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## **Risk stratification and anticoagulation strategies for post-PCI management in acute myocardial infarction patients with severe left ventricular dysfunction**

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**Abstract**--Background: Acute myocardial infarction (AMI) can result in severe left ventricular dysfunction (LVD) and cardiac failure, increasing risk of complications like stroke, thrombo-embolism, and recurrent AMI. Appropriate anticoagulation strategies are crucial for mitigating adverse events. The risk stratification of these patients involves evaluating their propensity for thrombotic and hemorrhagic events. Objectives: The study determined risk stratification and anticoagulation strategies for AMI patients with severe LVD post-PCI. Methods: At a tertiary hospital in Peshawar Pakistan, an investigation was conducted on 300 patients who presented with anterior AMI and 40% LVEF upon admission. Group A received anticoagulant therapy

as part of their post-PCI management, whereas Group B received standard post-PCI management without anticoagulant therapy. Various risk scores, including CHA<sub>2</sub>DS<sub>2</sub>-VASc and HAS-BLED score, and major adverse cardiovascular events, were used in assessing patient's risk of thrombosis events of bleeding through risk stratification. Results: Mean age of patients was 63.47±8.19 years, mean BMI was 28.76±3.0 and 193/300 (64.33%) were females. Hypertension, hyperlipidemia and diabetes were the prevailing comorbidities ( $p<0.05$ ) among the subjects. CHA<sub>2</sub>DS<sub>2</sub>-VASc scores classified patients into low-risk group (29.33%), medium risk (59.66%) and high-risk cohort (11%). HAS-BLED scores of Group A were comparatively higher and incidence of MACE was significantly lower in Group A treated with anticoagulants after PCI than RCT group. Conclusion: Patients who received anticoagulant therapy had higher risk of bleeding but a substantially lower incidence of MACE and mortality than those who did not. These results highlighted the relevance of individualized anticoagulation strategies based on risk stratification for improving outcomes in AMI patients with severe LVD following PCI. Validation and optimization of these strategies require additional study.

**Keywords**--CHA<sub>2</sub>DS<sub>2</sub>-VASc score, embolus, HAS-BLED score, stroke, thrombotic events.

## Introduction

Acute myocardial infarction is a prevalent cardiovascular condition that can result in severe LVD and heart failure. LVD is characterized by the incapacity of the left ventricle of the heart to efficiently pump blood, consequently lowered cardiac output and promoting morbidity and mortality<sup>1</sup>. In addition to cardiac failure, recurrent AMI, stroke, and thrombo-embolism, severe LVD is associated with an increased risk of adverse cardiovascular measures. To reduce risk of adverse outcomes in AMI patients with severe LVD, appropriate anticoagulation strategies are crucial<sup>2</sup>.

Since 1977, significant progress has been made in PCI. Utilizing lower profile balloons, bare-metal stents, drug-eluting stents, enhanced guidewire support, adjuvant drugs, and hemodynamic support devices has improved its short- and long-term outcomes. It has reduced mortality rates, limited infarct size and preserved LV systolic function in STEMI patients<sup>3-4</sup>. But research has revealed that 1/3<sup>rd</sup> of patients undergoing PCI suffered from LV dysfunction. Consequently, risk stratification and LVEF evaluation prior to PCI are essential. However, these evaluations are frequently overlooked, with only 46% of PCI patients ever obtaining LV classification. The primary reason for this is the need for prompt intervention in ACS, which leaves insufficient time for a comprehensive clinical assessment prior to PCI<sup>5</sup>. CHF contributes rise in morbidity and mortality following STEMI PCI, making it imperative to identify high-risk patients for more appropriate post-infarction therapies. Even in the context of ACS, we believe that LV assessment can aid in patient risk

stratification. This facilitates appropriate revascularization and ensures preoperative awareness of the high-risk nature of the surgery<sup>6-8</sup>.

Antithrombotic therapy is an integral part of the management of patients with AMI. To restore blood flow to the heart, PCI is a common revascularization procedure performed on AMI patients. Antithrombotic therapy, including aspirin and P2Y12 inhibitors, is a crucial aspect of AMI patients' post-PCI management. However, antithrombotic therapy increases the risk of hemorrhage<sup>9-11</sup>. Anticoagulation strategies for post-PCI management included the use of anticoagulant drugs like heparin, enoxaparin, bivalirudin, or fondaparinux, in addition to antiplatelet therapy with drugs like aspirin, clopidogrel, ticagrelor, or prasugrel<sup>12-13</sup>. Individual patient characteristics, such as age, comorbidities, and bleeding risk, should guide the selection of anticoagulant and antiplatelet therapy<sup>14</sup>. Overall, risk stratification and the appropriate selection of anticoagulation and other management strategies are essential for optimizing outcomes in AMI patients undergoing PCI who have severe LVD<sup>15-16</sup>.

A certain amount of research has been conducted on risk stratification and anticoagulation strategies for post-PCI management of AMI patients with severe LVD. But lack of consensus regarding the optimal anticoagulation strategy for post-PCI management of AMI patients represents a research lacuna. While anticoagulation therapy reduces menace of thrombotic events, it increases the risk of bleeding, especially in patients with a high risk of hemorrhage. In management of AMI patients with severe LVD, risk stratification and selection of anticoagulation strategies are crucial. While short-term outcomes, such as mortality and morbidity, have been studied, long-term outcomes have not been thoroughly investigated. Therefore, our investigation determined the most appropriate model for predicting the risk of thrombotic events and hemorrhages in AMI patients with severe LVD and examined efficacy and protection of various anticoagulation strategies, such as DAPT, VKA and DOAC, in the post-PCI management of AMI patients with severe LVD. It developed evidence-based recommendations for the selection of appropriate anticoagulation strategies and contributed to the improvement of post-PCI management to reduce the risk of adverse outcomes, such as heart failure, recurrent AMI, stroke, and thromboembolism, by addressing these objectives.

## **Material and Methods**

A randomized control investigation was conducted in Medical Training Institute, Lady Reading Hospital, Peshawar, Pakistan from January 2021 to December 2021 comprising 300 patients presented with anterior AMI and LVEF and underwent PCI. Patients in Group A (Anticoagulant Group) received anticoagulant therapy for post-PCI management and in accordance with established protocols, anticoagulant therapy was administered to patients in this cohort based on guidelines and clinical practice, the specific anticoagulant agent, dosage, and route of administration was determined, while participants of Group B received standard post-PCI management without anticoagulant therapy.

Diagnosis of AMI was through ECG based on identification of specific changes in the ECG pattern. ST-segment elevation in the leads corresponded to anterior wall

of left ventricle, namely leads V1 to V6 and leads I and aVL, which was suggestive of anterior AMI. Within the first few hours of symptom onset, the ST-segment elevation was typically accompanied by reciprocal ST-segment depression in inferior leads (II, III, and aVF). Q waves, T-wave inversion, and pathological Q waves indicated myocardial necrosis and scar formation, and served as additional ECG alterations present in anterior AMI, ST elevation in other leads, like right precordial leads (V1 and V2) or high lateral leads (I and aVL), indicated involvement of right ventricle or lateral wall of left ventricle, respectively.

Stratification of risk means assessing the patient's risk of thrombotic events and hemorrhage is required for risk stratification of AMI patients with severe LVD. Several risk scores, including CHA2DS2-VASc and HAS-BLED score, can be used for evaluating the patient's risk. Patients with CHA2DS2-VASc score of 2 or higher are deemed to having substantial risk of stroke and may require anticoagulation therapy.

Table 1  
CHA2DS2-VASc score chart

S. No	Risk Factor	Score
1	Congestive Heart Failure	1
2	Hypertension	1
3	Age 75 years or older	2
4	Diabetes Mellitus	1
5	Stroke or TIA or Thromboembolism history	2
6	Vascular disease (prior myocardial infarction, peripheral artery disease, aortic plaque)	1
7	Age 65-74 years	1
8	Sex category (female)	1

The total score ranges from 0 to 9, with higher scores indicating an increased risk of stroke in patients with NVAf.

The HAS-BLED score is used to anticipate the bleeding risk in anticoagulation therapy patients. The score takes into account many risk factors, including hypertension, abnormal liver and renal function, history or predisposition to bleed, stroke, an INR that fluctuates, age, and the use of medications or alcohol.

Table 2  
HAS-BLED score chart

S. No	Risk Factor	Score
1	Hypertension	1
2	Abnormal renal and liver function	1 or 2
3	Stroke history	1
4	Bleeding history or predisposition to bleeding	1 or 2
5	Labile international normalized ratio (INR)	1 or 2
6	Elderly (age > 65 years)	1
7	Drugs or alcohol use	1

The total score can range from 0 to 9, with a higher score indicating a greater risk of hemorrhage in anticoagulation-treated patients. The HAS-BLED score is utilized to evaluate the risk of bleeding in atrial fibrillation patients receiving anticoagulation therapy. For hemorrhage complications, a score of 0 or 1 is considered low risk, a score of 2 is considered intermediate risk, and a score of 3 or higher is considered high risk. Anticoagulation therapy with oral anticoagulants like warfarin or DOACs must be closely monitored in patients with a high HAS-BLED score, and the benefits of anticoagulation must be evaluated against the risk of bleeding.

Anticoagulation techniques involve antithrombotic agents, such as aspirin, P2Y12 inhibitors, and anticoagulants are utilized in AMI patients with severe LVD as part of anticoagulation strategies. The selection of anticoagulant therapy is contingent upon risk of patient's thrombotic events and hemorrhage. DAPT refers to dual antiplatelet therapy, comprising aspirin and a P2Y12 inhibitor, the cornerstone of antithrombotic therapy for post-PCI management of AMI patients. DAPT decreases the possibility of stent thrombosis and recurrent MI. Nonetheless, DAPT increases the risk of hemorrhage, especially in patients with a high risk of bleeding. Consequently, duration of DAPT should be tailored to the patient's risk of thrombotic events and hemorrhage. Other strategies involve Vitamin K Antagonists (VKA), DOACs (Direct Oral Anticoagulants) such as dabigatran, rivaroxaban, and apixaban that are safe and efficacious alternatives to VKA for the prevention of stroke. Baseline characteristics and procedural details of AMI patients were statistically analyzed. Continuous variables were depicted as Mean+SD for normal distributions. The frequency and percentage of categorical variables were displayed. ANOVA for continuous variables and chi-square test for categorical variables was employed. Institutional ethical approval was granted for this study.

## Results

We evaluated risk stratification and anticoagulation strategies for patients with AMI and severe LVD after PCI. The investigation included 300 patients with anterior AMI and LVEF of 40% upon admission. Patients were separated into two groups for post-PCI care. Group A received anticoagulant treatment, whereas Group B received standard post-PCI care without anticoagulation. Several risk scores, including CHA2DS2-VASc and HAS-BLED score, and MACE, were utilized to evaluate the efficacy of the anticoagulation strategy. These risk scores assisted in determining the propensity for thrombotic events and hemorrhage complications among patients.

Mean age of patients was 63.47+8.19 years, body mass index was 28.76+3.0, and the standard deviation was 3. The p-value (0.00001) indicates that there is a significant relationship between BMI and the outcome. 46% of the total number of patients were smokers, 26.33 percent of the patients had diabetes and sixty-eight percent of the patients had hypertension. Thirteen percent of patients had a family history of this cardiovascular condition. Overall, variables of age, BMI, smoking, diabetes, and hypertension were significantly associated ( $p < 0.05$ ) with the investigated outcome (Table 3). Prevalence of various comorbidities among the sample population was also recorded indicating that 76% of the patients had

hypertension, indicating the highest prevalence ( $p < 0.05$ ) of this comorbidity within the study population. 55% had hyperlipidemia, and 37% had diabetes mellitus, implying a substantial proportion of individuals with this metabolic condition. These comorbidities emphasized the patients' complex health profiles and affected their management and treatment strategies (Figure 1).

CHA2DS2-VASc scores of the study participants were classified into three risk categories: low, moderate, and high risk. To assess statistical significance for the differences between the groups, the F-value and p-value was acquired. The low-risk group comprised 88 (29.33%) of the total patient population, medium risk consisted 179 (59.66%) patients, and high-risk cohort consisted of 33 (11%) patients (Table 4). The distribution of participants in the experimental and control groups according to their HAS-BLED scores is shown in Table 5. Group A had 31 participants in the low-risk category (HAS-BLED scores 0-2), while Group B had 47 participants. Group A had 55 participants and Group B had 48 participants in the medium-risk category (HAS-BLED scores 3 to 5). Group A had 71 participants in the high-risk category (HAS-BLED scores  $>5$ ), while Group B had 55 participants (Table 5).

The MACE within 30 days of PCI in Group A and B was comparatively evaluated and it was seen that Group A experienced 13 fatalities (8.66%), while Group B experienced 15 deaths (10%). Group A experienced 16 recurrent MIs (10.66%), while Group B experienced 21 recurrent MIs (14%). Group A had 13 instances of revascularization (8.66%), while Group B had 17 cases (11.33%). Group A had two strokes (1.33%), while Group B had eleven strokes (7.33%). According to the available data, there are no statistically significant differences between Group A and B in terms of incidence of fatalities, recurrent MIs, revascularization, and strokes within 30 days following PCI. The incidence of MACE was significantly lower in Group A treated with anticoagulants after PCI compared to the RCT group especially the incidence of stroke post-PCI was significantly ( $p < 0.05$ ) reduced by the implementation of anticoagulant strategies (Table 6).

Table 3  
Demographic data of patients

S. No	Variable	Value (Mean+SD)	p-value	Significance level
1	Age (years)	63.47+8.19	0.00001	Significant
2	BMI	28.76+3.92	0.00001	Significant
3	Smoking n(%)	138 (46.0)	0.0270	Significant
4	Diabetes n(%)	79 (26.33)	0.0010	Significant
5	Hypertension n(%)	204 (68.0)	0.00001	Significant
6	Family History n(%)	39 (13.0)	0.0650	Non-significant
7	Gender (Females) n(%)	193 (64.33)	0.3452	Non-significant

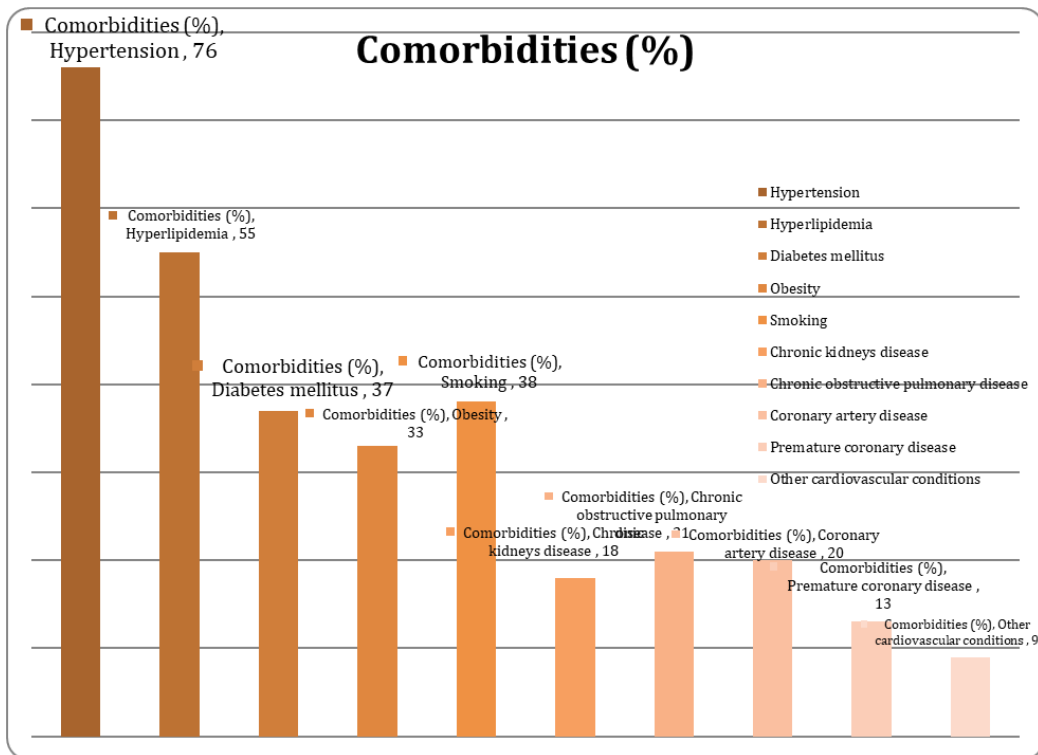


Figure 1. Medical history and comorbidities associated with AMI patients

Table 4  
CHA2DS2-VASc score results of the study patients

Groups	Low risk group	Medium risk group	High risk group	F-value	p-value
Scores	0-2	3-5	6-9	1812.33	0.00001*
Number of patients (n)	88	179	33		
Frequency (%)	29.33	59.66	11.0		

\*indicated the significant values at p<0.05

Table 5  
HAS-BLED scores of the participants in the experimental and control group

Groups	Group A n(%)	Group B n(%)	x2	p-value
Low risk (0-2)	31	47	2.2147	0.1367
Medium risk (3-5)	55	48	0.2313	0.6305
High risk (>5)	71	55	1.1898	0.2753

Table 6  
MACE of study groups 30 days post PCI

MACE	Group A n(%)	Group B n(%)	x2	p-value
Deaths	13 (8.66)	15 (10.0)	0.006	0.9384
Recurrent MI	16 (10.66)	21 (14.0)	0.2248	0.6354
Revascularization	13 (8.66)	17 (11.33)	0.1392	0.7091
Stroke	02 (1.33)	11 (7.33)	3.0469	0.8089

## Discussion

Based on their CHA<sub>2</sub>DS<sub>2</sub>-VASc scores, participants of this study were classified into three risk groups: low, moderate, and high. In addition, the participants were divided into two groups (Group A and Group B) according to their HAS-BLED scores, and the proportion of participants in each risk category was displayed. Group A and B were assessed for MACE within 30 days of PCI. Deaths, recurrent MI, revascularization, and strokes were evaluated as outcomes. The incidence of these outcomes was compared between the two groups. It was discovered that substantial difference between Group A, which received anticoagulants after PCI, and the control group (RCT group) in the incidence of MACE, particularly strokes was evident. The implementation of anticoagulant strategies reduced the incidence of stroke after PCI significantly ( $p < 0.05$ ). Moreover, the recurrent MI, revascularization and mortality rate was also lower in Group A than B. Patients bear mean age of 63.47±8.19 years, BMI of 28.76±3.0, and 193/300 (64.33%) of them were females. Among the patients, hypertension, hyperlipidemia, and diabetes were the most prevalent comorbidities ( $p < 0.05$ ). CHA<sub>2</sub>DS<sub>2</sub>-VASc scores categorized patients into low-risk (29.33%), medium-risk (59.66%), and high-risk (11%) groups. The incidence of MACE was considerably reduced in Group A treated with anticoagulants after PCI compared to the RCT group, which had lower HAS-BLED scores.

Our findings were in agreement with the study executed in China, whereby patients received PPAC (enoxaparin subcutaneously for 7 days). The primary endpoint was confirmed echocardiographic LVT at 30 days. Secondary endpoints were 30-day mortality, embolic events, and significant hemorrhage incidents<sup>17</sup>. Kontny et al. also investigated the prophylactic role of LMWH in AMI patients, treated with thrombolysis agents. Dalteparin addition during hospitalization significantly reduced the formation of LVT compared to placebo (13.8 vs. 21.9%)<sup>18</sup>. In one observational study, 5 days of PPAC plus DAPT following primary PCI in patients with anterior AMI was associated with a low incidence of LVT (4.7%)<sup>19</sup>. PPAC in STEMI patients undergoing post-PCI was associated with reduction in mortality without a rise in significant bleeding complications. Dedicated randomized trials utilizing modern STEMI management are required to corroborate these results<sup>20-21</sup>.

It was reported that anticoagulation was cornerstone of cardiovascular disease management. In the management of these disease states, strategies for anticoagulation that strike a balance between the risks of thrombus formation and clinically significant bleeding remained an intriguing area of active research,

as multiple new agents to optimize these risks become available for clinical use. In NSTEACS, anticoagulation with UFH or LMWH in addition to antiplatelet therapy likely reduced immediate adverse outcomes (angina, MI, emergent revascularization), whereas data supporting a sustained significant reduction in mortality are contradictory. Fondaparinux has been shown to have a superior safety profile compared to LMWH; however, its use has been limited by increased rates of catheter-associated thrombosis<sup>22-23</sup>.

## **Conclusion**

By balancing the risks of thrombus formation and clinically significant hemorrhage, anticoagulation plays a crucial role in managing cardiovascular ailments. Our research devised methods for optimizing this delicate equilibrium. In AMI patients, anticoagulation has shown to reduce adverse outcomes such as stroke, recurrent MI, and emergent revascularization. However, corroborating evidence for a sustained decline in mortality remains scant. Notably, the use of anticoagulants, specifically LMWH, is associated with high risk of catheter-associated thrombosis. Additionally, our study found that the experimental group had a marginally increased risk of hemorrhages. Consequently, caution should be exercised when contemplating the use of LMWH.

AMI patients with severe LVD had an increased risk of both thrombotic and hemorrhagic events. In the management of these patients undergoing PCI, risk stratification and anticoagulation strategy selection are essential. DAT remained cornerstone of antithrombotic therapy, and its duration should be individualized based on the patient's risk of thrombotic events and hemorrhage. It is crucial to managing AMI patients with severe LVD based on their risk profiles and clinical characteristics to reduce the risk of adverse outcomes. This personalized approach would help optimize anticoagulation strategies and strike the correct balance between thrombotic events and hemorrhage risk.

## **Limitations**

Addressing these limitations through larger, multicenter studies with randomized controlled designs would strengthen the evidence base and generate more conclusive findings regarding the risk stratification and anticoagulation strategies for AMI patients with severe LVD post-PCI.

## **Conflict of interest**

None.

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