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Original Article

Extended Balloon Inflation Technique for Primary Percutaneous Coronary Intervention for ST-Segment Elevation Myocardial Infarction during Stent Deployment

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ABSTRACT

Background: Primary percutaneous coronary intervention (PPCI) is the preferred method for treating ST-segment elevation myocardial infarction (STEMI), but the no-reflow phenomenon remains a significant challenge. This study investigates the efficacy of prolonged balloon inflation during stent deployment to reduce the incidence of no-reflow.

Objective: To assess whether extending the duration of balloon inflation during stent deployment in PPCI reduces the incidence of the no-reflow phenomenon compared to the conventional rapid inflation and deflation strategy.

Methods: This randomized controlled trial enrolled 122 patients at the National Institute of Cardiovascular Diseases, Pakistan, from February 2023 to January 2024. Patients were randomly assigned to either prolonged balloon inflation (PBSG) or conventional deployment (CDSG).

Results: The mean age in the PBSG was 59.83±10.10 years, and in the CDSG, it was 60.39±10.16 years. Male participants comprised 51.6%. The PBSG showed significantly lower immediate TIMI flow grades less than 3 (4.9% vs. 26.2%, P = 0.00), no-reflow incidence (0% vs. 26.2%, P = 0.00), corrected TIMI frame counts (36.96±4.25 vs. 46.13±6.82, P = 0.00), and higher ST-segment resolution ≥50% (77.0% vs. 57.4%, P = 0.02). Additionally, 59.0% in the PBSG achieved an MBG of 3 compared to 16.4% in the CDSG (P = 0.00).

Conclusion: Prolonged balloon inflation during stent deployment in PPCI significantly reduces the no-reflow phenomenon and improves myocardial perfusion in patients with STEMI.

Keywords: Balloon inflation, Myocardial infarction, No-reflow phenomenon, Percutaneous coronary intervention, Prolonged inflation strategy, STEMI, TIMI flow grade.

INTRODUCTION

Primary percutaneous coronary intervention (PPCI) has long been established as the standard and preferred method of reperfusion therapy for patients presenting with ST-segment elevation myocardial infarction (STEMI), a type of heart attack characterized by a distinctive pattern on the electrocardiogram. Compared to alternative reperfusion strategies such as fibrinolytic therapy, PPCI is associated with a higher rate of successful reperfusion, improved long-term outcomes, and a reduced risk of major bleeding complications (1, 2). The principal aim of reperfusion therapy in STEMI is to swiftly restore blood flow to the ischemic myocardium, thereby minimizing the size of the infarct and enhancing the overall prognosis.

However, a significant challenge during PPCI is the occurrence of the no-reflow phenomenon, which can diminish the beneficial effects of reperfusion therapy and lead to suboptimal clinical and functional outcomes. The incidence of the no-reflow phenomenon during primary PCI in STEMI patients is notably variable, with reported rates ranging from 5% to 50%. This variability can be attributed to a range of factors, including patient characteristics, the severity of coronary artery disease, the presence of thrombus, and specific procedural variables (3-5).

The no-reflow phenomenon results from a complex interplay of factors collectively known as microvascular obstruction (MVO). MVO is caused by ischemia-induced damage, reperfusion, endothelial cell swelling, thrombus dislodgment leading to embolization, and

Journal of Health and Rehabilitation Research 2791-156X JHRR

the release of atherosclerotic plaque fragments into the microvasculature (6). Achieving optimal stent deployment is crucial for improving outcomes in PPCI for STEMI. Traditionally, the procedure involves rapid balloon deflation, which entails a swift transition from high inflation pressure to negative pressure during coronary stent deployment. However, rapid deflation may induce significant siphonic effects and abrupt changes in coronary hemodynamics, potentially exacerbating the risk of MVO (7).

This study investigates whether extending the duration of balloon inflation during stent deployment in PPCI for STEMI offers advantages over the conventional rapid inflation and deflation technique. An extended inflation period may enhance stent apposition, improve vessel dilation, and promote better coronary blood flow. The objective of this research is to determine whether a prolonged balloon inflation duration can reduce the incidence of the no-reflow phenomenon, thereby potentially improving procedural success and patient outcomes in primary percutaneous coronary interventions.

MATERIAL AND METHODS

This randomized controlled trial was conducted over a 12-month period from February 2023 to January 2024 at the National Institute of Cardiovascular Diseases (NICVD) in Pakistan. After obtaining approval from the ethical committee of NICVD, the study enrolled 122 patients, both male and female, who met the inclusion criteria. These criteria stipulated that participants must have been diagnosed with ST-segment elevation myocardial infarction (STEMI) and referred for primary percutaneous coronary intervention (PPCI) within 12 hours after symptom onset. Eligible patients displayed ST-segment elevation of at least 1 mm in two or more contiguous leads, a presumed new left bundle branch block, or a confirmed true posterior myocardial infarction. The age range of participants was 18 to 75 years, and they possessed coronary artery lesions suitable for stent placement as determined by angiographic assessment during the primary PCI.

The exclusion criteria were stringent to ensure patient safety and data integrity. Excluded were patients with contraindications to primary PCI or coronary stenting, known allergies to contrast media, antiplatelet agents, or other medications essential for the procedure, and severe hemodynamic instability not amenable to PCI, such as cardiogenic shock. Also excluded were patients who had an intra-aortic balloon pump implant or were on extracorporeal membrane oxygenation, those with a history of thrombolysis, previous myocardial infarction, severe valvular disease, chronic obstructive pulmonary disease, pregnancy, previous coronary artery bypass grafting, or renal dysfunction with a glomerular filtration rate below 30 mL/min/1.73 m^2.

Patients fulfilling the inclusion criteria were divided into two groups through block randomization. Group A underwent prolonged balloon inflation during stent deployment, while Group B underwent a conventional deployment strategy. In Group A, the balloon inflation was maintained at low pressure for over 30 seconds after achieving the target balloon inflation pressure. In contrast, Group B's balloon inflation duration was under 10 seconds, with the operators granted discretion to adjust dilation, expansion pressure, and post-dilation procedures as needed. Direct stenting was employed when feasible; otherwise, predilation was performed with a single low-pressure inflation. Only the infarct-related artery was treated in all patients, using drug-eluting stents. Stent and balloon diameters were chosen based on visual estimation aiming for a balloon/vessel ratio of 1:1 for both groups.

If the no-reflow phenomenon persisted post-stent placement, therapeutic interventions such as nitroprusside and/or diltiazem were administered. For data analysis, SPSS Version 25 was utilized. The procedural preparations included administering 300 mg of oral aspirin and 600 mg of clopidogrel (or 180 mg of ticagrelor) immediately upon confirmation of STEMI, with additional anticoagulants, glycoprotein IIb/IIIa inhibitors, and thrombus aspiration left to the discretion of the treating physician. Patients were promptly transferred to the lab for cardiac catheterization following these protocols.

RESULTS

The study enrolled 122 patients, with a mean age of 60.11 ± 10.09 years. The analysis revealed minor differences in age between the two study groups; patients in the Prolonged Balloon Inflation Strategy Group (PBSG) had a mean age of 59.83 ± 10.10 years, whereas those in the Conventional Deployment Strategy Group (CDSG) averaged 60.39 ± 10.16 years. Gender distribution across the study was balanced, with 63 (51.6%) males and 59 (48.4%) females participating.

Baseline characteristics and procedural data, including the type of drug-eluting stent used, were comparable between the two groups, as detailed in the respective tables. The primary outcomes of the study, as outlined, significantly favored the PBSG over the CDSG. Notably, a lower proportion of patients in the PBSG exhibited a TIMI flow grade less than 3 immediately following stent deployment (3 patients, 4.9%), compared to the CDSG (16 patients, 26.2%; P = 0.00). Similarly, the incidence of the no-reflow phenomenon was non-existent in the PBSG (0%) and significantly present in the CDSG (16 patients, 26.2%; P = 0.00).

Additional findings included a significantly lower corrected TIMI frame count in the PBSG (36.96 ± 4.25) compared to the CDSG (46.13 ± 6.82; P = 0.00). The proportion of patients achieving a myocardial blush grade (MBG) of 3 was also markedly higher in the

PBSG (36 patients, 59.0%) than in the CDSG (10 patients, 16.4%; P = 0.00). Moreover, a greater number of PBSG patients demonstrated ST-segment resolution of 50% or more (47 patients, 77.0% vs. 35 patients, 57.4%; P = 0.02).

Secondary outcomes such as procedure time, radiation exposure, and contrast volume did not show significant differences between the groups. Likewise, the frequency of bleeding events and other clinical endpoints remained similar. Cardiac magnetic resonance (CMR) data further supported the superiority of the PBSG, indicating a potential reduction in the occurrence of microvascular obstruction (MVO). In the PBSG, MVO was observed in 3 out of 30 cases (10.0%), significantly lower than the 11 out of 20 cases (55.0%) observed in the CDSG (P = 0.001). The Myocardial Salvage Index was also higher in the PBSG (60.16 ± 4.13) compared to the CDSG (54.90 ± 3.38), reinforcing the clinical benefits of prolonged balloon inflation during stent deployment.

Table 1: Distribution of infants on the basis of gender (n=122)

Gender	Frequency	Percentage
Male	63	51.6
Female	59	48.4
Total	122	100.0

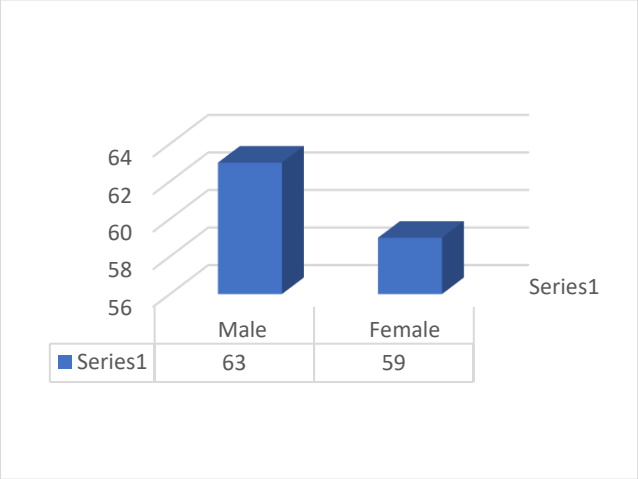

Figure 1: graph showing gender distribution

Table 2: Mean age of all enrolled infants (n=122)

Variables	Mean±SD
Age (years)	60.11±10.09

Table 3: Baseline characteristics of the patients of both groups.

	Groups		P-value
	PBSG	CDSG	
Age (years)	59.83±10.10	60.39±10.16	0.76
History			
Hypertension	25(41.0%)	19(31.1%)	0.25
Current smoking	29(47.5%)	21(34.4%)	0.14
Diabetes mellitus	13(21.3%)	7(11.5%)	0.14
Previous stroke	5(8.2%)	4(6.6%)	0.72
Fibrinolysis before randomization	1(1.6%)	2(3.3%)	0.55
Door to balloon time (min)	66.45±5.03	66.29±4.99	0.85
Pain onset to reperfusion (hour)	7.08±0.84	7.18±0.84	0.52
Target coronary artery			
Left coronary artery	26(42.6%)	24(39.3%)	

Left circumflex	5(8.2%)	9(14.8%)	
Right coronary artery	30(49.2%)	28(45.9%)	0.52
Multivessel coronary disease	37(60.7%)	39(63.9%)	0.70
Killip class			
1	52(85.2%)	54(88.5%)	
2	5(8.2%)	6(9.8%)	
3	3(4.9%)	1(1.6%)	0.54
4	1(1.6%)	0.0(0.0%)	
Systolic blood pressure in lab (mmHg)	129.4±129.4	121.8±121.8	0.00
Diastolic blood pressure in lab (mmHg)	80.14±4.94	76.88±6.05	0.51
Heart rate in lab (bpm)	79.62±6.24	85.55±7.23	0.00
Thrombus burden			
0	3(4.9%)	7(11.5%)	
1	8(13.1%)	12(19.7%)	
2	3(4.9%)	7(11.5%)	
3	3(4.9%)	8(13.1%)	0.05
4	7(11.5%)	3(4.9%)	
5	37(60.7%)	24(39.3%)	

Table 4: Baseline characteristics of the patients of both groups in term of procedural data and Type of drug-eluting stent.

	Groups		P-value
	PBSG	CDSG	
Characteristics of the procedural data			
Direct stenting	30(49.2%)	19(31.1%)	0.04
Thrombectomy	18(31.6%)	11(18.0%)	0.08
Predilation balloon diameter-mm	2.40±0.12	2.40±0.12	0.83
No. of stents	1.29±0.45	1.36±0.51	0.46
Type of drug-eluting stent			
PROMUS Element	54(88.5%)	58(95.1%)	0.18
GuReater	7(11.5%)	3(4.9%)	
Total stent length (mm)	33.03±1.78	30.25±3.00	0.00
Stent diameter (mm)	3.18±0.69	3.11±0.73	0.62
Inflation time(seconds)	36.27±4.3	16.91±30.11	0.00
Inflation pressure (atm)	12.75±1.4	12.80±1.4	0.84
Post dilation	8(13.1%)	12(19.7%)	0.32

Table 5: The primary outcomes

	Groups		P-value
	PBSG	CDSG	
The incidence of no-reflow	0(0.0%)	16(26.2%)	0.00
Pre-PCI TIMI flow			
TIMI 0–1	47(77.0%)	37(60.7%)	
TIMI 2	5(8.2%)	7(11.5%)	0.13
TIMI 3	9(14.8%)	17(27.9%)	
Immediate after PCI TIMI flow			
TIMI 0–1	0(0.0%)	3(4.9%)	

	Groups		P-value
	PBSG	CDSG	
TIMI 2	3(4.9%)	16(26.2%)	0.00
TIMI 3	58(95.1%)	42(68.9%)	
Myocardial blush grade after PCI			
0	0(0.0%)	0(0.0%)	
1	0(0.0%)	10(16.4%)	
2	25(41.0%)	41(67.2%)	0.00
3	36(59.0%)	10(16.4%)	
ST-segment resolution ≥ 50%	47(77.0%)	35(57.4%)	0.02
Corrected TIMI frame count	36.96±4.25	46.13±6.82	0.00

Table 6: The 2ndry outcomes

	Groups		P-value
	PBSG	CDSG	
30-day clinical outcomes	5(8.2%)	8(13.1%)	0.37
Target vessel revascularization	2(3.3%)	4(6.6%)	0.40
Recurrent myocardial infarction	2(3.3%)	3(4.9%)	0.64
Cardiovascular mortality	1(1.6%)	1(1.6%)	1.00
One-year clinical outcomes	6(9.8%)	9(14.8%)	0.40
Target vessel revascularization	2(3.3%)	3(4.9%)	0.64
Recurrent myocardial infarction	3(4.9%)	4(6.6%)	0.69
Cardiovascular mortality	1(1.6%)	2(3.3%)	0.55
Others			
Distal embolization of culprit vessels	1(1.6%)	1(1.6%)	1.0
Procedure time (min)	39.65±7.08	41.16±8.29	0.28
Radiation exposure time (min)	1206.7±755.7	934.59±453.8	0.13
Bleeding events	0.0(0.0%)	1(1.6%)	0.31

Table 6: Cardiac magnetic resonance (CMR) data

	Groups		P-value
	PBSG	CDSG	
Infarct size (%LVM)	13.16±1.24	13.70±1.29	0.02
Presence of MVO	3/30(10.0%)	11/20(55.0%)	0.001
Presence of IMH	8/8(26.7%)	8/20(40.0%)	0.32
Myocardial salvage index	60.16±4.13	54.90±3.38	0.00
LVEF	48.33±5.39	42.65±3.82	0.00

DISCUSSION

The primary objective of the current study was to evaluate the efficacy of an extended balloon inflation technique compared to the conventional rapid inflation and deflation approach during stent deployment in primary percutaneous coronary intervention (PPCI) for ST-segment elevation myocardial infarction (STEMI). The results demonstrated a markedly lower incidence of the no-reflow phenomenon in the Prolonged Balloon Inflation Strategy Group (PBSG) compared to the Conventional Deployment Strategy Group (CDSG), as evidenced by significantly fewer patients in the PBSG exhibiting an immediate TIMI flow grade less than 3 (4.9% vs 26.2%;

P = 0.00). Such findings align with previous studies indicating that extended balloon inflation can significantly reduce the occurrence of no-reflow, thereby potentially enhancing myocardial perfusion (8).

Moreover, the study revealed that patients in the PBSG had improved outcomes in terms of corrected TIMI frame count, ST-segment resolution, and Myocardial Blush Grade (MBG), suggesting better myocardial perfusion and less microvascular obstruction. These outcomes support the hypothesis that prolonged balloon inflation may facilitate better stent apposition and expansion, leading to improved blood flow restoration and myocardial salvage (8, 10).

Cardiac magnetic resonance (CMR) imaging further substantiated these findings, indicating a reduction in microvascular obstruction and improved cardiac function in the PBSG. This evidence points to the potential for extended balloon inflation to not only improve immediate angiographic results but also to enhance long-term myocardial recovery, an aspect supported by prior research (11, 12).

Despite these promising results, the study did not observe significant differences in clinical outcomes such as procedure time, radiation exposure, and contrast volume between the two groups, nor in the incidence of bleeding events or other procedural complications. This suggests that the extended balloon inflation technique does not introduce additional procedural risks compared to the conventional strategy.

However, the study is not without limitations. The absence of significant clinical outcome differences at 30-day and 1-year follow-ups suggests that while angiographic improvements are evident, these do not necessarily translate into tangible clinical benefits within the follow-up period. Additionally, the lack of widespread availability and the high cost associated with CMR limit its routine use, which could have provided more detailed insights into the myocardial tissue characteristics post-intervention.

Furthermore, the study's findings may be influenced by the selection bias inherent in the patient population, which was predominantly managed at a single center. Also, the variability in operator technique and decision-making, particularly regarding the use of thrombectomy and direct stenting, which was more frequent in the PBSG, could have affected the outcomes.

In conclusion, the extended balloon inflation technique appears to offer significant benefits in reducing the incidence of the no-reflow phenomenon and improving myocardial perfusion during PPCI for STEMI. However, these angiographic and perfusion improvements need further investigation to determine if they confer long-term clinical benefits. Future studies should also consider multi-center trials to validate these findings and explore the integration of routine advanced imaging modalities to better quantify the impact on myocardial recovery and function.

CONCLUSION

The findings from this study suggest that a strategy of extended balloon inflation during stent deployment in primary percutaneous coronary intervention (PPCI) for ST-segment elevation myocardial infarction (STEMI) can significantly reduce the occurrence of the no-reflow phenomenon and enhance microcirculatory perfusion. Implementing this technique may offer a feasible and effective approach to improving angiographic outcomes and myocardial recovery in STEMI patients, potentially leading to better long-term cardiac function. These results underscore the need for further research to validate the clinical implications of these findings and to assess their impact on long-term patient outcomes across diverse healthcare settings.

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