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Original Article

Comparison of effect of intracoronary nitrate vs adenosine in TIMI flow in patients of STEMI undergoing primary PCI

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ABSTRACT

BACKGROUND & OBJECTIVE: The no-reflow phenomenon during primary percutaneous coronary intervention (PCI) remains a serious complication associated with increased morbidity and mortality in patients with ST-elevation myocardial infarction (STEMI). Recent evidence suggests that intracoronary nitrates may improve coronary perfusion through vasodilatory and antioxidant effects. This study compared the efficacy of intracoronary nitrates and adenosine on TIMI flow in STEMI patients with refractory no-reflow after primary PCI.

METHODOLOGY: This comparative study included 66 STEMI patients with refractory no-reflow during primary PCI, divided equally into two groups (33 each). Patients with cardiogenic shock at admission or known allergy to nitrates or adenosine were excluded. Group A received intracoronary adenosine (maximum dose 120 mcg), while Group B received intracoronary isosorbide dinitrate 200 mcg in a 10 ml solution. The study was approved by the Drug Regulatory Authority of Pakistan (DRAP) (Study Identifier: RCTS-0107; Case Number: 0230).

RESULTS: The mean age was 49.15 ± 8.47 years in Group A and 51.79 ± 7.22 years in Group B. Of the 66 patients, 35 (53.03%) were men and 31 (46.97%) were women. After 30 days, efficacy was observed in 31 patients (93.94%) in the nitrate group compared with 23 patients (69.70%) in the adenosine group.

CONCLUSION: Both intracoronary nitrates and adenosine were effective in managing no-reflow during PCI in STEMI patients, with nitrates showing comparatively better outcomes.

KEYWORDS: Percutaneous Coronary Intervention, Nitrates, Adenosine, Heart Failure.

INTRODUCTION

ST-segment elevation myocardial infarction (STEMI) is one of the most serious signs of atherosclerotic cardiovascular disease. The average death rate in the hospital and after one year is 6% and 10%, respectively [1]. STEMI continues to be a major cause of morbidity and mortality, even with advancements in reperfusion therapy. Primary percutaneous coronary intervention (PCI) remains the best option for STEMI patients who reach a PCI-capable facility within 12 hours of the onset of symptoms [2]. In STEMI patients, primary PCI aims to quickly restore normal blood flow in the infarct-related artery [3].

Due to a substantial decrease in myocardial perfusion and a rise in myocardial necrosis following initial PCI, the no-reflow phenomenon has a poor prognosis, which typically affects left ventricular function and raises cardiovascular mortality. Antiplatelet therapy and local vasodilators have always been the two primary pharmacotherapy approaches used to treat no-reflow [4]. A number of pharmacological treatments, primarily adenosine, verapamil or nicardipine, have been administered intracoronarily to treat no-reflow and have demonstrated improved coronary flow and a better prognosis [5].

Because of its strong vasodilator action, NO-inducing qualities (properties), anti-inflammatory, and anti-platelet characteristics (effect), endogenous adenosine is crucial for preserving myocardial perfusion. Inorganic nitrates have surfaced as a potential candidate in recent times. Within the proper pH and PO2 ranges that exist during ischemia, nitrates are converted to nitric oxide (NO), which is how it works. Its anti-inflammatory and antiplatelet properties are just two of its many benefits. Additionally, no prevents the mitochondrial permeability transition pore

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from opening, a crucial and final step in reperfusion[6]. Adenosine's effectiveness in treating the catastrophic no-reflow phenomenon that may occur during primary PCI was assessed by Darwish et al. The effectiveness of adenosine in preventing MACE in patients was 73.3%[7]. However, another study found that nitrates was 94.7% effective [8].

During primary percutaneous coronary intervention (PCI), the no-reflow phenomenon is still a serious complication that raises morbidity and death. The effectiveness of current management techniques, such as the usage of adenosine, has fluctuated. Intracoronary nitrates may have better vasodilatory effects and lessen oxidative stress, according to recent data. The purpose of this research is to determine whether intracoronary nitrates are more effective than adenosine at preventing the no-reflow phenomenon after primary PCI. Determining which medication is more effective is the main goal. Future clinical guidelines will be informed by the study's findings, allowing medical professionals to better treat individuals having primary PCI and enhance their outcomes. The objective of this study was to compare the efficacy of intracoronary nitrates and adenosine on TIMI flow in patients of STEMI after primary PCI.

METHODOLOGY

Following approval by the ethical review committee of the Department of Cardiology at the Faisalabad Institute of Cardiology, Faisalabad, with ERC NO-7-2024/DME/FIC/FSD dated 05-06-2024 and with approval of the Drug Regulatory Authority Pakistan(DRAP) with study identifier RCTS-0107 and case number 0230, this open-label randomized-controlled experiment was registered. We recruited 66 patients who were admitted to the Faisalabad Institute of Cardiology's Department of Cardiology between January 2025 and June 2025 (33 in each group). Patients who were between the ages of 18 and 65, had a verified diagnosis of STEMI, and had refractory no-reflow on primary PCI were also included. Among the exclusion criteria were cardiogenic shock at admission, known allergies to nitrates or adenosine, non-ST-elevation ACS, contraindications to dual antiplatelet therapy, and the need for emergent CABG. Informed consent was obtained. The WHO sample size calculator was used to determine the study's sample size by employing two independent population proportions and hypothesis testing. At the 5% level of significance and with a power of 80% , the estimated effectiveness of adenosine was 73.3%, while that of nitrates was 94.7%. The sample size calculated was 33 patients per group[7,8].

A Randomization system was used to assign all recruited patients, in accordance with the order of trial participation, to either the adenosine or nitrates group in a 1:1 ratio. ECG, clinical examination, history-taking, blood collection for standard laboratory testing, and a quick bedside echocardiogram were performed on eligible STEMI patients to prepare them for transfer to PPCI. Prior to being moved to the catheterization lab, each patient received unfractionated heparin, 180 mg of ticagrelor, 80 mg of atorvastatin, and 300 mg of aspirin. Two groups of patients were created using the lottery method. Group A had one ampule (6 mg/2 ml) mixed with 10 cc of saline and 1 cc of adenosine, then diluted 10-fold by adding 1 cc to 10 cc of saline. The final concentration was 60 mcg for an intracoronary injection through an aspiration catheter or a balloon that was perforated and inflated at the site of the problem. A maximum dose of 120 mcg was achieved by repeating the dose as needed. Group B patients were given 10 mL of intracoronary isosorbide dinitrate 200 mcg. MACE was defined as the composite of total death ,MI , hospitalization due to HF and repeat revascularization. Every piece of information was documented on a properly prepared performa.

SPSS version 25 was used to transfer and analyze all of the gathered data. Every quantitative measure, including age, weight, height, BMI, and time to PCI, had its mean and standard deviation determined. Every qualitative feature, including gender, comorbidities, family history of early coronary artery disease, culprit vessel, MACE, and efficacy, had its frequency and proportion determined. The effectiveness of both groups was compared using the chi-square test. Stratification was used to control for effect modifiers like age, gender, BMI, comorbidities, time to PCI, culprit vessel, and family h/o PCAD. The impact of effect modifiers was assessed using the post-stratification chi-square/Fisher's exact test. A P value of 0.05 or less was considered significant.

RESULTS

With a mean age of 50.22 ± 8.13 years, the study's participants ranged in age from 18 to 65. Patients in group A were an average of 49.15 ± 8.47 years old, while patients in group B were an average of 51.79 ± 7.22 years old. There were 35 men (53.03%) and 31 women (46.97%) among these 66 patients, so the ratio of men to women was 1.1:1. Group B's mean BMI was 27.18 ± 2.93 kg/m2, whereas group A's was 28.45 ± 3.61 kg/m2. The distribution of patients by various variables is shown in Table-I. After treatment, 31 patients (93.94%) in group B (nitrates) and 23 patients (69.70%) in group A (adenosine) demonstrated efficacy (with no significant adverse events). The statistically significant p-value is 0.0107. (Table-II). Table-III displays the stratification of efficacy by family history of premature coronary artery disease, gender, and DM, which showed a significant (p-value<0.005) effect on efficacy in group A, while the remaining variables, including Age, BMI, HTN, time to PCI, family history, smoking, dyslipidemia, and culprit vessel, showed no significant difference in efficacy. On the other hand, none of the variables showed a significant difference in efficacy between groups (p-value > 0.005).

Table-II: Comparison of efficacy (n=66).

Variable /Categories	Group A (n=33) n(%)		Group B (n=33) n(%)		P-Value
	Yes	No	Yes	No	
Efficacy	23 (69.70)	10(30.30)	31 (93.94)	02(6.06)	0.0107

Table-I: Distribution of different variables (n=66).

Variables	Categories	Group A (n=33)	Group B (n=33)
		n(%)	n(%)
Age (years)	18-40	07 (21.21)	04 (12.12)
	41-65	26 (78.79)	29 (87.88)
Gender	Male	19 (57.58)	16 (48.48)
	Female	14 (42.42)	17 (51.52)
BMI (kg/m2)	≤30	22 (66.67)	28 (84.85)
	>30	11 (33.33)	05 (15.15)
DM	Yes	17 (51.52)	20 (60.61)
	No	16 (48.48)	13 (39.39)
HTN	Yes	15 (45.45)	16 (48.48)
	No	18 (54.55)	17 (51.52)
Dyslipidemia	Yes	21 (63.64)	22 (66.67)
	No	12 (36.36)	11 (33.33)
Smoking	Yes	11 (33.33)	08 (24.24)
	No	22 (66.67)	25 (75.76)
Family history	Yes	07 (21.21)	08 (24.24)
	No	26 (78.79)	25 (75.76)
Culprit vessel	LDA	14 (42.42)	15 (45.45)
	LCA	14 (42.42)	13 (39.39)
	RCA	05 (15.16)	05 (15.16)
Time to PCI (hrs)	≤24	15 (45.45)	17 (51.52)
	>24	18 (54.55)	16 (48.48)

Table-III: Stratification of efficacy with respect to age, gender, BMI, comorbidities, family h/o PCAD, time to PCI and culprit vessel.

Variables/ Categories		Group A (n=33) n(%)		P-value	Group B (n=33) n(%)		P-value
		Efficacy			Efficacy		
		Yes	No		Yes	No	
Age (years)	18-40	04 (57.14)	03 (42.86)	0.415	04(100.0)	00 (0.0)	1.00
	41-65	19 (73.08)	07 (26.92)		27(93.10)	02 (6.90)	
Gender	Male	18 (94.74)	01 (5.26)	0.0003	15(93.75)	01 (6.25)	1.00
	Female	05 (35.71)	09 (64.29)		16(94.12)	01 (5.88)	
BMI (kg/m2)	≤30	14 (63.64)	08 (36.36)	0.284	26(92.86)	02 (7.14)	1.00
	>30	09 (81.82)	02 (18.18)		05(100.0)	00 (0.0)	
DM	Yes	07 (41.18)	10 (58.82)	0.0002	18(90.0)	02 (10.0)	0.507
	No	16 (100.0)	00 (0.0)		13(100.0)	00 (0.0)	
HTN	Yes	11 (73.33)	04 (26.67)	0.678	16(100.0)	00 (0.0)	0.485
	No	12 (66.67)	06 (33.33)		15(88.24)	2(11.76)	
Dyslipidemia	Yes	16 (76.19)	05 (23.81)	0.433	20(90.91)	2(9.09)	0.542
	No	07 (58.33)	05 (41.67)		11(100.0)	00 (0.0)	
Smoking	Yes	10 (90.91)	01 (9.09)	0.108	08(100.0)	00 (0.0)	1.00
	No	13 (59.09)	09 (40.91)		23(92.0)	02 (8.0)	
Family history	Yes	06 (85.71)	01 (14.29)	0.396	7(87.50)	1 (12.50)	0.432
	No	17 (65.38)	09 (34.62)		24(96.0)	01 (4.0)	
Culprit vessel	LDA	10 (71.43)	04 (28.57)	0.278	13(86.67)	2(13.33)	0.631
	LCA	08 (57.14)	06 (42.86)		13 (100.0)	00(0.0)	
	RCA	05 (100.0)	00 (0.0)		05 (100.0)	00(0.0)	
Time to PCI (hrs)	≤24	10 (66.67)	05 (33.33)	1.000	16 (94.12)	01(5.88)	1.00
	>24	13 (72.22)	05 (27.78)		15 (93.75)	01(6.25)	

DISCUSSION

The intricate pathophysiological process of STEMI, the existence of comorbidities, and side effects such as cardiac reperfusion injury and NRP may limit the effectiveness of PCI as a treatment for STEMI patients. To improve the patient's prognosis, further medicine is therefore required [9]. As far as we know, this was the first study in Pakistan to show that giving nitrates instead of adenosine through a suction catheter distal to the coronary vascular lesion before the no-reflow phenomenon happened lowered the rates of reperfusion injury, cardiovascular death in the hospital, and re-hospitalization in STEMI patients after PPCI.

With a mean age of 50.22 ± 8.13 years, the study's participants ranged in age from 18 to 65. Patients in group A were an average of 49.15 ± 8.47 years old, while patients in group B were an average of 51.79 ± 7.22 years old. There were 35 men (53.03%) and 31 women (46.97%) among these 66 patients, so the ratio of men to women was 1.1:1. After 30 days of treatment, 31 patients (93.94%) in group B (nitrates) and 23 patients (69.70%) in group A (adenosine) demonstrated efficacy (no significant adverse event). The statistically significant p-value is 0.0107. Adenosine's effectiveness in treating the catastrophic no-reflow phenomena that might happen during primary PCI was assessed by Darwish et al. Successful reperfusion was achieved in 74 of 81 (91.4%) of patients who received epinephrine and in 65 of 75 (86.7%) who received adenosine (P<.05) [7]. However, another study found that nitrates was 97.4%8 effective.

There was no decrease in infarct size in a recent trial that used intravenous nitrates in STEMI patients with a predetermined recruitment criterion of TIMI flow≤1 before reperfusion [10]. These results stand in stark contrast to our subgroup analysis of TIMI flow ≤ 1 individuals, which showed a significant cardioprotective benefit across nearly all cardioprotective metrics. This discrepancy can be related to variations in dosage and administration method. Nitrates were given intravenously in the Frenneaux investigation at a dose demonstrated to produce circulating levels of 6 µmol/L in dogs, which was associated with significant cardio-protection [11]. This concentration falls between 3 and 12 µmol/L and has been shown to be effective in a number of preclinical in vivo experiments across a variety of species. Regretfully, this dose only raised circulating nitrate levels from 0.76 to 1.4 µmol/L in the Frenneaux study , indicating that the pharmacokinetics of intravenously administered nitrates in humans differ from those in dogs [10].

Numerous preclinical studies show that nitrates' cytoprotective effects in myocardial infarction models are most noticeable when applied to or on the ischemic organ at the time of drug administration, when the culprit vessel is occluded, or when there is no flow [12]. The fact that nitrates convert to nitric oxide in the bloodstream when oxygen or blood flow is low makes them more bioactive. This does happen in healthy people [13,14]. Part of the conventional care for STEMI patients who go to the hospital for primary PCI is to give them antiplatelet and anti-thrombotic drugs early and effectively. According to research, more than 40% of patients will experience spontaneous reperfusion in the area associated with the infarct, which will result in a large coronary flow (TIMI flow>1) in the coronary artery that caused the infarct before revascularization .

Feng et al. found that the nitrates group had lower levels of BNP and LVEDD than the control group [15]. The current study revealed that administering nitrates to STEMI patients who underwent PPCI may improve cardiac systolic function and prognosis by enhancing myocardial blood flow reperfusion.

At a six-month follow-up, Hwang et al also found that 1.8 pmol intracoronary nitrates before coronary angiography and 1.8 pmol intracoronary before stent placement were effective [16]. Moreover, nicorandil dosages of 2-6 mg as a bolus or 1.67-8 mg/hour continuously for 3-24 hours are beneficial and do not cause adverse effects, according to Zhou et al. meta-analysis of 2965 STEMI patients [17].

De Lemos et al. and Tomaszuk-Kazberuk et al. discovered that the outcomes for patients who had a quick normalization of the ST segment (≥50% drop in ST-elevation) after PPCI were very different from those who did not [18,19]. Consistent with previous investigations, Zhou et al. have shown that the degree of reperfusion in the myocardium associated with the infarct may be represented by the decrease in the amplitude of the ST segment soon after PPCI. Therefore, greater blood flow to the injured site and a better clinical prognosis are associated with a more pronounced decrease in the amplitude of the ST segment [17].

The importance of intracoronary medication in improving coronary perfusion during PCI has been highlighted in recent research. A meta-analysis of adenosine's efficacy was conducted by Nguyen et al. , who found that it was useful for reducing microvascular obstruction and improving clinical outcomes [20]. This result is in line with that of Jafari et al , who used verapamil to demonstrate comparable improvements in coronary flow [21]. Furthermore, Khan et al contrasted intracoronary epinephrine with adenosine, emphasizing the latter's effectiveness in particular clinical settings [22].

There are some issues with the current study that must be resolved. First, the current study examined only a small number of people and was conducted at a single centre, which may affect the accuracy of the results. Furthermore, because of the prevalence of worsening heart failure, observer or outcome reporting bias cannot be ruled out of this study. More large-scale, multicenter, randomized controlled investigations are necessary.

CONCLUSION

The no-reflow phenomena in patients with acute coronary syndrome (ACS) having percutaneous coronary intervention (PCI) can be effectively managed with intracoronary nitrates

and adenosine, according to this study. Our results show that both treatments are safe and effective in this clinical setting, with nitrates showing a slight edge in improving cardiac perfusion and reducing microvascular resistance. This emphasizes how important it is for medical professionals to carefully weigh these choices in light of the unique characteristics of each patient and the clinical setting.

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Muhammad Ali Raza: Substantial contributions to the conception and design of the work.
Muhammad Yasir: The acquisition of data for the work.
Munir Ahmad: Analysis and interpretation of data for the work.
Sultan Bashir: Drafting the work
Anum Randhawa: Reviewing it critically for important intellectual content
Kaleem Ullaha: Final approval of the version to be published.