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Original Article

An Ambispective Observational Study on the Efficacy of Different Antithrombotic Therapies in Preventing Recurrent Cardiac Events in Patients with Myocardial Infarction

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ABSTRACT

Background: Myocardial infarction remains a leading cause of cardiovascular morbidity and mortality in India. Antithrombotic therapy plays a crucial role in secondary prevention, yet comparative real-world data from Indian populations remain limited. **Objectives:** To compare the efficacy and safety of Dual Antiplatelet Therapy with Triple Antithrombotic Therapy in preventing recurrent cardiac events in post-myocardial infarction patients and evaluate the influence of demographics, comorbidities, and lifestyle factors. **Materials and Methods:** An ambispective, multi-centric, observational study enrolled 159 myocardial infarction patients (106 on Dual Antiplatelet Therapy, 53 on Triple Antithrombotic Therapy) across five hospitals in Gujarat, India. Efficacy was assessed by the Thrombolysis in Myocardial Infarction. Risk score (TIMI) and safety by the Bleeding Academic Research Consortium classification (BARC). Welch's t-test and Mann-Whitney U test were used for statistical comparisons. **Results:** Both therapies were predominantly prescribed to middle-aged males (50-69 years). Aspirin was universally used. Triple Antithrombotic Therapy patients had significantly higher baseline Thrombolysis in Myocardial Infarction scores (median 4.0 vs 2.0; $p<0.0001$). No bleeding events were recorded in either group. Diabetes significantly elevated risk scores in both groups. Hypertension was significant only in Dual Antiplatelet Therapy patients. Smoking was a statistically significant predictor of TIMI scores in both groups; its direction of effect in the DAPT group reflects the smoker's paradox, while in TAPT, smokers had markedly higher risk scores. **Conclusion:** Both therapies demonstrated short-term safety. Diabetes and smoking are the most impactful independent risk factors, underscoring the need for individualized treatment and aggressive lifestyle modification post-myocardial infarction.

Keywords: Antithrombotic therapy, Bleeding Academic Research Consortium, Dual antiplatelet therapy, Myocardial infarction, Recurrent cardiac events, Thrombolysis in Myocardial Infarction score, Triple antithrombotic therapy.

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INTRODUCTION

Myocardial Infarction (MI), commonly known as a heart attack, results from cessation of coronary blood flow due to thrombotic occlusion of an atherosclerotic vessel, leading to irreversible myocardial cell death. The negligible regenerative capacity of cardiac tissue and the consequent hemodynamic compromise make MI one of the most time-critical emergencies in clinical medicine (Ojha and Dhamoon, 2023).

Cardiovascular Disease (CVD) is the leading cause of death in India, accounting for approximately 29% of total mortality. An assessment of 500 MI patients in India identified Coronary Artery Disease (CAD; 31%), Hypertension (HTN; 20.9%), Diabetes Mellitus (DM; 15.01%), and smoking (12.5%) as the most prevalent risk factors (Gupta *et al*., 2020). More concerningly, MI now increasingly affects younger, economically active populations in Low- And Middle-Income Countries (LMICs), compounding its socioeconomic impact (Chan *et al*., 2016).

Globally, Acute Coronary Syndrome (ACS) causes nearly 7 million deaths annually and accounts for approximately half the cardiovascular disease burden, ranking as the primary cause of death in the Asia-Pacific region (Chan *et al*., 2016). The pathophysiological basis of ACS platelet hyperactivation, thrombus propagation, and endothelial injury forms the rationale for antithrombotic pharmacotherapy.

Dual Antiplatelet Therapy (DAPT), combining aspirin with a P2Y12 receptor inhibitor (clopidogrel, prasugrel, or ticagrelor), is the established standard of care for post-MI management and

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following Percutaneous Coronary Intervention (PCI). Landmark trials including CURE, PLATO, and PEGASUS Thrombolysis in Myocardial Infarction 54 have defined the optimal duration and drug combinations for DAPT (Abubakar *et al.*, 2023; Wallentin *et al.*, 2009). Triple Antithrombotic Therapy (TAPT) is adding an Oral Anticoagulant (OAC) to DAPT which is reserved for selected high-risk patients, due to its 2-3-fold higher bleeding risk (Neumann *et al.*, 2019).

Despite robust trial data, real-world evidence from Indian multi-centric settings comparing DAPT and TAPT outcomes. And the specific contributions of comorbidities and lifestyle factors remains distributed. This study aims to compare the efficacy and safety of DAPT versus TAPT in post-MI patients in a multi-centric Indian setting. A visual overview of the study design and key findings is presented as a graphical abstract (Figure 1).

MATERIALS AND METHODS

Study design and setting

This was an ambispective (combined retrospective-prospective), multi-centric, comparative observational study conducted from October 2024 to February 2025 across five hospitals: Metas Adventist Hospital (Surat), BAPS Pramukh Swami Hospital (Surat), Mahavir Heart Institute (Surat), Maitreya Hospital (Surat), and Kasturba Vaidyakiya Rahat Mandal (Valsad), India.

Ethics and informed consent

The study was approved by the Institutional Human Ethics Committee of Maliba Pharmacy College (Ref. No.: MPC/IHEC/22/2024; EC/NEW/INST/2024/GJ/0499; approved 23 October 2024). Written informed consent was obtained from all participants or their caretakers in English, Gujarati, and Hindi using validated back-translated consent forms.

Inclusion criteria

Patients aged≥18 years of either sex; confirmed diagnosis of MI; receiving antithrombotic therapy as DAPT (aspirin + P2Y12 inhibitor) or TAPT (aspirin + P2Y12 inhibitor + OAC); comprehensive medical records available; willing to participate with follow-up for 5 months post-MI event.

Exclusion criteria

Age<18 years; incomplete medical records; known drug allergy to study medications; history of bleeding diathesis, active bleeding, or previous stroke within 6 months; scheduled elective surgery within 24 months of PCI or major surgery within 15 days; pregnant or lactating women.

Data collection

A structured Case Report Form (CRF) captured patient demographics, medical and medication history, laboratory investigations, and social history. Data were sourced from inpatient records, medication charts, laboratory reports, and patient/caretaker interviews. Follow-up was conducted approximately 2.5 months post enrollment.

Outcome measures

Efficacy was assessed using the Thrombolysis in Myocardial Infarction (TIMI) risk score, which quantifies the probability of Major Adverse Cardiac Events (MACE) including recurrent MI, cardiovascular death, and urgent revascularization (range 0-7; score 0-1: 4.7% risk; score 6-7: 40.9% risk). Safety was evaluated using the Bleeding Academic Research Consortium (BARC) classification (Type 0: no bleeding; Type 5b: definite fatal bleeding).

Statistical analysis

Descriptive statistics summarized demographic and treatment data. The Mann-Whitney U test compared TIMI scores between DAPT and TAPT. Welch's unpaired t-test compared subgroup TIMI means. Effect size was calculated as R^2 (eta squared, η^2). Variance equality was assessed by F-test. Statistical significance threshold: $p<0.05$. Analyses performed using GraphPad Prism.

RESULTS

Patient demographics

A total of 159 patients were enrolled-106 on DAPT and 53 on TAPT. Overall, 123 patients (77.36%) were male and 36 (22.64%) were female. The 50-59 year age group was most represented (n=60; 37.74%), followed by the 60-69 year group (n=47; 29.56%), together comprising 67.3% of the cohort. Demographic distribution is presented in Table 1 and illustrated in Figures1-3.

Treatment regimen details

Aspirin (100 mg/day) was universally prescribed as the base agent in both regimens. In the DAPT group, ticagrelor (90 mg twice daily) was the most frequently selected second agent (79%), followed by clopidogrel (11%) and prasugrel (10%). In the TAPT group, prasugrel (53%) was the dominant P2Y12 inhibitor followed by ticagrelor (45%). Apixaban (5 mg twice daily) constituted the OAC in 96% of TAPT patients. Treatment distribution is detailed in Table 2 and Figures 1-2.

Efficacy assessment using TIMI score

Patients on TAPT had significantly higher median TIMI scores (4.0) compared to DAPT patients (2.0; Mann-Whitney U=687; Hodges-Lehmann difference=2.0; $p<0.0001$), reflecting risk-stratified prescribing. These results are presented in Table 3 and Figure 1.

Safety assessment using BARC score

No bleeding events were recorded in either treatment group throughout the study period. All 159 patients had a BARC score of 0, indicating absence of any clinically significant bleeding

complications. These findings are presented in Table 4 and Figure 4.

Impact of comorbidities on TIMI scores

DM significantly elevated TIMI scores in both DAPT (diabetics, n=43, mean=2.814 vs non-diabetics, n=63, mean=1.794; p<0.0001; R^2=0.2774) and TAPT (diabetics, n=22, mean=4.545 vs non-diabetics, n=31, mean=3.516; p=0.0005; R^2=0.2681) groups. HTN significantly elevated TIMI scores in DAPT (hypertensives, n=44, mean=2.636 vs non-hypertensives, n=62, mean=1.903; p=0.0006; R^2=0.1395) but not in TAPT (p=0.9038; R^2=0.0003). These findings are summarised in Figure 3.

Impact of smoking on TIMI scores

Smoking status was a statistically significant predictor of TIMI scores in both groups (Figure 3). In the DAPT group, smokers (n=36) had a lower mean TIMI score (2.556) compared to non-smokers (n=70; mean=3.083; p=0.0285; R^2=0.0851). This counterintuitive finding is consistent with the well-described 'smoker's paradox' in acute MI: smokers tend to present at a younger age with fewer comorbidities such as diabetes and hypertension, resulting in a lower baseline TIMI score despite the pro-thrombotic effects of tobacco. In the TAPT group, where patients are older and carry greater comorbidity burden, the expected direction was observed: smokers (n=14) had significantly higher TIMI scores (mean=4.857) than non-smokers (n=39; mean=3.615; p=0.0006; R^2=0.4451), with smoking alone explaining 44.5% of TIMI score variability.

DISCUSSION

This multi-centric observational study provides contemporary real-world evidence on antithrombotic therapy utilization and outcomes in Indian MI patients. The demographic profile is predominantly middle-aged males in the 50-69 year which aligns

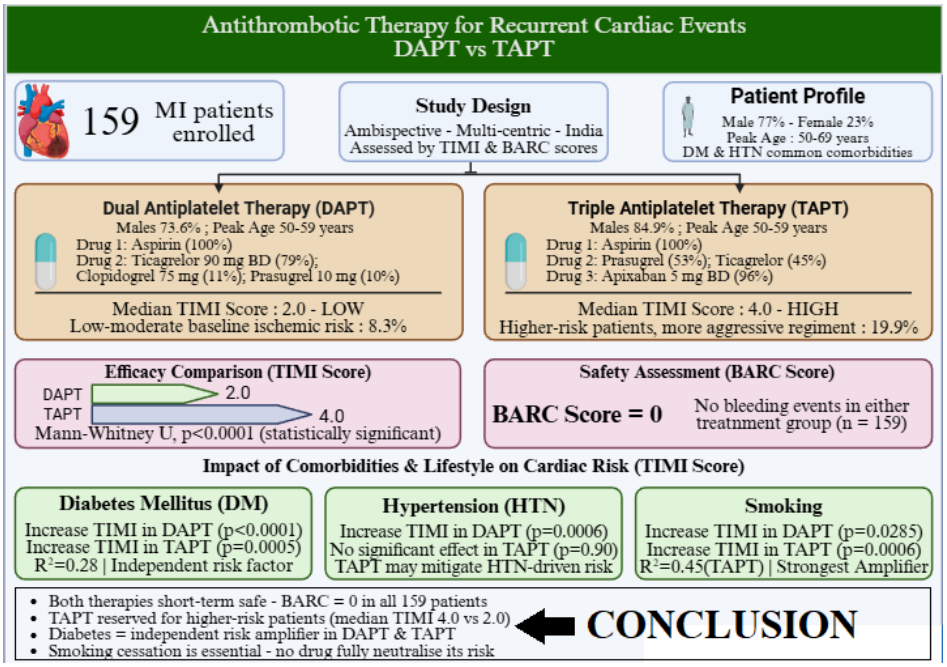

Figure 1: Graphical Abstract of Antithrombotic Therapy for Recurrent Cardiac Events: A Comparative Analysis of Dual Antiplatelet Therapy (DAPT) versus Triple Antiplatelet Therapy (TAPT) in Post-MI Patients-Efficacy, Safety, and the Impact of Comorbidities on Ischemic Risk.

Table 1: Demographic distribution of MI patients by age group, gender, and therapy type.

Age Group (years)	Overall Total	Overall Female	Overall Male	DAPT Total	DAPT Female	DAPT Male	TAPT Total	TAPT Female	TAPT Male
30-39	8	0	8	3	0	3	5	0	5
40-49	23	4	19	15	4	11	8	0	8
50-59	60	13	47	38	12	26	22	1	21
60-69	47	11	36	36	7	29	11	4	7
70-79	20	7	13	14	5	9	6	2	4
80-89	1	1	0	0	0	0	1	1	0
Total	159	36	123	106	28	78	53	8	45

DAPT: Dual Antiplatelet Therapy; TAPT: Triple Antithrombotic Therapy; MI: Myocardial Infarction; n: number of patients.

Table 2: Drug composition and distribution in DAPT and TAPT regimens.

Therapy Group	Drug Position	Drug Name	Number of Patients (*n*)	Percentage (%)
DAPT (*n*=106)	Drug 1 (Base)	Aspirin 100 mg/day	106	100%
DAPT	Drug 2 (P2Y12 inhibitor)	Ticagrelor 90 mg twice daily	84	79%
DAPT	Drug 2 (P2Y12 inhibitor)	Clopidogrel 75 mg once daily	12	11%
DAPT	Drug 2 (P2Y12 inhibitor)	Prasugrel 10 mg once daily	10	10%
TAPT (*n*=53)	Drug 1 (Base)	Aspirin 100 mg/day	53	100%
TAPT	Drug 2 (P2Y12 inhibitor)	Prasugrel 10 mg once daily	28	53%
TAPT	Drug 2 (P2Y12 inhibitor)	Ticagrelor 90 mg twice daily	24	45%
TAPT	Drug 2 (P2Y12 inhibitor)	Clopidogrel 75 mg once daily	1	2%
TAPT	Drug 3 (Oral anticoagulant)	Apixaban 5 mg twice daily	51	96%
TAPT	Drug 3 (Oral anticoagulant)	Clopidogrel 75 mg once daily	1	2%
TAPT	Drug 3 (Oral anticoagulant)	Ticagrelor 90 mg twice daily	1	2%

DAPT: Dual Antiplatelet Therapy; TAPT: Triple Antithrombotic Therapy; P2Y12: P2Y12 purinergic receptor inhibitor; OAC: Oral Anticoagulant; mg: milligrams; n: number of patients.

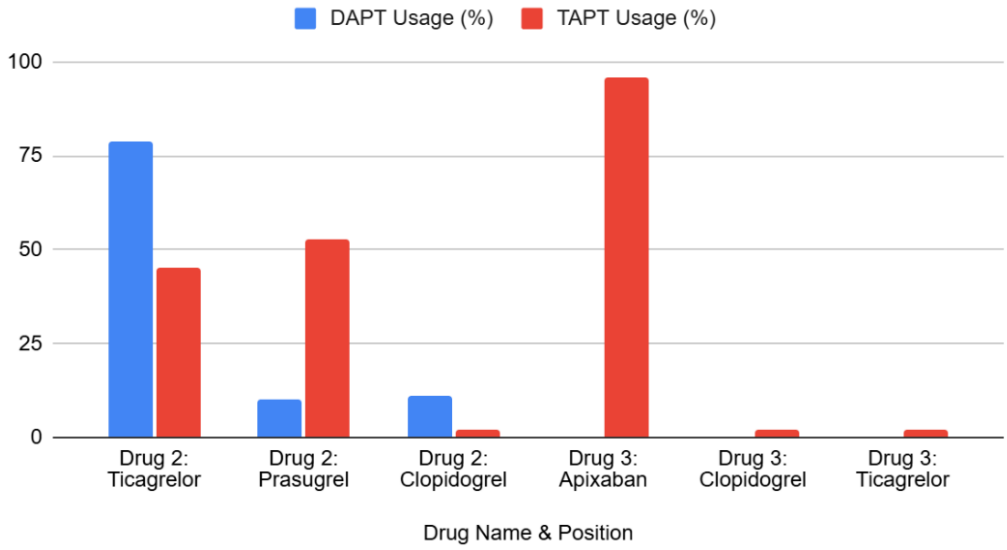

Figure 2: This bar charts shows overall patient demographics by age group and gender, alongside the distribution of secondary antiplatelet and oral anticoagulant utilization in the DAPT (*n*=106) and TAPT (*n*=53) groups.

with published Indian epidemiological data showing a younger onset of CVD compared to Western cohorts (Gupta *et al.*, 2020).

The predominance of ticagrelor in DAPT (79%) reflects adherence to current European Society of Cardiology (ESC) and American College of Cardiology/American Heart Association (ACC/AHA) guidelines, which recommend ticagrelor or prasugrel over clopidogrel in ACS (Valgimigli *et al.*, 2018). The landmark PLATO trial demonstrated ticagrelor's superiority over clopidogrel in reducing cardiovascular death, MI, and stroke (9.8% vs 11.7%; hazard ratio 0.84; 95% confidence interval 0.77-0.92; $p<0.001$) without a significant increase in major bleeding (Wallentin *et al.*, 2009). Ticagrelor's additional mechanism of increasing endogenous adenosine levels confers potential microvascular protection, further supporting its clinical preference (Pareek and Bhatt, 2018).

In TAPT, the dominance of prasugrel (53%) with apixaban as OAC (96%) reflects contemporary guideline recommendations. The ISAR-REACT 5 trial demonstrated prasugrel superiority over ticagrelor for MACE reduction in ACS (6.9% vs 9.3%; $p=0.006$) with comparable bleeding (Schupke *et al.*, 2019). Apixaban's selection over warfarin aligns with ESC guidance favouring Novel Oral Anticoagulants (NOACs) in TAPT for more predictable pharmacokinetics and lower intracranial bleeding risk (Neumann *et al.*, 2019).

The significantly higher median TIMI scores in TAPT patients (4.0 vs 2.0; $p<0.0001$) reflects deliberate risk-stratified prescribing. TAPT is guideline-indicated for patients with higher thrombotic risk, particularly those with concurrent atrial fibrillation (AF), and the observed TIMI difference quantifies the severity differential at baseline.

The absence of bleeding events (BARC=0) warrants cautious interpretation given the 5-month follow-up duration. Meta-analyses consistently show TAPT carries a 2-3-fold higher bleeding risk than DAPT alone (Neumann *et al.*, 2019). Longer follow-up would be necessary to detect such events in this cohort.

DM emerged as the most impactful comorbidity, significantly elevating TIMI scores in both DAPT (R^2=0.28; p<0.0001) and TAPT (R^2=0.27; p=0.0005) groups. Hyperglycaemia induces platelet hyperreactivity via glycoprotein IIb/IIIa upregulation, oxidative stress, and endothelial dysfunction, a pro-thrombotic milieu that standard antithrombotic regimens may not fully counteract (Sushritha *et al.*, 2020). HTN independently elevated ischemic risk in DAPT (p=0.0006) but not in TAPT (p=0.9038), suggesting the OAC component in TAPT may partially offset this short-term risk.

The relationship between smoking and TIMI risk scores in this study warrants careful interpretation. In the DAPT group, the paradoxically lower TIMI scores in smokers (mean=2.556 vs 3.083 in non-smokers; p=0.0285) reflect the well-established 'smoker's paradox' in MI: smokers tend to be younger, have fewer concurrent comorbidities such as DM and HTN, and therefore accumulate fewer TIMI risk points at baseline. This demographic profile, rather than a protective effect of tobacco, accounts for the lower score. Importantly, this should not be interpreted as low risk; these patients retain a residual pro-thrombotic burden from tobacco that the TIMI instrument underrepresents, and smoking cessation remains clinically imperative regardless of their score. In the TAPT group, which comprises older, higher-comorbidity patients, the expected direction was clearly demonstrated: smokers had significantly higher TIMI scores than non-smokers (mean=4.857 vs 3.615; p=0.0006; R^2=0.4451). The large effect size indicates that smoking status alone explained nearly 45% of TIMI score variability in this group, representing a true pharmacological ceiling effect where even intensive triple therapy cannot fully counteract the pro-thrombotic and inflammatory burden of active tobacco use. Across both groups, the statistically significant association of smoking with TIMI score variability underscores the imperative for aggressive smoking cessation as a cornerstone of post-MI care.

Table 3: Primary Clinical Outcomes (Efficacy and Safety).

Treatment Group	Total Patients (*n*)	Median TIMI Score	Hodges-Lehmann Difference	Mann-Whitney U	p-value (Efficacy)	Median BARC Score	Bleeding Events Recorded
Dual Antiplatelet Therapy (DAPT)	106	2	-	687	<0.0001	0	None
Triple Antithrombotic Therapy (TAPT)	53	4	2	-	-	0	None

TIMI: Thrombolysis in Myocardial Infarction; DAPT: Dual Antiplatelet Therapy; TAPT: Triple Antithrombotic Therapy; H-L: Hodges-Lehmann estimator; n: number of patients; p: probability value.

Table 4: Comprehensive Impact of Comorbidities and Lifestyle Factors on TIMI Risk Scores.

Therapy Group	Risk Factor Analyzed	N (With Factor / Smoker)	N (Without Factor / Non-Smoker)	Mean TIMI (With Factor)	Mean TIMI (Without Factor)	Welch's t-value	Degrees of Freedom (df)	95% Confidence Interval	*p*-value	Effect Size R^2 (η^2)
DAPT	Diabetes Mellitus	43	63	2.814	1.794	5.174	69.74	-1.414 to -0.627	<0.0001	0.2774
DAPT	Hypertension	44	62	2.636	1.903	3.59	79.52	-1.140 to -0.327	0.0006	0.1395
DAPT	Smoking Status	36	70	2.556	3.083	-	-	-	0.0285	0.0851
TAPT	Diabetes Mellitus	22	31	4.545	3.516	3.78	39	-1.580 to -0.479	0.0005	0.2681
TAPT	Hypertension	26	27	3.962	3.926	0.122	46.75	-0.626 to 0.554	0.9038	0.0003
TAPT	Smoking Status	14	39	4.857	3.615	-	-	-	0.0006	0.4451

BARC: Bleeding Academic Research Consortium; DAPT: Dual Antiplatelet Therapy; TAPT: Triple Antithrombotic Therapy; n: number of patients; BARC score 0 indicates absence of any bleeding event.

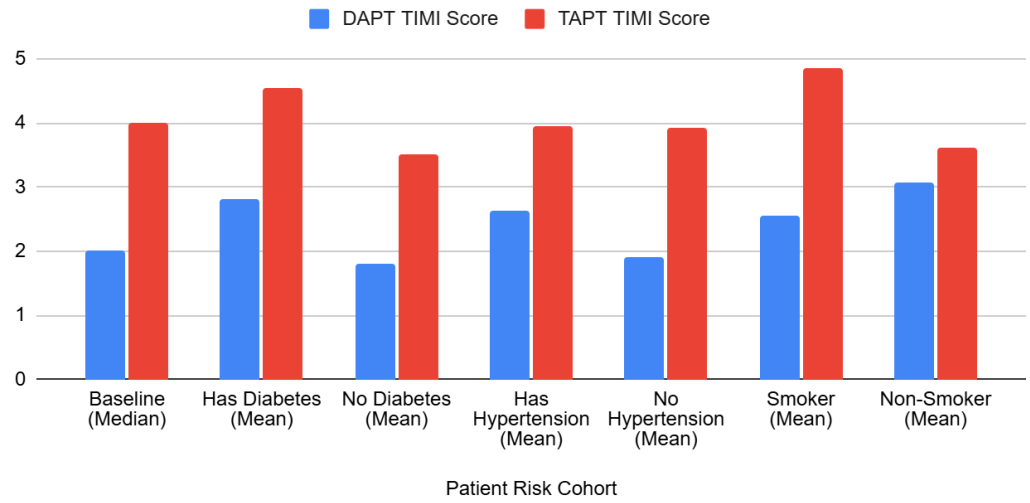

Figure 3: Grouped bar chart shows mean TIMI risk scores comparing the impact of comorbidities (diabetes, hypertension) and lifestyle factors (smoking) between patients in the DAPT and TAPT groups.

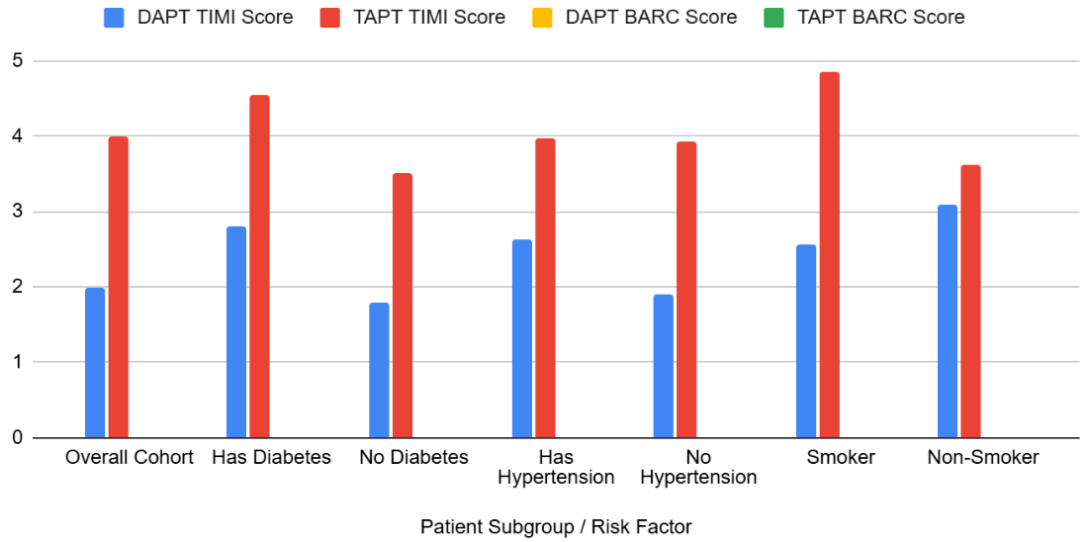

Figure 4: Grouped bar chart shows a comprehensive comparison of clinical efficacy (TIMI scores) and safety (BARC scores) across all evaluated patient subgroups. No bleeding events (BARC score=0) were recorded in either the DAPT or TAPT group across all 159 patients.

LIMITATIONS

The observational design precludes causal inference. The 5-month follow-up is insufficient to capture long-term MACE or bleeding events. The TAPT subgroup (n=53) limits statistical power. Multi-centric data collection may introduce site-level heterogeneity. Medication adherence was not formally quantified. Concurrent medications (statins, ACE inhibitors, beta-blockers) were not controlled for in comparisons.

CONCLUSION

Both DAPT and TAPT demonstrated short-term safety with no bleeding events in this observational cohort. TAPT is appropriately reserved for higher-risk MI patients as reflected by significantly elevated baseline TIMI scores. Aspirin combined with ticagrelor predominates in DAPT, while prasugrel with apixaban characterizes TAPT in this Indian cohort. DM is a consistent independent risk amplifier across both therapy groups. Smoking showed a statistically significant association with TIMI scores in both groups, with the direction of effect in DAPT reflecting the smoker's paradox (lower scores in younger smokers with fewer comorbidities), while in TAPT, smokers had substantially higher risk scores. Individualized antithrombotic strategies must be complemented by aggressive management of modifiable risk factors, particularly smoking cessation and glycaemic control to achieve meaningful reductions in post-MI cardiovascular risk. Prospective studies with extended follow-up and larger TAPT cohorts are needed to validate and extend these findings.

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ABBREVIATIONS

ACS: Acute Coronary Syndrome; **BARC:** Bleeding Academic Research Consortium; **CAD:** Coronary Artery Disease; **CVD:** Cardiovascular Disease; **DAPT:** Dual Antiplatelet Therapy; **DM:** Diabetes Mellitus; **HTN:** Hypertension; **MACE:** Major Adverse Cardiac Events; **MI:** Myocardial Infarction; **NOACs:** Novel Oral Anticoagulants; **OAC:** Oral Anticoagulant; **PCI:** Percutaneous Coronary Intervention; **TAPT:** Triple Antithrombotic Therapy; **TIMI:** Thrombolysis in Myocardial Infarction.

CONFLICT OF INTEREST

The authors declare that there is no conflict of interest.

AUTHOR CONTRIBUTIONS

Prince Manishkumar Mehta: Conceptualization, study design, development of methodology, patient enrollment, data collection, data curation, statistical analysis, interpretation of results, writing of the original draft, and review and editing of the final manuscript.

Shivam Vikasbhai Patel: Patient enrollment, data collection, contribution to data analysis, statistical analysis, interpretation of results, and review and editing of the manuscript.

Winnie Rakesh Desai: Assisted with data collection during the study period and development of methodology.

Ami Vyas: Supervision, guidance on study conceptualization and methodology, statistical oversight, interpretation of findings, and critical review and editing of the manuscript.

SUMMARY

This ambispective multi-centric study evaluated the efficacy and safety of Dual Antiplatelet Therapy (DAPT) versus Triple Antithrombotic Therapy (TAPT) in 159 Indian patients following Myocardial Infarction (MI). Results showed that TAPT was predominantly used for higher-risk patients, as indicated by significantly higher median TIMI scores compared to the DAPT group. Both therapies demonstrated short-term safety with no bleeding events recorded. Diabetes and smoking were identified as critical independent risk factors across both groups, with smoking exhibiting the "smoker's paradox" in the DAPT cohort.

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