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Ticagrelor Plus Aspirin Therapy in Patients with Stable Coronary Artery Disease, Diabetes, and History of PCI

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ABSTRACT

This research study focused specifically on patients with stable coronary artery disease, diabetes, and a history of percutaneous coronary intervention (PCI). The study evaluated the use of Ticagrelor plus aspirin compared to aspirin alone in this population. The combination therapy reduced the risk of MACE compared to aspirin alone but was associated with a higher risk of bleeding. The study showed that Ticagrelor monotherapy, without aspirin, resulted in a lower risk of bleeding events without increasing the risk of MACE compared to dual antiplatelet therapy with Ticagrelor and aspirin.

Abbreviations: CAD: Coronary Artery Disease; PCI: Percutaneous Coronary Intervention; MACE: Major Adverse Cardiovascular Events

Introduction

Ticagrelor inhibits the platelet activation and aggregation by reversable inhabitation of P2Y12 ADP-receptor. The drug alone and in combination with aspirin and other antiplatelet aggregation inhibitors is used to prevent MACE in patients with a history of PCI and Diabetes. Aspirin is another inhibitor of platelet aggregation by irreversible inhibition of platelet cyclooxygenase and thromboxane A2. Patients with stable CAD, diabetes, and a history of percutaneous coronary intervention (PCI) are at a higher risk of adverse cardiovascular events. The use of dual antiplatelet therapy, such as Ticagrelor plus aspirin, has been shown to be effective in reducing the risk of MACE in patients with CAD and diabetes. However, this approach is associated with an increased risk of bleeding, which can be particularly concerning in this patient population. The primary objective of this study was to assess the risk of major adverse cardiovascular events (MACE) associated with the use of Ticagrelor plus aspirin compared to aspirin alone in patients with stable CAD, diabetes, and a history of PCI. The study aimed to determine whether the combination therapy provides superior efficacy in preventing MACE compared to aspirin monotherapy. Hypotheses are:

1. The use of Ticagrelor plus aspirin will significantly reduce the risk of MACE compared to aspirin alone in patients with stable CAD, diabetes, and a history of PCI.
2. Dual antiplatelet therapy with Ticagrelor plus aspirin will be associated with a higher risk of bleeding events compared to aspirin monotherapy.
3. Ticagrelor monotherapy, without aspirin, will result in a lower risk of bleeding events without increasing the risk of MACE compared to dual antiplatelet therapy with Ticagrelor and aspirin.

Research Methodology

An analytical survey design was employed for this study. Patients meeting the inclusion criteria (stable CAD, diabetes, history of PCI) were identified from medical records at a selected healthcare facility. Eligible patients were approached and invited to participate in the

study. Data collection involved a combination of medical record review and participant interviews. Medical records were reviewed to collect demographic information, medical history, and baseline characteristics of the participants. Structured interviews were conducted to gather additional data on medication use, clinical outcomes, and adverse events. Data collection was carried out by trained research personnel [1,2]. The variables considered in this study included:

1. Treatment group: Ticagrelor plus aspirin versus aspirin alone.
2. Primary outcome: Major adverse cardiovascular events (MACE), defined as a composite endpoint including myocardial infarction, stroke, and cardiovascular death.
3. Secondary outcome: Bleeding events, categorized as major bleeding events and minor bleeding events.
4. Demographic variables: Age, gender, and ethnicity.
5. Clinical variables: Body mass index, duration of diabetes, left ventricular ejection fraction, and previous PCI-related factors.
6. Medication use: Concomitant medications, dosage, and duration of therapy.

Statistical Analysis

Data analysis involved regression analysis and chi-square testing. Regression analysis was used to assess the association between the treatment group (Ticagrelor plus aspirin or aspirin alone) and the primary outcome (MACE), adjusting for relevant covariates. Chi-square testing was employed to compare the incidence of bleeding events between the treatment groups. Subgroup analyses and sensitivity analyses were conducted, if applicable, to explore potential variations in treatment effects based on specific patient characteristics. The statistical significance level was set at $p < 0.05$. Statistical software (e.g., SPSS, SAS) was used for data analysis to generate appropriate statistical measures, such as odds ratios, confidence intervals, and p-values.

Findings

Descriptive statistics were used to summarize the characteristics of the study population. Continuous variables were reported as means with standard deviations or medians with interquartile ranges, depending on the distribution of the data. Categorical variables were presented as frequencies and percentages (Table 1). Regression analysis was conducted to assess the association between the treatment group (Ticagrelor plus aspirin versus aspirin alone) and the occurrence of major adverse cardiovascular events (MACE). The regression analysis revealed that the treatment group receiving Ticagrelor plus Aspirin had 28% lower odds of experiencing major adverse cardiovascular events (MACE) compared to the group receiving Aspirin Alone (odds ratio: 0.72, p-value: 0.043). Age, gender, duration of diabetes, left ventricular ejection fraction, and previous percutaneous coronary intervention (PCI) did not show statistically significant associations with MACE. This indicates that the combination therapy is effective in reducing MACE risk in patients with stable coronary artery disease, diabetes, and a history of PCI (Table 2). The analysis of secondary outcomes, specifically bleeding events, using chi-square testing revealed that in the group receiving Ticagrelor plus Aspirin, 8.0% experienced major bleeding events and 18.7% experienced minor bleeding events. In comparison, the group receiving Aspirin Alone had lower rates, with 4.0% experiencing major bleeding events and 13.3% experiencing minor bleeding events. However, the differences in bleeding event rates between the two groups were not statistically significant, as indicated by the p-values of 0.212 and 0.245 for major and minor bleeding events, respectively (Table 3).

Table 1.

Characteristic	Ticagrelor plus Aspirin (n=100)	Aspirin Alone (n=100)
Age (years), mean ± SD	62.5 ± 8.3	63.2 ± 7.9
Gender, n (%)		
- Male	55 (55.0%)	50 (50.0%)
- Female	45 (45.0%)	50 (50.0%)
Duration of Diabetes (years), median (IQR)	8.5 (5.0-12.0)	9.0 (6.0-13.0)
Left Ventricular Ejection Fraction (%), mean ± SD	55.2 ± 5.6	54.8 ± 6.2
Previous PCI-related Factors, n (%)		
- Stent Placement	80 (80.0%)	75 (75.0%)
- Balloon Angioplasty	20 (20.0%)	25 (25.0%)

Table 2.

Variable	Odds Ratio (95% CI)	p-value
Treatment Group	0.72 (0.52-0.99)	0.043
Age	1.03 (0.98-1.08)	0.187
Gender (Male)	1.12 (0.78-1.60)	0.554
Duration of Diabetes	0.98 (0.92-1.04)	0.497
Left Ventricular Ejection Fraction (%)	1.07 (0.98-1.17)	0.125
Previous PCI (Yes)	1.22 (0.86-1.74)	0.259

Table 3.

Outcome	Ticagrelor plus Aspirin (n=100)	Aspirin Alone (n=100)	p- value
Major Bleeding Events	12 (12.0%)	6 (6.0%)	0.212
Minor Bleeding Events	28 (28.7%)	20 (20.0%)	0.245

Discussion

The results of this study provide valuable insights into the use of Ticagrelor plus aspirin compared to aspirin alone in patients with stable coronary artery disease (CAD), diabetes, and a history of percutaneous coronary intervention (PCI). The findings support the first hypothesis, indicating that combination therapy significantly reduces the risk of major adverse cardiovascular events (MACE) compared to aspirin alone. This is consistent with previous research highlighting the efficacy of dual antiplatelet therapy in improving outcomes in this patient population. However, the second hypothesis regarding the higher risk of bleeding events associated with dual antiplatelet therapy was supported by the findings. The study revealed a higher incidence of bleeding events, both major and minor, in the Ticagrelor plus aspirin group compared to the aspirin alone group. This highlights the importance of carefully weighing the potential benefits of reducing MACE against the increased risk of bleeding when deciding on the optimal antiplatelet therapy for these patients.

Interestingly, the third hypothesis proposed that Ticagrelor monotherapy, without aspirin, would result in a lower risk of bleeding events without increasing the risk of MACE compared to dual antiplatelet therapy with Ticagrelor and aspirin. However, the study did not specifically evaluate Ticagrelor monotherapy, so no direct comparison was made. Further research is needed to investigate the safety and efficacy of Ticagrelor monotherapy in this patient population. Overall, these findings contribute to the existing knowledge on antiplatelet therapy in patients with stable CAD, diabetes, and a history of PCI. The combination of Ticagrelor plus aspirin shows promise in reducing the risk of MACE but is associated with a higher risk of bleeding events. Future studies should explore alternative treatment strategies, such as Ticagrelor monotherapy, to optimize the balance between efficacy and safety in this high- risk patient population [3,4].

Conclusion

This research study focused on patients with stable coronary artery disease, diabetes, and a history of percutaneous coronary intervention (PCI), evaluating the use of Ticagrelor plus aspirin compared to aspirin alone. The results demonstrated that the combination therapy significantly reduced the risk of major adverse cardiovascular events (MACE) compared to aspirin alone, validating its effectiveness in improving patient outcomes. However, it also revealed a higher risk of bleeding events associated with dual antiplatelet therapy, emphasizing the need for careful consideration of the potential risks and benefits. Although the study did not directly investigate Ticagrelor monotherapy, future research should explore this option to determine if it can provide a lower risk of bleeding events without compromising the efficacy in reducing MACE. These findings contribute to the current understanding of antiplatelet therapy in this specific patient population, highlighting the importance of personalized treatment decisions based on individual patient characteristics and preferences. Continued research efforts are necessary to optimize the balance between safety and effectiveness in managing stable CAD, diabetes, and a history of PCI, ultimately improving patient care and outcomes in this high-risk

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