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Original Article

A Cross-Sectional Observational Study to Assess Red Cell Distribution Width as a Novel Biomarker for the Prediction of Severity of Acute Ischemic Stroke

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ABSTRACT

Background: Stroke, a leading cause of death and disability, is primarily classified into ischemic and hemorrhagic types. Red Cell Distribution Width, measures the variability in red blood cell size, is an emerging biomarker linked to stroke severity. The primary aim of this study was to evaluate the utility of Red Cell Distribution Width in predicting stroke severity and to assess potential drug-drug interactions that could lead to adverse drug reactions in acute ischemic stroke patients. **Materials and Methods:** This study was conducted over a six-month period and included 120 patients diagnosed with cerebral infarction. Red Cell Distribution Width and other parameters were measured and correlated with stroke severity using the National Institutes of Health Stroke Scale and Glasgow Coma Scale scores. The patients were monitored throughout their stay. Pearson correlation analysis was employed for data evaluation. **Results:** Among 120 patients, 75% were male and 25% were female, with majority of patients aged between 55 and 85 years. The results indicated significantly higher values in patients with severe strokes (*p* value <0.001). A positive correlation was observed between Red Cell Distribution Width and the standard stroke score (r=0.11), while a weak negative correlation was found with Glasgow Coma Scale score (r=-0.04). Hemoglobin also exhibited a weak negative correlation with stroke severity. Drug-drug interactions were identified in 39% of patients, and adverse drug reactions included nasal bleeding and hematuria. **Conclusion:** Red Cell Distribution Width is a promising and accessible biomarker for assessing the severity of acute ischemic stroke and the associated mortality risk.

Keywords: Biomarkers, Ischemic stroke, NIHSS, Red cell distribution width, Stroke.

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INTRODUCTION

Stroke is one of the leading causes of death, with rates over 41.1 per 100,000 in 2021 (Feigin *et al*., 2021). According to Disability-Adjusted Life Years (DALYs), stroke is the second leading cause of death and the third leading cause of death with disability worldwide, the first being ischemic heart disease (Ma *et al*., 2021). It is divided into ischemic and hemorrhagic stroke. Diagnosis is primarily achieved via neuroimaging and neurological assessment tools such as the National Institutes of Health Stroke Scale (NIHSS) and the Canadian Neurological Scale (CNS). Timely diagnosis and intervention are crucial in stroke cases, as they significantly influence patient outcomes by reducing mortality and long-term disability (Gulati *et al*., 2021).

In recent years, Red Cell Distribution Width (RDW)-a parameter quantifying the variability in Red Blood Cell (RBC) sizes-has garnered attention as a prognostic indicator in Acute Ischemic Stroke (AIS) (Demir *et al*., 2015). It is a standard parameter included in Complete Blood Count (CBC) tests. Elevated RDW levels are associated with increased inflammation and oxidative stress (Zhang *et al*., 2021; Ghazizadeh *et al*., 2020), which are critical factors in many diseases, including cardiovascular conditions and strokes. Numerous studies have demonstrated a strong association between high RDW levels and adverse outcomes in cardiovascular diseases and stroke (Danese *et al*., 2015). For instance, higher RDW levels have been linked to greater stroke severity and poorer prognosis (Eyiol and Ertekin, 2024). While neuroimaging techniques are the foundation for AIS diagnosis, biochemical examination of cell damage may serve as a supplementary technique for preliminary assessment. A biomarker to identify and screen for AIS patients could be beneficial, especially for those who may benefit from thrombolytic therapy prior to hospitalization (Kou *et al*., 2022).

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The integration of RDW as a predictive tool not only holds potential in individual patient care but also serves as a vital element in broader public health initiatives (Zhang *et al.*, 2022). By providing an affordable and accessible means of assessing stroke severity, RDW contributes to a more equitable distribution of diagnostic resources, addressing disparities in healthcare access. Furthermore, ischemic stroke patients often contend with comorbidities and polypharmacy, which elevate the risk of Drug-Drug Interactions (DDIs). The increased susceptibility to these interactions can significantly alter the intended therapeutic effects, potentially leading to adverse outcomes. Timely identification of such interactions is essential for preventing adverse effects and may necessitate adjustments to the treatment plan.

This study aims to elucidate the potential of RDW as a predictive biomarker for AIS severity, correlating with established scoring scales (NIHSS and Glasgow Coma Scale), investigate the relationship between anemia and acute ischemic stroke, and evaluate the occurrence and implications of DDIs and Adverse Drug Reactions (ADRs) in this patient population. By exploring these objectives, the study seeks to enhance understanding of RDW in stroke prognosis and inform clinical practices to improve patient outcomes.

MATERIALS AND METHODS

This prospective observational study was conducted over a period of six months, from November 2023 to April 2024. Participants included in the study were patients diagnosed with AIS, confirmed through clinical evaluation and imaging studies. Inclusion criteria required that patients be aged 18 years or older and provide informed consent. Exclusion criteria included patients with haemorrhagic stroke, other significant comorbid conditions that could influence RDW levels (e.g., chronic inflammatory diseases, malignancies), or incomplete medical records. Before enrollment, all patients or their legal representatives were informed about the study's objectives, procedures, potential risks, and benefits. Consent was documented in writing, adhering to ethical standards and ensuring compliance with institutional and regulatory guidelines.

The severity of AIS in patients was assessed using the National Institutes of Health Stroke Scale (NIHSS) and the Glasgow Coma Scale (GCS) scores. These scales provided standardized measures of neurological impairment and stroke severity. Blood samples were collected to measure RDW, complete blood count, lipid profile, C-reactive Protein (CRP), and cardiac function tests. Throughout the hospital stay, patients were closely monitored for potential Drug-Drug Interactions (DDIs) and Adverse Drug Reactions (ADRs). This monitoring was essential for understanding the impact of medication regimens on patient outcomes and ensuring safe and effective treatment. The relationships between RDW, haemoglobin levels, and stroke severity were analysed using Pearson correlation coefficients. This statistical method allowed for the assessment of the strength and direction of the linear relationships between these variables, providing insights into the potential role of RDW as a biomarker for AIS severity.

RESULTS

Demographics

Out of 120 patients included in the study, 90 (75.00%) were male and 30 (25.00%) were female. The age group with the highest incidence of Acute Ischemic Stroke (AIS) was 61-70 years, accounting for 37 patients (30.83%). Hypertension was the most prevalent comorbidity, observed in 80 patients (66.67%), followed by diabetes mellitus in 27 patients (22.50%). Demographic details of the study population are summarized in Table 1.

Red Cell Distribution Width and Stroke Severity

Correlation with National Institutes of Health Stroke Scores

RDW was found to follow the upward trend along with stroke severity, as examined using NIHSS. The mean RDW progressively increased with 14.56±1.59 in minor strokes, 14.97±1.53 in moderate strokes, 15.41±1.74 in moderate to severe strokes, and 17.32±3.02 in severe strokes. This steady rise was statistically significant (p<0.001), with a Pearson correlation coefficient of 0.384.

Correlation with Glasgow Coma Scale Scores

Similarly, RDW values also showed a statistically significant relationship with Glasgow Coma Scale (GCS) scores. Patients with minor, moderate, and severe strokes had mean RDW levels in the rising levels of 15.33±2.16, 15.95±1.70, and 16.74±3.02, respectively. The overall correlation between GCS and RDW was negative (r=-0.309, p<0.001), with the strongest negative correlation observed in severe stroke patients (r=-0.75) (Table 2).

Haemoglobin Levels and Stroke Severity

In contrast, haemoglobin levels were inversely associated with stroke severity. The mean RDW followed a declining trend with 14.31±1.35 (median=13.95) in patients with minor stroke, 12.64±2.07 (median=13) in moderate stroke patients, 12.44±2.70 (median=12.7) in patients with moderate to severe stroke, and 11.22±2.13 (median=11.3) in severe stroke patients. These differences were statistically significant (p<0.001), with an overall correlation coefficient of 0.356 (Figure 1).

Comparison of Red Cell Distribution Width with Mortality in Patients

A majority of the patients (96%) were discharged after a variable hospital stay of 2-8 days while 4% of the patients died. Figure 2 shows that RDW values were correspondingly lower in surviving patients (median=13.8) than in patients who expired

(median=15.5) indicating an emerging mortality predictor (p-value=0.048).

Commonly Prescribed Drugs in Patients

In total, 95 medications were prescribed to the patients with AIS. Pantoprazole was prescribed in 99 patients out of 120 and was the most common drug (82.5%), followed by Ondansetron (75%), Clopidogrel (68.4%), and Aspirin (62.5%). Other commonly used medications included lipid-lowering agents (67.5%), antibiotics (53.4%), antiepileptics, hypoglycemics, antihypertensives, and lactulose.

Drug Interactions

A total of 52 drug interactions were identified in the patients with AIS, with majority being present in males. The most common drug classes (Figure 3) prescribed to AIS patients were anti-platelets, anti-hypertensives, and lipid-lowering agents, followed by antidiabetics, antipsychotics, and PPIs. The incidence rate of drug-drug interaction was 39.13%. Management of these interactions included drug withdrawal in 25.8% of cases, biochemical monitoring in 12.48%, and close symptomatic observation in 14.14% of subjects. In uncommon cases (0.83%), suspected drugs were switched.

Adverse Drug Reactions in Patients

Table 3 provides a summary of Adverse Drug Reactions (ADRs) occurring in AIS patients. Hematuria and anemia were the most common adverse events observed. Most ADRs involved antiplatelets and antifibrinolytics. Patients aged 51-90 years mostly experienced ADRs. Some notable cases included heparin-induced hematuria, atenolol-induced bradycardia, and tranexamic acid- and aspirin-clopidogrel-induced anemia. In all these cases, the suspected medications were discontinued, and follow-up investigations confirmed symptom resolution.

DISCUSSION

Acute Ischemic Stroke (AIS) is a prime cause of morbidity and mortality worldwide, demanding rapid diagnosis and prognostic evaluation for early management. While neuroimaging is required for evaluation, there is a need for a quick and easy test for predicting the severity of stroke, which can improve recovery rates and lessen the overall burden on healthcare systems (Xu *et al.*, 2022). RDW, being a standard component of complete blood count tests, offers a cost-effective and readily available measure for early diagnosis and treatment planning in AIS patients.

RDW was previously investigated as an indicator of inflammation in cases of acute myocardial infarction (Wissel *et al.*, 2014) and peripheral vascular disease (Shen *et al.*, 2022). It is related to acute ischemic stroke through mechanisms involving inflammation and oxidative stress (Joosse *et al.*, 2023), which lead to atherosclerosis, subsequently elevating the likelihood of ischemic stroke (Kong *et al.*, 2022). This process can also impact the structure of Red Blood Cells (RBCs) by modifying membrane proteins (Pretorius, 2018), leading to an extended lifespan of RBCs and premature release of larger RBCs into the peripheral circulation, thus increasing RDW (Chung *et al.*, 2022).

Our study results found that elevated RDW levels are positively correlated with stroke severity, as measured by NIHSS and GCS scores. Our observations align with Feng *et al.*, (2017), who conducted a meta-analysis and determined that there is a probable link between elevated RDW and conditions such as ischemic cerebrovascular disease, carotid artery atherosclerosis, and cerebral embolism (Feng *et al.*, 2017). Furthermore, Sarhan *et al.*, (2019) reported that RDW values higher than 14.6 significantly increased stroke risk by multiple folds, with an odds ratio of 4.38 (p<0.001), indicating that higher RDW levels are associated with poorer clinical outcomes and reinforcing its potential as a reliable biomarker (Sarhan *et al.*, 2019b).

In relation to our research, it was analyzed that the median RDW was higher in deceased patients (15.5) compared to those discharged alive (13.8), with a statistically significant correlation (p=0.048). Previous studies also reported higher RDW levels in

Table 1: Summary of patient demographic details.

Characteristic	n (%) (n=120)
Gender	
Male	90 (75.00)
Female	30 (25.00)
Age (years)	
21-30	2 (1.67)
31-40	7 (5.83)
41-50	22 (18.33)
51-60	35 (29.16)
61-70	37 (30.83)
71-80	16 (13.33)
81-90	1 (0.83)
Major Risk Factors	
Hypertension	34 (28.33)
Diabetes	27 (22.50)
Smoking	14 (12.00)
Ischemic heart disease	9 (7.50)
Overweight	4 (3.30)
Chest pain	3 (2.50)
Hypothyroidism	2 (1.66)
Hyperthyroidism	1 (0.83)
Valve replacement	1 (0.83)
Asthma	1 (0.83)

n=total number of subjects; n=number of subjects for a condition.

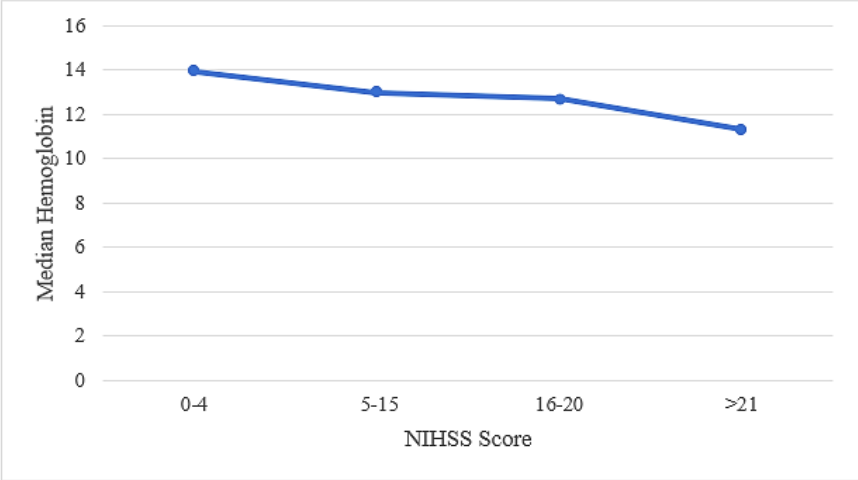

Figure 1: Relationship between NIHSS score and median hemoglobin levels in AIS patients. The graph shows a decreasing trend in hemoglobin levels with increasing stroke severity based on NIHSS categories. Reproduced at 91.54 mm column width.

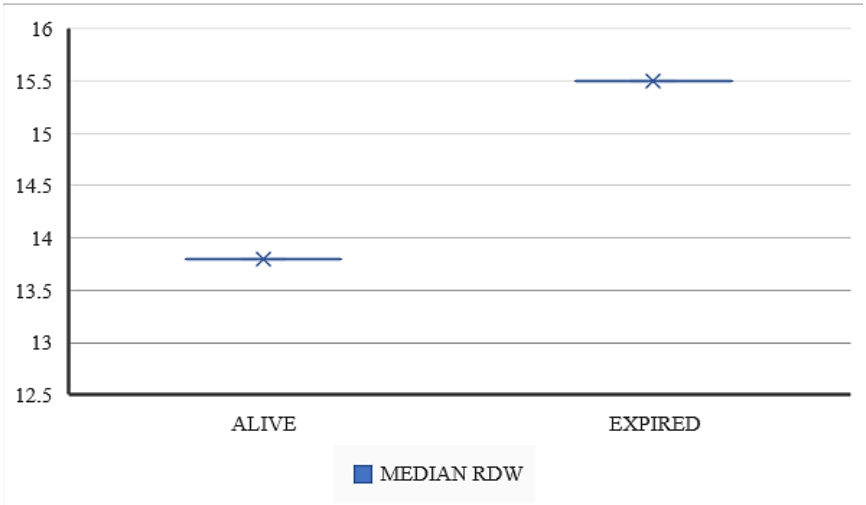

Figure 2: Comparison of median RDW values based on patient status (expired vs discharged). The chart indicates higher RDW levels in patients who expired, suggesting a potential association with poorer outcomes. Reproduced at 94.72 mm column width.

expired AIS patients; for instance, Ani and colleagues (2009) discovered that individuals with RDW values exceeding 13.9% were twice as likely to face mortality compared to the reference group (Ani and Ovbiagele, 2008). This suggests a potential link between RDW and AIS mortality.

The study also examined the relationship between hemoglobin levels and stroke severity, revealing a statistically significant negative correlation with NIHSS scores. This indicates that as stroke severity increased, hemoglobin levels decreased-a finding consistent with prior research by Tanné *et al.*, where 19% of severe AIS patients had anemia (Tanne *et al.*, 2010). Although the correlations were weak, hemoglobin levels still provide valuable information about the overall health status of stroke patients. Monitoring hemoglobin can help assess the patient's capacity to transport oxygen, which is critical in stroke recovery management (Kaiafa *et al.*, 2016).

Our study also highlighted the prevalence of Drug-Drug Interactions (DDIs) and Adverse Drug Reactions (ADRs). Antiplatelets and cholesterol-lowering medications were the most frequently prescribed drugs. However, prophylactic medications such as antibiotics, proton pump inhibitors, and anti-emetics were also commonly used. The prevalence and clinical implications of DDIs and ADRs were mainly associated with anticoagulants and antiplatelets. An incidence rate of 39.13% for DDIs underscores the importance of vigilant therapeutic monitoring.

ADRs observed included events such as hematuria and anemia, primarily linked to heparin, clopidogrel, aspirin, and tranexamic acid. Our findings support previous research indicating that the geriatric population is particularly susceptible to ADRs due to age-related physiological changes and comorbidities, emphasizing the importance of post-marketing surveillance and prompt withdrawal of suspected drugs upon ADR detection.

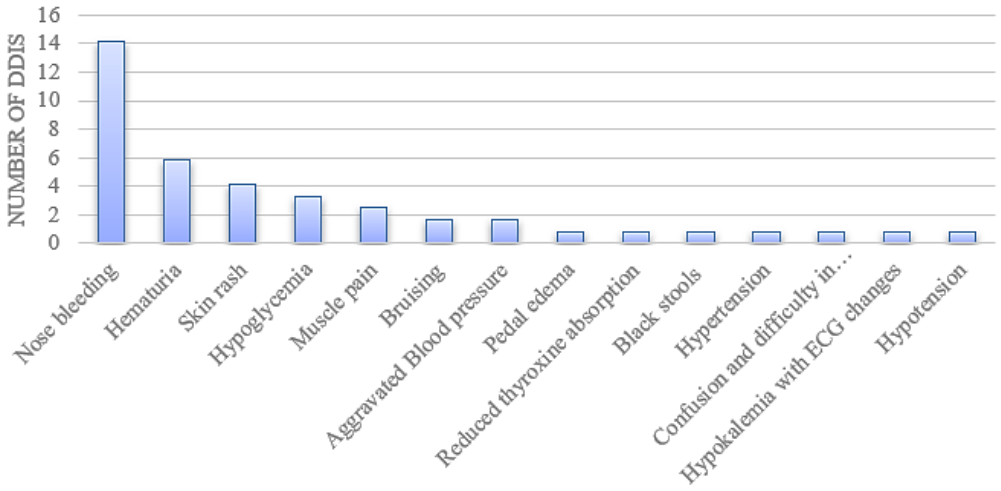

Figure 3: Frequency of drug-drug interactions observed among patients with acute ischemic stroke. The figure highlights the most common interacting drug classes used during inpatient care. Reproduced 86.78 mm column width.

Table 2: **Summary of RDW values with NIHSS and GCS severity index.**

Severity Index	Correlation coefficient	*p*-value
National Institutes of Health Stroke Scale		
Mild	0.4401	<0.001
Moderate	0.0714	<0.001
Moderate to Severe	0.0139	<0.001
Severe	0.0197	<0.001
Glasgow Coma Scale		
Mild	-0.022	0.017
Moderate	-0.274	0.086
Severe	-0.756	<0.001

Table 3: **ADRs found in Ischemic stroke patients.**

ADRs found	Number of cases	Percentage (*n*=120) (%)
Tranexamic acid-induced severe anemia	2	2
Heparin-induced Hematuria	1	0.83
Atenolol-induced Bradycardia	1	0.83
Clopidogrel-Aspirin induced anemia	1	0.83

These observations collectively validate the study hypothesis that hemoglobin and RDW levels are closely associated with stroke severity, and that judicious drug management is essential in AIS patients. Incorporating RDW into standard diagnostic algorithms may facilitate early risk stratification and guide clinical decision-making, especially in resource-limited settings. Additionally, reviewing medication charts and performing interaction checks can reduce the burden of preventable drug-related problems.

Nevertheless, this study has some limitations. The small sample size and relatively short duration may affect the generalizability of the results. The observed associations might have been influenced by potential confounding factors not fully accounted for, such as pre-existing comorbidities and varying treatment approaches. Larger, multicentric studies are necessary to validate these findings.

Future research should aim to validate RDW as a reliable biomarker for stroke severity across diverse populations and clinical settings. Investigating the optimal timing for RDW measurement in relation to stroke onset could also enhance its clinical utility. Longitudinal studies assessing RDW's role in stroke risk stratification, prognosis prediction, and post-stroke recovery would provide deeper insights into its potential applications.

CONCLUSION

A comprehensive analysis of RDW, hemoglobin, commonly prescribed drugs, drug interactions, and adverse drug reactions in AIS patients sheds light on the intricate landscape of stroke management. These findings underscore the critical role of monitoring biomarkers, managing drug regimens, and promptly addressing ADRs and DDIs to optimize patient outcomes and ensure the safety and efficacy of treatment strategies in the context of acute ischemic stroke. By delving deeper into the observed trends and addressing the limitations of small sample size and limited study duration, future research can pave the way for improved stroke prevention, early intervention, and ultimately, better patient outcomes.

ABBREVIATIONS

DALY: Disability-Adjusted Life Year; **NIHSS:** National Institutes of Health Stroke Scale; **CNS:** Canadian Neurological Scale; **RDW:** Red Cell Distribution Width; **CBC:** Complete Blood Count; **AIS:** Acute Ischemic Stroke; **DDI:** Drug-Drug Interaction; **GCS:** Glasgow Coma Scale; **ADR:** Adverse Drug Reaction; **CRP:** C-Reactive Protein; **PPI:** Proton Pump Inhibitor.

CONFLICT OF INTEREST

The authors declare that there is no conflict of interest.

AUTHOR CONTRIBUTIONS

EG designed experiments, evaluated patients, conducted analysis and wrote the final draft of the manuscript; AS provided feedback on the report, all the other authors and collaborators evaluated patients and helped in data collection.

ETHICAL APPROVAL

This research study was conducted prospectively from data obtained for clinical purposes and it is an observational study. All procedures performed in the study are in accordance with the ethical standards of the Parul University- Institutional Ethics Committee for Human Research and with the 1964 Helsinki Declaration and its later amendments. We confirm that we have read the Journal's position on issues involved in ethical publication and affirm that this work is consistent with those guidelines.

INFORMED CONSENT

Consent was obtained from patients for all procedures as appropriately needed.

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