DOOR TO BALLOON TIME IN ST-SEGMENT ELEVATION MYOCARDIAL INFARCTION (STEMI): A PROSPECTIVE STUDY

Abstract

Background:

ST-segment elevation myocardial infarction (STEMI) is the most acute manifestation of coronary artery disease and is associated with great morbidity and mortality. A complete thrombotic occlusion developing from an atherosclerotic plaque in an epicardial coronary vessel is the cause of STEMI in the majority of cases. Early diagnosis and immediate reperfusion are the most effective ways to limit myocardial ischaemia and infarct size and thereby reduce the risk of post-STEMI complications and heart failure. Primary percutaneous coronary intervention (PCI) has become the preferred reperfusion strategy in patients with STEMI; if PCI cannot be performed within 120 minutes of STEMI diagnosis, fibrinolysis therapy should be administered to dissolve the occluding thrombus.

Method:

7 adult patients with ST-segment–elevation myocardial infarction undergoing primary percutaneous coronary intervention in October 2021 were identified from the emergency. We used the regression discontinuity framework to test for discontinuity at 90 minutes among the included cases. We defined a novel variable, the remaining Door - Balloon as 90 minutes minus the time between hospital arrival and catheterization laboratory arrival. We estimated multivariable logistic regression models to assess the relationship between remaining Door - Balloon time and access site.

Results:

The results of primary PTCA in the month of October 2021 were performed in less than 90 minutes without any mortality in 7 patients.

Conclusion:

Our Data on mortality and morbidity benefits of primary angioplasty shows a 100% decrease in mortality of patients undergoing primary PTCA within 90 minutes as compared to international data which shows a 40 % decrease.

Keywords: Coronary artery disease; Primary PTCA; Angioplasty; Door – Balloon time

Introduction

ST-segment elevation myocardial infarction (STEMI) remains a major cause of premature death worldwide and, despite recent advances, controversies persist regarding its optimal management. Most STEMI is caused by atherosclerotic plaque rupture with vessel occlusion due to secondary thrombosis, with the extent of subsequent myocardial injury dependent on the area of myocardium subtended by the culprit vessel, duration of occlusion, and presence of collaterals. Therefore, expeditious restoration of vessel patency represents the cornerstone of treatment of this condition, and although widespread uptake of primary percutaneous coronary intervention (PPCI) has significantly improved outcomes, debate continues regarding optimal antithrombotic/anticoagulant and interventional strategies employed [1–4]. Acute coronary syndromes (ACSs) comprise the acute manifestations of CAD, including unstable angina (myocardial ischaemia without necrosis), non-ST-segment elevation myocardial infarction (NSTEMI), and ST-segment elevation myocardial infarction (STEMI) [5,6].

It has been well established that the optimal treatment for acute ST-segment elevation myocardial infarction (STEMI) is recanalization of the occluded coronary artery responsible for the infarct, by coronary angioplasty and stent placement, provided that this can be done in a timely manner. This results in improved left ventricular function and decreased mortality [7–9].

Primary percutaneous coronary angioplasty (PCI) is superior to fibrinolytic therapy as a reperfusion strategy in ST-segment–elevation myocardial infarction (STEMI) when performed expeditiously and expertly. Compared with fibrinolytic therapy, primary PCI results in higher stenosed-artery patency and lower rates of reinfarction, stroke, and death.

Rapid and complete restoration of coronary artery blood flow and myocardial perfusion is the mechanism by which reperfusion therapy reduces morbidity and mortality in STEMI. Longer times to treatment are inversely related to outcomes with both fibrinolytic therapy and PCI. Current guidelines for STEMI recommend a door-to-needle time within 30 minutes for fibrinolytic therapy and a door-to-balloon time within 90 minutes for primary PCI as treatment goals.

Myocardial infarction is confirmed on the basis of a suggestive patient history and one or more of the following criteria: (1) cardiac biomarker (eg, creatine kinase MB or troponin) elevation; (2) ECG evidence; and (3) scintigraphic, echocardiographic [10,11]. In the present work, we adopted a step process to reduce the door-to-balloon time in STEMI. We limited our analysis to patients (1) with symptoms of STEMI within 12 hours of presentation, (2) with associated ST-segment elevation in 2 or more leads or left bundle-branch block on their first ECG, and (3) who were transferred from an acute-care hospital.

Methodology

Adult patients with ST-segment–elevation myocardial infarction undergoing primary percutaneous coronary intervention in October 2021 were identified from the emergency. We used the regression discontinuity framework to test for discontinuity at 90 minutes among the included cases. We defined a novel variable, the remaining Door - Balloon as 90 minutes minus the time between hospital arrival and catheterization laboratory arrival. We estimated multivariable logistic regression models to assess the relationship between remaining Door - Balloon time and access site.

To make this process faster and to achieve Door – Balloon time in STEMI we adopted the following process.

1. Quick recognition of STEMI by doing ECG in <10 Minutes.
2. Alerting Cardiologist regarding STEMI.
3. Priority registration of STEMI patients.
4. Urgent sampling of blood investigations and reporting by coordinating with the lab.
5. Alert Cath lab for the preparation of ballooning (24X7) and the availability of the Cath lab team.
6. Quick preparation of the patient and shifting to Cath lab.

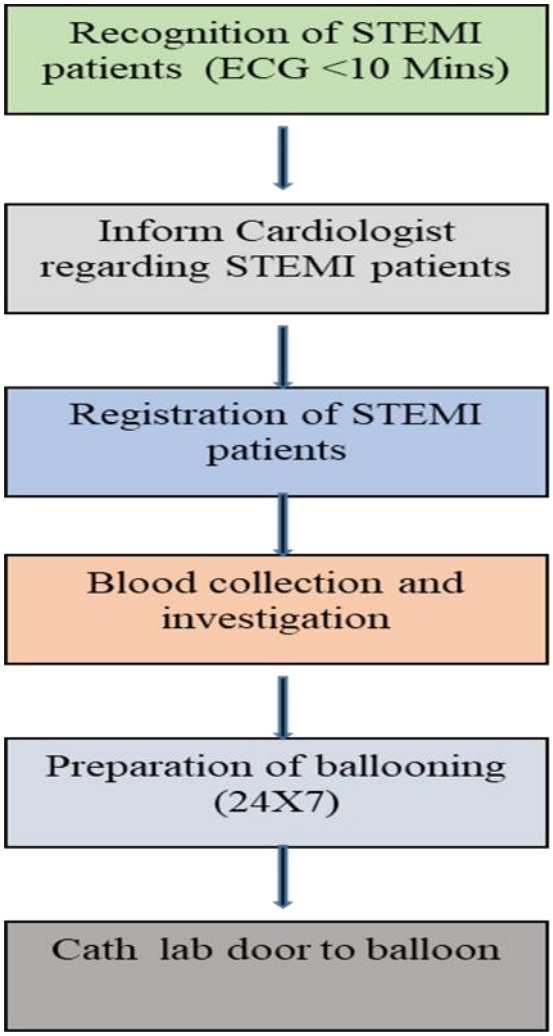

Figure 1: Study Procedure

Measurements

Baseline patient demographic and clinical characteristics were obtained for each patient as well as detailed procedural information of each primary PCI. The main independent variable was Door - Balloon time, which was calculated as the difference between the date/time of hospital arrival for STEMI and the date/time of first device activation. For our secondary analysis, we defined a novel variable, remaining Door - Balloon time, as 90 minutes minus the time between arrival to the medical facility and arrival to the catheterization laboratory when STEMI was noted on the first electrocardiogram.

STEMI is usually caused by acute thrombotic occlusion at the site of a ruptured atherosclerotic plaque. Early recanalization of the artery has been well established as the optimal treatment. As described by Bradley et al., small reductions in time at various stages

of the process added up to a significant decrease in the total Door - Balloon time, in our experience. Acceptable time limits are given in Table 1. Any such subdivisions of the total Door - Balloon time that is longer than acceptable were investigated, including discussion with individuals and departments involved.

Table 1: Specific components of the Door-to-Balloon timeline and their time interval goals

S. No.	Components of the Door-to-Balloon timeline	Minutes
1.	ED door to ECG	10
2.	ECG to STEMI alert	5
3.	STEMI alert to interventional cardiologist arrival	30
4.	ED door to Cath lab door	60
5.	Cath lab door to balloon	30

This approach resulted in a steady improvement in the measures being evaluated, as noted above. In fact, the improvement started before the program was formally instituted, presumably as a result of increased awareness of existing problems while planning was in progress. Following the initiation of the program, improvement continued over the months, as caregivers became increasingly familiar with the protocol, and has largely been maintained. Maintenance of a satisfactory Door - Balloon time has been an ongoing challenge, given a 24/7 operation involving a busy emergency department, and vigilance is needed to ensure continued success. Continued regular meetings of the Door-Balloon committee, with prompt feedback to involved individuals, have been felt to be the key to success. While we have been gratified to achieve the results described, we hope to effect further improvements in patient outcomes, by incorporating new innovations in the Cath lab and adjunctive techniques. In a process where time is crucial, there is an advantage to a uniform approach by all operators, and to using methods that do not risk causing delay. These considerations need to be balanced against the potential advantages of modifying the process, to incorporate changes shown to

improve prognosis. Such newer techniques were used in a small minority of the cases under review, and are not considered to have impacted the outcome of the group as a whole. They include:

1. **Radial artery as an access site.** Reduced complications and improved prognosis have been reported with this approach in the STEMI subset of the RIVAL study. While our cardiologists use radial access for most elective cases, the femoral artery has usually been used for STEMI patients, because of the greater predictability of rapid access. An appropriate process may be allotted for a period of perhaps 5 minutes, strictly timed, for radial access, with default to femoral approach if not successful in that time.

2. **Antithrombotic measures.** The use of bivalirudin, in place of heparin and a glycoprotein IIb/IIIa inhibitor, has been shown to reduce hemorrhagic complications and mortality and has been increasingly employed. The selection of oral antiplatelet therapy is also important, especially when bivalirudin is used during the intervention. Prasugrel has been associated with fewer recurrent infarctions and ischemic complications than clopidogrel, probably without increased bleeding risk. Ticagrelor use has reduced mortality and decreased stent thrombosis compared with clopidogrel, without an increase in major bleeding. These newer agents are likely to be increasingly preferred in selected cases.

3. **Thrombus aspiration.** Improved reperfusion has been reported when thrombus is aspirated before angioplasty, though published results of ongoing benefit have been variable. This technique is likely to be employed on a case-by-case basis, depending on anatomic findings. Because this will delay the actual balloon inflation, the term "door-to-device" has been suggested in place of "door-to-balloon" to more accurately reflect the time to arterial recanalization.

Data Collection

The study was conducted from 1st October to 31st October 2021. The total number of cases of STEMI received at SSB Heart and Multispecialty hospital done in between the above-mentioned date were 26 out of which 7 were taken into study depending on the selection criteria.

The selection criteria for the study are as follows:

1. Symptoms of STEMI within 12 hrs.
2. Associated ST-segment elevations in 2 or more leads or Left bundle branch blocks on their first ECG.
3. Bio Markers (CPKMB or TROPONIN) Elevations.
4. 2D-Echo Findings.

Exclusion criteria:

1. Recently undergone fibrinolytic therapy (Thrombolysis).
2. Presenting to Emergency with symptoms more than 24 hrs.
3. Unstable patients with symptoms of congestive heart failure, cardiogenic shock

As per selection criteria 7 patients were considered for further studies. The patients were personally reached out for receiving consent from them. Moreover, patients were notified about the study's purpose and that their information would be kept private, and that the content of each individual would only be evaluated by the researcher. Data has been evaluated on the basis of total STEMI Patients presented to ER.

Results

The results of this study show (Table 2) that in October 2021 primary PTCA was performed in less than 90 minutes without any mortality. The average time for the door to balloon was 5 mins to 80 mins. Out of 7 patients, 5 patients' primary PTCA was performed in less than 60 mins (Figure 2). It means 100 % success was achieved while performing primary PTCA.

Table 2: Details of primary PTCA for October 2021

S.No.	Date	IP No.	EMR in Time	CATH In Time	Door to Balloon Time
1	09-10-21	21/11303	15:00:00	15:20:00	00:20:00
2	10-10-21	21/11350	10:30:00	11:50:00	01:20:00

3	27-10-21	21/12277	00:10:00	01:00:00	00:50:00
4	28-10-21	21/12341	10:30:00	11:30:00	01:00:00
5	28-10-21	21/12352	14:30:00	14:35:00	00:05:00
6	28-10-21	21/12366	19:00:00	19:35:00	00:35:00
7	29-10-21	21/12457	16:20:00	16:45:00	00:25:00

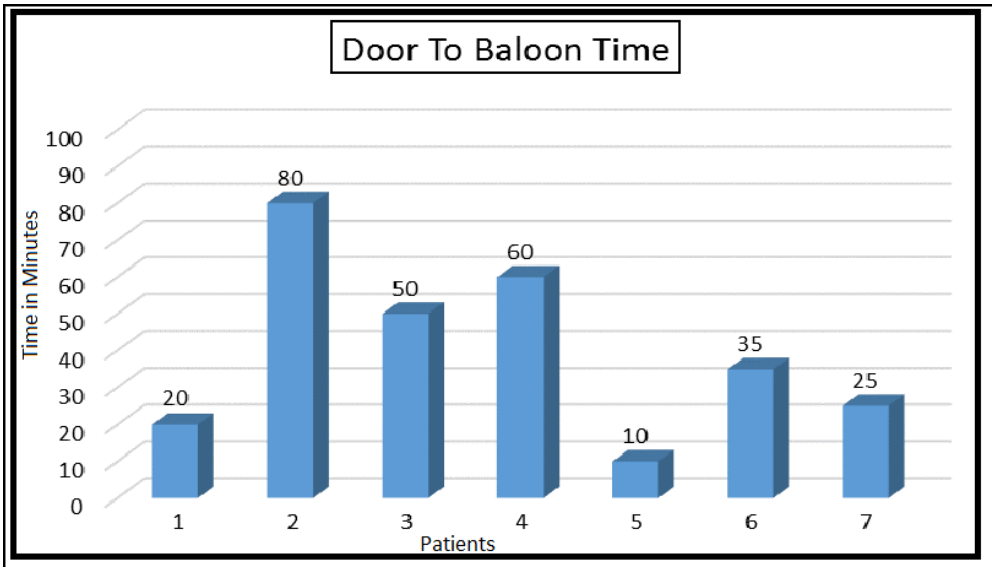

Figure 2: Graphical representation of door to balloon time (mins) V/S patients

Since implementing a protocol for the management of patients with acute STEMI, there has been largely successful maintenance of Door - Balloon time within the 90-minute ACC/AHA guideline, with the median recently mostly under 60 minutes. The ability of ambulance personnel to transmit high-quality ECGs, prior to hospital arrival has enhanced the process. Further improvement in outcomes is anticipated with evolving Cath lab techniques, including the increasing use of the trans-radial approach; of bivalirudin in place of heparin with a glycoprotein IIb/IIIa inhibitor; and in selected cases, of thrombectomy; and the use of newer platelet inhibitors.

Discussion

STEMI is the most acute manifestation of CAD, with substantial morbidity and mortality. Early reperfusion (re-establishing the blood flow in the occluded artery) is the most effective way to preserve the viability of the ischaemic myocardium and limit infarct size. Early diagnosis of STEMI is crucial to initiate appropriate treatment and should ideally be made within 10 minutes of first medical contact [12]. Initiatives have raised awareness of the importance of minimizing time to reperfusion with early diagnosis and immediate transfer to a facility with the option for cardiac catheterization and subsequent primary percutaneous coronary intervention (PCI) [13]. Developments in reperfusion therapies and preventive measures have contributed to a reduction in mortality from STEMI [14]. However, mortality seems to have plateaued, and a substantial amount of patients still experience recurrent cardiovascular events after STEMI [15]. Post- STEMI complications are decreasing [16], a reduction that is probably related to improved systems of care and the use of guideline-directed therapy. Management of STEMI remains an area of intense debate and interest; despite multiple clinical trials, there are still many questions to be answered regarding several aspects of care from pre-hospital management to the PPCI procedure itself. What is certain is that the impressive mortality and morbidity reductions already associated with PPCI are only likely to be improved further by such developments. This study represents the Primary PTCA timing of fewer than 90 minutes and an improved technique is developed with 100 % success in reducing mortality.

Conclusion

International data on mortality and morbidity benefits of primary angioplasty shows a 40% decrease in mortality of patients undergoing primary PTCA within 90 Minutes. Our Data on mortality and morbidity benefits of primary angioplasty shows a 100% decrease in mortality of patients undergoing primary PTCA within 90 minutes. We at SSB Heart and Multispecialty hospital have 100% compliance of Door – balloon time, decreasing the mortality and morbidity of the patients.

Recommendation

It enables comparison between patients that benefits from the intervention for a particular subset of patients. In the future also we aim to keep this practice for the benefit of the patients.

Follow up / Review

It is an ongoing prospective study.

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References

1. Mughal LH, Sastry S. Advances in the treatment of ST Elevation Myocardial Infarction in the UK. JRSM Cardiovasc Dis SAGE Publications; 2022;11:204800402210755.

2. Uddin MM, Mir T, Kaur J, Pervaiz E, Babu MA, Sheikh M. ST-elevation myocardial infarction among cardiac amyloidosis patients; a national readmission database study. Heart Fail. Rev. Springer; 2022.

3. Mughal LH, Sastry S. Advances in the treatment of ST Elevation Myocardial Infarction in the UK. JRSM Cardiovasc Dis 2022;11:204800402210755. Available from: https://journals.sagepub.com/doi/abs/10.1177/20480040221075519

4. Choudhury T, West NE, El-Omar M. ST elevation myocardial infarction. Clin Med (Northfield Il) 2016;16:277–82. Available from: https://www.rcpjournals.org/lookup/doi/10.7861/clinmedicine.16-3-277

5. Thygesen K, Alpert JS, Jaffe AS, Chaitman BR, Bax JJ, Morrow DA, et al. Fourth universal definition of myocardial infarction (2018) [Internet]. Russ. J. Cardiol. 2019. p. 107–38. Available from: https://experts.umn.edu/en/publications/fourth-universal-definition-of-myocardial-infarction-2018-2

6. Morrow DA. The fourth universal definition of myocardial infarction and the emerging importance of myocardial injury. Circulation. Lippincott Williams and Wilkins; 2020. p. 172–5.

7. Ibanez B, MacAya C, Sánchez-Brunete V, Pizarro G, Fernández-Friera L, Mateos A, et al. Effect of early metoprolol on infarct size in ST-segment-elevation myocardial infarction patients undergoing primary percutaneous coronary intervention: The effect of Metoprolol

in Cardioprotection during an Acute Myocardial Infarction (METOCARD-CNIC) Tri. Circulation. 2013. p. 1495–503.

8. Roffi M, Guagliumi G, Ibanez B, Ibanez B, Ibanez B. The obstacle course of reperfusion for ST-segment-elevation myocardial infarction in the COVID-19 pandemic. Circulation Lippincott Williams and Wilkins; 2020;1951–3.

9. Arslan F, Bongartz L, ten Berg JM, Jukema JW, Appelman Y, Liem AH, et al. 2017 ESC guidelines for the management of acute myocardial infarction in patients presenting with ST-segment elevation: comments from the Dutch ACS working group. Netherlands Hear J Bohn Stafleu van Loghum; 2018;26:417–21.

10. Thygesen K, Alpert JS, White HD. Universal Definition of Myocardial Infarction. J. Am. Coll. Cardiol. 2007. p. 2173–95.

11. Nallamothu BK, Bates ER, Herrin J, Wang Y, Bradley EH, Krumholz HM. Times to treatment in transfer patients undergoing primary percutaneous coronary intervention in the United States: National Registry of Myocardial Infarction (NRMI)-3/4 analysis. Circulation 2005;111:761–7.

12. Vogel B, Claessen BE, Arnold S V., Chan D, Cohen DJ, Giannitsis E, et al. ST-segment elevation myocardial infarction [Internet]. Nat. Rev. Dis. Prim. 2019. Available from: https://www.nature.com/articles/s41572-019-0090-3

13. Peterson ED, Roe MT, Rumsfeld JS, Shaw RE, Brindis RG, Fonarow GC, et al. A call to action (acute coronary treatment and intervention outcomes network):A National Effort to Promote Timely Clinical Feedback and Support Continuous Quality Improvement for Acute Myocardial Infarction. Circ Cardiovasc Qual Outcomes 2009;2:491–9.

14. O'Gara PT, Kushner FG, Ascheim DD, Casey DE, Chung MK, De Lemos JA, et al. 2013 ACCF/AHA guideline for the management of st-elevation myocardial infarction: A report of the American college of cardiology foundation/american heart association task force on practice guidelines. J Am Coll Cardiol Elsevier USA; 2013;61.

15. Jernberg T, Hasvold P, Henriksson M, Hjelm H, Thuresson M, Janzon M. Cardiovascular risk in post-myocardial infarction patients: Nationwide real world data demonstrate the importance of a long-term perspective [Internet]. Eur. Heart J. 2015. p. 1163-1170a.

Available from: https://academic.oup.com/eurheartj/article-abstract/36/19/1163/2293202

16. McManus DD, Gore J, Yarzebski J, Spencer F, Lessard D, Goldberg RJ. Recent trends in the incidence, treatment, and outcomes of patients with STEMI and NSTEMI. Am J Med 2011;124:40–7. Available from: https://www.sciencedirect.com/science/article/pii/S0002934310007369