Original article

Door-to-balloon: Where do we lose time? Single centre experience in India

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Abstract

Background/Aims: To assess the factors causing delay in attaining DTB time of < 90 min.
Methods: Eighty-five patients who underwent primary PCI from August 2008 to July 2009 were studied. From door-to-balloon, time was divided into 6 stages; any reason for delay was studied.
Results: The mean DTB time was 80.5 min (SD = 34.4, median time 75 min, range 30–195). DTB time was < 90 min in 76.5%, and DTB time > 90 min occurred in 23.5%. Mean door to ECG was 6.5 min (SD = 2.7), mean time for the decision of PCI was 7.5 min (SD = 10.5), mean time taken for the patient’s consent was 19.6 min (SD = 17.6), for STEMI team activation was 6.7 min (SD = 7.6), average time for financial process was 39.2 min (SD = 22.9). Average time for sheath to balloon was 5.2 min (SD = 1.7). Hospital related delay occurred in 5%, patient related delay in 80%, both together in 15%. 89.5% of patient related delay was due to delay in giving consent and financial reasons. There was no statistically significant delay for patients presented at morning or night and during the weekdays or weekend. Total mortality was 4.7%. Mortality among < 90 min was 3.1%, mortality among > 90 min was 10% (p = 0.2).
Conclusions: With effective hospital strategies, the DTB time of 90 min can be achieved in majority of patients. The chief delay in DTB time in this study was due to a delay in obtaining consent and financial reasons.

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1. Introduction

Cardiovascular disease has reached epidemic proportions in India. The urban Indians carry a 4-fold higher risk of coronary artery disease (CAD) than the Americans. The CAD burden especially is higher in younger Indian patients when compared to the west, leading to loss of productive life years. It is reported that about 50% of myocardial infarctions (MI)
occur in men below 50 years of age and 25% of these occur below 40 years. The CREATE registry has thrown light on some important factors in the management of ST elevation MI (STEMI). The incidence of STEMI is higher (60.6%) and the mortality is more (8.6%) in Indian population than that of developed countries. These statistics necessitate rigorous and effective treatment protocols in the management of STEMI.

The current recommendations, based on multiple randomized clinical trials, maintain primary PCI (PPCI) as the treatment of choice over thrombolysis in the management of STEMI, contingent upon treatment at centres with a skilled PCI laboratory and rapid initiation. Appropriately selected patients undergoing primary PCI were shown to have lower rates of nonfatal re-infarction, stroke, and short-term mortality than thrombolytic recipients in a meta-analysis of data from 23 randomized trials enrolling thrombolytic-eligible patients with STEMI. Many studies have revealed the importance of shorter door-to-balloon (DTB) time in the management of STEMI. Both ACC and ESC propose a DTB time of 90 min or PCI related delay of 60 min as standard, beyond which the benefit of PPCI over fibrinolysis is lost. Despite adequate measures, this is achieved in a small percentage of patients, the reasons being many. This study is undertaken to assess methodically whether a DTB time of less than 90 min can be achieved in the Indian setting and to assess the factors that cause delay.

2. Methods

This study was undertaken in the coronary care unit (CCU) of the Madras Medical Mission, Chennai, a 258-bedded tertiary cardiac center which has a 24 x 7 availability of PCI capable team and cardiac surgery back-up. The hospital has two state of the art cardiac catheterization labs and performed a total of 4497 catheterization procedures in 2011, out of which 1084 were PCIs.

3. Objectives

1. To evaluate whether the internationally recommended DTB time of 90 min for PPCI can be achieved in the Indian scenario.
2. To assess the factors that cause delay in achieving the target DTB time.
3. To determine whether DTB time of >90 min is associated with adverse outcomes (mortality at discharge).

3.1. Study population

Consecutive patients from August 2008 to July 2009 who presented with acute MI to our institute and underwent PPCI were studied prospectively.

3.2. Inclusion criterion

Patients with acute myocardial infarction willing to undergo PPCI.

3.3. Exclusion criterion

Cardiogenic shock and patients with acute myocardial infarction who underwent thrombolysis.

3.4. Study protocol

The data was documented by CCU team who were blinded to the study objectives.

From door-to-balloon, time was divided into 6 stages (Fig. 1):

1. Door to ECG time.
2. Time taken for decision of PCI by the CCU team.
3. Time taken for the consent for PPCI.
4. Time taken for STEMI team to be activated.
5. Time taken for financial process.
6. Time taken for sheath to balloon (first passage of any intracoronary device).

The goal for each step was 10 min. Any delay and the reason for delay were studied. The study was cleared by the ethics committee.

The institute as an exclusive cardiovascular unit does not have a separate emergency department; all the patients arrive at CCU in an emergency. When the patient with symptoms suggestive of STEMI presented to CCU, the time of arrival was noted by the person in charge of collecting the data. Patients with cardiogenic shock were excluded. ECG was called for; the time taken for the completion of ECG was noted. The ECG was assessed by the cardiologist. After a brief clinical/echocardiographic examination, complications of acute MI were ruled out and a decision for a revascularization was reached. The time taken for this decision was noted. The options of

![Fig. 1 – Flow chart depicting division of time intervals in PPCI.](image-url)
revascularization strategies, risks and benefits, cost involved and need for hospitalization were discussed with the patient/relatives of the patient. The time taken for the consent was noted; those who opted for primary PCI were included in the study and were followed up further. Patients who opted for thrombolysis were excluded. Then the STEMI team including the nursing staff and technicians were alerted, the time taken for this was noted. Patient’s attendants were required to concur with the estimated cost before the onset of procedure. The time to complete the financial process was noted. After the onset of procedure, the time taken for the first passage of intracoronary device was noted. The causes of any delay were documented.

4. Definitions

4.1. STEMI

Angina or anginal equivalent lasting for >20 min and ST – segment elevation of ≥1 mm in ≥2 contiguous leads, or new left bundle branch block, or true posterior MI with ST depression of ≥1 mm in ≥2 contiguous anterior leads.

4.2. Cardiogenic shock

Defined as prolonged hypotension (systolic blood pressure < 85 mmHg) with evidence of decreased organ perfusion caused by severe left ventricular dysfunction, right ventricular infarction, or mechanical complications of infarction and not due to hypovolemia, bradyarrhythmias, or tachyarrhythmias.

4.3. Diabetes mellitus

Fasting glucose >126 mg/dL or on treatment.

4.4. Systemic hypertension

Systolic blood pressure >140 mmHg and or diastolic pressure >90 mmHg, or on treatment.

4.5. Dyslipidemia

Fasting cholesterol >200 mg/dL or on treatment.

4.6. Door-to-balloon time

“Time from first hospital arrival to first attempt at reperfusion with any intracoronary device.”

4.7. Statistical analysis

Data were collected and managed on the excel worksheet. All continuous variables were expressed as the mean value ± standard deviation (SD). All categorical variables were presented as percentages and absolute values. Unpaired student’s ‘t’ test was used to compare the mean of continuous variables. Chi-square test was used to compare proportion. ‘p’ value <0.05 was considered statistically significant. Analyses were conducted using SPSS version 10.0.

5. Results

A total number of 136 patients presented with STEMI during the study period, 5 patients were excluded due to cardiogenic shock and 46 were thrombolysed. Eighty-five patients who underwent PPCI formed the study group. Table 1 shows the demographic and clinical characteristics of the study population.

The median time from symptom onset to hospital door for the study group was 180 min (range 30 – 605), with a mean time of 406.4 min. The mean DTB time was 80.5 min (SD = 34.4), median DTB time was 75 min (range 30 – 195). DTB time <90 min was achieved in 76.5% (n = 65) of patients and DTB time >90 min occurred in 23.5% (n = 20). Fig. 2 delineates the time intervals for 6 stages of DTB time. The mean door to ECG time was 6.5 min (SD = 2.7). After the ECG was taken, mean time taken for decision of PCI by the CCU team was 7.5 min (SD = 10.5). But the patient’s relatives consent to proceed further with their choice of revascularization strategy came after a mean of 19.6 min (SD = 17.6). The average time taken for our STEMI team, to be activated was 6.7 min (SD = 7.6). The mean time taken for the financial process to be completed was 39.2 min (SD = 22.9). Average time taken from sheath to first passage of any intracoronary device was 5.2 min (SD = 1.7).

Out of the DTB >90 min group, hospital related delay occurred in 5% (n = 1), patient related delay was responsible in

Table 1 – Baseline demographic and clinical characteristics of the study group.

<table>
<thead>
<tr>
<th>Characteristic</th>
<th>Number (%)</th>
</tr>
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<tbody>
<tr>
<td>Age (mean ± SD) years</td>
<td>57.8 ± 11.5</td>
</tr>
<tr>
<td>Male gender</td>
<td>72 (84.7)</td>
</tr>
<tr>
<td>Systemic hypertension</td>
<td>12 (14.1)</td>
</tr>
<tr>
<td>Diabetes</td>
<td>36 (42.4)</td>
</tr>
<tr>
<td>Dyslipidemia</td>
<td>9 (10.6)</td>
</tr>
<tr>
<td>Current smoker</td>
<td>15 (17.6)</td>
</tr>
<tr>
<td>Family history of CAD</td>
<td>3 (3.5)</td>
</tr>
<tr>
<td>Prior MI</td>
<td>2 (2.4)</td>
</tr>
<tr>
<td>Anterior myocardial infarction</td>
<td>38 (44.7)</td>
</tr>
<tr>
<td>Inferior myocardial infarction</td>
<td>25 (29.4)</td>
</tr>
</tbody>
</table>
80% \((n = 16)\), both together occurred in 15% \((n = 3)\) (Fig. 3). The hospital related causes were due to delay in STEMI team activation \((n = 1)\), decision for PCI was delayed due to subtle ECG changes or atypical presentation \((n = 2)\) and both our catheterization laboratories \((CL)\) being occupied \((n = 1)\). However, 89.5% \((17)\) of patient related delay was due to either delay in taking a decision for PCI or inability to oblige estimated finances after PCI or both together. 10.5% \((n = 2)\) of patients required stabilization of tachy/brady arrhythmias before shifting to the lab.

As depicted by Fig. 4, there was no statistically significant delay in attaining the optimal DTB times for patients presented at morning or at night-time \((56.5\% \text{ vs. } 43.5\%)\). Similar results were seen for the patients presented during the weekdays or weekend \((71.8\% \text{ vs. } 28.2\%)\). Total mortality in the study population was 4.7% \((n = 4)\). Mortality among <90 min was 3.1%, mortality among >90 min was 10% \((p' = 0.2)\).

6. Discussion

Numerous studies have established the fact that the mortality risk in acute MI declines with decreasing DTB time.\(^6\)\(^9\) An integrated teamwork along with feasible objectives and dedicated compliance are required to curtail DTB time to the greatest extent possible. Our study, to our knowledge, is the first study from the Indian subcontinent to analyze the delay in attaining the recommended DTB time and the results suggest that this indeed, is an achievable target despite few unavoidable aspects.

In this study, the mean age was 57.8 years, 84.7% were males. Prevalence of diabetes was high with 42.4%, however, only 14.1% were known to have hypertension at admission, but on monitoring their blood pressure during the hospitalization, this figure sharply rose to nearly 40%. This suggests that diabetes is more likely to be diagnosed and treated than hypertension; however, we need larger studies to confirm this. Other traditional risk factors of CAD like, smoking, dyslipidemia, family history of CAD are not very prevalent in this study population.

According to the study of Centres for Medicare & Medicaid Services (CMS) involving 900 hospitals from 2005 to 2010, the median door-to-balloon time in US fell from 96 min to 64 min. The proportion of STEMI patients who had door-to-balloon times within 90 min grew from 44% to 91%.\(^{10}\) In our study, mean DTB time was 80.56 min (median time 75 min, range 30–195) which is well within the international recommendations and 76.5% of STEMI patients had DTB <90 min. With the well structured protocols in place, we could minimize the time intervals involving the institution i.e., door to ECG, decision for revascularization, time to activate STEMI team and time from sheath to balloon. But the prominent time delays came in the form of time taken for the patient’s consent for the procedure \((19.6\text{ min})\) and time taken for approval of anticipated cost \((39.15\text{ min})\). The overall awareness of acute MI and its management is very low among most of the patients and the relatives, that a majority of them spent at least 15 min discussing what has been explained to them with either their kin or their primary physician on the phone. Once the decision for PCI was given, the next hurdle was to think about arranging the finances. The patients who had some form of insurance scheme had much lower time intervals for financial...
process from the billing department (10–15 min) than those who had no insurance. This despite of our hospital not insisting on the payment at the time of procedure, but the relatives only requiring to sign a ‘Financial’. This form had specially been designed to avoid delay in optimal treatment for want of immediate finances. For many people, even signing this form took a lot of deliberation. According to CREATE registry three quarters of patients with acute coronary syndrome paid the expenses on their own and only about a tenth had some form of insurance coverage. This primarily was the cause for delay in DTB time in our study.

Our data is in stark contrast to the data from the developed countries, where consent for PCI and financial decisions were not even considered as facets of DTB time. In a study involving 2034 referral patients, 30.4% achieved DTB < 90 min, 26.4% had delay awaiting transport, emergency department delay occurred in 14.3% and nondiagnostic ECG, diagnostic dilemma, cardiac arrest/shock constituted the rest of the delay. In another study, time to transport and patients presenting during on-call hours accounted as the major causes of delay in PPCI. Bradley EH in 2006 published a similar study in 13,387 patients from 340 hospitals undergoing PPCI. The time intervals in higher-performing hospitals (top 20%) were, door to ECG was 7.9 min (SD = 1.7), ECG to CL was 47.8 min (SD = 7.1) and 29 min (SD = 5.4) for CL to balloon. The achievement of shorter DTB time in higher-performing hospitals was contributed to better coordination. Planned protocols and teamwork helped achieve shorter DTB times in STEMI management. Joel T Levis et al published a study using ‘Heart Alert’ protocol though which DTB time < 90 min was attained in 97% of patients. However, the longest time delay in this study was the time spent in the emergency department.

We, at our institute have implemented various strategies and protocols for minimizing DTB time (Table 2). We believe this is especially important in Indian perspective where the time from pain onset to hospital may be longer. Fig. 5 shows the decrease in mean DTB time from 2006 to 2011 (91 min—68.6 min) and the increase in percent of patients with DTB time < 90 min (68%–83%). The mortality benefit in this study among DTB < 90 min (3.1% vs 10%) was not statistically significant; this may be due the small sample size.

### 7. Limitations

Our study does have few limitations. This is a study involving a single urban tertiary care centre. There was no follow up data; the statistics were limited to in-hospital mortality outcomes.

### 8. Conclusion

PPCI is a life saving procedure in the management of acute MI. With effective hospital strategies, the DTB time of less than 90 min can be accomplished in majority of patients. Public awareness and promotion of health schemes are indispensable to convene the goals of reduction of DTB time.

### Funding

None.

### Conflicts of interest

All authors have none to declare.

### References


