Section: General Medicine

Original Research Article

COMPARATIVE STUDY OF THE HEMATOLOGICAL INDICES IN PATIENTS WITH AND WITHOUT TYPE 2 DIABETES MELLITUS

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ABSTRACT

Background: In this study we compared hematological indices in patients with and without Type 2 Diabetes Mellitus and evaluated the association of hematological indices with microvascular complications of T2DM and with HbA1c. **Materials and Methods:** A cross sectional comparative study of 100 inpatients with type 2 diabetes mellitus according to ADA 2020 guidelines[1], with age more than 30 years and another 100 subjects without diabetes mellitus. Relevant history, physical examination, Complete blood count (CBC), RFT, FBS, HbA_1C, urine p/c ratio were done. Data entry was done in Microsoft excel and analyzed using SPSS software version 17. **Result:** Total white blood cells, absolute neutrophil count and neutrophil to lymphocyte ratio were increased significantly in diabetic patients compared with controls. Platelet indices, namely MPV, PCT, PDW, and P/LCR were significantly higher in diabetic individuals than in controls. Hematological indices were higher in uncontrolled diabetes than in controlled diabetes. **Conclusion:** The study showed statistically significant difference in some hematological parameters of diabetic patients compared to controls. Thus, hematological indices could be useful indicators of vascular complication and glycemic control in type 2 DM patients.

INTRODUCTION

Type 2 diabetes mellitus (DM) is a leading cause of morbidity and mortality worldwide. World Health Organization estimated that more than 180 million people worldwide are affected by the disease and expected that this number will be doubled by the year 2030.

A case control study among 300 diabetics and 200 non-diabetics by Archana Buch,[2] et al found that MPV and PDW were significantly increased in diabetic patients with complications as compared to diabetics without complications and nondiabetic group. They found statistically significant correlation of MPV with diabetic retinopathy, nephropathy, and diabetic foot. PDW was significantly increased in diabetic retinopathy and nephropathy. The study concluded that MPV and PDW are predictive biomarkers of diabetic vascular complications. They are more significant in microvascular complications than macrovascular complications.

Raminderjit Kaur,[3] et al describe the actual mechanisms and ways how platelet dysfunction occurs in patients with diabetes especially and finally culminating into major micro and macrovascular complications. The metabolic milieu of T2DM, including insulin resistance, hyperglycemia and release of excess free fatty acids, along with other metabolic abnormalities affect vascular wall by a series of events including endothelial dysfunction, platelet hyperactivity, oxidative stress and low-grade inflammation.

Zeliha Hekimsoy,[4] et al studied altered platelet morphology and function in patients with diabetes mellitus. MPV was significantly higher and the mean platelet count was significantly lower in diabetics compared to age- and sex-matched nondiabetic healthy controls. Their results show a significantly higher MPV in diabetic patients than in the non-diabetic controls which suggests that platelets may play a role in the micro- and macrovascular complications of diabetic patients.

Refik Demirtunc,[5] et al in his study assessed the platelet activity and aggregation potential among diabetics, by measuring mean platelet volume as part of whole blood count. It has been shown that MPV was significantly higher in patients with DM

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than in controls. In diabetic patients, there was a significant positive correlation between MPV and HbA1c levels but not diabetic vascular complications. When compared between the controlled and uncontrolled diabetic group, uncontrolled group had significantly higher MPV than controlled groups. MPV of the patients with improved glycemic control was significantly decreased compared to baseline MPV.

Study by Orhan Ateş,[6] at al proves correlation between the degree of retinopathy and mean values of MPV in diabetic patients. They also found an association between the degree of retinopathy and mean values of MPV. These finding suggest a role for platelets in the pathogenesis of vascular complications.

Mustafa Ünübol,[7] et al in their study investigated the association of microalbuminuria - an indicator glycemic control and microangiopathy - with mean platelet volume (MPV). This study proved a significant positive relationship between microalbuminuria - a microvascular complication of diabetes - and MPV. Sonali Jindal,[8] et al in their study proved that the platelet indices namely PDW and MPV were significantly higher in diabetics than controls. These platelet indices were higher in diabetics with microvascular complications than those without it. They had positive correlation with HbA1c.

Thomas Alex Kodiatte,[9] et al in his study showed a strong positive correlation with fasting blood glucose, postprandial glucose and HbA1C levels with MPV. Results showed a significantly higher MPV in diabetic patients than in the nondiabetic subjects which indicates that elevated MPV could be either the cause for or due to the effect of the vascular complications.

A meta-analysis by Francesco Zaccardi,[10] et al on 39 case- control and cross-sectional studies observed that mean platelet volume was significantly higher in T2DM, IFG but not in metabolic syndrome. Platelet distribution width was wider in T2DM.

Objectives

- To compare the hematological indices in patients with and without Type 2 Diabetes Mellitus admitted to the Department of Internal Medicine of Govt. Medical College, Trivandrum.
- To evaluate the association of hematological indices with microvascular complications of T2DM
- To evaluate the association of hematological indices with HbA1c.

MATERIALS AND METHODS

Study Design: Hospital based cross sectional comparative study.

Study Setting: Tertiary care Centre- OP and IP wards of Department of Internal Medicine, Government Medical College Trivandrum.

Study Period: JULY 2020- JUNE 2021

Study Population

Inclusion Criteria

All patients with Type 2 Diabetes Mellitus with FBS > 126mg/dL, aged>30yrs. The Comparison Group will contain normal subjects whose FBS<100mg/dL, HbA1c< 5.7 and aged > 30yrs.

Exclusion Criteria

- Male patients with Hb<12mg% and female patients with Hb<11mg%
- Patients on antiplatelets and anti thrombotics.
- Patients with diagnosed malignancy
- Patients with acute febrile illness
- Recent tropical fever
- Patients with cardiac failure
- Patients with CKD not due to T2DM

Sample Size: Calculated using the formula:

$$n = \frac{(Z_{1-\alpha/2} + Z_{1-\beta/2})^2 (S_1^2 + S_2^2)}{(\mu_1 - \mu_2)^2}$$

Where,

- $Z_{1-\alpha/2}$ **:**1.96 for 5% level of significance
- $Z_{1-\beta/2}$ **:**0.84 for 80% power
- S_1**:** standard deviation of group 1 i.e., 1.1
- S_2**:** standard deviation of group 2 i.e., 1.1
- μ_1**:** mean of group 1 i.e., 10.4
- μ_2**:** mean of group 2 i.e., 9.9

After substituting the values to the formula,

$$n = \frac{(1.96 + 0.84)^2 (1.21+1.21)}{(10.4-9.9)^2}$$

n= 75.89

Sample size was determined as 100 patients and 100 controls.

Sampling Technique

All subjects meeting the inclusion criteria and exclusion criteria consenting to participate in the study were recruited by continuous sampling.

Data Collection Procedure

Relevant history of the case was sought, physical and clinical examination were done and blood samples were drawn for relevant investigations. Fundus examination, urine p/c ratio were done when needed. A structured proforma was used to record data. Study variables included age, sex, socio-economic class, BMI, Blood Pressure, FBS, Creatinine, MPV, Plateletcrit, PDW, WBC count, Platelet to Lymphocyte Ratio, Neutrophil to Lymphocyte Ratio, HbA1c, Urine p/c ratio, presence or absence of neuropathy and presence or absence of retinopathy

Data Analysis

Data analysis was done using appropriate statistical software. Categorical variables will be expressed as proportions and quantitative variables as mean and standard deviation. Association will be tested using

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Chi Square test, T test. p<0.05 will be considered as statistically significant.

Ethical Concerns

Institutional Ethics Committee clearance was obtained. All expenses were met by the investigator. Confidentiality was ensured and maintained throughout the study.

RESULTS

Table 1: Distribution of Age among cases and controls.

Age in years	Cases		Control		χ2	df	p
	N	%	N	%			
≤40	18	18	63	63	45.996	4	<0.001
41 - 50	31	31	20	20			
51 - 60	22	22	10	10			
61 - 70	19	19	6	6			
>70	10	10	1	1			
Total	100	100	100	100			

Mean age among controls is 40yrs and cases is 53yrs.

Table 2: Distribution of gender among cases and controls

	Cases		Controls		χ2	df	p
	N	%	N	%			
Female	39	39	39	39	0.000	1	1
Male	61	61	61	61			
Total	100	100	100	100			

Table 3: Distribution of comorbidities among patients

Co-morbidities	Frequency	Percentage
Hypertension	46	46
Dyslipidemia	51	51
Chronic kidney disease	9	9
Cerebrovascular accident	2	2

Table 4: Patients with Controlled (HbA1c<7) and Uncontrolled (HbA1c>7) diabetes among cases

	Frequency	Percent
Controlled DM	16	16
Uncontrolled DM	84	84
Total	100	100

Table 5: Distribution of patients with Neuropathy Nephropathy Retinopathy in controlled and uncontrolled diabetes

Variable		Controlled DM	Uncontrolled DM
Neuropathy	Present	0	25
	Absent	16	59
Nephropathy	Present	4	69
	Absent	12	15
Retinopathy	Present	0	40
	Absent	16	44

Table 6: Mean Body Mass Index among cases and controls.

Category	N	BMI		t	p
		Mean	SD		
Cases	100	23.96	1.91	6.48	<0.001
Control	100	21.93	2.48		

Among cases BMI ranges between 22-25.8, while in controls it is between 19.5-24.5.

Table 7: Mean Fasting Blood Sugars among cases and controls.

Category	N	FBS mg/dl		t	p
		Mean	SD		
Cases	100	175.80	42.17	20.924	<0.001
Control	100	85.73	8.63		

Among cases FBS ranges between 133-217mg/dL, while in controls it is between 79- 92mg/dL

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Table 8: Mean Creatinine among cases and controls.

Category	N	Creatinine mg/dl		p
		Mean	SD	
Cases	100	1.18	0.39	<0.001
Control	100	0.87	0.12	

Among cases creatinine ranges between 0.78-1.58mg/dL amongst majority of the cases, while in controls it is between 0.75-0.99mg/dl

Table 9: Mean HbA1c among cases and controls.

Category	N	HbA1C %		t	p
		Mean	SD		
Cases	100	8.45	1.42	23.008	<0.001
Control	100	5.14	0.19		

Among cases HbA1c ranges between 7.02-9.87, while in controls it is between 4.99-5.33.

Table 10: Mean HbA1c among cases having Neuropathy, Nephropathy and Retinopathy

Variables	HbA1C %	
	Mean	SD
Neuropathy	10.01	1.23
Nephropathy	8.99	1.33
Retinopathy	9.75	1.17

Table 11: Mean Hemoglobin among cases and controls

Category	N	Hb gm/dl		t	p
		Mean	SD		
Cases	100	13.36	1.10	2.697	0.008
Control	100	13.81	1.22		

Among cases Hemoglobin ranges between 12.2-14.4g/dl, while in controls it is between 12.5-15g/dl.

Table 12: Mean WBC count among cases and controls

Category	N	WBC cells/cumm		p
		Mean	SD	
Cases	100	9174.00	1697.27	0.001
Control	100	8373.50	1608.25	

Among cases WBC count ranges between 7500-10,800 cells/cumm, while in controls it is between 6700-9900cells/cumm.

Table 13: Mean of Mean Platelet Volume (MPV) among cases and controls

Category	N	MPV fL		t	p
		Mean	SD		
Cases	100	9.32	1.43	5.611	<0.001
Control	100	8.40	0.80		

Among cases MPV ranges between 7.9-10.75, while in controls it is between 7.2-9.2.

Table 14: Mean Plateletcrit (PCT) among cases and controls

Category	N	PCT %		t	p
		Mean	SD		
Cases	100	0.21	0.04	6.962	<0.001
Control	100	0.17	0.03		

Among cases PCT ranges between 0.17-0.25, while in controls it is between 0.14-0.20.

Table 15: Mean Platelet Distribution Width (PDW) among cases and controls

Category	N	PDW %		t	p
		Mean	SD		
Cases	100	14.55	2.52	6.26	0.001
Control	100	12.70	1.56		

Among cases PDW ranges between 12-17, while in controls it is between11.1- 14.2.

Table 16: Mean Platelet to Lymphocyte ratio (PLR) among cases and controls.

Category	N	PLR		t	p
		Mean	SD		
Cases	100	140.73	44.39	3.151	0.002
Control	100	122.25	38.31		

Among cases PLR ranges between 100.4-185.9, while in controls it is between 84.06-160.5.

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Table 17: Mean Neutrophil to lymphocyte ratio (NLR) among cases and controls

Category	N	NLR		t	p
		Mean	SD		
Cases	100	3.56	2.00	4.752	<0.001
Control	100	2.48	1.11		

Among cases NLR ranges between 1.56-5.56, while in controls it is between 1.37-3.59.

Table 18: Comparison of mean values of hematological indices among patients with controlled and uncontrolled diabetes

Variables	Controlled DM		Uncontrolled DM)		p
	mean	SD	mean	SD	
MPV	8.69	0.45	9.44	1.52	<0.001
PCT	0.18	0.02	0.21	0.04	0.004
PLR	125.06	23.31	143.71	46.86	0.02
NLR	2.47	1.60	3.77	2.01	0.008

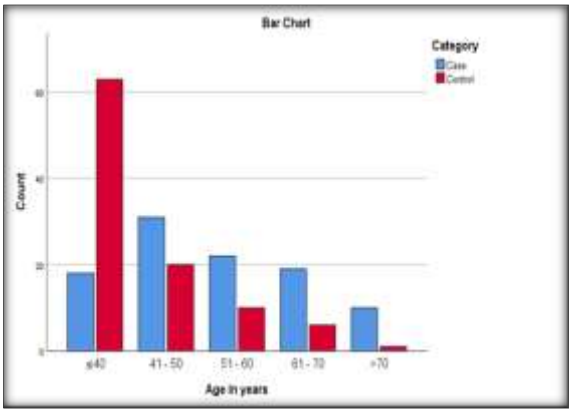

Figure 1: Distribution of Age among cases and controls

Mean age among controls is 40yrs and cases is 53yrs.

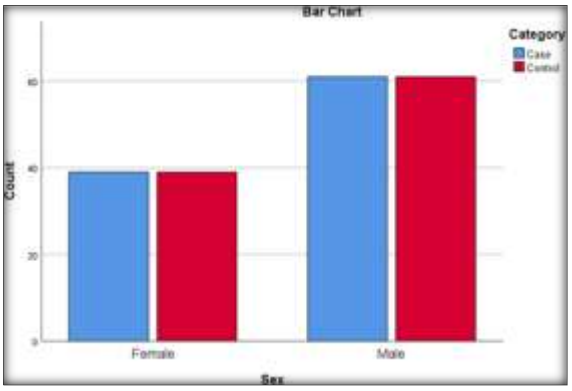

Figure 2: Distribution of gender among cases and controls

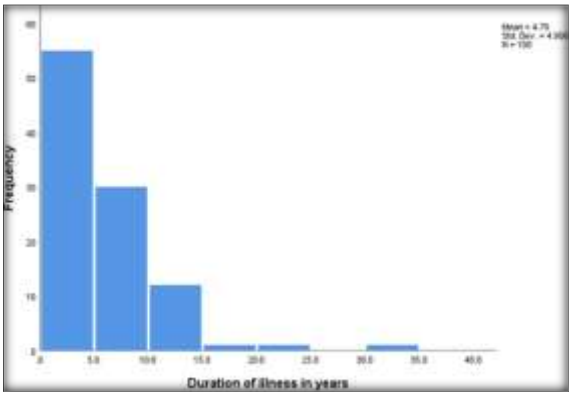

Figure 3: Duration of diabetes among the cases

The mean duration of diabetes among patients was 4.8yrs.

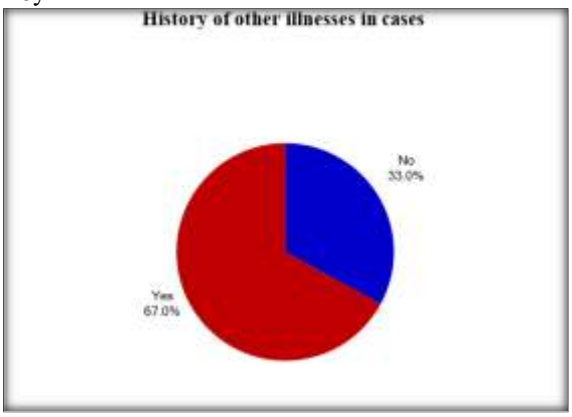

Figure 4: Number of patients having others illnesses

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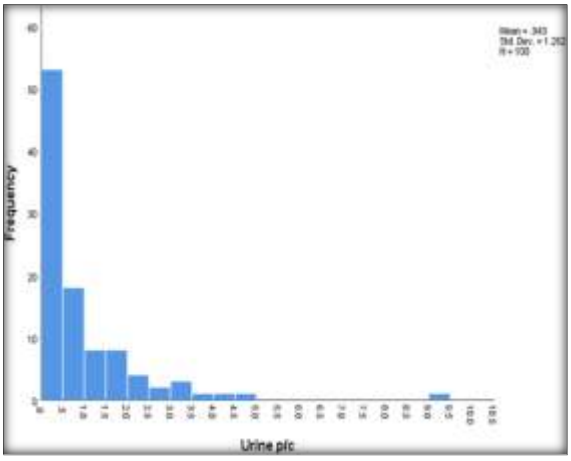

Figure 5: Distribution of urine protein creatinine (Urine p/c) ratio among cases

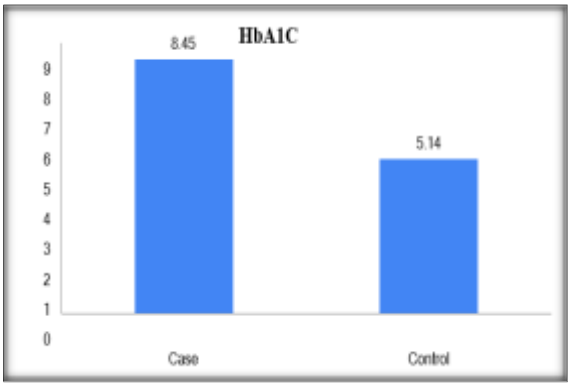

Figure 6: Mean HbA1c among cases and controls

Among cases HbA1c ranges between 7.02-9.87, while in controls it is between 4.99-5.33.

DISCUSSION

Diabetes is a metabolic disorder characterized by hyperglycemia and metabolic dysregulation leading to secondary micro and macrovascular complications. The present study was undertaken to study the hematological indices in patients with and without Type 2 Diabetes Mellitus and to aid in early detection of complications due to diabetes.

In this study a total of 200 subjects were recruited. Of these 100 patients were having diabetes and another 100 non-diabetic controls. Among them 61 were males and 39 were females in each group.

It was observed that BMI in the diabetic group (23.96±1.91) was significantly higher than that in control group (21.93 ± 2.48). In this study the mean HbA1c among diabetics was 8.45±1.42. Based on HbA1c the diabetics were divided into controlled and uncontrolled groups. Among 100 cases 84 had uncontrolled diabetes. The mean FBS values among cases were 175.8±42.1mg/dl and FBS in controls was 85.73±8.63.

It was observed that the incidence of micro and macrovascular complications where higher in the uncontrolled group. In this study the Mean HbA1c in patients having Neuropathy is 10.01 ± 1.23, Nephropathy is 8.99 ± 1.33 and Retinopathy is 9.75 ± 1.77. Similar results were observed in the study conducted by Archana Buch2 et al were, Neuropathy was 8.93 ± 2.19, Nephropathy was 9.19 ± 1.98 and Retinopathy was 9.39 ± 2.1.

The hematological indices namely hemoglobin in this study is lower among diabetics (13.36 ± 1.1) than controls (13.81±1.2), whereas, in a study by Belete Biadgo,[11] et al Hb in diabetics was (15.2 ± 1.7) and controls (15.1±1.5) but did not have any statistical significance.

In this study, it was observed that MPV and PCT were higher in diabetics vs controls. Results obtained in the study conducted by Levent Demirtas12 et al for MPV in diabetics (9.2±0.7) vs controls (8.8±0.5) and PCT in diabetics (0.23±0.04) vs controls (0.21±0.02) were comparable with the present study.

A higher PDW in diabetics (14.55±2.52) was seen vs controls (12.7±1.56), which were similar to results obtained in the study conducted by Belete Biadgo,[11] et al for PDW in diabetics (14.77±2.1) vs controls (13.5±2.1).

PLR was higher in diabetics (140.77±44.3) vs controls (122.2±38.3). Study conducted by Levent Demirtas,[12] et al for PLR in diabetics (106.96±20.1) vs controls (101.3±21.4) showed similar results.

In this study NLR in diabetics (3.56±2) was higher vs controls (2.48±1.1) similar to results obtained in the study conducted by Levent Demirtas,[12] et al for NLR in diabetics (2.75±0.52) vs controls (2.58±0.5).

It was also observed that the hematological indices namely MPV, PDW, PCT, PLR and NLR were comparatively higher in uncontrolled DM than controlled DM. Similar observations were also made in studies conducted by Milosevic,[13] et al and Rajas Walinjkar,[14] et al.

A characteristic finding noted in this study is that the patients with controlled DM had closer results as that of control group, namely MPV [diabetics(8.69±0.45) vs controls(8.4±0.8), PCT [diabetics(0.18±0.02) vs controls(0.17±0.03)], PLR [diabetics(125±23.3) vs controls(122.2±38.3)] and NLR in diabetics(2.47±1.60) vs controls(2.48±1.1), which suggest that diabetes when controlled the endothelial dysfunction and inflammation is minimal which in turn reduces the incidence of complications related to diabetes.

Hematological indices could be used as markers for potential diabetic vascular complications as well as assessing glycemic control in type 2 diabetes.

Limitations of the study

- The platelet indices are also affected by thyroid and rheumatic diseases which were not considered in this study.
- Since it is a cross-sectional study, the follow up of the cases was not possible to determine the prognostic significance of our findings and the change in the hematological indices in the

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uncontrolled group once the diabetes is controlled.

Since this study was done from a pool of patients who were admitted to a particular institution, a larger study with a bigger study population to be done to increase the external validity of the disease.

Multiple cohort studies to be considered as patients can be followed up to look for the progression or regression of the parameters in the due course of the disease.

NLR is an upcoming marker of systemic inflammation and extensive studies need to be conducted as we have limited data on its association with diabetes mellitus and its complications.

CONCLUSION

The hematological indices in patients with Type 2 Diabetes Mellitus is higher than the non-diabetic individuals. The hematological indices of controlled DM group were similar to controls ushering the need for effective control of diabetes. The uncontrolled DM group had hematological indices higher than controlled DM group suggesting a positive association of hematological indices with HbA1c. These are easily available, simple, convenient, non-invasive, and easy to interpret methods to determine platelet dysfunction and in turn predict the presence of microvascular complications.

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