A Comparative Study between pharmacoinvasive strategy and primary Percutaneous Coronary angioplasty on left ventricle function in patients presenting by acute ST Segment Elevation Myocardial Infarction

ABSTRACT:

Background: Ischemic heart disease is considered the most common cause of death, worldwide. It accounts for 1.8 million deaths annually in Europe alone. According to the center for disease control (CDC) it's the most common cause of deaths in Egypt accounting for more than one fifth of the total death count per year (21%), followed by stroke, then cancer.

Aim: This work aimed to study and assess the efficacy of a pharmacoinvasive strategy compared with a primary PCI strategy on the left ventricle function in treatment of patient with myocardial infarction.

Methods: Our study was prospective non randomized which compares between two groups, both of which had first time acute STEMI admitted to our Tanta University Hospital within the accepted time, which are (group 1) patients who had primary PCI for the infract related artery as a reperfusion therapy and (group 2) patients who had thrombolytic followed by coronary angiography with a window to PCI (pharmacoinvasive technique). Coronary angiography was performed either immediately in case of failed thrombolytic therapy or within 3-24 hrs. Following thrombolytic in case of successful thrombolytic.

Both groups presented to the hospital within the accepted time window for reperfusion therapy either (thrombolytic or primary PCI), within 12hrs.

Result: The study compared between the two groups in the acute stage during hospitalization of the patients and after discharge according to Clinical outcomes: (mortality, major adverse cardiac events (MACE) as heart failure symptoms, re-infarction and Cardiac death),angiographic findings (base line TIMI flow score and final TIMI score, single or multi-vessel disease) , angiographic complications as dissection and no-reflow, occurrence of contrast induced nephropathy and cerebrovascular events and LV systolic function assessment by echocardiography

Conclusion: In this study, we highlighted the importance of total ischemic time and importance of patient and system related delays in influencing outcomes of STEMI.

Keywords: Myocardial infarction, Revascularization, PCI.

1. INTRODUCTION:

Ischemic heart disease is considered the most common cause of death, worldwide. It accounts for 1.8 million deaths annually in Europe alone. According to the center for disease control (CDC) it's the most common cause of deaths in Egypt accounting for more than one fifth of the total death count per year (21%), followed by stroke, then cancer. [1]

According to the European Society of Cardiology (ESC), the Incidence of ST segment elevation acute myocardial infarction (STEMI) has decreased in Europe and USA with relative increase in Non ST segment elevation acute coronary syndrome (NSTEACS).2 However, in Egypt there is no enough data on prevalence of subtypes of acute coronary syndromes (ACS). [3]

The Egyptian National Hypertension Project has provided the two principal sources of information on the epidemiology of coronary heart disease in the region; in addition to data from the World Health Organization (WHO). [4]

There is a need for more recent data on the epidemiology of coronary heart disease in the region, given the projected sharp increases in the prevalence of coronary heart disease in the Middle Eastern countries described earlier.1 The ESC and AHA guidelines showed superiority to primary PCI over the use of thrombolytic therapy in STEMI management. However, only about one-third of United States (US) hospitals currently have the capability to perform primary PCI twenty-four hours, seven days a week. This means that a substantial number of STEMI patients will need to either have the ambulance bypass the closest hospital or be transferred from non-

PCI hospitals. Any significant delays may negate the benefit of primary PCI over fibrinolysis. Current guidelines from the European Society of Cardiology (ESC) and the American Heart Association (AHA)/ American College of Cardiology Foundation (ACCF) recommend fibrinolysis if PCI cannot be performed within 120 minutes from first medical contact. [2]

Despite these recommendations, recent data from the US National Cardiovascular Data Registry showed that only 51% of STEMI patients transferred for Primary PCI achieved the recommended first door to balloon time of less than 120 minutes. [5]

2. PATIENTS AND METHODS:

2.1 Study design and population:

Our study was prospective non randomized which compares between two groups, both of which had first time acute STEMI admitted to our Tanta University Hospital within the accepted time , which are:

Group 1: patients who had primary PCI for the infracted related artery as a reperfusion therapy.

Group 2: patients who had thrombolytic followed by coronary angiography with a window to PCI (pharmacoinvasive technique). Coronary angiography was performed either immediately in case of failed thrombolytic therapy or within 3-24 hrs following thrombolytic in case of successful thrombolytic.

Both groups presented to the hospital within the accepted time window for reperfusion therapy either (thrombolytic or primary PCI), within 12hrs.

The study compared between those two groups in the acute stage during hospitalization of the patients according to the following

a- Clinical outcomes: (mortality, major adverse cardiac events (MACE) as heart failure symptoms, re-infarction and Cardiac death)

b- Angiographic findings (base line TIMI flow score and final TIMI score, single or multi-vessel disease) and angiographic complications as dissection and no-reflow, occurrence of contrast induced nephropathy and cerebrovascular events.

c- LV systolic function assessment by echocardiography

Follow up after three months;

a- Clinical outcomes: (mortality, major adverse cardiac events
(MACE) as heart failure symptoms, re-infarction and cardiac death)

b- LV systolic function assessment by echocardiography

2.3 Inclusion criteria:

1. Patients presenting by STEMI within 12 hrs and treated with primary PCI or pharmacoinvasive technique

2.4 Exclusion criteria:

1. Patients with prior myocardial infarction
2. Patient with previously deployed stent.
3. Patient with STEMI and mechanical complication
4. Patient underdone (CABG).
5. Patient with impaired left ventricular ejection fraction EF less than 40%

2.5 Statistical analysis:

Normally distributed scale variables were expressed as mean + standard deviation. Non-normally distributed variables were expressed as median and range. Categorical variables were expressed in numbers and percentages. Analyses of categorical variables were performed by chi-square test. Parametric scale variables were analyzed by independent sample t test, and nonparametric scale variables were analyzed by Mann-Whitney U test. Multivariate logistic regression analyses were performed to determine the independent predictors of remodeling.

3. RESULTS

Gender distribution:

150 patients included in the study, 83 of the study population were males and 67 were females. Group I included 53 males (55.2%) and 43 females (44.8%). Group II included 30 males (55.6%) and 24 females (44.4%). There was no statistically significant difference between the two groups (P value =.967) (Table 1).

Table (1): Comparison between the two studied groups according to demographic data

Demographic data	Total (n=150)		Group I (n=96)		Group II (n=54)		Test of sig.	P
	No.	%	No.	%	No.	%		
Sex								
Male	83	55.3	53	55.2	30	55.6	χ^2= 0.002	0.967
Female	67	44.7	43	44.8	24	44.4		

IQR: **Inter quartile range** SD: **Standard deviation**
χ^2: **Chi square test** **t: Student t-test**
p: p value for comparing between **the two studied groups**
Group I: Primary PCI, Group II: Pharmacoinvasive technique

Considering Risk factor:
a) Diabetes Mellitus (DM): 66 patients of the study population were diabetic. In group I, 43 patients were diabetics (44.8%), while in Group II, 23 patients were diabetics (42.6%). There was no statistically significant difference between the studied groups (P value 0.795). (Table 2).
b) Hypertension (HTN): 66 patients of the study population were hypertensive. In group I, 46 patients were hypertensive (47.9%), while in Group II, 20 patients were hypertensive (37%). There was no statistically significant difference between the two groups (P value =0.198) (Table 2).
c) Smoking: 66 patients of the study population were active smokers. In group I, 46 patients were smokers (47.9%), while in Group II, 20 patients were active smokers (37%). There was no statistically significant difference between the two groups (P value =0.189) (Table 2)

Table (2): Comparison between the two studied groups according to medical history

Medical history	Total (n=150)		Group I (n=96)		Group II (n=54)		□□	P
	No.	%	No.	%	No.	%		
DM	66	44.0	43	44.8	23	42.6	0.068	0.795
Smoker	66	44.0	46	47.9	20	37.0	1.660	0.198
HTN	66	44.0	46	47.9	20	37.0	1.660	0.198

χ^2: Chi square test **FE: Fisher Exact**
p: p value for comparing between the two studied groups
*: Statistically significant at $p \leq 0.05$
Group I: Primary PCI, Group II: Pharmacoinvasive technique

Considering clinical presentation:
Killip class: 115 of the study population presented with Killip class I, while 29 patients presented with Killip class II and 6 patients presented by Killip class III. In group I; 70 patients presented with Killip class I (72.9 %), 21 patients presented with Killip class II (21.9%) and 5 patients presented with Killip class III (5.2 %), while in group II; 45 patients presented with Killip class I (83.3%), 8 patients presented with Killip class II (14.8%) and one patient presented with Killip class III (1.9%). There was no statistically significant difference between the studied groups (P value = 0.137). (Table 3).

Table (3): Comparison between the two studied groups according to Killip Class

Killip	Total (n=150)		Group I (n=96)		Group II (n=54)		Test of sig.	P
	No.	%	No.	%	No.	%		
1	115	76.7	70	72.9	45	83.3	χ^2= 2.087	^{MC}p= 0.391
2	29	19.3	21	21.9	8	14.8		
3	6	4.0	5	5.2	1	1.9		

Min. – Max.	1.0 – 3.0	1.0 – 3.0	1.0 – 3.0	U= 2312.500	0.137
Mean ± SD.	1.27 ± 0.53	1.32 ± 0.57	1.19 ± 0.44		
Median (IQR)	1.0 (1.0–1.0)	1.0 (1.0–2.0)	1.0 (1.0–1.0)		

IQR: **Inter quartile range** SD: **Standard deviation**
χ^2: **Chi square test** MC: **Monte Carlo** **U: Mann Whitney test**
p: p value for comparing between **the two studied groups**
Group I: Primary PCI, **Group II: Pharmacoinvasive technique**

Angiographic result:
TIMI flow score:
+ Group I treated by primary PCI: Baseline TIMI flow: 87 patients had TIMI flow < 3 (90.6), and 9 patients had TIMI III flow (9.4%).Final TIMI flow: 10 patients had TIMI flow < 3 (10.4), and 86 patients had TIMI III flow (89.6%).
+ Group II treated by pharmacoinvasive technique: Baseline TIMI flow: 27 patients had TIMI flow < 3 (50%), and 27 patients had TIMI III flow (50%).Final TIMI flow: 3 patients had TIMI flow < 3 (5.5%), and 51 patients had TIMI III flow (94.5%). As would be expected the base line TIMI flow between both groups showed statistical significant difference (P < 0.001). While, final TIMI flow between both groups showed no statistical significance (P = 0.179) (Table 4).
Table (4): Comparison between the two studied groups according to TIMI

TIMI Flow	Group I (n=96)		Group II (n=54)		Test of sig.	P
	No.	%	No.	%		
Baseline						
< 3	87	90.6	27	50	χ^2= 40.414	< 0.001
3	9	9.4	27	50		
Final						
< 3	10	10.4	3	5.5	χ^2= 1.802	0.175
3	86	89.6	51	94.5		

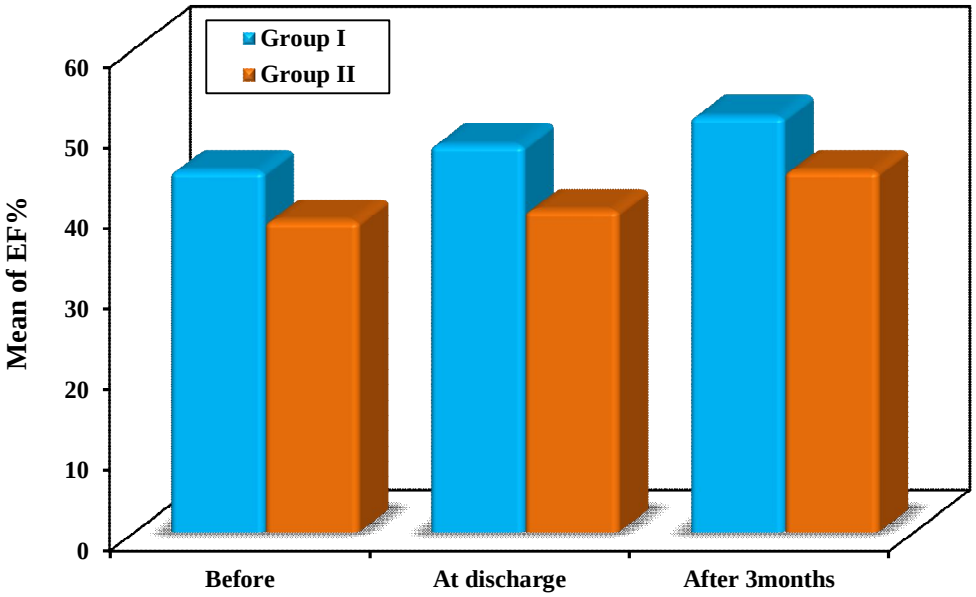
IQR: **Inter quartile range** SD: **Standard deviation**
χ^2: **Chi square test** MC: **Monte Carlo** **U: Mann Whitney test**
p: p value for comparing between **the two studied groups**
Group I: Primary PCI, Group II: Pharmacoinvasive technique

Echocardiographic study:

- **Ejection fraction assessment:**

- ***Before Starting Strategy of ttt*** : In Group I, EF was ranged from 25 – 70% (Mean =47.88 ± 9.18)with a median 50 % while In Group II EF was ranged from 30-68% (47.34±9.45)with a median 45 % There was no statically significant between two groups (P wave = 0.682)
- ***At Discharge :*** In Group I, EF was ranged from 35-60%(48.18±7.19)with a median 50% while In Group II, EF was ranged from 30-60% (40.0±5.32)with a median 40% there was statically significant between two groups (p wave =less than 0.001)
- ***After three months of follow up*** : In Group I, EF was ranged from 35-60 %(Mean 51.67±5.46) with a median 50 % while In Group II ,EF ranged from 30-60% (mean 44.91±4.90) with a median 45 % There was statically significant between two groups (p wave Less than 0.001) (figure 1)

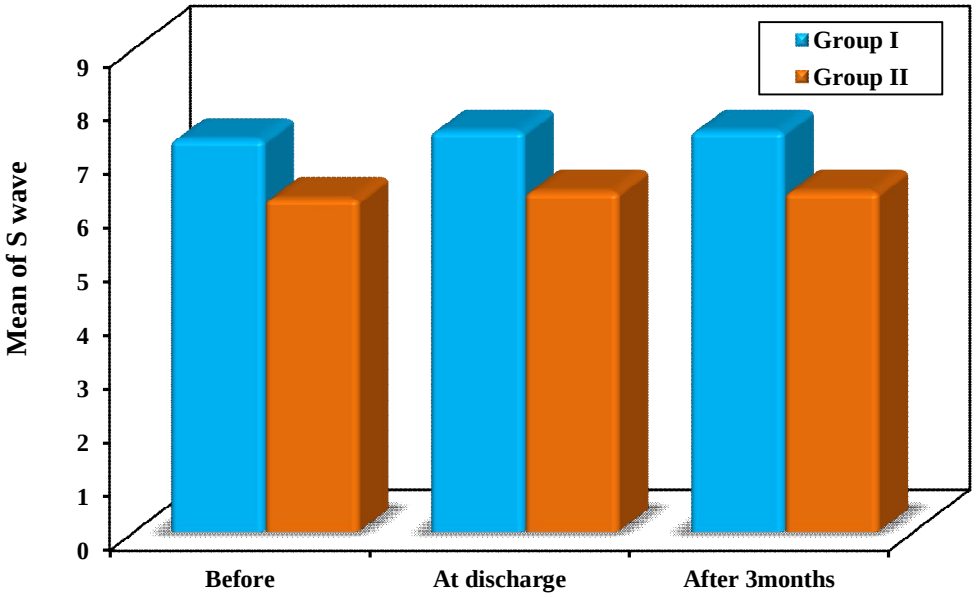
Figure (1) EF value between two groups.



❖ **S wave assessment:**

- ***Before Starting of ttt strategy*** :: In Group I, (S Wave) was ranged from 5-11 cm/s (mean 7.31±1.46) with a median 7 while In Group II S wave was ranged from 5-9 cm/s (mean 6.21±1.01) with a median 6 There was statically significant between two groups (P wave Less than 0.001) (figure 2).
- ***At Discharge*** : In group I, (S wave) ranged from 5-10cm/s (mean 7.47±1.27) With a median 8 while In group II (s wave) ranged from 5-9cm/s (mean 6.34±0.88) with a median 6 There was statically Significant between two groups (P wave Less than 0.001) (figure2).
- ***After three months of Follow Up*** : - In Group I (S wave) ranged from 5-10 cm/s (mean 7.47±1.27) with a median 8 In group II (S wave) ranged from 5 -9cm/s (mean 6.34±0.88) with a median 6 There was statically significant between two groups (P wave less than 0.001) (figure 2).

Figure (2): S wave value between two groups.



Regarding major adverse outcome during hospital admission:

Major Adverse Cardiac Events (MACE):

ϖ In Hospital complications:

• Coronary artery dissection occurred in one patient only of group I (1.0%) while in Group II occurred in 3 patients (5.6%). • Cerebrovascular events occurred in 3 patients of group I (3%). • Contrast induced nephropathy (CIN) occurred in one patient of group I (1.0%) while in group II occurred in also one patient (1.9%) .• Vascular complications (Limb Ischemia) occurred in one patient of group I (1.0%) while in group II occurred in also one patient (1.9 %). • Bleeding complication: 14 of the study population had bleeding complications. In group I, 4 patients had bleeding complications during hospital stay (3.7%). While in group II, 10 patients had bleeding complications during hospital stay (18.8%). That was statistically significant between both groups (P = 0.009).

• In-hospital Mortality: in Group I , It was 1.0 % (one patient) while in Group II , it was 16.7% (9 Patients) which was statically significant between two Groups (P wave 0.001). • None of the patients of the study population suffered from re-infarction during the hospital stay (0%) (Table 5).

• In-hospital congestive heart failure (CHF): 16 patient of the study population had symptoms of congestive heart failure. In group I, 6 patients suffered from CHF (6 %), and in group II, 10 patients suffered from CHF (19 %) which is statically significant between two groups (P wave 0.005).**(Table 5)**

Table (5): Comparison between the two studied groups according to in hospital complications and MACE:

Complication	Group I (n=96)		Group II (n=54)		χ^2	^{FE}p
	No.	%	No.	%		
Dissection	1	1.0	3	5.6	2.713	0.133
Re infarction	0	0.0	0	0.0	–	–
CVS	1	1.0	1	1.9	0.172	1.000
CIN	1	1.0	4	7.4	4.346	0.057
Limb ischemia	1	1.0	1	1.9	0.172	1.000
HF	6	6.0	10	19.0	7.726*	0.005*
Mortality	1	1.0	9	16.7	13.560*	<0.001*
Hge	4	3.7	10	18.8	6.771*	0.009*

χ^2: **Chi square test** FE**: Fisher Exact**

p: p value for comparing between **the two studied groups**

*: Statistically significant at $p \leq 0.05$

Group I: Primary PCI, Group II: Pharmacoinvasive technique

 Follow up MACE after 3 months:

• Follow up Mortality: 16 of the study population died after three months follow up. In group I, 6 patients died (6.0%). While in group II, 10 patients died (19.0%) which was statistically significant between two groups (P wave 0.005).

• Four of the patients of group II suffered from re-infarction after three months follow up (7.4%)

• Follow up congestive heart failure (CHF): 10 of the study Population had symptoms of congestive heart failure after three months follow up. In group I, one patient suffered from CHF after three months follow up (1%), and in group II, 9 patients suffered from CHF after three months follow up (16.7%) which was statistically significant between two groups (P wave 0.001).(table 6)

Table (6); Comparison between the two studied groups according to in hospital complications and MACE after three months:

Complication	Group I (n=96)		Group II (n=54)		χ^2	FE p
	No.	%	No.	%		
Re infarction	1	1.0	4	7.4	4.346	0.057
Mortality	6	6.0	10	19.0	7.726*	0.005*
HF	1	1.0	9	16.7	13.560*	<0.001*

χ^2: **Chi square test** FE**: Fisher Exact**
p: p value for comparing between **the two studied groups**
*: Statistically significant at $p \leq 0.05$
Group I: Primary PCI, Group II: Pharmacoinvasive technique

DISCUSSION:

- **Regarding the demographics in this study:**

In our study, Males represent 55.3%, while females represent 44.7% of the patient presented by STEMI with a ratio of 3.5:1. The age of the study population ranged from 40-70 years which was in concordant with a study conducted by Vaidya et al. in which the ratio of males to females having MI was 5:1 in the study population. Also, this came in agreement with the AHA statistical annual updated report by Mozaffarian et al. that found that STEMI is more prevalent in men than women. [13,14] Also this agrees with the study conducted by Blondeau et al. in which about 70% of the STEMI cases were males. [6]

Men are 3 to 5 times more likely to have coronary heart disease than women. However, the risk for women increases after menopause, by about 5 to 10 years following menopause, the risk of coronary heart disease for women increases to the same rate as men. Many women before menopause seem to be partly protected from coronary heart disease and stroke by natural estrogen.

- **Regarding risk factors for developing STEMI:**

In this study 66 patients were diabetics 44%, and 66 were hypertensive 44% , while 66 were active smokers 44% this came in agreement with a study conducted by Chow et al. Smoking has a strong pro-thrombotic effect, and smoking cessation is potentially the most (cost) effective of all secondary prevention measures. [7]

In the 2018 AHA statistical update about heart disease and stroke by Benjamin et al. stated that tobacco use remains the leading cause of preventable death in the United States and globally. It was estimated to account for 7.2 million deaths worldwide in 2015. [9]

Smoking cessation interventions should start during hospitalization, when smoking is not allowed, and continue during the post-discharge follow-up period. The beneficial effect of smoking cessation in patients with CAD, including a majority suffering an MI, has been shown in a meta-analysis conducted by Critchley et al. (20 observational studies, including 12603 patients reporting a 36% reduction of mortality in quitters. [7]

- **Regarding the clinical presentation of the two groups at hospital admission:**

In this study 98 of the study population presented by anterior STEMI in which LAD was the culprit lesion (65.3%), 48 patients presented by inferior STEMI (32.0%) and 4 patients presented by lateral STEMI (2.7%) also Most patients in this study presented by Killip class I about 76.7% while 19.3% presented by Killip class II and only 4% presented by Killip Class III. This came in agreement by the STREAM trial in which the majority of cases presented by anterior STEMI and patients presenting by Killip class I represented majority of their study population. [8] The median time delay from the onset of symptoms to first medical contact (FMC) was similar in the two study groups. In group I, treated by primary PCI time from onset of symptoms to FMC ranged from 30 minutes to 12 hours with mean duration 4.94 ± 3.45 hours with median 4.0 hours but in group II time from onset of symptoms to FMC ranged from 1-12 hrs. With mean 6.07 ± 3.67 hours and median 5.0 hrs. (P 0.061) It was found that 67 of the patients had multi-vessel coronary disease (44.7%) and 83 patients had single culprit vessel disease 55.3%.[8]

- **Regarding angiographic findings**

In group I, it was found that the patients had multi-vessel coronary disease (44.8%) and patients had single culprit vessel disease (55.2%). And in group II, patients had multi-vessel coronary disease (44.4%), this finding was similar in both study groups (P=0.967).Both study groups were compared regarding base line TIMI flow in coronary angiography. In group II, treated with fibrinolytic agents 50% of cases achieved TIMI III flow. While patients achieved either TIMI flow 0, 1 or 2 (50%). Of which urgent angiography and PCI was required in patients who didn't meet criteria of successful reperfusion by thrombolytic therapy (19%), the remainder cases underwent timely arranged coronary angiography and PCI within 24 hours. But as would be expected in group I,

only cases achieved base line TIMI III flow (10%) and remainder patients of the study group achieved either TIMI 0, 1 or 2 (90%). (P < 0.001).
After PCI, patency rates were high in the two study groups with final TIMI III achieved in 90% and 95% of patients in group I and II respectively.
In the STREAM trial, in the group treated by fibrinolysis most patients presented by base line TIMI III 58.5% while in the group treated by primary PCI most patients achieved base line TIMI 0 (59.3%). but the final TIMI III flow was achieved similarly in the group treated by pharmacoinvasive technique and group treated by primary PCI 91% and 92% respectively. [8]
Also in the FAST-MI trial initial TIMI flow for group treated by primary PCI in 18% of patients. And 37% of patients treated by fibrinolysis While the final TIMI flow was 89% in group treated by primary PCI and 84% in patients treated by fibrinolysis. [10]

- **Regarding major adverse outcome during hospital admission:**

Regarding in-hospital Re-infarction: there were no evidence for this complication in two groups
Dissection occurred in group I (1.0%) (P 0.133). Also Contrast induced nephropathy occurred in one case of group I, and 4 of group II (P 0.057) with no significant statistical difference between the two groups. Congestive heart failure symptoms occurred in 6.0% of patients in group I and 19.0% in group II (P 0.005) Bleeding complication occurred more in the pharmacoinvasive arm compared with primary PCI arm with 10 patients suffered from different types of bleeding complication (18.8%) compared to patients of group I (3.7%).This came in agreement with the STREAM trial, which compared outcomes in patients treated with Pharmacoinvasive therapy or Primary PCI presenting within 3 h after symptom onset, unable to undergo Primary PCI within 1 hr. The primary end point was a composite of death, shock, congestive heart failure, or re-infarction up to 30 days, The primary end point occurred in (12.4%) in the fibrinolysis group and in (14.3%) in the primary PCI group. More intracranial hemorrhages occurred in the fibrinolysis group than in the primary PCI group, before adjusting the protocol to half dose Tenecteplase instead of full dose. The bleeding complication incidence were equal in both arms. [8]
In the FAST-MI trial, they assessed 5-year mortality in STEMI patients from the French registry of Acute ST-elevation or non-ST elevation Myocardial Infarction (FAST-MI) 2005 according to use and type of reperfusion therapy. Of 1492 STEMI patients with first call <12 hours from onset, 447 (30%) received fibrinolysis (66% pre-hospital; 97% with subsequent angiography, 84% with subsequent PCI), 583 (39%) had Primary PCI and 462 (31%) received no reperfusion. There was a numerical excess of stroke, and ventricular fibrillation with the fibrinolytic-based strategy, and an excess of cardiogenic shock with primary PCI. However, none of the in-hospital complications differed significantly for the two reperfusion strategies. In the FAST-MI trial major bleeding complication occurred more with the primary PCI arm with no statistical difference (P0.29) [11]

- **Regarding echocardiography**

In this study the ejection fraction show improvement in short term just after PCI and long-term out come after 3 months with primary PCI which was statically significant (p=less than 0.001) similar to study done by Kaushik et al in which When comparing the Ejection Fraction between different groups before intervention, revealed mean value of 41.78% (SD-5.81, SE-1.01) in the PPCI group. For pharmocoinvasive and delayed group it was 48.43% (SD-5.44, SE-1.01), and 46.93% (SD-6.21, SE- 1.11) respectively. [12]
Comparison between Pre-Intervention EF and Post intervention EF before discharge in Primary PCI group revealed improvement from mean of 42.60% to 46.76% with statistical significant p value of (0.0025). At 1 month mean EF was 52.13 (p value 0.0001) and at after 6 months EF was 54.80 with p value (0.0001) compared to pre-interventional value. [12]
In this study there were no statically significant in EF in pharmacoinvasive group however When Ejection Fraction was compared in Pharmacoinvasive Group in different time period in study of Kaushik et al Comparison between Pre-Intervention EF and Post intervention EF before discharge revealed improvement in EF from 48.36% to 51.06% with p value of(0.06). At 1 month the LVEF was 52.86% (p value of 0.0047) and at 6 months 54.23% with p value of 0.0007. Comparison between Post intervention EF before discharge and Post intervention EF after1 month of discharge did not reveal significant value (p=0.2540) and at 6 months (p=0.0620) [12]

4. CONCLUSION:

In this study, we highlighted the importance of total ischemic time and importance of patient and system related delays in influencing outcomes of STEMI. Therefore, in daily clinical practice pharmacoinvasive strategy is considered safe alternative to primary PCI. Especially considering logistical issues and delay in the initiation of management.

CONSENT (WHERE EVER APPLICABLE)

Written informed consent was obtained from all patients in this. Ref No; C-250-219.

ETHICAL APPROVAL

Ethics approval and consent to participate: this study was approved by the local ethics committee of Faculty of Medicine, Tanta University, Egypt.

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