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Safety of primary PCI with early discharge? A comparative study of 36 vs > 36 hours primary PCI discharge protocol".

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INTRODUCTION

The incidence of coronary artery disease is on the rise in developing world.¹ Primary PCI remains the gold standard for management of acute ST elevation myocardial infarction (STEMI), albeit with its associated health costs. Adaptation of Primary PCI programs in such regions have improved the standards of STEMI management²⁻⁴, however it leads to a parallel rise in the health costs due to use of costly equipment and intensive coronary care unit stays.⁵ Early discharge in stable patients after Primary PCI has gained attraction as one of the ways to reduce health costs while ensuring patient safety.5,6 Previous studies have established safety of an early discharge within 48 hours after Primary PCI.5,6 In this study we will study the Safety of even an earlier discharge within 36 hours. The latest European society of cardiology guidelines on STEMI encourages but also highlights the sparsity of data on an early

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ABSTRACT... Objectives: In this study we aimed at establishing the safety of a very early discharge within 24 to 36 hours after a primary PCI. Study Design: Prospective Comparative study. Setting: Punjab Institute of Cardiology, Lahore. Period: July to December 2019. Material **& Methods:** We randomly assigned a \leq 36 hours discharge protocol to the very low risk patients after a primary PCI. FASTEST score was used to identify the low risk group. Comparison was made at 30 days between early discharge and ordinary discharge low risk groups for outcomes like reinfarction, stent thrombosis (ST), target lesion revascularization (TLR), bleeding, stroke and death. Results: Among 329 very low risk primary PCI patients, 161 were randomly assigned to early discharge group and 168 to ordinary discharge group. The outcomes were similar at 01 month in early vs ordinary discharge groups. There was no significant difference in the rate of reinfarction (1.24% vs 1.79%, P value 0.68), ST (1.24% vs 1.19%, P values 0.96), TLR (1.24% vs 1.19%, P value 0.96) and bleeding (0.62% vs 0.59%, P value 0.97). There was no mortality or stroke. Conclusions: Using any of the scoring systems, very low risk patients should be routinely identified after primary PCI. Short term major adverse outcomes remain at a low and a very early discharge protocol can be safely implemented in this subgroup. In addition to saving health costs, this can be of particular value during outbreaks like COVID-19.

Key words: Acute Myocardial Infarction, Fastest Score, Primary PCI, Very Early Discharge.

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> discharge policy after Primary PCI.⁷ This study may contribute to establish the safety of an early discharge policy in stable patients after a Primary PCI.

MATERIAL & METHODS

This study was conducted at Punjab institute of cardiology from July to December 2019. It was a comparative study. All the patients who fell into low risk group after successful primary PCI were included into study after obtaining informed consent. The FASTEST score⁸ was used to include the patient into low risk group. For inclusion into low risk group, all the parameters of FASTEST score should be absent in a patient except the age can be upto 85 years. Preloading, post procedure dual antiplatelet and statin dose was similar in all patients, while ACEi and beta-blockers were adjusted according to individual patient's hemodynamics. Intra procedural Heparin was

the anticoagulant in all patients. Patients were randomly assigned into two groups. Group-A was discharged within 36 hours after the procedure, while group-B was discharged after 36 hours. All patients were followed at 01 week and at 01 month after the index procedure. At 01 month. outcomes were noted including reinfarction, stent thrombosis (ST), target lesion revascularization (TLR), bleeding, stroke and death. The revised Academic Research Consortium (ARC-2) criteria was used to define reinfarction. ST. TLR. stroke and death.9 The US National Cardiovascular Data Registry (NCDR) criteria was used to define significant bleed.¹⁰ The study was approved by the institutional ethical review committee (RTPGME-Research-101) and complies with the declaration of Helsinki.

Inclusion Criteria

Patients with STEMI who remain hemodynamically stable and pain-free after Primary PCI.

None of the parameters of FASTEST score should be present, except the age limit was 20 to 85 years.

Exclusion Criteria

Patients experiencing ventricular arrythmias, shock or persistent heart failure after completion of a successful PPCI.

Patients with co-morbidities or any major surgery with in last 03 months.

All data was analyzed using SPSS version 22. Continuous variables like age was presented as mean and standard deviation. Baseline parameters of both groups were tabulated. Individual outcomes were analyzed for group-A and B. Independent samples t-test was used to compare the outcomes in both groups. Equal variance was assumed for both groups to interpret the result of t-test. Keeping the confidence interval at 95 percent, a p value of <0.05 was considered significant.

RESULTS

A total 329 patients undergoing Primary PCI met our inclusion criteria. There were 251 (76.3%) men. Minimum age was 22 years, maximum 83 and mean $49.1(\pm 11)$ years. Almost two third of the patients were hypertensive (71.1%). This was followed by diabetes, positive family history and smoking as predominant risk factors (59.3%, 46.2% and 43.8% respectively). The LAD was culprit vessel (63.8%) in majority of the patients. The baseline characteristics and drugs prescription were similar in both groups (Table-I). Dual antiplatelet and statins were prescribed across all and beta blockers and ACEi/ARB in most of the patients on discharge. (Table-II)

	Group-A (early discharge) n=161	Group-B (ordinary discharge) n=168
Mean age (years)	49 ± 9.6	49.2 ± 12
Gender (men)	124 (77%)	127 (75.6%)
Hypertension	113 (70.2%)	121 (72 %)
Diabetes	92 (58.4%)	103 (61.3%)
Family history	72 (44.7%)	80 (47.6%)
Smoking	71 (44.1%)	73(43.5%)
Drug abuse	1 (0.6%)	2 (1.2%)
Anterior wall MI	102 (63.4%)	110 (65.5%)
URBAN	131 (81.4%)	139 (82.7%)
Radial approach	149(92.5%)	155(91.7%)
LAD culprit	101 (62.7%)	109 (64.9%)
LCX culprit	14 (8.7%)	15(8.9%)
RCA culprit	46 (28.6%)	44 (26.2%)

Table-I. Baseline characteristics and risk profile (n=329).

LAD: Left anterior descending artery, LCX: left circumflex artery, RCA: right coronary artery, LMS: left main stem

	Group-A (early discharge)n=161	Group-B (ordinary discharge)n=168
aspirin	100%	100%
clopidogrel	100%	100%
statin	100%	100%
B blocker	96.2 %	96.4 %
ACEi/ARB	88.8 %	89.3 %

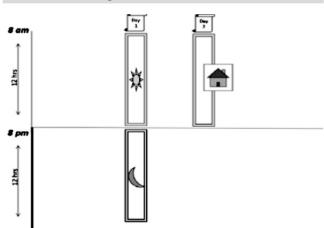
Table-II. Frequency of drug prescription at discharge
after Primary PCI.ACEi: Angiotensin converting enzyme inhibitor, ARB:
angiotensin receptor blocker

At one month follow up, the rate of reinfarction was similar in both groups (1.24% vs 1.79%, P

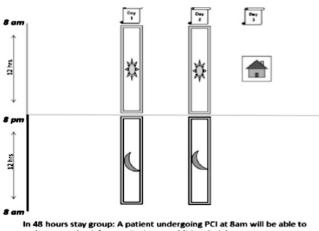
value 0.68). Moreover, there was no significant difference in other outcomes like stent thrombosis (1.24% vs 1.19%, P values 0.96), TLR (1.24% vs 1.19%, P values 0.96) and bleeding (0.62% vs 0.59%, P value 0.97). The overall complications rate remained low in both groups and there was no mortality or stroke.

	Group-A (early discharge) n=161	Group-B (ordinary discharge) n=168	P- Value
Reinfarction	2 (1.24%)	3 (1.79%)	0.68
Stent thrombosis	2 (1.24%)	2 (1.19%)	0.96
TLR	2 (1.24%)	2 (1.19%)	0.96
Major bleed	1 (0.62%)	1 (0.59%)	0.97
Stroke	Nil	Nil	
Death	Nil	Nil	

Table-III. Outcomes at 01 month in both groups. TLR: Target lesion Revascularization



In 36 hours stay group: A patient undergoing PCI at 8am will be able to go home next day after a single night stay



go home on day 3rd necessitating an additional night stay

DISCUSSION

The overall expected complications rate remains low in patients who are stable during and initial 06 hours after a Primary PCI.6 This may have application in devising an early discharge plan strategy. In this study we randomly assigned stable patients an early discharge strategy, to evaluate its safety. Care has to be taken not to forget maintaining a plan for patient counselling, rehabilitation and secondary prevention. We implemented this on the next morning during hospital stay, at 01 week and 01 month follow up visits. The results of our study are encouraging, showing the early discharge strategy to be safe. The overall incidence of reinfarction¹¹, stent thrombosis¹² and major bleed¹³ were even lower than contemporary studies. The need for target vessel revascularization also remained low. There was no mortality in our study. The reason of low complications rate might be due to inclusion of only stable patients and those with shock, ventricular arrythmias or LVF post PCI were excluded from the study.14,15

The low bleeding complications can be explained due to very high use of radial approach (more than 90%), which has strong inverse relation with bleeding.13 The results of our study are in line with previous studies, but the validity of our study can be more in terms of being a prospective study, while others have analyzed the data retrospectively. Only one previous study has shown an increased rate of rehospitalization in the early discharge group but the population being studied was more heterogeous.⁵ Our study population was more homogeneous in terms of risk profile and procedural parameters in both groups. So, the results are more valid for post procedure stable STEMI patients. Regarding duration of stay, previous studies have also shown early discharge in stable patients to be safe⁵, but the minimum duration of hospitalization for early discharge group was ≥72 hours in most of these or at least 48 hours, after a Primary PCI.5,6 The important main difference from previous studies is the very early discharge in our patients within 36 hours of procedure. Practically a 36 hours stay means a single night stay for a procedure taking place during morning hours (see schematic

diagram-1).

Comparison of previous early discharge studies focusing a 48-hour discharge vs our study focusing on a discharge within 36 hours. (Practical difference on days inside the hospital when patient is discharged in less than 36 hours vs in 48 hours after the procedure).

An early discharge will enable to unload the health services, decrease health costs and may decrease psychological stress of individual patients, as highlighted in previous studies.⁶ This also help minimize patients' exposure to hospital environment during outbreaks, like COVID-19 pandemic. As outbreaks from same or similar organisms are expected to recur, a very early discharge policy in patients who remain stable after PPCI can be studied on a larger scale for its potential to get it included into the guidelines for use during such situations.

CONCLUSIONS

Using any of the scoring systems, very low risk patients should be routinely identified after primary PCI. Short term major adverse outcomes remain at a low and a very early discharge protocol can be safely implemented in this subgroup. In addition to saving health costs, this can be of particular value during outbreaks like COVID-19. **Copyright**© **22 Sep, 2020.**

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2	Belal S Mohyuddin	Designing, Data collection and analysis.	belae
3	Abubakar Mirza	Data collection and analysis.	thuble
4	Nabeel Akbar	Data collection, Manuscript writing.	Waln!
5	Muhammad Zaman	Data collection.	Dum