

Clinical and Angiographic Predictors of suboptimal Coronary Flow After Primary Percutaneous Coronary Intervention in Patients with ST-Elevation Myocardial Infarction

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Original Article

Abstract

INTRODUCTION: This study aimed to investigate the clinical and angiographic characteristics of patients with ST-elevation myocardial infarction who experienced primary percutaneous coronary intervention failure.

METHOD: This retrospective observational study was derived from the Primary Angioplasty Registry of Sina Hospital (PARS). A total of 548 consecutive patients with ST-elevation myocardial infarction who underwent primary percutaneous coronary intervention between November 2016 and January 2019 were evaluated. Percutaneous coronary intervention failure was defined as Thrombolysis in Myocardial Infarction (TIMI) flow ≤ 2 or corrected TIMI frame count (cTFC) ≥ 28 .

RESULTS: The study population consisted of 458 (83.6%) males and 90 (16.4%) females with a mean age of 59.2 ± 12.49 years. TIMI flow 3 was achieved in 499 (91.1%) patients after the procedure, while 49 (8.9%) patients developed TIMI ≤ 2 . The findings showed that cTFC ≥ 28 was present in 50 (9.1%) patients, while 489 (89.2%) patients had cTFC < 28 . Multiple regression analysis shows that age 1.04 (1.01, 1.07), duration of pain onset to first medical contact time 1.04 (1.00, 1.18), and left anterior descending artery involvement 3.15 (1.21, 8.11) were independent predictors of TIMI ≤ 2 .

CONCLUSION: Even though TIMI ≤ 2 was uncommon among the study population, it was associated with adverse in-hospital outcomes. The results indicate that earlier emergency medical service arrival and shorter transfer time to the referral center can dramatically reduce the primary percutaneous coronary intervention failure rate.

Keywords: Primary Percutaneous Coronary Intervention, ST-Elevation Myocardial Infarction, Thrombolysis in Myocardial Infarction

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Introduction

Primary percutaneous coronary intervention (PCI) is by far the most preferred method of management in the treatment of patients with ST-elevation myocardial infarction (STEMI)¹. However, despite the widespread use of primary PCI and advancements in its technique and technology, unsuccessful coronary reperfusion is

still one of the most challenging aspects of the primary PCI²⁻⁴.

Thrombolysis in Myocardial Infarction (TIMI) flow ≤ 2 and Corrected TIMI Frame Count (cTFC) are the two measures used to assess effective epicardial reperfusion after primary PCI. TIMI flow grade 3 and cTFC < 28 are used

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in several works of literature as indicators of successful primary PCI^{5,6}. It is shown that patients developing TIMI flow grade 3 after primary PCI have better short-term and long-term outcomes compared with those with TIMI ≤ 2 ⁶. Previous studies have shown that many factors including age, sex, previous medication use, and lesion length could affect the angiographic success and the rate of achieving TIMI flow grade 3⁵⁻¹². It has been also suggested that TIMI flow grade ≤ 2 is associated with in-hospital adverse events¹³. Several studies have shown that cTFC < 28 is associated with a lower mortality rate in patients undergoing primary PCI¹⁴.

Previously, there has been only one study in the Iranian population demonstrating the effect of different factors on primary PCI success⁸; however, independent predictors of TIMI flow grade 3 were not identified. Additionally, the effects of modifiable variables such as pain onset to first medical contact time and immediate activation of emergency services, named project-247, on achieving successful primary PCI were investigated. In this study, the aim was to determine the predictors of unsuccessful primary PCI in acute STEMI among the Iranian population.

Materials and Methods

Study Design

This was a retrospective observational study derived from the Primary Angioplasty Registry of Sina Hospital (PARS). Methodological details of the PARS registry have been published previously¹⁵. In brief, consecutive patients presenting with acute STEMI from November 2016 to January 2019 who underwent primary PCI were entered in the present study. From 564 patients present in the registry, 16 were excluded due to missing data and 548 subjects were included for the analysis. The study was approved by the ethics committee of Tehran University of Medical Sciences (IR.TUMS.MEDICINE.REC.1398.244).

STEMI was defined as having one of these criteria⁵:

- a) Ischemic symptoms < 12 hours
- b) New ST elevation in at least two anatomically

contiguous leads (ST-elevation > 2.5 mm in men younger than 40 years, > 2 mm in men older than 40 years or > 1.5 mm in women in leads V2-V3 and/or ≥ 1 mm in other contiguous leads)

- c) Posterior STEMI defined as ST depression > 1 mm in at least two contiguous anterior leads or ST elevation > 0.5 mm in at least two contiguous posterior leads

- d) New complete left bundle branch block

ECG characteristics of STEMI were then confirmed with a troponin level higher than the 99th percentile upper reference limit. Exclusion criteria were patient age under 18 years old, presence of any contraindications for reperfusion¹, arrival after 12 hours of first symptom, and patient discontent with primary PCI.

Project-247, a special service to diagnose STEMI patients at the site and to transfer them to the nearest primary PCI center, is thoroughly described in the PARS study¹⁵. Data collection methods and risk factor definitions are also explained in the same study¹⁵.

Thrombolysis in Myocardial Infarction (TIMI) grade flow is a scoring system used for assessing coronary blood flow during primary PCI. TIMI grade flow = 3 indicates optimal reperfusion while TIMI grade flow ≤ 2 is considered suboptimal⁵. Corrected TIMI Frame Count (cTFC) is defined as the number of frames required for the contrast to opacify a standard distal coronary landmark, adjusted for the culprit vessel length⁵. Angiographic data of patients were further reviewed by two independent interventionists to measure TIMI flow grade and cTFC. These measurements were performed in a blinded manner. Any discrepancies were resolved by consensus.

Procedure

Upon ambulance arrival, all patients were given 160 to 325 mg of aspirin and 600 mg of clopidogrel before the procedure. The interventional cardiologist was immediately ready for the catheterization. Glycoprotein IIb/IIIa inhibitors, balloon dilatation, stents, and intra-aortic balloon pump were used based on the interventionists' clinical judgment. All patients were discharged from the coronary care unit with

DAPT (dual antiplatelet therapy) and statins after full recovery.

Statistical Analysis

Categorical data were reported as frequency (percentage) while continuous data were expressed as mean \pm standard deviation (SD). Categorical variables were compared between the groups using chi-square or Fisher's exact test as appropriate while continuous data were compared using an independent T-test. Logistic regression with stepwise elimination was used for model development. Univariate logistic regression analysis was first employed. Variables with a P-value < 0.1 in univariate testing were entered in the multiple regression analysis and were reviewed for clinical relevance. Factors with

a P-value < 0.1 that were entered in the model are as follows: age, pain onset to the first medical contact time, left anterior descending (LAD) coronary artery infarction.

Odds ratios (ORs) with 95% confidence interval (CI) were calculated for independent predictors of TIMI ≤ 2 . The Statistical Package for Social Sciences (SPSS, Version 19.0) (IBM Company, USA) was used for data analysis.

Results

The study population consisted of 458 (83.6%) males and 90 (16.4%) females with a mean age of 59.2 ± 12.49 years. TIMI flow grade < 3 occurred in 49 (8.9%) patients while 50 (9.1%) patients had a cTFC ≥ 28 .

Table 1. Demographic and clinical characteristics of the patients

Characteristic†	TIMI ≤ 2 N = 49	TIMI = 3 N = 499	P*	cTFC ≥ 28 N = 50	cTFC < 28 N = 489	P*
Age (years)	63.51 \pm 12.06	58.81 \pm 12.46	0.012	61.66 \pm 12.46	58.89 \pm 12.45	0.134
Gender (female)	12 (24.5%)	78 (15.6%)	0.110	8 (16.0%)	79 (16.2%)	0.977
Heart rate (beats/minute)	81.56 \pm 15.29	81.13 \pm 16.50	0.871	81.13 \pm 16.31	81.23 \pm 16.46	0.969
Pain onset to FMC (minutes)	242.03 \pm 338.03	130.80 \pm 182.46	0.103	170.33 \pm 246.10	134.66 \pm 194.43	0.396
Door to device time (minutes)	44.34 \pm 44.27	42.65 \pm 82.59	0.913	33.84 \pm 25.21	43.50 \pm 83.40	0.557
FMC to device time (minutes)	112.53 \pm 52.67	109.18 \pm 78.48	0.819	117.19 \pm 56.11	108.02 \pm 76.57	0.551
Past medical history						
Diabetes mellitus	15 (30.6%)	135 (27.2%)	0.323	8 (16.0%)	137 (27.8%)	0.209
Hypertension	16 (32.7%)	171 (34.3%)	0.939	12 (24.0%)	172 (35.2%)	0.362
Current Smoking	14 (28.6%)	200 (40.1%)	0.795	17 (34.0%)	195 (39.9%)	0.474
Previous PCI	4 (8.2%)	38 (7.6%)	>0.99	2 (4.0%)	37 (7.6%)	0.562
Previous CABG	2 (4.1%)	9 (1.8%)	0.302	1 (2.0%)	9 (1.8%)	>0.99
Drug history						
Statin	6 (12.2%)	72 (14.4%)	0.512	3 (6.0%)	72 (14.7%)	0.077
Clopidogrel	2 (4.1%)	50 (10.0%)	0.130	1 (2.0%)	49 (10.0%)	0.069
Nitrate	2 (4.1%)	38 (7.6%)	0.407	2 (4.0%)	37 (7.6%)	0.564
CCB	1 (2.0%)	16 (3.2%)	>0.99	2 (4.0%)	15 (3.1%)	0.669
ACEI or ARB	7 (14.3%)	96 (19.2%)	0.291	2 (4.0%)	98 (20.0%)	0.005

† Continuous variables are presented as mean \pm standard deviation and categorical variables are presented as number (percentage).

* Statistically significant P-values are bolded.

Abbreviations: ACEI = Angiotensin Convertase Enzyme Inhibitor; ARB = Angiotensin Receptor Blocker; CABG = Coronary Artery Bypass Graft; CCB = Calcium Channel Blocker; FMC = First Medical Contact; PCI = Percutaneous Coronary Intervention.

Patients with younger age were more likely to achieve TIMI flow grade 3 after primary PCI (P value = 0.012). Other baseline characteristics such as gender, blood pressure at presentation, time from pain onset to first medical contact, past medical history, and drug history were not significantly correlated with the final TIMI flow. No demographic parameters were associated with cTFC \geq 28. Table 1 presents the demographic and clinical characteristics of the patients.

Patients with a final TIMI flow grade $<$ 3 were more likely to be affected by adverse outcomes like orotracheal intubation (P value = 0.004), ventricular fibrillation (P value = 0.008), cardiogenic shock (P value = 0.026), and death (P value = 0.001). In-hospital data associated with cTFC \geq 28 were intubation (P value = 0.037), and death

(P value = 0.007) (Table 2).

Higher predilatation balloon diameter (P value = 0.030, 0.047) and postdilatation (P value = 0.005, 0.001) were significantly correlated with TIMI flow = 3 and cTFC $<$ 28 with respective P values. Glycoprotein IIb/IIIa inhibitor use was also correlated with the aforementioned outcomes (P value = 0.011, 0.001). Other angiographic characteristics of the patients are demonstrated in Table 3.

Age (OR: 1.04 (1.01, 1.07), P = 0.009), duration of pain onset to first medical contact time (OR = 1.04 (1.00, 1.18), P = 0.038), and LAD involvement (OR = 3.15 (1.21, 8.11), P = 0.018) were identified as independent predictors of TIMI \leq 2. The Hosmer and Lemeshow Test for the final model was not significant (P value = 0.653), which indicates a good model fit (Table 4).

Table 2. Adverse events and complications of the study patients with suboptimal (TIMI \leq 2) and optimal flow (TIMI = 3)

	TIMI \leq 2 N = 49	TIMI = 3 N = 499	P	cTFC \geq 28 N = 50	cTFC $<$ 28 N = 489	P
Left ventricular ejection fraction	41.46 \pm 11.51	42.78 \pm 11.21	0.471	43.55 \pm 11.38	42.57 \pm 11.18	0.574
Hospital-stay, days	4.90 \pm 3.24	4.72 \pm 2.92	0.696	5.52 \pm 3.66	4.65 \pm 2.84	0.111
Death	9 (18.4%)	15 (3.0%)	0.001	6 (12.0%)	14 (2.9%)	0.007
AV node block	3 (6.1%)	8 (1.6%)	0.066	1 (2.0%)	8 (1.6%)	0.586
Stable VT	1 (2.0%)	8 (1.6%)	0.572	2 (4.0%)	7 (1.4%)	0.200
Unstable VT	9 (18.4%)	33 (6.6%)	0.008	6 (12.0%)	32 (6.5%)	0.150
Early VF	1 (12.5%)	17 (14.9%)	$>$ 0.99	1 (9.1%)	15 (13.9%)	$>$ 0.99
Late VF	2 (22.2%)	0 (0.0%)	0.006	2 (16.7%)	0 (0.0%)	0.011
Cardiac arrest	11 (22.4%)	39 (7.8%)	0.002	8 (16.0%)	36 (7.4%)	0.052
Intubation	7 (14.3%)	18 (3.6%)	0.004	5 (10.0%)	16 (3.3%)	0.037
Cardiogenic shock	10 (20.4%)	50 (10.0%)	0.026	8 (16.0%)	47 (9.6%)	0.155
Project-247	39 (79.6%)	383 (77.7%)	0.759	42 (84.0%)	373 (77.2%)	0.272
Stent thrombosis	1 (2.0%)	7 (1.4%)	0.530	0 (0.0%)	7 (1.4%)	$>$0.99

Early VF = ventricular fibrillation in the first 48 hours after primary PCI; Late VF = ventricular fibrillation after 48 hours of the primary PCI; Stable VT = ventricular tachycardia with stable hemodynamics; VT unstable = ventricular tachycardia with unstable hemodynamics; TIMI = thrombolysis in myocardial infarction

Table 3. Angiographic characteristics of the patients

	TIMI ≤ 2 N = 49	TIMI = 3 N = 499	P	cTFC ≥ 28 N = 50	cTFC < 28 N = 489	P
Stent diameter	3.05 \pm 0.39	3.08 \pm 0.72	0.753	3.12 \pm 0.38	3.08 \pm 0.72	0.725
Stent length	28.79 \pm 8.24	28.51 \pm 8.92	0.848	29.83 \pm 7.57	28.44 \pm 8.95	0.264
Postdilatation balloon diameter	3.34 \pm 0.42	3.32 \pm 0.43	0.786	3.42 \pm 0.41	3.31 \pm 0.43	0.225
SBP mmHg	129.28 \pm 26.53	133.88 \pm 28.64	0.317	129.04 \pm 25.54	134.30 \pm 28.40	0.249
DBP mmHg	73.45 \pm 9.65	75.49 \pm 11.31	0.258	73.92 \pm 10.21	75.64 \pm 10.97	0.331
Predilatation balloon diameter	1.99 \pm 0.33	2.11 \pm 0.32	0.030	2.00 \pm 0.32	2.11 \pm 0.31	0.047
Femoral access	48 (98.0%)	489 (98.0%)	>0.99	49 (98.0%)	479 (98.0%)	>0.99
Postdilatation	23 (59.0%)	357 (78.6%)	0.005	25 (58.1%)	354 (79.6%)	0.001
Stent placement	39 (79.6%)	454 (91.0%)	0.021	43 (86.0%)	445 (91.0%)	0.305
Predilatation	40 (81.6%)	330 (66.1%)	0.027	40 (80.0%)	325 (66.5%)	0.051
Thrombosuction	15 (30.6%)	118 (23.6%)	0.278	19 (38.0%)	110 (22.5%)	0.014
Killip > 2 at presentation	6 (12.2%)	32 (6.4%)	0.137	4 (8.0%)	31 (6.3%)	0.554
LAD territory	34 (69.4%)	255 (51.1%)	0.014	25 (50.0%)	261 (53.4%)	0.649
RCA territory	8 (16.3%)	166 (33.3%)	0.015	12 (24.0%)	158 (32.3%)	0.228
PDA territory	0 (0.0%)	3 (0.6%)	>0.99	0 (0.0%)	3 (0.6%)	>0.99
Pre procedure TIMI ≥ 2	5 (10.2%)	71 (14.6%)	0.397	4 (8.0%)	72 (15.2%)	0.171
Adenosine use	21 (50.0%)	169 (43.6%)	0.424	24 (60.0%)	165 (43.1%)	0.041
Glycoprotein IIb/IIIa inhibitor use (eptifibatide)	21 (48.8%)	119 (29.9%)	0.011	28 (63.6%)	109 (28.0%)	0.001

DBP = Diastolic Blood Pressure; LAD = Left Anterior Descending; PDA = Posterior Descending Artery Pressure; RCA = Right Coronary Artery; SBP = Systolic Blood.

Table 4. Odds ratios of variables associated with the risk of final suboptimal flow (TIMI ≤ 2) after primary PCI

Variables	P value [†]	P value*	OR	95% CI
Age (per year)	0.013	0.009	1.04	1.01 – 1.07
LAD territory	0.016	0.018	3.15	1.21 – 8.11
Pain onset to first medical contact (per hour)	0.012	0.038	1.04	1.00 – 1.18

Hosmer and Lemeshow Test = 0.653; CI = Confidence Interval; OR = Odds Ratio. [†] P value from univariate regression. * P value from Multiple regression model.

Discussion

In the present study, the clinical and angiographic predictors of suboptimal coronary flow in patients with ST-elevation myocardial infarction undergoing primary PCI were investigated. Multivariate analysis revealed age, pain onset to first medical contact, and LAD involvement as independent predictors of TIMI ≤ 2 . The pathophysiology

behind TIMI ≤ 2 flow and the no-reflow phenomenon is presumed to be microvascular damage. Although the precise mechanism for this phenomenon is not well understood, many parameters such as capillary endothelial damage, regional swellings in the capillary wall and intraluminal protrusions, leukocyte intravascular plugging, and microemboli resulting from thrombolysis are hypothesized to be responsible¹⁶.

In the center where this study was conducted, the failure rate (TIMI ≤ 2) of 8.7% compares fairly well with other centers around the world^{5,6}. A study in 2014 by Levi et al.⁹ reported a PCI failure rate of 5.4% while Zhou et al.¹⁰ outlined a failure rate of 17.3%. Due to the higher in-hospital adverse events such as arrhythmias, cardiogenic shock, and death in patients with TIMI ≤ 2 and cTFC ≥ 28 , better recognition of the underlying risk factors may help in reducing the complications^{5,6,9}.

Previous studies have shown age ≥ 70 years, diabetes, hyperglycemia, large vessels with lipid pool-like image, the severity of myocardial damage (number of Q-waves), the size of the risk area, the occlusion status of the infarct-related artery, longer time to emergency room presentation, initial TIMI flow grade 0 or 1, and LVEF (Left Ventricular Ejection Fraction) $< 50\%$ as predictors of TIMI ≤ 2 ^{3,5,6,17}.

Older age was an independent predictor of TIMI ≤ 2 in this study with an OR of 1.04. It has been suggested that senility is associated with physiologic changes in vasculature¹⁸ and has been a predictor of TIMI ≤ 2 in various studies^{5,6,9}. The mechanism is not known but it may stem from atherosclerotic changes in coronary arteries seen in older individuals.

Longer time between symptom onset and first medical contact was another predictor of TIMI ≤ 2 in the present investigation. Various studies define ischemic time differently but it is universally agreed that longer times cause more myocardial necrosis which leads to increased microvasculature damage and the resulting increased PCI failure^{5,6,17}. This delay between symptom onset and medical care is also the most preventable predictor and serious measures should be taken to reduce this time. In addition, patient transfer to the primary PCI facilities with the project-247 did not affect the PCI successfulness. It appears that some of the delay from the patients' symptom onset to first medical contact is due to later activation of the emergency service by the patients. Educating the patients about the STEMI symptoms and importance of immediate medical contact can help in this regard.

The investigation identified LAD involvement

as an independent predictor of TIMI ≤ 2 with an OR of 3.15, whereas right coronary artery (RCA) involvement was associated with TIMI = 3. This finding is in accordance with previous CADILLAC studies which suggest LAD involvements are more prevalent in patients with TIMI ≤ 2 or myocardial blush grade (MBG) < 3 ^{19,20}. The CADILLAC investigators hint that the possible mechanism behind reduced epicardial reperfusion after PCI may be the result of hindered myocardial perfusion^{19,20}. Another study on this subject is the APEX-AMI trial which reported no significant difference in the infarct location or the culprit's vessel between TIMI = 3 and TIMI ≤ 2 groups. The APEX-AMI group attributes their finding to the improved catheter-based technology, the lower rate of distal embolization, and aggressive antiplatelet therapy used in their study⁵.

While initial coronary patency defined as TIMI 2/3 was not associated with developing TIMI 3 after PCI in this investigation, several studies have reported initial TIMI flow as an independent predictor of post-procedural TIMI flow and cTFC^{5,6,9,10}. The study by Karwowski et al. suggested that although total occlusion in LAD-infarcts results in higher mortality, pre-PCI TIMI is not predictive of mortality in RCA-infarcts. They hypothesized that the lower infarct size associated with RCA-MI may explain this finding²¹. Additionally, the sample size of the current study is relatively smaller when compared with the mentioned investigations. This may explain the discrepancy between this finding and other studies.

Female gender, ischemic time, pre-PCI TIMI flow grade 2/3, and history of nitrate or calcium channel blocker intake were identified as parameters associated with cTFC ≥ 28 in previous studies^{5,8}. The analysis revealed that a history of previous angiotensin-converting enzyme inhibitor or angiotensin receptor blockers use is more common in patients with final cTFC < 28 . Although prior nitrate or calcium channel blocker (CCB) intake was not related to post-procedural cTFC < 28 , studies have shown its correlation with developing better myocardial blush grade after PCI. As a

result, due to the better prognosis associated with MBG > 3, it is important to take note of the patients' prior medication use⁸.

History of statin use was not correlated with developing lower cTFC in this study which is in contradiction with findings of Celik et al.²². Celik et al. study suggested that 40 mg atorvastatin intake per day for at least 6 months reduced final cTFC in AMI patients undergoing primary PCI. The study by Lev et al. reported a lower 30-day mortality rate in STEMI patients with prior statin use who were managed by primary PCI²³. ARMYDA-ACS trial indicated that preprocedural treatment with atorvastatin resulted in an 88% risk reduction in 30-day major adverse cardiac events²⁴.

On the other hand, the study by Eshraghi et al. reported no improvements in cTFC and TIMI flow in statin users⁸. Although statins have anti-thrombotic and anti-inflammatory effects, it is possible that higher doses of them are required to improve the outcomes of primary PCI patients. This may explain the discrepancies between the present studies.

Glycoprotein IIb/IIIa inhibitor administration during primary PCI was more common among patients with final TIMI ≤ 2 or cTFC ≥ 28 . This finding may be due to the interventionist's inclination to administer the drug in patients who do not achieve TIMI = 3 by the regular procedure. For similar reasons, thrombosuction was associated with cTFC ≥ 28 . Additionally, cTFC ≥ 28 was less common in patients receiving balloon dilation after stent placement, however, it occurred more in patients who received balloon dilation before stent placement. Most probably this is the result of the interventionist's decision not to perform post dilatation in patients with a slow flow. It seems that post dilatation was only used after making sure that no-reflow phenomenon is not the case.

Limitations

This study was a retrospective investigation, so any causal relationship between the variables should be considered with caution. Furthermore, a limited sample size may hinder

the predictive capacity of the multivariate analysis, and any association between clinical characteristics of the patients and the outcomes should be interpreted carefully.

Conclusion

Although TIMI ≤ 2 did not frequently occur in this study, it was associated with adverse in-hospital outcomes. Older age, LAD involvement, and longer ischemia time were identified as independent predictors of TIMI ≤ 2 , which may assist physicians in managing high-risk patients. Prioritizing patient education and faster emergency unit activation should also be considered to reduce ischemia time.

Conflict of Interest

None declared.

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