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COMPARATIVE OUTCOMES OF PRIMARY PERCUTANEOUS CORONARY INTERVENTION AND THROMBOLYTIC THERAPY IN STEMI PATIENTS: A SINGLE-CENTER ANALYSIS

Iqtidar Ud Din[1], Wajid khan[2], Tanveer Ahmad[3], Shah Hussain[*4], Hassan Danish[5], Farah Ahmad[6]

[1]*Professor of Cardiology QHAMC /NMC, MTI Nowshera*
[2]*Medical officer, Cardiology QHAMC/NMC MTI Nowshera*
[3]*Assistant Professor, Cardiology QHAMC/NMC, MTI Nowshera*
[*4]*Medical officer, Cardiology QHAMC/NMC, MTI Nowshera.*
[5]*Associate Professor of Community Health Sciences Zia Ud Din University & Medical College Karachi*
[6]*Professor of Community Health Sciences Zia Ud Din University & Medical College Karachi*

[*4]Shahhussain189@gmail.com

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Corresponding Author: *
Shah Hussain

Abstract

Background: *ST Elevation Myocardial Infarction is one type of myocardial infarction which has a severe course and it requires immediate treatment. Primary Percutaneous Coronary Intervention is considered now as the standard of care to treat ST Elevation Myocardial Infarction patients around the world because its outcomes are superior to those of the thrombolytics. Nonetheless, using the Primary Percutaneous Coronary Intervention in the developing countries has some economic and logistical issues and limitations such that research needs to be done to determine its practicality.*

Objectives: *Objectives of this trial is to compare the outcomes and clinical efficacy in relation to mortality, rate of recurrent myocardial infarction, recovery as well as to compare early percutaneous coronary intervention to thrombolytic therapy in patients with ST Elevation Myocardial Infarction.*

Study Design: A quasi-experimental trial, having a conventional group of thrombolytic therapy versus and interventional group who undergone primary Percutaneous Coronary Intervention.

Place and Duration of Study: This Study Conducted at Cardiology Department Qazi Hussain Ahmad Medical Complex, Nowshera, over 12 months post-approval from January 2022 to January 2023.

Methods: *This interventional trial comprised a total of 404 STEMI patients with 202 in the PPCI study arm and 202 in the thrombolytic arm. Sample data collected were on clinical holding measures such as clinical milestones, such as hemodynamic stability, mortality, procedural duration, and patient stability. Descriptive data were analyzed by using SPSS 22, means and standard deviations and student 't' test with $p<0.05$ was used for inferential statistics. They were also taken after two weeks from discharge and then after six weeks.*

Results: *In Hospital mortality was lower in Primary Percutaneous Coronary Intervention (PPCI) group than in the conventional group. 8 % in PPCI vs 13 %*

in thrombolytic treatment group respectively; P value = 0.03. Overall outcomes were better in the Primary Percutaneous Coronary Intervention group compared to thrombolytic group.

Conclusions: *Further, the efficacy of the PPCI strategy over thrombolytic therapy was definitively established by an overall decrease in mortality, shorter time to recovery, and fewer side effects and lower rate of complications. The integration of Primary Percutaneous Coronary Intervention into a routine regimen of STEMI process in resource-challenged region can really enhance the better outcome*

INTRODUCTION

Patients having ST Elevation Myocardial infarction (STEMI) presents with severe chest pain and ST-segment elevation and is a severe type of coronary artery disease. The disease is a medical emergency in which at least one coronary artery is totally occluded. Re-establishment of coronary flow, prevention of further myocardial injury, and timely treatment to improve the clinical outcomes and mortality are necessary [1, 2]. Such treatment protocols are not only important for life saving and reduction of mortality but also plays a significant role in the early recovery, low profile of adverse events, future better functional capacity and improved cardiac outputs or better ejection fractions (EF). In the past, thrombolytic therapy has been the cornerstone of treatment of STEMI, which has shown substantial reduction in mortality if given early and in the recommended time period of window. Nonetheless, thrombolytics also have some drawbacks: the patients may not achieve complete re-canalization, more often suffer from re-ischemia and has the double danger of bleeding events as well [3, 4]. In the last two decades, primary percutaneous coronary intervention commonly abbreviated as PPCI has become the preference of treatment for STEMI patients and has gained practical establishment in the renowned medical centers.The various guidelines of national and international cardiac societies for the management of ST-segment elevation myocardial reperfusion across the world recommend PPCI over thrombolytics given the fact that it is effective in the activation of complete reperfusion, infarct size reduction and better post-PCI clinical outcome [5, 6]. PPCI is the process of acutely re-canalizing the blocked coronary artery using balloons and stents by interventional cardiac procedures. It is based on lower mortality rate, reduced likelihood of further myocardial infarction and less complications than thrombolytics treatment [7]. Notwithstanding these benefits, the practical application of PPCI in our resource-poor environments remains problematic because of paradigmatic capital expenses inclusive of costly PPCI structure and pertinent as well as deficiency of trained human resources and logistics [8]. Fibrinolysis remains in practice in Pakistan with increasing implementation of PPCI at some centers. Over the last few years, the PPCI has gained more practical approach in some centers while few other are following their pace as well.

Proper comparative effectiveness and outcome of these interventions in STEMI patients by these interventions are however lacking in multiple hospitals due to lack of adequate local data. This facility is available in various hospitals and adequately trained staff is also available but effective utilization is still awaited in emergency departments. Knowledge of these distinctions might also play a part in therapeutic and policy planning by bringing forward optimal STEMI care in Pakistan. The purpose of this research article is to compare the results of PPCI with thrombolytic therapy for STEMI patients in Qazi Hussain Ahmad Medical Complex Nowshera. Primary outcome measures are: in-hospital mortality, recurrent myocardial infarction, Major Adverse Cardiac Event (MACE), cardiogenic shock or hemodynamic stability. This study aims to assess and compare the outcomes of PPCI and thrombolytic treatment in our medical institute through the comparison of these patients after interventions. We aim to compare the two defined groups and check the outcomes for establishing the facts to keep a track for future improved clinical practice for continuous quality improvements.

Methods

This quasi-experimental study has been carried out in the Cardiology Department of Qazi Hussain Ahmad Medical Complex, Nowshera over 12 months. Recruitment was done by simple random sampling and the total of 404 patients with STEMI were grouped into the PPCI group (n=202) and the thrombolytic therapy group (n=202). The thrombolytic therapy group was considered as conventional group while the group of patients who received PPCI was considered as interventional group. The criteria for subjects' selection included following characteristics: STEMI on ECG, patients aged 25 to 60, and informed consent for enrollment in the trial. Excluded participants were those who had non-emergency orthopedic or neurosurgical procedures, those with considerable co morbidities, and those who cannot undergo invasive procedures or had already diffuse triple vessel diseases or waiting for CABG. Those patients who had metastatic disease, chronic kidney or liver disease or coagulation disorders were also excluded. Drug-eluting stents used in the PPCI were Federal Drugs Agency (FDA) approved while the thrombolytic used in the study was streptokinase provided by the hospital. Patients were followed for clinical endpoints, such as in-hospital mortality, recurrent myocardial infarction, hemodynamic stability or instability (in the form of cardiogenic shock) and MACE at discharge and at 2 and 6 weeks.

Patients in both the treatment groups were on the guideline directed medical treatment like betablockers, nitrates, dual antiplatelet treatment and standard dose of statins as per the set protocols and guidelines for treatment of STEMI. Patients from both the treatment groups were kept admitted for 3 to 4 days from date of admission as well as first and second follow ups. The data was collected through a questionnaire and the fed into the SPSS for statistical analysis. Both the treatment groups were finally assessed for clinical outcomes as mentioned. Descriptive data were analyzed by using SPSS, means and standard deviations and student 't' test with $p<0.05$ was used for inferential statistics. They were also taken after two weeks from discharge and then after six weeks for the mentioned milestones.

Data Collection

Information was collected through administrated questionnaires and from the medical records of the hospitals. Patients were followed from date of diagnosis, and baseline demographics, clinical presentation, procedural details, and outcomes were recorded from admission, during hospital stay and then on first and second follow up. Time to intervention of do-or-balloon and door-to-needle times were also documented in the questionnaires.

Statistical Analysis

After collection of the data from patients of both the treatment groups it was fed into the SPSS version. Statistical analysis was done by the use of SPSS. For data measured on a continuous scale, the equality of the means was compared using the test of means with continuous variables presented as mean ± S.D. Categorical variables were presented as proportions and compared across the study. A P value of < 0.05 was used as the criteria to determine statistically significant results. For comparison of the means and percentages of the two treatment groups, i.e, conventional group (thrombolytic group) versus intervention group (PPCI group), independent T test was applied. For the assessment of clinical outcomes between the two treatment groups (thrombolytic versus PPCI groups), chi square test was applied. A two-way ANNOVA test was applied to check the treatment () intervention versus conventional) and time taken for event (recovery or other events). The analysis of results was done by showing the use of tables and charts.

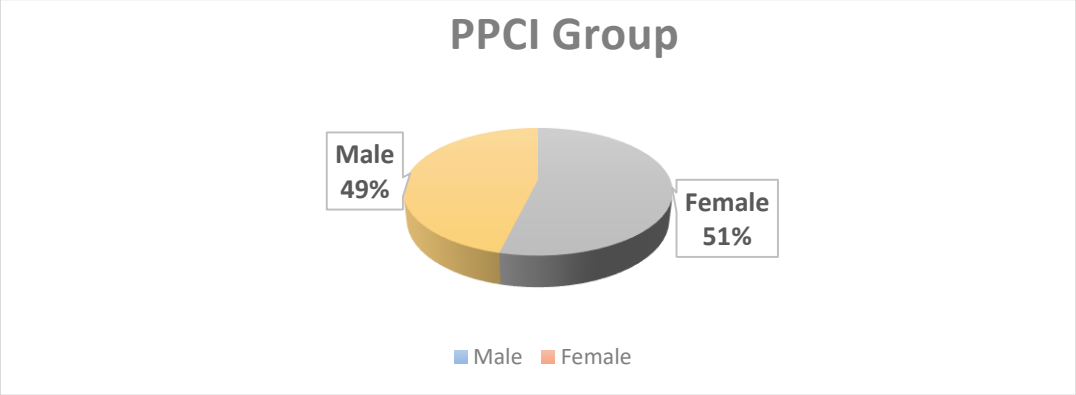
Results

The data collected from both the treatment groups i.e, PPCI group and thrombolytic treatment group were fed in the SPSS. A total of 404 patients were included with simple randomized technique. 202 patients were included in PPCI group and 202 in the thrombolytic treatment group. The mortality was lower in the PPCI group and hence survival rate was better in the same (PPCI) group. While thrombolytic group had a higher mortality and hence a lower survival rate compared to the PPCI group. The mean time for recovery was lower in the PPCI group at discharge than in the thrombolytic group which supports a better outcome in PPCI group. The new

onset of MACE was seen in 15 % of PPCI patients as against of thrombolytic group patients which was 28 % shows a grave outcome for thrombolytic group. Furthermore, a high level of early mobilization was recorded in PPCI patients than in the thrombolytic patients with a statistically significant difference between both the treatment groups suggestive of a better outcome in PPCI group. Recurrence of MACE and angina was more in the thrombolytic group while was lower in the PPCI group. Mean age was approximately 47.5 years in PPCI group and was 49.3 years in thrombolytic group.

Table 1: Patient gender distribution and Baseline Characteristics

Variable	PPCI Group	Thrombolytics Group
Male (%)	49% (n=99)	48.5% (N=98)
Female (%)	51% (N=103)	51.5 (n=104)



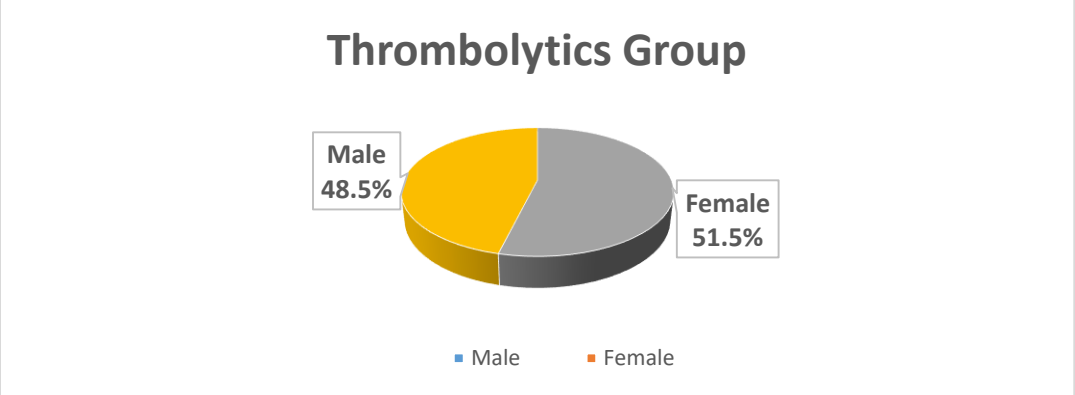
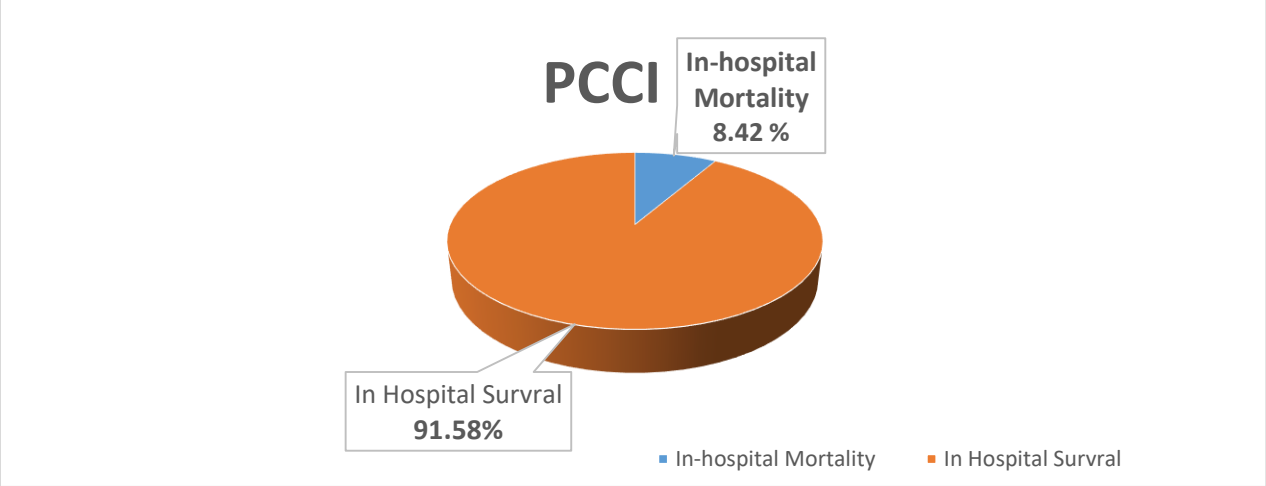
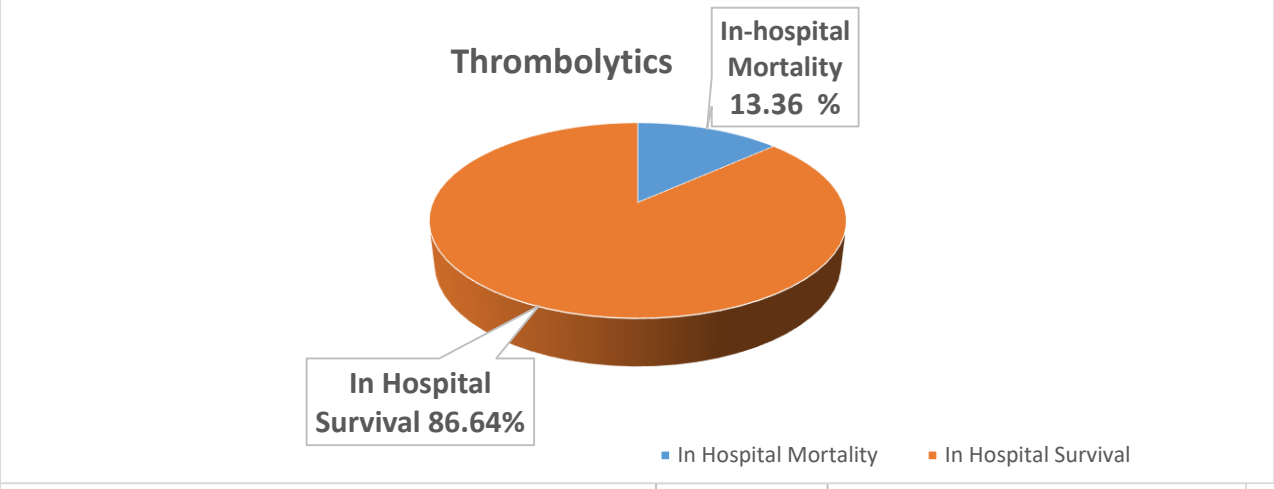
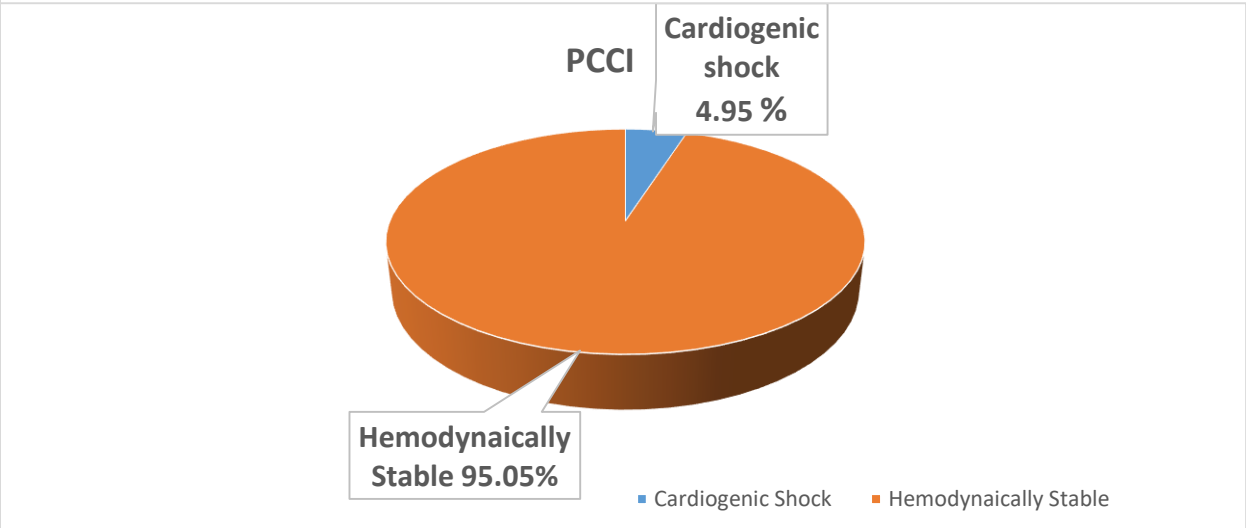


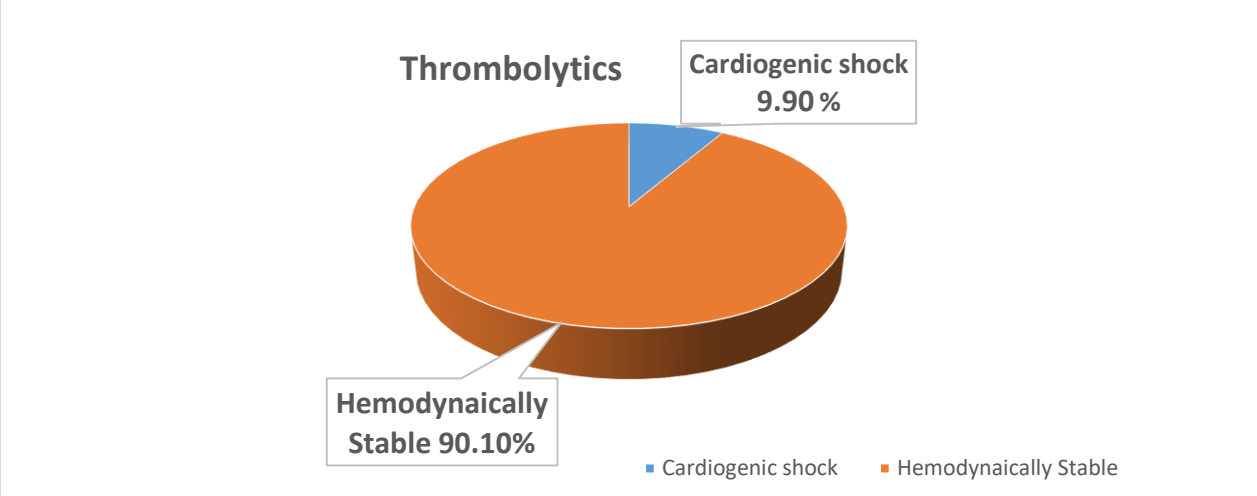
Table 2: Adverse Clinical Outcomes Comparison

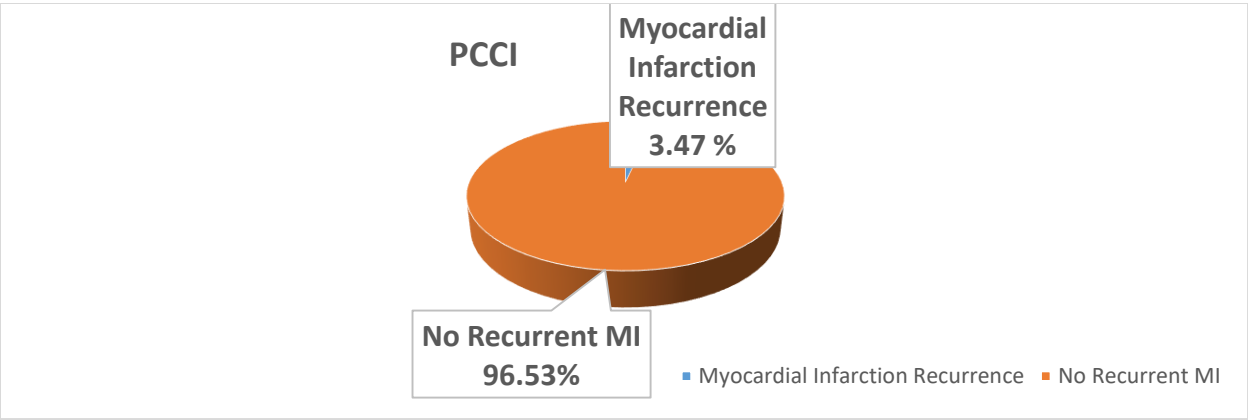
Outcome	PPCI (%)	Thrombolytics (%)
In-hospital Mortality	8.42 (n=17)	13.36 (n=27)
Cardiogenic shock	4.95 (n=10)	9.90 (n=20)
Myocardial Infarction Recurrence	3.47(n=7)	7.4 (n=15)


PCCI
In-hospital Mortality 8.42 %
In Hospital Survral 91.58%
In-hospital Mortality
In Hospital Survral


Thrombolytics
In-hospital Mortality 13.36 %
In Hospital Survival 86.64%
In Hospital Mortality
In Hospital Survival


PCCI
Cardiogenic shock 4.95 %
Hemodynaically Stable 95.05%
Cardiogenic Shock
Hemodynaically Stable


Thrombolytics
Cardiogenic shock
9.90 %
Hemodynaically
Stable 90.10%
Cardiogenic shock
Hemodynaically Stable


PCCI
Myocardial
Infarction
Recurrence
3.47 %
No Recurrent MI
96.53%
Myocardial Infarction Recurrence
No Recurrent MI

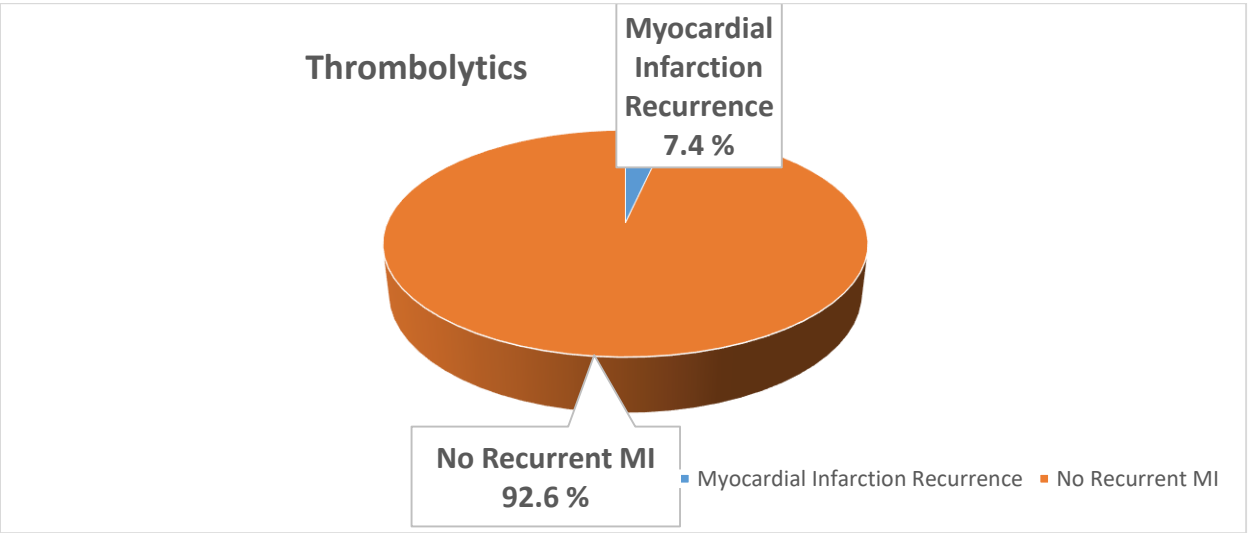

Thrombolytics
Myocardial
Infarction
Recurrence
7.4 %
No Recurrent MI
92.6 %
Myocardial Infarction Recurrence
No Recurrent MI

Table 3: Procedural and Recovery Timings and better outcomes

Variable	(PPCI)	(Thrombolytics)
Survival	91.58 (n=185)	86.64 (n=175)
Hemodynamic Stability	95.5 (n=192)	90.1 (n=182)
No recurrence of MI	96.53 (n=195)	92.6 (n=187)

Discussions

Comparing our study with similar studies conducted previously in other institutes at national or international level, this study showed that comparing PPCI with thrombolytic treatment in patients with STEMIs, the PPCI is considered as more beneficial in multiple aspects. The lower rate of in-hospital mortality noted in this study in PPCI group as compared to the thrombolytic treatment shows that PPCI is more beneficial (10,11). Incidence of MACE in the PPCI group are in conformity with previous studies done in developed and developing countries (12,15). Geng et al. who conducted a meta-analysis on PPCI proved that this approach had more benefits on lowering the mortality and rates of re-infarction than the thrombolytic therapy [9,13]. Hence, the survival rates in PPCI are higher compared to thrombolytic treatment. Likewise, the ESC guidelines for myocardial revascularization, PPCI is highlighted as a gold standard because of better clinical outcomes and lower complications [10,14]. These outcomes support these findings, further establishing that PPCI resulted in better hemodynamic stability and quicker recovery time. Door to balloon (in PPCI group) and door to needle time (in thrombolytic treatment group) are important parameters representing successful reperfusion in the treatment of STEMI in either group. In the present trial, the mean door to ballon time was within 90 minutes which lies within the internationally set protocols that is below 90 minutes like other studies on the same topic [11,16]. While, the thrombolytics treatment was served within the standard set protocols of 30 minutes, the PPCI group was also in accepted parameters. However, the thrombolytic group developed more recurrent myocardial infarction, MACE and other complications related to hemodynamic instability and cardiogenic shock, further supporting the clinical benefits of PPCI [12,17]. This is consistent with outcomes reported in the study by Chen et al., exposing the fact that all the major risks in PPCI are less because of controlled procedural setting and thereby reduced the use of treatment for systemic thrombolysis [13, 21]. In addition to the above, we observed during the trial, a reduced incidence of arrhythmia and heart failure in the PPCI group; Jolly et al. agrees that PPCI enhances myocardial salvaging and minimizes overall long-term heart failure and hence, leading to improved quality of life and almost complete recovery as compared to thrombolytic treatment [19, 20]. Even though, lack of resources presents a serious challenge to the use of PPCI in the low- and middle-income countries but it should be encouraged wherever possible (21,22). In their study, Valle et al. highlighted the issue of geographical variation in PPCI use, while more developed countries embedded this treatment more because of their superior health systems [16,23]. Therefore, our study calls the attention of the healthcare policymakers towards need to investing more in PPCI facilities in resource constraint nations like Pakistan (24). Researchers and workers, including Shah et al.'s focus on PPCI's economic viability, define conditions under which one might enhance accessibility [25, 26]. Therefore, although this study strengthens the argument for the superiority of PPCI, reality issues of accessibility or feasibility, costs, and further education/training of interventional cardiologists remain the areas with implications for successful global deployment (27). Future studies should address cost-utility assessment, follow-up, late mortality and methods to increase the use of PPCI [28, 29]. Overall, this study opens the new perspectives in understanding the benefits of PPCI approach in management of STEMI connecting with the promotion of this approach and to replace thrombolytic treatment whenever and wherever possible. In Pakistan, the superior results in lowering the mortality, MACE and other complications should incorporates the facility of early coronary intervention in the form of PPCI into national

cardiac care frameworks. Thus, the elimination of some of the economic, financial and logistical issues will be mandatory to replace PPCI as a practical approach and reduce the use of thrombolytic treatment as whenever and wherever possible. We should collectively improve the cardiac services in the STEMI management in our country as rest of the developed world has done it in the previous decades. [20].

Conclusion

The results of this study established the fact of better outcomes like early recovery and better survival with lower mortality after the Primary Percutaneous Coronary Intervention (PPCI) over thrombolytic therapy in acute management of ST-Elevation Myocardial Infarction (STEMI) in our institute. PPCI had overall reduced in-hospital mortality, including MACE and led to better functional recovery. The incidence of adverse outcomes and complications like mortality, cardiogenic shock, recurrence of infarction was higher in thrombolytic treatment. These results suggest that PPCI should be adopted into the kind of STEMI treatment process in our institute and also recommends the same for our country.

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Authors Contribution

Concept & Design of Study: Iqtidar Ud Din[1],Shah Hussain[2]

Drafting: Tanveer Ahmad[3],Shah Hussain[4]

Data Analysis: Hassan Danish[5],Farah Ahmad[6]

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