Effect of Post Dilatation on TIMI Flow in Patients Undergoing Primary Percutaneous Coronary Intervention

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ABSTRACT

Objective: To evaluate impact of post dilatation performed with Non-Compliant Balloon on Angiographical outcome (that is TIMI flow grade) in patients who underwent the primary percutaneous coronary intervention.

Study Design: Retrospective cross-sectional study.

Place and Duration of Study: At Tertiary Cardiac Care Center, Rawalpindi Pakistan from Nov 2020 to Apr 2021.

Methodology: The retrospective data of the all the patients with STEMI was assessed via non-probability consecutive sampling technique and analyzed statistically. The study participants were classified into two categories based on whether they underwent post-dilatation or not, i.e., Category-I: patients who underwent post-dilatation with NC balloon and Category-II: patients who did not undergo post-dilatation. The primary study end-point was post-dilatation TIMI flow grade. Continuous study variables were expressed as Mean±SD and categorical variables as frequencies and percentages. Chi square test was applied to find the association between study variables by keeping 95% CI and 5 % margin of error. *p*-value <0.05 was considered statistically significant.

Results: The study included (n=410) eligible patients in total. Majority were males (n=303; 73.9%), 217 (52.9 %) patients underwent PD procedure. TIMI flow grade did not differ significantly between the two study categories (*p*-value > 0.05). Post-procedural success rate was 81.3% for patients with PD.

Conclusion: The current study illustrates that PD does not adversely affect the final angiographic outcomes when performed after primary angioplasty.

Keywords: Myocardial infarction, Post dilatation, PCI, STEMI, TIMI flow.

INTRODUCTION

Acute myocardial infarction is the usual cause of high morbidity, mortality and cost with greatly increasing burden in South Asia compared to any other region in the world including Pakistan.[1] Due to the emergence of coronary-care units and the outcomes deduced from the randomized clinical trials on Percutaneous Coronary Intervention (PCI), reperfusion therapy, long-termed treatment with numerous pharmacological agents have considerably brought about a change in the therapeutic approach which has consequently led to low in-hospital mortality rates and have made the future outlook of the acute MI survivors better, as reviewed by Reed *et al*.[2] New and advanced treatments,[3] will continue to develop, but the prevention of coronary heart disease in high-risk groups and effective delivery of the acute treatment remain challenging.

Being available for the last 6 decades and emerging in its modern era in early 1990s, thrombolytic therapy, being a less invasive and potentially effective means of treatment of patients possessing occluded peripheral arteries and veins, gained importance as an initial intervention achieved through the administration of thrombolytic agents into the occluded vessels via a catheter.[4] Based on placebo-controlled, large, randomized trials, it emerged as a standard of care for acute myocardial infarction. However, it possessed various drawback such as, bleeding complications,[4] failure of achievement of arterial patency in 20-26 % patients and increased rate of recurrent ischemia.[5] Due to the limitations of thrombolytic therapy, the interest has been shifted to utilization of Primary Coronary Intervention (PCI) as an alternative procedure to treat the patients of acute myocardial infarction achieved through stent deployment in the occluded vessel.

As compared to thrombolysis, primary angioplasty, also known as Primary Percutaneous Coronary Intervention (PCI) has been linked to improved treatment outcomes in patients with ST-segment Elevation

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Myocardial Infarction (STEMI).[6] Today, PCI with the deployment of Drug-Eluting Stent is the most preferable procedure for the restoration of blood circulation in patients with acute STEMI.[7] Despite the evolution of PCI in respect of its equipment and technical approach, long-term and acute complications like restenosis and thrombosis are still existent and major issue being discussed.[8-10] Inadequate expansion of the stent has been reported as a considerable risk factor for these complications by various cardiologists, indicating towards the necessity of optimization of the deployed stent.

Current study was aimed to evaluate the impact of post dilatation performed with Non-Compliant Balloon on Angiographical outcome (that is TIMI flow grade) in patients who underwent the primary percutaneous coronary intervention.

METHODOLOGY

The current study design was retrospective cohort and the retrospective data of the patients with STEMI admitted from November 2020 to April 2021, at emergency department of a tertiary cardiac care center, Rawalpindi Pakistan and underwent primary PCI is assessed. After approval from IERB (letter #7/10/R&D/2021/114). The patients with complete 6 months follow-up records were included in the study via non-probability consecutive sampling technique

Sample Size: By taking 50% prevalence, the sample size calculated was n=383 by WHO calculator. However, the data was collected from 410 eligible patients meeting inclusion criteria.

Inclusion Criteria: The patients were acceptable angiographic results (i.e., less than 20% residual stenosis) after the deployed stent.

Exclusion Criteria: Patients having contraindication for coronary angiography, valvular heart disease or non-ischemic dilated cardiomyopathy, myocardial infarction with non-obstructive coronary artery disease (MINOCA) or with previous history of CABG were excluded from this study

All the patients underwent PCI for Infarct Related Artery (IRA). The study participants were classified into two categories based on whether they underwent post- dilatation or not, i.e., Category-I: patients who underwent post-dilatation with NC balloon and Category-II: patients who did not undergo post-dilatation (Figure). The primary study end-point was post-dilatation TIMI flow grade which was assessed and compared between the two categories. A clinical follow up was maintained for 6 months.

Demographical data of the patients included gender and age. The clinical baseline characteristics of the patients recorded for the study included Body Mass Index (BMI), smoking, Diabetes Mellitus and Hypertension.

The angiographic variables included the culprit artery and post dilatation TIMI flow grade of the patients. The TIMI classification was applied for the grading of TIMI flow IRA and the TIMI flow grade (0-3) was evaluated as per the protocol outlined past literature.[11,12] All the clinical, demographic and angiographic data was obtained from the medical angiographic reports of the patients from the registry.

The Infarct Related Artery (IRA) was identified in the patients as to be Left Circumflex Artery (LCX), Right Coronary Artery (RCA) and Left Anterior Descending (LAD).

The Thrombolysis in Myocardial Infarction (TIMI) flow grade was constituted in early 1980s by TIMI study group to contribute to the uniform measurement of coronary reperfusion in ST-segment Elevation Myocardial Infarction (STEMI) patients. TIMI flow Grade-0, Grade-1, Grade-2 and Grade-3 represented total occlusion, penetration without perfusion, partial perfusion, and normal perfusion, respectively. TIMI flow grade is easy to use, logical and visible. It has been consistent and important in the prediction of outcomes in patients with STEMI from the era of thrombolytic to Primary Percutaneous Coronary Intervention (PCI). TIMI flow Grade-3 was defined as procedural success in this study.

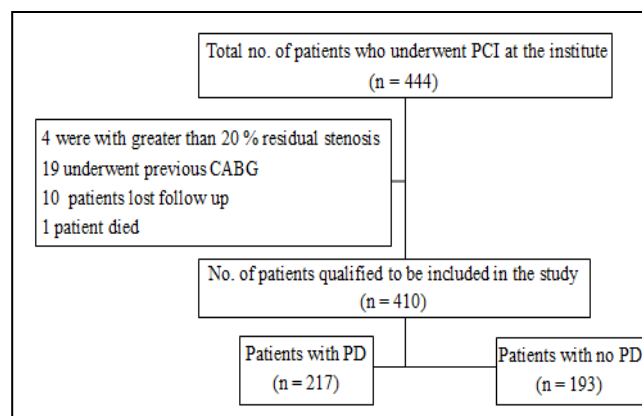Non-Compliant Balloons are used to expand the stent at specific diameter and exert high pressure.

Figure: The Selection Procedure of the Patients for the Study

For the statistical analysis of the data, SPSS-20 was used. Mean±SD and percentages were used to express continuous and categorical variables, respectively. The association between the categorical variables of the two categories was assessed by chi-square test and that of the continuous variables was assessed by independent t-test. The statistically significant *p*-value was considered to be <0.05. All the study participants were notified about the study and study was approved from local administrative and ethical committee.

RESULTS

The study included (n=410) eligible patients in total. Table-I demonstrates the demographic features of the patients (n=303 males, n=107 females, mean age 56.9 + 12.3 years). On the basis of PD, the patients were classified into 2 categories where Category-I constituted of the patients with PD performed (n=217, 52.9%) and Category-II constituted of the patients with no PD performed (n=193, 47%). No significant difference was observed for gender, age, BMI, Heart rate, Hypertension, Diabetes Mellitus and cigarette smoking.

Table-I: Demographic and Baseline Clinical Characteristics (n=410)

Variable	Category I (n=217)	Category II (n=193)	*p*-value
Gender			
Male	160 (73.7%)	143 (74.0%)	0.56
Female	57 (26.3 %)	50 (25.9%)	
Age (years)	57.7 ± 11.9	56.4 ± 13.0	0.16
Body mass index (kg/m2)	28.0 ± 4.8	27.3 ± 3.5	0.21
Hypertension	67 (30.8%)	59 (30.0%)	0.91
Diabetes mellitus	41 (18.9%)	44 (22.8%)	0.34
Current smoker	89 (41.0%)	67 (34.7%)	0.12
Heart rate (beats/min)	79.5 ± 17.7	83.5 ± 20.8	0.16

The culprit artery was LAD in majority of patients in Category-II (98 vs 101, *p*=0.02). No significant difference was observed between the two categories indicating toward the similar Post-procedural TIMI flow grade, irrespective of PD (*p*>0.05). Post-procedural success rate was (n=157; 81.3%) for patients with PD, shown in Table-II.

Table-II: Angiographical Characteristics and Post-Procedural TIMI Flow Grade of Patients (n=410)

Variable	Category I (n=217)	Category II (n=193)	*p*-value
Culprit Artery			
LAD	98 (45.1 %)	101 (52.3 %)	0.02
LCX	51 (23.5 %)	43 (22.2 %)	0.15
RCA	68 (31.3 %)	49 (25.3 %)	0.19
Post-procedural TIMI Flow Grade			
0/1	5 (2.3 %)	4 (2.0 %)	0.13
2	47 (21.6 %)	32 (16.5 %)	0.15
3	165 (76 %)	157 (81.3 %)	0.43

LAD, left anterior descending; RCA, right coronary artery; LCX, left circumflex artery; TIMI, thrombolysis in myocardial infarction

DISCUSSION

In the current study, no significant difference was observed between the 2 categories with regard to angiographical results, i.e., the post dilatation TIMI score. At present, mainly Non-Compliant balloon catheters are used for the pre-dilatation of heavily calcified lesions, post-dilatation of implanted stent to enhance the parameters of expansion, dealing with coronary bifurcation lesion through kissing balloon technique and management of cases with restenosis, particularly in previously implanted stents.[13-15] According to several studies, use of Non-Compliant (NC) balloon for Post Dilatation (PD) is found to be associated with optimal expansion hence higher frequency of optimal stent deployment, lower rates of Target Vessel Revascularization (TVR) and better clinical outcomes of the patients going through elective angioplasty.[16] This study focuses on the evaluation of impacts of PD performed with Non-Compliant balloon on angiographical outcome (that is TIMI flow grade) in patients who went through the primary PCI.

Our study results are in line with other studies,[17] not suggesting the strategy of routine post dilatation following PCI irrespective of the primary angiography results based on the TIMI flow scoring. However, the procedural success rate in the current study settings were satisfactory in the patients with PD and were in close alignment with a recently conducted study.[18,19] but contrary to some others,[20-21] that suggest post-dilatation routinely even in the current era specially for complex lesions.

Only a minute fraction of patients exhibited no perfusion after PD (4 patients, 2.0%). The impaired blood perfusion could be attributed to the vasoconstriction induced by post dilatation.[22] Impairment of the coronary flow was reported by Huang *et al.*[23] to be reversible and show a good response to administered intracoronary vasodilators. In most cases, no perfusion due to distal thrombus embolization occurs right after the stent deployment or pre- dilatation. Consequently, it is improbable that there would be no perfusion after PD because of the distal thrombus embolization. Moreover, in patients without PD, any existing thrombus might get dissolved and result in incomplete stent apposition which serve as an essential factor for the prediction of stent thrombosis. Even though there is lack of sufficient randomized data that could support the use of PD, the application of noncompliant balloons at high pressures to perform post-dilation is considered to be wiser in most of the patients going

through PCI. Although, unfavourably, performing post-dilation in all the patients encountering stent implantation is not cost-effective and practical. The selection of those situations where there is increased suboptimal stent delivery risk, particularly in the implantation of DES, would be more rational.[24]

One of the findings of our study was that the culprit artery in most of the cases in both categories was LAD. Moreover, we found that LAD was the culprit artery in significantly greater number of patients in non-PD group (p = 0.02) which was in line with the results of Tasal, *et al*.[25]

LIMITATIONS OF STUDY

Our study possessed certain limitations. This study was conducted over a small sample size, and we did not evaluate the other angiographical variables indicative of the effects of PD procedure, that include the post-procedural final TIMI frame count (cTFC), Myocardial Blush Grade (MBG) and Major Adverse Cardiac Events (MACE) i.e., death, stent thrombosis and TVR. There is a need of additional studies for the evaluation of our clinical outcomes in case larger population are targeted for the study and over prolonged follow-up span.

CONCLUSION

The current study illustrates that post dilation does not adversely affect the final angiographic outcomes when performed after primary angioplasty.

Author's Contribution

Following authors have made substantial contributions to the manuscript as under:

MAA: Manuscript writing, concept and editing

NAS: Concept, Intellectual contribution and final approval

KA: Study design, drafting the manuscript & critical review

WUR: Formatting, critical review and manuscript writing

HMS: Data analysis, data collection and proof reading

ARK: Data analysis, data collection and proof reading

MNT: Data collection, data analysis and review of article

AS: Drafting the manuscript, proof reading & critical review

JK: Intellectual contribution, concept and final approval

SQ: Data collection, review of article, editing

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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