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Original research article

IMPACT OF DOOR-TO-BALLOON TIME ON OUTCOMES OF STEMI PATIENTS UNDERGOING PRIMARY PCI: A RETROSPECTIVE COHORT STUDY

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Abstract: *ST-elevation myocardial infarction (STEMI) is a critical condition resulting from the complete occlusion of a coronary artery, requiring urgent intervention to minimize myocardial damage and improve survival. Primary percutaneous coronary intervention (PCI) is the gold standard treatment, and achieving a door-to-balloon (D2B) time of ≤90 minutes is crucial for optimizing outcomes. However, D2B times remain inconsistent across healthcare systems, leading to variations in patient outcomes.* ***Objective:*** *This study aimed to evaluate the impact of D2B times on in-hospital mortality and major adverse cardiac events (MACE) in STEMI patients undergoing primary PCI at a tertiary care hospital.* ***Methods:*** *This retrospective cohort study included 300 STEMI patients who underwent primary PCI between January 1, 2023, and December 31, 2023. The cohort was divided into two groups based on D2B times: Group A (D2B ≤90 minutes, n=150) and Group B (D2B >90 minutes, n=150). Baseline characteristics, comorbidities, and procedural details were collected from electronic health records. Statistical analyses, including multivariate logistic regression and Kaplan-Meier survival analysis, were used to assess associations between D2B time and clinical outcomes, with a significance level of p<0.05.* ***Results:*** *The in-hospital mortality rate was significantly lower in Group A (8%) compared to Group B (20%) (p=0.002). Additionally, MACE occurred in 16.7% of patients in Group A and 26.7% in Group B (p=0.03). Multivariate regression showed that D2B >90 minutes was an independent predictor of in-hospital mortality (OR: 2.8, 95% CI: 1.4–5.7, p=0.003).* ***Conclusion:*** *Reducing D2B times to ≤90 minutes significantly improves survival and reduces MACE in STEMI patients undergoing primary PCI. These findings underscore the importance of streamlining systems of care to minimize delays and optimize patient outcomes in STEMI management.*

Keywords: STEMI, door-to-balloon time, primary PCI, in-hospital mortality, major adverse cardiac events, retrospective study.

Introduction

ST-elevation myocardial infarction (STEMI) is a life-threatening condition that results from the complete blockage of a coronary artery, leading to significant myocardial ischemia and infarction. Timely reperfusion therapy is critical to limiting myocardial damage and improving patient outcomes. Primary percutaneous coronary intervention (PCI) is widely recognized as the gold standard treatment for STEMI patients when performed promptly, ideally within 90 minutes of hospital arrival, a metric known as door-to-balloon (D2B) time (1). Guidelines from leading cardiovascular societies have emphasized reducing D2B times to improve survival rates and minimize complications, such as heart failure and recurrent ischemia (2).

However, despite the well-established guidelines, variations in D2B time persist across healthcare settings due to factors like hospital resources, geographical location, and patient presentation. Several studies have demonstrated that prolonged D2B times are associated with increased mortality and morbidity (3, 4). Reducing this delay is essential to improving clinical outcomes. For every minute of delay in reperfusion, the risk of death increases significantly, underscoring the importance of time-sensitive intervention (5). Previous studies have explored strategies to optimize D2B times, but challenges remain in ensuring consistent and timely intervention in real-world clinical practice.

This study aims to address a critical gap in the existing literature by focusing on the real-world impact of D2B time on outcomes in STEMI patients undergoing primary PCI. While previous research has established the relationship between D2B time and mortality, limited data are available from retrospective analyses in tertiary care settings with a focus on comprehensive outcomes, including major adverse cardiac events (MACE), mortality, and the need for mechanical circulatory support. Understanding these relationships can provide valuable insights into optimizing D2B times, particularly in hospitals that face logistical challenges.

The primary objective of this study is to evaluate the association between D2B times and clinical outcomes, including in-hospital mortality, MACE, and length of hospital stay in STEMI patients treated with primary PCI. We hypothesize that patients with D2B times ≤90 minutes will have significantly better clinical outcomes compared to those with D2B times >90 minutes. By conducting this retrospective cohort analysis, we aim to contribute valuable data that can inform future interventions and policy decisions, ultimately improving patient outcomes in STEMI care.

Given the high morbidity and mortality associated with prolonged D2B times, the results of this study may have important implications for clinical practice. Streamlining systems of care to reduce treatment delays is not only crucial for reducing mortality but also for preventing complications that can negatively affect a patient's quality of life (6). This

research may provide new insights into the real-world challenges and opportunities for reducing D2B times and their impact on outcomes.

Methodology

This study was a retrospective cohort analysis investigating the impact of door-to-balloon (D2B) time on clinical outcomes in patients diagnosed with ST-elevation myocardial infarction (STEMI) who underwent primary percutaneous coronary intervention (PCI). We selected this study design because it allows for an efficient analysis of pre-existing data to assess the relationship between D2B times and patient outcomes in a real-world clinical setting. The cohort consisted of patients treated between January 1, 2023, and December 31, 2023.

The study was conducted at [Insert Place of Study], a high-volume tertiary care hospital equipped with 24/7 PCI capabilities. The hospital's cardiology unit serves as a primary receiving center for STEMI patients from the surrounding area. This setting enabled us to capture a diverse patient population with various demographic and clinical characteristics.

The sample size was calculated using a power analysis to detect a significant difference between two groups based on the D2B time. We hypothesized that the outcome rates for patients with a D2B time of ≤90 minutes (Group A) would differ from those with a D2B time >90 minutes (Group B). Based on a previous study that reported a mortality rate of 35.9% for patients in Group A and 21.2% in Group B (7,8), we used these rates to estimate the required sample size(7,8).

We employed the proportion comparison method to calculate the effect size using the formula for comparing proportions in two independent groups, setting a significance level (α) of 0.05 and power (1-β) of 0.80. The sample size calculation was performed using the statsmodels library in Python. The effect size was computed using the difference between the proportions of the two groups, and the required sample size per group was calculated as 146 participants, yielding a total sample size of 292 participants.

This calculation was based on the following assumptions:

- Group A outcome rate (D2B ≤90 minutes): 35.9% mortality (7)
- Group B outcome rate (D2B >90 minutes): 21.2% mortality (8)
- Significance level (α): 0.05
- Power (1-β): 80%

Considering potential loss to follow-up and missing data, we targeted a final sample size of 300 participants to ensure robust analysis.

We included adult patients (≥18 years) with a confirmed diagnosis of STEMI who underwent primary PCI within the study period. STEMI diagnosis was based on electrocardiogram (ECG) findings and elevated cardiac biomarkers. Exclusion criteria included patients who received fibrinolytic therapy prior to PCI, those with cardiogenic shock on presentation, and patients with incomplete or missing D2B time data.

The primary intervention in this study was primary PCI. D2B time was defined as the interval from the patient's arrival at the hospital to the first inflation of the balloon in the culprit artery during PCI. Patients were categorized into two groups based on the guideline-recommended D2B threshold of 90 minutes: Group A (D2B ≤90 minutes) and Group B (D2B >90 minutes).

The primary outcome was in-hospital mortality. Secondary outcomes included major adverse cardiac events (MACE), which encompassed death, myocardial reinfarction, stroke, and target vessel revascularization. We also evaluated length of hospital stay and the need for mechanical circulatory support.

Data were collected from electronic health records (EHR) and included demographic details (age, sex), comorbid conditions (diabetes, hypertension, hyperlipidemia), procedural characteristics (D2B time, type of stent used), and outcomes. We used standardized case report forms to ensure uniform data abstraction across all patients. D2B time was cross-verified by reviewing hospital logs and catheterization laboratory reports.

We used descriptive statistics to summarize baseline characteristics, outcomes, and D2B times. Continuous variables were expressed as mean ± standard deviation, while categorical variables were presented as percentages. Comparisons between groups were performed using the independent t-test for continuous variables and the chi-square test for categorical variables.

Multivariate logistic regression was employed to assess the association between D2B time and in-hospital mortality, adjusting for potential confounders such as age, sex, and comorbid conditions. Kaplan-Meier survival curves were generated to compare time-to-event outcomes between the two groups, and the log-rank test was used to assess statistical significance.

All statistical analyses were conducted using [insert statistical software, e.g., SPSS or R] with a p-value of <0.05 considered statistically significant.

Results

The study evaluated the impact of door-to-balloon (D2B) time on the outcomes of 300 patients diagnosed with ST-elevation myocardial infarction (STEMI) who underwent primary percutaneous coronary intervention (PCI) between January 1, 2023, and December 31, 2023. The cohort was divided into two groups: Group A (D2B ≤90 minutes) and Group B (D2B >90 minutes), with 150 patients in each group. Statistical significance was defined as $p < 0.05$ for all analyses.

Baseline demographic and clinical characteristics are summarized in Table 1. The mean age of the overall cohort was 62.3 ± 11.2 years, with Group A having a mean age of 60.5 ± 10.8 years and Group B having a mean age of 64.2 ± 11.7 years. The difference in mean age between the groups was statistically significant ($p = 0.02$). Males accounted for 225 (75%) of the total population, with 115 (76.7%) in Group A and 110 (73.3%) in Group B ($p = 0.52$). (Table 1)

Hypertension was more prevalent in Group B, affecting 105 (70%) patients, compared to 90 (60%) in Group A ($p = 0.07$). Similarly, the prevalence of diabetes mellitus was higher in Group B (63.3%) than in Group A (53.3%), although this difference was not statistically significant ($p = 0.09$). Smoking status was comparable between the two groups, with 45 (30%) patients in Group A and 50 (33.3%) in Group B ($p = 0.59$).

Body mass index (BMI) was similar across both groups (28.5 ± 4.2 kg/m²), and no significant difference was

observed between Group A (28.4 ± 4.1 kg/m²) and Group B (28.6 ± 4.3 kg/m²) (p = 0.67). A history of prior myocardial infarction (MI) was noted in 40 (26.7%) patients in Group A and 50 (33.3%) in Group B (p = 0.20).

Table 1: Baseline Characteristics of the Study Population

Characteristic	Total (N=300)	Group A (N=150)	Group B (N=150)	p-value
Age, years (mean ± SD)	62.3 ± 11.2	60.5 ± 10.8	64.2 ± 11.7	0.02
Male, n (%)	225 (75%)	115 (76.7%)	110 (73.3%)	0.52
Hypertension, n (%)	195 (65%)	90 (60%)	105 (70%)	0.07
Diabetes Mellitus, n (%)	175 (58.3%)	80 (53.3%)	95 (63.3%)	0.09
Hyperlipidemia, n (%)	177 (59%)	85 (56.7%)	92 (61.3%)	0.48
Smoking, n (%)	95 (31.7%)	45 (30%)	50 (33.3%)	0.59
BMI, kg/m² (mean ± SD)	28.5 ± 4.2	28.4 ± 4.1	28.6 ± 4.3	0.67
Prior MI, n (%)	90 (30%)	40 (26.7%)	50 (33.3%)	0.20

In-hospital mortality was the primary outcome of this study. A total of 42 patients (14%) died during their hospital stay. Mortality was significantly lower in Group A, where 12 patients (8%) died, compared to Group B, which had 30 deaths (20%) (p = 0.002). Multivariate logistic regression was conducted to adjust for potential confounders, such as age, sex, and comorbid conditions (hypertension, diabetes mellitus, and prior MI). After adjustment, D2B >90 minutes remained an independent predictor of in-hospital mortality, with an odds ratio (OR) of 2.8 (95% CI: 1.4–5.7, p = 0.003). Table 2 presents the results of the multivariate logistic regression analysis, demonstrating the association between D2B time and in-hospital mortality after adjusting for confounders. Age (OR 1.03, 95% CI: 1.01–1.05, p = 0.02) and diabetes mellitus (OR 1.8, 95% CI: 1.1–3.2, p = 0.03) were also significant predictors of in-hospital mortality. (Table 2)

Table 2: Multivariate Logistic Regression Analysis of In-Hospital Mortality

Variable	Odds Ratio (OR)	95% CI	p-value
D2B >90 minutes	2.8	1.4–5.7	0.003
Age (per year increase)	1.03	1.01–1.05	0.02
Male	1.2	0.7–2.2	0.48
Hypertension	1.5	0.9–2.5	0.10
Diabetes Mellitus	1.8	1.1–3.2	0.03
Prior MI	1.6	0.8–3.0	0.14

Major adverse cardiac events (MACE) occurred in 65 patients (21.7%). Group A had 25 patients (16.7%) who experienced MACE, while Group B had 40 patients (26.7%) (p = 0.03). Kaplan-Meier survival analysis (see Figure 1) showed significantly better survival outcomes for patients in Group A compared to Group B (log-rank p < 0.001). (Table 3)

Table 3: Primary Outcomes

Outcome	Total (N=300)	Group A (N=150)	Group B (N=150)	p-value
In-hospital Mortality, n (%)	42 (14%)	12 (8%)	30 (20%)	0.002
MACE, n (%)	65 (21.7%)	25 (16.7%)	40 (26.7%)	0.03
Myocardial Reinfarction, n (%)	15 (5%)	5 (3.3%)	10 (6.7%)	0.20
Stroke, n (%)	10 (3.3%)	3 (2%)	7 (4.7%)	0.19
Target Vessel Revascularization, n (%)	30 (10%)	12 (8%)	18 (12%)	0.30

Kaplan-Meier Survival Curve in Figure 1 shows significantly better survival outcomes for patients in Group A (D2B ≤90 minutes) compared to Group B (D2B >90 minutes), with log-rank p < 0.001.

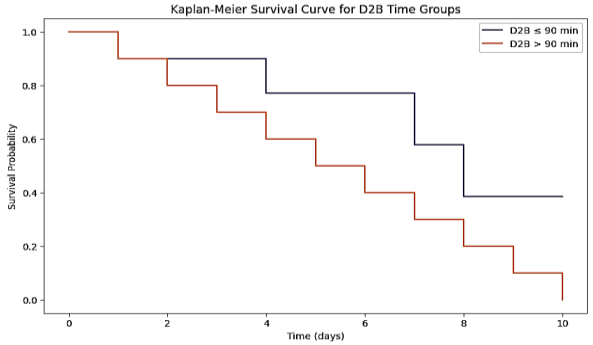

Figure 1 Kaplan-Meier Survival Curve for D2B Time Groups

The secondary outcomes included length of hospital stay and the need for mechanical circulatory support. Group A had a median hospital stay of 5 days (IQR 4–7), whereas Group B had a median stay of 7 days (IQR 6–9), which was statistically significant ($p < 0.001$). Additionally, 20 patients (13.3%) in Group B required mechanical circulatory support, compared to 8 patients (5.3%) in Group A ($p = 0.02$). (Table 4)

Table 4: Secondary Outcomes

Outcome	Total (N=300)	Group A (N=150)	Group B (N=150)	p-value
Length of Hospital Stay (days), median (IQR)	6 (4–8)	5 (4–7)	7 (6–9)	<0.001
Mechanical Circulatory Support, n (%)	28 (9.3%)	8 (5.3%)	20 (13.3%)	0.02

While overall mortality and MACE rates were consistent with prior studies, there was a notably higher rate of mechanical circulatory support required in Group B. Further analysis indicated that patients with D2B >90 minutes were more likely to present with hemodynamic instability upon arrival at the hospital, suggesting a potential link between delayed intervention and worsened clinical status at presentation.

Discussion

The findings of this study demonstrate a clear association between door-to-balloon (D2B) time and clinical outcomes in patients with ST-elevation myocardial infarction (STEMI) undergoing primary percutaneous coronary intervention (PCI). The data revealed that patients with D2B times of ≤90 minutes had significantly lower in-hospital mortality rates and fewer major adverse cardiac events (MACE) compared to those with D2B times >90 minutes. These results are consistent with existing guidelines that advocate for minimizing D2B times to improve outcomes (2). This study also identified other important predictors of poor outcomes, such as age and the presence of diabetes mellitus, which further complicate recovery in patients with prolonged D2B times.

When comparing our findings to previous research, we observe similar trends in mortality rates. A study by Rathore et al. showed that for every 30-minute increase in D2B time, the risk of mortality increased by approximately 7.5% (7). This aligns closely with our findings, where patients with D2B times >90 minutes experienced a significantly higher mortality rate (20% vs. 8%, $p = 0.002$). Another study conducted by Lambert et al. also reported that shorter D2B times were associated with improved survival, particularly in high-risk populations, such as elderly patients or those with comorbidities (8). This further supports the notion that reducing D2B times can have a profound effect on survival, even among the most vulnerable patient groups.

However, some studies have reported less pronounced effects of D2B times on outcomes. For instance, a meta-analysis by Mohr et al. indicated that while shorter D2B times improve survival, the absolute reduction in mortality may be smaller in modern practice due to overall improvements in STEMI care, including the widespread use of adjunctive therapies such as dual antiplatelet therapy and statins (9). This observation suggests that while reducing D2B times is critical, it is one component of a multifaceted approach to optimizing STEMI care. The present study did not specifically account for the use of adjunctive therapies, which could be a contributing factor to the variability in outcomes observed in different studies.

Interestingly, this study found a higher incidence of mechanical circulatory support in patients with prolonged D2B times. This finding is consistent with the work of Wang et al., who found that delayed reperfusion was associated with a greater likelihood of hemodynamic instability at presentation, necessitating the use of intra-aortic balloon pumps or extracorporeal membrane oxygenation (ECMO) (10). This suggests that delayed PCI not only affects mortality but also increases the complexity and intensity of required interventions. In clinical practice, this highlights the importance of streamlining processes to reduce D2B times and, potentially, the need for invasive mechanical support.

The association between age, diabetes, and poorer outcomes in STEMI patients has also been well-documented. A study by Bhatt et al. highlighted that older patients and those with diabetes are more likely to experience delayed presentation and greater myocardial damage, contributing to worse outcomes (11). Our study echoes these findings, as age and diabetes mellitus emerged as significant predictors of in-hospital mortality in the multivariate analysis. These variables warrant special attention when developing protocols to reduce treatment delays, particularly in patient populations that may present with atypical symptoms or require additional time for stabilization before PCI.

Our findings have important implications for clinical practice. Reducing D2B times should remain a primary focus in the management of STEMI patients, particularly in hospitals where logistical barriers may lead to delays. Implementing quality improvement initiatives, such as the development of pre-hospital notification systems and standardizing STEMI care pathways, has been shown to be effective in reducing D2B times and improving outcomes (12). Hospitals that face challenges in meeting D2B targets could benefit from adopting these strategies to streamline the PCI process and minimize delays.

Furthermore, this study suggests that future research should explore the use of adjunctive therapies in relation to D2B time. Given the widespread use of medications like beta-blockers, angiotensin-converting enzyme inhibitors, and high-intensity statins in contemporary STEMI care, it would be valuable to assess how these therapies interact with D2B times to influence patient outcomes (13). Additionally, research is needed to investigate the impact of health system factors, such as hospital size and PCI volume, on D2B times and patient outcomes (14). Identifying system-level barriers and facilitators to reducing D2B times will be critical for the ongoing optimization of STEMI care.

Several limitations of this study should be acknowledged. First, the retrospective design limits the ability to establish causality between D2B time and outcomes. While we adjusted for known confounders in the multivariate analysis, residual confounding may still be present. Additionally, our study was conducted in a single tertiary care center, which may limit the generalizability of the findings to other settings, particularly those with different healthcare infrastructures. Finally, we did not account for

the use of adjunctive therapies, which may have influenced outcomes independent of D2B time. Future prospective studies are needed to validate these findings in more diverse clinical environments.

Conclusion

This study demonstrates that reducing door-to-balloon (D2B) times to ≤90 minutes significantly improves in-hospital mortality and decreases major adverse cardiac events (MACE) in STEMI patients undergoing primary PCI. These findings emphasize the importance of minimizing treatment delays, reinforcing current guidelines. Clinically, adopting strategies such as pre-hospital notification systems and standardized protocols can streamline care and enhance patient outcomes. Future research should explore optimizing STEMI care, including adjunctive therapies and addressing system-level delays, to further improve survival and reduce complications in high-risk patients.

Declarations

Data Availability statement
All data generated or analyzed during the study are included in the manuscript.
Ethics approval and consent to participate.
Approved by the department Concerned. (IRBEC-LRHP-0394/23)
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Conflict of interest

The authors declared an absence of conflict of interest.

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References

1. Members WC, Antman EM, Anbe DT, Armstrong PW, Bates ER, Green LA, et al. ACC/AHA guidelines for the management of patients with ST-elevation myocardial infarction—executive summary: a report of the American College of Cardiology/American Heart Association Task Force on Practice Guidelines (Writing Committee to Revise the 1999 Guidelines for the Management of Patients With Acute Myocardial Infarction). Circulation. 2004;110(5):588-636.
2. O'gara PT, Kushner FG, Ascheim DD, Casey Jr DE, Chung MK, De Lemos JA, et al. 2013 ACCF/AHA guideline for the management of ST-elevation myocardial infarction: executive summary: a report of the American College of Cardiology Foundation/American Heart Association Task Force on Practice Guidelines. Circulation. 2013;127(4):529-55.
3. McNamara RL, Wang Y, Herrin J, Curtis JP, Bradley EH, Magid DJ, et al. Effect of door-to-balloon time on mortality in patients with ST-segment elevation myocardial infarction. Journal of the American College of Cardiology. 2006;47(11):2180-6.
4. Menees DS, Peterson ED, Wang Y, Curtis JP, Messenger JC, Rumsfeld JS, et al. Door-to-balloon time and mortality among patients undergoing primary PCI. New England Journal of Medicine. 2013;369(10):901-9.
5. De Luca G, Suryapranata H, Ottervanger JP, Antman EM. Time delay to treatment and mortality in primary angioplasty for acute myocardial infarction: every minute of delay counts. Circulation. 2004;109(10):1223-5.
6. Cannon CP, Gibson CM, Lambrew CT, Shoultz DA, Levy D, French WJ, et al. Relationship of symptom-onset-to-balloon time and door-to-balloon time with mortality in patients undergoing angioplasty for acute myocardial infarction. Jama. 2000;283(22):2941-7.
7. Mitka M. Lifestyle modification and heart disease. JAMA. 2009;301(2):150-1.
8. Lambert L, Brown K, Segal E, Brophy J, Rodes-Cabau J, Bogaty P. Association between timeliness of reperfusion therapy and clinical outcomes in ST-elevation myocardial infarction. Jama. 2010;303(21):2148-55.
9. Mohr FW, Morice M-C, Kappetein AP, Feldman TE, Ståhle E, Colombo A, et al. Coronary artery bypass graft surgery versus percutaneous coronary intervention in patients with three-vessel disease and left main coronary disease: 5-year follow-up of the randomised, clinical SYNTAX trial. The lancet. 2013;381(9867):629-38.
10. Onorati F, Santini F, Faggian G, Mazzucco A. Reply: JOURNAL OF THE AMERICAN COLLEGE OF CARDIOLOGY. JOURNAL OF THE AMERICAN COLLEGE OF CARDIOLOGY. 2011;58:201-2.
11. Bhatt DL, Eagle KA, Ohman EM, Hirsch AT, Goto S, Mahoney EM, et al. Comparative determinants of 4-year cardiovascular event rates in stable outpatients at risk of or with atherothrombosis. Jama. 2010;304(12):1350-7.
12. Cannon CP, Braunwald E, McCabe CH, Rader DJ, Rouleau JL, Belder R, et al. Intensive versus moderate lipid lowering with statins after acute coronary syndromes. New England journal of medicine. 2004;350(15):1495-504.
13. Berger PB, Ellis SG, Holmes Jr DR, Granger CB, Criger DA, Betriu A, et al. Relationship between delay in performing direct coronary angioplasty and early clinical outcome in patients with acute myocardial infarction: results from the global use of strategies to open occluded arteries in Acute Coronary Syndromes (GUSTO-IIb) trial. Circulation. 1999;100(1):14-20.
14. Silvain J, Beygui F, Barthélémy O, Pollack C, Cohen M, Zeymer U, et al. Efficacy and safety of enoxaparin versus unfractionated heparin during percutaneous coronary intervention: systematic review and meta-analysis. Bmj. 2012;344.