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ORIGINAL ARTICLE

The outcome of Intracoronary Tirofiban administration at Primary Percutaneous Coronary Intervention in St-Elevation Myocardial Infarction Patients

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Abstract

Background: ST-elevation myocardial infarction results from obstruction of coronary flow due to intracoronary thrombus formation. Primary PCI is the gold standard and class-I indication for revascularization following STEMI. Investigators in this study aimed to evaluate the TIMI flow and myocardial blush grade after intracoronary Tirofiban administration in patients with STEMI during the primary percutaneous coronary intervention (PPCI) and its outcome.

Methodology: This Cohort study was conducted at Cardiology Department, Niazi Medical & Dental College, Sargodha, after getting informed consent from patients with STEMI. Primary PCI was done in these patients, and two groups were formed. Tirofiban and Non-tirofiban group on basis of Tirofiban administration. Variables included TIMI Grade flow, myocardial blush, major bleeding, minor bleeding, hematoma, MACE, and mortality. P<0.05 was considered statistically significant.

Results: The mean age of the study groups was 41.64 ± 12.30 years, with 74% (N=250) males. It was seen that 39 (31.2%) vs 41 (32.8%) with p-value of 0.786 were hypertensive, 28 (22.4%) vs 34 (27.2%) diabetic were having p-value of 0.380 whereas 34 (27.2%) vs 37 (29.6%) with p-value of 0.674 were smokers. TIMI flow grades in both groups were not similar and showed significant differences, indicating that both groups were independent, with a p-value <0.05. The myocardial blush grade was compared in the two groups and the results showed that the score in both the groups was not similar, having significant differences as the p-value was 0.001; major bleeding compared with minor showed statistical insignificance, which indicated that there is a relationship between the two groups. (p-value=0.625 & 0.705 respectively).

Conclusion Administration of intracoronary Tirofiban was associated with superior clinical prognosis in terms of TIMI flow and myocardial blush grades compared with the other group at primary PCI.

Keywords

STEMI, Primary coronary intervention, Tirofiban.

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Introduction

Coronary heart disease, acute coronary syndrome, is the leading cause of death worldwide. Globally, CVD is considered to be the most common cause of mortality and disability, affecting around 17.7 million deaths in 2015[1]. The disease burden is not equally distributed; it targets populations living in low and middle-income countries[1,2]. STEMI results from sudden occlusion of an epicardial coronary artery due to rupture of an atherosclerotic plaque leading to thrombus formation. Effective and rapid restoration of blood flow to ischemic myocardial tissue is the most important initial goal in treating patients with STEMI. As per American Heart Association guidelines, primary PCI, if available, is considered the gold standard tool for the revascularization of the infarct-related artery. Restoration of blood flow through an infarct-related artery in ST-segment elevation myocardial infarction (STEMI) patients can be achieved by either the timely performed primary percutaneous coronary intervention (PPCI) or medical therapy consisting of thrombolysis to save the diseased myocardium and decrease mortality[3]. Primary PCI is better than medical treatment, provided it is carried out by skilled professionals[4]. It is conducted in the infarct-related artery within 12 hours of symptoms and when the door to balloon time is 90 minutes[5,6].

The dilemma following PPCI in more than 20% of patients is no reflow or slow reflow owing to huge clot burden, low LVEF, and myocardial salvage[7]. No reflows or slow reflow is improved by the use of vasodilators like adenosine, nitrates, or verapamil and with the use of dual antiplatelets. Due to their oral route, these drugs might not completely stop the platelets from aggregating. So, complications may still be present after PCI[8]. Glycoprotein IIb/IIIa inhibitors (GPIs) are another class of antiplatelets consisting of abciximab, eptifibatide, and tirofiban can be another option in patients with huge clot burdens. They are associated with decreased platelet aggregation, reduced post PCI myocardial infarction frequency, and improved vessel patency of the vessel[9,10,11]. GPIs are given class IIa indication during PCI by the European society of cardiology[11]. However, the use of unfractionated heparin (UHF) during PCI is still controversial, but it has a sure short place for bailout problems like slow flow, obstructed vessels, and other complex conditions[12,13].

Tirofiban is a small non-peptide molecule that is a more prominent GPI. It is preferred over the others due to its availability, cost-effectiveness, and fewer side effects[14]. According to European guidelines, either high dose (25mcg/kg) or low dose (10mcg/kg) intravenous tirofiban followed by its infusion at 0.15mcg/kg/min in patients having a fair renal profile, whereas American guidelines suggest high dose tirofiban in STEMI cases[13]. Optimal platelet plug inhibition cannot be achieved by 10mcg/kg of tirofiban 14. Tirofiban is usually given via intra-arterial or intravenous routes. The infarct-related artery takes up higher drug concentration during intracoronary injection[15].

The topic of the present study is unique as it has not been studied in Pakistan. TIMI flow grade and Myocardial blush grading are defined as,

TIMI Flow Grade: TIMI Flow grade is an angiographic scoring scheme from 0-3 referring to levels of coronary blood flow assessed during percutaneous coronary angioplasty:

TIMI 0 Flow	**No perfusion**	**Absence of any ante-grade flow beyond a coronary occlusion.**
TIMI 1 Flow	Penetration without perfusion	Faint ante-grade coronary flow beyond the occlusion. Incomplete filling of the distal coronary bed
TIMI 2 Flow	Partial reperfusion	Delayed or sluggish ante-grade flow Complete filling of the distal territory.
TIMI 3 Flow	Normal flow	Fills the distal coronary bed completely

Myocardial Blush Grade (MBG): MBG is used to assess perfusion in the capillary bed at the tissue level.

MBG 0	**Absence of myocardial blush**
MBG 1	Minimal myocardial blush
MBG 2	Moderate myocardial blush
MBG 3	Normal myocardial blush

Methodology

This cohort study was conducted at the Cardiology department, Niazi Medical & Dental College, Sargodha, Pakistan, for a duration of twelve months. Non-probability consecutive sampling technique was used for sampling. The sample size of 250 (125 in each group) was assessed by using a 95% confidence level and 80% power of test with an expected percentage of TIMI grade 3 flow in approximately 22% of patients of the Tirofiban group and 10% of the control group in patients with STEMI (Salarifar, 2014) by the following formula:

$$n = \frac{\left\{ z_{1-\alpha}\sqrt{2\bar{P}(1-\bar{P})} + z_{1-\beta}\sqrt{P_1(1-P_1)+P_2(1-P_2)} \right\}^2}{(P_1-P_2)^2}$$

Inclusion/Exclusion Criteria

Patients aged between 30 to 70 years of both genders presenting with STEMI were included in the study. At the same time, Patients with a history of CVA, history of transient ischemic attack (TIA), previous history of bleeding or/and active bleeding, surgery/trauma history, renal failure, international normalized ratio (INR) range > 1.5, patients on fibrinolytic therapy within 24 hours were excluded.

Data Collection Procedure

The approval from the ethics committee of the hospital was taken. After approval, those patients who fulfilled the inclusion criteria were enrolled in this trial. Earlier to inclusion, informed written consent was taken from each study participant. The patients were informed about the procedure and its possible significance in terms of disadvantages and advantages. Demographic details of the patients were also collected. The patients were allocated into two groups. The Tirofiban group received a high dose of intracoronary tirofiban in a dose of 25mcg/kg intracoronary bolus of tirofiban and then IV infusion at 0.15mcg/kg/min for 12 hours, while the non-tirofiban group didn't receive tirofiban at the time of primary PCI. Every patient received 300mg Aspirin, 600mg clopidogrel, and 5000 IU of unfractionated heparin (UFH) before the emergency department procedure. The patients will continue to receive aspirin 300mg daily and clopidogrel 150mg daily (for one year) at the physician's discretion. The initial angiograms and those attained after PPCI was studied by a single blinded investigator (Director cardiac cath. Lab.), and the TIMI flow and myocardial blush grade will be measured. The patients were monitored in the hospital for three days and 30 days after PCI (in the outpatient clinic) for mortality, CVA, and MI needs for crucial revascularization, hematoma, and major or minor bleeding.

Data Analysis

All the information was documented in a Proforma devised by the principal investigator. Data was entered and analyzed through SPSS v. 21. Quantitative variables like height, age, weight, BMI, and duration of chest pain were calculated as mean ± SD. Qualitative variables like gender, H/o diabetes, ischemic heart disease, smoking, family history, thrombolysis (given or not), and LV systolic function presented as frequency and percentage. Relative risk was calculated to measure the association between LV systolic function and thrombolysis. RR>1 was considered significant. Data was stratified for age, gender, body mass index, H/o diabetes, ischemic heart disease, smoking, and family history. Post-stratification, RR was calculated to measure the association between LV dysfunction and thrombolysis. RR>1 was considered significant.

Results

Collected data were statistically analyzed using SPSS v23.0. Variables included TIMI Grade flow, myocardial blush grade, major bleeding, minor bleeding, hematoma, MACE, and mortality. Results were expressed as standard deviations (SD) and means, along with percentages and frequencies. Chi-square was used for categorical variables. A sample t-test was used to associate the means between the continuous variables. P<0.05 deliberated the significant differences. The mean age of the study groups was 41.64 ± 12.30 years, with 74% (N=184) males. The average age of the Tirofiban group was 40.40 ± 12.41 compared with the non-tirofiban group, 42.88 ± 12.90. There were 36% (90) participants of age 20-35 years, 34% (85) were of age 36-50 years, remaining patients, 30% (75), were between 51-65 years, so the age range was 20-65 years in our study. Male patients were184 (73.60%), whereas the females were66 (26.40%). It was seen than that 39 (31.2%) vs 41 (32.8%) with p-value of 0.786 were hypertensive patients, 28 (22.4%) vs 34 (27.2%) diabetic patients were having p-value of 0.380. whereas 34 (27.2%) vs 37 (29.6%) with p-value of 0.674 were smokers. TIMI flow grades in both groups were not similar and showed a significant difference, which indicated that both the groups were independent with a p-value <0.05. The myocardial blush grade was compared in the two groups; results showed that the score in both the groups was not similar, having a significant difference as the p-value was 0.001; major bleeding compared with minor also showed statistical insignificance, which indicated that there is a relationship between the two groups. (p-value= 0.625 & 0.705 respectively). The Chi-square results regarding MACE (major bleed, hematoma at puncture site, and mortality) in Tirofiban and Non-tirofiban groups were not statistically significant, with p-values of 0.338, 0.447, and 0.591, respectively.

The finding of clinical outcomes showed that 86(34.3%) patients had TIMI flow grade in partial reperfusion,164(65.6%) patients had normal myocardial blush grade,70(28.0%) had major bleeding, whereas 62(24.8%) patients had minor bleeding. The result of my current study showed that hematoma was observed in 72(28.8%), MACE in 84(33.6%) patients, and mortality in 6(2.4%) patients (Table 1).

Table 1: Descriptive Statistic of Clinical Outcomes

Variables		Frequency	Percentage
TIMI Grade Flow	No Perfusion	0	0
	Penetration without perfusion."	24	9.6
	Partial Reperfusion	86	34.3
	Normal	140	56.0
Myocardial Blush	Absence	0	0.0
	Minimal	16	6.4
	Moderate	70	28.0
	Normal	164	65.6
Major Bleeding	Yes	18	7.20
	No	232	92.8
Minor Bleeding	Yes	32	12.8
	No	218	87.2
Hematoma	Yes	72	28.8
	No	178	71.2
MACE	Yes	84	33.6
	No	166	66.4
Mortality	Yes	7	2.8
	No	243	97.2

The frequency of distribution with MACE included MI, CVA, and revascularization. Findings showed that myocardial infarction was observed in 20 (8.0%) patients, 30 (12%) suffered from CVA (stroke), and 34 (13.6%) patients were undergoing redo-angiography. (Table 2).

Table 2: Frequency Distribution with Respect to MACE

Variables	Frequency	Percentage
Myocardial Infarction (MI)	20	8.0
Cerebrovascular accident (CVA)	30	12.0
Revascularization	34	13.6

The p-value of MACE (MI, CVA & Revascularization) in the two groups was statistically insignificant as the values were 0.351, 0.436, and 0.373, respectively, which showed that variables of MACE were not independent as p-value > 0.05 (Table 3).

Table 3: Comparison of groups with Respect to MACE

Variables	Research Groups				p-value
	Tirofiban Group f(%)		Non-tirofiban Group f(%)		
	Yes	No	Yes	No	
Myocardial Infarction (MI)	8(6.40%)	117(93.6%)	12(9.6%)	113(90.4%)	0.351
Cerebrovascular accident (CVA)	13(10.4%)	112(89.6%)	17(13.6%)	108 (86.4%)	0.436
Revascularization	16(12.8%)	109(87.2%)	21(16.8%)	104(83.2%)	0.373

Discussion

This analysis/trial was conducted to see the outcome of intracoronary administration of tirofiban in relation to TIMI flow and myocardial blush grade during PPCI. Either timely PPCI can achieve recanalization of the vessel in STEMI patients or via medical management to save the diseased myocardium and decrease mortality[3]. The improved treatment received by STEMI patients is PPCI in comparison to medical treatment[4]. Over the past 10 years, the best treatment for acute myocardial infarction (MI) is PPCI to achieve complete reperfusion and thus decrease the death rate[16]. The advantages of PCI are improvement in myocardial blood flow and normal TIMI flow grade, thus fewer chances of cardiovascular events[8]. When percutaneous coronary intervention is performed, the vascular complication is more commonly encountered and, as a result, leads to an increase in the number of deaths along with an economic burden on the patient. These complications also put the patients at risk of coronary artery disease and, death[17]. Even after successful placement of stents, no-reflow phenomena can occur, which according to the RIVIERA study, is considered the second most dangerous angiographic-related problem[18]. Therefore, additional medical treatments like GPI are used, decreasing platelet aggregation and improving vessel patency, so the clinical outcome is better[9,10]. When tirofiban (GP IIa/IIIB inhibitor) is given via intra-arterial injection, it allows efficient drug absorption in the diseased area and inhibits platelet aggregation[15]. Glycoprotein IIa/IIIb inhibitors, especially tirofiban, can be given through venous and intra-arterial routes. It has been proposed that tirofiban, when it is given through the intra-arterial pathway, has better efficacy in the infarct area and has better platelet inhibition function. Moreover, this route has a low bleeding risk[19,8].

The findings illustrated by Erdim et al. (2010) showed that intracoronary low dose bolus uptake of tirofiban, followed by 36 hours of IV infusion at

0.15 mcg/kg/min, did not help in dropping MACE values in relation to intravenous uptake in 84 patients who were treated with primary PCI. The mean age was 56±10 years in the IV tirofiban group (IV group) and 55±12 years in the IC tirofiban group (IC group)[20]. These findings on age support our study.

The risk factors of this study: hypertension, diabetes mellitus, and smoking of research patients, were statistically non-significant as the p-value were 0.786, 0.380, and 0.674, respectively. Kirma et al. (2012) worked on 49 patients, where intravenous high dose bolus plus maintenance was given to 24 patients and intracoronary bolus only on 25 patients. Age, male sex, and other risk factors like high blood pressure, smoking, and diabetes mellitus (DM) were non-significant as p values were 0.34, 0.46, and 0.19 in both the groups[21], just like our study.

Ma et al. (2020) studied 226 patients in which he made two groups of intracoronary and intravenous bolus doses followed by a maintenance infusion. All the variables like age, female sex, high blood pressure, smoking, and DM were non-significant, with the p-value of high blood pressure, smoking, and DM being 0.678, 0.831, and 0.976, respectively[22]. These two values of TIMI flow grade 3 and MBG are favored by Candemir et al. (2012), who studied 56 patients and compared high dose tirofiban through the intracoronary route with 34 patients vs. 22 patients with high dose tirofiban via the intravenous route. They found TIMI flow grade 3 after PCI in 72.5% vs. 27.5% of patients, respectively, whereas MBG 3 was 94% versus 73%. These two variables significantly favor high-dose tirofiban via the intracoronary route over the intravenous route. The results assume that intracoronary injection of glycoprotein IIb/IIIa inhibitors causes a clot to dissolve immediately as there are more drug levels present in coronaries causing glycoprotein receptors to inhibit, hence stopping platelets from plugging and improving circulation[23].

In this study, major bleeding and minor bleeding showed non-significant results between the two groups with a p-value >0.05. Their values were 0.625 and 0.705, respectively. This is favored by the study conducted by Wu et al., who performed the first research on intracoronary tirofiban and found that an even lower dose of tirofiban has a remarkable impact on the results. Their results showed that major bleeding in the intravenous group is 8.8%, whereas in the intracoronary group is 1.7% which is also non-significant (p-value 0.201). The same is found with minor bleeding, in which minor bleeding in intravenous is 7.0% and 10.3% in intracoronary cases is also non-significant (p-value 0.763)[24].

The findings from the present study regarding hematoma, MACE, and mortality in the intracoronary tirofiban group were not statistically significant, as the p-value were 0.338, 0.447, and 0.591, respectively. The mortality in both groups was observed as 3(2.4%) & 4(3.2%), respectively. Candemir's study results were unable to show any betterment in the prognosis after 30 days because major adverse cardiovascular events were observed after a period of one month and found bleeding, death, and re-infarction to be non-significant and hence do not prefer one route over the other[23]. Erdim et al. conducted a study and observed that major adverse cardiovascular event during a hospital stay is 2.7% and 2.1% in the intracoronary and intravenous group, respectively, with a p-value of 1.00. The separate parts of the MACE in intracoronary versus intravenous groups: deaths were 2.1% as compared to 2.7%, repeat revascularization was 4.1% versus 8.3%, recurrent MI 4.1% whereas 8.3% respectively[20]. These MACE values support our study. El-Hefny et al. gave tirofiban to 50 patients via intracoronary and 50 patients via intravenous route during the primary percutaneous coronary intervention of AMI patients and compared its outcome if associated with a decrease in infarct expansion or not. These patients underwent PPCI who suffered from anterior myocardial infarction and reached the hospital within the time frame and were given glycoprotein IIb/IIIa inhibitors either through the intracoronary or intravenous course. Patients with intracoronary tirofiban had a decrease in infarct size and fewer chances of heart failure due to

preserved LV function. But there was no significant difference in the main adverse cardiovascular events or bleeding chances with either strategy[25].

The study was restricted by smaller sample size; larger studies with satisfactory statistical tools were required to certify this approach. Furthermore, this was a single-center experimental trial, and multicenter investigations that measure these outcomes' value are warranted. Additionally, more accurate procedures, for example, cardiac magnetic resonance imaging (MRI), should have been used to assess cardiac functions and myocardial perfusion in future studies.

Conclusion

Administration of intracoronary Tirofiban is associated with superior clinical prognosis in terms of TIMI flow and myocardial blush grades compared with non-administration in patients with STEMI undergoing PPCI.

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