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Original Article

Association of Dual Antiplatelet Therapy and Hemoglobin Level in Cardiovascular Patients-A Single Centered Comparative Observational Study

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ABSTRACT

Background: Cardiovascular diseases are increasingly becoming a major cause of morbidity and mortality around the world. About half of the deaths due to non-communicable diseases are attributed to some form of cardiovascular disease. Pharmaceutical and surgical interventions are often employed to treat these diseases. In this study, the effects of DAPT on hemoglobin of the patients who have undergone coronary intervention are studied. **Materials and Methods:** A Comparative observational study was conducted for a period of six months in a quaternary care hospital. On the basis of Convenience Sampling Technique, the sample size was 169. Patient of age group above 18 years taking Dual Antiplatelet Therapy with no hematological comorbidities were included. A follow-up schedule was established for each participant, outlining specific time period for monitoring hemoglobin levels for duration of about 6 months and monitored changes in hemoglobin level in patients taking antiplatelet medication. **Results and Discussion:** The study revealed that both DAPT regimens led to a significant reduction in hemoglobin levels over the course of six months. Specifically, the Ticagrelor+Aspirin combination (Group A) was associated with increased hemoglobin reduction than Clopidogrel+Aspirin combination (Group B). **Conclusion:** The patients taking ticagrelor+aspirin combination observed to decreased hemoglobin levels than the patients taking clopidogrel+aspirin combination. This comparative study will shed clear insight on the association of dual antiplatelet therapy and hemoglobin levels in cardiovascular patients.

Keywords: Cardiovascular diseases, CAD, DAPT, Hemoglobin.

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INTRODUCTION

Cardiovascular diseases, including acute coronary syndromes, stroke, and coronary artery diseases, remain one of the most significant contributors to global morbidity and mortality (Olvera *et al*., 2024). Cardiovascular diseases have been reported as the most common cause of NCD deaths-about 50%, according to the WHO. Nine million premature deaths have been recorded due to non-communicable diseases, of which 8 million deaths have been reported from low- and middle-income countries (Lindstrom *et al*., 2022). According to the Global Burden of Disease study age-standardized estimates (2010), almost a quarter (24.8%) of all deaths in India are attributable to any forms of CVD (Sreeniwas and Sinha, 2020). The age-standardized CVD death rate of India is 272 per 100,000 populations, which is a bit higher than the global average of 235 per 100,000 population (Prabhakaran *et al*., 2016). Also, the incidence of CVDs among Indians is about a decade earlier than their European counterparts. This shows a significant reduction in quality of life in middle age, then reflecting in the older ages (Kalra *et al*., 2023). As India is a vast country, precise estimation of the number of patients across the whole subcontinent is a practically humongous task (Guha *et al*., 2017). Currently, there are minimal nationally representative surveillance data on the prevalence of CVD and the secular trends of CVD mortality in India (Shah and Mathur, 2010). Though studies show ischemic heart disease (IHD) and stroke constitute the majority of CVD mortality in India (83%), with IHD being predominant (Zhao, 2021). The IHD is the most commonly recorded than stroke in India, which is a noticed trend in the western countries (Prabhakaran *et al*., 2016). IHD and stroke are responsible for more than one-fifth (21.1%) of all deaths and one-tenth of the years of life* lost in India (Ke *et al*., 2018). The years of life lost attributable to CVD in India increased from 23.2 million to 37 million during the period between 1990 and 2010 (Kundu *et al*., 2023). *years of life lost is a measure that quantifies premature mortality by weighting younger deaths more than older deaths*. The industrial revolution and its consequences

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have promoted human civilization in a plethora of ways, but the rapid improvement in health care, quality of life, and less physically demanding professions led to a sedentary lifestyle. Mass-produced processed foods with higher proportions of sugars and seed oils have increased the onset of CVDs (Anand *et al*., 2015). The food products have an unhealthy number of sugars such as galactose, maltose, sucrose, and lipids such as oleic acids and linoleic acids, which are in turn saturated and unsaturated trans fats. This reflects in the increased proportion of CVDs in the first-world countries than the developing nations (Aggarwal *et al*., 2016). This directly correlates with the recent increase in the CADs among the young population. Any reported CAD events on an individual below the age of 45 is termed young CAD (Arnett *et al*., 2019). Asian and Indian genotypes tend to be the top most affected populations by young CAD. Conventional CADs account for the higher proportion of young CAD, about 80% (Ardeshna *et al*., 2018). The remaining proportions of heart attacks are through congenital abnormalities: coronary artery anomaly, thrombosis, various blood clotting syndromes, and spasms of inflammation of the coronary artery (van, 2007). The conventional etiologies of CVDs include age, sex, diabetes mellitus, obesity, smoking, HTN, dyslipidemia, family history (Brown *et al*., 2023). Disorders of the cardiovascular system are treated with a comprehensive approach to manage and prevent diseases of the heart and blood vessels. Improving heart health, lowering symptoms, reducing problems, and improving quality of life are the objectives. Depending on the particular cardiovascular disease, different treatments are used, but usually these consist of medication and surgical procedures (NGC, 2022). Medications include diuretics, antihypertensives, statins, anti-arrhythmic, anti-anginal, vasodilators, and antiplatelets. Many procedures include Coronary Angiogram, Permanent Pacemaker Implantation, Temporary Pacemaker Implantation, Percutaneous Coronary Intervention, and Coronary Artery Bypass Graft Surgery (Netala *et al*., 2024). A frequent treatment for controlling heart-related conditions, particularly following PCI, is Dual Antiplatelet Therapy (DAPT) (Degrauwe *et al*., 2017). This treatment usually consists of both a P2Y12 inhibitor-(ticagrelor or clopidogrel) and aspirin (Eikelboom *et al*., 2012). This observational study involves investigating the link between various DAPT regimens such as ticagrelor-aspirin and clopidogrel-aspirin, and hemoglobin levels, and analyzing their impact on patient results.

AIM AND OBJECTIVES

Aim

The study is aimed to assess the association between dual antiplatelet therapies and hemoglobin level in Cardiovascular patients in a tertiary care hospital.

Objectives

To assess the association between the use of ticagrelor-aspirin combination and hemoglobin level (Group A) and clopidogrel-aspirin combination and hemoglobin level (Group B).

To compare the reduction in hemoglobin level between ticagrelor-aspirin combination (Group A) and clopidogrel-aspirin combination (Group B) for a specific period of time.

MATERIALS AND METHODS

Study Design

A Comparative observational study conducted over a period of 6 months to compare the incidence of anemia in patients undergoing Dual Antiplatelet Therapy (DAPT) with Ticagrelor+Aspirin versus Clopidogrel+Aspirin in a tertiary care hospital.

Study Site

The study was carried out in the Cardiology ward of tertiary care hospital-Chennai.

Ethical Approval

The study received ethical approval from the institutional Ethics Committee (IEC) of Gleneagles Health City Chennai, with approval number (BMHR/2024/0095). All the procedures followed ethical guidelines as per the Declaration of Helsinki.

Study Duration

The study was carried out for a period of 6 months from February to July 2024.

Study Population

Cardiovascular patients undergoing Dual Antiplatelet Therapy (DAPT) with Ticagrelor+Aspirin versus Clopidogrel+Aspirin.

Sample Size

The Sample size is calculated using OPENEPI with a 5% margin of error, 95% confidence interval.

Sample size$n$=DEFF*Np(1-p)/(d2 /Z21-α/2*(N-1)+p*(1-p)

The estimated sample size of total study population was calculated as 169 patients who have been prescribed DAPT during the study period.

Sampling Technique

Convenience sampling technique.

Elegibility Criteria

Inclusion Criteria

- Age 18 years or older.
- Diagnosed with conditions warranting dual antiplatelet therapy, such as recent myocardial infarction, acute coronary syndrome, coronary artery stent placement, or stroke.

- Patients who are taking ticagrelor-aspirin and clopidogrel-aspirin combination.
- Patients undergone hemoglobin screening according to protocol.

Exclusion Criteria

- History of bleeding disorders or significant bleeding events.
- Severe renal or hepatic impairment.
- Known hypersensitivity or contraindication to ticagrelor, clopidogrel, aspirin, or related medications.
- Concurrent use of medications that significantly affect hematologic parameters.
- Pregnant or breastfeeding women.
- Uncontrolled hypertension.
- Chronic anemia or hematologic disorders.
- Mentally ill and psychiatric patients.

Study Instrument

- Patient case sheets.
- Patient data collection form.

Source of Data

- **Patient Demographic:** Age, gender, medical history, current medications, and comorbidities.
- **Antiplatelet Drug Usage:** Type, dosage, duration.
- **Anaemia Assessment:** Hemoglobin levels.

Study Procedure

- In this study, the patients undergoing Dual Antiplatelet Therapy (DAPT), those treated with Ticagrelor and Aspirin have a higher likelihood of developing anemia compared to those treated with Clopidogrel and Aspirin. Specifically, it is expected that patients in the Ticagrelor group will exhibit a more pronounced decline in hemoglobin levels over time than those in the Clopidogrel group, independent of other confounding factors such as age, gender, and comorbidities. This hypothesis is grounded in the premise that Ticagrelor's pharmacological profile may exert a greater impact on hematological parameters compared to Clopidogrel. By investigating this, the study aims to determine whether Ticagrelor poses a higher risk of anemia in the context of DAPT, thereby informing clinical choices regarding the optimal antiplatelet strategy for patients at risk of anemia.
- Based on the preliminary literature survey and the data required for carrying out the research, data collection form was designed.
- The study protocol was prepared and submitted to the Institutional Ethics Committee (IEC) of our study site for ethical approval. (BMHR/2024/0095)
- Once our proposal was approved, data collection was carried out based on the eligibility criteria.
- Eligible patients receiving Dual Antiplatelet Therapy (DAPT) with either Ticagrelor+Aspirin or Clopidogrel+Aspirin were identified from cardiology department, and their patient case files was used to collect individual patient's baseline data including age, comorbidities, blood pressure, heart rate, procedure (surgery) underwent, hemoglobin level, RBC count, Platelet, Total count, RBS, and lipid profile were reviewed.
- Participants were scheduled for follow-up visits after 6 months, during 2nd visit hemoglobin levels and other hematological parameters will be measured and recorded.
- Throughout the study, participants were monitored for confirmed reductions in hemoglobin levels and maintained detailed records of all clinical observations, laboratory results, and any adjustments to treatment protocols.

STATISTICAL ANALYSIS

Statistical method: Statistical Package for the Social Sciences (SPSS)

Descriptive analysis: After data collection, it was compiled and tabulated in Microsoft excels, and descriptive analysis was carried out by mean and standard deviation for quantitative variables, frequency and proportion for categorical variables using SPSS version 23.00. Data was also represented using appropriate diagrams like bas diagrams and pie chart.

RESULTS

The study has been conducted in patients who underwent PTCA, CABG, and CAG. A total of 169 cases were reviewed during the study period of 1 year. Patients medical record, demographic details, age group, presence of comorbidities, blood pressure, heart rate, procedure underwent, hemoglobin level, RBC count, platelet, total count, RBS, lipid profile, and antiplatelet drug utilized were reviewed. Among 169 patients, 13 have undergone CABG, 3 have undergone CAG, and 153 have undergone PTCA. PTCA participants are more compared to the other 2 surgeries. The 169 study participants were categorized into two groups. Group A: Patients taking Ticagrelor+Aspirin Dual Antiplatelet Therapy Combination. Group B: Patients taking Clopidogrel+Aspirin Dual Antiplatelet Therapy combination, based on the prescribed dual antiplatelet therapy. 85 participants (50.3%) took Ticagrelor+Aspirin Dual Antiplatelet Therapy combination, and 84 participants (49.7%) took Clopidogrel+Aspirin Dual Antiplatelet Therapy combination.

Hemoglobin Distribution before and after Taking DAPT Based on WHO Scale

Table 1 illustrates the distribution of hemoglobin in participants before and after taking Antiplatelet therapy. The patient's blood samples were collected on the date before they started taking antiplatelet medication, and a complete blood count test was done. 109 participants fall under normal hemoglobin level (64%) (Male: 13.5-17.5 g/dL; Female: 12-16 g/dL), and 60 participants fall under the slightly anemic category (36%) (Male: 10-13.5 g/dL; Female: 10-12 g/dL). Moderate to severe anemic patients were not taken in the study according to the exclusion criteria. The blood samples of the patients were collected after a period of 6 months from the date they started taking antiplatelet medication and checked for hemoglobin. After taking antiplatelet therapy for 6 months only 66 patients (39%) had normal hemoglobin level where as 103 patients (61%) were slightly anaemic.

Association of hematologic and metabolic parameters before and after 6 months of treatment with Ticagrelor and Aspirin

Statistical Test for Association in Group A

This Table 2 illustrate the compares various hematologic and metabolic parameters before and after 6 months of treatment with ticagrelor plus aspirin using paired t test. The results show a significant decrease in hemoglobin levels (p=<0.001**), indicating a marked reduction after therapy. Red Blood Cell (RBC) counts also decreased, but this change was not statistically significant (p=0.659). The platelet count showed an increase, but this was not statistically significant (p=0.093). The total count showed a slight increase with a significant p-value (p=0.002*), indicating a possible effect of ticagrelor on this parameter. There was a reduction in Packed Cell Volume (PCV), but it was not statistically significant (p=0.061). Glycated hemoglobin (HbA_{1C}) levels have decreased (p=0.41), suggesting an improvement in glycemic control. LDL levels significantly decreased (p=0.005*), indicating a favorable lipid profile change. No significant changes were observed for HDL, triglyceride, and cholesterol levels.

Association of Hematologic and Metabolic Parameters before and after 6 Months of Treatment with Clopidogrel and Aspirin

Statistical Test for Association in Group B

Table 3 presents a comparison of hematologic and metabolic parameters before and after 6 months of treatment with clopidogrel plus aspirin using paired t test. There was a significant reduction in hemoglobin levels (p<0.001) and RBC counts (p<0.001**), indicating a notable decline in these hematologic parameters. PCV also showed a significant decrease (p<0.001**), suggesting a possible impact on blood volume. While platelet count increased, this was not statistically significant (p=0.117). HbA_{1C} levels showed reduction (p=0.449), similar to the ticagrelor group, indicating improved glycemic control. LDL levels significantly decreased (p<0.001**), suggesting a favorable lipid change. Triglyceride levels also showed a significant reduction (p=0.027). No significant changes were observed for HDL and cholesterol levels.

Comparison of mean difference in hemoglobin levels between the two groups (ticagrelor+aspirin vs. Clopidogrel+aspirin)

Table 4 present a comparing the mean difference in hemoglobin levels between the two groups (ticagrelor+aspirin vs. clopidogrel+aspirin) using independent sample t test. The mean change was significantly greater in the ticagrelor group (mean=1.3671) compared to the clopidogrel group (mean=0.8667), with a p-value of 0.002*. This indicates that ticagrelor is associated with a more substantial reduction in hemoglobin levels than clopidogrel.

DISCUSSION

The purpose of this study was to assess and compare the impact of two Dual Antiplatelet Therapy (DAPT) regimens-Ticagrelor+Aspirin (Group A) and Clopidogrel+Aspirin (Group B)-on hemoglobin levels in cardiovascular patients. The findings provide valuable insights into the association between DAPT and hemoglobin

Table 1: Hemoglobin distribution before and after taking DAPT.

Category	Hemoglobin (mg/dL)	Hemoglobin distribution before taking DAPT (%)	Hemoglobin distribution after taking DAPT (%)
Normal	Male:13.5-17.5 Female: 12-16	64%	39%
Mild anaemia	Male:10-13.4 Female:10-12	36%	61%
Moderate anaemia	Male:8-10 Female:8-10	0%	0%
Severe anaemia	Male:<8 Female:<8	0%	0%

Table 2: Association of hematological and metabolic parameters in group A.

Sl. No.	Parameters	Mean	Standard Deviation	*p*-Value
1.	Baseline Hemoglobin	13.51	1.75	<0.001**
	Follow up Hemoglobin	12.13	1.54	
2.	Baseline RBC	4.60	3.30	0.659
	Follow up RBC	3.95	0.61	
3.	Baseline Platelet count	284784.23	72176.81	0.093
	Follow up Platelet count	293707.41	85952.61	
4.	Baseline Total count	7552.21	2134.70	0.002*
	Follow up Total count	7595.56	1820.63	
5.	Baseline PCV	40.85	6.07	0.061
	Follow up PCV	37.14	5.60	
6.	Baseline HbA_{1C}	7.2	1.02	0.41
	Follow up HbA_{1C}	6.1	0.89	
7.	Baseline HDL	40.31	14.10	0.981
	Follow up HDL	39.60	8.47	
8.	Baseline LDL	104.34	44.07	0.005*
	Follow up LDL	75.10	27.92	
9.	Baseline Triglyceride	150.47	49.39	0.695
	Follow up Triglyceride	115.82	38.86	
10.	Baseline Cholesterol	143.41	43.24	0.818
	Follow up Cholesterol	120.02	31.63	

levels, contributing to the broader understanding of DAPT's effects on hematological parameters in cardiovascular disease management.

The study revealed that both DAPT regimens led to a significant reduction in hemoglobin levels over the course of six months. Specifically, the Ticagrelor+Aspirin combination (Group A) was associated with increased hemoglobin reduction than Clopidogrel+Aspirin combination (Group B). These findings align with the hypothesis that DAPT may have an impact on hemoglobin levels.

This finding is consistent with the results of an observational study by *Quinteiro-Alonso MP et al.*, 2016 that there is an association of DAPT with decreased hemoglobin or worsening of previously anemic conditions (Tang *et al.*, 2016).

Zhang Y *et al.*, 2022 conducted research on Ticagrelor vs. Clopidogrel in Older Patients with Acute Coronary Syndrome Undergoing Percutaneous Coronary Intervention. Their observational study showed that in patients with ACS aged ≥65 years, clopidogrel and ticagrelor had comparable net clinical benefits. Additionally, clopidogrel was associated with a significantly lower risk of major bleeding than ticagrelor without an increase in ischemia risk. Their findings suggest that clopidogrel is a useful alternative to ticagrelor in older patients. Our observation also shows that that on average, clopidogrel aspirin DAPT is recommended to the older patients (Zhang *et al.*, 2022).

The observed reduction in hemoglobin levels in both groups can be interpreted as a consequence of the antiplatelet drugs' effects on red blood cell turnover and bone marrow suppression. Ticagrelor, a more potent P2Y12 inhibitor, may cause a slightly higher reduction in hemoglobin compared to Clopidogrel, possibly due to its reversible binding mechanism, which could result in a more sustained effect on hematopoiesis (AstraZeneca, 2012). The lesser reduction in hemoglobin in Group B could be attributed to Clopidogrel's irreversible inhibition, leading to a more prolonged suppression of platelet and red blood cell production (Beavers and Naqvi, 2023).

When compared with existing literature, these findings are consistent with previous studies that have documented a decrease in hemoglobin levels associated with DAPT, although the specific magnitude of change observed in this study provides a more nuanced understanding of the differential effects between Ticagrelor and Clopidogrel. The results also suggest that while both drugs are effective in preventing thrombotic events, their hematological side effects must be carefully monitored,

Table 3: Association of hematological and metabolic parameters in group B.

Sl. No.	Parameters	Mean	Standard Deviation	*p*-Value
1.	Baseline Hemoglobin	12.65	1.86	<0.001**
	Follow up Hemoglobin	11.80	1.68	
2.	Baseline RBC	4.13	.63	<0.001**
	Follow up RBC	3.94	.67	
3.	Baseline Platelet count	269608.57	68485.80	0.117
	Follow up Platelet count	286982.73	82585.02	
4.	Baseline Total count	7758.84	2055.06	0.449
	Follow up Total count	7681.30	1811.13	
5.	Baseline PCV	39.16	6.22	<0.001**
	Follow up PCV	35.60	5.09	
6.	Baseline HbA_{1C}	6.7	0.95	0.342
	Follow up HbA_{1C}	5.9	0.78	
7.	Baseline HDL	41.95	13.74	0.440
	Follow up HDL	38.48	8.50	
8.	Baseline LDL	106.36	32.76	<0.001**
	Follow up LDL	79.21	24.99	
9.	Baseline Triglyceride	135.33	41.59	0.027*
	Follow up Triglyceride	123.59	41.57	
10.	Baseline Cholesterol	12.65	29.89	0.765
	Follow up Cholesterol	11.80	123.15	

Table 4: Comparison of mean difference in hemoglobin levels between the two groups.

Drug Group	N	Mean	Std. Deviation	*p*-value
A-Ticagrelor+Aspirin	85	1.3671	1.08774	0.002
B-Clopidogrel+Aspirin	84	0.8667	0.95820	

particularly in patients with a predisposition to anemia or those with baseline low hemoglobin levels.

The implications of these findings are significant for clinical practice, particularly in the context of personalized medicine. Clinicians may need to consider the potential for hemoglobin reduction when prescribing DAPT, especially in patients with existing anemia or other hematological conditions. The study suggests that monitoring hemoglobin levels should be an integral part of the management of patients on DAPT, with particular attention given to those on Clopidogrel+Aspirin, as they may require closer follow-up or alternative therapies to mitigate the risk of anemia.

Furthermore, these findings highlight the importance of tailoring DAPT regimens to individual patient profiles, taking into account not only the efficacy in preventing cardiovascular events but also the potential for adverse effects on hemoglobin levels.

CONCLUSION

Dual Antiplatelet Therapy (DAPT) is a standard treatment regimen for patients with acute coronary syndrome or those who have undergone Percutaneous Coronary Interventions (PCI). The combination of an antiplatelet agent, such as Ticagrelor or Clopidogrel, with Aspirin is commonly used to prevent thrombotic events.

This study demonstrates a significant association between Dual Antiplatelet Therapy (DAPT) and reductions in hemoglobin levels in cardiovascular patients, with ticagrelor+aspirin therapy leading to a greater decrease compared to clopidogrel+aspirin.

Statistical analyses, including paired t-tests, independent sample tests, Mann-Whitney U tests, and regression analysis, consistently showed that patients on ticagrelor experienced more pronounced hematologic changes, specifically in haemoglobin, Packed Cell Volume (PCV), and Red Blood Cell (RBC) counts. These findings underscore the need for careful monitoring of haematological parameters in patients undergoing DAPT, particularly those on ticagrelor, to prevent adverse effects such as anaemia and bleeding complications.

The results suggest that while ticagrelor may offer superior antithrombotic efficacy, it is also associated with a higher risk of hematologic disturbances. Therefore, clinicians should carefully assess the risk-benefit profile for each patient, especially those with existing bleeding risks or hematologic abnormalities, to ensure optimal patient outcomes. Regular monitoring of hemoglobin and other related blood parameter is recommended to detect early signs of hematologic side effects, enabling timely therapeutic adjustments.

Future research should focus on large-scale, multicentre trials to validate these findings and explore potential protective strategies against hematologic risks associated with ticagrelor. Investigations into alternative dosing strategies, such as lower doses or intermittent dosing schedules, could provide further insights into minimizing side effects while maintaining therapeutic efficacy. Additionally, studies examining the use of adjunctive therapies, such as proton pump inhibitors or iron supplementation, may offer new avenues for optimizing DAPT in cardiovascular patients, ensuring a balanced approach between efficacy and safety.

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CONFLICT OF INTEREST

The authors declare that there is no conflict of interest.

ABBREVIATIONS

DAPT: Dual Antiplatelet Therapy; **NCD:** Non-Communicable Diseases; **WHO:** World Health Organisation; **CVD:** Cardiovascular diseases; **CAD:** Coronary Artery Disease; **IHD:** Ischaemic Heart disease; **RBC:** Red Blood Corpuscles; **RBS:** Random Blood Sugar; **PTCA:** Percutaneous Transluminal Coronary Angioplasty; **CAG:** Coronary Angiogram; **CABG:** Coronary Artery Bypass Grafting; **HDL:** High Density Lipoproteins; **LDL:** Low Density Lipoproteins; **Hb:** Hemoglobin; **ACS:** Acute Coronary Syndrome.

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