0.73
B2	25.74% (26)	25.74% (26)	1
C	39.6% (40)	36.63% (37)	0.66
% stenosis			
>90%	49.5% (50)	52.47% (53)	0.67
80-90%	48.51% (49)	44.55% (45)	0.57
<80%	1.98% (2)	2.97% (3)	0.65
Calcification			
None/Mild	72.27% (73)	70.29% (71)	0.76
Moderate	19.8% (20)	19.8% (20)	1
Severe	7.92% (8)	9.9% (10)	0.62
Tortuosity			
<45	90.09% (91)	82.17% (83)	0.11
45-90	9.9% (10)	17.82% (18)	0.11
Thrombus	45.54% (46)	36.63% (37)	0.2
Pre TIMI Flow			
0	41.58% (42)	52.47% (53)	0.12
1	34.65% (35)	23.76% (24)	0.09
2	18.81% (19)	14.85% (15)	0.45
3	4.95% (5)	8.91% (9)	0.27

Table No. 3: Major Adverse Cardiac Event

Parameters	Cohort-I	Cohort-II	P Value	OR	CI (95%)
Death	0.99% (1)	1.98% (2)	0.57	0.5	0.04 to 5.54
Myocardial infarction	3.96% (4)	4.95% (5)	0.73	0.79	0.20 to 3.03
Revascularisation	1.98% (2)	3.96% (4)	0.42	0.49	0.08 to 2.73
sub acute thrombosis	1.98% (2)	3.96% (4)	0.42	0.49	0.08 to 2.73
Over all MACE	8.91% (9)	14.85% (15)	0.2	0.56	0.23 to 1.35

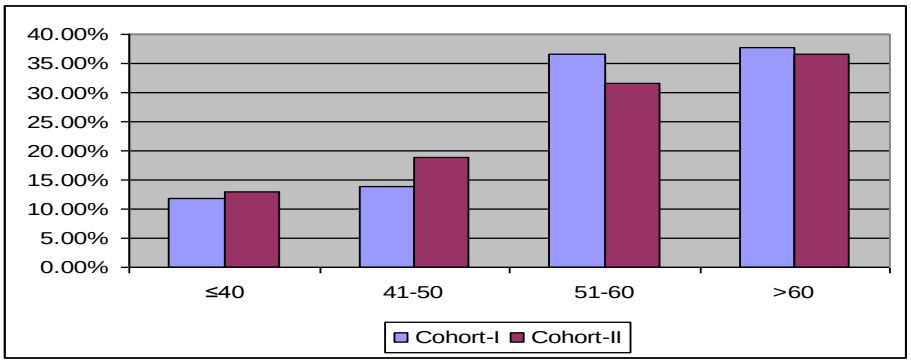

Fig. 1: Age wise distribution of patients

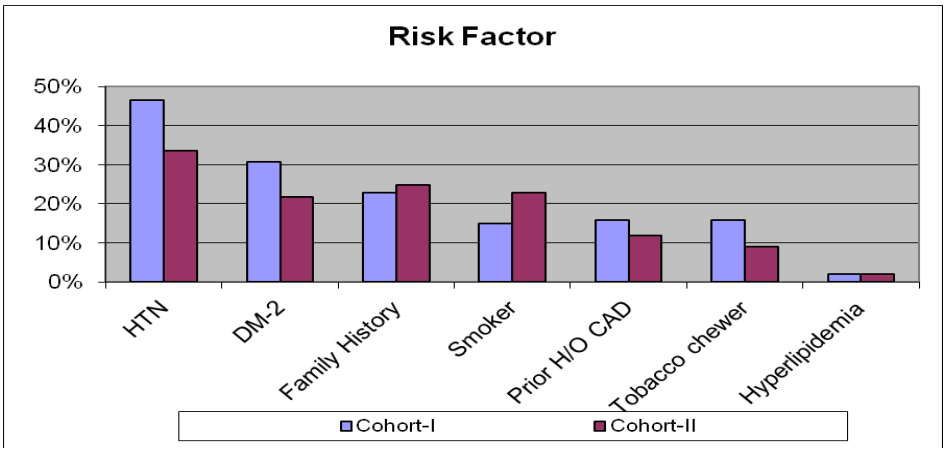

Fig. 2: Risk factors of Acute Coronary Syndromes

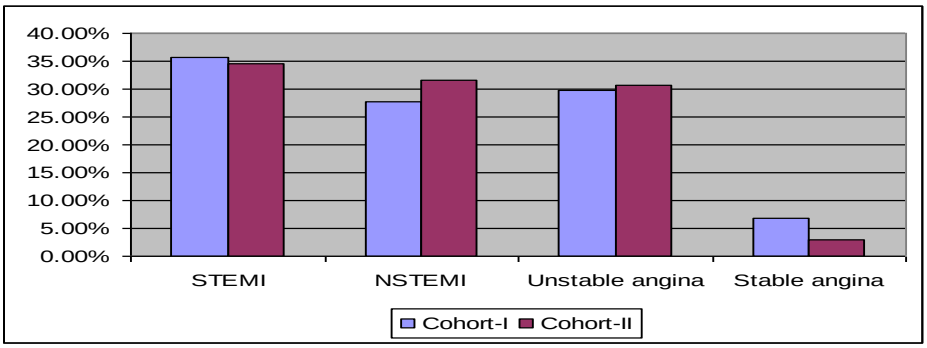

Fig. 3: Diagnosis of Patients

CONCLUSION

The use of DES in the setting of Acute Coronary Syndrome is associated with lower Major Adverse Cardiac Event (MACE) rate compared to BMS without compromising the overall safety over the course of one-year follow-up. The long-term safety of drug-eluting stents needs to be ascertained in large, randomized trials.

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REFERENCES:

1. KJ Raihanathul Misiriya, N Sudhayakumar, S Abdul Khadar et al. The Clinical Spectrum of Acute Coronary Syndromes: Experience from a Major Center in Kerala. J. Assoc. Physicians India, **2009**: 57; 377-83.
2. Andrew MD, Chatterjee K. Angioplasty versus Bypass Surgery for Coronary Artery Disease. Circulation, **2002**; 106: 187-90.
3. Xavier D, Pais P, Xie C, et al. Treatment and outcomes of acute coronary syndromes in India (CREATE). The Lancet., **1962**; 371: 1435-42.
4. Bavry AA, Kumbhani DJ, Helton TJ, Borek PP, Mood GR, Bhatt DL. Late thrombosis of drug-eluting stents: a meta-analysis of randomized clinical trials. Am. J. Med. **2006**: 119; 1056-61.
5. Nordmann AJ, Briel M, Bucher HC. Mortality in randomized controlled trials comparing drug-eluting vs. bare metal stents in coronary artery disease: a metaanalysis. Eur. Heart. J., **2006**: 27; 2784-814.
6. Daemen J. Late coronary stent thrombosis of DES in routine clinical practice: data from large two-institutional cohort study, Lancet., **2007**; 369: 667-78.
7. Aoki J, Colombo A, Dudek D, et al.Persistent remodeling and neointimal suppression 2 years after polymer-based, paclitaxel- eluting stent implantation: insights from serial intravascular ultrasound analysis in the TAXUS II study. Circulation, **2005**; 112: 3876-83.

8. Fujii K, Carlier SG, Mintz GS, et al. Stent under expansion and residual reference segment stenos is are related to stent thrombosis after sirolimus-eluting stent implantation: an intravascular ultrasound study. J. Am. Coll. Cardiol., **2005**: 45; 995-98.

9. Pfisterer M, Brunner-La Rocca HP, Buser PT, et al. Late clinical events after clopidogrel discontinuation may limit the benefit of drug-eluting stents: an observational study of drug-eluting versus baremetal stents. J. Am. Coll. Cardiol., **2006**: 48; 2584-91.

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