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Assessments of coagulation profile among good glycemic control and poor glycemic control type 2 diabetic patient attending at Wolkite University specialized hospital, Central Ethiopia: a comparative study

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Abstract

Introduction *Diabetes Mellitus (DM) is a worldwide health issue that is defined by elevated blood glucose levels and impaired metabolism of fat, carbohydrates, and proteins. Atherothrombotic events are very likely to occur in patients with diabetes mellitus. This results in the development of both microvascular and macrovascular complications.*

Objective To compare the coagulation profile parameters between patients with good glycemic control and poor glycemic control and to evaluate the association of coagulation profile and glycemic control in type 2 DM patients.

Materials and methods This study was conducted in Wolkite university specialized hospital on 90 type 2 Diabetics patients among which 45 were with good glycemic control and 45 were with poor glycemic control. Seven ml blood samples were collected from each study participant and analyzed to assess coagulation profile including Platelet Count, activated Partial Thromboplastin Time (aPTT), and Prothrombin Time (PT). Using SPSS 21.0, an independent sample t-test was used for statistical analysis.

Results According to the current study, when comparing Type 2 Diabetes with poor glycemic control to those with good glycemic control, there was an increase in PT and aPTT concentration (statistically significant, $p < 0.05$). The platelet counts of the two groups did not differ significantly.

Conclusion People with Type 2 diabetes have altered coagulation profiles, which have demonstrated that hyperglycemia causes abnormalities in coagulation. Patients with Type 2 diabetes who have poor glycemic control are particularly vulnerable to atherothrombotic and hemorrhagic events. In order to prevent the onset of microvascular and macrovascular illness as soon as possible, physicians may find it helpful to evaluate the coagulation profile of diabetic patients.

Keywords Coagulation, Glycemic Control, Type 2 diabetes Mellitus

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Introduction

Diabetes mellitus (DM) is a metabolic disorder characterized by persistent hyperglycemia triggered by the pancreas' inability to make enough insulin (type 1 DM) or the body's inability to efficiently utilize the insulin it produces (type 2 DM). It is the most serious and common chronic diseases, causing life threatening, disabling and costly complications [1]. According to the International Diabetes Federation estimation, the prevalence of diabetes in 2021 was 10.5% and this is estimated to be would increase to 11.3% by 2030 and 12.2% by 2040 globally [2]. Countries that account for the highest number of DM patients are China (140.9 million), followed by India (74.2 million), Pakistan (33.0 million) and the United States (32.2 million) [3]. Globally, type 2 DM constitutes about 90–95% of DM cases diagnosed [4].

Type 2 DM Patients are more likely to experience macrovascular and microvascular complications, which can result in higher medical expenses and a lower quality of life. Furthermore, it was noted that patients with type 2 diabetes had a 15% higher chance of premature death and a 20-year shorter life expectancy [2]. Cardiovascular disease is the most common manifestation of diabetic macrovascular complications. Patients with diabetes are two to four times more likely to develop coronary artery disease [5]. Patients with diabetes are also found to have an elevated risk of thrombotic problems [6]. One cause of morbidity and mortality among T2 DM patients are partly due to dysregulated hemostasis [7].

Hemostasis is a complex process in which multiple components of the blood clotting system are activated in response to vessel injury, to control bleeding [8]. However, due to hyperglycemia, which causes platelet hyper reactivity, hyperfibrinogenemia, increased thrombin production, and decreased fibrinolysis; type 2 DM patients are more likely to experience bleeding disorder. Insulin resistance, endothelial dysfunction, hyperglycemia, and an enhanced inflammatory state are the main mechanisms underlying these changes, and they all have an immediate effect on platelet function, coagulation factors, and clot formation [9]. An enhanced clotting tendency in type 2 DM is caused by the glycosylation of vital proteins and an increase in the plasma levels of certain clotting factors [10]. Recovery of the injured organs to normal is doubtful even with strict treatment [11].

Good glycemic control (Hemoglobin A1C (HbA1c) < 7.0%) in type 2 DM prevents or slows down the progression of complications [12–14]. Glycemic control is thus considered as the main therapeutic goal for the prevention of complications in T2DM. Hence, coagulation tests are used as monitoring tools for patients with coagulopathy, as the use of therapeutic agents tends to be based on their corrective effect on laboratory tests of hemostatic function. However, in the study area, despite

its negative impact, diabetic patients are not routinely examined to determine their thrombotic status. As a result, they usually see a physician after they manifest complications and the organs are exposed to the disease. Not only in the study area but also in Africa, there is also a scarcity of data on the coagulation profile of diabetic patients based on HbA1c levels. Hence, this study was aimed to compare the coagulation profile in type 2 DM patients with poor glycemic control and good glycemic control and to evaluate the association between coagulation profile and glycemic control in type 2 DM patients.

Materials and methods

Study design, setting and population

A facility-based comparative cross-sectional study was conducted in the outpatient department of Wolkite University Specialized Hospital (WKUSH) from April 8 to July 25, 2023. WKUSH is located in the Gurage Zone, Central Ethiopia. The hospital is located 170 km away from the capital city of Ethiopia, Addis Ababa, and it provides services for more than 1.2 million inhabitants living in the Gurage zone and surrounding districts. Type 2 diabetes mellitus patients attending outpatient departments in WUSH were the study population of this study.

Sample size determination and sampling techniques

For this study, a total of 90 adult type 2 diabetic patients were selected. All the study subjects were on oral hypoglycemic drugs. The two-population mean formula with the assistance of G-Power software version 3.1 was used to determine the sample size. A 95% confidence interval (2-tailed, $\alpha=0.05$), 80% power, a 1:1 control-to-case ratio, and an effect size (d) of 0.45 were all taken into account during the process. From a prior study, we extracted the mean and standard deviation values for activated partial thromboplastin time (aPTT) in both the good glycemic control groups and the poor glycemic diabetic patients [15]. The Voorhis and Morgan rule of thumb was used to improve precision [16]. Ninety was the ultimate sample size, with forty-five individuals in each group.

Participants in the study were chosen using a systematic random sampling technique; in this process, the order in which follow-up visits were attended served as a sampling frame because systematic sampling is employed when population lists are available. The sampling interval (kth value) was calculated by dividing the total number of type 2 diabetic patients who have follow-up in WKUSH by the sample size; in this case, according to the hospital's quarterly report, 672 type 2 diabetic patients had follow-up appointments, and the sample size needed for the study was 90. As a result, the kth value was computed as 672 divided by 90, this resulted in a value of approximately 7. The initial seven participants' medical record numbers were written on separate pieces of paper. The

first participant was then chosen via the lottery method. Consequently, after the first participant was selected by a lottery method, the participants at every 7 interval of the follow-up visit order were interviewed.

Inclusion and exclusion criteria

All type 2 diabetic patients that availed during the study period and signed the consent were included in the study, while patients on drugs altering their coagulation profile, patients with liver disease, patients with a history of coagulation disorder, and patients with malignancy and coronary artery disease were excluded from the study.

Operational definition

Glycemic control was defined based on to the American diabetes association (ADA) standards of medical care in diabetes 2021 recommendation. Accordingly good glycemic control was defined as a HbA1c value <7% and poor glycemic control was defined as a HbA1c level $\geq 7\%$ [17]. Dyslipidemia is defined when one or more of the following are present according to the National Educational Program. TC ≥ 200 mg/dl, HDL-C <40 mg/dl for males and <50 mg/dl for females, LDL-C ≥ 130 mg/dl, TG ≥ 150 mg/dl [18]. A history of hypertension, being on antihypertensive medication, or having an average of three readings of systolic and/or diastolic blood pressure greater than 140/90 mm Hg were considered to be indicators of hypertension.

Data collection procedures

After the selection of the study subjects, the nature, purpose, and benefit of the study were explained to each subject in detail. They were encouraged to participate on a voluntary basis. Informed written consent was obtained from the participants. A pre-tested structured questionnaire was used to obtain the socio-demographic characteristics of study subjects via face-to-face interviews. The questionnaire includes variables for the assessment of socio-demographic characteristics, mainly gender and age. Clinical data were also collected using a data collection sheet with physical examinations and medical record reviews. Family history of bleeding, history of drug intake within two weeks, smoking habits, and taking any traditional medicine were collected. Anthropometric measurements of the subjects were done, and blood pressure was measured. With aseptic precaution, 7 ml of venous blood was collected from an antecubital vein by a disposable plastic syringe from each subject for estimation of PT and APTT levels by an auto-analyzer in the laboratory of WKUSH.

Sample collection and laboratory analysis

After the study participant has given a written informed consent or assent form, a venous blood sample was

collected by laboratory technologists using a syringe and needle collection system. A total of 7 ml of whole blood was collected, and then 3 ml of blood was transferred to an ethylene di-amine tetraacetic acid (EDTA) test tube for HbA1c analysis, 2 ml of blood was transferred to SST, and 2 ml of blood was transferred to a 3.2% sodium citrate anticoagulated test tube for the coagulation test. The platelet count was done by the ADVIA[®] 560 automatic hematology analyzer. Coagulation profile tests (PT/INR and aPTT) were analyzed by an urit-610 coagulation analyzer. The lipid profile and HbA1c were analyzed by the Cobas C 311 analyzer.

Data quality assurance and management

The questionnaire was prepared in English and translated to Amharic, then converted back to English to check for uniformity. The pretest of the questionnaire was done on 5% of the participants at Wolkite Health Center. All study participants were informed about the purpose and significance of the study before data collection to make them fully concerned about their responses. The collected data were checked daily for consistency and accuracy. Data collection was watchfully supervised by the principal investigator. The quality of the sample was maintained by examining if it met accepted parameters such as hemolysis, clotting, volume, and collection time. After the blood is withdrawn, it dispensed into the wall of the test tube to avoid hemolysis. All reagents were checked for expiration dates and prepared in compliance with the manufacturer's guidelines. The three-levels of commercial hematology cell controls (low, normal, and high) were run daily. Every day before the samples were examined, an identical normal and abnormally lyophilized sample was utilized for the coagulation test.

Statistical analysis

The data were coded and double-entered into EpiData version 3.1, and then transferred to SPSS version 21 for analysis. Descriptive statistics like frequencies and tables were used to summarize the characteristics of the study population. The chi-square test was used to determine the significance of the assumed association. An independent sample t-test is used to compare the means of the coagulation profile between the good glycemic control group and the poor glycemic control group to see if there is a statistically significant difference between them. A *P*-value of less than 0.05 was considered statistically significant.

Results

Comparison of baseline characteristics of patients with good glycemic control group and poor glycemic control group among type 2 DM patients

A total of 90 patients were included in the study with 45 in good GC (HA1c < 7%) and 45 in poor GC (HbA1c ≥ 7%) group. The proportions of male and female participants were (58.9%) and (41.1%), respectively. Majorities (83.3%) of the participants have less than 5 year duration of diabetes. Only 13 (14.4%) of the study participants have a BMI within the normal range. Among lifestyle factors, about quarter (25.6%) of the participants are smokers and significant portion of the participants (41.1%) consume alcohol. Our finding also showed that being males (64.4%) is more likely to be in good glycemic control than female (35.6%). However, no significant variation was noted in being males and female ($P=0.28$). A very balanced distribution between good and poor glycemic control among smokers and non-smokers were observed. However, no significant variation was noted in cigarette smoking and didn't smoking (Table 1).

Comparison of the mean value of parameters with good glycemic control group and poor glycemic control group

The finding of this study indicate that mean PT is significantly higher in the good glycemic control group (11.04 s) compared to the poor glycemic control group (9.68 s), with a p -value < 0.001, indicating strong statistical significance. This suggests that patients with better glycemic control have slightly longer coagulation times, which could imply a reduced risk of clot-related complications. Likewise, the mean aPTT is also significantly higher in patients with good glycemic control group (27.10 s) compared to the poor glycemic control group (20.23 s), with

a p -value < 0.001. Similar to the PT test results, this suggests that patients with better glycemic control have a longer coagulation process. The result further noted that the mean platelet counts are 2.52 lakhs in the good glycemic control group and 2.46 lakhs in the poor glycemic control group, with a p -value of 0.55. This suggests there is no statistically significant difference in platelet counts between the two groups.

The patient's mean BMI is significantly lower in a good glycemic control group (26.31 kg/m²) compared to the poor glycemic control group (27.62 kg/m²), with a p -value of 0.004. This indicates that patients with better glycemic control tend to have a lower BMI. Also, the mean duration of diabetes is slightly lower in a good glycemic control group (3.87 years) compared to the poor glycemic control group (4.36 years), but this difference is not statistically significant (p -value = 0.15). Also, the mean patient age is slightly lower in the good glycemic control group (41.51 years) compared to the poor glycemic control group (44.13 years); with a p -value of 0.25, indicating no significant difference in age between the two groups (Table 2).

Discussion

In DM, the vascular endothelium, which is the body's main line of defense against thrombosis, is aberrant [19]. Hyperglycemia is characterized by an increase in tissue factors and coagulation factors and a decrease in endogenous anticoagulants, such as protein C and antithrombin III. Thus, individuals with type 2 diabetes have a greater risk for coagulation along with decreased fibrinolysis [19]. However, the advantage of determining thrombotic status has not been sufficiently noted by the patient and even by the stakeholders. Hence, this study was aimed

Table 1 Comparison of baseline characteristics of patients with good GC (HA1c < 7%) and poor GC (HbA1c ≥ 7%) among type 2 DM patients at WKUSH, 2023

Variable	Category	Good GC (HA1c < 7%)	Poor GC (HbA1c ≥ 7)	Total	P-Value
		Frequency (%)	Frequency (%)	Frequency (%)	
Gender	Male	29 (64.4%)	24 (53.3%)	53 (58.9%)	$P=0.28$
	Female	16 (35.6%)	21 (46.7%)	37 (41.1%)	
Alcohol drink	Yes	21 (46.7%)	16 (35.6%)	37 (41.1%)	$P=0.28$
	No	24 (53.3%)	29 (64.4%)	53 (58.9%)	
Smoking	Yes	11 (24.4%)	12 (26.7%)	23 (25.6%)	$P=0.80$
	No	34 (75.6%)	33 (73.3%)	67 (74.4%)	
Duration of DM	1–5 year	38 (84.4%)	37 (82.2%)	75 (83.3%)	$P=0.77$
	> 5 year	7 (15.6%)	8 (17.8%)	15 (16.7%)	
Hypertension	Yes	21 (46.7%)	24 (53.3%)	45 (50.0%)	$P=0.52$
	No	24 (53.3%)	21 (46.7%)	45 (50.0%)	
BMI	Normal	7 (15.6%)	6 (13.3%)	13 (14.4%)	$P=0.03$
	Overweight	35 (77.8%)	28 (62.2%)	63 (70%)	
	Obese	3 (6.7%)	11 (24.4%)	14 (15.6%)	
Dyslipidemia	Yes	10 (22.2%)	44 (97.8%)	54 (60.0%)	$P < 0.001$
	No	35 (77.8%)	1 (2.2%)	36 (40.0%)	

Table 2 Comparison of the mean value of parameters with good glycemic control group and poor glycemic control group among type 2 DM patients at WKUSH, 2023

Coagulation parameter	Good GC (HbA1c < 7%)			poor GC (HbA1c ≥ 7)			P-Value
	Mean	SD	SEM	Mean	SD	SEM	
PT test (sec)	11.04	1.45	0.21	9.68	1.27	0.19	<i>P</i> < 0.001
aPTT test (sec)	27.10	6.73	1.00	20.23	3.20	0.47	<i>P</i> < 0.001
PLT lakhs	2.52	0.46	0.06	2.46	0.44	0.06	<i>P</i> = 0.55
BMI (kg/m ²)	26.31	1.81	0.27	27.62	2.36	0.35	<i>P</i> = 0.004
Duration of DM (years)	3.87	1.47	0.21	4.36	1.73	0.25	<i>P</i> = 0.15
Age (years)	41.51	10.27	1.53	44.13	11.19	1.66	<i>P</i> = 0.25

PT: Prothrombin time; APTT: Activated partial thromboplastin time; SEM: Standard error of mean; BMI: Body Mass Index; lakhs equivalent to 100,000; GC: Glycemic control

at comparing the coagulation profiles of type 2 diabetes patients with good glycemic control (HbA1c < 7%) and poor glycemic control group (HbA1c ≥ 7%).

This study indicated that diabetics in the good glycemic control group had a higher mean platelet count (2.52 lakhs) than diabetics in the poor glycemic control group (2.46 lakhs); however, this difference was statistically insignificant (*P* = 0.55). This finding is supported by studies conducted by Binia S et al. [15] and Kaur N et al. [20], which showed that platelet counts were high in good glycemic control group when compared with poor glycemic control group. On the contrary, an increase in platelet count with increasing glycemic levels was noted in a study done in India [21]. Diabetes-related production of nitric oxide and thrombopoietin may be the cause of the elevated platelet count [22].

In this study, a significant difference in PT was noted between controlled diabetics (11.04 ± 1.45) and the uncontrolled diabetic group (9.68 ± 1.27). This difference was statistically significant with a *P*-value of < 0.001. This indicates that the functionality of platelets could be adversely affected by poor glycemic control, and the relationship between platelet functionality and glycemic control might be potentially influenced by other factors such as the duration of diabetes and concurrent medical conditions [23]. A comparative cross-sectional study conducted in southern India also revealed that patients with poor glycemic control had lower levels of PT concentration (13.81 ± 0.41) when compared with good glycemic control patients (14.86 ± 0.68); however, this difference was statistically insignificant (*P* = 0.189) which contradicts our findings [15]. Another comparative cross-sectional study conducted in North-West Nigeria revealed that the PT of uncontrolled diabetics (20.620 ± 2.849) was higher than that of controlled diabetics (16.720 ± 2.339). This difference was statistically significant with a *P*-value of less than 0.05, which is consistent with our findings [24].

In our study, a marked difference in APTT was also noted between good glycemic control patients (27.10 ± 6.73) and poor glycemic control patients (20.23 ± 3.20), with a *P*-value of < 0.001, which is

statistically significant. This result was consistent with a study conducted by Binia S et al., which was statistically significant with a *P*-value of 0.0007 and the a mean in poor glycemic control patients and good glycemic control patients was (33.83 ± 0.49) and (31.74 ± 0.33), respectively [15].

Our finding was also consistent with a comparative cross-sectional study conducted in north-west Nigeria, indicating statistical significance with a *P*-value of < 0.05. In contrast to our findings, it was discovered that individuals with poor glycemic control exhibited a greater aPTT level (58.460 ± 4.146) in contrast to those with good glycemic control (43.260 ± 5.587) [24]. One possible explanation for the rise in PT could be the activation of the extrinsic pathway by the conversion of inactive factor VII to active factor VII. A decrease in factor VIII activity is the cause of prolonged aPTT. aPTT indicates the integrity of the intrinsic pathway. Factor VIII is a cofactor for factor IXa in the intrinsic pathway; hence, a decrease in factor VIII could alter aPTT [24–26]. Hence, diabetic patients who had poor glycemic control had a greater risk of hypercoagulability than those with good glycemic control [27].

In our study, a marked difference in BMI was also noted between good glycemic control patients (26.31 ± 1.81) and poor glycemic control patients (27.62 ± 2.36), with a *P*-value of < 0.004, which is statistically significant. The significant association between lower BMI and better glycemic control supports findings from the “Look AHEAD” trial (2013), which emphasized the role of weight loss in improving various metabolic parameters in T2DM, including glycemic control. This underscores the multifactorial nature of diabetes management, where weight management plays a crucial role in achieving optimal outcomes [28].

Conclusion and recommendation

The current study showed that, the coagulation profiles of diabetics with a HbA1c ≥ 7% differed significantly from those of people with type 2 diabetes with a HbA1c < 7%, indicating that hyperglycemia causes disorders in coagulation. Atherothrombotic and hemorrhagic events are

more likely to occur in type 2 diabetic patients with poor glycemic control; glycemic levels have been consistently linked to variations in aPTT and PT. A tendency towards hemorrhagic issues is indicated by elevated PT and aPTT. Consequently, to reduce the incidence and prevalence of vascular burden and improve the quality of life for Type 2 diabetic patients, the coagulation profile ought to be taken into account as one of the routine screening tests for diabetes patients. In order to evaluate the long-term effects of better glycemic control on coagulation patterns and cardiovascular outcomes in T2DM patients, future research should concentrate on longitudinal studies. Furthermore, investigating the molecular mechanisms behind these correlations may provide novel targets for therapeutic interventions aimed at lowering cardiovascular risk in this demographic.

Abbreviations

PT	Prothrombin time
APTT	Activated partial thromboplastin time
SEM	Standard error of mean
BMI	Body Mass Index
GC	Glycemic control
DM	Diabetes mellitus
HbA1c	Hemoglobin A1C
WKUSH	Wolkite University specialized hospital

Supplementary Information

The online version contains supplementary material available at <https://doi.org/10.1186/s12902-024-01730-1>.

Supplementary Material 1. S1: File. English version of questioner.

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Author contributions

B.F and S.A were involved in conception and design and the acquisition of data. B.F took the lead in data generation, analysis, and drafting the manuscript. B.F, D.A, S.A and Z.H have reviewed the draft manuscript critically for important intellectual content. All authors were involved in the analysis and interpretation of the data, as well as final approval of the version to be submitted to this journal.

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Data availability

The datasets analyzed during the current study are available from the corresponding author upon reasonable request.

Declarations

Ethical approval and consent to participate

Before any attempt to collect data, approval to conduct the study was obtained from Wolkite University College of Medicine and Health Science. Each participant (patient) was notified about the purpose of the study, the right to refuse to participate in the study, and the anonymity and confidentiality of the information gathered. The study protocol was submitted to the department of Medical Laboratory Sciences and Ethical Committee

(Institutional Review Board) of the Wolkite University College of Medicine and Health Sciences before the data collection starts. The data collection was undertaken after approval of the research proposal by Institutional Review Board) of Wolkite University, College of Medicine, Health Sciences, with protocol number **RCSU/ILC/048/15**. This study was conducted following the 1975 Helsinki declaration, as revised in 2008, and its later amendments or comparable ethical standards. The authors have no competing interests in financial support, publication of this research, patents, or royalties through this collaborative research. All authors were equally involved in the discussed research work. There is no financial conflict with the subject matter discussed in the manuscript.

Consent for publication

Not applicable.

Competing interests

The authors declare no competing interests.

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