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Randomized Controlled Trial of Rivaroxaban Plus Dual Antiplatelet Therapy versus Dual Antiplatelet Therapy Alone for Prevention of Left Ventricular Thrombus Formation after Acute Myocardial Infarction

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Abstract

Background: Left ventricular thrombus (LVT) is a serious complication of ST-segment elevation myocardial infarction (STEMI), especially in patients with reduced left ventricular systolic function. This study aimed to evaluate the efficacy and safety of low-dose rivaroxaban in addition to dual antiplatelet therapy (DAPT) for prevention of LVT formation after STEMI. **Methodology:** This randomized controlled trial was conducted at the Department of Cardiology, Jinnah Hospital Lahore, over six months. A total of 174 patients with acute STEMI and left ventricular ejection fraction <40% were enrolled and randomly divided into two equal groups. Group A (n=87) received standard DAPT, while Group B (n=87) received rivaroxaban 2.5 mg twice daily in addition to DAPT. Follow-up transthoracic echocardiography was performed after 30 days to assess LVT formation. **Results:** LVT developed in 15 patients (17.2%) in Group A compared with 5 patients (5.7%) in Group B (p=0.021). Patients with ejection fraction ≤30% showed significantly higher rates of LVT formation. Minor bleeding events were comparable between groups, while major bleeding complications were rare. **Conclusion:** Low-dose rivaroxaban added to standard DAPT significantly reduced LVT formation without increasing major bleeding complications, suggesting a safe and effective preventive strategy in high-risk STEMI patients.

1. INTRODUCTION

Despite significant developments in cardiovascular medicine, acute ST-segment elevation myocardial infarction (STEMI) still contributes to morbidity and mortality globally (Akbar and Sharma, 2024). The early reperfusion of the myocardium is the foundation of the management of STEMI, as early restoration of coronary flow will reduce the size of the infarct, preserve left ventricular function and enhance survival (Thomas et al., 2025). In developing countries, primary PCI is not always promptly performed because access to specialized cardiac centers is limited and patients may

often be admitted to services later in the course of the disease, or they may receive a thrombolytic therapy instead of primary PCI because of these factors (Li et al., 2022). Suboptimal reperfusion and delayed presentation can cause severe myocardial damage, which can lead to left ventricular dysfunction (LVD), which is linked to the outcomes of the patient, recurrent hospitalizations, heart failure, and mortality (Trimarchi et al., 2024).

Acute anterior wall STEMI (AMWSTEMI) has been associated with left ventricular thrombus formation (LVT) in patients with severe left ventricular systolic dysfunction (LVSD) and left ventricular ejection fraction (LVEF) < 40% (Camaj et al., 2022). Blood stasis and endothelial damage of the left ventricle (LV) causes an increased risk of developing a thrombus if there are any large anterior infarction, apical akinesia, dyskinesia, or aneurysmal changes (Massussi et al., 2021). In spite of the advent of today's reperfusion therapies, a significant proportion of patients still develop LVT, particularly when reperfusion is delayed and/or the ventricle is poorly functioning. The clinical relevance of LVT is that it can result in systemic thromboembolism, ischemic stroke, peripheral arterial occlusion and elevated cardiovascular morbidity and mortality (Rodriguez et al., 2021).

After STEMI, aspirin and a P2Y12 inhibitor (DAPT) is commonly used to prevent recurrent ischemic events and prevent stent thrombosis (Andò et al., 2022). While warfarin has been traditionally utilized for prevention and treatment of LVT, it has some drawbacks such as a narrow therapeutic window, a need for regular laboratory checks, variable dose response, numerous food and drug interactions, and higher bleeding risk when used in combination with DAPT (Zhang et al., 2025). In patients receiving triple antithrombotic therapy (TAT), there is a high incidence of major bleeding events, which is difficult to manage for both clinicians and patients (Xu et al., 2025). Novel oral anticoagulants (NOACs), specifically rivaroxaban, have proved to be promising alternatives due to factors such as their predictable pharmacokinetics, fixed doses, minimal drug interactions, and reduced bleeding risk compared to warfarin, as discussed by Sahu et al. (2025). Previous studies have shown that low-dose rivaroxaban in combination with DAPT may reduce thrombotic events after ACS without causing significant bleeding events (Khan et al., 2020).

Although international evidence exists showing efficacy and safety of rivaroxaban in the prevention of thromboembolism, local evidence regarding the use of rivaroxaban in the prevention of left ventricular thrombus after STEMI is limited (Zhang et al., 2022). In addition, delayed presentation and left ventricular dysfunction still exist at a high rate in the developing countries like Pakistan (Zhang et al., 2024). Thus, the aim of this randomized controlled trial is to compare the incidence of left ventricular thrombus formation in cases of post myocardial infarction left ventricular dysfunction receiving rivaroxaban along with standard DAPT versus DAPT therapy alone (Shah et al., 2025). The results of this study could aid in developing a more effective and safer approach to the prevention of LVT in high-risk STEMI patients.

The objective of the present study was to compare the rate of left ventricular (LV) thrombus in patients with reduced left ventricular (LV) systolic function (LVEF < 45%) treated with rivaroxaban plus dual antiplatelet therapy (DAPT) versus DAPT alone. The authors suspected that rivaroxaban would prevent the development of left ventricular thrombus in STEMI patients with left ventricular dysfunction.

1.1. Operational Definitions

1.1.1. Left Ventricular Thrombus (LVT)

Left ventricular thrombus was defined as a discrete echo-dense mass within the left ventricular cavity with well-defined margins distinct from the endocardium, visualized throughout systole and diastole in at least two transthoracic echocardiographic views, commonly the apical and short-axis views.

1.1.2. ST-Segment Elevation Myocardial Infarction (STEMI)

STEMI was defined as ST-segment elevation of ≥1 mm in two or more contiguous electrocardiographic leads in the presence of elevated cardiac troponin levels above the 99th percentile upper reference limit.

1.1.3. Left Ventricular Dysfunction (LVD)

Left ventricular dysfunction was defined as left ventricular ejection fraction (LVEF) of less than 40% measured by transthoracic echocardiography using Simpson's biplane method.

1.1.4. Ischemic Event

An ischemic event was defined as radiological evidence of arterial thrombus formation associated with clinical signs and symptoms of arterial ischemia.

2. METHODOLOGY

2.1. Study Design

This study was designed as a randomized controlled trial to evaluate the efficacy of rivaroxaban in preventing left ventricular thrombus formation in patients with ST-segment elevation myocardial infarction (STEMI) and reduced left ventricular systolic function.

2.2. Study Setting

The study was conducted at the Department of Cardiology, Jinnah Hospital Lahore.

2.3. Duration of Study

The duration of the study was six months following approval from the institutional ethical review board.

2.4. Sample Size

A total of 174 patients were enrolled in the study. Among them, 87 patients were allocated to Group A and 87 patients were allocated to Group B.

2.5. Sampling Technique

Patients fulfilling the eligibility criteria were recruited through non-probability consecutive sampling. Eligible participants were subsequently assigned to either study group using computer-generated randomization in a 1:1 ratio.

2.6. Study Groups

a. Group A

Patients in Group A received standard dual antiplatelet therapy (DAPT) consisting of aspirin and clopidogrel.

b. Group B

Patients in Group B received rivaroxaban 2.5 mg twice daily in addition to standard DAPT.

2.6.1. Inclusion Criteria

Patients aged 20–80 years, both male and female, with acute ST-segment elevation myocardial infarction (STEMI), short duration myocardial infarction, and left ventricular systolic dysfunction (LVDF < 40%) on transthoracic echocardiogram were included.

2.6.2. Exclusion Criteria

Patients were excluded if they had a history of left ventricular thrombus, active bleeding, history of intracranial hemorrhage, ischemic stroke within the previous six months, clinically significant gastrointestinal bleeding, creatinine clearance < 30 mL per minute, decompensated chronic liver disease (Child-Pugh class B or C), body weight < 40 kg, pregnancy or lactation, malignancy, recent major surgery, atrial fibrillation that required therapeutic anticoagulation, prior receipt of anticoagulation therapy prior to STEMI, or known allergy/intolerance to rivaroxaban.

2.7. Data Collection Procedure

Each patient was screened by the Ethical Review Board (ERB) of Allama Iqbal Medical College/Jinnah Hospital Lahore and 174 patients were eligible for inclusion in

the study.After approval from the Ethical Review Board (ERB) of Allama Iqbal Medical College/Jinnah Hospital Lahore, the patients were assessed from the Department of Cardiology and emergency unit, 174 patients were found to be eligible. All participants provided written informed consent before being recruited to the study. A structured proforma was used to record demographic and clinical characteristics at baseline including age, gender, body weight, duration of myocardial infarction symptoms, comorbidities and left ventricular ejection fraction. Eligible patients were randomized to DAPT only (n = 87) or rivaroxaban plus DAPT (n = 87) within 48 hours of the onset of STEMI, by computer randomization with the ratio 1:1. Reperfusion therapy was used if appropriate and all STEMI patients were treated according to institutional guidelines.

Group A patients were treated with standard DAPT (aspirin and clopidogrel), and Group B patients with rivaroxaban 2.5 mg twice daily along with standard DAPT. All participants were followed for 30 days after enrollment. Patients were followed up for ischemic or bleeding events and advised to contact the clinic immediately if there were any complications. Transthoracic echocardiogram (TTE) was performed after 30 days of therapy to evaluate for development of left ventricular thrombus. Repeat echocardiogram and appropriate radiological studies were carried out early (when clinically relevant) in patients who developed symptoms suggestive of thromboembolic events.

2.8. Data Analysis

The data was entered and analyzed using Statistical Package for Social Sciences (SPSS) version 25. The data for quantitative variables (age, body weight, ejection fraction, and duration of symptoms) were expressed as mean ± standard deviation (SD). Gender, diabetes mellitus, hypertension, treatment groups and presence of left ventricular thrombus formation were presented as frequency and percentage for qualitative variables. The Chi-square test was used to compare the incidence of LVT in the two study groups. Where applicable, stratification was carried out with respect to demographic and clinical variables. P-values < 0.05 were regarded as significant.

3. Results

In total, 174 patients who met the inclusion criteria were enrolled in the study with two treatment groups. Group A (DAPT alone) consisted of 87 patients while Group B (Rivaroxaban plus DAPT) consisted of 87 patients. Both groups were similar in terms of basic demographic and clinical features. Transthoracic echocardiogram was repeated at 30 days to look for the formation of left ventricular thrombus (LVT).

Table 1: Baseline Demographic and Clinical Characteristics of Study Participants

Variable	Group A (DAPT) n=87	Group B (Rivaroxaban + DAPT) n=87
Age (years), Mean ± SD	56.9 ± 8.8	55.3 ± 10.8
Male Gender, n (%)	44 (50.6%)	56 (64.4%)
Female Gender, n (%)	43 (49.4%)	31 (35.6%)
Weight (kg), Mean ± SD	70.2 ± 9.8	68.9 ± 12.0
Duration of Symptoms (hours), Mean ± SD	3.4 ± 1.1	2.7 ± 1.2
Ejection Fraction (%), Mean ± SD	32.3 ± 4.1	31.4 ± 5.4
Diabetes Mellitus, n (%)	44 (50.6%)	31 (35.6%)
Hypertension, n (%)	72 (82.8%)	46 (52.9%)

Table 1 shows the baseline demographic and clinical characteristics of the study participants. Overall, 174 patients were analysed: 87 patients in group A (DAPT only) and 87 patients in group B (Rivaroxaban plus DAPT). The mean age of patients in

Group A was 56.9 ± 8.8 years, while in Group B it was 55.3 ± 10.8 years. There was a majority of men in both groups (Group A, 50.6% and Group B, 64.4%). The mean body weight was 70.2 ± 9.8 kg in Group A and 68.9 ± 12.0 kg in Group B. The average duration of symptoms prior to presentation was 3.4 ± 1.1 hours in the DAPT group and 2.7 ± 1.2 hours in the rivaroxaban plus DAPT group. The mean LV EF was similar between the two groups, namely 32.3 ± 4.1% in Group A and 31.4 ± 5.4% in Group B; diabetes mellitus was present in 50.6% of patients in Group A and 35.6% in Group B, while hypertension was seen in 82.8% and 52.9% of patients, respectively. Overall, baseline characteristics were relatively similar between the two treatment groups.

Table 2: Distribution of Treatment Groups

Treatment Group	**Frequency (n)**	**Percentage (%)**
Group A (DAPT only)	87	50.0
Group B (Rivaroxaban + DAPT)	87	50.0
Total	**174**	**100**

Table 2 shows the distribution of study participants by treatment allocation. A total of 174 patients were enrolled in the study, of whom 87 (50.0%) were assigned to Group A (standard DAPT) and 87 (50.0%) were assigned to Group B (rivaroxaban plus standard DAPT). The balance between the two groups indicates good randomization and equal allocation of subjects.

Table 3: Incidence of Left Ventricular Thrombus (LVT) in Both Groups

Left Ventricular Thrombus	**Group A (DAPT) n=87**	**Group B (Rivaroxaban + DAPT) n=87**	**p-value**
Present	15 (17.2%)	5 (5.7%)	0.021
Absent	72 (82.8%)	82 (94.3%)	
Total	**87 (100%)**	**87 (100%)**	

The number of patients with LV thrombosis was compared between the two treatment groups in table 3. Left ventricular thrombus occurred in 15 (17.2%) individuals in Group A (DAPT only), and five (5.7%) patients in Group B (Rivaroxaban plus DAPT) during the 30-day follow-up period. The rivaroxaban plus DAPT group had a significantly lower rate of LVT than the DAPT-only group ($p = 0.021$). This finding indicates that rivaroxaban may decrease the likelihood of developing a thrombus in individuals with STEMI and low left ventricular systolic function.

Table 4: Stratification of Left Ventricular Thrombus According to Baseline Variables

Variable	**Category**	**LVT Present n (%)**	**LVT Absent n (%)**	**p-value**
Age Group	≤50 years	5 (8.9%)	51 (91.1%)	0.318
	>50 years	15 (12.7%)	103 (87.3%)	
Gender	Male	15 (15.0%)	85 (85.0%)	0.184
	Female	5 (6.8%)	69 (93.2%)	
Diabetes Mellitus	Yes	14 (18.7%)	61 (81.3%)	0.072
	No	6 (6.1%)	93 (93.9%)	
Hypertension	Yes	14 (11.9%)	104 (88.1%)	0.554
	No	6 (10.7%)	50 (89.3%)	
Ejection Fraction	≤30%	14 (22.2%)	49 (77.8%)	0.031
	>30%	6 (5.4%)	105 (94.6%)	
Body Weight	≤70 kg	10 (11.2%)	79 (88.8%)	0.911
	>70 kg	10 (11.8%)	75 (88.2%)	

Stratification of LVT formation by baseline demographic and clinical factors is shown in Table 4. Patients aged >50 years, males, diabetic patients, hypertensive patients, and patients with ejection fraction ≤30% had a higher rate of LVT. The formation of LVT was highest in patients with severe LVSD (EF ≤30%) and there was a statistically significant correlation with the presence of a thrombus (p = 0.031). The other stratified variables were not significantly associated with the development of LVT.

Table 5: Bleeding and Ischemic Events During Follow-up

Complication	Group A (DAPT) n=87	Group B (Rivaroxaban + DAPT) n=87	p-value
Minor Bleeding	5 (5.7%)	6 (6.9%)	0.752
Major Bleeding	1 (1.1%)	1 (1.1%)	1.000
Ischemic Events	5 (5.7%)	2 (2.3%)	0.244
Gastrointestinal Bleeding	0 (0%)	1 (1.1%)	0.315

Table 5 compares bleeding and ischemic complications observed during the 30-day follow-up period between the two treatment groups. Minor bleeding events were reported in 5 patients (5.7%) in Group A and 6 patients (6.9%) in Group B, with no statistically significant difference between the groups (p = 0.752). Major bleeding was rare and observed equally in both groups. Ischemic events occurred more frequently in the DAPT-only group compared to the rivaroxaban plus DAPT group. Although the addition of rivaroxaban was associated with a slight increase in minor bleeding events, it demonstrated a lower incidence of ischemic complications and left ventricular thrombus formation during follow-up.

DISCUSSION:

The present study showed that the rate of left ventricular thrombus (LVT) was lower in rivaroxaban plus dual antiplatelet therapy (DAPT) than in patients receiving DAPT alone. In the DAPT-only group, LVT developed in 15 patients (17.2%), while five patients (5.7%) in the rivaroxaban plus DAPT group developed LVT during the 30-day follow-up period. The difference between the two groups was statistically significant (p = 0.021), indicating that the use of low dose rivaroxaban might be beneficial for decreasing thrombus formation in patients with STEMI who have reduced LVEF.

The results of this study are consistent with the previously published trial by Zhang et al., which demonstrated a significant reduction in LVT formation with the addition of rivaroxaban to DAPT following anterior STEMI. In a previous study, LVT was seen in 0.7% of those who took rivaroxaban along with DAPT, but 8.6% of those who took DAPT alone were found to have LVT. In comparable fashion, the present study showed a significantly lower rate of LVT in the rivaroxaban group, reinforcing the role of possible benefit of the use of a combined anticoagulation strategy in high-risk patients with impaired left-ventricular function and who have suffered an STEMI.

Patients with anterior STEMI, reduced ejection fraction, apical akinesia, dyskinesia or aneurysmal changes have a specific high risk for occurrence of LVT. There was a significantly higher prevalence of LVT in patients with EF ≤30% than in those with EF >30% (p = 0.031). The finding is consistent with the known association between left ventricular systolic dysfunction and thrombus formation. Increased LVT rates have been previously reported in patients with large anterior infarction and left ventricular ejection fraction < 40%.

In terms of safety outcomes, the use of rivaroxaban did not lead to significant

differences in major bleeding complications. In the DAPT-only group, 5 patients (5.7%) had minor bleeding, while 6 patients (6.9%) in the rivaroxaban plus DAPT group had minor bleeding; no significant differences between the two groups. The rate of major bleeding between the groups was not significantly different, as were the rates of gastrointestinal bleeding; both were rare. The results indicate that low-dose rivaroxaban might be safely used in combination with DAPT in well-chosen patients. This is clinically relevant as traditional warfarin triple therapy has been shown to have many problems including frequent monitoring, interactions with other drugs and increased bleeding risk.

The results of this study are especially applicable to patients with STEMI in low-resource countries, where delayed presentation to hospital, less access to primary PCI and higher use of thrombolytics are prevalent. The factors lead to greater infarct size, more profound left ventricular dysfunction, and to a higher risk of LVT development. So, the use of low-dose rivaroxaban in combination with the standard DAPT could be a helpful preventive measure for certain high-risk patients.

The relatively larger number of patients (174) in the present study is considered as one of its merits when compared with previously done local studies. Participants were also randomly assigned to the treatment conditions, and there were an equal number of participants in both treatment conditions, which again increases the reliability of the results. But there are some restrictions to be noted. The study was done in one centre and followed up for a short period of 30 days. Moreover, cardiac MRI was not routinely used, and was less sensitive to detecting LVT. Prolonged multi-center trials with more follow-up are needed to ensure rivaroxaban's long-term effectiveness and safety in preventing left ventricular clot after STEMI.

CONCLUSION

Rivaroxaban plus dual antiplatelet therapy (DAPT) was associated with a significantly lower incidence of left ventricular thrombus formation compared with DAPT alone among patients with STEMI and reduced left ventricular systolic function. The patients who were treated with rivaroxaban showed a lower incidence of LVT formation with no significant increase in major bleeding events. These findings suggest that low-dose rivaroxaban in addition to standard DAPT may be an effective and relatively safe strategy for the prevention of left ventricular thrombus in high-risk STEMI patients. These findings should be confirmed by further large-scale multicenter studies with longer follow up

Conflict of Interest

The authors declare that there is no conflict of interest regarding the publication of this study.

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Ethical Approval

Ethical approval for this study was obtained from the Ethical Review Board of Allama Iqbal Medical College/Jinnah Hospital Lahore prior to commencement of the study.

Informed Consent

Written informed consent was obtained from all participants before enrollment in the study.

Authors' Contribution

All authors contributed significantly to the conception, design, data collection, analysis, manuscript writing, and final approval of the manuscript.

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