PAKISTAN JOURNAL OF Cardiovascular Intervention

OPEN ACCESS

ORIGINAL ARTICLE

Incidence, predictors, and risk stratification of the no-reflow phenomenon during primary percutaneous coronary intervention in st-elevation myocardial infarction: A Prospective Observational Study.

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Citation:
Ahmad J, Shah HA, Shah T, Khan MU, Rahim T, Kundi A, Afzal Z. Incidence, predictors, and risk stratification of the no-reflow phenomenon during primary percutaneous coronary intervention in ST-elevation myocardial infarction: A Prospective Observational Study. PJCVI. 2025; 5(2): 65-73

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DOI: 10.58889/PJCVI.5.2.65.73

Funding:
This research received no specific grant from any funding agency in the public, commercial, or not-for-profit sectors.

Conflicts of Interests:
The authors declare no conflict of interest related to this publication.

Received 07/02/2025
Accepted 10/04/2025
First Published 01/12/2025

Abstract

Background: To determine the incidence, identify independent predictors, and develop a clinically applicable risk stratification model for angiographic no-reflow in patients with ST-segment elevation myocardial infarction (STEMI) undergoing primary percutaneous coronary intervention (PCI).

Methodology: All consecutive adult patients (≥18 years) presenting with STEMI within 24 hours of symptom onset and undergoing primary PCI were enrolled. Patients with prior myocardial infarction, recent revascularization, cardiogenic shock, or severe renal failure were excluded. Clinical, demographic, and angiographic variables were recorded using standardized definitions. No-reflow was defined as Thrombolysis in Myocardial Infarction (TIMI) flow grade ≤2 or TIMI grade 3 with myocardial blush grade ≤1 after final PCI. Independent predictors were identified using multivariate logistic regression, and a weighted risk score was derived from β-coefficients.

Results: Among 650 patients (mean age 56.6 ± 13.3 years; 18% females), no-reflow occurred in 159 patients (24.5%). Independent predictors included age ≥60 years (adjusted odds ratio [OR] 13.82, 95% confidence interval [CI] 8.08–23.65), total ischemic time ≥6 hours (OR 4.75, 95% CI 2.88–7.83), high thrombus burden (OR 4.36, 95% CI 2.63–7.23), anterior myocardial infarction (OR 2.86, 95% CI 1.75–4.67), and diabetes mellitus (OR 2.29, 95% CI 1.39–3.77). The model demonstrated excellent discrimination (area under the curve [AUC] 0.896) and good calibration (Hosmer-Lemeshow p=0.49). Risk stratification showed a marked gradient in no-reflow rates from 1.8% in low-risk to 68.2% in very high-risk groups.

Conclusion: The no-reflow phenomenon complicates approximately one-quarter of primary PCI procedures in STEMI. A simple five-parameter risk score based on routinely available variables provides robust risk stratification and may facilitate targeted preventive strategies in high-risk patients.

Keywords

Diabetes Mellitus, Myocardial Infarction, No-Reflow Phenomenon, Percutaneous Coronary Intervention, Risk Factors, Time-to-Treatment.

Introduction

Successful restoration of epicardial coronary blood flow does not necessarily translate into adequate myocardial perfusion. The angiographic no-reflow phenomenon represents a critical limitation of reperfusion therapy, characterized by impaired microvascular perfusion despite successful reopening of the infarct-related artery. Globally, the reported incidence of no-reflow varies widely, ranging from 5% to 50%, with most contemporary studies indicating rates between 15% and 30%[1]. Similar incidence patterns have been observed in Asian populations, where rates between 12% and 31% have been reported[2].

In Pakistan, available data suggest that the incidence of no-reflow ranges from 13% to 28%[3]. However, most of these studies are limited by single-center designs, relatively small sample sizes, and heterogeneity in definitions and procedural protocols. Furthermore, many earlier studies were conducted before the widespread adoption of contemporary primary PCI techniques, limiting their applicability to current clinical practice. Importantly, prior local research has largely focused on descriptive epidemiology and simple associations, without developing or validating quantitative risk prediction tools tailored to the regional population.

The clinical significance of the no-reflow phenomenon is substantial. It has been consistently associated with adverse outcomes, including a 2–3-fold increase in mortality and major adverse cardiac events (MACE)[4-7]. The underlying pathophysiology is multifactorial, involving distal embolization, ischemia–reperfusion injury, endothelial dysfunction, and microvascular spasm. Early identification of patients at high risk for no-reflow is therefore essential to enable targeted preventive strategies and optimize procedural planning in busy catheterization laboratories.

Although several international risk models have been proposed, their generalizability to South Asian populations remains uncertain due to differences in demographics, comorbidity profiles, healthcare access, and treatment delays. Moreover, the absence of locally derived and validated prediction tools limits their practical utility in routine clinical settings within Pakistan.

In this context, the present prospective observational study was designed to address these gaps by (1) determining the contemporary incidence of no-reflow in patients with STEMI undergoing primary PCI, (2) identifying independent clinical and angiographic predictors, (3) developing a simple and practical risk stratification model based on routinely available variables, and (4) evaluating its discriminative performance. By utilizing a larger, contemporary cohort and standardized definitions, this study aims to provide clinically relevant evidence and a pragmatic risk prediction tool tailored to the Pakistani population.

Methodology

Study Design

This study was conducted as a prospective observational investigation designed to evaluate the incidence and predictors of the no-reflow phenomenon among patients presenting with ST-segment elevation myocardial infarction (STEMI) undergoing primary percutaneous coronary intervention (PCI). The prospective nature of the study allowed for systematic data collection and temporal assessment of predictors in relation to outcomes, thereby enhancing internal validity and minimizing recall bias.

Ethics

Ethical approval for the study was obtained from the Institutional Review Committee of Lady Reading Hospital. All procedures adhered to the ethical principles outlined in the Declaration of Helsinki. Written informed consent was obtained from all participants prior to enrollment, ensuring voluntary participation and confidentiality of patient information.

Setting

The study was carried out at the Department of Cardiology, Lady Reading Hospital, Peshawar, Pakistan, a high-volume tertiary care referral center with established primary PCI services. Patient enrollment was conducted over a defined period from August 2023 to February 2024, reflecting

contemporary clinical practice and PCI protocols in a real-world South Asian healthcare setting.

Participants

All consecutive adult patients (≥18 years) presenting with STEMI within 24 hours of symptom onset and planned for primary PCI were included. STEMI was defined by chest pain accompanied by ST-segment elevation ≥1 mm in contiguous leads. Patients were excluded if they had a history of myocardial infarction or revascularization within the preceding six months, presented with cardiogenic shock, had severe renal impairment (estimated glomerular filtration rate <30 mL/min/1.73 m^2), or declined consent. These exclusion criteria were applied to ensure a relatively homogeneous study population undergoing standard PCI and to reduce confounding from conditions associated with distinct pathophysiology and prognosis.

Variables

The primary outcome variable was the occurrence of the no-reflow phenomenon, defined angiographically as Thrombolysis in Myocardial Infarction (TIMI) flow grade ≤2 or TIMI grade 3 with myocardial blush grade ≤1 following final balloon or stent deployment. Independent variables included demographic characteristics (age, sex), clinical factors (diabetes mellitus, hypertension, smoking status), and angiographic/procedural variables such as thrombus burden, infarct location, and total ischemic time.

Data Sources / Measurement

Clinical, demographic, and angiographic data were collected prospectively using standardized data collection forms. All procedures were performed using contemporary PCI techniques, including radial artery access, administration of unfractionated heparin (100 IU/kg), and use of second-generation drug-eluting stents. Thrombus burden was assessed angiographically at initial contrast injection using the TIMI thrombus grading system, with high thrombus burden defined as grade ≥4. Total ischemic time was calculated as the duration from symptom onset to first balloon inflation, ensuring objective measurement of treatment delay.

Bias

Efforts were made to minimize potential sources of bias. Selection bias was reduced through consecutive patient enrollment. Measurement bias was minimized by using standardized definitions (e.g., TIMI flow, myocardial blush grade) and consistent procedural protocols. However, residual confounding may persist due to unmeasured variables such as operator experience and procedural nuances, which were not systematically recorded.

Study Size

A total of 650 patients meeting the eligibility criteria were enrolled during the study period. The sample size reflects a large, single-center cohort and was considered sufficient to allow robust multivariable analysis and development of a predictive model with adequate statistical power.

Quantitative Variables

Continuous variables, such as age and ischemic time, were analyzed as either continuous or categorized variables (e.g., age ≥60 years, ischemic time ≥6 hours) based on clinically relevant thresholds. Categorical variables were expressed as frequencies and percentages, while continuous variables were summarized as mean ± standard deviation, facilitating both clinical interpretability and statistical modeling.

Statistical Methods

Data analysis was performed using the SPSS version 26. Group comparisons were conducted using the chi-square test for categorical variables. Variables demonstrating a significance level of $p < 0.10$ in univariate analysis were entered into a forward stepwise logistic regression model to identify independent predictors. A liberal threshold at the univariate stage was intentionally selected to avoid exclusion of potentially relevant variables, while a stricter threshold of $p < 0.05$ was applied in the final model. Adjusted odds ratios (ORs) with 95% confidence intervals (CIs) were reported. Model performance was evaluated using discrimination (area under the curve, AUC) and calibration (Hosmer-Lemeshow goodness-of-fit test). A weighted risk score was subsequently developed by rounding β-coefficients of independent predictors to the nearest integer, facilitating practical bedside application

consistent with established cardiovascular risk models.

Results

Participants

A total of 650 consecutive patients fulfilling the eligibility criteria were enrolled during the study period. All participants underwent primary percutaneous coronary intervention (PCI) and were included in the final analysis, with no exclusions after enrollment. The study cohort therefore represents a complete dataset of patients presenting with ST-segment elevation myocardial infarction (STEMI) managed with contemporary primary PCI at the study center.

Descriptive Data

The baseline demographic and clinical characteristics of the study population are summarized in relation to key risk factors (Tables 2 and 4). The mean age of the cohort was 56.6 ± 13.3 years, with 41.8% of patients aged ≥60 years. Females constituted 18% of the study population. Cardiovascular risk factors were common, with diabetes mellitus present in 29.8% and hypertension in 48.8% of patients, while 56.8% were current smokers. From an angiographic perspective, a high thrombus burden (TIMI grade ≥4) was observed in 47.4% of patients, and anterior myocardial infarction was identified in 50.5% of cases. Prolonged ischemic time (≥6 hours) was noted in 44.5% of the cohort (Table 4), reflecting delays in presentation and/or access to care.

Outcome Data

The primary outcome, angiographic no-reflow, was documented in 159 out of 650 patients, corresponding to an overall incidence of 24.5%. Among these, transient no-reflow occurred in 93 patients (14.3% of total; 58.5% of no-reflow cases), whereas persistent no-reflow was observed in 66 patients (10.2% of total; 41.5% of no-reflow cases), as detailed in Table 1. These findings highlight that nearly one-quarter of STEMI patients undergoing primary PCI experienced impaired microvascular perfusion despite successful epicardial recanalization.

Main Results

Univariate analysis identified several clinical and angiographic variables significantly associated with the occurrence of no-reflow (Table 2). These included older age (≥60 years), diabetes mellitus, hypertension, prolonged ischemic time (≥6 hours), high thrombus burden, anterior myocardial infarction, longer lesion length, and larger reference vessel diameter. Interestingly, current smoking demonstrated a protective association (odds ratio 0.58), consistent with previously described paradoxical effects. On multivariate logistic regression analysis, five variables remained independent predictors of no-reflow (Table 3). Age ≥60 years emerged as the strongest predictor, followed by prolonged ischemic time ≥6 hours, high thrombus burden, anterior myocardial infarction, and diabetes mellitus. These predictors formed the basis of the risk stratification model. The predictive model demonstrated excellent performance, with strong discrimination (area under the curve [AUC] = 0.896, 95% CI: 0.866–0.925) and good calibration (Hosmer-Lemeshow p=0.49), as illustrated in Figure 1.

Based on the weighted contribution of each predictor, a risk score ranging from 0 to 9 points was developed (Table 4). Patients were subsequently stratified into four risk categories, demonstrating a clear and clinically meaningful gradient in no-reflow rates (Table 5). The incidence of no-reflow increased progressively from 1.8% in the low-risk group (0–2 points) to 5.7% in the moderate-risk group (3–4 points), 23.1% in the high-risk group (5–6 points), and 68.2% in the very high-risk group (7–9 points). This represents a substantial escalation in risk across categories and underscores the strong predictive capacity and practical clinical utility of the derived scoring system.

Table 1: Types of no-reflow (n=650)

No-Reflow Type	Total	% within no-reflow
Persistent No-Reflow	66 (10.2%)	41.5%
Transient No-Reflow	93 (14.3%)	58.5%
Total No-Reflow	159 (24.5%)	100.0%

TIMI flow <3 or TIMI 3 with an MBG of 0-1 throughout the procedure

Table 2: Selected clinical and angiographic predictors - univariate analysis (n=650).

Clinical Predictor	OR (95% CI)	p-value
Age ≥60 years	15.44 (9.51-25.05)	<0.001
Diabetes Mellitus	2.89 (1.99-4.21)	<0.001
High Thrombus Burden	3.73 (2.53-5.49)	<0.001
Total Ischemic Time ≥6 hours	4.57 (3.09-6.77)	<0.001

CI: Confidence Interval

Table 3: Independent predictors of no-reflow - multivariate logistic regression.

Clinical Predictor	OR Ratio (95% CI)	p-value
Age ≥60 years	15.44 (9.51-25.05)	<0.001
Diabetes Mellitus	2.89 (1.99-4.21)	<0.001
High Thrombus Burden	3.73 (2.53-5.49)	<0.001
Total Ischemic Time ≥6 hours	4.57 (3.09-6.77)	<0.001

OR: Odds Ratio; CI: Confidence Interval

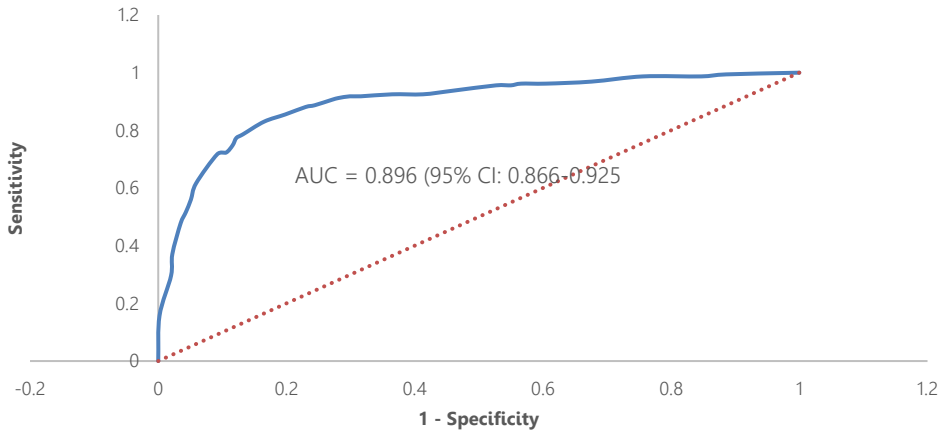

Figure 1: Area Under Curver.

Table 4: Risk stratification and observed no-reflow rates

Risk Factor	Points	Prevalence in Cohort
Age ≥60 years	3	272 (41.8%)
Total ischemic time ≥6 hours	2	289 (44.5%)
High thrombus burden	2	308 (47.4%)
Anterior MI location	1	328 (50.5%)

Diabetes mellitus	1	194 (29.8%)

Table 5: No-reflow rates by risk category

Risk Category	Points	Patients n (%)	No-Reflow Cases n (%)	No-Reflow Rate (%)
Low Risk	0-2	157 (24.2)	3 (1.9)	1.8
Moderate Risk	3-4	245 (37.7)	14 (9.0)	5.7
High Risk	5-6	178 (27.4)	41 (25.8)	23.1
Very High Risk	7-9	70 (10.8)	48 (30.2)	68.2
Total	0-9	650 (100.0)	159 (100.0)	24.5

Discussion

In this prospective observational study, we observed a 24.5% incidence of the no-reflow phenomenon among patients with ST-segment elevation myocardial infarction (STEMI) undergoing primary PCI. This finding is consistent with contemporary international data, reinforcing that no-reflow remains a persistent and clinically significant challenge despite advances in reperfusion strategies. For instance, Oikonomou et al. reported an incidence of 22% in a large European cohort[8], while Yang et al. and Stiermaier et al. documented rates of 26% and 23.5%, respectively, in Asian and European populations[9,10].

Regionally, our results align closely with recent Pakistani studies, which report incidence rates ranging from 18.5% to 25%[4-6]. Minor variations across studies may be attributed to differences in patient characteristics, ischemic time, institutional protocols, and definitions of no-reflow. Importantly, our study contributes contemporary data from a relatively large cohort using standardized angiographic criteria, thereby strengthening the reliability and relevance of these findings within the South Asian context.

Advanced age (≥60 years) emerged as the strongest independent predictor of no-reflow in our cohort. This observation is consistent with prior studies demonstrating a markedly increased risk among elderly patients[9,11]. Age-related microvascular dysfunction, endothelial impairment, and a higher burden of comorbidities likely contribute to this association. Similarly, prolonged total ischemic time (≥6 hours) was identified as a key predictor, underscoring the critical importance of timely reperfusion. Previous studies have shown that delays in treatment significantly increase the risk of microvascular injury and no-reflow, with incremental increases in risk observed with each hour of delay[12,13].

High thrombus burden was another strong predictor, consistent with the established role of distal embolization and microvascular obstruction in the pathogenesis of no-reflow. Meta-analyses and large clinical studies have consistently demonstrated a 3–4-fold increase in risk associated with higher thrombus grades[14,15]. Anterior myocardial infarction also independently predicted no-reflow, likely reflecting the larger myocardial territory at risk and greater thrombotic burden associated with left anterior descending artery occlusion[16].

Diabetes mellitus was significantly associated with no-reflow, which is in line with the known effects of diabetic microangiopathy, endothelial dysfunction, and impaired vasodilatory response[17]. Although smoking appeared protective in univariate analysis, this association did not persist after multivariate adjustment, consistent with the well-described "smoker's paradox," which is largely attributed to confounding by younger age and fewer comorbidities among smokers[18].

A key strength of this study is the development of a simple, clinically applicable risk stratification model based on five readily available variables. The model demonstrated excellent discrimination (AUC 0.896) and good calibration, indicating strong predictive performance. This is comparable to

established international models, such as those reported by Niccoli et al. (AUC 0.84) and Heusch et al. (AUC 0.87)[19,20]. Importantly, the primary value of our model lies not in outperforming existing tools, but in its derivation and internal validation within a South Asian population, enhancing its contextual relevance and applicability.

The risk score demonstrated a clear gradient in no-reflow risk across categories, with a dramatic increase from low- to very high-risk groups. This stratification has important clinical implications. It enables early identification of high-risk patients and facilitates tailored preventive strategies, such as consideration of thrombus aspiration, use of glycoprotein IIb/IIIa inhibitors, or intensified post-procedural monitoring. In resource-constrained settings, such targeted approaches may improve outcomes while optimizing resource utilization.

Despite significant technological advancements, the persistence of no-reflow across different populations and time periods highlights the complexity of its underlying pathophysiology. Current treatment strategies primarily address epicardial flow restoration but may not adequately target microvascular injury. Future research should focus on novel therapeutic approaches, including pharmacological modulation of reperfusion injury, advanced thrombectomy techniques, and integration of biomarker-driven or personalized treatment strategies.

Limitations

Several limitations of this study should be acknowledged. First, the single-center design may limit the generalizability of the findings to other healthcare settings, particularly smaller or non-urban centers. As a tertiary referral hospital, our institution may receive more complex or advanced cases, introducing potential referral bias and possibly overestimating the incidence of no-reflow. Second, long-term clinical outcomes, including mortality, heart failure, and repeat revascularization, were not assessed. Therefore, the prognostic implications of the derived risk score beyond the index hospitalization could not be evaluated. Future longitudinal studies are needed to validate the clinical impact of this model over extended follow-up periods. Third, biochemical markers such as peak troponin levels, brain natriuretic peptide, and inflammatory biomarkers were not routinely collected in this cohort and were therefore unavailable for inclusion in the predictive model. These markers may provide incremental prognostic value and should be explored in future studies. Fourth, operator experience and procedural techniques were not systematically recorded. Variations in technical expertise, device selection, and procedural strategies may influence the occurrence of no-reflow and could introduce unmeasured confounding. Finally, although the model demonstrated excellent internal performance, external validation in independent populations is required before widespread clinical implementation. Multicenter studies across diverse populations would further strengthen the robustness and generalizability of the proposed risk score.

Conclusion

The no-reflow phenomenon remains a common and clinically significant complication, affecting approximately one in four patients undergoing primary PCI for STEMI. Advanced age, prolonged ischemic time, high thrombus burden, anterior infarction, and diabetes mellitus are key independent predictors that can be integrated into a simple and practical risk stratification tool. The derived five-parameter risk score demonstrated excellent predictive performance and provides a feasible approach for early risk assessment using routinely available clinical and angiographic variables. Its application in clinical practice may facilitate targeted preventive strategies, improve procedural planning, and optimize outcomes, particularly in resource-limited healthcare settings.

Acknowledgment

The authors extend their appreciation to the catheterization laboratory staff, nursing team, and coronary care unit personnel of the Department of Cardiology, Lady Reading Hospital MTI, Peshawar, Pakistan, for their dedicated support in patient management and data acquisition.

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