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Research Brief

Door to balloon time in patients presenting with acute ST elevation myocardial infarction and time factors influencing it; an observational study from a tertiary care teaching hospital in India

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ABSTRACT

The objective of this prospective observational study was to assess the door-to-balloon time (D2B), in acute ST-segment elevation myocardial infarction (STEMI) patients and the time factors influencing it. The following timeframes were measured during the study: ED to ECG time, ED to coronary care unit time (ED2CCU), consent time, post-consent to balloon time (POSTCONSENT2B) and D2B. Effective D2B was 54 ± 12.2 min. Of the dependent variables, D2B had a strong positive correlation ($\rho = 0.903$) with consent time. This study sheds light on consent time a previously unrecognized entity as a significantly influencing factor for the D2B time.

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1. Introduction

Cardiovascular diseases are the leading cause for mortality in India, with Ischemic heart disease leading the category for death and disability.[1] The incidence and the mortality due to ST-segment elevation myocardial infarction (STEMI) in India is higher than that of most developed countries.[2,3] The door-to-balloon time (D2B) and its association with morbidity and mortality in STEMI management is well established globally.[4–6] In this study, we sought to determine the D2B time for primary percutaneous coronary intervention (PCI) and the various time frames influencing the D2B in acute STEMI.

2. Methods

This prospective observational study was conducted in a tertiary care teaching hospital over a period of one year after the approval from the Institutional Review Board and Ethics Committee.

All clinically confirmed consecutive cases of acute STEMI who themselves or their proxy in lieu gave a written informed consent were included in the study. They were assessed, stabilized, and then shifted to the coronary care unit (CCU) after catheterization lab activation by Emergency Physician (EP), as per institutional protocol. Patients were shifted to the catheterization lab adjacent to CCU after consent was obtained for PCI from the bystander. Patient data were collected as per a pre-approved structured proforma.

2.1. Variables

The following time factors affecting D2B time were recorded during the study (Fig. 1).

- ED to ECG time (**ED2ECG**), defined as the time taken from arrival to the ED to confirming the STEMI on ECG,
- ED to CCU time (**ED2CCU**), defined as the time taken for a patient diagnosed with acute STEMI to be transferred from ED to CCU,
- **Consent** time, defined as the time taken by patient or their surrogate for documenting consent to PCI after initiation of

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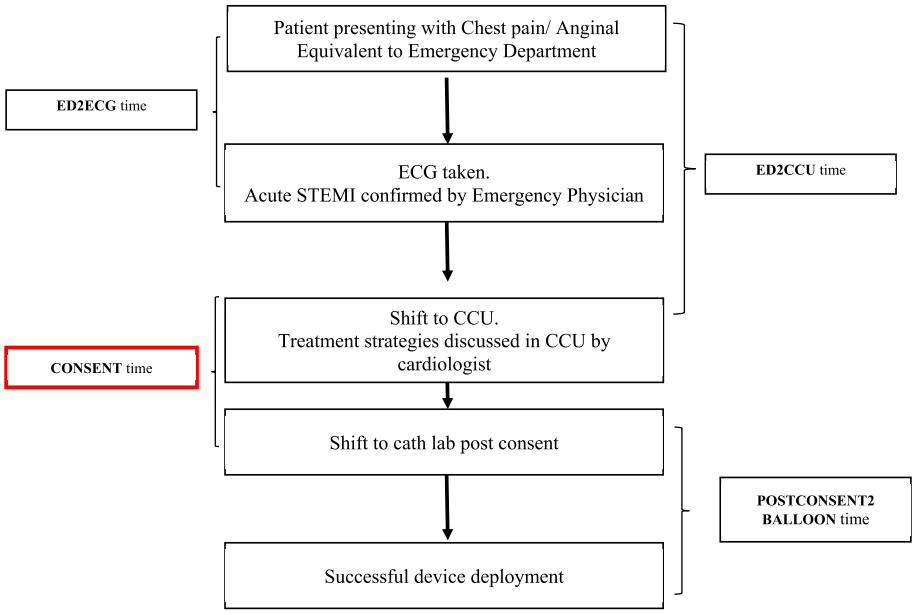

Fig. 1. Time factors flow chart. ED- Emergency Department**; ECG-** Electrocardiogram**; CCU-** Coronary Care Unit**; STEMI-** ST segment elevation myocardial infarction; **ED2ECG-** Emergency Department to ECG time; **ED2CCU-** Emergency Department to Coronary Care Unit time; **POSTCONSENT2B**- Post-consent to balloon time.

discussion, which was done by the interventional cardiologist as per the institutional protocol.

- Post-consent to balloon time (**POSTCONSENT2B),** defined as the time taken for the definitive procedure in the catheterization lab (balloon deployment) after documenting consent and
- Door-to-balloon time (**D2B**), which was defined as the time taken from arrival to the ED to balloon deployment in the catheterization lab.

Sample size calculation: At confidence interval of 95%, margin of error of 5% assuming a population proportion of 0.5, population size of 31 lakhs in the district (unlimited population), a minimum sample size of 385 was calculated. Consecutive sampling was done throughout the predetermined study duration.

Table 1
Baseline characteristics.

Variable (unit)	Result
Mean age (mean SD) in years	58.6 ± 12.05
Male gender; n (%)	391 (78.2%)
Systemic hypertension n (%)	175(35%)
Diabetes mellitus n (%)	200(40%)
Dyslipidemia n (%)	126 (25.2%)
Past history of CAD n (%)	18 (3.6%)
Family history of CAD n (%)	130 (26%)
Patient education status (above 10th standard) n (%)	394 (78.8%)
Smoking n (%)	274(54.8%)
Diet- mixed diet n (%)	490 (98%)

SD- Standard Deviation; CAD- Coronary Artery Disease.

Statistical analysis: Statistical analysis was carried out using International Business Machines Statistical Package for the Social Sciences. The data for continuous variables are presented as Mean ± SD. Spearman's correlation (ρ) was done to ascertain correlation amongst time delays.

3. Results

A total of 500 consecutive patients presenting to the ED with acute STEMI were included in the study. The baseline characteristics are outlined in Table 1.

The mean ED2ECG was 5.4 ± 1.8 min, ED2CCU 15.7 ± 3.7 min, consent time 23.9 ± 10.5 min, POSTCONSENT2B 14.3 ± 3 min and D2B 54 ± 12.2 min. Spearman's correlation (ρ) of ED2ECG, ED2CCU, consent time and POSTCONSENT2B with D2B showed significant positive correlation with consent time ($\rho = 0.903$) (Table 2).

4. Discussion

The D2B in our study (54 ± 12.2 min) was well within the current American College of Cardiology (ACC) and American Heart Association (ACC/AHA) guideline recommendation.[7] ACC and AHA have incorporated D2B as a quality metric in performance of hospitals catering to STEMI patients.[7,8] Longer D2B times are associated with significantly high mortality rates.[4,9]

Of all the time factors affecting D2B studied, consent time correlated with it the most. Removal of consent for life saving interventions like thrombolysis in stroke or myocardial infarction have been suggested by many.[10] The caretaker plays a pivotal role in

Table 2
Time factors studied.

Time factors	Mean	Std. Deviation	P value	Spearmann correlation coefficient (ρ)
ED2ECG (min)	5.4	1.9	<0.01	0.0228
ED2CCU (min)	15.7	3.7	<0.01	0.395
CONSENT (min)	24.0	10.5	<0.01	0.903
POSTCONSENT2B (min)	14.3	3.1	<0.01	0.316

ED2ECG- Emergency Department to Electrocardiogram time; **ED2CCU-** Emergency Department to Coronary Care Unit time; **POSTCONSENT2B** Post-consent to balloon time.

giving consent for definitive treatment. In India, healthcare expenditure is from one's own pocket rather than insurance or national schemes.[11–13] Our study observed a similar trend with 90% bystanders citing financial constraints during counselling although they were not asked to pay prior to treatment but to document in a consent form agreeing to treatment costs. Studies and guidelines in India, should address this variable, which significantly delays the D2B in our setting. Consent time varies widely and may not be solved by changing protocols or guidelines. The solution probably lies in addressing the healthcare cost concerns for the patient and provision of a universal scheme covering primary PCI.

The current system in the hospital where this study was carried out was successful in achieving guideline prescribed D2B in 98.6% of patients. Probable reasons for this achievement are that, the system employed several published strategies like; EP activating the catheterization lab team, ensuring catheterization lab team arrival within 20 min of call, cardiologist availability at all time, efficient coordination between cardiology department and ED and a regular audit system which was aimed at improving definitive treatment.[14,15]

5. Conclusion

The system present in the centre was able to achieve a D2B of 54 ± 12.2 min and was most significantly influenced by consent time. However, further studies in other states are needed to validate the importance of the consent time in the Indian setting.

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