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# Fibrinogen Levels as Thrombotic Markers among Sudanese Patients with Type Two Diabetes Mellitus

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**Abstract**

**Background:** Fibrinogen, a key protein in blood clot formation, plays a crucial role in hemostasis. In diabetic patients, elevated fibrinogen levels are commonly observed and are associated with increased risks of cardiovascular events, inflammation, and thrombotic complications.

**Objective:** To evaluate fibrinogen levels among Sudanese patients with type 2 diabetes mellitus.

**Methods:** A case-control study was conducted in Khartoum State between July and October 2024. A total of 100 participants were enrolled: 50 patients with type 2 diabetes (cases) and 50 apparently healthy individuals (controls). Demographic data and clinical variables were collected using a structured questionnaire, and statistical analysis was performed using SPSS.

**Results:** The mean fibrinogen level was significantly higher in the diabetic group compared to the control group. Specifically, diabetic patients had a mean fibrinogen level of 411.3 ± 12.4 mg/dl, while controls had a mean level of 304.4 ± 8.1 mg/dl (p = 0.000). A significant positive correlation was observed between fibrinogen levels and disease duration (R = 0.762, p = 0.03), indicating that fibrinogen levels tended to rise with longer disease duration. In contrast, an insignificant negative correlation was found between fibrinogen levels and age (R = –0.168, p = 0.34).

**Conclusion:** Fibrinogen levels are significantly elevated in patients with type 2 diabetes mellitus compared to healthy controls. Furthermore, fibrinogen levels show a strong positive correlation with disease duration, underscoring their potential role as a marker of disease progression.

**Keywords:** Fibrinogen; Type 2 Diabetes Mellitus; Hyperglycemia; Prothrombotic State; Cardiovascular Risk

**Background:**

Diabetes mellitus (DM) is a group of metabolic disorders characterized by chronic hyperglycemia, resulting from either impaired insulin secretion, resistance to insulin action, or both [1]. It arises from a complex interplay between genetic predisposition and environmental factors [2]. Globally, the prevalence of diabetes is increasing at an alarming rate, with type 2 diabetes mellitus (T2DM) rising more rapidly than type 1 diabetes due to aging populations, urbanization, sedentary lifestyles, and increasing rates of obesity [3]. Chronic hyperglycemia is strongly linked to the development of both microvascular and macrovascular complications, which remain the leading causes of morbidity and mortality in diabetic patients [4].

Fibrinogen, a soluble glycoprotein produced in the liver, is a key component of the coagulation cascade. When activated by thrombin, fibrinogen is converted into fibrin monomers that polymerize to form the structural framework of a blood clot [5, 6]. Elevated fibrinogen levels are frequently observed in diabetes, reflecting increased hepatic synthesis mediated by pro-inflammatory cytokines and hyperinsulinemia [7, 8, 9]. Poor glycemic control contributes further, as persistent hyperglycemia induces glycation of fibrinogen, altering its structure and function. These modifications result in denser, more rigid fibrin networks with thinner fibers and smaller pores, which are more resistant to fibrinolysis compared to diabetic patients [10, 11, and 12]. Consequently, diabetic patients are predisposed to a prothrombotic state and a heightened risk of cardiovascular events [13, 14]. Elevated fibrinogen levels have also been linked to established risk factors such as advancing age, obesity, smoking, and physical inactivity, further amplifying cardiovascular risk [7, 14, 15]. Globally, diabetes remains a major health challenge. In 2019, an estimated 463 million adults were living with diabetes, a number projected to rise to 700 million by 2045. Type 2 diabetes accounts for 90–95% of all cases [16]. The disease imposes significant health and economic burdens, particularly in low- and middle-income countries, where healthcare systems often struggle to manage the growing prevalence [16]. Diagnosis is

established using fasting plasma glucose, oral glucose tolerance tests, hemoglobin A1c levels, or random glucose testing in the presence of clinical symptoms [17]. Management involves lifestyle modification, pharmacological therapy including oral hypoglycemic agents and insulin, and careful monitoring of cardiovascular risk factors [18].

Several studies have investigated the association between fibrinogen and diabetes. Desai et al. (2012) found a trend of elevated fibrinogen in diabetics, particularly among men and those with lower BMI, though results did not reach statistical significance [19]. In a subsequent study, Razek et al. (2019) demonstrated significantly higher plasma fibrinogen levels and HbA1c among diabetic patients compared with non-diabetic controls [7]. Gupta et al. (2016) reported significantly higher fibrinogen levels in diabetics compared to non-diabetics (386.04 ± 132.87 vs. 314.38 ± 97.42; $p < 0.001$), with positive correlations to glycemic control, smoking, hypertension, and ischemic heart disease [20]. Similarly, Bembde et al. (2011) observed substantially elevated fibrinogen in diabetic patients (656 ± 130 mg/dL) compared to controls (324 ± 139 mg/dL) and noted significant associations with age, BMI, smoking, hypertension, and HbA1c [12]. Kafle et al. (2010) also concluded that fibrinogen was significantly higher in diabetic patients. especially those with concurrent coronary artery disease, reinforcing its role as a marker of vascular risk [21].

Fibrinogen serves not only as a central mediator of coagulation but also as an indicator of inflammation and cardiovascular risk. Its persistent elevation in diabetes and strong association with both disease duration and vascular complications highlight its potential role as a biomarker of disease progression. Investigating fibrinogen levels in Sudanese patients with type 2 diabetes could provide valuable insights into the prothrombotic state associated with the disease and inform strategies to mitigate related complications.

**Methods:**

This descriptive case–control study was conducted in Khartoum State, Sudan, between July and October 2024, and included Sudanese patients diagnosed with type 2 diabetes mellitus. The general objective of the study was to evaluate fibrinogen levels among Sudanese patients with type 2 diabetes mellitus in Khartoum State. Specifically, the study aimed to determine fibrinogen levels among Sudanese patients with type 2 diabetes mellitus and a control group, to compare fibrinogen levels between patients with type 2 diabetes mellitus and healthy controls, and to assess the correlation between fibrinogen levels and both age and duration of disease in type 2 diabetic patients.

Eligible participants were adults diagnosed with type 2 diabetes mellitus, confirmed by medical records or a physician's diagnosis. Individuals with type 1 diabetes, gestational diabetes, or secondary forms of diabetes were excluded. In addition, pregnant women, patients with severe complications such as end-stage renal disease, and those undergoing treatments likely to interfere with study outcomes, such as corticosteroids or anticoagulants, were not included.

A total of 100 participants were enrolled in the study, comprising 50 patients with type 2 diabetes mellitus as the case group and 50 apparently healthy individuals as the control group. Data were collected using a structured questionnaire designed to obtain information on demographic, clinical, and laboratory data. Participants were asked to provide their ID, age, and gender, as well as the duration of their diabetes, the presence of other medical conditions (indicated by "yes" or "no," with specification if applicable), and any medications currently being taken (indicated by "yes" or "no," with specification if applicable). Plasma fibrinogen levels (mg/dL) were recorded as part of the laboratory data.

For sample collection, five milliliters (5 mL) of venous whole blood were obtained under aseptic conditions into tubes containing 3.2% sodium citrate as an anticoagulant. The samples were centrifuged at 2000 rpm for 15 minutes to separate plasma, which was then carefully transferred into plain containers and stored at 2–8°C until analysis. Plasma fibrinogen levels were determined using the Clauss method with the Diagen Fibrinogen Determination Kit. This method utilizes an excess of thrombin to convert fibrinogen to fibrin in diluted plasma, with the clotting time inversely proportional to the fibrinogen concentration. For each test, 100 µL of plasma was diluted with 900 µL of buffer, and then 200 µL of the diluted plasma was mixed with 100 µL of thrombin reagent in a test tube. Timing was started immediately, and the clotting time was recorded upon fibrin clot formation. The measured clotting time was compared to the standard calibration curve provided in the kit. Control samples with known fibrinogen concentrations were included for quality assurance. The normal reference range for plasma fibrinogen is 150–400 mg/dL.

Data were entered into Microsoft Excel and analyzed using SPSS version 23. Results were expressed numerically as mean, standard deviation, and median, and graphically using frequency tables and charts. Comparisons between groups were performed using the independent t-test.

**Ethical Considerations**

Ethical approval for the study was obtained from the institutional ethical committee of Al-Zaiem Al-azhari University and Al-Awaffi Medical Center, where the research was conducted. Written informed consent was obtained from all participants prior to their enrollment in the study.

**Statistical Analysis**

Data were analyzed using the Statistical Package for the Social Sciences (SPSS) software version 29.0. The results were expressed as mean ± standard deviation (SD). Paired t-test was used to compare results of control and treated samples. A p-value $\leq 0.05$ was considered statistically significant

**Results:**

We conducted a case-control study in Khartoum State to investigate fibrinogen levels among Sudanese patients with type 2 diabetes mellitus. The study population included 54 females and 46 males.

The descriptive statistics showed that the mean age of the case group (patients) was 49.2 ± 2.7 years, ranging from 28 to 62 years. In contrast, the control group had a mean age of 43.2 ± 1.9 years, with a range of 31 to 69 years. The duration of diabetes among the case group varied between 1 and 13 years, with a mean duration of 6.3 ± 0.9 years (Table 1).

The mean fibrinogen levels were significantly higher in the case group compared to the control group. Patients with type 2 diabetes had a mean fibrinogen level of 411.3 ± 12.4 mg/dl, while the control group had a mean level of 304.4 ± 8.1 mg/dl. This difference was statistically significant ($p = 0.00$) (Table 2).

When analyzed by sex, males showed slightly higher fibrinogen levels than females. Male participants had a mean fibrinogen level of 417.2 ± 13.6 mg/dl, whereas females had a mean of 413.3 ± 10.3 mg/dl. However, this difference was not statistically significant ($p = 0.16$) (Table 3).

Correlation analysis revealed a significant positive relationship between fibrinogen levels and disease duration ($R = 0.762$, $p = 0.03$), indicating that fibrinogen levels tended to rise with longer duration of diabetes. In contrast, the gender and age with fibrinogen levels both showed a negative correlation with age ($R = –0.168$, $p = 0.34$), suggesting no meaningful association (Table 4).

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**Table 1. Descriptive Statistics of the Study Groups**

| Variable | Group | No. | Minimum (years) | Maximum (years) | Mean ± SD (years) |
|---|---|---|---|---|---|
| Age | Controls | 50 | 31 | 69 | 43.2 ± 1.9 |
| Age | Cases | 50 | 28 | 62 | 49.2 ± 2.7 |
| Duration of disease | Cases | 50 | 1 | 13 | 6.3 ± 0.9 |

**Table 2. Mean Fibrinogen Levels among Study Groups**

| Group | Mean ± SD (mg/dL) | p-value |
|---|---|---|
| Cases | 411.3 ± 12.4 | |
| Controls | 304.4 ± 8.1 | 0.00 * |

*Significant at $p < 0.05$

**Table 3. Mean Fibrinogen Levels by Gender**

| Gender | No. | Mean ± SD (mg/dL) | p-value |
|---|---|---|---|
| Males | 46 | 417.2 ± 13.6 | |
| Females | 54 | 413.3 ± 10.3 | 0.16 ** |

**Table 4. Correlation between Fibrinogen Levels, Age, and Duration of Disease**

| Variable | Correlation Coefficient (R) | p-value |
|---|---|---|
| Duration of disease | 0.762 | 0.03 * |
| Age | -0.168 | 0.34** |

*Significant at $p < 0.05$

**Not statistically significant

**Discussion:**

In comparing the current study's findings on fibrinogen levels among patients with type 2 diabetes mellitus (T2DM) to previous research, several important details emerge that highlight the role of fibrinogen as a biomarker in diabetes.

Our study found that diabetic patients exhibited significantly higher fibrinogen levels (411.3 ± 12.4 mg/dl) compared to controls (304.4 ± 8.1 mg/dl), with a *p*-value of 0.00, indicating a statistically significant difference. This result agrees with the findings of Razek et al. (2019) [7], who reported that fibrinogen levels were significantly higher in diabetic patients (4.01 ± 1.89 g/dl) than in controls (2.79 ± 0.55 g/dl) ($P < 0.001$). The consistent finding of elevated fibrinogen levels in T2DM patients across both studies suggests a strong association between diabetes and increased fibrinogen concentrations, likely related to the heightened inflammatory and prothrombotic states observed in diabetes.

Similarly, Gupta et al. (2016) demonstrated a comparable pattern, showing that fibrinogen levels in diabetic patients (386.04 ± 132.87 mg/dl) were significantly higher than those in non-diabetic controls (314.38 ± 97.42 mg/dl) ($P < 0.001$) [20]. This supports our results, emphasizing the significant role of fibrinogen in the pathophysiology of diabetes and its potential as a marker for cardiovascular risk due to its involvement in thrombogenesis. Gupta's study also highlighted correlations between fibrinogen levels, glycemic control (HbA1c), and other risk factors such as smoking and hypertension, which are factors not directly assessed in our study but consistent with the understanding that fibrinogen levels reflect systemic inflammation and metabolic derangements in diabetes.

Bembde et al. (2018)(24) further reinforced this trend by reporting markedly higher fibrinogen levels in diabetic patients (656 ± 130 mg/dl) compared to controls (324 ± 139 mg/dl), with significant associations between fibrinogen and variables such as age, BMI, hypertension, smoking, and ischemic heart disease (all $P < 0.01$) [12]. Although we did not examine these correlations in depth, the observed significant positive correlation between

fibrinogen levels and disease duration (R = 0.762, *P* = 0.03) aligns with Bembde's findings, indicating that fibrinogen levels tend to increase with prolonged disease duration and poor glycemic control.

In contrast, Desai et al. (2012) found no significant difference in fibrinogen levels between diabetic patients with BMI < 25 kg/m² and controls (*p* = 0.097) [19]. Furthermore, they observed a non-significant trend of higher fibrinogen levels in male diabetics, which is similar to our finding, where the difference between males and females was not statistically significant (*P* = 0.16). These findings suggest that while gender-related variations in fibrinogen may exist, they may not always reach statistical significance, particularly in smaller sample sizes or in the presence of confounding factors.

Finally, Kafle et al. (2010) reported significantly elevated fibrinogen levels in diabetic patients compared to controls in a comparative study involving individuals with diabetes and coronary artery disease (CAD) [21]. This reinforces the association between elevated fibrinogen and T2DM, highlighting its dual role as an inflammatory and prothrombotic marker linked to both diabetes and its cardiovascular complications.

**Conclusion:**

The results of the current study indicate that fibrinogen levels are significantly higher in patients with type 2 diabetes mellitus compared to healthy controls. Furthermore, a significant positive correlation was observed between fibrinogen levels and the duration of diabetes, suggesting that longer disease duration may contribute to elevated fibrinogen concentrations. In contrast, there was no significant correlation between fibrinogen levels and age, indicating that age alone may not be a major determinant of fibrinogen variation among diabetic patients.

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