

An Observational Study Of Cardiovascular Outcome In Patients Undergoing Primary Pci With Indian Manufactured Des

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ABSTRACT

Background: Raising cardiovascular diseases and its associated comorbidity, health risks and consequences carry a massive health care system and economic burden on the society. **Aim:** To compare the different Indian manufactured drug eluting stents (DES) in patients undergoing primary percutaneous coronary intervention (PCI) with primary objective of major adverse cardiac and cerebrovascular events (MACCE). **Study design:** Observational, retrospective, and prospective study. **Methodology:** Study conducted at Sunshine Heart Institute from Jan 2016 to April 2018 in all the patients who have undergone primary PCI with Indian manufactured DES. The baseline clinical, procedural, in-hospital data and follow-up data was taken at 01, 03, 06 and 12 months, till end of study period at regular intervals, after the index procedure. **Results:** 163 patients were considered for the data analysis in 3 groups i.e. Premier (51), Tetrilimus (47) & YCF (65). **Conclusion:** All the three study groups have shown similar primary and secondary outcomes. However, further studies are required on large scale for accurate assessment and evaluation.

Keywords: Cardiovascular, Percutaneous, Coronary Intervention

1. INTRODUCTION:

Cardiovascular disorders such as myocardial infarction (MI) and heart failure, remains the leading causes of death worldwide. Acute MI results mostly from acute thrombotic occlusion of an epicardial coronary artery, typically after disruption or erosion of an atherosclerotic plaque and exposure of thrombogenic material (Plaque lipid content, collagen, and sub endothelial extracellular matrix) to circulating blood. The aim of treating ST elevation MI (STEMI) is restoration of myocardial perfusion by recanalization of the occluded vessel. Early reperfusion is associated with better outcomes. Initially, coronary balloon angioplasty was performed for discrete, proximal, noncalcified subtotal lesions located in 1 coronary artery¹. A 10-year follow-up of Gruentzig's early Zurich series revealed an overall survival rate of 90% and of 95% for those with single-vessel disease. Later, percutaneous transluminal coronary angioplasty (PTCA) was conceived and shepherded into worldwide acceptance and application by Andreas R. Gruentzig; this technique has now eclipsed coronary bypass

surgery as the most frequently performed revascularization procedure. Reintervention rates for patients undergoing percutaneous coronary intervention (PCI) have fallen steadily from the POBA period to the stent period and are now even lower with the drug-eluting stent (DES)².

Recent guidelines have stated the proven efficacy of primary PCI for acute STEMI as a class I indication. The primary PCI to define is the percutaneous coronary intervention with angioplasty and/or stenting without preceding fibrinolysis. Though PCI for stable angina do not impact MI or death & HF, it reduces these end points in high-risk acute coronary syndromes (ACS)³.

This study is aimed to collect baseline clinical, procedural data & obtain in-hospital, 01, 03, 06 and 12 months, till end of study period (at regular intervals), follow-up data, to compare major adverse cardiac and cerebrovascular events (MACCE) i.e., Death, MI, Target Lesion Revascularization (TLR), Stroke, Major Bleeding not related to CABG, in patients who have undergone primary PCI with Indian manufactured DES.

2. MATERIALS AND METHODS:

The study proforma was designed to collect information including patients' demographics and clinical details like age, gender, height, weight, history of diabetes, hypertension, dyslipidemia, smoking, past cardiac history (PTCA/CABG). Hospital charts were reviewed for further information, including electrocardiogram (ECG), ST-segment analysis and laboratory data including hemoglobin, serum creatinine, cardiac enzymes, inflammatory markers like CRP, etc. Angiographic and procedural details (culprit vessel, number of diseased vessels, use of stents, GP IIb/IIIa inhibitors, etc.) were also collected⁴. Timing variables were computed including window period which is defined as the time from symptom onset until arrival at the hospital. The primary end point was in-hospital, at 01, 03, 06 and 12 months, till end of study period at regular intervals, follow-up data, to compare MACCE.

Study Design and Study Population:

Study type: Observational

Study design: Observational model

Time perspective: Retrospective and prospective study⁵

Sample Size Calculation: Reference data: The following studies have been considered as benchmark for sample size calculations (Table 1).

Table 1: Reference data

Stent name	Reference	Incidence of MACE*
Tetralimus	Sridhar Kasturi et al.	0.96% in 30 days
YCF	Xhepa et al.	1.5% In 30 days
Metafor SES	VithalaSuryaprakash Rao et al.	1.6% in 3 years

MACE (Major Advance Cardiac Events) which include cardiac death, MI, TLR, and target vessel revascularization

Formula used for sample size calculation:

The number of subjects required for each group is given by

$$n = \frac{p_1(1 - p_1) + p_2(1 - p_2)}{(p_1 - p_2)^2} * f(\alpha, \beta)$$

Type I error (α): Threshold probability for rejecting the null Hypothesis. Type I error rate.
 α (two-tailed) taken at 0.05 (95% of confidence)

Type II error (β):

Probability of failing to reject the null hypothesis under the alternative hypothesis. Type II error rate.

β taken at 0.10 (Power of 90%)

Function of α & β at $\alpha=0.05$ and $\beta=0.10$

$f(\alpha, \beta) = 10.5$

Results of sample size (Table 2) calculations with the above formula under various circumstances:

Table 2: Minimum sample size

Stent 1	Stent 2	Min sample needed in each group*
Metafor SES	Tetralimus	23
Tetralimus	Sirolimus	28
Tetralimus	YCF	29

* with 95% confidence and 90% Power of study

Hence, in summary, *~30 is the minimum sample required for each stent type.*

Study population: All patients who have undergone primary PCI with Indian manufactured DES at Sunshine hospital, Secunderabad, Telangana from Jan 2016 to April 2018. A total of 189 patients were initially included in the study. These patients were implanted with four different Indian manufactured DES, of which, 71 patients were implanted with YCF, 55 with Premier, 50 with Tetralimus and 13 with Metafor stents. 14 Patients (6 - YCF, 4- Premier, 3- Tetralimus, 1- Metafor) were excluded from the final study as they were lost to follow-up, hence the study has 175 patients i.e. 65-YCF, 51-Premier, 47-Tetralimus & 12-Metafor. The group of 12 patients treated with Metafor were also excluded from the analysis as considering such small group of patients would give insignificant comparative analysis and only 163 patients were considered⁶.

Baseline clinical, procedural, in-hospital data and follow-up data, which will be collected either by extraction from existing databases in consecutive fashion where follow-up data existed, or follow-up will be obtained by telephonic contact or personal review at 01, 03, 06 and 12 months, till end of study period at regular intervals, after the index procedure⁷.

Participant Identification:

Inclusion criteria:

All the patients undergoing primary PCI who will meet the following criteria:

- Patients > 18 years old and of either sex.
- Patients in whom primary PCI was performed using Indian Manufactured DES (alone).

- Patients who require single- or multi-vessel primary PCI of de novo or re-stenotic target lesion (including in-stent re-stenotic lesions)⁸.
- Patients who have willingly given informed consent.

Exclusion criteria:

- Pregnancy/breastfeeding.
- High probability of being unavailable for follow-up visits.
- Patients with previous history of allergy to radiographic contrast or severe anaphylaxis.
- Patients with severe renal insufficiency (eGFR <30 ml/min).
- Any other concomitant medical/surgical condition in the patient, which in the opinion of the investigator can influence the outcomes in the study subjects⁹.

Data Collection and Follow-Up:

A detailed baseline, clinical and procedural data were collected for each patient included in this study. Follow-up data were collected either by extraction from existing database in consecutive manner where follow-up existed, or follow-up data will be obtained by telephonic contact at 01, 03, 06 and 12 months, till the end of the study period after the index procedure¹⁰.

Statistical Analysis:

The baseline continuous variables were expressed as means with standard deviation (SD). Differences between the groups were assessed with one-way Analysis of Variance. The Categorical variables were expressed as counts and percentages and difference between the groups were assessed with the chi-square test. P value of <0.05 was considered statistically significant. Statistical Package for Social Sciences (SPSS) version – 15.0. was used to analyze the data¹¹.

3. RESULTS:

A total of 163 patients in three different groups i.e., YCF, Premier & Tetrilimus were included in the analysis with patient population of 65-YCF, 51-Premier, 47-Tetrilimus.

I. Distribution of age in different groups:

Table 3: Distribution of age in entire study population

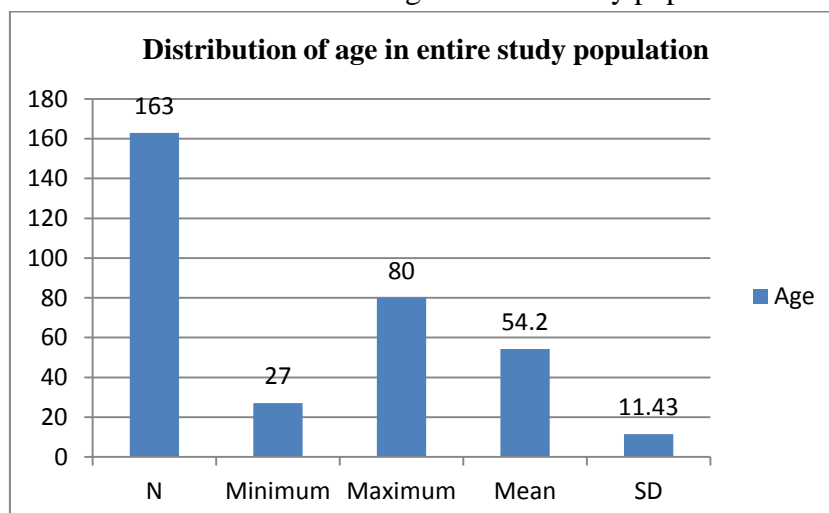


Table 4: Distribution of age in each group

	Mean	SD	Minimum	Maximum	p-value
PREMIER (51)	52.24	11.10	32	80	.260
TETRILIMUS (47)	56.00	11.99	32	78	
YCF (65)	54.45	11.21	27	77	

The table 3 and 4 shows that the mean age of patients in study population was 54.20 ± 11.43 . Mean age in Premier, Tetrilimus and YCF stent group was found to be 52.24 ± 11.10 , 56.00 ± 11.99 and 54.45 ± 11.21 years, respectively. But there was no significant difference in age distribution between each group (p-value=0.260)

II. Gender distribution in different study groups:

Table 5: Gender distribution in entire study population

Gender	Number (n)	Percentage (%)
Male	124	76.1
Female	39	23.9
Total	163	100

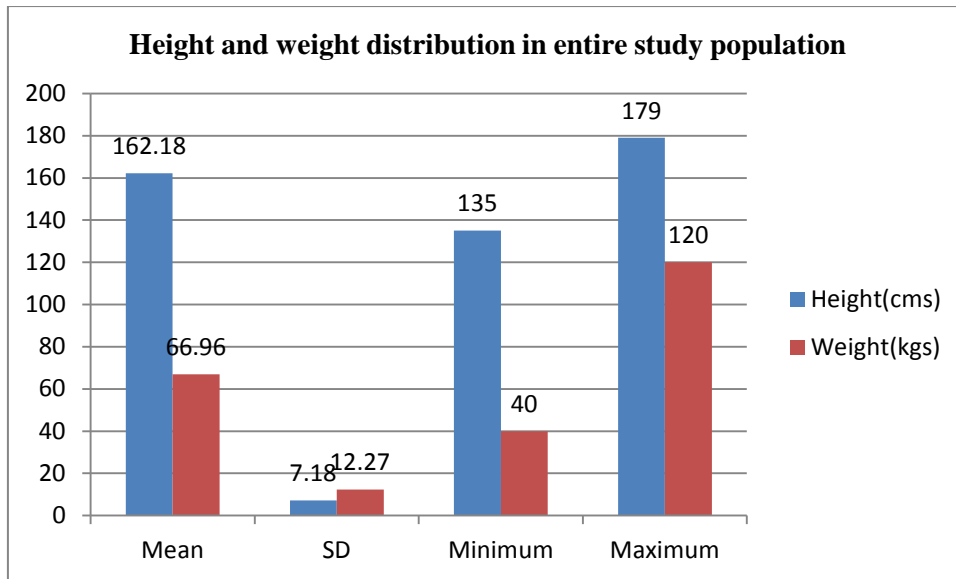
This table 5 and 6 shows male predominance in our study which comprised of about 76.1% of patient population. From the table below, we draw that 38(75%), 35(74%) and 51(78%) male patients were involved in Premier, Tetrilimus and YCF stent group respectively, but there was no significant difference in each group (p-value=0.844).

Table 6: Sex distribution in each group

Sex	PREMIER (51)	TETRILIMUS (47)	YCF (65)	p-value
Male	38(75%)	35(74%)	51(78%)	.844
Female	13(25%)	12(26%)	14(22%)	

III. Height and weight distribution in study groups:

Table 7: Height and weight distribution in entire study population



The overall mean height and weight of the patients involved in this study was found to be 162.18 ± 7.18 cms and 66.96 ± 12.27 kgs, respectively.

Table 8: Mean Height in different study groups

	Mean	Std. Deviation	Minimum	Maximum	P value
PREMIER (51)	162.61	7.05	148	175	.790
TETRILIMUS (47)	161.62	7.97	135	175	
YCF (65)	162.25	6.74	150	179	

Table 9: Mean weight in different study group

	Mean	Std. Deviation	Minimum	Maximum	p-value
PREMIER (51)	68.39	17.22	45	120	0.607
TETRILIMUS (47)	66.30	9.69	46	91	
YCF (65)	66.32	8.93	40	90	

There was no significant difference in mean height and weight in between the groups (Table 7,8 and 9).

IV. Risk Factors:

Table 10: Risk factors in entire study population

Risk Factors	Number (n)	Percentage (%)
HISTORY OF (PTCA/CABG)	10	6.1%
HTN	77	47.2%
DM	57	35%
SMOKER	67	41.1%
TOBACCO	4	2.5%

Table 11: Risk factors in each group

RISK FACTORS	PREMIER (51)		TETRILIMUS (47)		YCF (65)		p-value
	n	%	N	%	n	%	
CARDIC HISTORY	1	1.96%	5	10.64%	4	6.15%	.202
HTN	17	33.33%	27	57.45%	33	50.77%	.044
DM	14	27.45%	19	40.43%	24	36.92%	.369
SMOKER	20	39.2%	21	44.68%	26	40.00%	0
TOBACCO	2	3.92%	2	4.26%	0	0	.255

The tables 10 and 11 and chart diagram shows that hypertension [77 (47.2%)] was observed in majority of the patients followed by smoking [67 (41.1%) patients], diabetes [57 (35%) patients], cardiac history [10 (6.1%) patients] and tobacco [4 (2.5%) patients], in the order. Of all the study population, cardiac history [5 (10.6%) patients], hypertension [27 (57.5%) patients], diabetes [19 (40.4%) patients], and smoking [21 (44.7%) patients] was found to be higher in Tetrilimus group compared to the other groups.

V. Laboratory investigations:

Table 12: Laboratory investigation in entire study population

Parameters	Mean	SD	Minimum	Maximum
TRIGLYCERIDES	123.26	58.03	34	436
LDL	84.76	35.47	1.90	228
HDL	30.41	8.12	16	62
TOTAL CHOLESTEROL	140.53	41.46	90	295
TROP-I	20.77	33.10	1.3	184.35
CRP	34.06	61.24	.50	297.55
CPK-MB	51.08	81.48	.50	355.80

RBS	160.94	66.49	80.00	413.00
HB	13.65	2.32	5.90	17.5

Table 13: Laboratory investigations in each group

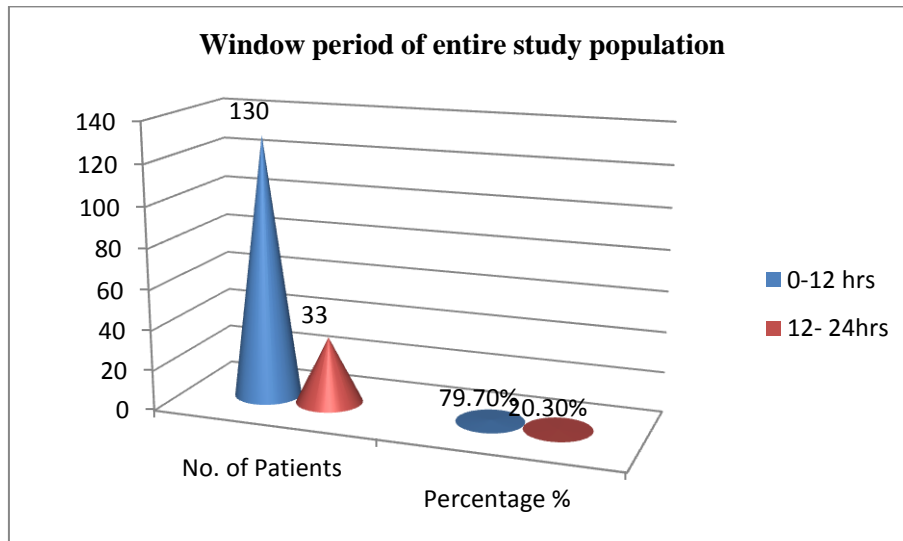
	PREMIER (51)		TETRALIMUS (47)		YCF (65)		p-value
	Mean	SD	Mean	SD	Mean	SD	
TRIGLYCERIDES	130.82	54.30	111.72	47.34	125.66	66.78	0.244
LDL	96.55	42.48	77.79	29.94	80.55	31.08	0.014
HDL	30.00	6.72	29.38	7.44	31.49	9.49	0.364
TOTAL CHOLESTEROL	152.98	49.91	134.34	36.67	135.25	35.48	0.034
TROP-I	17.75	30.78	20.40	23.07	23.41	40.43	0.659
CRP	34.56	57.17	38.04	77.65	30.78	50.83	0.826
CPK-MB	49.84	80.92	53.54	85.79	50.28	79.95	0.970
RBS	141.22	52.18	184.83	61.88	159.15	74.69	0.004
HB	13.58	2.54	13.65	2.35	13.82	2.14	0.844

The overall mean levels of random blood sugar (RBS), hemoglobin (Hb) levels were found to be 160.9 ± 66.4 mg/dL, 13.6 ± 2.3 g/dL respectively. The RBS level (184.83 ± 61.88 mg/dL), Hb (13.65 ± 2.35 g/dL) were found to be more in Tetralimus group followed by YCF and premier groups.

The overall mean levels of triglycerides, LDL, HDL and total cholesterol was found to be 123.26 ± 58.03 , 84.76 ± 35.47 , 30.41 ± 8.12 and 140.53 ± 41.4 mg/dL, respectively. From the above table, it was observed that triglycerides (130.82 ± 54.30 mg/dL), LDL (96.55 ± 42.48 mg/dL) and total cholesterol (152.98 ± 49.91 mg/dL) level was found to be higher in premier group compared to the other groups. The HDL level (31.49 ± 9.49 mg/dL) was found to be more in YCF group than in the other groups (Table 12 and 13).

VI. Window Period:

Table 14: Window period of entire study population



The current study had majority of patients i.e., 130 (79.7%) presented within 12 hours of window period (Table 14).

VII. Electrocardiographic findings:

Table 15: ECG findings in entire study group

ECG	N	Percentage %
AWMI	96	59
ASWMI	4	2.4
ALWMI	8	5
IWMI	49	30
IW + RVMI	3	1.8
IW + PW	3	1.8
Total	163	100

Among the study population, majority had AWMI (59%) followed by IWMI (30%), ALWMI (5%), ASWMI (2.4%), IW+RVMI (1.8%) & IW+PWMI (1.8%) in the order (Table 15).

VIII. Drugs used:

Table 16: Drugs used

Class	Drug	N	%
ANTI PLATELETS	ASPIRIN	163	100
	CLOPIDOGREL	139	85
	TICAGRELOR	25	15
	PRASUGREL	-	-
	GPIIb-IIIa BLOCKERS	-	-
ANTI COAGULANT	HEPARIN	163	100
	BIVALURIDIN	-	-

	LMWH	-	-
STATINS		163	100
INTRA CORONARY	NTG	8	5
	NICORANDIL	10	6
	EPTIFIBATIDE	2	1

The table 16 indicates that Aspirin, Heparin & Statins were used in all the study population 163 (100%), followed by Clopidogrel, which was used in 139 (85%) patients, while Ticagrelor was used in 25 (15%) patients. Nicorandil was used in 10 (6%) patients and Nitroglycerin was used in 8 (5%) patients.

IX. Coronary angiography:

Table 17: Coronary angiography findings in entire study population

	N	%
SVD	92	56.4
DVD	53	32.5
TVD	18	11
Total	163	100

Table 18: Coronary angiography findings in each study

	PREMIER (51) n(%)	TETRILIMUS (47) n(%)	YCF (65) n(%)	p-value
SVD	35(68.63%)	27(57.44%)	30(46.15%)	0.171
DVD	11(21.57%)	16(34.04%)	26(40%)	
TVD	5(9.80%)	4(8.51%)	9(13.84%)	

Among 163 patients, 92 patients had Single Vessel Disease (SVD), 53 patients had Double Vessel Disease (DVD) and 18 patients had Triple Vessel Disease (TVD). Out of 92 patients who had SVD, 35 (68.63%), 27 (57.44%) and 30 (46.15%) patients belong to Premier, Tetrilimus and YCF group, respectively (p=0.171). Of 53 patients who had DVD, 11(21.57%), 16(34.04%) & 26(40%) belong to Premier, Tetrilimus and YCF group, respectively and of 18 patients with TVD, 5(9.80%), 4(8.51%) & 9(13.84%) belong to Premier, Tetrilimus and YCF group, respectively. But the difference between groups was statistically insignificant (Table 17 and 18).

X. Primary Outcome:

Table 19: MACCE in entire study population

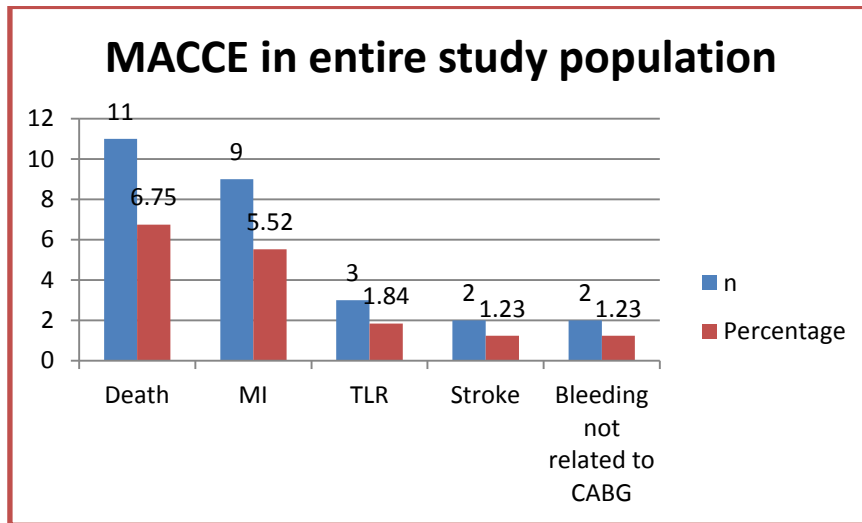
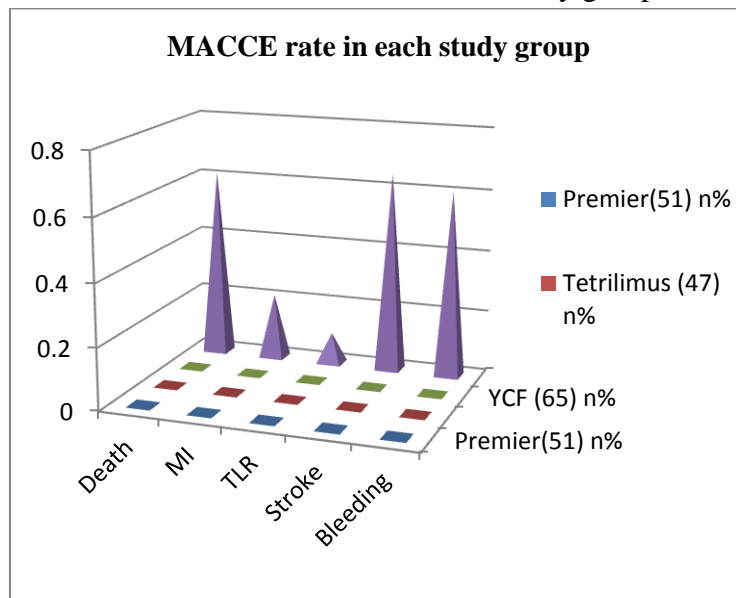


Table 20: MACCE rate in each study group



The above graph and tables 19 and 20 show that, of the study population, MACCE was observed in 27 patients. Among the 27 patients, 11 patients died, 9 patients had myocardial infarction (MI), 3 patients underwent TLR, 2 patients had stroke & 2 patients had major bleeding not related to CABG, However, there was no statistically significant difference between groups in primary outcome.

Table 21: Primary outcome at 3 months in each study groups

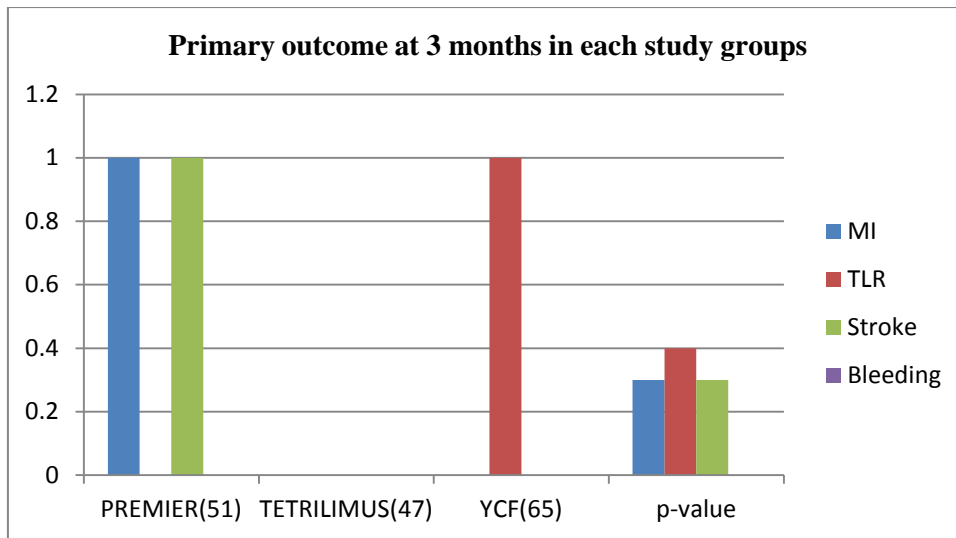


Table 22: Primary outcome at 6 months in each study groups

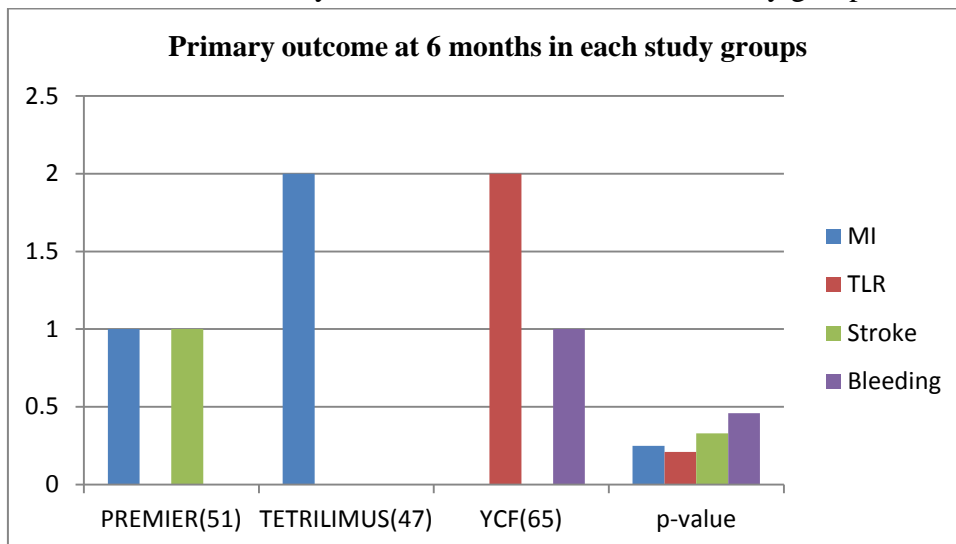


Table 23: Primary outcome at 12 months in each study groups

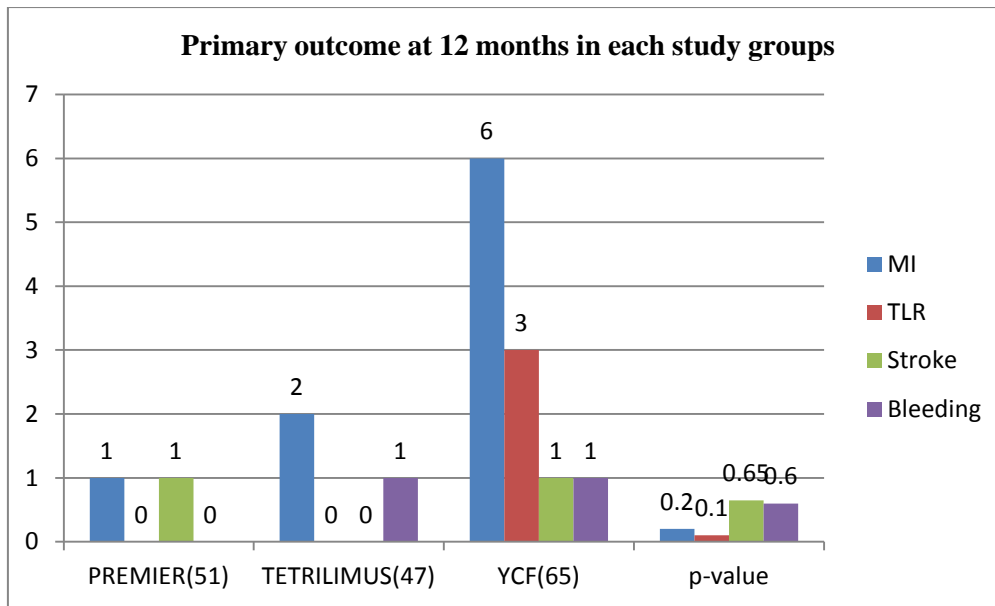
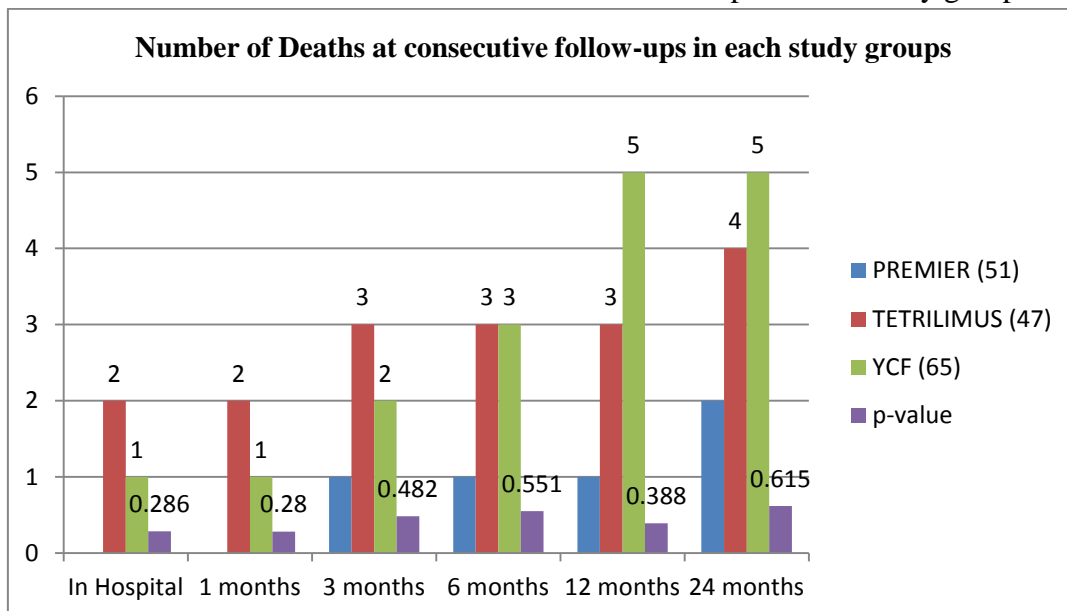
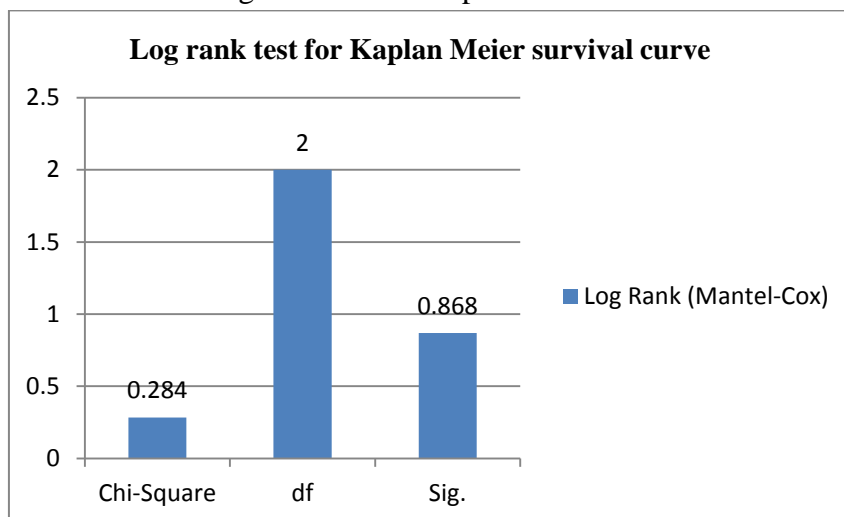


Table 24: Number of Deaths at consecutive follow-ups in each study groups



In the above table, in hospital and one-month follow-up had 3 deaths. 6 months follow-up had 6 deaths, 12-month follow-up had 9 deaths and end of study period follow-up had 11 deaths (Table 21 to 24).

Table 25: Log rank test for Kaplan Meier survival curve



The above table 25 shows that according to log rank test the Kaplan Meier survival curve does not show any statistical significance in the death events between the study groups.

4. DISCUSSION:

A total of 163 patients after excluding patients that were lost to follow-up and the Metafor group, were considered in three treatment arms of the study. The mean age of the population was found to be 54.20 ± 11.43 years. It was observed that Indians tend to experience cardiovascular disease at younger age than the Western inhabitants¹². Many western inhabitants tend to suffer from cardiovascular disease in 6th decade of their life. In our study, the three treatment arms i.e. Premier, Tetrilimus, and Yukon Choice Flex (YCF) had mean age of 52.24, 56 and 54.45 years respectively. Studies involving cardiovascular disease on Indian population have also shown mean age comparable to the present study. Males are at higher risk of developing cardiovascular diseases due to a greater number of risk factors associated with them¹³. The present study has 76.1% of male patients. Other literatures have also shown that male population was predominantly higher than the female population. Women have less incidence of coronary artery disease than men due to the levels of estrogen, a female hormone¹⁴. This hormone is naturally known to provide protection to heart and is less likely to suffer from heart problems than men. The major risk factors observed in the present study were hypertension involving 47.2% of the study population, smoking 41.1% of population followed by diabetes mellitus in 35% of subjects¹⁵.

The levels of total cholesterol and its individual components were comparable and there was no significant difference (p value >0.05) between the three treatment arms of the study.

Random blood sugar levels were evaluated for each patient included in this study. Patients in the Tetrilimus treatment arm had the highest amount of blood sugar levels than Premier and YCF.

The present study had 130 patients presented within window period of <12hrs. Window period i.e., time from symptom onset to presentation to hospital significantly affects patient outcome. Door to balloon time (according to current guidelines, door to wire crossing time) is

an independent predictor of patient outcome regardless of baseline risk factors and window period¹⁶.

The study has shown that the primary outcome (i.e., MACCE rate) is highest in the YCF group with 16 reported events. However, there was no statistically significant difference between the three treatment groups regarding MACCE rates (p value >0.05). Some noteworthy things from the present study are, number of patients in YCF treatment arm were almost one and a half times than the Tetrilimus treatment arm¹⁷.

Metafor included 4.6% of patients with STEMI, whereas other three groups included 100% STEMI patients, which might govern the outcome. Follow-up at 6 months and 1 year showed death rates of 1.6% & 2.4% in Metafor group, 46% & 76.9% in YCF group, 19.6% & 58.8% in Premier group & 63.8% in Tetrilimus group, which means highest death rate in YCF group. The rate of MI was 0.4% & 0.8% in Metafor group, 9.23% at 12 months in YCF group, 1.96% in Premier group & 4.25% in Tetrilimus group, i.e., highest number of MI in YCF group. No TLR in Metafor, Tetrilimus & Premier groups, whereas YCF showed 3.07% & 4.62% at 6 months and 1 year respectively, which can be attributed to the relatively large sample size¹⁸. However, P value was >0.05 which means there is no statistical significance in MACE rate.

Other literatures checking [65-67] safety and efficacy of Indian manufacture stents have shown 12 months event rates ranging from 2% to 10%. Literature reporting very long-term clinical outcomes of an Indian manufactured stent showed 12.5% MACCE rate at 7 years¹⁹.

5. CONCLUSION

The increasing number of cases in India with CAD and ACS leading to raising morbidity and mortality rate, makes it most important to evaluate the safety and efficacy of the treatment option available. The evolution of Angioplasty from the era of POBA to PTCA, showed drastic improvement in patient outcome. Further advancements in PTCA were made from usage of BMS to DES. The FDA approved 2nd generation DES like Xience, Endeavour, Promus etc. are used worldwide but are more expensive. Hence many studies were conducted drawing comparison between Indian manufactured DES and Imported DES and have shown non-inferiority. But no studies were taken up to compare the outcomes between different Indian DES. Hence the present study was taken up. This study draws a conclusion that all the three treatment groups have almost similar outcome of efficacy and safety, thus we are justified in using any Indian manufactured DES which are more economical and equally efficacious. However, this was a single center, and a small-scale study and large-scale studies are required for further evaluation.

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