ABSTRACT

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

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

**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.

**Conclusions:** 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.

1. INTRODUCTION

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

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

In STEMI primary percutaneous coronary angioplasty (PCI) is superior to fibrinolytic therapy as a reperfusion strategy when performed by experts. Primary PCI when compared with fibrinolytic therapy, results in lower rates of reinfarction, stroke, and death and higher stenosed-artery patency.

Myocardial perfusion is the mechanism by which reperfusion therapy and rapid and complete restoration of coronary artery blood flow reduce morbidity and mortality in STEMI. The outcomes with both fibrinolytic therapy and PCI that relate longer times to treatment are inverse. Current guidelines for STEMI recommend a door-to-balloon time within 90 minutes for primary PCI as treatment goals and a door-to-needle time within 30 minutes for fibrinolytic therapy.

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

2. METHODOLOGY

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

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. An 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.

2.1 Measurements

Patient baseline demographic and clinical characteristics were obtained as well as detailed procedural information of each primary PCI. The primary independent variable was Door - Balloon time, which was calculated based on the
difference between the time/date of first device activation and the time/date of hospital arrival for STEMI. The secondary analysis, 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, we defined a novel variable.

![Fig. 1. Study procedure](image)

Acute thrombotic occlusion at the site of a ruptured atherosclerotic plaque causes STEMI. According to Bradley et al., in our experience, a significant decrease in the total Door - Balloon time is because of small reductions in time at various stages of the process. Acceptable time limits for the process are given in Table 1. The total Door - Balloon time that is longer than acceptable was investigated, including discussion with departments and individuals involved.

As noted above, the approach resulted in a steady improvement in the measures being evaluated, and in fact, the improvement started before the program was formally started, while planning was in progress presumably as a result of increased awareness of the existing problem. For the improvement continued over the months, following the initiation of the program, as experts became familiar with the protocol, and largely been maintained it. To maintain 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. Regular meetings of the Door-Balloon experts committee and feedback of individuals have been felt to be the key to success. We hope to effect further improvements in patient outcomes, by incorporating new innovations in the Cath lab and adjunctive techniques. Where time is crucial in this process there is an advantage to a uniform approach by all operators those using methods that do not risk causing the delay. All these considerations need to be balanced against the potential advantages to incorporate changes shown to improve prognosis and of modifying the process, such as newer techniques were used in a small minority of the cases and are not considered to have impacted the outcome of the group.

The techniques include:

1. **An access site is the Radial artery:** In the STEMI subset of the RIVAL study improved prognosis and reduced complications have been reported. Because of the greater predictability of rapid access the femoral artery has usually been used for STEMI patients by our cardiologists, the radial access for most elective cases. A process may be allotted for a period of 5 minutes, strictly timed, for radial access, with a femoral approach if not successful in that time.

2. **Measures of Antithrombotic:** In place of heparin and a glycoprotein IIb/IIIa inhibitor, the use of bivalirudin, has been shown to mortality and reduce hemorrhagic complications and has been increasingly employed. Ticagrelor use has reduced mortality without an increase in major bleeding and also decreased stent thrombosis compared with clopidogrel.

3. **Thrombus aspiration in angioplasty:** Thrombus is aspirated before angioplasty; improved reperfusion has been reported when published results of ongoing benefit have been variable. This technique is likely to be employed on anatomic findings and on a case-by-case basis. This will delay the actual balloon inflation; the term "door-to-device" has been suggested in place of "door-to-balloon" to more accurately for the time of arterial recanalization.
Table 1. The Door-to-Balloon timeline components and their time interval

<table>
<thead>
<tr>
<th>S. No.</th>
<th>Components of the Door-to-Balloon timeline</th>
<th>Minutes</th>
</tr>
</thead>
<tbody>
<tr>
<td>1.</td>
<td>ED Door to ECG</td>
<td>10</td>
</tr>
<tr>
<td>2.</td>
<td>ECG to STEMI alert</td>
<td>5</td>
</tr>
<tr>
<td>3.</td>
<td>STEMI alert to interventional cardiologist arrival</td>
<td>30</td>
</tr>
<tr>
<td>4.</td>
<td>ED door to cath lab door</td>
<td>60</td>
</tr>
<tr>
<td>5.</td>
<td>Cath lab door to balloon</td>
<td>30</td>
</tr>
</tbody>
</table>

2.2 Data Collection

This 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. STEMI symptoms within 12 hrs.
2. ST-segment elevations are associated with 2 or more leads or Left bundle branch blocks on their first ECG.
4. 2D-Echo Findings.

Exclusion criteria:

1. Recently undergone fibrinolytic therapy (Thrombolysis).
2. Presenting to Emergency with symptoms more than 24 hrs.

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.

3. 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 (Fig. 2). It means 100% success was achieved while performing primary PTCA.

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

Table 2. Details of primary PTCA for October 2021

<table>
<thead>
<tr>
<th>S. No.</th>
<th>Date</th>
<th>IP No.</th>
<th>EMR in Time</th>
<th>CATH in Time</th>
<th>Door to Balloon Time</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>09-10-21</td>
<td>21/11303</td>
<td>15:00:00</td>
<td>15:20:00</td>
<td>00:20:00</td>
</tr>
<tr>
<td>2</td>
<td>10-10-21</td>
<td>21/11350</td>
<td>10:30:00</td>
<td>11:50:00</td>
<td>01:20:00</td>
</tr>
<tr>
<td>3</td>
<td>27-10-21</td>
<td>21/12277</td>
<td>00:10:00</td>
<td>01:00:00</td>
<td>00:50:00</td>
</tr>
<tr>
<td>4</td>
<td>28-10-21</td>
<td>21/12341</td>
<td>10:30:00</td>
<td>11:30:00</td>
<td>01:00:00</td>
</tr>
<tr>
<td>5</td>
<td>28-10-21</td>
<td>21/12352</td>
<td>14:30:00</td>
<td>14:35:00</td>
<td>00:05:00</td>
</tr>
<tr>
<td>6</td>
<td>28-10-21</td>
<td>21/12366</td>
<td>19:00:00</td>
<td>19:35:00</td>
<td>00:35:00</td>
</tr>
<tr>
<td>7</td>
<td>29-10-21</td>
<td>21/12457</td>
<td>16:20:00</td>
<td>16:45:00</td>
<td>00:25:00</td>
</tr>
</tbody>
</table>
4. DISCUSSION

“The most acute manifestation of CAD is STEMI with substantial mortality and morbidity. Reperfusion is the most effective way to preserve the ischaemic myocardium viability and infarct size limitation. STEMI early diagnosis is crucial to initiate appropriate treatment and should be diagnosed within 10 minutes of the first medical meeting” [12]. “The early diagnosis raised the importance of minimizing time to reperfusion and an immediate transfer for cardiac catheterization and subsequent primary percutaneous coronary intervention (PCI)” [13]. “Improvements in time management in reperfusion therapies and preventive measures have contributed to a reduction in STEMI mortality” [14]. “However, a substantial number of patients still experience recurrent cardiovascular events after STEMI and mortality seem to have been plateaued” [15]. “A reduction that is probably related to improved systems of care and the use of guideline-directed therapy as post-STEMI complications are decreasing” [16]. Despite multiple clinical trials; still, the management of STEMI remains an area of intense debate and interest. There are still many questions to be answered regarding pre-hospital management of the PPCI procedure. But still, the impressive morbidity and mortality reductions already associated with PPCI are only likely to be improved. This study represents the Primary PTCA timing of fewer than 90 minutes and an improved technique is developed with 100 % success in reducing mortality.

5. 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.

6. 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.

CONSENT

As per international standard or university standard, patients’ written consent has been collected and preserved by the author(s).

ETHICAL APPROVAL

As per international standard or university standard written ethical approval has been collected and preserved by the author(s).
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COMPETING INTERESTS
Authors have declared that no competing interests exist.

REFERENCES


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