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Original Article

Mapping Adverse Drug Reactions Burden in Mono- and Dual-Antiplatelet Therapy: A Prospective Hospital-Based Study in CAD Patients

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ABSTRACT

Background: Antiplatelet therapy is central to managing Coronary Artery Disease (CAD), but benefits are offset by Adverse Drug Reactions (ADRs), particularly bleeding. **Objectives:** To compare the causality, severity, and preventability of ADRs associated with mono- and dual-antiplatelet therapy among hospitalized CAD patients. **Materials and Methods:** A six-month prospective observational study in a tertiary care hospital included adult CAD patients on MAPT or DAPT. ADRs were identified via interviews and record reviews, then assessed using WHO-UMC, Hartwig-Siegel, and standard preventability tools. Data were analyzed using SPSS 26.0. **Results:** Of 252 patients, 179 ADRs were found (125 in DAPT; 54 in MAPT). Gastrointestinal bleeding was most common. Intracranial hemorrhage and ticagrelor-induced dyspnea were more frequent with DAPT. DAPT ADRs more often required drug withdrawal or dose modification**. Conclusion:** DAPT has a significantly higher ADR burden than monotherapy. Many ADRs are preventable, highlighting the need for individualized selection and vigilant monitoring.

Keywords: Adverse drug reactions, Antiplatelet therapy, Bleeding, Coronary artery disease, Dual antiplatelet therapy, Pharmacovigilance.

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INTRODUCTION

Coronary Artery Disease (CAD) remains a leading cause of global morbidity and mortality, with an estimated 200 million affected individuals and 10 million annual deaths worldwide (Jourdi *et al*., 2022). Antiplatelet therapy forms the cornerstone of secondary prevention in CAD, reducing thrombotic complications through inhibition of platelet aggregation. Aspirin, a cyclooxygenase-1 inhibitor, has served as the foundational monotherapy for decades due to its cost-effectiveness and proven cardiovascular risk reduction (Watanabe *et al*., 2024). The evolution of antiplatelet regimens introduced DAPT combining aspirin with P2Y12 receptor inhibitors (clopidogrel, prasugrel, ticagrelor), demonstrating superior efficacy in Acute Coronary Syndrome (ACS) and Percutaneous Coronary Intervention (PCI) settings compared to aspirin alone (Virk *et al*., 2023) While these therapies significantly reduce Major Adverse Cardiovascular Events (MACE), their benefits are counterbalanced by dose-dependent bleeding risks and non-hemorrhagic adverse effects that complicate long-term management (Floyd, 2020).

The therapeutic benefits of antiplatelet agents are tempered by their adverse effect profiles, which exhibit substantial prevalence across populations. GI complications affect 15-20% of aspirin users, ranging from dyspepsia to life-threatening ulcers and bleeding (Sorrentino *et al*., 2020). Ticagrelor induces dyspnea in 10-15% of patients through unclear pulmonary mechanisms, while prasugrel carries elevated bleeding risks in elderly patients and those with prior stroke (Zou *et al*., 2023; Guthrie, 2011). Bleeding events themselves demonstrate a 3-5-fold mortality increase, with intracranial hemorrhage proving particularly catastrophic. Recent registry data indicates 60.1% of elderly CAD patients experience antiplatelet therapy cessation within 5 years, frequently due to adverse effects or bleeding complications (Guthrie, 2011; Kang *et al*., 2022). This high discontinuation rate underscores the imperative for rigorous Adverse Drug Reaction (ADR) assessment, as unplanned therapy interruption elevates thrombotic risk by two to three-fold (Passacquale *et al*., 2022).

Comprehensive ADR evaluation requires structured causality, severity, and preventability analysis. The Naranjo scale and WHO-UMC criteria facilitate causality assessment by temporal relationship, rechallenge phenomena, and alternative etiology exclusion (Manjhi *et al*., 2024; Abubakar *et al*., 2023). Severity

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stratification plays a vital role in guiding clinical management while minor ecchymosis may only require observation, gastrointestinal bleeding often demands prompt intervention with proton pump inhibitors, endoscopic therapy, and temporary discontinuation of antiplatelet agents. Preventability analysis suggests that nearly 38% of antiplatelet-associated bleeding events could be avoided through proactive PPI use in high-risk patients and individualized regimen selection based on bleeding risk scores. Although mono- and dual-antiplatelet therapies have transformed coronary artery disease management by markedly reducing thrombotic events, their use is frequently complicated by bleeding and gastrointestinal adverse effects that may necessitate treatment interruption and heighten cardiovascular risk. Comparative data evaluating inpatient ADR patterns between MAPT and DAPT in Indian CAD patients are limited. Therefore, the objective of this study was to compare the causality, severity, and preventability of adverse drug reactions associated with MAPT and DAPT among hospitalized CAD patients.

MATERIALS AND METHODS

Study Design

A prospective observational study was conducted over a period of six months from April 2025 to September 2025 in the Cardiology and General Medicine Departments of a tertiary care teaching hospital.

Study Population

The study included male and female patients aged ≥18 years diagnosed with coronary artery disease and receiving antiplatelet therapy, either mono-antiplatelet or dual antiplatelet therapy, during their hospital stay. Patients were excluded if they were receiving antiplatelet therapy for conditions other than CAD (such as stroke or peripheral artery disease), outpatients, declined to provide written informed consent, or were pregnant or lactating.

Data Collection Procedure

Data was collected through patient interviews, review of medical records, and direct observation during inpatient care. The information recorded included demographic details such as age, sex, weight, and comorbidities. Drug-related data covered the antiplatelet regimen, including type, dose, frequency, and duration of use. Additionally, details of concurrent medications and relevant laboratory results were documented. For each suspected Adverse Drug Reaction (ADR), information regarding the onset time, clinical features, duration, and management was also systematically recorded.

ADR Identification and Documentation

Suspected ADRs were identified based on clinical presentation, physician diagnosis, laboratory investigations, and patient reports. Each ADR was documented in a Suspected Adverse Drug Reaction reporting form version 1.4 which includes suspected drug, dose, reaction details, and outcome.

Data analysis

All collected data were entered into Microsoft Excel and analyzed using IBM SPSS Statistics version 26.0. Categorical variables such as age groups, gender distribution, comorbidities, and antiplatelet therapy patterns were summarized using frequencies and percentages.

Adverse drug reactions were analyzed by calculating their incidence, severity, predictability, seriousness, and causality using standard tool such as WHO-UMC criteria, and Hartwig-Siegel severity scale. The distribution of System Organ Classes (SOC) and Preferred Terms (PT) was also presented in percentages.

RESULTS

A total of 252 hospitalized CAD patients receiving antiplatelet therapy were evaluated. Of these, majority of the patients were receiving DAPT [180 (71.4%)]. Among the study population, 179 ADRs were analyzed, of which 54 ADRs occurred in the MAPT group and 125 ADRs in the DAPT group. Age distribution

Table 1: Demographic and Clinical Characteristics of Patients with CAD (*n*=252).

Variable	MAPT group (*n*=72)	DAPT group (*n*=180)
Age Group (years)		
18-30	19 (26.4%)	25 (13.9%)
31-45	26 (36.1%)	23 (12.8%)
46-60	12 (16.7%)	31 (17.2%)
61-75	8 (11.1%)	43 (23.9%)
>75	7 (9.7%)	58 (32.2%)
Gender		
Male	30 (41.7%)	134 (74.4%)
Female	42 (58.3%)	46 (25.6%)
Comorbidities		
Hypertension	38 (52.8%)	112 (62.2%)
Diabetes Mellitus	20 (27.8%)	76 (42.2%)
Dyslipidemia	32 (44.4%)	98 (54.4%)
Chronic Kidney Disease (CKD)	10 (13.9%)	29 (16.1%)
Heart Failure	8 (11.1%)	28 (15.6%)
COPD	4 (5.6%)	14 (7.8%)
Anemia	18 (25.0%)	64 (35.6%)
Hypothyroidism	6 (8.3%)	15 (8.3%)
Liver Disease	2 (2.8%)	6 (3.3%)
No Comorbidity	6 (8.3%)	12 (6.7%)

Table 2: Causality, Preventability and Severity Assessment of ADRs.

Causality Category (WHO-UMC scale)	Number of ADRs seen in MAPT group	Number of ADRs seen in DAPT group
Certain	6	24
Probable/Likely	21	43
Possible	24	53
Unlikely	3	5
Preventability Category (Modified Schumock and Thornton criteria)	**Number of ADRs seen in MAPT group**	**Number of ADRs seen in DAPT group**
Definitely Preventable	7	23
Probably Preventable	16	53
Not Preventable	31	49
Severity Level (Modified Hartwig and Siegel Severity Assessment Scale)	**Number of ADRs seen in MAPT group**	**Number of ADRs seen in DAPT group**
Mild	29	54
Moderate	18	59
Severe	7	12

differed markedly between the two groups. Younger patients (18-45 years) were more frequently managed with MAPT (62.5%) compared with DAPT (26.7%). In contrast, patients aged >75 years constituted the largest proportion of the DAPT cohort (32.2%) versus 9.7% in the MAPT group. Males predominated in the DAPT group (74.4%), whereas females were more common in the MAPT group (58.3%). Comorbidities were more prevalent among DAPT patients, particularly hypertension (62.2%), diabetes mellitus (42.2%), and dyslipidemia (54.4%), compared with MAPT (52.8%, 27.8%, and 44.4%, respectively). Only 6.7% of DAPT patients had no comorbidity, compared with 8.3% in MAPT (Refer Table 1).

Causality assessment using the WHO-UMC scale showed that the possible category represented the highest proportion of ADRs in the DAPT group (42.4%), whereas the unlikely category accounted for the lowest (4.0%). For preventability, probably preventable ADRs were most frequent (42.4%), while definitely preventable events were least common (18.4%). Regarding severity, moderate reactions formed the largest proportion (47.2%), whereas severe reactions constituted the smallest share (9.6%). These exact extremes emphasize the greater overall ADR burden observed with dual antiplatelet therapy (Refer Table 2).

Actions taken for ADR management varied between groups, with the MAPT group most commonly requiring no dose change (the highest action rate at 66.7%), while drug withdrawal was the least frequent intervention (14.8%). In contrast, among DAPT patients, drug withdrawal represented the most frequent action (29.6%), whereas maintaining the same dose was the least common (46.4%). These extremes indicate that ADRs in the DAPT group more often necessitated treatment modification or discontinuation compared to MAPT (Refer Table 3).

Table 3: Action Taken for ADRs.

Action Taken	MAPT group	DAPT group
Drug Withdrawn	08	37
Dose Reduced	10	30
Dose not Changed	36	58

Across all MedDRA system organ classes, gastrointestinal disorders represented the highest contribution to ADRs, accounting for 25.1% of all events, while nervous system disorders and skin and subcutaneous tissue disorders showed the lowest individual contributions at 5.0% and 6.1%, respectively. At the preferred-term level, gastrointestinal bleeding was the most frequently reported ADR (25.1%), whereas petechiae constituted the least common reaction (1.1%). Notably, all intracranial hemorrhage cases (2.4% of DAPT ADRs) were reported exclusively in patients receiving dual therapy, underscoring the greater bleeding risk associated with DAPT compared with MAPT (Refer Table 4).

Among individual antiplatelet agents, aspirin monotherapy contributed the highest proportion of ADRs (40.7%), whereas prasugrel showed the lowest (5.6%) among monotherapy-related reactions. Within dual therapy regimens, the aspirin + clopidogrel combination accounted for the greatest ADR burden (60.0%), while aspirin + prasugrel contributed the fewest (3.2%). Overall, patients receiving DAPT experienced a broader range and higher intensity of adverse events compared with those on monotherapy (Refer Table 5).

DISCUSSION

In the current study, Adverse Drug Reactions (ADRs) associated with antiplatelet therapy were commonly observed among middle-aged and elderly patients, particularly males with underlying comorbidities such as hypertension, diabetes, and dyslipidemia. This trend mirrors the demographic and clinical characteristics of typical coronary artery disease cohorts reported in earlier studies (Mahadevappa *et al*., 2022; Gozzo *et al*., 2017; Wei *et al*., 2024). The higher ADR occurrence in these groups may be attributed to increased disease burden, polypharmacy, and physiological changes related to aging, all of which can influence drug metabolism and response. These findings emphasize the need for individualized risk-benefit assessment when prescribing antiplatelet agents in complex, comorbid CAD populations.

Abubakar *et al*. (2023) emphasized the efficacy of DAPT in reducing major adverse cardiovascular events, particularly with aspirin plus P2Y12 inhibitors, while their study focused on therapeutic outcomes, our work complemented this by highlighting ADRs, especially their preventability and severity in real-world CAD settings. Both identified bleeding, particularly gastrointestinal, as a key complication (Abubakar *et al*., 2023).

A study by Mahadevappa *et al*. (2022) similarly analyzed ADRs in ACS using Naranjo and WHO-UMC scales. Both studies

Table 4: ADR Distribution by MedDRA System Organ Class (SOC) and Preferred Terms (PT).

System Organ Class	Preferred Term	MAPT (*n*=54)	DAPT (*n*=125)	Total (*n*=179)
Gastrointestinal disorders	Gastrointestinal bleeding	12	33	45
	Gum bleeding	5	13	18
	Diarrhea	2	4	6
Respiratory, thoracic and mediastinal disorders	Epistaxis	7	14	21
	Dyspnea	6	11	17
Skin and subcutaneous tissue disorders	Bruising	12	20	32
	Petechiae	1	1	2
	Rash	2	4	6
Blood and lymphatic system disorders	Thrombocytopenia	2	6	8
Renal and urinary disorders	Hematuria	3	12	15
Nervous system disorders	Intracranial hemorrhage	0	3	3
	Headache	2	4	6
	Total	54	125	179

Table 5: ADR Distribution by Specific Antiplatelet Drugs.

Therapy Type	Drugs	Number of ADRs seen	ADRs Observed
Monotherapy	Aspirin	22	GI Bleeding, Epistaxis, Rash, Headache
	Clopidogrel	14	Bruising, Gum Bleeding, Thrombocytopenia, Hematuria
	Ticagrelor	15	Dyspnea, Bleeding, Headache, Diarrhea
	Prasugrel	3	GI Bleeding, Petechiae, Rash
Dual Therapy	Aspirin+Clopidogrel	75	GI Bleeding, Bruising, Epistaxis, Gum Bleeding, Hematuria
	Aspirin+Ticagrelor	46	Dyspnea, Rash, Gum Bleeding, Intracranial Hemorrhage, Diarrhea
	Aspirin+Prasugrel	4	GI Bleeding, Petechiae, Thrombocytopenia, Bruising
Total	-	179	-

found most ADRs predictable and preventable. However, while their common ADRs included headaches and heparin-related effects, our study identified GI bleeding, bruising, epistaxis and ticagrelor-induced dyspnea as predominant, reflecting a broader CAD population (Mahadevappa *et al*., 2022).

Gozzo *et al*. (2017) reported that clopidogrel accounted for the highest ADRs, while prasugrel and ticagrelor were linked with more serious reactions (Gozzo *et al*., 2017). Present findings uphold these safety concerns, particularly ticagrelor-associated dyspnea and prasugrel-related bleeding, adding clinical causality and preventability data lacking in pharmacovigilance reports. Together, these findings confirm the importance of closely monitoring newer antiplatelet agents and tailoring therapy to patient risk profiles.

Wei *et al*. (2024) described ticagrelor's potent platelet inhibition but frequent ADRs, especially dyspnea and bleeding, attributed to ENT1 inhibition (Wei *et al*., 2024). Current findings paralleled this clinical pattern, reinforcing the need for patient-specific therapy and close monitoring. Patrono *et al*. (2017) highlighted efficacy-guided selection of aspirin and clopidogrel while recommending newer agents for select patients (Patrono *et al*., 2017). Our study supports these recommendations, showing more severe ADRs with newer DAPT agents, underscoring the need for individualized therapy.

Hirose *et al*. (2025) demonstrated regimen-dependent platelet aggregation reduction, with higher activity in ACS patients (Hirose *et al*., 2025). This aligns with our observation of higher ADR frequency and severity among DAPT users. Gangavarapu *et al*. (2024) concluded that newer antiplatelets reduce MACE but increase bleeding and dyspnea risks (Gangavarapu *et al*., 2024). Our study substantiates this at the clinical level, showing ticagrelor-based DAPT associated with distinct ADR patterns, reinforcing the importance of balancing efficacy with safety through vigilant monitoring.

LIMITATIONS

The present study was limited by its single-center design and modest sample size, which may restrict generalizability. Additionally, the observational nature precludes establishing definitive causal relationships. Nevertheless, it offers valuable real-world insight into the safety profile of mono- and dual-antiplatelet therapies among Indian CAD patients.

CONCLUSION

The present study highlights that adverse drug reactions are common among hospitalized CAD patients receiving antiplatelet therapy, with DAPT demonstrating a notably higher ADR burden than MAPT. DAPT was associated with increased frequency and severity of bleeding-related events such as gastrointestinal bleeding, epistaxis, bruising, hematuria, and intracranial hemorrhage along with distinct reactions like ticagrelor-induced dyspnea. Although most ADRs were classified as probable or possible, a significant proportion were both predictable and preventable, emphasizing missed opportunities for risk mitigation.

The findings reinforce the necessity for individualized antiplatelet selection, especially in elderly patients and those with multiple comorbidities. Routine monitoring, early identification of high-risk patients, and adoption of preventive strategies such as appropriate PPI co-prescription, dose adjustment, and close surveillance of newer P2Y12 inhibitors can substantially reduce clinically significant harm. Strengthening pharmacovigilance practices and ensuring vigilant ADR documentation can further enhance patient safety. Overall, optimizing antiplatelet therapy through personalized care and proactive monitoring is essential to balance therapeutic efficacy with safety in the management of CAD.

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ABBREVIATIONS

ACS: Acute Coronary Syndrome; **ADR:** Adverse Drug Reaction; **CAD:** Coronary Artery Disease; **CHC:** Community Health Centre; **CTRI:** Clinical Trials Registry of India; **DAPT:** Dual Antiplatelet Therapy; **ECG:** Electrocardiogram; **ENT1:** Equilibrative Nucleoside Transporter; **GI:** Gastrointestinal; **HOD:** Head of Department; **ICH:** Intracranial Hemorrhage; **KAHER:** KLE Academy of Higher Education and Research; **MACE:** Major Adverse Cardiovascular Events; **MAPT:** Mono-Antiplatelet Therapy; **MedDRA:** Medical Dictionary for Regulatory Activities; **MRC:** Medical Research Center; **PCI:** Percutaneous Coronary Intervention; **PHC:** Primary Health Centre; **PIL:** Patient Information Leaflet; **PPI:** Proton Pump Inhibitor; **PT:** Preferred Term; **SOC:** System Organ Class; **SPSS:** Statistical Package for the Social Sciences; **WHO-UMC:** World Health Organization-Uppsala Monitoring Centre.

CONFLICT OF INTEREST

The authors declare that there is no conflict of interest.

ETHICAL APPROVAL AND CONSENT TO PARTICIPATE

The study protocol was approved by the Ethics committee (Ethical Permission No: KAHER/EC/24-25/D-742), and the study was registered in the Clinical Trials Registry of India (CTRI/2025/04/084937). Written informed consent was obtained from each participant before enrolment.

AUTHORS' CONTRIBUTIONS

Conceptualization, Patient recruitment, Clinical assessment, Data collection, Writing - MSR, Supervision, methodology, Critical revision of the manuscript, Data validation, Review - MSG. All authors read and approved the final manuscript.

SUMMARY

This prospective study assessed Adverse Drug Reactions (ADRs) associated with mono- and dual-antiplatelet therapy in 252 hospitalized coronary artery disease patients and found a significantly higher ADR burden with dual therapy. Bleeding-related events, particularly gastrointestinal bleeding, were the most common, with severe reactions, intracranial hemorrhage, and ticagrelor-induced dyspnea occurring more frequently in the DAPT group. Most ADRs were predictable and potentially preventable, highlighting the need for individualized antiplatelet selection and strengthened pharmacovigilance to improve patient safety.

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