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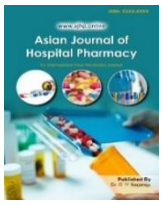

EVALUATION OF DUAL ANTIPLATELET THERAPY IN PATIENTS WITH MYOCARDIAL INFARCTION: SAFETY AND EFFICACY ANALYSIS

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Abstract
Myocardial infarction (MI) is a major cardiovascular emergency associated with myocardial ischemia and necrosis resulting from reduced coronary blood flow. Dual antiplatelet therapy (DAPT), consisting of aspirin combined with a P2Y12 inhibitor, is routinely used to prevent recurrent ischemic events, although bleeding remains an important safety concern. This prospective observational study evaluated the prescribing patterns, efficacy, safety, medication adherence, and adverse drug reactions associated with DAPT among patients with MI. The study was conducted over six months in the Department of Cardiology of a tertiary care teaching hospital and included 100 patients receiving DAPT. Demographic, clinical, treatment, adherence, and adverse drug reaction data were collected using a structured case record form. Medication adherence was assessed using the Morisky Medication Adherence Scale, while adverse drug reactions were evaluated using the WHO–UMC causality assessment scale. The mean patient age was 62.68 ± 10.15 years, 65% were aged above 60 years, and 75% were male. Aspirin plus clopidogrel was the most frequently prescribed regimen (43%), followed by aspirin plus prasugrel (31%) and aspirin plus ticagrelor (26%). Moderate adherence predominated, while adverse drug reactions occurred in 70% of patients, mainly bleeding-related events. Individualized DAPT selection based on thrombotic and bleeding risks may improve safety, adherence, and secondary prevention outcomes following MI.

Keywords: *Myocardial infraction, Dual Antiplatelet Therapy (DAPT), Platelet Inhibition, Medication Adherence, Adverse Drug Reactions (ADRs) and Treatment Efficacy.*

INTRODUCTION

Myocardial infarction (MI) is a major cardiovascular emergency resulting from acute reduction or interruption of coronary blood flow, leading to myocardial ischemia and necrosis. Despite advances in reperfusion and pharmacological therapy, MI remains an important cause of morbidity and mortality worldwide [1]. Platelet activation and thrombus formation play a central role in the development of acute coronary syndromes; therefore, antiplatelet therapy is an essential component of MI management and secondary prevention [2].

Dual antiplatelet therapy (DAPT), consisting of aspirin combined with a P2Y12 receptor inhibitor such as clopidogrel, prasugrel, or ticagrelor, reduces platelet aggregation and the risk of recurrent ischemic events [3]. Clinical trials have demonstrated the benefits of DAPT in patients with acute coronary syndromes, although the choice of P2Y12 inhibitor should consider both ischemic protection and bleeding risk [4–6]. Prasugrel and ticagrelor provide more potent and rapid platelet inhibition than clopidogrel but may be associated with increased bleeding in selected patients [5,6].

Bleeding complications are among the major limitations of DAPT and may include gastrointestinal bleeding, epistaxis, bruising, and other clinically relevant events. In addition, poor medication adherence or premature discontinuation of therapy can compromise treatment effectiveness and increase the risk of recurrent cardiovascular events. [7,8] Therefore, individualised selection of DAPT based on patient characteristics, thrombotic risk, bleeding risk, and treatment adherence is important for optimising clinical outcomes.

The present prospective observational study was undertaken to evaluate the safety and efficacy of DAPT in patients with MI, with particular emphasis on prescribing patterns, medication adherence, and adverse drug reactions. The study also compared commonly prescribed DAPT regimens to provide real-world evidence for optimising antiplatelet therapy and secondary prevention following MI.

MATERIALS AND METHODS

Study Design and Setting

A hospital-based, prospective, observational, non-interventional cohort study was conducted over a period of six months in the Department of Cardiology, SVS Medical College and Hospital, Mahbubnagar, Telangana, India. The study included adult patients diagnosed with myocardial infarction (MI) who received dual antiplatelet therapy (DAPT). Ethical approval was obtained before initiation of the study, and written informed consent was obtained from all participants.

Sample Size

A total of 100 patients diagnosed with MI and receiving DAPT during the study period were enrolled. The sample size was determined based on patient availability, hospital admission rates, and the feasibility of completing the study within the specified period.

Inclusion Criteria

Patients were included if they:

- Were aged ≥18 years.
- Had a confirmed diagnosis of acute MI (STEMI or NSTEMI) based on clinical findings, ECG, and cardiac biomarkers.
- Were initiated on DAPT consisting of aspirin plus a P2Y12 inhibitor.
- Provided written informed consent.

Exclusion Criteria

Patients were excluded if they:

- Had contraindications to antiplatelet therapy, including active major bleeding or known hypersensitivity.
- Were receiving ongoing oral anticoagulant therapy for another indication.
- Had a life expectancy of less than one year due to serious non-cardiac illness.
- Were unwilling or unable to participate in follow-up.
- Were enrolled in another interventional clinical trial that could influence the antiplatelet regimen.

Study Procedure and Data Collection

Eligible patients were enrolled after obtaining informed consent and were assigned unique study identification numbers. Data were collected using a structured Case Record Form, including demographic characteristics, clinical history, type of MI, prescribed antiplatelet drugs, dosage, treatment duration, concomitant medications, and relevant laboratory investigations. Patients were followed periodically to assess treatment outcomes, medication adherence, and adverse drug reactions (ADRs).

Medication adherence was assessed using the 8-item Morisky Medication Adherence Scale (MMAS-8). ADRs were identified through patient interviews, clinical examination, and review of medical records. The causality of suspected ADRs was assessed using the WHO–UMC causality assessment scale, and their severity was evaluated using standard severity criteri[9-12].

Materials, Investigations, and Interventions

No additional diagnostic investigations or therapeutic interventions were performed specifically for the study. The study was observational, and all treatments were provided as part of routine clinical care. Data were obtained through patient interviews, questionnaires, and review of medical records.

Risk Minimisation and Confidentiality

The study involved minimal risk because no additional intervention was performed. Patient confidentiality and anonymity were maintained throughout the study. Each participant was identified using a unique study code, and the collected information was used exclusively for research purposes.

Statistical Analysis

Data collected from the Case Record Forms were coded, entered, verified, and analysed using IBM SPSS Statistics version 23.0 and GraphPad Prism version 9.0. Continuous variables were expressed as mean ± standard deviation (SD) or median with interquartile range (IQR), depending on data distribution. Categorical variables were presented as frequencies and percentages. Logistic regression analysis was performed to identify factors associated with the occurrence of ADRs. A p-value <0.05 was considered statistically significant [13-18].

Ethical Considerations

The study was conducted in accordance with applicable ethical principles and institutional requirements. Ethical approval was obtained from the Institutional Ethics Committee of SVS Medical College and Hospital before commencement of the study (IEC Reference No.: IEC/DHR-03/ (04-6)/2025). Written informed consent was obtained from all participants before enrolment.

RESULTS AND DISCUSSION

A total of 100 patients with myocardial infarction (MI) receiving dual antiplatelet therapy (DAPT) were enrolled during the six-month study period. The results were evaluated with respect to demographic characteristics, DAPT prescribing patterns, medication adherence, adverse drug reactions (ADRs), and comparative treatment profiles.

Age-wise Distribution of Patients

Among the 100 patients, the majority were aged >60 years (65%), followed by those aged 40–60 years (32%). Only 3% of patients belonged to the 18–39-year age group. The mean age of the study population was 62.68 ± 10.15 years, indicating a predominance of older adults.

Table 01: Age-wise distribution of patients with myocardial infarction

Age group (years)	Frequency	Percentage
18–39	3	3.0
40–60	32	32.0
>60	65	65.0
Total	**100**	**100.0**

Gender-wise Distribution of Patients

Of the 100 patients, 75 (75%) were males and 25 (25%) were females. Thus, males constituted the predominant proportion of the study population.

Table 02: Gender-wise distribution of patients with myocardial infarction

Gender	Frequency	Percentage
Male	75	75.0
Female	25	25.0
Total	**100**	**100.0**

Distribution of Prescribed DAPT Regimens

Aspirin plus clopidogrel was the most frequently prescribed DAPT regimen, accounting for 43% of patients. Aspirin plus prasugrel and aspirin plus ticagrelor were prescribed in 31% and 26% of patients, respectively.

Table 03: Distribution of prescribed dual antiplatelet therapy regimens

DAPT regimen	Patients, n	Percentage
Aspirin + Clopidogrel	43	43.0
Aspirin + Prasugrel	31	31.0
Aspirin + Ticagrelor	26	26.0
Total	**100**	**100.0**

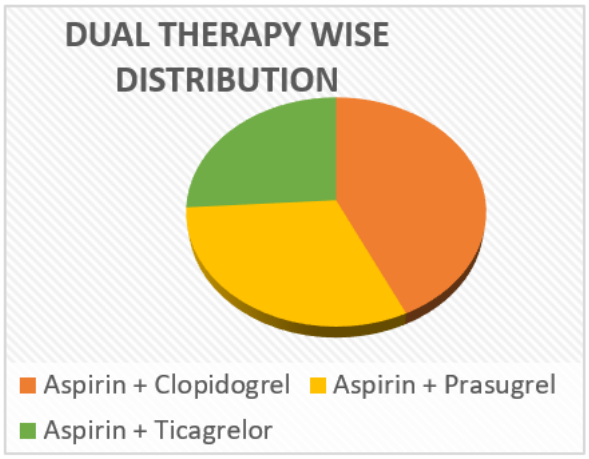

Figure 01: Distribution of prescribed DAPT regimens.

DAPT Adherence during Follow-up

DAPT adherence was assessed at discharge, 3 months, and 6 months. At discharge, 32% of patients had high adherence, 56% had medium adherence, and 12% had low adherence. At 3 months, high adherence decreased to 22%, while medium and low adherence increased to 61% and 17%, respectively. At 6 months, high adherence further declined to 9%, whereas medium and low adherence increased to 69% and 22%, respectively. Thus, a progressive reduction in high adherence was observed during follow-up.

Table 04: DAPT adherence at discharge, 3 months, and 6 months

Follow-up	High adherence, n (%)	Medium adherence, n (%)	Low adherence, n (%)
At discharge	32 (32.0)	56 (56.0)	12 (12.0)
3 months	22 (22.0)	61 (61.0)	17 (17.0)
6 months	9 (9.0)	69 (69.0)	22 (22.0)

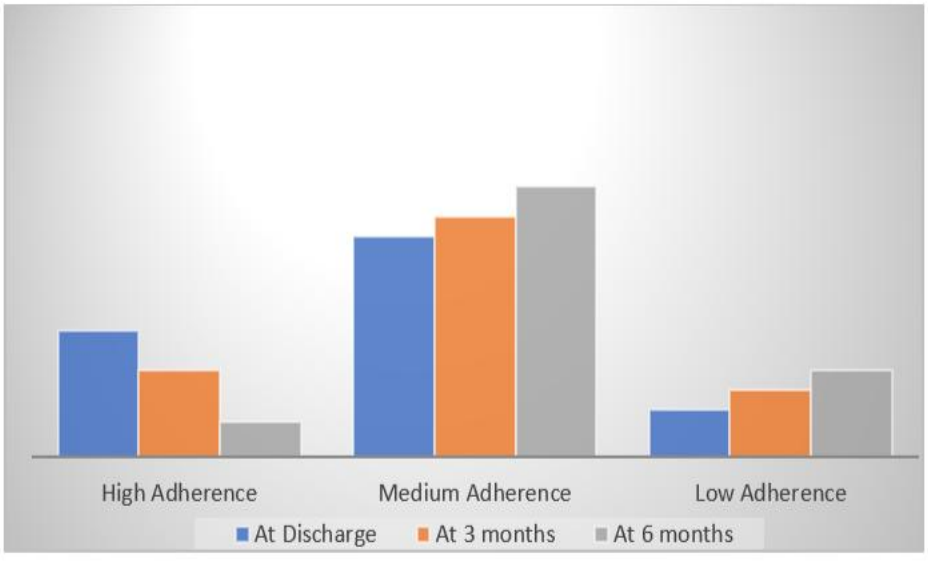

Figure 02: DAPT adherence at discharge, 3 months, and 6 months.

Gender-wise Distribution of DAPT Adherence

Medium adherence was the predominant category in both male and female patients. Among males, 60.0% demonstrated medium adherence, compared with 65.0% among females. High adherence was observed in 23.3% of males and 17.5% of females, while low adherence was observed in 16.7% and 17.5%, respectively.

Table 05: Gender-wise distribution of DAPT adherence levels

Gender	High adherence, n (%)	Medium adherence, n (%)	Low adherence, n (%)
Male	14 (23.3)	36 (60.0)	10 (16.7)
Female	7 (17.5)	26 (65.0)	7 (17.5)
Total	**21**	**62**	**17**

Overall Distribution of DAPT Adherence

Overall, medium adherence was observed in 62% of patients, followed by high adherence in 21% and low adherence in 17%. These findings indicate that medium adherence was the predominant adherence category in the study population.

Table 06: Overall distribution of DAPT adherence levels

Adherence level	Patients, n	Percentage
High	21	21.0
Medium	62	62.0
Low	17	17.0
Total	**100**	**100.0**

Distribution of Adverse Drug Reactions

ADRs were reported in 70% of the study population, while 30% of patients experienced no ADRs. Gastrointestinal bleeding was the most frequently reported ADR (19%), followed by minor bleeding (16%) and epistaxis (14%). Major bleeding, gastrointestinal upset, rashes, and dyspnea were reported in 7%, 6%, 5%, and 3% of patients, respectively. Overall, bleeding-related events constituted the predominant ADRs.

Table 07: Distribution of adverse drug reactions among patients receiving DAPT

Type of ADR	Patients, n (%)
Dyspnea	3 (3.0)
Epistaxis	14 (14.0)
GI bleeding	19 (19.0)
GI upset	6 (6.0)
Major bleeding	7 (7.0)
Minor bleeding	16 (16.0)
Rashes	5 (5.0)
No ADR	30 (30.0)
Total	**100 (100.0)**

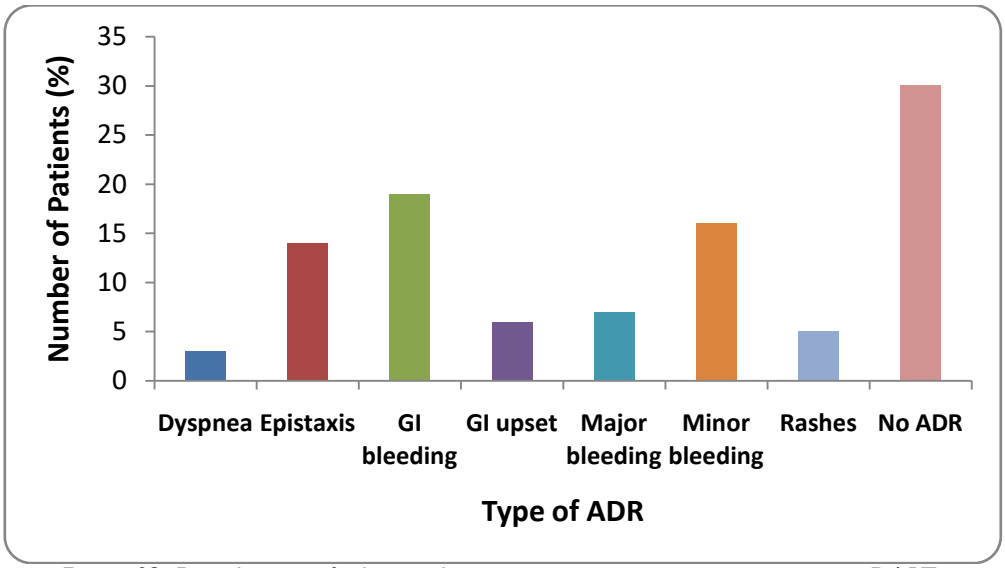

Figure 03: Distribution of adverse drug reactions among patients receiving DAPT.

Comparison of Aspirin Plus Clopidogrel and Aspirin Plus Prasugrel

Among the 74 patients receiving either aspirin plus clopidogrel or aspirin plus prasugrel, 43 (58.1%) received clopidogrel and 31 (41.9%) received prasugrel. Loading-dose adherence was reported as good for both regimens, while maintenance adherence was comparatively higher in the clopidogrel group. These findings indicate a greater utilization of aspirin plus clopidogrel and comparatively better maintenance adherence in the present study.

Table 08: Comparison of aspirin plus clopidogrel and aspirin plus prasugrel based on adherence and clinical profile

Parameter	Aspirin + Clopidogrel	Aspirin + Prasugrel
Patients, n (%)	43 (58.1)	31 (41.9)
Loading-dose adherence	Good	Good
Maintenance-dose adherence	High	Moderate to high
Overall treatment adherence	Higher	Slightly lower

CONCLUSION

This prospective observational study demonstrates that dual antiplatelet therapy (DAPT) remains an important component of secondary prevention in patients with myocardial infarction. Aspirin combined with clopidogrel was the most frequently prescribed regimen, followed by prasugrel and ticagrelor. Although DAPT provides essential protection against recurrent ischemic events, the findings highlight important concerns regarding medication adherence and treatment-related adverse drug reactions. Moderate adherence was predominant among the study population, while bleeding-related adverse events represented the major safety concern. These findings emphasize the need for careful assessment of individual thrombotic and bleeding risks when selecting and continuing DAPT. Regular monitoring, patient counselling, appropriate follow-up, and reinforcement of medication adherence may help improve treatment safety and effectiveness. Overall, individualized DAPT management can contribute to better secondary prevention outcomes and may reduce avoidable complications in patients recovering from myocardial infarction.

FUNDING

Nil.

CONFLICT OF INTEREST

The authors declare that there are no conflicts of interest regarding the publication of this paper.

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AUTHOR CONTRIBUTIONS

Musarrath Mubeen conceived and designed the study, supervised the research work, and drafted the manuscript. Alapati Sathya Sai Guptha, Mangali Pallavi, and Nenavath Pandu contributed to data collection, data analysis, and manuscript preparation. All authors reviewed and approved the final version of the manuscript.

ETHICAL STATEMENT

Ethical approval was obtained from the Institutional Ethics Committee of SVS Medical College and Hospital before initiation of the study. With Reference Number: IEC/DHR-03/(04-6)/2025.

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