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A STUDY ON SERUM FIBRINOGEN IN PATIENTS WITH DIABETES MELLITUS AND ITS ROLE AS AN INFLAMMATORY MARKER OF DIABETES MELLITUS AND IT'S COMPLICATIONS

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ABSTRACT

Background: Diabetes mellitus is a common metabolic disorder characterised by chronic hyperglycaemia and is associated with a high burden of both microvascular and macrovascular complications. Emerging evidence highlights the role of haemostatic abnormalities—particularly elevated serum fibrinogen—in the pathogenesis of vascular complications in diabetes due to increased thrombogenicity, endothelial dysfunction, and systemic inflammation. Fibrinogen, an acute-phase reactant, may serve as a predictive biomarker for poor glycaemic control and diabetes-related complications. This study assessed serum fibrinogen levels in individuals with diabetes mellitus and explored its association with glycaemic parameters and diabetic complications.

Methods: This cross-sectional observational study included 134 adults with confirmed diabetes mellitus attending Fakhruddin Ali Ahmed Medical College and Hospital, Barpeta, Assam, over a period of one year. Clinical evaluation, anthropometry, and laboratory investigations—including HbA1c, fasting and postprandial blood glucose, lipid profile, urine albumin-to-creatinine ratio, renal function tests, and serum fibrinogen—were performed. Diabetic complications (retinopathy, nephropathy, neuropathy, cardiovascular disease, peripheral vascular disease, and stroke) were assessed using standard clinical, biochemical, imaging, and electrophysiological criteria. Categorical variables were analysed using Chi-square or Fisher's exact test, while continuous variables were expressed as mean ± standard deviation. Pearson correlation was used to assess associations between clinical parameters and fibrinogen, with $p<0.05$ considered statistically significant.

Results: Among 134 participants, serum fibrinogen levels were normal in 33.6%, mildly elevated in 29.9%, moderately elevated in 22.4%, and severely elevated in 14.2%. Fibrinogen levels increased progressively with longer duration of diabetes ($p=0.03$ for 5–10 years; $p=0.01$ for >10 years). Patients with complications had significantly higher fibrinogen levels (retinopathy 411.3±130.4 mg/dL, nephropathy 425.6±140.3 mg/dL, neuropathy 402.7±122.9 mg/dL, cardiovascular disease 430.1±120.5 mg/dL) compared to those without complications (350.5±105.3 mg/dL) ($p<0.05$). Serum fibrinogen showed strong positive correlations with age ($r=0.27$), body mass index ($r=0.45$), duration of diabetes ($r=0.32$), HbA1c ($r=0.56$), fasting blood glucose ($r=0.47$), postprandial blood glucose ($r=0.53$), total cholesterol ($r=0.37$), low-density lipoprotein cholesterol ($r=0.41$), triglycerides ($r=0.43$), systolic blood pressure ($r=0.33$), and diastolic blood pressure ($r=0.28$). A negative but non-significant correlation was noted with high-density lipoprotein cholesterol ($r = –0.18$, $p = 0.07$).

Conclusion: Serum fibrinogen levels were significantly elevated in diabetic individuals, especially those with poor glycaemic control, longer duration of diabetes and established microvascular and macrovascular complications. This study demonstrated a strong correlation between fibrinogen level and glycaemic indices, lipid abnormalities, and blood pressure, underscoring its role as a marker of inflammation and vascular risk in diabetes mellitus.

Keywords*: Diabetes mellitus; Serum fibrinogen; Inflammatory marker; Hyperfibrinogenaemia; Glycaemic control; Diabetic complications; Retinopathy; Nephropathy; Neuropathy; Cardiovascular disease; Peripheral vascular disease; Stroke; Insulin resistance; Dyslipidaemia; Endothelial dysfunction.*

INTRODUCTION

Diabetes mellitus is a group of common metabolic diseases characterised by hyperglycaemia. (1) In 2019, non-communicable diseases accounted for 74% of global mortality, with diabetes responsible for 1.6 million deaths, ranking it as the ninth leading cause of death worldwide, according to the World Health Organisation (WHO). India, often designated as the 'diabetic capital of the world', reports the highest number of cases globally. Findings from the Indian Council of Medical Research's comprehensive national epidemiological survey reveal diabetes prevalence ranging from 3.5% to 8.7% in rural populations and from 5.8% to 15.5% in urban populations. (2)

The associated macrovascular and microvascular complications of DM are the primary cause of its burden. In adults with diabetes, coronary artery disease continues to be the leading cause of death, accounting for roughly three times as many deaths as in those without the disease. (3) The role of haemostatic factors, especially fibrinogen, in the onset of atherosclerosis and its consequences has come under increasing scrutiny in the past decade. (4) Fibrinogen seems to play a role in the early stages of atherosclerotic plaque formation as well as the later phases of the progression of cardiovascular disease. The pathophysiology of atherosclerosis is significantly influenced by inflammation, as monocytes that migrate into atherosclerotic lesions develop into macrophages and release pro-inflammatory cytokines like interleukin-6, which in turn triggers hepatic synthesis of fibrinogen, thereby raising plasma fibrinogen levels. The increased cardiovascular morbidity and mortality observed in diabetics that cannot be entirely explained by traditional risk factors, such as smoking, high blood pressure, and high cholesterol. (5) There is mounting evidence that the pathophysiology of diabetes-related macrovascular and microvascular complications is influenced by dysregulated haemostasis. Additionally, increased thrombogenicity is linked to impaired glucose tolerance, partly due to elevated plasma fibrinogen concentrations that enhance blood viscosity and platelet aggregation. (6)

Fibrinogen is a "circulating glycoprotein composed of three pairs of polypeptide chains forming a dimeric structure" that serves as the main coagulation protein in blood. (7) Additionally, it is an "acute-phase reactant," meaning that when systemic inflammation occurs, its concentration rises. Fibrinogen is also associated with diabetic nephropathy (DN). (8) Increased fibrinogen levels are frequently seen in diabetics and have been identified as a separate risk factor that accelerates the development of DN. (9,10)

The prothrombotic state of diabetic patients has significant etiological, prophylactic, and therapeutic ramifications. Notably, fibrinogen levels may be changed by lifestyle changes and possibly medication, which implies that measuring them could be a useful tool for predicting and preventing complications related to diabetes. Given the limited data from Northeast India, on evaluating the relationship between serum fibrinogen, glycaemic control and its complications, this study aims to (1) assess serum fibrinogen levels in patients with diabetes mellitus and (2) evaluate their association with glycaemic indices and diabetic complications

METHODOLOGY

This cross-sectional observational study was conducted on 134 individuals aged 18 years and above, diagnosed with DM (both newly diagnosed and known cases), who attended the outpatient department or were admitted to the Department of Medicine at FAAMCH, Barpeta, Assam, over a period of one year.

Inclusion criteria: Inclusion criteria were patients aged 18 years or older with a confirmed diagnosis of DM.
Exclusion criteria: Exclusion criteria included individuals with known coagulation abnormalities or those on anticoagulant therapy, individuals presenting with active infections or inflammatory conditions such as fever, or postoperative status, and those who did not provide informed consent.

Data collection: Ethical clearance was obtained from the Institutional Ethics Committee of FAAMCH, Barpeta. Written informed consent was obtained from all participants prior to their inclusion in the study.

All participants underwent a comprehensive clinical evaluation, including medical history and physical examination. Laboratory investigations comprised fasting and postprandial blood glucose, HbA1c, urine routine and albumin-to-creatinine ratio (ACR), serum fibrinogen, blood urea, serum creatinine, fasting lipid profile, PT/INR, aPTT, ECG, abdominal ultrasonography, and Doppler studies. Diabetes was diagnosed according to ADA criteria: HbA1c ≥6.5%, fasting plasma glucose ≥126 mg/dL, 2-hour plasma glucose >200 mg/dL during OGTT with 75 g glucose, or random plasma glucose ≥ 200 mg/dL in the presence of classic symptoms of hyperglycaemia. Diabetic complications were assessed as follows: retinopathy via dilated fundus examination; neuropathy through motor and sensory assessments, including monofilament, tuning fork, and cortical sensory tests; nephropathy via serum creatinine, eGFR (Cockcroft-Gault), urine ACR, and renal ultrasound; cardiovascular disease based on clinical history and ECG findings; peripheral vascular disease through pulse examination and Doppler imaging; and stroke through clinical evaluation and CT/MRI imaging.

Data were analysed using SPSS Statistics for Windows. Categorical variables were expressed as frequency and percentage, while continuous variables were presented as mean ± standard deviation (SD). Associations between categorical variables were analysed using the Chi-square test or Fisher's exact test, as appropriate. A p-value <0.05 was considered statistically significant at a 95% confidence interval.

RESULTS

In this study, fibrinogen levels were measured in 134 individuals diagnosed with diabetes mellitus. The levels were then correlated with age, body mass index (BMI), duration of diabetes, HbA1c, fasting blood glucose, postprandial blood glucose, total cholesterol, LDL, HDL, triglycerides, systolic blood pressure, and diastolic blood pressure.

The mean age of participants was 56.1 ± 8.7 years, with the majority aged between 40–59 years (58%), followed by ≥60 years (36%), and a smaller proportion <40 years (6%). Males comprised 51% of the cohort, while females accounted for 49%. The mean duration of diabetes was 8.2 ± 3.1 years; 37.3% had diabetes for ≤5 years, 44.8% for 5–10 years, and 17.9% for more than 10 years. Regarding lifestyle factors,59.7% were physically inactive. A family history of diabetes was present in 67.9% of cases. Comorbid conditions were frequently observed. Hypertension was the most common (78.4%), followed by dyslipidaemia (66.4%), obesity (40.3%), peripheral vascular disease (19.4%), and coronary artery disease (14.9%). In terms of glycaemic control, all participants (n = 134) had HbA1c levels ≥6.5%, consistent with the diagnostic criteria for diabetes. Similarly, all patients had fasting blood glucose levels ≥126 mg/dL and postprandial blood glucose levels ≥200 mg/dL, confirming hyperglycaemia across the cohort. Dyslipidaemia was also prevalent: total cholesterol levels ≥200 mg/dL were observed in 62.7% of participants; LDL ≥130 mg/dL in 17.9%; HDL <40 mg/dL in 43.3%; and triglyceride levels ≥150 mg/dL in 76.1% of the cohort.

Diabetic complications were widespread: neuropathy (38.1%) was most common, followed by retinopathy (35.8%), nephropathy (28.4%), cardiovascular disease (23.9%), peripheral vascular disease (19.4%), and stroke (6.7%). (Table 1)

Table 1: Key characteristics of study population(n=134)

Parameter	Category/Value	n (%) / Mean ± SD
Age Group (years)	<40	8 (6.0%)
	40–59	78 (58.0%)
	≥60	48 (36.0%)
	Mean Age	**56.1 ± 8.7**
Sex	Male	68 (51.0%)
	Female	66 (49.0%)
Duration of Diabetes (years)	≤5	50 (37.3%)
	5–10	60 (44.8%)
	>10	24 (17.9%)
	Mean Duration	**8.2 ± 3.1**
Physical Activity	Active	54 (40.3%)
	Inactive	80 (59.7%)
Family History of Diabetes	Present	91 (67.9%)
	Absent	43 (32.1%)
Comorbidities	Hypertension	105 (78.4%)
	Dyslipidemia	89 (66.4%)
	Obesity	54 (40.3%)
	Coronary Artery Disease (CAD)	20 (14.9%)
	Peripheral Vascular Disease (PVD)	26 (19.4%)
HbA1c (%)	≥ 6.5%	134 (100%)
Total Cholesterol (mg/dL)	<200	50 (37.3%)

	200–239	61 (45.5%)
	≥240	23 (17.2%)
LDL Cholesterol (mg/dL)	<100	43 (32.1%)
	100–129	67 (50.0%)
	≥130	24 (17.9%)
HDL Cholesterol (mg/dL)	<40	58 (43.3%)
	40–59	63 (47.0%)
	≥60	13 (9.7%)
Triglycerides (mg/dL)	<150	32 (23.9%)
	150–199	56 (41.8%)
	≥200	46 (34.3%)
Diabetic Complications	Neuropathy	51 (38.1%)
	Retinopathy	48 (35.8%)
	Nephropathy	38 (28.4%)
	Cardiovascular Disease	32 (23.9%)
	Stroke	9 (6.7%)

The serum fibrinogen levels of the study population(Table 2) were categorised into four groups: 33.6% (n = 45) of participants had normal levels (<300 mg/dL), 29.9% (n = 40) had mildly elevated levels (300–400 mg/dL), 22.4% (n = 30) had moderately elevated levels (400–500 mg/dL), and 14.2% (n = 19) had severely elevated levels (>500 mg/dL).

Table 2: Serum Fibrinogen levels among the study population (n=134)

Fibrinogen Level Category	Fibrinogen Range (mg/dL)	Frequency (n)	Percentage (%)
Normal	<300	45	33.6%
Mildly Elevated	300–400	40	29.9%
Moderately Elevated	400–500	30	22.4%
Severely Elevated	>500	19	14.2%
Total	—	**134**	**100%**

The laboratory investigations in this study revealed key findings related to serum fibrinogen levels and other clinical markers among diabetic patients. (Table 3) An analysis of serum fibrinogen levels by duration of diabetes showed a statistically significant increasing trend. Patients with diabetes duration ≤5 years (n = 50) had a mean fibrinogen level of 387.4 ± 98.1 mg/dL. Those with a duration of 5–10 years (n = 60) had a mean level of 423.6 ± 105.2 mg/dL (p = 0.03), while those with duration >10 years (n = 24) had a mean level of 469.2 ± 121.4 mg/dL (p = 0.01). This trend suggests a progressive increase in serum fibrinogen with longer duration of diabetes, possibly reflecting chronic systemic inflammation.

Patients with diabetic complications had significantly higher serum fibrinogen levels compared to those without complications. Among the patients with complications (n = 84), the mean fibrinogen levels for specific conditions were as follows: diabetic retinopathy (411.3 ± 130.4 mg/dL), nephropathy (425.6 ± 140.3 mg/dL), neuropathy (402.7 ± 122.9 mg/dL), cardiovascular disease (430.1 ± 120.5 mg/dL). In contrast, participants without complications (n = 50) had a mean fibrinogen level of 350.5 ± 105.3 mg/dL. The difference in fibrinogen levels between the two groups was statistically significant ($p < 0.05$), indicating a strong association between elevated fibrinogen and the presence of diabetic complications.

Pearson correlation analysis demonstrated statistically significant positive correlations between serum fibrinogen levels and multiple clinical parameters. Specifically, fibrinogen levels were positively correlated with age ($r = 0.27$, $p = 0.003$), body mass index (BMI) ($r = 0.45$, $p < 0.001$), duration of diabetes ($r = 0.32$, $p = 0.001$), HbA1c ($r = 0.56$, $p < 0.001$), fasting blood glucose ($r = 0.47$, $p < 0.001$), postprandial blood glucose ($r = 0.53$, $p < 0.001$), total cholesterol ($r = 0.37$, $p < 0.001$), LDL cholesterol ($r = 0.41$, $p < 0.001$), triglycerides ($r = 0.43$, $p < 0.001$), systolic blood pressure ($r = 0.33$, $p = 0.001$), and diastolic blood pressure ($r = 0.28$, $p = 0.002$). A negative correlation was observed between serum fibrinogen and HDL cholesterol ($r = -0.18$), although this was not statistically significant ($p = 0.07$). These findings indicate that elevated serum fibrinogen levels are associated with older age, higher BMI, longer duration of diabetes, poor glycaemic control, dyslipidaemia, and increased blood pressure, all of which are key cardiovascular and metabolic risk factors in diabetic patients.

Table 3: Association of serum fibrinogen levels with various parameters

Parameter	Category	Mean ± SD (mg/dL) / Correlation Coefficient (r)	p-value
Serum Fibrinogen by Duration of Diabetes	≤ 5 years (n = 50)	387.4 ± 98.1	—
	5–10 years (n = 60)	423.6 ± 105.2	0.03

	> 10 years (n = 24)	469.2 ± 121.4	0.01
Serum Fibrinogen by Diabetic Complications	Diabetic Retinopathy (n = 84)	411.3 ± 130.4	—
	Diabetic Nephropathy	425.6 ± 140.3	—
	Diabetic Neuropathy	402.7 ± 122.9	—
	Cardiovascular Disease	430.1 ± 120.5	—
	No Complications (n = 50)	350.5 ± 105.3	< 0.05
Pearson Correlation of Serum Fibrinogen with Clinical Parameters	Age (years)	0.27	0.003
	Body Mass Index (BMI, kg/m²)	0.45	< 0.001
	Duration of Diabetes (years)	0.32	0.001
	HbA1c (%)	0.56	< 0.001
	Fasting Blood Glucose (mg/dL)	0.47	< 0.001
	Postprandial Blood Glucose (mg/dL)	0.53	< 0.001
	Total Cholesterol (mg/dL)	0.37	< 0.001
	LDL Cholesterol (mg/dL)	0.41	< 0.001
	Triglycerides (mg/dL)	0.43	< 0.001
	Systolic Blood Pressure (mmHg)	0.33	0.001
	Diastolic Blood Pressure (mmHg)	0.28	0.002
	HDL Cholesterol (mg/dL)	-0.18	0.07

DISCUSSION

Metabolic dysregulation in diabetes mellitus leads to platelet hyperactivity, characterised by increased platelet size and enhanced release of dense granules containing adenosine diphosphate, serotonin, and calcium, thereby promoting platelet aggregation and contributing to a prothrombotic state. Individuals in this prothrombotic state are more likely to experience vascular occlusive events. These, in turn, exacerbate both microvascular and macrovascular complications, which are closely linked to increased morbidity and mortality. Vascular pathology is further exacerbated by endothelial dysfunction, which is known to be an independent predictor of cardiovascular risk in diabetes. In this context, fibrinogen, a sensitive indicator of subclinical inflammation, has been implicated; elevated levels frequently indicate inadequate glycaemic control and contribute to the development of hyperfibrinogenaemia and the vascular sequelae that accompany it. (11,12)

In this study, serum fibrinogen levels among individuals with diabetes mellitus were assessed, and their associations with key metabolic markers and diabetic complications were investigated. The results unequivocally showed that diabetic patients had higher fibrinogen concentrations, with those who presented with complications like retinopathy, nephropathy, neuropathy, cardiovascular disease having noticeably higher levels. These findings suggest that fibrinogen serves as an important inflammatory biomarker in the pathogenesis of both microvascular and macrovascular diabetic complications.

Our results demonstrate a strong correlation between fibrinogen and insulin resistance, which is consistent with Sproston and Ashworth (13). BMI and fibrinogen have a moderately positive correlation ($r = 0.45$, $p < 0.001$), which implies fibrinogen plays a role in the inflammatory environment that promotes insulin resistance. In a similar study, Wang et al.(14) showed a robust correlation between fibrinogen and HOMA-IR, confirming its function in diabetes-related chronic inflammation.

Studies by Dandona et al.(15) and Bembde et al. (1), who suggested fibrinogen as a sign of inadequate glycaemic control and chronic inflammation, endorse the significant correlation between fibrinogen and HbA1c ($r = 0.56$, $p < 0.001$) found in our study. According to these findings, better glycaemic control may lower fibrinogen levels and the likelihood of complications.

In the current study, in diabetics, elevated fibrinogen levels were significantly linked to cardiovascular disease (430.1 ± 120.5 mg/dL), which is consistent with previous research by Ridker et al.(16) that found fibrinogen to be a predictor of cardiovascular events in DM. Our findings were supported by Lam TH et al.(17), who also reported that diabetic patients had a higher risk of coronary artery disease due to elevated fibrinogen.

Increased fibrinogen levels (425.6 ± 140.3 mg/dL) were observed in patients with diabetic nephropathy; these results were similar to those of Schena et al.(18) and Le DS et al.(19), who found a strong correlation between fibrinogen and renal impairment in diabetes. These results lend credence to the involvement of fibrinogen in microvascular damage and endothelial dysfunction, which accelerate the course of nephropathy.

In this study, patients with diabetic neuropathy exhibited elevated fibrinogen levels (402.7 ± 122.9 mg/dL), consistent with Bodman et al.(20), who reported a strong link between fibrinogen and nerve dysfunction. Similarly, individuals with a history of stroke showed higher fibrinogen levels, supporting Daugaard et al (21) findings that fibrinogen is associated with increased ischemic stroke risk in diabetes.

The cross-sectional design of this study restricts the ability to conclude the causal relationship between high fibrinogen and complications from diabetes. Furthermore, confounding variables like diet, genetic predispositions, and medication use were not completely taken into consideration. To elucidate these associations, more longitudinal and interventional research is required. Furthermore, combining other inflammatory markers like CRP and IL-6 could offer a more thorough understanding of the inflammatory processes in diabetes, as fibrinogen levels may be impacted by infection, stress, or comorbidities.

CONCLUSION

This study demonstrates that serum fibrinogen is significantly higher in patients with diabetes with poor glycaemic control and with complications and may serve as an inflammatory marker in diabetes mellitus and has potential to use as predictive biomarker, therapeutic target and risk stratification. However, given the cross-sectional nature and limited sample size of the present study, larger prospective studies with longer follow-up are required to establish its predictive and therapeutic relevance.

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