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# Comparison of Coagulation Profile in Type 2 Diabetes Mellitus Patients at Durame General Hospital, South East Ethiopia: Comparative Cross-sectional Study

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## Abstract

**Background:** Diabetes mellitus is related to disturbances of hemostasis that could subsidize the occurrence of thrombogenic complications. Diabetic patients are exposed to thrombosis, which arises from cardiovascular events, the rest from cerebrovascular events along with peripheral vascular complications, and these are correlated with diabetes results for most of its morbidity, and mortality. The current study was carried out to determine the coagulation profiles of type 2 diabetes mellitus patients in comparison with apparently healthy controls. **Methods:** A comparative cross-sectional study was carried out at Durame General Hospital from June 2023 to January 2024. Socio-demographic and clinical data were collected using questionnaires and checklists. Platelet parameters were determined from EDTA anticoagulated venous blood using an Adevia560 hematological analyzer, whereas coagulation analysis was done using an ARES LiNEAR coagulation analyzer from citrated plasma. Kolmogorov-Smirnov tests were used to check distribution, and data was analyzed using SPSS version 26 software. An unpaired t-test was used to compare the mean between groups and the Kruskal Wallis test for the comparison of different categories in groups. Statistical significance was designed at ($P< 0.05$). **Results:** There was a significant shortening of prothrombine time (PT) (12.9±1.5, vs 13.5±1.3), ($p=0.02$), and International normalized ration (INR) (1.08±0.16, vs 1.13±0.17), ($p= 0.04$) and significant increase of platelet count, MPV (12.1±1.9, vs 10.9±1.5, $p<0.001$), PDW (16.7±2.1, vs 15.5±1.8, $p<0.001$ between diabetics compared to controls respectively. Platelet count showed a weak positive correlation with fasting blood glucose level ($r=0.26$, $p=0.02$). **Conclusion:** The present study revealed reduced values of PT, and INR, and increased values of Plt count, MPV, and PDW among type 2 diabetic patients compared to apparently healthy controls. Thus, the finding is suggestive of hypercoagulable tendencies of diabetic patients compared to controls.

**Keywords**

Type 2 Diabetes Mellitus, coagulation profiles, platelet indices, hypercoagulable state, comparative study, Ethiopia

## 1. Introduction

Diabetes mellitus is group of genetically heterogenous metabolic disorders that causes for glucose intolerance, connected with impaired insulin secretion and action. The diseases affects how the body uses blood sugar (glucose), which is induced by both genetic, and environmental factors [1]. Diabetes mellitus relies on its origin, and clinical manifestation; type one diabetes, type two diabetes, pregnancy-induced (gestational) diabetes, and variants of other specialized classes, or subtypes [2]. Type 2 diabetes mellitus (T2DM) is suddenly raising important global health issues, closely associated with the epidemics of overweight, and which is high risk for both micro and macrovascular complications, owing to hyperglycaemia and insulin resistance [3].

Worldwide incidence and prevalence of type 2 diabetes mellitus have accelerated as a result of urbanization, and changes in lifestyle. As global burden increment of diabetes is appraised to be 9.3% (463 million people) in 2019 and rising to 10.9% (700 million) by 2045 [4]. Type two diabetes should be evaluated, and treated as a heterogeneous disorder with multiple pathophysiological abnormalities, varying susceptibility to complications, and varied clinical response to therapeutic intervention. Ultimately, to cure for T2DM will require corroboration of its molecular aetiology and effective interventions to combat the epidemic [5].

Patients with diabetes could show thrombophilia and high levels of coagulation factors, including both type 1, and type 2, which is due to upregulation of coagulation factors and prolongation of clot lysis, and increased concentration of coagulation factors is widely reported in type 2 diabetes mellitus [6, 7]. Coagulation is dynamic process, and comprehending of the clotting system has drived over the recent years in in versatile health conditions. In spite of the fact that the classical division of the system into intrinsic and extrinsic paths is up-to-date and valid, the newer insights into coagulation lay out more authentic elucidation[8]. The Activated partial thromboplastin time (APTT), and the prothrombin time (PT), later refined as the international normalized ratio (INR) these tests are commonly used to identify defects of the intrinsic, extrinsic, and terminal common pathways of the coagulation process[9].

Hyperglycemia and insulin insensitivity cause changes in a number of platelets and activation, as well as qualitative and quantitative alteration of coagulatory and fibrinolytic factors, leading to fibrinolysis-resistant clots in patients with diabetes, and another coexisting factor [10]. The Anomalies of coagulation are involved in all stages, affecting both the generation of thrombus, and its hindrance of fibrinolysis, and hyperglycemia probably determines these abnormalities through process of non-enzymatic glycation [11].

In a report of a study on coagulation impairment in type two diabetes mellitus, activated partial thromboplastin times (APTT) and prothrombin time (PT) were illustrated shortened values in diabetes mellitus in contrast to the control group, and there was a strong significant variation [12]. Additionally, study indicates mean prothrombin time was greater in the cases than the controls, and it was significant, whereas, Platelet count, INR, and activated partial thromboplastin times (APTT) did not revealed significant differences observed [13]. A study underlines the link between diabetes mellitus, and altered coagulation profiles, emphasizing the importance of routine PT and APTT assessments. Effective glycemic control is not exclusively vital in managing diabetes but also plays a vital role in mitigating prothrombic states [14].

## 2. Method

### 2.1 Study design, setting, and period

The study done was a comparative cross-sectional study of comparison of coagulation profile in type 2 diabetes mellitus, and healthy controls. The study was carried out at Durame General Hospital, Southeastern Ethiopia. Data on fasting blood sugar, coagulation profile, and selected platelet parameters of type 2 diabetes patients with matched controls were collected. The duration of the study was from June 1, 2023 to May 2024.

### 2.2 Eligibility criteria

Type 2 diabetic patients of adult age groups >18 years giving consent, and apparently healthy subjects of adult who were matched to case groups in the study. Individuals who take oral anti-coagulant, anti-platelet, and fibrinolytic drug therapy, a history of chronic illness (hypertension, malignancy, liver disease) were deferred from the study.

### 2.3 Laboratory procedures

Each participant was examined by a physician to assess the general clinical status. Laboratory investigation of the sample was venous blood taken from the study participants, using an EDTA tube for platelet parameters test, citrated plasma was used for coagulation analysis by Ares liner coagulation analyzer, and using serum separator tube for glucose measurement. Fasting blood sample was estimated using (Dimension EXL200) automated clinical chemistry analyzer. platelet parameters were tested using a fully automated Advia560 hematological analyzer, and coagulation analysis was done by Ares liner coagulation analyzer.

### 2.4 Data collection and analysis

The participants were aged between 28 to 65. Socio-demographic data was collected through self-administered questionnaire for those who can read and face to face interview for those who cannot read. The respondent reads the questions and fills him/herself in the presence of an interviewer to give assistance. Clinical information was obtained from the chronic outpatient department with the help of physicians. Descriptive data of participants were reported as mean ± SD. Data were checked for normal distribution, Kolmogorov-Smirnov test was used. Student's t-test 2-tailed, Pearson's correlation analysis, and Kruskal Wallis analysis were used in this study using SPSS version 26 software. A p-value <0.05 was set to determine statistically significant differences.

### 2.5 Ethical consideration

Ethical clearance was obtained from Addis Ababa University College of Health Science, Department of Medical Laboratory Sciences, Department of Research and Ethics Committee (DREC/728/23). A support letter was written to Durame General Hospital to get permission. Informed consent was obtained from each of the participants at the time of enrollment for the study.

## 3. Result

### 3.1 Sociodemographic characteristics

A total of 204 participants were part of the study with 102 case groups, and 102 controls. Thus, females constituted 45.6%, while males constituted 54.4% overall, and there is no statistical difference between the gender of cases and control groups. The mean age of the case groups was 48.4±8.7, and 46.8±8 years, respectively. The majority of participants belong to the 41-50 years age category (41.2% among cases and 45.1% among controls), followed by 31-40 years (19.6% among cases Residence of our study participants in urban were 75.5% of case group and 70.6% in control, while in rural 24.5% in case group and 29.4% in control groups (Table 1).

### 3.2 Gender-based distribution of basic coagulation and platelet parameters

Variation of basic coagulation profile and selected parameters based on the gender difference in type two diabetic group and those without. All of the profiles in the case group did not demonstrate significant differences between males and females. Notwithstanding control, groups revealed a statistical difference in platelet distribution width (PDW), (15±1.4, P=0.02), and platelet count (209.8±36.8, p=0.04) (Table 2).

### 3.3 Comparison of the hemostatic profile according to Gylcemic level

Based on good, and poor glycemic control of hemostatic results revealed that platelet count (p=0.027) was a statistically significant difference, whereas other parameters were not illustrated as statistically significant (Table 3).

**Table 1. Sociodemographic characteristics of the study participants**

| Variables | Case group | | Control group | | P value |
|---|---|---|---|---|---|
| | Frequency (N) | Percentage | Frequency(N) | Percentage | |
| **Gender** | | | | | |
| Male | 54 | 52.9% | 57 | 55.9% | 0.78 |
| Female | 48 | 47.1% | 45 | 44.1% | |
| **Age group** | | | | | |
| 18-30 | 3 | 2.9% | 4 | 3.9% | 0.19 |
| 31-40 | 20 | 19.6% | 25 | 24.5% | |
| 41-50 | 42 | 41.2% | 46 | 45.1% | |
| 51-60 | 25 | 24.5% | 20 | 19.6% | |
| >=61 | 12 | 11.8% | 7 | 6.9 | |
| **Marital status** | | | | | 0.39 |
| Married | 92 | 90.2% | 84 | 82.4 | |
| Unmarried | 6 | 5.9% | 15 | 14.7 | |
| Divorced/widowed | 4 | 3.9% | 3 | 2.9% | |
| **Residence** | | | | | |
| Urban | 77 | 75.5% | 72 | 70.6% | 0.53 |
| Rural | 25 | 24.5% | 30 | 29.4% | |
| **Occupation** | | | | | |
| Employed | 23 | 22.5 | 16 | 15.7 | 0.132 |
| Self-employed | 46 | 45.1 | 44 | 43.1 | |
| Others | 33 | 32.4 | 42 | 41.2 | |
| **Educational status** | | | | | |
| No formal education | 31 | 30.4% | 38 | 37.3 | 0.33 |
| Primary school | 33 | 32.4% | 32 | 31.4 | |
| Secondary school | 21 | 20.6% | 19 | 18.6 | |
| Tertiary education | 17 | 16.7% | 13 | 12.7 | |

**Table 2. Gender-based distribution of basic coagulation profile and platelet parameters**

| Parameters | Diabetics group | | | Non-diabetes group | | |
|---|---|---|---|---|---|---|
| | Male (M±SD | Female (M±SD) | P value | Male (M±SD) | Female (M±SD) | P value |
| PT, sec | 12.8±1.5 | 13.1+1.4 | 0.3 | 13.6±1.3 | 13.5±1.3 | 0.78 |
| INR | 1.07±0.16 | 1.08±0.17 | 0.86 | 1.15±0.16 | 1.14±0.15 | 0.82 |
| APTT, sec | 37.5±5.5 | 37±6.1 | 0.68 | 35.9±5.1 | 35.9±4.5 | 0.99 |
| Platelet count $10^3$/ul | 234±57.4 | 235.5±50.8 | 0.88 | 227.7+47.6 | 209.8+36.8 | 0.04 |
| MPV, fl | 12.2±1.8 | 11.8±2 | 0.36 | 11.1+1.7 | 10.7+1.3 | 0.2 |
| PDW, fl | 16.8+2.1 | 16.4+2.2 | 0.36 | 15.9+1.9 | 15+1.4 | 0.02 |

Notes. Independent t-test was used Significance level at p<0.05; FBS, Fasting Blood Sugar, PT, Prothrombin Time, APTT, Activated Partial Thromboplastin Time, INR, International Normalized Ratio, MPV, mean platelet volume; PDW, platelet distribution width, fl, femto litre.

**Table 3. Comparison of the hemostatic profile according to Gylcemic level**

| Parameters | FBS mg/dl <126 | FBS mg/dl ≥126 | P value |
|---|---|---|---|
| PT | 13.3±1.5 | 12.8±1.5 | 0.121 |
| INR | 1.09±0.16 | 1.07±0.17 | 0.463 |
| APTT | 38.3±5.8 | 36.5±5.6 | 0.149 |
| PLT count | 214±44.2 | 244.8±56 | 0.007 |
| MPV | 11.7±1.96 | 12.2±1.89 | 0.211 |
| PDW | 16.4±2.0 | 16.8±2.2 | 0.333 |

Notes. t-test was used for comparison**;** p-value level of significance at p<0.05.

### 3.4 Comparison of hemostatic parameters of cases and control groups

The mean of prothrombin time (PT) (12.9±1.5, vs 13.5±1.3, p=0.02), and international normalized ratio (INR) (1.08±0.16, vs 1.13±0.17, p= 0.04) results were significantly low in diabetics vs control groups respectively. whereas, Platelet counts, mean platelet volume (MPV), and platelet distribution width (PDW) were significantly higher in case groups compared to controls. On the contrary activated partial thromboplastin time (APTT) of the mean value (37.2±5.7, vs 35.8±4.8) was not found to illustrate a significant difference(p=0.072) (Table 4).

**Table 4. Comparison of basic coagulation and platelet parameters between case, and controls**

| Parameters | Cases (Mean±SD) | Controls (Mean±SD) | P value |
|---|---|---|---|
| FBS | 145.9±34.2 | 87.7±10.9 | <0.01 |
| PT (sec) | 12.9±1.5 | 13.5±1.3 | 0.02 |
| INR (sec) | 1.08±0.16 | 1.13±0.17 | 0.04 |
| APTT (sec) | 37.2±5.7 | 35.8±4.8 | 0.072 |
| Platelet count $10^3$/ul | 238.4±54.2 | 216.9±41.8 | 0.03 |
| MPV fl | 12.1±1.9 | 10.9±1.5 | <0.001 |
| PDW fl | 16.7±2.1 | 15.5±1.8 | <0.001 |

Notes. An Independent t-test was used; Significance was considered at p< 0.05.

### 3.5 Correlation of blood glucose level with hemostatic profiles

The correlational analysis stated that no significant relationships of fasting blood glucose (FBS) with basic hemostatic variables PT (p= 0.6), INR (p= 0.96), APTT (p = 0.23), in a similar manner platelet parameters mean platelet volume (MPV), platelet distribution width (PDW) were not give out significant difference with exception of weak positive correlation between glucose level and Platelet count (r= 0.26, p=0.02) in case groups, and PT value in control groups (r=0.22, p=0.03) (Table 5).

**Table 5. Correlation of blood glucose level with hemostatic profiles, and anthropometrics**

| Parameters | Case group | | Controls | |
|---|---|---|---|---|
| | r | P value | r | P value |
| PT (sec) | -0.053 | 0.6 | 0.22 | 0.03 |
| INR | 0.004 | 0.96 | 0.1 | 0.31 |
| APTT (sec) | -0.12 | 0.23 | -0.06 | 0.58 |
| PLT count$10^3$/µL | 0.26 | 0.02 | 0.04 | 0.6 |
| MPV fl | 0.036 | 0.72 | -0.07 | 0.5 |
| PDW fl | 0.11 | 0.29 | -0.006 | 0.96 |
| BMI | 0.09 | 0.34 | -0.82 | 0.41 |
| SBP | -0.004 | 0.96 | -0.79 | 0.43 |
| DBP | 0.12 | 0.22 | 0.75 | 0.45 |

Notes. Pearson correlation coefficient; significance was considered at p< 0.05.

### 3.6 Relationship between coagulation parameters and duration of illness

The coagulation profiles across the three groups of the duration of illness were evaluated using the Kruskal-Wallis test. The PT results showed significant differences between the groups (H=8.5, df=2, p=0.014). Pairwise comparison result revealed to (<5->10, p=0.011, 6 to10->10, P=0.04). Whereas APTT, INR, platelet count, MPV, and PDW between groups did not illustrate statistically significant differences (Table 6).

**Table 6. Relationship between coagulation parameters and duration of illness**

| Variables | Duration in year | Mean rank | P value |
|---|---|---|---|
| PT, sec | <5 | 52.5 | 0.014 |
| | 6-10 | 57.3 | |
| | >110 | 27.6 | |
| INR, sec | <5 | 50.2 | 0.33 |
| | 6-10 | 56.5 | |
| | >10 | 42.1 | |
| APTT, sec | <5 | 52.2 | 0.11 |
| | 6-10 | 55.6 | |
| | >10 | 34.5 | |
| Platelet cout/$10^3$ | <5 | 52.9 | 0.3 |
| | 6-10 | 45.5 | |
| | >10 | 62.0 | |
| MPV fl | <5 | 47 | 0.22 |
| | 6-10 | 58 | |
| | >10 | 52.8 | |
| PDW fl | <5 | 52.3 | 0.78 |
| | 6-10 | 52 | |
| | >10 | 45.6 | |

Notes. Kruskal Wallis test was used; P< 0.05 is statistically significant.

## 4. Discussion

Diabetes mellitus affects numerous biological systems such as fibrinolytic, and coagulation systems that are linked with changes in blood coagulability, including remodeling of clot structure, kinetics of clot formation, and lysis [15]. People with metabolic syndrome, as in type 2 diabetes, show a model of coagulation factors that enhance thrombosis or hinder thrombolysis, and it is attributed to a heavy risk of atherothrombotic complications affecting the peripheral arterial trees, cerebral, and coronary [16].

The goal of the current study was to compare the coagulation tests in patients with type two diabetes, and healthy individuals. In diabetic patients with non-insulin dependence, there is structural damage and functional detriment of the endothelium, which has proven to be required for stimulating different clotting factors. It is presumed that high levels of von Willibrand factor (vWF) in DM indicate excessive activation of coagulation factors, which may result in shorter PT and APTT in diabetic patients than in the healthy control [17].

The present study showed significantly shortened PT, and INR values, while the APTT result of the study revealed insignificant differences between diabetics compared to healthy controls. On the other hand, significantly higher platelet count, mean platelet volume (MPV), and platelet distribution width (PDW) in type 2 diabetes compared to non-diabetics. These findings might be exhibiting an increased predisposition to thrombotic events in type 2 diabetes patients over non-diabetic controls. Many studies have shown that coagulation anomaly appeared in the course of diabetes mellitus, resulting in prothrombic conditions, and this observation is presumed to emanate from hyperglycemia [18].

Our study finding is consistent with a comparative study conducted in India, prothrombin time in diabetes mellitus type 2 is shortened as compared to controls with a significant difference, whereas APTT did not show a significant difference between Type 2 DM and controls [19]. The results of the present study align with prior research studies that have also observed decreased prothrombin time (PT) and INR in individuals with type 2 diabetes compared with non-diabetics, which is statistically significant [20]. In contrast to the current study priorly conducted a comparative cross-sectional study in Ethiopia, revealed a statistically significant negative correlation of fasting blood sugar with PT, INR, and APTT [21].

The protraction of APTT is might be as a result of in-vitro interference of fibrin clump generation through inhibitors, and it could be also occurred as a consequence of damage to the liver where majority of the clotting factors are synthesized. Thus, increased levels of APTT, and PT are consistent with aberrated coagulation mechanisms and can be interpreted as a propensity for bleeding [22].

Contrasting to the current study the results of previous finding indicates that the levels of PT and INR did not show a statistically significant difference between cases and healthy controls, shortened value of APTT with a statistically significant difference between cases and controls [23, 24]. Besides, contrary to the current study comparative cross-sectional study in Libya PT value and platelet count indicated statistically insignificant differences [25]. The reasons for these contradictory results have not been satisfactorily explained and justified the need for additional studies, and the balance of thrombosis and hemostasis in diabetes also depends on the effects of antidiabetic and other drugs used in this condition as these drugs varied effects on this process. Hence it is possible to include a combination of drugs in diabetes that favorably affect thrombohaemorrhagic balance [26].

The present study showed that a significantly high value of mean platelet volume, platelet count, and platelet distribution width in type two diabetes contrasted to nondiabetic controls. Similarly, a comparative study, reported by Jain A.et al. signified that the mean platelet distribution width and mean platelet volume in the case group were greater than in the control group, and it gave out a statistically significant difference [27]. In the present study, we found changes in type two diabetes and controls of some coagulation abnormality indicators, the clear mechanism of this relationship still needs to be explored. The current study was conducted by using screening methods of coagulation profile only, and to evalute specific factor assays, fibrynolytic tests such as D dimer and fibrinogen were not integrated to the study.

## 5. Conclusion

Our study demonstrated that PT and INR were both significantly shortened among diabetic subjects compared to controls, and platelet count, PDW, and MPV were significantly greater in diabetic over healthy controls, however, APTT didn`t show a significant difference. These findings might suggest the hypercoagulable tendency of diabetic patients compared to controls.

## Authors' contribution

All authors participated and contributed to the final manuscript. AY. Performed data collection, feeding, performing statistical analysis. TZ. and TM. Supervise data and other materials of study. All authors read and gave final approval of the version to be published; have agreed on the journal to which the article has been submitted; and all are agreed to be accountable for all aspects of this work.

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## Conflict of interest

The authors declare that the research was conducted in the absence of any financial, or commercial relationships that could be as a potential conflict of interest.

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