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Original Research Article

COMPARISON OF DEFLATED BALLOON-FACILITATED DIRECT STENTING AND CONVENTIONAL BALLOON PRE-DILATATION IN PRIMARY PERCUTANEOUS CORONARY INTERVENTION FOR ST-SEGMENT ELEVATION MYOCARDIAL INFARCTION

Sarfraz Hussain Sahito[1], Muhammad Aslam[2], Iram Jehan Balouch[3], Gianchand[4], Mashooque Ali Dasti[5], Muhammad Hashim Kalwar[6], Imran Ellahi Soomro[7]

[1]Assistant Professor Adult Cardiology, Sindh Institute of Cardiovascular Diseases Khairpur Pakistan.
[2]Associate Professor Adult Cardiology, Sindh Institute of Cardiovascular Diseases Nawabshah Pakistan.
[3]Associate Professor Adult Cardiology, Sindh Institute of Cardiovascular Diseases Hyderabad Pakistan.
[4]Assistant Professor Adult Cardiology, Sindh Institute of Cardiovascular Diseases Mithi Pakistan.
[5]Associate Professor Adult Cardiology, Sindh Institute of Cardiovascular Diseases Sehwan Pakistan.
[6]Associate Professor Adult Cardiology, Sindh Institute of Cardiovascular Diseases Sukkur Pakistan.
[7]Professor Cardiology, People's University of Medical and Health sciences for women Nawabshah Pakistan.

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Corresponding Author:
Dr. Sarfraz Hussain Sahito,
Assistant Professor Adult Cardiology, Sindh Institute of Cardiovascular Diseases Khairpur Pakistan.
Email: sarfrazarham12@gmail.com

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ABSTRACT

Background: Primary PPCI is the most crucial reperfusion intervention when it comes to ST-segment elevation myocardial infarction (STEMI). This research will focus on direct stenting (DBDS) and traditional balloon pre-dilatement of the reperfusion in PPCI through the comparison of safety and effectiveness. Study design is Prospective comparative study. This study was conducted at People's University of Medical and Health sciences for women Nawabshah from August 2024 to August 2025.

Materials and Methods: STEMI patients who presented to the hospital not more than 12 hours of the onset of the symptoms with thrombolysis during Myocardial infarction and to whom there was less than 1mm runoff or no runoff at all following guidewire insertion were included, (n=110). The patients were separated into two groups (PPCI with DBDS, group 1, n=55 and PPCI with the conventional balloon pre-dilatation, group 2, n=55). Measures were also the outcomes of the procedure like incidence of no-reflow, the use of time and contrast volume.

Results: Group 2 demonstrated a lower incidence of no-reflow compared to group 1, indicating better microvascular perfusion. Group 1 achieved shorter mean procedure times and required significantly less contrast. No major procedural complications were observed in either group.

Conclusion: Conventional balloon pre-dilatation before stenting appears to be safer in preventing no-reflow in PPCI, while DBDS offers advantages in procedural efficiency and reduced contrast use. In cases with compromised distal runoff, balloon pre-dilatation may provide a more effective approach than DBDS.

Keywords: ST-segment elevation myocardial infarction, primary percutaneous coronary intervention, deflated balloon-facilitated direct stenting, balloon pre-dilatation, no-reflow, coronary intervention, procedure efficiency, contrast volume.

INTRODUCTION

STEMI represents a critical form of acute coronary syndrome in which rapid restoration of coronary blood flow is essential to salvage myocardium and limit infarct size. Primary PPCI is the guideline recommended reperfusion strategy in eligible patients presenting within the time window of benefit.[1,2] However, even after successful

reopening of the epicardial artery, impaired microvascular perfusion, commonly known as the no reflow phenomenon, remains a major challenge. The no reflow phenomenon is strongly associated with larger infarct size, adverse remodeling, higher rates of heart failure, and increased short and long term
mortality.[3-6]

The mechanisms underlying no reflow are multifactorial and include distal microembolization of thrombotic or atheromatous debris, ischemia–reperfusion injury, endothelial swelling, capillary plugging by leukocytes and platelets, vasospasm, and microvascular dysfunction.[3,7,8] Given its prognostic importance, minimizing the risk of no reflow is a key goal in optimizing PPCl strategies.

A procedural variable which could affect the risk of no reflow is whether to direct stent (i.e. place the stent without any balloon dilatation) or balloon pre dilate (before the stent is placed) the stent. Direct stenting has been suggested in order to minimize vessel trauma, distal embolization, decrease the time and contrast exposure of the procedure and, in consequence, even reduce microvascular injury.[9-11] Both observational and randomized research in stable and non ST elevation acute coronary syndrome groups have indicated that direct stenting yields positive results in the select lesions.[12-14] Some reports also show that direct stenting can also help to decrease the occurrence of no reflow in comparison to traditional predilatation in STEMI.[15,16] Nevertheless, direct stenting is not always possible in case of complete occlusion of the lesion or in case of runoff at the distal end in the absence of a wire after crossing, which restricts its overall usability.

Just to eliminate this shortcoming, an adapted method was developed called DBDS. A DBDS procedure involves the insertion of a deflated (unexpanded) balloon into the lesion following wire crossing to aid in negotiating and shaping the distal vessel path, and is then removed, followed by the delivery of the stents, without performing full balloon inflation.[17,18] Proponents of DBDS believe it can be used to direct stent even in occlusive lesions, which could be both beneficial in direct stenting but does not disrupt distal flow or traumatize vessels.[18] Early research has shown that DBDS may be possible and safe in some of the subsets of STEMI, and that procedural success rates are acceptable.[17,18]

However, there are few data on the comparison of DBDS with the classical balloon pre dilatation method, particularly in STEMI cases. There has been some evidence that balloon predilatation prior to stenting can permit more controlled lesion expansion, diminish stent underexpansion / malapposition, and identify dissections prior to stent placement.[5,19] Conversely, predilation balloon inflation per se could liberate thromboembolism debris and induce microembolization, thus causing no reflow.[12,20] The conflict between procedural control and the risk of microvascular injury makes it clear that the direct comparative assessment is necessary.

When it comes to the treatment of STEMI that requires time and microvascular condition to play an important role in determining clinical outcome, it becomes extremely important to find out what the best stenting solution would be. There are limited studies that have explicitly covered the question of whether DBDS is net beneficial compared to traditional balloon pre-dilatement in primary PCI of STEMI patients especially when there is no distal runoff present. Further, a trade off should be made between the efficiency of the procedure (e.g. reduced procedure time, reduced contrast use) and the safety associated with the preservation of microvascular perfusion.

As such, we developed a comparative research to determine the effectiveness and safety of DBDS as compared to traditional balloon pre dilatization in participants undergoing PPCI due to STEMI who had flow less than TIMI 1 or no distal runoff following wire insertion. Angiographic no reflow incidence was our major endpoint. The procedural duration, contrast volume, procedural complications, and surrogate perfusion outcomes were the secondary means of examination. This analysis in a cohort of 110 patients will help to explain whether DBDS can be used as an effective alternative to the standard balloon pre dilatation procedure in the difficult group of the STEMI patients with failed distal runoff.

MATERIALS AND METHODS

This is a non-randomized, controlled, prospective study which was done for the comparison of the efficacy and safety of DBDS with the conventional balloon pre-dilatation in primary PPCI for the patients with STEMI. A written informed consent was taken from all participants before enrolling them in the study. Patient confidentiality was strictly maintained.

A total of 110 STEMI patients presenting within 12 hours of symptom onset with thrombolysis in myocardial infarction flow less than 1 or absent distal runoff after wire passage were included. Patients were excluded if they had TIMI flow ≥1 or distal runoff after wire passage, significant left main disease, triple-vessel disease, chronic kidney disease with estimated glomerular filtration rate less than 60 mL/min, history of cerebrovascular stroke, peripheral arterial disease, or other major comorbidities. Baseline demographic data, cardiovascular risk factors including hypertension, diabetes, smoking, and dyslipidemia, prior myocardial infarction, and family history of premature coronary artery disease were recorded.

Patients were divided into two equal groups. In the first group, PPCI was performed using DBDS in 55 patients. In the second group, PPCI was performed

with conventional balloon pre-dilatation before stenting in 55 patients. All the procedures were carried out by interventional cardiologists following standard protocols of the procedures. In the DBDS group, a deflated balloon was inserted in the lesion after passing guidewire to facilitate the delivery of stent without pre-dilatation. In the conventional group, balloon pre-dilatation was done before the stent was deployed. Procedure notes contain information regarding time, contrast volume and instant angiographic results.

The main one was the no-reflow following PPCI. Time, contrast use, post-procedural TIMI flow, myocardial ejection grade, post-procedural ST-segment resolution in electrocardiogram, left ventricular ejection fraction measured through echocardiography, and major cardiovascular events such as re-infarction, heart failure, stroke, and death were the secondary outcomes. Clinical evaluation involved vital signs, BMI, physical examination and Killip classification. The laboratory studies consisted of CBC, RFTs, and cardiac biomarkers. The pre and post PPCI electrocardiography and coronary angiography were used to measure the flow and perfusion outcomes.

In order to reduce confounding, the groups were matched in terms of age and gender. The use of standardized procedural methods and constant data gathering procedures were used and the analysis of the data was done through an intention-to-treat method. Continuous variables (procedure time, TIMI flow, myocardial blush grade, and ST-segment resolution) were represented in the form of means and standard deviations, and such categorical variables as TIMI grade, myocardial blush grade, and major adverse cardiovascular events were expressed as frequencies and percentages. The sample size of the study was 110 patients which was determined by feasible reasons and not power calculations.

RESULTS

The two groups of studies had comparable baseline characteristics and sociodemographic characteristics. There was also male predominance in both groups at 72.7 and 69.1 percent, respectively, in the DBDS and conventional balloon pre-dilatation groups. The age mean of the patients in the DBDS was 52.1 ± 10.3 years as compared to conventional group 54.6 ± 11.8 years ($t(108) = -1.213$, $p = 0.228$), which was not significant. The cardiovascular risk factors, such as hypertension, diabetes, or the family history of ischemic heart disease, were also equally distributed without significant differences. The prevalence of smoking was a slight difference between the two groups (DBDS and 54.5%), but the difference was not statistically significant ($p = 0.073$). No one dropped out of the study and all participants attended it.

Assessment of post-procedural outcomes demonstrated that conventional balloon pre-dilatation was associated with more favorable microvascular perfusion. The incidence of myocardial blush grade II-III was higher in the conventional group compared to the DBDS group (92.7% vs 76.4%, $X^2(108) = 6.14$, $p = 0.013$). Similarly, regression of ST-segment elevation by more than 50–70% on post-PPCI electrocardiogram was observed in 94.5% of patients in the conventional group versus 81.8% in the DBDS group ($X^2(108) = 5.02$, $p = 0.025$). The difference in TIMI flow post-procedure was not statistically significant between groups ($p = 0.847$).

The incidence of no-reflow was significantly lower in the conventional pre-dilatation group (5.5%) compared to the DBDS group (21.8%) ($X^2(108) = 7.42$, $p = 0.006$), indicating better microvascular perfusion with balloon pre-dilatation. Total procedure time was slightly longer in the conventional group (51.3 ± 12.7 minutes) than in the DBDS group (46.9 ± 14.2 minutes), approaching but not reaching statistical significance ($t(108) = 1.92$, $p = 0.057$). In contrast, contrast volume usage was significantly higher in the conventional group (119.4 ± 26.8 ml) compared to the DBDS group (101.6 ± 18.5 ml) ($t(108) = 4.12$, $p < 0.001$).

Other procedural and post-procedural parameters, including the route of vascular access, door-to-balloon time, infarct-related artery, type of STEMI, site of occlusion, use of GP IIb/IIIa inhibitors, and left ventricular ejection fraction, did not differ significantly between the two groups. Major adverse cardiovascular events (MACE), including reinfarction, heart failure, stroke, and in-hospital mortality, were infrequent and comparable across both groups.

Overall, these results suggest that while DBDS offers the advantage of slightly shorter procedural time and lower contrast usage, conventional balloon pre-dilatation before stenting is associated with improved microvascular perfusion and a lower incidence of no-reflow in patients undergoing primary PCI for STEMI.

Table 1: Baseline Characteristics and Procedural Outcomes of Study Groups

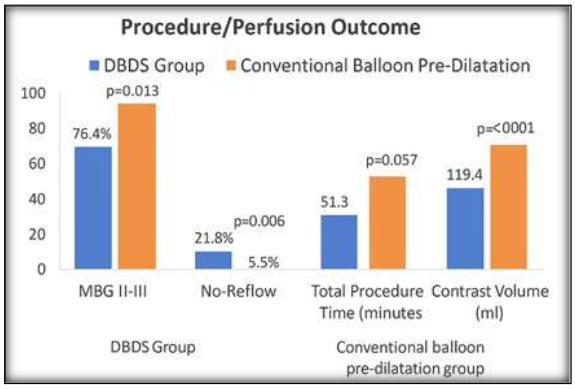
Parameter	DBDS Group (n=55)	Conventional Balloon Pre-Dilatation Group (n=55)	P-value
Age (years) Mean ± SD	52.1 ± 10.3	54.6 ± 11.8	0.228
Male, n (%)	40 (72.7%)	38 (69.1%)	0.671
Hypertension, n (%)	22 (40%)	24 (43.6%)	0.716
Diabetes Mellitus, n (%)	19 (34.5%)	18 (32.7%)	0.841
Smoking, n (%)	38 (69.1%)	30 (54.5%)	0.073
Dyslipidemia, n (%)	6 (10.9%)	10 (18.2%)	0.259
Family history of IHD, n (%)	5 (9.1%)	6 (10.9%)	0.754

Pain-to-Door Time (hours) Mean ± SD	6.4 ± 2.8	5.9 ± 3.1	0.349
MBG II-III, n (%)	42 (76.4%)	51 (92.7%)	0.013
ST-Segment Regression >50–70%, n (%)	45 (81.8%)	52 (94.5%)	0.025
No-Reflow, n (%)	12 (21.8%)	3 (5.5%)	0.006
Total Procedure Time (minutes) Mean ± SD	46.9 ± 14.2	51.3 ± 12.7	0.057
Contrast Volume (ml) Mean ± SD	101.6 ± 18.5	119.4 ± 26.8	<0.001
Door-to-Balloon Time (minutes) Mean ± SD	88.3 ± 15.2	87.5 ± 14.9	0.764
Left Ventricular Ejection Fraction (%) Mean ± SD	51.2 ± 6.8	50.6 ± 7.1	0.621
MACE, n (%)	2 (3.6%)	3 (5.5%)	0.648

Table 2: Comparison of Procedural and Perfusion Outcomes Between Study Groups

Outcome	DBDS Group (n=55)	Conventional Balloon Pre-Dilatation Group (n=55)	P-value
MBG II-III, n (%)	42 (76.4%)	51 (92.7%)	0.013
ST-Segment Regression >50–70%, n (%)	45 (81.8%)	52 (94.5%)	0.025
No-Reflow, n (%)	12 (21.8%)	3 (5.5%)	0.006
Total Procedure Time (minutes) Mean ± SD	46.9 ± 14.2	51.3 ± 12.7	0.057
Contrast Volume (ml) Mean ± SD	101.6 ± 18.5	119.4 ± 26.8	<0.001

This bar graph gives comparison of DBDS group and conventional balloon pre-dilatation group.



DISCUSSION

In this study of 110 patients with STEMI undergoing primary PPCI, we found that the strategy of conventional balloon pre dilatation before stenting was associated with a significantly lower incidence of the no reflow phenomenon, higher myocardial blush grade (MBG II III), and greater ST segment resolution compared with DBDS. At the same time, DBDS showed advantages in procedural efficiency, with shorter mean procedural times and significantly reduced contrast volume use. These findings reflect a nuanced trade off between procedural speed/contrast usage and microvascular perfusion outcomes.

Our findings align and also diverge with previously published data in several important ways. For example, the large registry from the EUROTRANSFER Registry (1,419 STEMI patients) found that direct stenting (i.e., without pre dilatation) was associated with a lower rate of no reflow (1.4% vs. 3.4%) and higher rates of TIMI grade 3 flow and ST segment resolution compared to conventional stenting after pre dilatation.[21] This suggests that in selected patients direct stenting may offer microvascular perfusion benefits. However, in our cohort, specifically selected for impaired distal runoff or TIMI flow <1, the conventional pre dilatation arm out performed DBDS, suggesting that lesion/flow characteristics may moderate the benefit of direct techniques.

In a UK multicentre observational study of 1,562 PPCI patients, direct stenting was independently associated with improved 30 day and one year survival (3.27% vs. 8.48% at one year) compared to pre dilatation.[22] Though our study was not powered for long term mortality and focused on angiographic/perfusion endpoints, the survival benefit in that cohort underscores the potential clinical relevance of improved microvascular reperfusion with direct stenting in appropriately selected patients.

A systematic review and meta analysis of 9,331 STEMI patients (12 studies) compared direct stenting versus stenting with pre dilatation and reported overall lower mortality with direct stenting (OR 0.56; 95% CI 0.37 0.86; p=0.008).[23] However, that analysis included heterogeneous populations and lesion subsets. Our data suggest that when distal runoff is compromised, i.e., in the high risk subgroup we studied, pre dilatation may be advantageous.

In earlier non STEMI and stable coronary disease settings, a randomized trial (249 patients) comparing direct stenting vs. pre dilatation found no significant difference in acute vessel trauma, late luminal loss or restenosis at six month follow up.[24] This suggests that in less complex lesions the choice between approaches may matter less for microvascular perfusion, but in the STEMI setting, with high thrombus burden and microvascular risk, the strategy may become more critical.

The recent sub study from the COMPARE CRUSH trial in STEMI patients with high thrombus burden (336 patients) showed that direct stenting led to significantly lower corrected TIMI frame count (cTFC) and higher complete ST segment resolution (72% vs 59%, OR 1.82; p=0.02) compared to pre dilatation; but TIMI 3 flow and MBG did not differ significantly between groups.[25] These findings highlight that even direct techniques do not guarantee improved perfusion in very high thrombus settings, and lesion specific factors remain key. Our

study, by contrast, observed better perfusion outcomes in the pre dilatation group in a flow compromised cohort, reinforcing that patient/lesion selection matters.

In the technique specific domain, a pilot study of the DBDS technique (n=309 occlusions after wiring) demonstrated feasibility (success ~68%) and very low complication rate (one no reflow event) but lacked a direct comparative arm.[26] Our findings build on this by comparing DBDS head to head with conventional pre dilatation, and showing that in our cohort DBDS was less favorable for perfusion outcomes though more efficient procedurally.

Several important observations emerge from our data in light of this literature. First, procedural efficiency (less contrast and shorter time) is a consistent advantage of direct stenting or DBDS, as seen in our shorter procedure times and contrast volumes, and similarly in non STEMI trials.[24] This is clinically relevant especially in high bleeding or high renal risk populations. Second, improved perfusion (lower no reflow, higher MBG) is not uniformly achieved by direct techniques; our data suggest that when distal runoff is poor or TIMI flow is absent after wire passage, pre dilatation may offer better microvascular protection by allowing controlled initial lumen expansion and detection of complications/dissections before stenting. Third, lesion and baseline flow characteristics appear to drive which strategy is optimal: the benefits of direct or DBDS techniques may accrue only in lesions with preserved distal runoff, minimal thrombus, and good wiring characteristics.

CONCLUSION

In this prospective comparative study of STEMI patients undergoing PPCI with impaired distal runoff, conventional balloon pre-dilatation before stenting was associated with a significantly lower incidence of no-reflow, higher myocardial blush grade, and greater ST-segment resolution compared to DBDS. On the other hand, DBDS had benefits in its performance during the procedure, as they had shorter procedure times and used less contrast. These results imply that although DBDS can be a better choice in the scenario when reducing the amount of time and exposure to contrast is an important factor, the traditional balloon pre-dilatation can be considered a safer method of maintaining the microvascular perfusion in the patient with impaired distal flow. Patient and lesion characteristics should therefore guide the choice of stenting strategy in PPCI for STEMI.

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