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A comparative study on clinical outcomes of pharmacoinvasive strategy versus primary percutaneous coronary intervention in acute myocardial infarction patients

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Abstract

Objective. *To compare clinical outcomes of pharmacoinvasive (PI) strategy versus primary percutaneous coronary intervention (PPCI) in patients with AMI (acute myocardial infarction) still needs more evaluation.*

Methods. *This is a single centre, retrospective, non-randomized study comparing the two treatment strategies. A total of 3073 consecutive AMI cases were identified between 2015 and 2019.*

Results. *The pharmacoinvasive strategy group comprised of 18.5% (n=569) and primary PCI group comprised of 81.5% (n=2504) patients. The patients in PI group were younger, their mean age was 54.8± 12 years vs 56.4± 11.5 years (P<0.003) in PPCI group. Arabic speakers were 47.1% vs 40.9% (P<0.000), South Asians 25.3% vs 30.2% (P<0.018), smokers 39.9% vs 31.5% (P< 0.000) and anterior MI was 55% vs 54% (P< 0.000) in PI vs PPCI group respectively. Transradial approach was utilized in 84.4% in PI vs 75.4% (P<0.000) in PPCI group. Median door to balloon time (calculated from arrival to our hospital emergency till establishment of TIMI III flow in the culprit vessel) in PPCI group was 92 minutes. In-hospital mortality tended to be higher in PPCI vs PI as 3.6% vs 1.9% (P<0.049). LV ejection fraction was observed to be higher in PI group i-e 42.2±11% vs 40.5±11% (P<0.000) in PPCI group.*

Conclusion. *Pharmacoinvasive strategy has almost equal efficacy as compared with primary PCI and it represents a reasonable, non-inferior alternative when primary PCI is not readily available especially in patients presenting early after symptom onset.*

Keywords: *Pharmacoinvasive strategy, Primary Percutaneous Coronary Intervention, Acute Myocardial Infarction, ST-Elevation Myocardial Infarction, Thrombolysis in Myocardial Infarction, Left Ventricle.*

Conflict of interest: None declared.

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Introduction

The strategy of pharmacoinvasive (PI) therapy consists of fibrinolysis and transfer for percutaneous coronary intervention (PCI). It is not well studied as compared to primary PCI (PPCI) in patients with ST-Elevation myocardial infarction (STEMI) [1]. Primary PCI has been set as the best reperfusion option in patients with acute MI, if it is performed in a guideline directed timely fashion [2]. A large number of patients with acute MI present to those hospitals which have no facility for coronary interventions, so they receive fibrinolytics as the initial reperfusion therapy [3]. Pharmacoinvasive strategy is thought to be the treatment of choice for those communities where access to primary PCI is difficult [4]. Large scale studies comparing the efficacy and outcomes of these two strategies are still awaited [5]. The best candidates for primary PCI are those who present with cardiogenic shock, high risk of bleeding with fibrinolytic therapy, more than 3 to 4 hours after onset of symptoms or those who have very short times to be transferred to PCI capable hospital. While for initial fibrinolytic therapy are those who have low bleeding risk, present very early after onset of symptoms (<2 to 3 hours) to a non-PCI-capable hospital or who have longer transfer time to a PCI-capable hospital [6]. Many clinical trials have shown equivalence of early (3–24 hr) post-thrombolysis PCI to primary PCI in patients with STEMI [7,8].

In this study we have compared the efficacy of pharmacoinvasive strategy (PI) to primary percutaneous coronary intervention (PPCI) in those patients

who cannot readily approach for primary PCI in a timely fashion.

Material and Methods

Study Design

This is a single centre, retrospective, non-randomized, cross sectional study and did not require informed consent for data collection for this registry.

Patient Selection

Our centre is the only primary PCI-capable facility, available in the region. Patients were selected from Makkah STEMI registry and included all patients who presented with STEMI and either primary PCI or pharmacoinvasive strategy was performed.

Inclusion and Exclusion criteria

Key inclusion criteria:

i) Pharmacoinvasive strategy: Patients with acute myocardial infarction and successful reperfusion after thrombolytic therapy defined as at least 50 % ST segment resolution and improvement of chest pain.

ii) Primary PCI: Patients with acute myocardial infarction defined as having chest pain lasting more than 30 min along with ST segment elevation in 2 contiguous leads of at least 1 mm except≥ 2 mm in V2–3 or presumed new onset left bundle branch block (LBBB).

Key exclusion criteria:

There were no exclusion criteria other than standard contraindications for thrombolytic therapy and coronary angiography.

The patients were divided into two groups.

Group 1 (Pharmacoinvasive strategy group): Those patients who received thrombolytic therapy at their primary hospital and were immediately referred for routine PCI from 4 hours up to approximately 5 days.

Group 2 (Primary PCI group): Those patients who were directly shifted as acute STEMI for primary PCI. The timing of shifting was within 1–12 hours of onset of chest pain.

Study Medications

The Streptokinase, ateplase or whatever thrombolytic agent available at primary hospital was administered in the standard dosing regimen as per guidelines.

Technique for Coronary Angiography and PCI

The pimary PCI and routine PCI were performed with standard protocols by highly experienced operators. Transfemoral or transradial approach was adopted according to patient's condition. Diagnostic coronary angiography was consummated to explore infarct-related artery. Thrombus aspiration and glycoprotein's inhibitors were administered in lesions with heavy thrombus burden and/or impaired TIMI flow during or after the procedure. The operators determined the length and diameter of implanted stents.

Data Collection

Data for all patients was extracted from medical records, electronic case notes, echocardiography and angiography records. We initially aimed to compare baseline characteristics, lab findings, ejection fraction and primary in-hospital outcomes of PI strategy versus PPCI in eligible patients with acute myocardial infarction.

Statistical Analysis

Data management and statistical analysis were performed using SPSS software. Discrete variables were reported using counts and percentages and continuous variables were described by the mean and standard deviation. We evaluated differences between the PI and PPCI using the t-test or Mann-Whitney U test for continuous variables and the χ^2 test or Fisher exact test for categorical variables. $P<0.05$ was considered statistically significant

Results

Baseline Clinical Characteristics

A total of 3073 consecutive patients with STEMI who were admitted to the coronary care unit or cardiac day care unit at King Abdullah Medical City, Makkah during the period starting from January 2015 to July 2019 were analyzed. Among these patients, 569 patients (18.5 %) were assessed to be in pharmcoinvasive strategy group and 2504 patients (81.5 %) in primary PCI group. No significant difference was observed for gender, diabetics, hypertensives or for those with previous ischemic heart disease. Smokers comprised of 39.9 % vs 31.5 % of PI vs PPCI group ($P<0.001$). Among this multiethnic population, the pilgrims comprised of 33 % of total population and 17.4 % received PI while 36.2 % received PPCI ($P<0.001$). The clinical characteristics are presented in Table 1.

Infarct Related Characteristics

Larger infarct size which was defined as the higher mean value of second troponin I, was noticed to be significantly higher in primary PCI group that is 109± 234 ng/ml vs. 68± 187 ng/ml in PI group ($P<0.001$).

Table 1. **Clinical characteristics of Pharmacoinvasive Strategy vs Primary PCI**

Variables	PI N=569 (18.5%)	PPCI N=2504 (81.5%)	P Value
Age (years) Mean± SD Median (IQR)	54.8± 12 55 (47–61)	56.4± 11.5 57 (49–64)	<0.003
Gender (Male)	489 (85.9%)	2086 (83.3%)	NS
Arabic speaking	268 (47.1%)	1023 (40.9%)	<0.001
South Asians	144 (25.3%)	756 (30.2%)	NS
Pilgrims	99 (17.4%)	907 (36.2%)	<0.001
Co-morbidities			
DM	310 (54.5%)	1357 (54.2%)	NS
HTN	296 (52%)	1345 (53.7%)	NS
Smoking	227 (39.9%)	790 (31.5%)	<0.001
BMI<30	162 (28.5%)	704 (28.1%)	NS
CVA	11 (1.9%)	66 (2.6%)	NS
Dyslipidemia	89 (15.6%)	356 (14.2%)	NS
IHD	129 (22.7%)	488 (19.5%)	NS
Previous Revascularization	30 (5.3%)	184 (7.3%)	NS
Infarct Related Characteristics			
Anterior MI	312 (54.8%)	1347 (53.8%)	NS
2nd Max Troponin I level (ng/ml) Mean± SD Median (IQR)	68.8±187.8 15.5 (3–57.1)	101.9±234 44.9(12.7–121.1)	<0.001
Procedure related characteristics:			
Fluoroscopy Time Mean± SD Median (IQR)	10.2± 13.8 7.3 (4.1–12.4)	11± 9.8 8.5 (5.3–14)	<0.001
Contrast Mean± SD Median (IQR)	119.5± 65.4 110 (70–150)	132± 67.7 120 (90–160)	<0.001
Number of Stents>2	248 (43.6%) 28.4%	1285 (51.3%) 33.9%	<0.001
Critical Time Intervals			
DTA (min) Mean± SD Median (IQR)	317.5± 241.3 278 (119–459)	155± 215 77 (27–165.2)	<0.001
DTB (min) Mean± SD Median (IQR)	326.9± 244.1 291(112–475)	169.7± 217.2 92 (41–179)	<0.001

PI= pharmaco-invasive, PPCI=primary percutaneous coronary intervention, MI=myocardial infarction IQR=inter quartile range, DM=diabetes mellitus, HTN=hypertension, CVA=cerebrovascular accident, IHD=ischemic heart disease, BMI=body mass index, DTA=door to access time, DTB=door to balloon time, NS= not significant.

Procedure Related Characteristics

It was observed that transradial approach was the preferred method for transcutaneous puncture in 84.4% of patients who received PI strategy and 75.4% of PPCI (P<0.001). In PI and PPCI groups, left main stem disease was estimated to be 2.1% vs 3.1% and triple vessel coronary artery disease was observed in 18.1% vs 15% respectively. Moreover, tirofiban was utilized in 11.8% vs 27.1%, thrombus aspiration in 4.2% vs 14.1%, mean fluoroscopy time was evaluated to be 10.2± 13.8 minutes vs 11± 9.8 minutes, contrast volume as 119.5± 65.4 ml vs 132± 67.7 ml and the requirement to use more than 02 stents per procedure was 28.4% vs 33.9% in PI vs PPCI groups respectively and all these parameters were determined to be statistically significant P<0.001 (Figure 1).

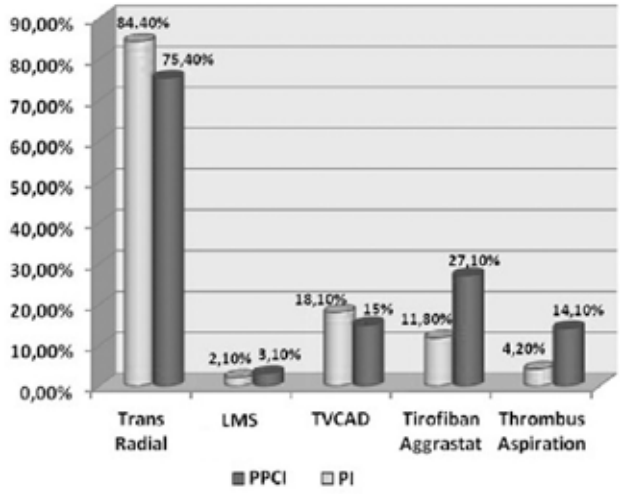

Fig. 1. Procedure related characteristics. PI= pharmaco-invasive, PPCI=primary percutaneous coronary intervention, LMS=left main stem, TVCAD=triple vessel coronary artery disease

Critical Time Intervals

As expected significant difference was observed in critical timings data between both groups. The estimated thrombolysis to balloon time was agreed and accepted to be in range from 240 minutes to 475 minutes. The median time from admission time to successful transcutaneous access, described as door to access time (DTA) was significantly shorter in the PPCI group (77 min; IQR: 27 to 165 min) as compared with the PI group (278 min; IQR: 119 to 459 min) (P<0.001). The median door to balloon time (DTB) which was defined as "the time from admission to first coronary artery intervention for primary PCI found successful in achieving TIMI III flow in an occluded culprit artery" was determined as 92 min (IQR: 41 to 179 min) for the primary PCI group and 291 min for the pharmacoinvasive strategy group (IQR: 112 to 475 min) (P<0.001).

In-Hospital Clinical Outcomes

The rate of the primary composite outcome such as mortality was not found to be significant i-e 1.9% vs 3.6% (P<0.049) for the PI and PPCI groups respectively. Also there was no significant difference in parameters like TIMI major bleeding defined as haemoglobin drop>3 g/dl, pulmonary oedema at time of presentation, intubation/ventilation, cardiogenic shock or cardiac arrest (Figure 2). Post PCI ejection fraction in PI group vs PPCI group was evaluated as

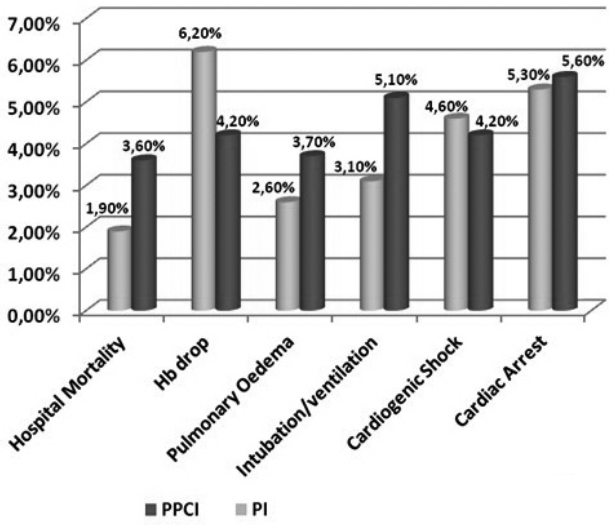

Fig. 2. In-hospital clinical outcomes. PI= pharmaco-invasive, PPCI=primary percutaneous coronary intervention, Hb drop=haemoglobin drop

Table 2. **Immediate in-Hospital outcomes**

Variables	PI N=569 (18.5%)	PPCI N=2504 (81.5%)	P Value
Post PCI EF Mean± SD Median (IQR)	42.3± 10.7 45 (35–50)	40.6± 10.6 40 (35–50)	<0.001
Length of Stay Mean± SD Median (IQR)	7.5± 9.1 4 (3–9)	5.2± 7.5 3 (2–6)	<0.001

PI= pharmaco-invasive, PPCI=primary percutaneous coronary intervention, Post PCI EF=post percutaneous coronary intervention ejection fraction), SD=standard deviation, IQR=inter quartile range

42.3± 10.7% vs. 40.6± 10.6% (P<0.001) respectively (Table 2).

Discussion

The underlying principle for the pharmacoinvasive strategy is that the initial fibrinolytic therapy is implemented for early restoration of coronary blood flow and subsequent invasive strategy applied to reopen the infarct related artery with early elective PCI. The objective to study pharmacoinvasive strategy is that despite the widespread use of primary PCI, still in our setup many areas have no timely access to primary PCI centres so pharmacoinvasive therapy would be a worth mentioning strategy for timely salvage of myocardium [9].

In the current study, we aimed to study differences in demographic data and compared immediate in-hospital outcomes between the two groups including pilgrim population and concluded that there was no major difference in terms of immediate in-hospital complications or mortality. However, it was observed that the patients receiving PPCI had lower ejection fraction (EF) which more empowers the need of timely reperfusion in the form of pharmacological reperfusion to even high risk cases.

Current study is unique in the view that we studied multiethnic population of Makkah region including pilgrims. The results are in accordance with Stars Saudi Arabia STEMI registry [15].

Although fibrinolysis can be administered in a timely fashion but it is also sometimes associated with higher rates of non-reperfusion and re-infarction that is why fibrinolysis followed by timely PCI can alleviate this risk [13]. A large meta-analysis of 7 trials showed that early PCI after fibrinolysis has been associated with a decreased risk of the combined endpoint of death and re-infarction without a significant increase in the risk of major bleeding or stroke. In fact, this meta-analysis compared rescue PCI in all studies and not primary PCI however the importance of timely reperfusion had been strongly addressed [14].

Likewise, our results are similar to FASTMI, in which patients with STEMI received PPCI and fibrinolysis followed by PCI or no reperfusion. Time to reperfusion was significantly shorter with fibrinolysis followed by PCI than by PPCI [11]. Although we did not study time to reperfusion but regarding in-hospital outcomes we observed no difference between pharmacoinvasive strategy and primary PCI [10, 11, 12]. Regarding critical timing data, our median door to balloon time for primary PCI was determined to be 92 minutes which is in accordance with AHA guidelines, O Gara et al. and ESC guidelines [6,7].

Our study depicted similar efficacy for pharmacoinvasive strategy when routine PCI was performed after thrombolysis and found that there was no difference in the composite endpoint of death, shock, congestive heart failure, or reinfarction at 30 days between the two treatment strategies [9].

Conclusion

This large observational study concludes that the patients with acute myocardial infarction who received pharmacoinvasive treatment strategy had better ejection fraction and similar immediate clinical outcomes when compared with primary PCI. With the growing number of high risk STEMI patients presenting early, pharmacoinvasive strategy seems to be a realistic alternative to reduce total ischemic time for better preservation of ejection fraction and salvage the myocardium.

Study Limitations

This non-randomized, retrospective analysis of a registry data has the usual limitations inherent to observational studies. There may be selection bias in patients in pharmacoinvasive arm because it is obvious that mostly those patients who were alive and stable after thrombolytic therapy were referred for further interventional therapy and more ill, patients with co-morbidities or those who were not fit enough to be transferred such as frail patients with high risk of mortality were excluded at primary centres from referring for interventional therapy. Follow up data is deficient which is needed for analysis of long term outcomes.

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Conflict of interest: None declared.

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