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Observational Study Of Primary And Pharmacoinvasive Intervention And Their Outcome In Patients With Acute Myocardial Infarction In A Tertiary Care Centre

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Abstract:
Background*: The treatment of choice is STEMI is Primary PCI (ACC/AHA Class IA recommendation). ACC/AHA has given a Class IIa recommendation for Pharmacoinvasive Strategy, while European society of Cardiology has given Class I recommendation for Pharmacoinvasive strategy.*
Materials and Methods*: An Observational study done including 229 STEMI patients admitted within a window period of 24hrs over a period of 1 year (2022) who underwent Primary PCI or Pharmacoinvasive therapy at our Centre. The Clinicoangiographic profile and End points and Complications, Duration of hospitalisation and Mortality outcome on follow up at 90 days in both the groups were analysed. Statistical analysis were done using SPSS software 22.0*
Results*: Out of the 229 patients 49 were in the Primary Strategy group (PG) and 180 patients were in the Pharmacoinvasive strategy group (PIG). There was statistically signification association (p value < 0.05) in parameters like Age, Lysis, Access site, P/PI PTCA, Lipid profile, CAG Impression, Advice.*
Conclusion: *From our study it is conclude that STEMI patients undergoing Primary and Pharmacoinvasive Intervention had no statistically significant difference in End point of MACE and mortality outcome at 90 days. This study also shows that Pharmacoinvasive Intervention is non- inferior to Primary intervention in management of STEMI patients.*
Key Word*: STEMI, PG (Primary Strategy Group), PIG (Pharmacoinvasive strategy Group), CAG*

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I. INTRODUCTION

The treatment of choice is STEMI is Primary PCI (ACC/AHA Class IA recommendation). But in real world situations, timely PCI remains a challenge especially in developing countries and timely transfer to such centres also remains a huge challenge considering the lack of emergency ambulance services and the state of our road infrastructure. Pharmacoinvasive strategy refers to angiography with a view to revascularize infarct related vessel 3-24 hours after fibrinolysis. ACC/AHA has given a class IIa recommendation, while European society of Cardiology has given class I recommendation for this strategy. We will analyse whether Pharmacoinvasive strategy is non inferior to Primary PCI in a setting like ours where Streptokinase is used as a fibrinolytic agent mostly as compared to the western countries.

II. MATERIAL AND METHODS

This prospective comparative study was carried out on STEMI patients of Department of Cardiology at Government Kilpauk Medical College and Hospital, Chennai , Tamilnadu from January 2022 to December 2022. A total 229 adult subjects (both male and females) of aged ≥ 18 years were included for this study.
Study Design: Prospective open label observational study
Study Location: This was a tertiary care teaching hospital based study done in Department of Cardiology at Government Kilpauk Medical College and Hospital, Chennai , Tamilnadu .
Study Duration: January 2022 to December 2022.
Sample size: 229 patients.
Sample size calculation: The sample size was estimated on the basis of a single proportion design. We assumed that the confidence interval of 10% and confidence level of 95%. The sample size actually obtained for this study was 96 patients for each group but as we considered only the STEMI patients undergoing Primary or Pharmacoinvasive Intervention for 1 year (2022), the exact sample size could not be implemented.

Subjects & selection method: The study population was drawn from Acute Coronary Syndrome patients who presented to Government Kilpauk Medical College and Hospital with STEMI within a window period of 24hrs and underwent Primary or Pharmacoinvasive Intervention from January 2022 to December 2022. Data collected retrospectively from department records. 229 patients were included in the study. The Clinicoangiographic profile and End points (Reinfarction within 30 days , Cardiogenic shock and Death) and Complications, Duration of hospitalisation and Mortality outcome on follow up at 90 days in both the groups were analysed in this study.

Inclusion criteria:

1. All Acute Myocardial Infarction Patients with ST Elevation and STEMI Equivalent in ECG
2. Either sex
3. Aged ≥ 18 years,
4. Presentation Window Period of 24 hrs
5. Patients who underwent Primary or Pharmacoinvasive Intervention
6. Duration of 1 year (2022)
7. Follow up of Patients for 90 days

Exclusion criteria:

1. Unstable Angina Patients
2. NSTEMI Patients
3. Patients presenting with STEMI Mimickers after confirmation and ruling out Acute MI
4. Presentation Window Period of more than 24 hrs.
5. Chronic Stable Angina Patients
6. Active Bleeding or Hemorrhage & other Contraindications for lysis
7. Severe renal impairment (eGFR <30 ml/min)

Procedure methodology

After written informed consent was obtained, a well-designed questionnaire was used to collect the data of the recruited patients retrospectively from Medical department records (MRD). The questionnaire included socio-demographic characteristics such as age, gender, risk factors with Comorbidities, lifestyle habits like Smoking and Alcohol consumption and drug abuse and parameters like LVEF, Diagnosis, Lysed or Not lysed were included. Biochemistry laboratory investigations such as Random blood sugar, Lipid profile including total cholesterol, HDL and LDL cholesterol levels and Triglycerides level.

Angiographic parameters like Access site, P/PI CAG, P/PI PTCA, CAG Impression, SVD, DVD, PTCA/CABG/OMT, PTCA vessel, TIMI Flow. The Clinicoangiographic profile and End points (Reinfarction within 30 days , Cardiogenic shock and Death) and Complications, Duration of hospitalisation and Mortality outcome on follow up at 90 days in both the groups were analysed in this study.

Information about the type of Intervention underwent by the STEMI patients was taken from the Case Sheets with CAG/ PTCA reports from MRD. Baseline characteristics of the patients were collected

Statistical analysis

Data was analyzed using SPSS version 29 (SPSS Inc., Chicago, IL). Student's *t*-test was used to ascertain the significance of differences between mean values of two continuous variables and confirmed by nonparametric Mann-Whitney test. Chi-square and Fisher exact tests were performed to test for differences in proportions of categorical variables between two groups. The level $P < 0.05$ was considered as the cutoff value or significance.

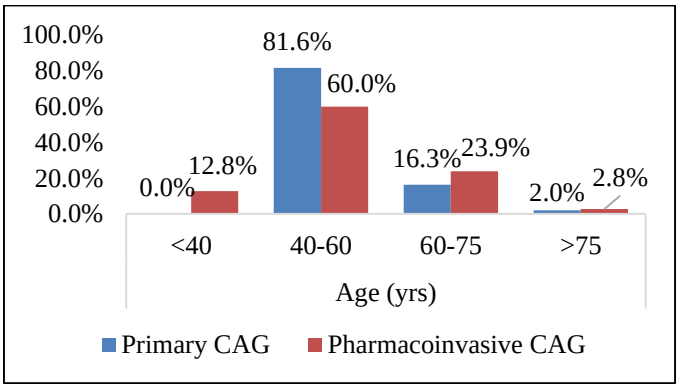
III. RESULT

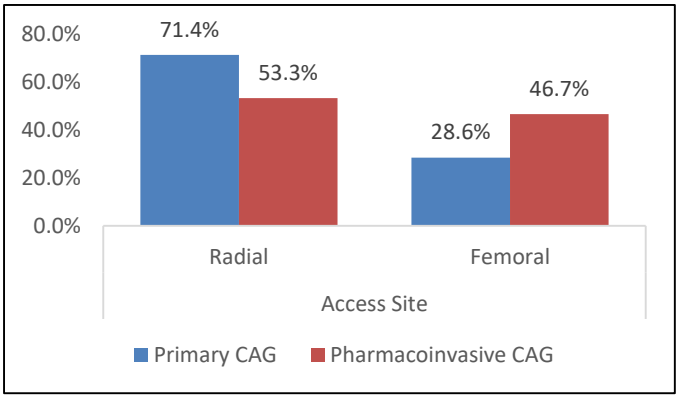
Out of the 229 patients 49 were in the Primary Strategy group (PG) and 180 patients were in the Pharmacoinvasive strategy group (PIG). There was statistically significant association (p value < 0.05) in parameters like Age, Lysis, Access site, P/PI PTCA, Lipid profile, CAG Impression, Advice. Table 1 shows the various parameters analysed in both the groups followed by the bar diagrams of the statistically significant association parameters.

Table No.1

. PARAMETERS		P/PI CAG				P value
		Primary CAG		Pharmacoinvasive CAG		
		Count	Row N %	Count	Row N %	
Age	<40	0	0.0%	23	12.8%	**0.013**

	40-60	40	81.6%	108	60.0%	
	60-75	8	16.3%	43	23.9%	
	>75	1	2%	5	2.8%	
Sex	Male	43	22.8%	146	77.2%	
	Female	6	15.0%	34	85.0%	0.277
	Transgender	0	0.0%	0	0.0%	
RBS	<180	24	18.3%	107	81.7%	
	181-300	18	26.1%	51	73.9%	0.439
	>301	5	21.7%	18	78.3%	
Diagnosis	AWMI	28	19.5%	116	80.5%	
	IWMI	19	25.3%	56	74.7%	
	IWMI+RVMI	0	0.0%	5	100.0%	0.458
	HLWMI	2	40.0%	3	60.0%	
LVEF	Mild	21	19.6%	86	80.4%	
	Moderate	27	22.7%	92	77.3%	0.751
	Severe	1	33.3%	2	66.7%	
Lysed/ Not Lysed	Streptokinase	7	4.5%	150	95.5%	
	Tenecteplase	18	66.7%	9	33.3%	**<0.0001**
	Not Lysed	23	53.5%	20	46.5%	
Access Site	Radial	35	26.7%	96	73.3%	**0.023**
	Femoral	14	14.3%	84	85.7%	
P/PI PTCA	Not done	7	12.7%	48	87.3%	
	Primary PTCA	39	95.1%	2	4.9%	
	Pharmacoinvasive PTCA	2	1.5%	129	98.5%	**<0.0001**
	POBA	1	50.0%	1	50.0%	





Out of the 229 patients as depicted in Table No.1 , majority of the patients were in the age group 40-60 yrs (p=0.013) with more male than female patients. Majority of the patients had AWMI in both groups with Moderate LVSD in PG and Mild LVSD in PIG with blood sugar in range of 181-300mg/dl. Most of the patients were lysed with Streptokinase than Tenecteplase in the PIG (p<0.0001). Low dose Intracoronary Streptokinase (250k units) and Tirofiban (25ug/kg) used in Primary cases with Ostial lesions with huge thrombus burden in

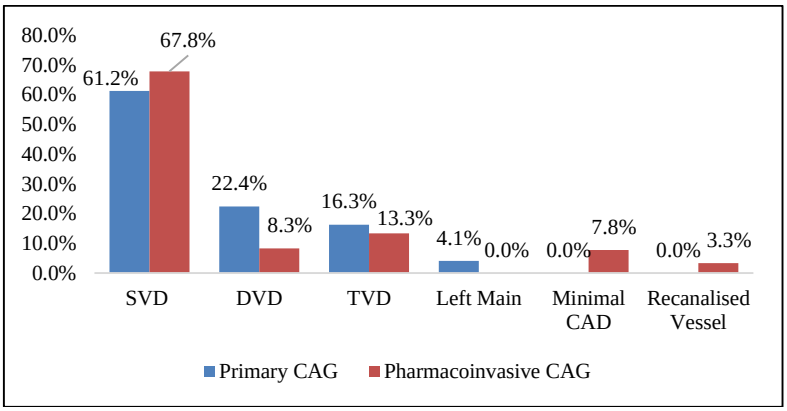
hemodynamically stable patients and check CAG after 2 days revealed TIMI 3 Flow with Recanalised Culprit Vessel in 7 patients. 3 patients in the PG had undergone Thrombus aspiration of which 1 patient developed Cardiogenic Shock. For performing CAG and PCI the Radial access used more than Femoral (p=0.023) and PTCA done in majority 79.6% in PG and 71.7% in PIG group (p< 0.0001).

Table No.2

Risk factors	Primary CAG		Pharmacoinvasive CAG		P value
	Count	Row N %	Count	Row N %	
T2DM	20	23.0%	67	77.0%	<0.0001
SHTN	16	20.8%	61	79.2%	
Dyslipidemia	2	28.6%	5	71.4%	
Smoking	17	17.5%	80	82.5%	
Alcoholism	15	17.6%	70	82.4%	
CKD	6	37.5%	10	62.5%	
CVA	1	50.0%	1	50.0%	
Post Covid	3	42.9%	4	57.1%	

Table No.3

Lipid Profile	P/PI CAG				P value
	Primary CAG		Pharmacoinvasive CAG		
	Count	Row N %	Count	Row N %	
Increased LDL	20	17.2%	96	82.8%	0.088
Increased Triglycerides	20	22.2%	70	77.8%	
Decreased HDL	1	100.0%	0	0.0%	



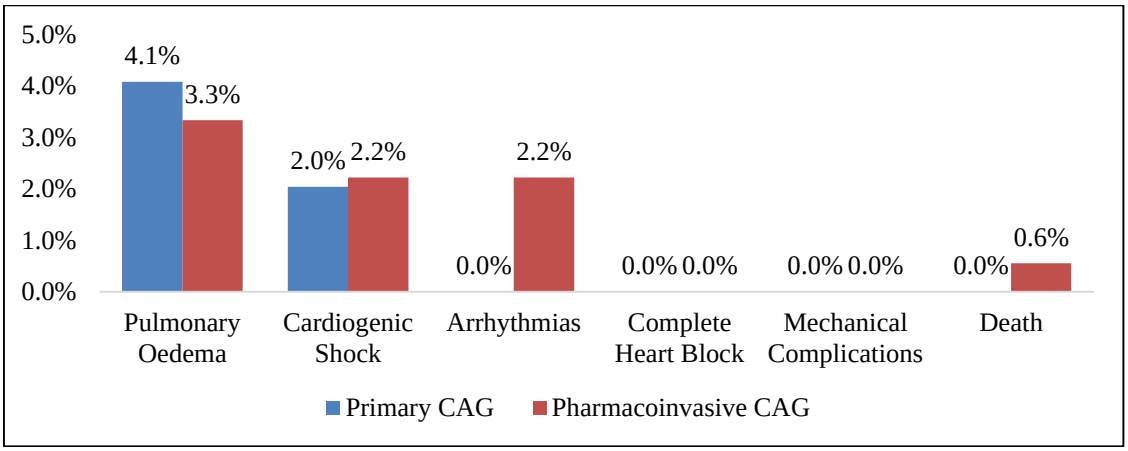
Among risk factors shown in Table No.2 majority of the patients in PG group were Smokers followed by Diabetics whereas Smokers & Alcoholics followed by Diabetics in the PIG group with insignificance. Table No.3 denotes predominant patients in both group had elevated LDL and Triglycerides with significant statistical difference (p= 0.088). After performing CAG majority had undergone PTCA in both group significant with LAD as the culprit vessel as depicted by bar diagram and Table No.6 & Table No.7

Table No.4

CAG IMP	P/PI CAG				P value
	Primary CAG		Pharmacoinvasive CAG		
	Count	Column N %	Count	Column N %	
SVD	30	61.2%	122	67.8%	0.001
DVD	11	22.4%	15	8.3%	
TVD	8	16.3%	24	13.3%	
Left Main	2	4.1%	0	0.0%	
Minimal CAD	0	0.0%	14	7.8%	
Recanalised Vessel	0	0.0%	6	3.3%	

Table No.5

		P/PI CAG				P value
		Primary CAG		Pharmacoinvasive CAG		
		Count	Row N %	Count	Row N %	
SVD	LAD	23	20.2%	91	79.8%	0.474
	LCX	1	7.7%	12	92.3%	
	RCA	6	24.0%	19	76.0%	
DVD	LAD & LCX	3	37.5%	5	62.5%	0.77
	LAD & RCA	6	50.0%	6	50.0%	
	RCA & LCX	1	50.0%	1	50.0%	
	RCA& LCX	0	0.0%	1	100.0%	
TIMI Flow	Flow	48	21.9%	171	78.1%	0.369
	Slow Flow	0	0.0%	0	0.0%	
	No Flow	1	10.0%	9	90.0%	
Durationof Hospitalisation (Days)	<5	42	20.3%	165	79.7%	0.31
	6-10	6	30.0%	14	70.0%	
	>11	0	0.0%	0	0.0%	
Mortality outcome at 90 days	Alive	46	21.4%	169	78.6%	0.886
	Death	3	23.1%	10	76.9%	



The predominant patients in both group had SVD of statistically significance (p=0.001) with SVD of LAD and DVD (LAD & RCA) with TIMI 3 flow as shown in Table No.4 & table No.5. There was no statistically significant difference among duration of hospitalization in Table No.5 and complications in both groups as shown in abr diagram. Among Endpoint 3 patients had reinfarction in the PIG, Cardiogenic shock in 1 patient in PG & 4 patients in PIG and 1 patient died within a week in th PIG group with no significant difference. Table No.5 showing Mortality outcome at 90 days include 3 patients in PG and 10 patients in the PIG group is statistically insignificant.

IV. DISCUSSION

The prevalence of Cardiovascular Disease (CVD) in India is around 54.5 million. CVD is the leading cause of mortality in the country (25% of all lives lost). The CVD death rate in India is 272 per 1 Lakh compared to the global average of 235 per 1 lakh population. ST elevation Myocardial Infarction(STEMI), Non ST elevation Myocardial Infarction (NSTEMI) and Unstable angina, forms the entire spectrum of Acute coronary syndrome (ACS).One of the gravest complications of Coronary artery disease is STEMI which involves total occlusion of infarct related artery. Coronary reperfusion in the setting of STEMI is established mainly by these two modalities 1) Pharmacological (Fibrinolysis) 2) Mechanical (Primary PCI). Apart from these two treatment modalities, one strategy that has proved beneficial in this patient population is the Pharmacoinvasive strategy. Pharmacoinvasive strategy refers to routine angiography with a view to revascularization of infarct related artery 3-24 hours after fibrinolysis. The goal of treatment is to reduce the total ischemic time which refers to the time period between the onset of symptoms and administration of reperfusion strategy which will result in restoration of coronary blood flow in the infarct related artery. The treatment of choice is STEMI is Primary PCI (ACC/AHA Class IA recommendation) while ACC/AHA has given a class IIa recommendation and European society of Cardiology has given class I recommendation for Pharmacoinvasive strategy.

Several trials (CARESS-in-AMI, TRANSFER AMI, WEST study, STREAM, STEP AMI etc.) have addressed the potential benefit of Pharmacoinvasive strategy. CREATE and Kerala ACS Registry shows that there is significant delay in patient presentation, and initiation of timely reperfusion. Pharmaco-invasive approach helps to shorten the time to reperfusion of infarct related artery by initiation of lysis. PCI in 3-24 hours helps to consolidate the initial reperfusion process and prevent reclusion of the infarct related artery.

In our study out of the 229 patients, 49 were in the Primary Strategy group (PG) and 180 patients were in the Pharmacoinvasive strategy group (PIG). The sociodemographic, clinical, laboratory and angiographic parameters were analysed in both the groups. There was statistically significant association (p value < 0.05) in parameters like Age, Lysis, Access site, P/PI PTCA, Lipid profile, CAG Impression, Advice. Our study shows majority of patients in both the group were in the age group 40-60 yrs (p=0.013) with more male than female patients. Majority of the patients had AWMI in both groups with Moderate LVSD in PG and Mild LVSD in PIG with blood sugar in range of 181-300mg/dl. Most of the patients were lysed with Streptokinase than Tenecteplase in the PIG (p<0.0001). The new finding which we noted in our study was use of Low dose Intracoronary Streptokinase (250k units) and Tirofiban (25ug/kg) used in Primary cases with Ostial lesions with huge thrombus burden in hemodynamically stable patients and check CAG after 2 days revealed TIMI 3 Flow with Recanalised Culprit Vessel in 7 patients. 3 patients in the PG had undergone Thrombus aspiration of which 1 patient developed Cardiogenic Shock. For performing CAG and PCI the Radial access used more than Femoral (p=0.023) and PTCA done in majority 79.6% in PG and 71.7% in PIG (p< 0.0001).

Among risk factors majority of the patients in PG group were Smokers followed by Diabetics whereas Smokers & Alcoholics followed by Diabetics in the PIG group with insignificance. Predominant patients in both group had elevated LDL and TGs with significant statistical difference (p= 0.088). After performing CAG majority had undergone PTCA in both group significant statistically with LAD as the culprit vessel.The predominant patients in both group had SVD of statistically significance (p=0.001) with SVD of LAD and DVD (LAD & RCA) with TIMI 3 flow. There was no statistically significant difference among duration of hospitalisation and complications in both groups. Among Endpoint 3 patients had Reinfarction in the PIG, Cardiogenic shock in 1 patient in PG & 4 patients in PIG and 1 patient died within a week in th PIG group with no significant difference. Mortality outcome at 90 days include 3 patients(6.1%) in PG and 10 patients(5.6%) in the PIG group is statistically insignificant. Hence from our study the incidence of Composite end points, Complications and Mortality outcome at 90 days had no statistically significant difference between both groups hence Pharmacoinvasive Strategy is non- inferior to Primary Strategy in treatment of STEMI patients

V. CONCLUSION

From our study it is concluded that STEMI patients undergoing Primary and Pharmacoinvasive Intervention had no statistically significant difference in End point of MACE and mortality outcome at 90 days and Streptokinase being used in majority compared to Tenecteplase in the PIG group for lysis. The unique feature found in our study is the role of Low dose Intracoronary Streptokinase in Primary cases with Ostial lesions with huge thrombus burden in hemodynamically stable patients and check CAG after 2 days. Most of the Triple vessel disease patients had Diabetes mellitus and Hypertension as risk factors. This study shows that Pharmacoinvasive Intervention is non- inferior to Primary intervention in management of STEMI.

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