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ADULT CARDIOLOGY

# Comparison of Early In-Hospital Outcomes between Minimal Manipulation and Maximal Fielding during Primary PCI and its Impact on TIMI Flow

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## ABSTRACT

***Objective***: To determine the association between minimal and maximal manipulation and slow/no flow during Primary Percutaneous Coronary Intervention (PPCI) and its associated outcomes.
***Study Design***: Analytical, Cross-Sectional study.
***Place and Duration of Study***: Armed Forces Institute of Cardiology/National Institute of Heart Diseases, from Mar to May 2023
***Methodology***: Total 189 patients were enrolled through non-probability consecutive sampling in the present study. ST-Elevation Myocardial Infarction (STEMI) patients irrespective of age and gender were included. Patients were grouped into minimal and maximal manipulation groups and subsequently PPCI was proceeded. During procedure, TIMI-flow grading was assessed and patients were further grouped into no flow (TIMI-0 or 1), slow flow (TIMI-2) and normal flow (TIMI-3) group. Outcome variables including TIMI-flow, arrhythmia, Heart Failure (HF) and in-hospital mortality were observed. Chi-square test and student t-test were applied and $p$-value <0.05 was taken as significant.
***Results***: The mean age of the study sample (n=189) was 60.2±11.6 years. 153(80.9%) participants were males and 36(19.0%) were females. 132(69.8%) patients had normal flow,34(17.9%) had slow flow and 23(12.2%) had no flow. 95(50.3%) patients had minimal manipulations and 94(49.7%) had maximal manipulation. There was insignificant association of type of manipulation with HF, type of arrhythmias and type of blood flow ($p$>0.05). Frequency of mortality was higher in maximal manipulation group 7(7.4%). In relation to reflow; diabetes, multiple pre-stenting balloon inflation and multiple post-stenting balloon inflation, and type of arrhythmia were significantly associated ($p$<0.05). However, insignificant association was found with mortality ($p$=0.44) and higher mortality was notable in no-reflow group 2(8.7%).
***Conclusion***: There was no role of minimal and maximal manipulation in developing slow flow/no flow during primary PCI.

**Keywords**: Coronary artery disease, Maximal fielding, Minimal manipulation, No-flow, Primary percutaneous coronary intervention, Slow-flow, TIMI flow.

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## INTRODUCTION

Coronary Artery Disease (CAD) prevalence has increased in emerging nations, which has burdened the patients with ST-Elevation Myocardial Infarction (STEMI) at the emergency departments of healthcare. STEMI manifests as an acute coronary syndrome with clinical symptoms and ST-segment elevation on the Electrocardiogram (ECG). CVD cases increased to two folds from 271 Million to 523 Million from 1990 to 2019, while Cardiovascular Disease (CVD) fatalities grew gradually from 12.1 Million to 18.6 Million during 1990-2019.[1]

Primary Percutaneous Coronary Intervention (PPCI) is basically the percutaneous catheterization during 12 hours of STEMI indications and without prior fibrinolysis.[2] Although in the case of STEMI, following a prior attempt at fibrinolysis that failed, PCI is regarded as percutaneous catheter intervention as rescue PCI.[3] It is considered to be the treatment of choice for STEMI but no flow or slow flow can be its significant consequence, affecting both angiographic and clinical outcomes,[4] while TIMI grade 0 or 1 by angiographic coronary perfusion is the standard interpretation for no flow. Slow flow is characterized by angiographic coronary perfusion of TIMI grade 2.[5] In spite of the fact that there is no evidence of angiographic blockage, spasm, or dissection of the epicardial arteries, this situation is known as "slow/no flow". It is extremely complicated and arises during the PCI, when coronary arteries received inadequate circulation.[6,7]

Studies have examined a variety of PPCI procedure parameters to find deteriorating factors that would ultimately affect patients' short-and long-term outcomes.[6] Minimal and maximal manipulations are one of them. Minimal manipulation can be defined as two or less than two pre-stenting/post stenting balloon inflations and maximal manipulation is more than two pre-stenting/post stenting

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balloon inflations.[4,5] The element that can be identified as the most commonly amongst these, is thrombus load.[8] Micro vascular obstruction, which is caused by thrombus micro-embolization, ischemia, perivascular-edema, and reperfusion itself, is the main reason of slow flow or no flow occurrence.[9] In addition, the probability of the no flow/slow flow phenomenon increased because of the pre dilatation of balloon inflations, longer stent inflations, and various post-stenting balloon inflations.[10]

Limited literature was found on this topic in our population so the purpose of this study was to determine whether or not avoiding these factors lessened the incidence of slow flow/no flow during primary PCI and its impact on patients outcomes. The aim of current study was to determine the association between minimal and maximal manipulation and slow/no-flow during PPCI and its associated in-hospital outcomes.

## METHODOLOGY

This was an Analytical, Cross-sectional study conducted at Armed Forces Institute of Cardiology/ National Institute of Heart Diseases, Rawalpindi, Pakistan during three months (from March to May 2023). Data was collected through non probability consecutive sampling technique after seeking approval from Institutional Ethical Review Board (IERB) with reference to letter no. 9/2/ R&D/2023/253.

A sample size of 184 patients was calculated by using WHO sample size calculator, with reference to the prevalence 13.9% of slow-flow/no-flow during PPCI[11] and keeping confidence level of 95% and margin of error of 5%. However, data was gathered from 189 patients.

**Inclusion Criteria**: All STEMI patients irrespective of age and gender who underwent primary PCI were included in this study.

**Exclusion Criteria**: Patients who had routine PCI, rescue PCI, facilitated PCI and Plain Old Balloon Angioplasty (POBA) patients were excluded from the study.

TIMI flow was categorized into TIMI-0 or 1 (no-reflow), TIMI-2 (slow flow) and TIMI-3 (normal flow).[9] Minimal manipulation was defined as two or less than two pre-stenting/post stenting balloon inflations and maximal manipulation as more than two pre-stenting/ post stenting balloon inflations.[4,5]

A total of 189 patients fulfilling study inclusion criteria were enrolled. Written informed consent was obtained from all patients. The information regarding demographic characteristics and baseline characteristics of the enrolled patients were recorded on pre-designed proforma. According to standard ACS treatment protocol, patients were given 300mg disprin, 300mg clopidogrel and 10000IU Heparin. Patients were grouped into minimal manipulation and maximal manipulation groups by the Senior Cardiologist according to the pre and post-stenting balloon inflation and subsequently primary PCI was proceeded. During procedure, TIMI flow grading was assessed and patients were further grouped into slow flow/no flow group or normal flow group. Procedure was performed by experienced Interventional Cardiologist who was aware of the complications and managed the procedural complications including slow flow/no flow. Those patients who experienced slow flow/no flow were treated with standard medications including Adenosine, Adrenaline and Tirofiban. Outcomes in terms of TIMI flow were noted. Moreover, during hospital stay, further complications like arrhythmia, heart failure and death were assessed and noted down. Data collected during the course of research was kept confidential.

Data analysis was performed with IBM Statistical Package for Social Sciences (SPSS) version 21:00. Quantitative variables were expressed as mean and standard deviation and qualitative variables as frequency and percentage. Chi-square test and Fisher Exact test were used to find association between manipulations and TIMI flow. All results were considered as statistically significant with *p*-value $\leq 0.05$.

## RESULTS

A total of One hundred and eighty-nine (n=189) patients were included in this study. The mean age of the study sample was 60.2±11.6 years. 153 (80.9%) were male and 36(19.1%) were female patients. Patients were divided into two groups on the basis of manipulation; 95(50.3%) had minimal manipulations and 94(49.7%) had maximal manipulation (Figure-1).

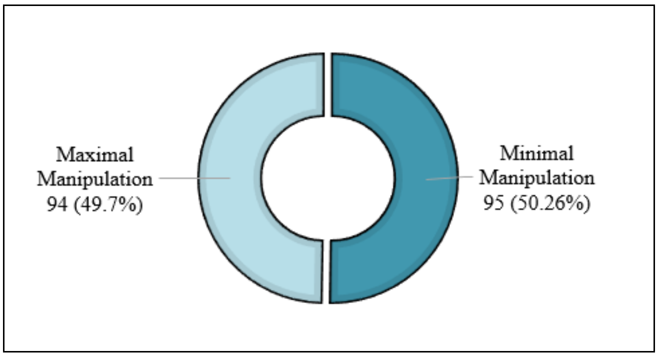


**Figure-1: Frequency Distribution of Manipulations (n=189)**

Clinical characteristics showed that 9(4.8%) patients had LVEF ≤40%, 91(48.1%) patients were hypertensive, 64(33.9%) patients were diabetic, 5(2.6%) had hyperlipidemia.

**Table-I: Demographics and Procedural Details of the Study Participants (n=189)**

| Study Variables | | Frequency(%) |
|---|---|---|
| Gender | Male | 153(80.9) |
| | Female | 36(19.0) |
| **Age (years) (Mean±SD)** | | 60.2±11.6 |
| Comorbids | Hypertensive | 91(48.1) |
| | Diabetic | 64(33.9) |
| | Hyperlipidemia | 5(2.6) |
| | Smoker | 43(22.8) |
| | Family history of Coronary Artery Disease | 28 (14.8) |
| **Left Ventricular Ejection Fraction ≤40%** | | 9(4.8) |
| Technique | Minimal Manipulation (balloon inflations ≤2) | 95(50.3) |
| | Maximal Manipulation (balloon inflations >2) | 94(49.7) |
| Procedural Details | Multiple pre stenting balloon inflation | 95(50.3) |
| | Multiple post stenting balloon inflation | 61 (32.3) |
| | Prolong stent inflation | 10(5.3) |
| In-hospital Outcomes | Arrhythmia | 44(23.3) |
| | Heart failure | 25(13.2) |
| | Mortality | 8(4.2) |

43(22.8%) were smokers, 28(14.8%) had family history of CAD. 95(50.3%) had multiple pre-stenting balloon inflation, 61(32.3%) had multiple post stenting balloon inflation, 10(5.3%) had prolonged stent inflation, 44(23.3%) had arrhythmias, 25(13.2%) had heart failure and 8(4.2%) patients had mortality (Table-I).

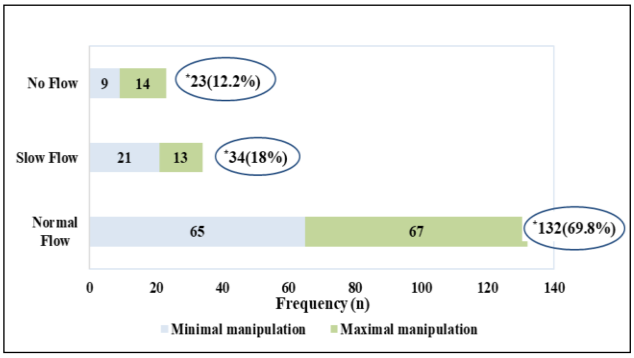


**Figure-2: TIMI Flow Relevant to Minimal and Maximal Manipulations (n=189)**

**Total Count with Percentage*

Comparison of type of manipulation with demographic, procedural and outcome parameters was done and there was significant association found with gender (*p*=0.04), type of coronary vessel (*p*=0.001), pre and post stenting balloon inflation (*p*<0.001) and with mortality 8(4.2%) (*p*=0.03). Frequency of mortality was higher in maximal manipulation group 7(7.4%). There was insignificant association of manipulation with heart failure, type of arrhythmias and TIMI flow (*p*>0.05). Majority of maximal manipulation group patients post-operatively developed arrhythmias in comparison to minimal manipulation group (25.5% vs 21.1%

**Table-II: Comparison of Type of Manipulations with Baseline Characteristics and Outcomes (n=189)**

| Study Variables | | | Type of Manipulations: Minimal (n=95) Frequency(%) | Type of Manipulations: Maximal (n=94) Frequency(%) | *p*-value |
|---|---|---|---|---|---|
| **Age (years) (Mean±SD)** | | | 59.3±12.0 | 61.0±11.2 | 0.33 |
| Gender | Male | | 71(74.7) | 82(87.2) | 0.04 |
| | Female | | 24(25.3) | 12(12.8) | |
| Comorbids | Hypertension | | 40(42.1) | 51(54.3) | 0.12 |
| | Diabetes | | 32(33.7) | 32(34.0) | 1.00 |
| | Hyperlipidemia | | 2(2.1) | 3(3.2) | 0.99 |
| | Smoker | | 18(18.9) | 25(26.6) | 0.28 |
| | Family history of CAD* | | 15(15.8) | 13(13.8) | 0.86 |
| **Left Ventricular Ejection Fraction ≤40%** | | | 3(3.2) | 6(6.4) | 0.48 |
| Target Vessels | LAD* | | 61(64.2) | 36(38.3) | 0.001 |
| | RCA* | | 21(22.1) | 43(45.7) | |
| | Ramus Intermedius | | 2(2.1) | 2(2.1) | |
| | LCX* | | 11(45.8) | 13(54.2) | |
| Procedural Details | Multiple pre-stenting balloon inflation | | 24(25.3) | 71(75.5) | <0.001 |
| | Multiple post-stenting balloon inflation | | 15(15.8) | 46(48.9) | <0.001 |
| | Prolong stent inflation | | 6(6.3) | 4(4.3) | 0.75 |
| In-Hospital Outcomes | Heart failure | | 15(15.8) | 10(10.6) | 0.40 |
| | Type of Arrhythmias | Ventricular tachycardia | 15(15.8) | 13(13.8) | 0.45 |
| | | Third degree AV- block | 4(4.2) | 6(6.4) | |
| | | Bradycardia | -- | 3(3.2) | |
| | | Complete heart block | 1(1.1) | 2(2.1) | |
| | TIMI Flow | Normal flow (TIMI-III) | 65(68.4) | 67(71.3) | 0.23 |
| | | Slow flow (TIMI-II) | 21(22.1) | 13(13.8) | |
| | | No flow (TIMI-I) | 9(9.5) | 14(14.9) | |
| | Mortality | | 1(1.1) | 7(7.4) | 0.03 |

*CAD=Coronary Artery Disease; PPCI= Primary Percutaneous Coronary Intervention; LAD=Left Anterior Descending Artery; RCA= Right Coronary Artery; LCX= Left Circumflex Artery* respectively) as shown in Table-II.

Figure-2 showed study participants grouped into three categories on the basis of TIMI flow i.e. 132 (69.8%) normal flow, 34(18%) slow flow and 23 (12.2%) no flow with reference to type of manipulations. Table-III showed comparison between types of TIMI flow, comorbids, procedural and outcome variables and significant findings were noticed with diabetes ($p$=0.04), multiple pre-stenting balloon inflation, multiple post-stenting balloon inflation, arrhythmias and type of arrhythmias ($p$<0.01). However, insignificant association was found with mortality ($p$=0.44). Higher mortality rate was noted in no-reflow group 2(8.7%).

**Table-III: Association of baseline characteristics and outcomes with TIMI flow (n=189)**

| Study Variables | | | Type of Flow | | | *p*-value |
|---|---|---|---|---|---|---|
| | | | Normal Flow (TIMI-III) (n=132) Frequency(%) | Slow Flow (TIMI-II) (n=34) Frequency(%) | No Flow (TIMI-I) (n=23) Frequency(%) | |
| Age (years) (Mean+SD) | | | 59.10±12.00 | 61.06±10.47 | 65.09±8.57 | 0.06 |
| Gender | Male | | 111 (84.1) | 25 (73.5) | 17 (73.9) | 0.24 |
| | Female | | 21 (15.9) | 9 (26.5) | 6 (26.1) | |
| Left Ventricular Ejection Fraction ≤ 40% | | | 4 (3.0) | 2 (5.9) | 3 (13.0) | 0.10 |
| Hypertension | | | 58 (43.9) | 17 (50.0) | 16 (69.6) | 0.07 |
| Diabetes | | | 41 (31.1) | 10 (29.4) | 13 (56.5) | 0.04 |
| Hyperlipidemia | | | 3 (2.3) | 1 (2.9) | 1 (4.3) | 0.62 |
| Smoker | | | 35 (26.5) | 4 (11.8) | 4 (17.4) | 0.15 |
| Family history of CAD | | | 19 (14.4) | 6 (17.6) | 3 (13) | 0.90 |
| Target vessels | LAD | | 72 (54.5) | 16 (47.1) | 9 (39.1) | 0.17 |
| | RCA | | 39 (29.5) | 12 (35.3) | 13 (56.5) | |
| | Ramus Intermedius | | 4 (3.0) | -- | -- | |
| | LCX | | 17 (12.9) | 6 (17.6) | 1 (4.3) | |
| Types of Manipulation | Minimal Manipulation (balloon inflations<2) | | 65 (49.2) | 21 (61.8) | 9 (39.1) | 0.23 |
| | Maximal Manipulation (balloon inflations>2) | | 67 (50.8) | 13 (38.2) | 14 (60.9) | |
| Procedural Details | Multiple pre stenting balloon inflation | | 58 (43.9) | 18 (52.9) | 19(82.6) | 0.002 |
| | Multiple post stenting balloon inflation | | 34 (25.8) | 11 (32.4) | 16 (69.6) | <0.001 |
| | Prolong stent inflation | | 4 (3.0) | 3 (8.8) | 3 (13.0) | 0.05 |
| In-hospital Outcomes | Heart failure | | 13 (9.8) | 7 (20.6) | 5 (21.7) | 0.09 |
| | Type of Arrhythmias | Ventricular tachycardia | 14 (10.6) | 6 (17.6) | 8 (34.8) | <0.001 |
| | | Third degree AV-block | -- | 10 (29.4) | -- | |
| | | Bradycardia | 3 (2.3) | -- | -- | |
| | | Complete heart block | 3 (2.3) | -- | -- | |
| | Mortality | | 4 (3) | 2 (5.9) | 2 (8.7) | 0.44 |

*CAD=Coronary Artery Disease; PPCI=normal flow Primary Percutaneous Coronary Intervention; LAD=Left Anterior Descending Artery; RCA=Right Coronary Artery; LCX= Left Circumflex Artery; AV= Atrio-ventricular*

## DISCUSSION

The underlying reason of the no-reflow phenomena in individuals with STEMI following primary PCI is complicated. Endothelial dysfunction, micro vascular dysfunction, spasm, embolization, and reperfusion injury are some of the potential underlying causes of no-reflow phenomena.[12] The reported rate of the slow and no-reflow phenomenon following primary PCI for STEMI patients was 34(18.0%) and 23(12.2%) respectively in the current study. Out of 189 patients, the mean age was 60.2±11.6 years. In relation to reflow, significant findings were observed with diabetes ($p$=0.04), multiple pre-stenting balloon inflation ($p$=0.002), multiple post-stenting balloon inflation ($p$<0.001), arrhythmias ($p$<0.001) and type of arrhythmia ($p$<0.001). Differences in the no-reflow between several studies might be due to diverse sample sizes and different sample selection criteria of research populations. An incidence rate of 31.3% in no-reflow was reported by Alidoosti *et al.*,[12] which is similar to the study done by Sahin *et al.*, who reported of 32.8% incidence.[13] In contrast, other researchers reported incidence rates of 12.0%, and 14.3% documented in literature,[14,15] which is similar to our findings (12.2%).

According to a research by Sahin *et al.*,[13] myocardial no-reflow was independently correlated with LAD involvement. Infarction in the proximal LAD was linked to a 3.5-fold probability of angiographic no-reflow stated by Margo *et al.*,[14] while, Iwakura *et al.*, noted this connection between the culprit lesion in the proximal LAD and myocardial no-reflow.[16] In the univariate analysis by Alidoosti *et al.*, patients with LAD involvement had a higher rate of experiencing the no-reflow phenomena than patients with involvement of the left circumflex artery or the right coronary artery. However the findings of their multivariate analysis didn't depict that the LAD as a separate indicator for the no-reflow phenomena.[12] However, current study's findings revealed that in LAD, 16(16.5%) patients had slow flow and 9(9.3%) had no reflow, while with other vessels including RCA, LCX and Ramus Intermedius (RI) very few patients were observed in slow/no reflow group but these findings were not significant ($p$=0.17).

Alhamaydeh *et al.,* reported significant association between age and slow/no-reflow phenomenon that contradicts our study ($p$>0.05). Elderly patients with MI have an increased risk of mortality and had a poor success rate with PPCI.[17] Elderly patients are more likely to have diffused coronary atherosclerosis, significant vascular calcification, distal embolization, and microcirculation dysfunction. These pathological alterations are linked to old age, that could be a factor in the no-reflow phenomena caused by primary PCI's distal embolisation.[13] Similar to our study's findings, El Hefnawi *et al*., showed no statistical difference among the reflow groups and age ($p$>0.05) and came to the conclusion that no reflow (independent predictor of poor clinical outcomes and mortality) is caused by microvascular obstruction. There is limited data available which showed how ageing affects no reflow.[6]

When compared with echocardiography and cardiac MRI (CMRI), the no-reflow rate of less than 1% was reported in patients who underwent cardiac angiography by a recent study. Around 2.91% of the study population had no flow, while 25.7% had slow flow. Slow flow and no flow linked with worsened clinical outcomes. In NSTEMI, no flow is a particularly strong indicator of poor coronary prognosis.[18] It was contrary to the findings of former study, showed 5% slow flow and 25% no-reflow. No reflow phenomenon after PPCI was linked with higher mortality i.e. doubled the normal flow. Age and gender did not significantly correlate with slow or no flow, although arrhythmias, low EF, MI and history of HF were all associated with the development of slow or no blood flow. Investigators concluded that slow to no reflow with heart failure was most likely linked with inflammation, endothelial dysfunction and thrombus-burden.[19] Zhou *et al*.,[20] conducted a study on 312 patients and observed no statistical difference between patient reflow and in-hospital outcomes ($p$>0.05). Although Fajar *et al*.,[21] showed a statistical significant difference between the study groups with outcomes after PPCI and they observed a significant relation with arrhythmias ($p$<0.05). Similar findings were observed in our study with age ($p$>0.05), diabetes ($p$=0.04) and with arrhythmias ($p$<0.001).

Elakabawi *et al*., reported that elder patient population (>60 years) and patients who had blood pressure at lower side usually had increased suboptimal flow after PPCI. This study also claimed that factors including LVEF <50%, higher heart rate and blood pressure of <90mmHg leads to no reflow and increased mortality rate.[22]

## LIMITATIONS OF STUDY

It was a single centered study with a smaller sample size. Multi-centered studies with larger sample size and long term follow-up studies are required. Secondly, only one parameter (cardiac angiography) was used to determine reflow phenomenon, while echocardiography and MRI are also used by many studies and MRI is considered to be the gold standard for the evaluation of micro vascular obstruction.

## CONCLUSION

There is no role of minimal and maximal manipulation in developing slow flow/no flow during primary PCI. Although slow/no flow had significant findings with age and post PPCI outcomes including arrhythmias. No significant findings of manipulation with reflow and patients' outcomes was observed.

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**Conflict of Interest:** None.

**Authors' Contribution**

Following authors have made substantial contributions to the manuscript:

IK, ZAKK, & MNK: Study Design, Manuscript Writing, Acquisition of Data, Critical Review, Study Design, approval of the final version to be published.

MH, & SKAJ: Editing, Data Analysis, Data Management, approval of the final version to be published.

NAS, SKS: Basic Concept, Critical Review, Intellectual Contribution, approval of the final version to be published.

Authors agree to be accountable for all aspects of the work in ensuring that questions related to the accuracy or integrity of any part of the work are appropriately investigated and resolved.

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