Section A-Research paper

CROSS-SECTIONAL, DESCRIPTIVE, AND NON-INTERVENTIONAL COMPARATIVE EVALUATION OF PLATELET VOLUME IN PATIENTS WITH DIABETES MELLITUS AND NON-DIABETIC PATIENTS SUFFERING FROM ACUTE ISCHEMIC STROKE.

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ABSTRACT

The second largest cause of long-term morbidity and the second most prevalent stroke worldwide is acute ischemic stroke. Ischemic stroke, which accounts for 80% of all strokes, and hemorrhagic stroke, which may occur intracerebrally or subarachnoidally, are the two primary forms of stroke. Studies have shown that platelets are important in the pathophysiology of cerebral atherothrombotic events and ischemic processes because of their activities in platelet adhesion, release response, and aggregation. Thus, larger MPVs signal a worse future. Increased platelet activation may indicate increased stroke severity. We planned our study to assess and compare MPV in type 2 diabetic and non-diabetic patients with acute ischemic stroke. Our study found that diabetics had statistically larger MPVs. Diabetes and mean platelet volume showed a positive correlation.

Keywords: Acute Ischemic Stroke, MPV Type 2 Diabetic And Non-Diabetic Patient**.**

INTRODUCTION

Acute ischemic stroke (AIS) is the second most prevalent primary reason for mortality worldwide and the second most prevalent cause of long-term morbidity. Ischemic stroke, which accounts for more than 80% of all strokes, and hemorrhagic stroke, which may occur intracerebrally or subarachnoidally, are the two primary kinds.[1] In this case, an unexpected intracranial vessel closure reduces cerebral blood flow. The underlying illness of AIS is atherothrombotic disease. The relationship between fibrin synthesis, platelet activation, and fibrinolysis is crucial in atherothrombotic events in acute ischemic stroke (AIS) and may affect stroke prognosis and pathogenesis. Platelets play a vital role in the pathogenesis of cerebral atherothrombotic events and ischemic processes because they play these roles in platelet adhesion, release response, and aggregation.[2,3]

"The mean platelet volume (MPV) is calculated by hematological analyzers based on the volume distribution of platelets in a blood sample during a routine morphological test".[4] The MPV varies between 7.5% and 12.0%, but large platelets should represent 0.2% to 5.0% of the whole platelet population. Many disorders upset this healthy equilibrium. Changes in the MPV/PLT ratio may be caused by considerably increased or abnormal thrombocytopoiesis, increased wear, or the effect of activating drugs on blood platelets.[4] However, from various studies, it has been proven that the greater the MPV, the worse the prognosis. Hence, increased platelet activation may be a sign of increased stroke severity and prognosis. Hence , our study was structured to evaluate & compare MPV with type 2 diabetes & non-diabetic patients with acute ischemic stroke involving different parameters.

AIM

The primary goal of the study was to evaluate and compare MPV with type 2 diabetes and non-diabetic patients with acute ischemic stroke, involving many measures.

INCLUSION CRITERIA

1. Those patients who have been diagnosed previously with acute ischemic stroke with CT & MRI investigations.
2. Male & female genders were included in the study with age range of 18 years and above.

EXCLUSION CRITERIA

1. Patients had any past history of haemorrhagic stroke, Trasient ischemic attacks, Renal , Hepatic insufficiency, organ transplantation, other immunosuppressive aetiologies, type 1 diabetes mellitus, thrombocytopenia, disseminated intravascular coagulation(DIC) , thrombosis, hemoglobinopathies & patients with fever on presentation to the hospital .
2. Patients who were diagnosed with viral fever (eg. Dengue, malaria etc).
3. Patients on antiplatelet drugs, heparin, oral anticoagulant & steroids.
4. Patients suffering from malignancy, chronic inflammatory disease (for eg. Connective tissue disorder such as vasculitis, rheumatoid arthritis, systemic lupus erythematosus).

MATERIALS & METHOD

TYPE OF STUDY= Cross sectional, descriptive and non-interventional comparative study.

SETTING= This study was conducted among hospitalized patients at Krishna Hospital and Medical Research Centre in Karad, Maharashtra.

STUDY DURATION = over a period of 18 months (October 2018 to March 2020).

ETHICAL COMMITTEE CLEARANCE= This study received IEC approval. After receiving informed and written consent, a total of 100 patients met the study's inclusion criteria.

INVESTIGATION

The study involved conducting haemoglobin estimation, platelet count, mean platelet volume, and imaging studies such as magnetic resonance imaging (MRI) or computed tomography (CT) brain scans on all patients.

STASTICAL ANALYSIS

The data frequency distribution was shown using graphs and tables. We determined the mean SD for correctly dispersed numerical results. Using INSTAT Version 8.0, an Indian statistical program, the statistical study was carried out. Pearson's correlation was used to find relationships. 'r' values of 0.2-0.39 indicate weakness, 0.40-0.59 moderateness, and 0.60-0.79 strength. To study the relationship between two quantitative variables, we employed the independent 't' test and Z-test. To be statistically significant, P-values must be less than 0.05.

RESULT

We had enrolled a total of 100 subjects in the present prospective observational study, 50 of whom were designated as cases and 50 as controls.

1. **GENDER**

Gender	DM		Non-DM	
	(n=50)	%	(n=50)	%
Male	29	58	28	56
Female	21	42	22	44
Total	50	100	50	100
M:F ratio	1:0.72		1:0.78	

TABLE 1: GENDER DISTRIBUTION AMONG PATIENTS INVOLVED IN THE STUDY.

The gender-wise distribution of study subjects was examined. It was shown that males accounted for 58% of study subjects with diabetes mellitus and females for 42%. Males made up 56% of the non-diabetic study group, while females made up 44%. In the diabetes group, the ratio of males to females was 0.72 to 1, whereas in the control group it was 0.78 to 1.

2. AGE

Age group	DM		Non-DM	
	Number	%	Number	%
Less than 25	0	0	0	0
26-35	1	2	3	6
36-45	2	4	5	10
46-55	10	20	7	14
56-65	18	36	16	32
More than 65	19	38	19	38
Total	50	100	50	100
Mean age	62.2 ± 11.20 years		62.84 ± 10.59 years	

TABLE 2: AGE RANGE OF PATIENTS.

The present study analyzed the participants ages. The diabetic group was made up of 36% subjects aged 56 to 65 and 20% subjects aged 46 to 55. The diabetic group's study subjects had a mean age of 62.2 ± 11.20 years. In the non-diabetic study, 38% of the subjects belonged to the diabetic age group of 65 years or older, followed by 32% who belonged to the diabetic age group of 56 to 65 years. The study subjects in the non-diabetic group had a mean age of was 62.84 ±10.59 years.

3. Modifiable Risk Factor for Acute Ischemic Stroke

Habits	DM		Non-DM	
	Number	%	Number	%
Alcoholism	17	34	16	32
Smoker	12	24	13	26
Tobacco user	9	18	7	14
Dyslipidemia	22	44	24	48
HTN	38	76	41	82

TABLE 3: PERSONAL HABITS

The present study observed the patients daily behaviors. 34% of diabetics consumed alcohol regularly, 24% smoked, and 18% used tobacco. Dyslipidemia and hypertension were observed in 44% of study subjects. The non-diabetic group comprised 32% of patients who

drank, 26% who were smokers, and 14% who used tobacco. Dyslipidemia was seen in 48% of study patients and hypertension in 82%.

4. HbA1c levels among study subjects:

HbA1c distribution	Mean	SD
DM	7.67	2.07
Non-DM	5.47	1.64
	T-value: 9.739, p-value: <0.0001	

TABLE 4: HbA1c level

The present study assessed the HbA1c levels among the study subjects. The mean HbA1c levels in the diabetic and non-diabetic groups were 7.67 2.07 and 5.47 1.64, respectively. The diabetic group exhibited significantly higher mean HbA1c levels in comparison to the control group. (T = 9.738, p = 0.0001).

5. Hypertension:

The systolic blood pressure of study subjects was measured in the present study. The diabetic group had a mean systolic blood pressure of 158.6 mmHg, whereas the non-diabetic group had a systolic blood pressure of 143 mmHg. The study subjects' diastolic blood pressure was assessed. The mean diastolic blood pressure of the diabetic group was 87.8 mm Hg, whereas the control group's was 82.4 mm Hg.

SBP	Mean	SD
DM	158.6	9.1
Non-DM	143	8.01
Significance	The t-value is -2.95997. The p-value is .001929. The result is significant at $p < .05$.	

TABLE 5: SYSTOLIC BP

DBP	**Mean**	**SD**
DM	87.8	6.73
Non-DM	82.4	7.02
Significance	The t-value is -2.21435. The p-value is .014561. The result is significant at p < .05.	

TABLE 6: : DIASTOLIC BP

6. LIPID PROFILE

Lipid profile	**DM**		**Non-DM**		**Significance**
	Mean	**SD**	**Mean**	**SD**	
TC	164.32	51.91	147.76	47.62	T-value: 1.97, p-value: 0.05
TG	129.3	34.66	111.56	29.27	T-value: 1.07, p-value: 0.28
HDL	48.02	10.47	44.98	9.93	T-value: 1.29, p-value: 0.2
LDL	87.92	44.81	79.38	46.46	T-value: 1.14, p-value: 0.25

TABLE 7: LIPID PROFILE PARAMETERS

The lipid profiles of two groups of subjects were evaluated in the present study. The mean total cholesterol, triglyceride, HDL, and LDL levels in the diabetic group were 164.32, 129.53, 48.02, and 87.92, respectively. "The non-diabetic group's mean total cholesterol, triglycerides, HDL, and LDL levels were 147.76, 111.56, 44.98, and 79.38, respectively".

7. MEAN PLATELET VOLUME

MPV	Mean	SD
DM	10.17	1.13
Non-DM	8.659	0.96
Significance	The t-value is 15.22. The p-value is <0.0001. The result is significant at p < .05.	

TABLE 8: DISTRIBUTION OF MPV IN GROUPS.

The current investigation examined the average platelet volume within the cohort of participants. The study found that the mean platelet volume was 10.17 ± 1.13 in the group with diabetes, while it was 8.65 ± 0.96 in the group without diabetes. Upon conducting an analysis of the mean platelet volume levels in the study participants, it was determined that the disparity in mean platelet volume between the cohort with diabetes and the cohort without diabetes was statistically significant (t-value = 15.22). The statistical significance level, as indicated by the p-value, is less than 0.0001. The obtained outcome exhibits statistical significance at a significance level of.05.

8. CORRELATION BETWEEN MPV AND HbA1$_C$

CORRELATION BETWEEN MPV AND HBA1c		MPV
HbA1c	**Pearson Correlation**	0.857
	Sig. (2-tailed)	<0.001
	N	100

TABLE 9: CORRELATION OF MPV WITH HbA1c.

This study aimed to investigate the correlation between mean platelet volume (MPV) and glycated hemoglobin (HbA1c) levels in the subjects. A statistically significant positive

correlation was observed between MPV and HbA1c levels, with a r value of 0.857 and a p-value of 0.001.

9. COMPARISON OF DISTRIBUTION OF PARAMETERS

Variables	**DM (Mean ± SD)**	**Non-DM (Mean ± SD)**	**P-value**
Age	62.2 ± 11.20 years	62.84 ± 10.59 years	=0.01
HbA1c	7.67 ± 2.07	5.47 ± 1.64	<0.0001
Systolic blood pressure	158.6 ± 9.1	143 ± 8.01	0.0019
Diastolic blood pressure	87.8 ± 6.73	82.4 ± 7.02	<0.05
Total cholesterol	164.32 ± 51.91	147.76 ± 47.62	0.03
Triglyceride	129.3 ± 34.66	111.56 ± 29.27	0.28
HDL	48.02 ± 10.47	44.98 ± 9.93	0.2
LDL	87.92 ± 44.81	79.38 ± 46.46	0.25
MPV	10.17 ± 1.13	8.65 ± 0.96	<0.05

TABLE 10: COMPARISON OF DISTRIBUTION OF VARIOUS PARAMETERS .

10. CORRELATION OF MEAN PLATELET VOLUME WITH VARIOUS PARAMETERS:

Parameters	*(r)*	
	DM	Non-DM
HbA1c	0.15	0.00
Triglyceride	0.09	0.03
Age	0.13	0.03

HDL	-0.23	-0.16

TABLE 11: CORRELATION OF MPV & PARAMETERS

"The present study correlated numerous parameters with mean platelet volume. Diabetics had a positive correlation (r = 0.15 between HbA1c levels and mean platelet volume, whereas non-diabetics had a weak positive correlation (r = 0.00). Triglyceride levels showed a weak positive correlation (r = 0.09) with MPV in diabetics. The correlation of age with MPV showed a positive association among diabetics (r = 0.13) and a weak association in non-diabetics (r = 0.03). Both diabetics and non-diabetics showed a negative association with HDL levels when they were correlated with MPV (r = -0.23 and -0.16, respectively)".

DISCUSSION

Patients with AIS present with an abrupt loss of neurological function due to vascular causes, in this instance due to an intravascular thrombus. MRI or CT scans that confirmed the clinical presentation indicated AIS.Diabetes mellitus, dyslipidemia, systemic hypertension, smoking, cardiovascular disease, and other significant risk factors contribute to AIS. Diabetes mellitus is a COMM on AIS risk. "Studies have shown that Type 2 diabetes mellitus patients have decreased insulin production and increased insulin resistance".[5] Endothelial dysfunction and vascular abnormalities are caused by blood sugar levels. Patients with diabetes have atherosclerotic complications, including thrombus development, as a result of pathophysiological alterations in their cerebral vasculature. Increased MPV is caused by diabetes mellitus due to platelet size and reactivity. Due to high levels of thromboxane A2 and atherogenic soluble platelet P-selectin. The risk of AIS is increased by active metabolites caused by age, high blood pressure, diabetes mellitus, and obesity. Platelet count is significant, but mean platelet volume is crucial for hemostasis. This inexpensive, commonly accessible blood measurement has been shown to predict AIS risk accurately. Multiple studies have shown that AIS patients had greater MPV than the control group. Our results matched the preceding study. "This study investigated whether an increased MPV value in patients with diabetes mellitus increases the risk of acute ischemic stroke. This study calculated mean platelet volume in diabetic and non-diabetic patients".[5,]

NON-MODIFIABLE RISK FACTOR FOR ACUTE ISCHEMIC STROKE

1. GENDER

The present study population's total diabetic group (case) consisted of 50 persons (50%), 29 of whom were males and 21 of whom were females. The non-diabetic group (control) included 50 patients, 28 (56%) of whom were males and 2 (44% were females). In the diabetic group, the ratio of males to females was 0.72 to 1, whereas in the control group, it was 0.78 to 1. According to the findings, AIS was more frequent in males, which is consistent with a previous study. The male gender is the most common risk factor for stroke. The likelihood of males participating in this study was shown to be higher. However, the difference was not statistically significant.

2. AGE

"The age distribution of the subjects was assessed in the present study. 19 (38%), 18 (36%), 10 (20%), 2 (4%), and 1 (2%) of the diabetic group were older than 65 years. In the diabetic group, the mean age of the study subjects was 62.2 + 11.20 years. In the non-diabetic group, 19 (38%) were in the diabetic age group of more than 65 years, 16 (32%) were 56 to 65 years old, 7 (14%) were 46 to 55 years old, 5 (10%) were 36 to 45 years old, and 3 (6%) were 26 to 35 years old. Non-diabetic subjects with a mean age of 62.84 +/- 10.59 years comprised the study group. The majority of patients were over 50. Age is the most non-controllable stroke risk factor".

MODIFIABLE RISK FACTOR FOR ACUTE ISCHEMIC STROKE

The present study observed subjects' daily behaviors. In the diabetic group, 17 (34%) of the study subjects drank alcohol, 12 (24%) smoked, and 9 (18%) used tobacco. In the study, hypertension and dyslipidemia were observed in 38 (76%) of the subjects. In the non-diabetic group, 16 (32%) of the subjects reported past alcohol intake, 13 (26%) were smokers, and 7 (14%) were diabetic users. Hypertension was observed in 41 (82%) and dyslipidemia in 24 (48%) study subjects. In their study, Narasimhamurthy et al. recruited 150 patients, 63 of whom (42% had alcohol intake) and 61 of whom (41% were smokers).

DIABETES MELLITUS

"The present study measured HbA1C levels among the study subjects. The mean HbA1C levels were observed to be 7.67 2.07 in the diabetic group, which included 50 patients, and 5.47 1.64 in the non-diabetic group, which also included 50 patients. The HbA1C levels in the two groups were compared using the Student's t test. The mean HbA1C levels in the diabetic group were significantly higher than those in the non-diabetic group, as was observed. (T-value = 9.739, p-value = 0.0001)".

HYPERTENSION

"Throughout the present study, the subjects' systolic blood pressure was monitored. The diabetic group had a mean systolic blood pressure of 158.6 ± 9.1 mmHg, whereas the non-diabetic group had a mean systolic blood pressure of 143 ± 8.01 mmHg. The mean diastolic blood pressure in the study group was 87.8 ± 6.73 mmHg in diabetic subjects and 82.4 ± 7.02 mmHg in control subjects".

LIPID PROFILE

The study examined the lipid profiles of both groups of subjects and analyzed their features. The study found that the average total cholesterol level for the group with diabetes was 164.32 ± 51.91, while the mean triglyceride level was 129.3 ± 34.66. Additionally, the group's high-density lipoprotein levels were 48.02 ± 10.47, and their low-density lipoprotein levels were 87.92 ± 44.81. The mean total cholesterol, triglyceride levels, HDL levels, and LDL levels of the non-diabetic group were 147.76 (47.62), 111.56 (29.27), 44.98 (9.93), and

79.38 (46.46), respectively. There was no statistically significant difference observed between the two groups.

MEAN PLATELET VOLUME

The present study examined the study subjects' mean platelet volume. In the diabetic group, mean platelet volume was observed to be 10.17 ± 1.13 and in the non-diabetic group, 8.65± 0.96. The diabetic group's mean platelet volume was statistically significant (t-value = 15.22) using the student's t-test. 1/million is the p-value. 0.05 is significant. DM patients had a significantly higher MPV (10.16 ± 0.89 fL) than non-diabetics (8.25 0.91 fL; p 0.001). Acute Ischemic Stroke in diabetic patients is significantly related to increased MPV levels because MPV is necessary for hemostasis. A simple blood test called the mean platelet volume (MPV) measures platelet reactivity and predicts stroke severity and prognosis in diabetics. The discrete risk factor for stroke in high-risk groups is recognized to be MPV. The utilization of MPV testing could potentially furnish valuable prognostic insights to medical practitioners who are managing patients afflicted with cerebrovascular disease. "In recent decades, there has been a resurgence of scholarly interest in the correlation between mean platelet volume (MPV) and inflammation and thrombosis. Studies have reported a significant elevation in MPV levels among patients diagnosed with acute ischemic stroke".

CORRELATION BETWEEN MPV AND HBA1C

In the present study, MPV and HbA1c levels were correlated among the subjects. We observed a significant positive correlation (r = 0.875 and p = 0.001) between MPV and HbA1c levels.

Study (p value of MPV in diabetes mellitus)	**Mean MPV value in Diabetic**
Patil P et al (n=79) (≤0.001)	10.16
Zuberi B F (n=612) (0.000)	9.34
Narasimhamurthy et al (n=150) (<0.001)	10.81
Thankappan PK et al (n=50) (= 0.078)	7.12
Zeliha Hekimsoy et al (n=245) (=0.001)	10.62
Ezgi Yenigun et al (n=215) (<0.01)	9.2

N Papanas et al (n=416) (=0.01)	14.2
Kodiatte,T A (n=600) (=0.001)	8.29
Current study (n=100) (<0.001)	10.17

TABLE 12: COMPARISON OF DIFFERENT STUDIES FOR MPV & DM.

AUTHOR & YEAR	TYPE OF STUDY AND YEAR	OBSERVATIONS	CONCLUSION
Patil P et al[6]	Cross-sectional (n=79)	The mean MPVamong diabeticsubset was found tobe 10.16 ± 0.89 (p ≤0.001)	Diabetic subjects have higher MPV ascompared to non-diabetics with detrimental effect on morbidity and mortality outcomes in acute ischemic stroke.
Goel A et al[7]	Cross-sectional (n=100)	MPV was significantly higher(p< 0.01) amongstcases of acuteischemic stroke as compared to controls	Raised MPV andMPV/PC ratio is relatedto higher incidence ofischemic stroke
Narasimhamurthy et al[8]	Prospective Study (n=150)	MPV and PDW were elevated in patients who suffered a severe stroke defined asmodified Rankin score of 3 to 6	MPV and PDW can be considered as laboratory markers forthe risk of acuteischemic stroke
Thankappan PK et al[9]	Case control study (n=50)	Statistically significant relationbetween mean platelet volume andrisk of thrombotic stroke was	Elevation of MPV inacute phase of thrombotic stroke is observed

		observed	
Ezgi Yenigun et al[10]	(n=215)	Higher mean platelet volume was observed in the type 2 diabetes mellitus(p value <0.01) andPre-diabetics groups as compared to the Control group	This study showed positive associationbetween MPV andHbA1c levels. Also, among Japanese patients, MPV andarterial stiffness in type 2 diabetes mellitus patients was observed.

TABLE 13: COMPARISON OF VARIOUS STUDIES WITH PRESENT STUDY.

CONCLUSION

In terms of global mortality and disability, the majority of strokes are ischemic, behind only myocardial infarction. Acute diabetic stroke is associated with high mean platelet volume (MPV), which is associated with diabetic morbidity and stroke. A high MPV value is associated with acute ischemic stroke. Ischemic stroke and myocardial infarction are shown to increase MPV risk. Diabetes mellitus is at epidemic levels. It has been shown that the MPV of diabetic patients with reduced platelet function is higher. Cell damage may occur in people with type 2 diabetes mellitus. A recent study showed that diabetic patients had higher levels of glycosylated proteins. MPV predicts diabetic stroke. Diabetics have statistically greater MPVs than non-diabetics. The incidence of AIS in patients with diabetes and mean platelet volume showed a positive correlation.

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