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RESEARCH ARTICLE

Efficacy and safety of tirofiban as an adjunctive therapy in patients with acute ST-segment elevation myocardial infarction undergoing percutaneous transluminal coronary angioplasty

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ABSTRACT

Background: The introduction of stents and the use of platelet glycoprotein IIb/IIIa inhibitors, either alone or in combination with reduced-dose fibrinolytic therapy, has allowed percutaneous coronary intervention (PCI) to be performed more safely and synergistically following pharmacologic reperfusion therapy. **Aims and Objectives:** The present study was conducted to evaluate the efficacy and safety of tirofiban as an adjunct to angioplasty/stenting in acute ST-elevation myocardial infarction (MI) patients. **Materials and Methods:** A total of 156 consecutive patients diagnosed with acute ST-segment elevation MI (STEMI) presenting within 12 h of symptoms were randomly allocated to primary PCI alone or primary PCI along with tirofiban. Clinical characteristics, angiographic findings (including thrombolysis in MI [TIMI] flow rate), and ST-segment resolution were compared post-procedurally; left ventricular ejection fraction (LVEF) and major adverse cardiac events (MACE, including death, reinfarction, and target vessel revascularization) were compared at 30 days clinical follow-up. **Results:** Post-procedurally, TIMI Grade 3 reflow was significantly different between two groups ($P = 0.01$) and was associated with better in-hospital outcomes in tirofiban group compared with control group. Greater resolution of ST-elevation was achieved in patients given tirofiban than in non-tirofiban group, and the results were highly significant. Statistically significant improvement in LVEF was also observed in tirofiban group. There was non-significant difference in MACE and bleeding complications between two groups. **Conclusion:** Adjunctive tirofiban therapy for patients with acute STEMI, who underwent primary PCI, seems to be safe and effective treatment modality to achieve improved reperfusion, better LVEF, and clinical outcome at 30 days follow-up.

KEY WORDS: Tirofiban; Percutaneous Coronary Intervention; ST-segment Elevation Myocardial Infarction

INTRODUCTION

Ischemic heart disease accounts for the majority of deaths among men and women in the whole world, with acute myocardial infarction (MI) as the leading cause with 8-10% urban prevalence and 3-4% rural prevalence in India.[1] According to recent guidelines, primary percutaneous coronary intervention (PCI) is now the first therapeutic option for acute ST-segment elevation MI (STEMI) patients within 12 h of onset of symptoms.[2,3] However, even successful PCI sometimes fails to avoid myocardial damage and is associated with adverse clinical outcome.[4] In addition, platelet reactivity is pivotal in the pathogenesis of complications after PCI.[5] The introduction of stents and the use of platelet glycoprotein (gp) IIb/IIIa inhibitors, either alone or in combination with

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reduced-dose fibrinolytic therapy, has allowed PCI to be performed more safely and synergistically. Inhibitors of gp IIb/IIIa receptor are potent antiplatelet agents and act by a mechanism distinct from that of aspirin or thienopyridine platelet inhibitors. There are three gp IIb-IIIa receptor inhibitors currently in clinical use: Abciximab, eptifibatide, and tirofiban.[6] Tirofiban stands out as a useful adjunct to PCI because it is a small non-peptide molecule and does not elicit an adverse immune reaction.[7] Immediate onset, rapid reversal of antiplatelet activity after drug discontinuation, suitability for multiple repeat administration, and high specificity for IIb/IIIa receptors are its major advantages. Therefore, this study was planned to evaluate the efficacy and safety of tirofiban as an adjunct to percutaneous transluminal coronary angioplasty (PTCA) to generate productive data which will help in determining the relative advantage offered by tirofiban in these patients.

MATERIALS AND METHODS

The present randomized, parallel group, prospective study was conducted by the Post-graduate Department of Pharmacology and therapeutics in collaboration with the Department of Cardiology, Government Medical College (GMC) Jammu, a tertiary care hospital for a period of 1-year. Proper Institutional Ethics Committee approval was obtained before commencing the study. Written informed consent was obtained from the participants.

Patients with STEMI within 12 h of symptom onset in the age group of 18-70 years of both sexes, who were to undergo PTCA, were considered eligible for inclusion in the present study. Patients with cardiogenic shock, intra-aortic balloon pump, serum creatinine >2.5 mg/dl, hemoglobin (Hb) <9 g/dl, and bleeding diathesis were excluded from the study. Other exclusion criteria were history of stroke within 30 days before hospitalization or any history of hemorrhagic stroke, known history of intracranial disease/ intracranial neoplasm, active ongoing or recent clinical bleeding or bleeding diathesis, administration of gp IIb/IIIa inhibitors in previous 2 weeks, malignant hypertension, previous stroke in last 6 months, major surgery within the previous 6 weeks, thrombocytopenia (platelet count <100,000/mm^3), severe liver failure and allergy or intolerance to drugs received.

A total of 156 patients were assessed for eligibility, and 43 patients were excluded from the study for various reasons: 18 males and 14 females had no or non-significant coronary artery disease (CAD), and 11 males were not willing for the procedure. 113 patients were randomized into two groups: Group A (non-tirofiban), 43 patients and Group B (tirofiban), 70 patients. 8 patients were lost to follow-up in Group A and 19 patients were lost to follow-up in Group B and could not be traced. 86 patients finally completed the study and were analyzed: 35 in the Group A (non-tirofiban) and 51 in the Group B (tirofiban).

Complete history and demographic features were recorded in all the patients and included the history of hypertension, diabetes mellitus, dyslipidemia, smoking, family history of CAD including premature CAD in the patient as well as family. The patients were also subjected to complete physical examination and relevant laboratory investigations including hematological profile, hepatic profile, renal parameters, electrocardiogram (ECG), and X-ray (Chest-skiagram). ECG recordings were done in the emergency room and 2 h after primary PCI. ST-segment elevation in millimeters was measured 20 millisecond after the J point. The sum of ST-segment elevations was determined in leads I, aVL, and V1 through V6 for anterior infarction and in leads II, III, aVF, V5, and V6 for inferior infarction. The sum of ST-elevation 2 h post-PCI is subtracted from the sum of ST-elevation in first ECG, and the difference between the two measurements was termed as the resolution of the ST-segment elevation, and the average of all the readings in each group was taken as mean resolution of the sum of ST-segment elevation.

Patients upon admission were managed in accordance with the protocol followed by the Department of Cardiology, GMC, and were administered baseline medications which included the administration of aspirin (150 mg), clopidogrel (300 mg), and statin (atorvastatin 40-80 mg) 4 h before the procedure. Unfractionated heparin at 100 IU/kg body weight was also administered. Beta-blockers, angiotensin converting enzyme-inhibitors were continued if the patient was already on these drugs. Patients in Group A (non-tirofiban) got their lesions angiographied and underwent PTCA only while the patients in comparator Group B (tirofiban group) got gp IIb/IIIa inhibitor drug tirofiban before being subjected to PTCA. Tirofiban was administered in the strength of 5 mg/100 ml. A 30-40 ml bolus (1500 µg) (25 µg/kg) was administered at the start of the procedure. This was followed by 0.15 µg/kg/min infusion (250-300 ml) for next 24-48 h.

Then, the two groups of patients were followed for a period of 1-month and were analyzed for various outcome features. Efficacy was assessed based on outcomes including ST-segment resolution (STR) in ECG, thrombolysis in MI (TIMI) Grade 3 flow percentage, and left ventricular ejection fraction (LVEF), chest pain, re-hospitalization due to non-STEMI/STEMI, cardiovascular system related deaths were also observed. Safety was assessed in accordance with the occurrence of various adverse events including major and minor hemorrhages, cardiovascular system related death, cerebrovascular events such as intracerebral hemorrhage and other adverse events. Hemorrhagic events were classified

as major or minor by use of standard TIMI definitions,[8] a clinically overt hemorrhage with a Hb drop of >5 g/dL was considered major, and a clinically overt hemorrhage with a Hb drop of 3-5 g/dL was considered minor.

Statistical Analysis

Data were analyzed with the help of computer software Microsoft Excel and Statistical Package for Social Sciences (SPSS) version 12.0 for Windows. Continuous variables are presented as mean and standard deviation, whereas categorical variables are presented as percentages. Baseline comparability was assessed with the help of appropriate statistical test. Independent *t*-test and Chi-square test were used to evaluate statistical significance in means and proportions between two groups. A $P < 0.05$ was considered statistically significant. All the *P* values reported are two-tailed. The analysis was conducted in accordance to intention to treat analysis.

RESULTS

The two groups were well matched with respect to baseline characteristics and key angiographic features (Tables 1 and 2). There were significant differences in the outcomes between the two groups with respect to pre- and post-procedural TIMI Grade 3 flow of infarct-related artery, resolution of the sum of ST-segment elevation, and average hospital stay. The major adverse cardiac events (MACE) rate at 30 days was reduced, and LVEF was higher in tirofiban group than the non-tirofiban group.

TIMI Flow Rate

TIMI flow rate percentage between two groups before the procedure was nearly similar. After procedure, TIMI Grade 3 reflow (non-tirofiban: 85.71% and tirofiban: 98%) was significantly significant different between two groups with a $P = 0.01$ (highly significant) and was associated with better in-hospital outcomes in tirofiban group compared with control group (Figure 1).

ECG and Echocardiographic Assessments

Greater resolution of ST-elevation was achieved in patients given tirofiban than in non-tirofiban group, and the results were highly significant. Mean STR being 10.4 ± 3.04 mm in tirofiban group versus 5.3 ± 2.14 mm in non-tirofiban group ($P = 0.0001$; Table 3). Statistically significant improvement in LVEF was also observed in tirofiban group than the non-tirofiban group and was also associated with better patient outcomes (Table 3).

Safety Parameter Assessment

The rate of major bleeding and thrombocytopenia did not differ significantly between the two groups. There were no statistically significant differences in 30 days mortality or combined major cardiac events between the study and control group patients (Tables 4 and 5).

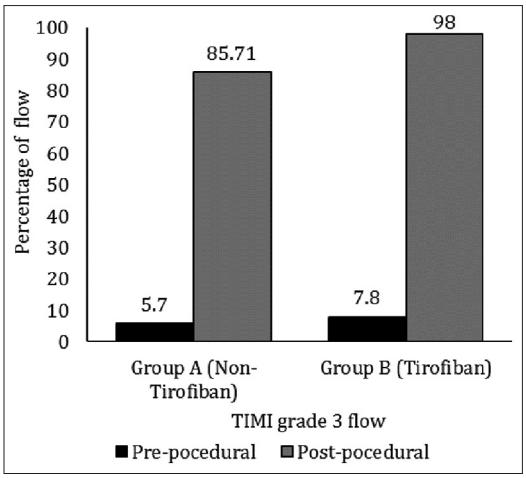

Figure 1: Pre- and post-procedural thrombolysis in myocardial infarction Grade 3 flow in both groups

Table 1: Baseline characteristics of two groups

Characteristic	Nontirofiban (A) (*n*=35)	Tirofiban (B) (*n*=51)	Statistical inference
Age (years) (mean±SD)	48.5±9.5	52.4±10.3	NS
Gender			
Males - *n* (%)	26 (74.28)	37 (72.5)	NS
Females - *n* (%)	09 (25.71)	14 (27.45)	NS
Weight (kg) (mean±SD)	54.8±61	56.2±5.9	NS
Prior MI	11 (31.42)	19 (37.25)	NS
Current smoker *n* (%)	19 (54.28)	26 (50.98)	NS
Diabetes mellitus *n* (%)	7 (20)	12 (23.53)	NS
Hypertension (%)	10 (28.57)	17 (33.33)	NS
Hyperlipidemia (%)	16 (45.71)	27 (52.94)	NS

Diabetes mellitus: 2 abnormal fasting plasma determinations ≥126 mg/dl (7 mmol/L). Hyperlipidemia: Elevated of total cholesterol (≥200 mg/dl) or elevated low density lipoprotein (≥160 mg/dl). Hypertension: systolic blood pressure ≥140 mmHg or diastolic blood pressure ≥90 mmHg on 2 occasions. Current smoker: Currently smokes cigarettes daily or occasionally. NS: Non significant, SD: Standard deviation, MI: Myocardial infarction

DISCUSSION

The present study shows that in patients with STEMI, routine pre-procedural initiation of tirofiban, a gp IIb-IIIa inhibitor in addition to aspirin, heparin, and clopidogrel improves STR after PCI. This finding was associated with an improved outcome free from adverse angiographic or clinical events at 30 days follow-up without a significant increase in major bleeding. According to the current guidelines, the major goal of treatment for acute STEMI is to achieve rapid and complete restoration of myocardial reperfusion and sufficient blood supply of the myocardium. Optimal timing of reperfusion is extremely crucial for limiting infarct size and improving left ventricular function and clinical outcomes.[9] Platelets play an integral role in the formation of thrombus in acute coronary syndrome, during and after PCI and thrombotic complications following it.[10] Results from many studies suggested that platelet gp IIb/IIIa inhibitors could safely and significantly improve reperfusion of infarct area and clinical outcomes of patients with STEMI.[11-13]

Table 2: Angiographic features of patients at baseline

Characteristic *n* (%)	Nontirofiban (A) (*n*=35)	Tirofiban (B) (*n*=51)	Statistical inference
Acute anterior MI	18 (51.42)	28 (54.9)	*P*=0.81, NS
Acute inferior MI	12 (34.28)	18 (35.29)	
Other	5 (14.28)	5 (9.8)	
LAD	17 (48.57)	27 (52.94)	*P*=0.4, NS
LCX	6 (17.14)	6 (11.76)	
RCA	12 (34.28)	18 (35.29)	

NS: Non significant, MI: Myocardial infarction, RCA: Right coronary artery, LAD: Left anterior descending

Angiographic results of our study suggest that administration of tirofiban along with PCI improves TIMI flow Grade 3 following primary PCI. There is a nearly linear correlation between higher rates of early TIMI Grade 3 flow and improved survival, regardless of whether reperfusion is achieved with thrombolysis or primary PCI.[14] The results of studies[11,15,16] are also in conformity with our study.

Improvement in LVEF percentage was another positive finding of our study. LVEF is the fraction of the left ventricular end-diastolic volume that is ejected with each beat with the normal adult value being 0.55-0.70. Gain in LVEF reflects the ultimate functional improvement that can be achieved with this procedure. Left ventricular performance parameters 1 week after PCI were much more improved in tirofiban group than those in the placebo group.[17] Improvement in LVEF in the tirofiban group at 30 days following PCI was also observed by other studies.[2,16,18-20]

Another important finding in our study was statistically significant improvement in STR in patients in tirofiban group than those in the non-tirofiban group. This meant that much clinically significant advantage could be achieved by the administration of tirofiban along with PTCA. ST-elevations >0.1 mV in a limb lead or >0.2 mV in a precordial lead was considered significant.[21] The importance of ST-resolution has also been shown in a study by Shah and others.[22] When grouped according to ST-segment elevation resolution

Table 3: Comparison of ST-segment changes and LVEF in two groups

Parameter	Nontirofiban (A) (*n*=35)	Tirofiban (B) (*n*=51)	*t*-test	Statistical inference
Sum of ST-elevation before procedure (mm) (mean±SD)	13±2.9	14.5±3.8	1.9	*P*=0.051, NS
Sum of ST- elevation after procedure (mm)	7.7±2.9	4.11±1.19	6.94	*P*=0.0001, HS
∑STR (mm) (mean±SD)	5.3±2.14	10.4±3.04	8.56	*P*=0.0001, HS
LVEF % at 30 days (mean±SD)	0.46±0.09	0.51±0.07	2.89	*P*=0.004, HS

NS: Non significant, SD: Standard deviation, LVEF: Left ventricular ejection fraction, HS: Highly significant

Table 4: Safety parameters

Parameter	Nontirofiban (A) (*n*=35)	Tirofiban (B) (*n*=51)	Statistical inference
Preprocedural Hb (mean±SD)	10.4±1.5	10.1±1.2	NS
Postprocedural Hb (mean±SD)	9.02±103	8.9±1.3	NS
Hb fall >5 g/dl	1 (2.8)	2 (3.9)	NS
Hb at 30 days (g/dl) (mean±SD)	9.6±1.18	9.53±0.77	NS
Preprocedural platelet count (mean±SD)	2.38±0.36 lacs/mm^3	2.46±0.4	NS
Postprocedural platelet count (mean±SD)	1.96±0.1 lacs/mm^3	1.91±0.13	NS
Thrombocytopenia (<100,000/mm^3) at 12 h	1 (2.8)	2 (3.9)	NS
Platelet count at 30 days (mean±SD)	1.88±0.33	1.74±0.38	NS
Severe thrombocytopenia (<50,000/mm^3)	0	0	NS

NS: Non significant, SD: Standard deviation, Hb: Hemoglobin

Table 5: MACE and bleeding complications at 30 days

Parameter	Nontirofiban (A)	Tirofiban (B)	Statistical inference
Combined 30-day MACE (%)	6 (17.14)	2 (3.9)	*P*=0.057, NS
Death (%)	3 (8.6)	2 (3.9)	*P*=0.39, NS
Nonfatal MI (%)	3 (8.6)	0	*P*=0.06, NS
TVR (%)	3 (8.6)	0	*P*=0.06, NS
Bleeding complications at 30 days *n* (%)	4 (11.4)	7 (13.7 year)	*P*=1, NS

NS: Non significant, MI: Myocardial infarction, MACE: Major adverse cardiac events, TVR: Target vessel revascularization

characteristics, patients whose ST-segment elevation resolved had significantly lower incidence of the mortality than those whose ST-segment elevation persisted. Very similar results have been found out by other studies.[23,24]

Thrombocytopenia and bleeding are potential adverse effects of gp IIb-IIIa receptor antagonists. In our study, MACE and other complications after PCI in tirofiban regimen were also not significantly different from those in the non-tirofiban group. These values appear to correlate with preserved efficacy and enhanced safety. These results are also in concordance with study[25] which showed that there was no statistically significant rise in thrombocytopenia or major bleeding associated with tirofiban despite the concomitant use of aspirin and heparin.

CONCLUSION

The present study shows that in patients with STEMI, routine pre-procedural initiation of tirofiban, a gp IIb/IIIa inhibitor in addition to aspirin, heparin, and clopidogrel improves STR after PCI. This finding was associated with an improved outcome free from adverse angiographic or clinical events at 30 days follow-up without a significant increase in major bleeding.

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