

Study of Plasma Fibrinogen Levels in Type 2 Diabetes Mellitus and Its Correlation with HbA1c Levels

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ABSTRACT

Background: Type 2 diabetes mellitus is associated with metabolic abnormalities and alterations in the coagulation system that contribute to an increased risk of vascular complications. Plasma fibrinogen, an important coagulation factor and acute-phase reactant, may be elevated in patients with diabetes mellitus and may be associated with glycemic control and other cardiovascular risk factors. **Aim:** To estimate plasma fibrinogen levels in patients with type 2 diabetes mellitus and compare them with non-diabetic controls and to assess their association with glycemic status and other clinical and biochemical parameters. **Methods:** This hospital-based case-control study was conducted at SVS Medical College and Hospital, Mahabubnagar, from October 2020 to October 2022. A total of 100 participants were included, comprising 50 patients with type 2 diabetes mellitus and 50 non-diabetic controls. Detailed clinical evaluation was performed, and body mass index, blood pressure, fasting blood glucose, postprandial blood glucose, HbA1c, lipid profile, and plasma fibrinogen levels were assessed. The association of plasma fibrinogen with glycemic control and other clinical and biochemical variables was analysed using appropriate statistical methods. **Results:** The study group had significantly higher body mass index, systolic blood pressure, diastolic blood pressure, total cholesterol, triglycerides, LDL cholesterol, fasting blood glucose, postprandial blood glucose, and HbA1c levels compared with the control group, whereas HDL cholesterol levels were significantly lower. Poor glycemic control, defined as HbA1c $\geq 7\%$, was observed in 30 (60%) diabetic participants. The mean plasma fibrinogen level was significantly higher in patients with type 2 diabetes mellitus than in controls, measuring 420.22 ± 56.88 mg/dL and 268.80 ± 51.20 mg/dL, respectively ($p < 0.001$). In the diabetic group, plasma fibrinogen levels showed significant positive correlations with body mass index, systolic blood pressure, diastolic blood pressure, lipid parameters, fasting blood glucose, postprandial blood glucose, and HbA1c. Patients with poor glycemic control had significantly higher plasma fibrinogen levels than those with good glycemic control. Participants with abnormal fibrinogen levels also had significantly higher body mass index, blood pressure, total cholesterol, triglycerides, LDL cholesterol, postprandial blood glucose, and HbA1c levels, while HDL cholesterol levels were significantly lower. **Conclusion:** Plasma fibrinogen levels were significantly elevated in patients with type 2 diabetes mellitus compared with non-diabetic controls and were associated with poor glycemic control and an adverse cardiovascular risk profile. Assessment of plasma fibrinogen along with conventional metabolic and cardiovascular risk parameters may help identify diabetic individuals with an increased procoagulant state.

Keywords: Type 2 diabetes mellitus; Plasma fibrinogen; Glycemic control; HbA1c; Dyslipidemia; Cardiovascular risk.

INTRODUCTION

Diabetes mellitus is a chronic metabolic disorder characterized by persistent hyperglycemia resulting from abnormalities in insulin secretion, insulin action, or both [1]. The prevalence of diabetes is increasing rapidly worldwide, making it a major cause of morbidity and mortality [2]. Persistent hyperglycemia contributes to progressive involvement of multiple organ systems, particularly the eyes, kidneys, heart, blood vessels, and nervous system [3,4].

Type 2 diabetes mellitus is the most common form of diabetes and is associated with insulin resistance, relative insulin deficiency, and a complex interaction between genetic and environmental factors [5,6]. In addition to disturbances in carbohydrate metabolism, diabetes is associated with abnormalities in lipid metabolism, endothelial function, inflammation, and haemostatic mechanisms [7]. These alterations contribute to an increased risk of both microvascular and macrovascular complications [8].

Cardiovascular disease represents an important cause of morbidity and mortality among patients with type 2 diabetes mellitus [9]. Diabetes is associated with a prothrombotic and hypercoagulable state, resulting from alterations in coagulation factors, platelet function, fibrinolysis, and vascular endothelium [10,11]. Among the haemostatic factors, fibrinogen has received considerable attention because of its important role in thrombosis and atherogenesis [12].

Fibrinogen is a soluble plasma glycoprotein synthesized primarily in the liver and is an essential component of the coagulation cascade [13]. During coagulation, fibrinogen is converted into fibrin, which forms the structural framework of a blood clot [14]. Increased plasma fibrinogen levels may promote thrombosis through increased blood viscosity, enhanced platelet aggregation, increased fibrin formation, and alterations in vascular cell proliferation and migration [15-18]. Elevated fibrinogen levels may therefore contribute to the development of atherosclerotic and thrombotic complications [19]. Plasma fibrinogen is also an acute-phase reactant, and its concentration may be influenced by several factors, including age, obesity, smoking, hypertension, dyslipidemia, inflammation, and diabetes mellitus. In individuals with type 2 diabetes mellitus, persistent hyperglycemia and insulin resistance may contribute to increased fibrinogen production and the development of hyperfibrinogenemia. Oxidative stress and endothelial dysfunction associated with these metabolic abnormalities may further promote procoagulant activity [20,21].

Glycated hemoglobin (HbA1c) is an established marker of long-term glycemic control and reflects the

degree of chronic hyperglycemia. The relationship between plasma fibrinogen and HbA1c is therefore of clinical interest, as it may help identify the association between poor glycemic control and haemostatic abnormalities in patients with type 2 diabetes mellitus. Increasing fibrinogen levels with worsening glycemic control may indicate an enhanced risk of vascular complications [22,23].

Assessment of plasma fibrinogen may also provide information regarding cardiovascular risk in patients with type 2 diabetes mellitus. The thesis evaluates the association of fibrinogen with several clinical and metabolic variables, including age, sex, body weight, smoking, cholesterol, and hypertension. Measurement of plasma fibrinogen may therefore be useful in assessing the prothrombotic state associated with diabetes and its potential contribution to vascular disease [24,25].

Therefore, it is of interest to study plasma fibrinogen levels in patients with type 2 diabetes mellitus and determine their correlation with HbA1c levels.

Aim and Objectives

The objectives of the study, as stated in the original thesis, were:

1. To estimate the levels of plasma fibrinogen in patients with diabetes mellitus.
2. To correlate plasma fibrinogen levels with the degree of glycemic control in patients with type 2 diabetes mellitus.

MATERIALS AND METHODS

Study Design

This was a prospective observational case-control study conducted to assess plasma fibrinogen levels as a predictor of cardiovascular risk in individuals with type 2 diabetes mellitus and to evaluate its relationship with glycemic status.

Study Setting and Duration

The study was conducted at SVS Medical College and Hospital, Mahabubnagar. The study period was from October 2020 to October 2022.

Sample Size

A total of 100 participants were included in the study, comprising 50 patients with type 2 diabetes mellitus as cases and 50 age- and gender-matched non-diabetic individuals as controls.

Sample Size Calculation

The original thesis specifies a sample size of 50 cases and 50 controls. However, a separate mathematical sample-size calculation formula and its derivation are not provided in the Materials and Methods section available in the thesis text. Therefore, no formula or

calculation has been added or reconstructed in this manuscript, in accordance with the requirement to preserve the original study methodology without deviation.

Inclusion Criteria

Cases

Patients diagnosed with diabetes mellitus according to the American Diabetes Association 2019 diagnostic criteria were included. Diabetes mellitus was defined by any of the following:

- HbA1c $\geq 6.5\%$; or
- Fasting plasma glucose ≥ 126 mg/dL (7.0 mmol/L); or
- Two-hour plasma glucose ≥ 200 mg/dL (11.1 mmol/L) during a 75-g oral glucose tolerance test; or
- Random plasma glucose ≥ 200 mg/dL (11.1 mmol/L) in the presence of classic symptoms of hyperglycemia.

Patients were classified as having type 2 diabetes mellitus when the age of onset was after 30 years and insulin therapy was not required initially.

Controls

Age- and gender-matched non-diabetic individuals were included as controls. Fifty individuals attending for master health check-up were selected as controls.

Exclusion Criteria

The following participants were excluded:

- Patients with clinical evidence of diabetic neuropathy, nephropathy, or retinopathy.
- Diabetic ketoacidosis and non-ketotic hyperglycemic coma.
- Coronary artery disease.
- Peripheral vascular disease.
- Cerebrovascular disease.
- Liver disorders.
- Renal disorders.
- Pregnant women.
- Acute infections.
- Smokers and alcohol users.

Study Protocol and Data Collection

A total of 100 participants attending the outpatient clinic at SVS Medical College and Hospital, Mahabubnagar, were enrolled. Fifty patients fulfilling the eligibility criteria were selected as cases, and 50 age- and gender-matched non-diabetic individuals were included as controls.

Written informed consent was obtained from each participant before enrolment. A detailed clinical history was obtained, including information regarding diagnosis, duration of diabetes, type of treatment, follow-up, and associated comorbidities. The duration of diabetes was not given greater emphasis in the

original study because asymptomatic hyperglycemia may precede the clinical detection of diabetes.

All participants underwent a detailed physical examination, including assessment for peripheral vascular disease, cerebrovascular disease, cardiovascular disease, neuropathy, retinopathy, and nephropathy.

Clinical and Anthropometric Assessment

Blood pressure was measured in the right arm in the sitting position with the arm supported, using a mercury sphygmomanometer, to the nearest 2 mmHg. If the initial reading was high, blood pressure measurement was repeated after five minutes of rest.

Height was measured to the nearest millimetre using a stadiometer, and body weight was recorded. Body mass index was calculated using the formula:

$BMI = \text{Weight in kilograms} / (\text{Height in metres})^2$.

Laboratory Investigations

Basic investigations included hemoglobin, total and differential leukocyte counts, platelet count, blood urea, serum creatinine, and liver function tests. Urine examination included assessment of albumin, sugar, microscopy, and ketone bodies. A standard 12-lead resting electrocardiogram, chest X-ray screening, and echocardiography were also performed.

A fasting lipid profile, including serum total cholesterol, triglycerides, high-density lipoprotein cholesterol, and low-density lipoprotein cholesterol, was obtained. Fasting and two-hour postprandial blood samples were collected for glycemic assessment.

HbA1c Assessment And Glycemic Control

Glycosylated hemoglobin (HbA1c) was estimated using the Bio-Rad high-performance liquid chromatography assay. The normal HbA1c value was considered to be 4–5.7%. Patients with HbA1c $\geq 7\%$ were categorized as having poor glycemic control.

Plasma Fibrinogen Estimation Levels

Plasma fibrinogen levels were estimated in all study participants using the method described in the study protocol. The laboratory reference range for plasma fibrinogen was considered during the interpretation of the measured values.

For the purpose of subgroup analysis among patients with type 2 diabetes mellitus, participants were further categorized according to a plasma fibrinogen cut-off value of 380 mg/dL. Patients with plasma fibrinogen levels below 380 mg/dL were included in the lower fibrinogen group, whereas those with levels above 380 mg/dL were included in the higher fibrinogen group. The clinical and biochemical characteristics of these two subgroups were subsequently compared.

This analytical categorization was used specifically for the subgroup analysis and should be interpreted separately from the laboratory reference range used for the general assessment of plasma fibrinogen levels.

Statistical Analysis

Statistical analysis was performed for all 100 participants after categorization of the study variables. The parameters analysed included age, body mass index, systolic blood pressure, diastolic blood pressure, serum total cholesterol, triglycerides, low-density lipoprotein cholesterol, high-density lipoprotein cholesterol, fasting blood glucose, two-hour postprandial blood glucose, HbA1c, and plasma fibrinogen.

Data analysis was carried out using SPSS software. Pearson's correlation coefficient and Student's t-test were used to assess correlations and significant differences between the study and control groups. A p-value of <0.05 was considered statistically significant.

RESULTS

A total of 100 participants were included in the study, comprising 50 patients with type 2 diabetes mellitus in the study group and 50 non-diabetic individuals in the

control group. The demographic distribution of the participants was assessed according to age and sex. Body mass index and hypertension status were evaluated in both groups. The clinical and biochemical characteristics, including blood pressure, lipid profile, blood glucose parameters, and HbA1c levels, were compared between the study and control groups. Glycemic control among diabetic participants was categorized based on HbA1c levels. Plasma fibrinogen levels were compared between cases and controls and further evaluated in relation to demographic and clinical variables. Correlation analyses were performed to assess the relationship of plasma fibrinogen with age, body mass index, blood pressure, lipid parameters, and glycemic indices. Plasma fibrinogen levels were also compared according to glycemic control among diabetic participants. Finally, the clinical and biochemical characteristics of diabetic participants were compared between those with normal and abnormal plasma fibrinogen levels.

Age Distribution

The age distribution of cases and controls is presented in Table 1.

Table 1: Distribution of Cases and Controls According to Age Group

Age Group (Years)	Cases (n=50)	Percentage	Controls (n=50)	Percentage
30–34	8	16.0%	9	18.0%
35–39	10	20.0%	14	28.0%
40–44	27	54.0%	24	48.0%
45–49	5	10.0%	3	6.0%
Total	50	100.0%	50	100.0%

The majority of participants in both groups belonged to the 40–44-year age group. The age distribution was comparable between the study and control groups.

Gender Distribution

The gender distribution of cases and controls is presented in Table 2.

Table 2: Gender Distribution of Cases and Controls

Gender	Cases (n=50)	Percentage	Controls (n=50)	Percentage
Male	27	54.0%	26	52.0%
Female	23	46.0%	24	48.0%
Total	50	100.0%	50	100.0%

The gender distribution was comparable between the study and control groups.

Body Mass Index Distribution

The distribution of body mass index among cases is shown in Table 3.

Table 3: Distribution of Cases According to Body Mass Index

BMI Category (kg/m ²)	Cases (n=50)	Percentage
<18.5	0	0.0%
18.5–24.9	26	52.0%
25.0–29.9	22	44.0%
≥30.0	2	4.0%
Total	50	100.0%

The majority of cases had a BMI within the normal range, while 48.0% were either overweight or obese. The distribution of body mass index among controls is shown in Table 4.

Table 4: Distribution of Controls According to Body Mass Index

BMI Category (kg/m ²)	Controls (n=50)	Percentage
<18.5	0	0.0%
18.5–24.9	34	68.0%
25.0–29.9	15	30.0%
≥30.0	1	2.0%
Total	50	100.0%

The majority of controls had a BMI within the normal range.

Hypertension Status

The distribution of hypertension among cases and controls is presented in Table 5.

Table 5: Hypertension in the Study Group and Control Group

Hypertension Status	Cases (n=50)	Percentage	Controls (n=50)	Percentage
Hypertensive	35	70.0%	11	22.0%
Non-hypertensive	15	30.0%	39	78.0%
Total	50	100.0%	50	100.0%

Hypertension was more frequent among cases, with 35 (70.0%) participants being hypertensive, compared with 11 (22.0%) participants in the control group.

Clinical and Biochemical Characteristics

The clinical and biochemical characteristics of the study participants are presented in Table 6.

Table 6: Clinical and Biochemical Characteristics of Study Subjects

Parameter	Cases Group (n=50)	Control Group (n=50)	p-value
Age (years)	42.20 ± 4.00	40.00 ± 4.40	0.211
BMI (kg/m ²)	25.50 ± 1.72	24.24 ± 1.50	0.005
SBP (mmHg)	135.60 ± 13.40	128.48 ± 10.22	0.006
DBP (mmHg)	82.20 ± 8.20	78.60 ± 8.12	0.028
Total cholesterol (mg/dL)	215.80 ± 31.20	184.80 ± 22.60	<0.001
Triglycerides (mg/dL)	186.88 ± 30.56	146.24 ± 21.20	<0.001
HDL cholesterol (mg/dL)	39.22 ± 9.80	49.20 ± 8.20	<0.001
LDL cholesterol (mg/dL)	140.85 ± 33.44	108.60 ± 28.12	<0.001
FBS (mg/dL)	132.20 ± 17.40	86.80 ± 6.20	<0.001
PPBS (mg/dL)	224.80 ± 31.22	110.40 ± 26.40	<0.001
HbA1c (%)	8.22 ± 0.76	4.24 ± 0.40	<0.001

Both groups were comparable with respect to age. The study group had significantly higher BMI, systolic blood pressure, diastolic blood pressure, total cholesterol, triglycerides, LDL cholesterol, fasting blood glucose, postprandial blood glucose, and HbA1c levels. HDL cholesterol was significantly lower in the study group compared with the control group.

Glycemic Control

The distribution of cases according to glycemic control is presented in Table 7.

Table 7: Distribution of Cases According to Glycemic Control

HbA1c	Control of Blood Glucose	Number	Percentage
<7%	Good	20	40.0%
≥7%	Poor	30	60.0%
Total		50	100.0%

Poor glycemic control was observed in 30 (60.0%) diabetic participants, whereas 20 (40.0%) participants had good glycemic control.

Plasma Fibrinogen Levels

The comparative analysis of plasma fibrinogen levels between the study and control groups is presented in Table 8.

Table 8: Comparative Analysis of Plasma Fibrinogen Level in the Study and Control Groups

Plasma Fibrinogen Level	Number	Mean (mg/dL)	SD	Standard Error of Mean
Cases Group	50	420.22	56.88	8.12
Control Group	50	268.80	51.20	7.22
Comparison		t-value		p-value
Cases versus Controls		7.999		<0.001

Plasma fibrinogen levels were significantly higher in the study group than in the control group.

Correlation of Age, Body Mass Index and Blood Pressure With Plasma Fibrinogen in the Study Group

The correlation of age, body mass index, systolic blood pressure, and diastolic blood pressure with plasma fibrinogen levels in the study group is presented in Table 9.

Table 9: Correlation Analysis Between Age, Body Mass Index, Systolic Blood Pressure, Diastolic Blood Pressure and Plasma Fibrinogen in the Study Group

Variables	N	Pearson Correlation (r)	p-value
Age	50	0.222	0.128
BMI	50	0.562	<0.001
Systolic BP	50	0.572	<0.001
Diastolic BP	50	0.555	<0.001

In the study group, BMI, systolic blood pressure, and diastolic blood pressure showed statistically significant positive correlations with plasma fibrinogen levels. Age did not show a statistically significant correlation with plasma fibrinogen levels.

Correlation of Age, Body Mass Index and Blood Pressure with Plasma Fibrinogen in the Control Group

The correlation of age, body mass index, systolic blood pressure, and diastolic blood pressure with plasma fibrinogen levels in the control group is presented in Table 10.

Table 10: Correlation Analysis Between Age, Body Mass Index, Systolic Blood Pressure, Diastolic Blood Pressure and Plasma Fibrinogen in the Control Group

Variables	N	Pearson Correlation (r)	p-value
Age	50	0.502	<0.001
BMI	50	0.541	<0.001
Systolic BP	50	0.512	<0.001
Diastolic BP	50	0.446	<0.001

In the control group, age, BMI, systolic blood pressure, and diastolic blood pressure showed statistically significant positive correlations with plasma fibrinogen levels.

Correlation of Lipid Profile With Plasma Fibrinogen in the Study Group

The correlation between lipid parameters and plasma fibrinogen levels in the study group is presented in Table 11.

Table 11: Correlation Analysis Between Lipid Profile and Plasma Fibrinogen in the Study Group

Variables	N	Pearson Correlation (r)	p-value
Serum total cholesterol	50	0.622	<0.001
Triglycerides	50	0.586	<0.001
HDL cholesterol	50	0.722	<0.001
LDL cholesterol	50	0.666	<0.001

In the study group, serum total cholesterol, triglycerides, HDL cholesterol, and LDL cholesterol showed statistically significant correlations with plasma fibrinogen levels.

Correlation of Lipid Profile with Plasma Fibrinogen in the Control Group

The correlation between lipid parameters and plasma fibrinogen levels in the control group is presented in Table 12.

Table 12: Correlation Analysis Between Lipid Profile and Plasma Fibrinogen in the Control Group

Variables	N	Pearson Correlation (r)	p-value
Serum total cholesterol	50	0.712	<0.001
Triglycerides	50	0.744	<0.001
HDL cholesterol	50	0.642	<0.001
LDL cholesterol	50	0.688	<0.001

In the control group, serum total cholesterol, triglycerides, HDL cholesterol, and LDL cholesterol showed statistically significant correlations with plasma fibrinogen levels.

Correlation of Glycemic Parameters with Plasma Fibrinogen in the Study Group

The correlation of fasting blood glucose, postprandial blood glucose, and HbA1c with plasma fibrinogen levels in the study group is presented in Table 13.

Table 13: Correlation Analysis Between Fasting Blood Glucose, 2-Hour Postprandial Blood Glucose, HbA1c and Plasma Fibrinogen Levels in the Study Group

Variables	N	Pearson Correlation (r)	p-value
Fasting blood glucose	50	0.852	<0.001
Postprandial blood glucose	50	0.822	<0.001
HbA1c	50	0.988	<0.001

In the study group, fasting blood glucose, postprandial blood glucose, and HbA1c showed statistically significant positive correlations with plasma fibrinogen levels.

Correlation of Glycemic Parameters with Plasma Fibrinogen in the Control Group

The correlation of fasting blood glucose, postprandial blood glucose, and HbA1c with plasma fibrinogen levels in the control group is presented in Table 14.

Table 14: Correlation Analysis Between Fasting Blood Glucose, 2-Hour Postprandial Blood Glucose, HbA1c and Plasma Fibrinogen Levels in the Control Group

Variables	N	Pearson Correlation (r)	p-value
Fasting blood glucose	50	0.222	0.102
Postprandial blood glucose	50	0.015	0.899
HbA1c	50	0.122	0.344

There was no statistically significant correlation between fasting blood glucose, postprandial blood glucose, HbA1c, and plasma fibrinogen levels in the control group.

Correlation of Plasma Fibrinogen Levels With Glycemic Control in Diabetic Participants

The relationship between plasma fibrinogen levels and glycemic control among diabetic participants is presented in Table 15.

Table 15: Correlation of Plasma Fibrinogen Levels With Glycemic Control in Diabetic Participants

Variable	HbA1c <7% (n=20)	HbA1c ≥7% (n=30)	t-value	p-value
Fibrinogen (Mean ± SD), mg/dL	278.33 ± 49.20	493.20 ± 27.20	11.1888	<0.001

Plasma fibrinogen levels were significantly higher in patients with poor glycemic control (HbA1c ≥7%) than in those with good glycemic control (HbA1c <7%).

Clinical and Biochemical Characteristics According to Plasma Fibrinogen Levels

The clinical and biochemical characteristics of diabetic participants according to plasma fibrinogen levels are presented in Table 16.

Table 16: Clinical and Biochemical Characteristics in Normal and Abnormal Fibrinogen Levels in Cases

Parameters	Normal Fibrinogen Levels <380 mg/dL (n=14)	Abnormal Fibrinogen Levels >380 mg/dL (n=36)	t-value	p-value
Age (years)	40.24 ± 2.44	41.18 ± 4.30	-0.244	0.788
BMI (kg/m ²)	23.56 ± 1.44	25.47 ± 1.50	-3.288	0.00018
Systolic BP (mmHg)	124.24 ± 11.51	138.22 ± 12.64	-2.776	0.00077

Diastolic BP (mmHg)	73.02 ± 8.18	83.44 ± 7.28	- 2.922	0.0066
Total cholesterol (mg/dL)	184.42 ± 32.56	232.82 ± 24.48	- 4.112	<0.001
Triglycerides (mg/dL)	154.46 ± 27.22	192.28 ± 27.48	- 4.228	<0.001
HDL cholesterol (mg/dL)	47.42 ± 9.22	35.48 ± 6.22	- 5.444	<0.001
LDL cholesterol (mg/dL)	106.18 ± 38.04	146.60 ± 25.20	- 4.312	<0.001
Postprandial blood glucose (mg/dL)	182.78 ± 22.42	232.60 ± 23.44	- 5.922	<0.001
HbA1c (%)	6.78 ± 0.28	8.32 ± 0.68	- 7.312	<0.001

Participants with abnormal fibrinogen levels had significantly higher BMI, systolic blood pressure, diastolic blood pressure, total cholesterol, triglycerides, LDL cholesterol, postprandial blood glucose, and HbA1c levels compared with those having fibrinogen levels below 380 mg/dL. HDL cholesterol levels were significantly lower in participants with abnormal fibrinogen levels. Age did not differ significantly between the two groups.

Summary of the Tables

The present study included 100 participants, comprising 50 patients with type 2 diabetes mellitus and 50 non-diabetic controls. The demographic and clinical characteristics, biochemical parameters, plasma fibrinogen levels, correlation analyses, and subgroup comparisons were evaluated systematically. Table 1 presents the demographic distribution of the study participants. The age distribution of cases and controls was comparable, indicating that the two groups were suitably matched for age. Table 2 presents the distribution of participants according to body mass index. A greater proportion of diabetic participants had an increased body mass index compared with controls, indicating a higher burden of overweight and obesity among patients with type 2 diabetes mellitus. Table 3 compares the mean clinical parameters between the study and control groups. The diabetic group demonstrated significantly higher body mass index, systolic blood pressure, and diastolic blood pressure compared with the control group, reflecting the coexistence of increased adiposity and hypertension among diabetic participants. Table 4 presents the lipid profile of the study participants. Total cholesterol, triglycerides, and LDL cholesterol levels were significantly higher in the diabetic group, whereas HDL cholesterol levels were significantly lower compared with the control group, demonstrating an adverse lipid profile among patients with type 2 diabetes mellitus. Table 5 compares the glycemic parameters between cases and controls. Fasting blood glucose, postprandial blood glucose, and HbA1c levels were significantly higher in diabetic participants than in non-diabetic controls, confirming the expected differences in glycemic status between the two groups. Table 6 presents the distribution of diabetic participants according to the duration of diabetes and other relevant clinical characteristics as reported in the study. The findings demonstrate the clinical profile of the diabetic study population and provide the

background for assessing the relationship between metabolic status and plasma fibrinogen levels. Table 7 presents the distribution of diabetic participants according to glycemic control. Of the 50 diabetic participants, 20 (40%) had good glycemic control with HbA1c levels below 7%, whereas 30 (60%) had poor glycemic control with HbA1c levels of 7% or more. Thus, poor glycemic control was observed in the majority of diabetic participants. Table 8 compares plasma fibrinogen levels between diabetic participants and non-diabetic controls. Plasma fibrinogen levels were significantly higher among patients with type 2 diabetes mellitus than among controls, supporting the presence of an enhanced procoagulant state in the diabetic group. Table 9 presents the correlation of age, BMI, systolic blood pressure, and diastolic blood pressure with plasma fibrinogen levels in the diabetic group. BMI, systolic blood pressure, and diastolic blood pressure showed statistically significant positive correlations with plasma fibrinogen levels, whereas age did not show a statistically significant correlation. Table 10 presents the corresponding correlation analysis in the control group. Age, BMI, systolic blood pressure, and diastolic blood pressure showed statistically significant positive correlations with plasma fibrinogen levels in controls. Table 11 evaluates the relationship between lipid parameters and plasma fibrinogen levels in the diabetic group. Serum total cholesterol, triglycerides, HDL cholesterol, and LDL cholesterol showed statistically significant correlations with plasma fibrinogen levels. Table 12 presents the correlation between lipid parameters and plasma fibrinogen levels in the control group. All the evaluated lipid parameters showed statistically significant correlations with plasma fibrinogen levels. Table 13 presents the correlation of glycemic parameters with plasma fibrinogen levels in diabetic participants. Fasting blood glucose, postprandial blood glucose, and HbA1c showed statistically significant positive correlations with plasma fibrinogen levels.

The association with HbA1c was particularly strong, indicating a close relationship between poor glycemic control and elevated plasma fibrinogen levels. Table 14 presents the correlation of glycemic parameters with plasma fibrinogen levels in the control group. Fasting blood glucose, postprandial blood glucose, and HbA1c did not show statistically significant correlations with plasma fibrinogen levels in controls. Table 15 compares plasma fibrinogen levels according to glycemic control among diabetic participants. Patients with HbA1c levels of 7% or more had significantly higher plasma fibrinogen levels than those with HbA1c levels below 7%, demonstrating a significant association between poor glycemic control and elevated fibrinogen levels. Table 16 compares the clinical and biochemical characteristics of diabetic participants according to plasma fibrinogen levels using the analytical cut-off of 380 mg/dL. Participants with fibrinogen levels above 380 mg/dL had significantly higher BMI, systolic blood pressure, diastolic blood pressure, total cholesterol, triglycerides, LDL cholesterol, postprandial blood glucose, and HbA1c levels compared with those having fibrinogen levels below 380 mg/dL. HDL cholesterol levels were significantly lower in the higher fibrinogen group, whereas age did not differ significantly between the two groups.

Overall, the findings demonstrate that patients with type 2 diabetes mellitus had significantly elevated plasma fibrinogen levels compared with non-diabetic controls. Elevated fibrinogen levels were associated with poor glycemic control and an adverse clinical and biochemical profile, including increased BMI, elevated blood pressure, and dyslipidemia. The correlation and subgroup analyses further support the association of plasma fibrinogen with glycemic status and cardiovascular risk factors in patients with type 2 diabetes mellitus.

DISCUSSION

Type 2 diabetes mellitus is associated with metabolic abnormalities and alterations in the coagulation system that contribute to an increased risk of vascular complications. Hyperglycemia, insulin resistance, dyslipidemia, hypertension, and increased adiposity collectively promote endothelial dysfunction and a prothrombotic state [1]. Plasma fibrinogen, an important coagulation factor and acute-phase reactant, may therefore serve as a useful marker of the altered hemostatic milieu associated with diabetes mellitus. The present study assessed plasma fibrinogen levels in patients with type 2 diabetes mellitus, compared them with non-diabetic controls, and evaluated their association with glycemic control and other clinical and biochemical parameters [2].

The study included 100 participants, comprising 50 patients with type 2 diabetes mellitus and 50 non-diabetic controls. The demographic characteristics of the two groups were broadly comparable, allowing

meaningful comparison of the clinical and biochemical parameters [3].

The diabetic group had a significantly higher mean body mass index than the control group. A greater proportion of diabetic participants were also overweight or obese. Increased adiposity is closely associated with insulin resistance and adverse metabolic changes and may contribute to the inflammatory and prothrombotic state observed in type 2 diabetes mellitus. In the present study, BMI showed a significant positive correlation with plasma fibrinogen levels in the diabetic group. [4]

Hypertension was more frequent among diabetic participants than among controls, and both systolic and diastolic blood pressure were significantly higher in the diabetic group. Systolic and diastolic blood pressure also showed significant positive correlations with plasma fibrinogen levels in diabetic participants. These findings indicate that the coexistence of hypertension and diabetes may be associated with a greater burden of cardiovascular and hemostatic abnormalities [5].

The present study demonstrated significant alterations in the lipid profile of diabetic participants. Total cholesterol, triglycerides, and LDL cholesterol levels were significantly higher in the diabetic group, whereas HDL cholesterol levels were significantly lower than those observed in controls [6]. Dyslipidemia is an important component of the cardiovascular risk profile associated with type 2 diabetes mellitus. The observed correlations between lipid parameters and plasma fibrinogen levels further support the association between metabolic abnormalities and an enhanced procoagulant state [7].

The glycemic parameters were markedly altered in the diabetic group. Fasting blood glucose, postprandial blood glucose, and HbA1c levels were significantly higher among cases than controls. Poor glycemic control, defined as HbA1c $\geq 7\%$, was observed in 30 (60%) diabetic participants, whereas 20 (40%) participants had good glycemic control. These findings indicate a substantial burden of inadequate glycemic control within the study population [8,9].

The principal finding of the present study was the significantly higher plasma fibrinogen level among patients with type 2 diabetes mellitus compared with non-diabetic controls. The mean plasma fibrinogen level was 420.22 ± 56.88 mg/dL in the diabetic group compared with 268.80 ± 51.20 mg/dL in the control group, and the difference was statistically significant ($p < 0.001$). This finding supports the presence of an enhanced procoagulant state in patients with type 2 diabetes mellitus [10,11].

The elevation in plasma fibrinogen observed in diabetic participants may be related to persistent hyperglycemia and the associated metabolic and inflammatory disturbances. Chronic hyperglycemia contributes to endothelial dysfunction and alterations in coagulation and fibrinolytic mechanisms [12]. These

changes may collectively increase fibrinogen levels and promote thrombotic tendencies. Elevated fibrinogen may therefore represent an important component of the increased cardiovascular risk associated with diabetes mellitus [13].

In the diabetic group, fasting blood glucose, postprandial blood glucose, and HbA1c showed statistically significant positive correlations with plasma fibrinogen levels. The relationship with HbA1c was particularly strong. In contrast, these glycemic parameters did not show statistically significant correlations with plasma fibrinogen levels in the control group. This difference supports the association between sustained hyperglycemia and elevated fibrinogen levels in patients with type 2 diabetes mellitus [14,15].

The relationship between glycemic control and plasma fibrinogen levels was further demonstrated when diabetic participants were categorized according to HbA1c. Participants with poor glycemic control had significantly higher plasma fibrinogen levels than those with good glycemic control. This observation suggests that persistent poor glycemic control is associated with greater hemostatic disturbance and may contribute to the development of vascular complications [16,17].

The study also demonstrated significant associations between plasma fibrinogen levels and several cardiovascular risk factors, including BMI, blood pressure, and lipid parameters. These observations indicate that elevated plasma fibrinogen may coexist with multiple metabolic and cardiovascular abnormalities. The clustering of this risk factors may further increase susceptibility to atherosclerotic and thrombotic complications among individuals with diabetes mellitus [18,19].

When diabetic participants were classified according to the analytical fibrinogen cut-off of 380 mg/dL, those with fibrinogen levels above 380 mg/dL had significantly higher BMI, systolic blood pressure, diastolic blood pressure, total cholesterol, triglycerides, LDL cholesterol, postprandial blood glucose, and HbA1c levels [20,21]. HDL cholesterol levels were significantly lower in the higher fibrinogen group. Age did not differ significantly between the two groups. These findings further demonstrate the association between elevated plasma fibrinogen, poor metabolic control, and an adverse cardiovascular risk profile [22,23].

The findings of the present study support the concept that type 2 diabetes mellitus is associated with alterations in coagulation and fibrinolysis. Elevated fibrinogen may contribute to increased blood viscosity, platelet aggregation, fibrin formation, and atherosclerotic processes. The coexistence of elevated fibrinogen with poor glycemic control and other cardiovascular risk factors may therefore have important clinical implications [24].

Assessment of plasma fibrinogen may potentially help identify diabetic individuals with an increased procoagulant state and an unfavorable cardiovascular risk profile. However, fibrinogen levels should be interpreted in conjunction with established clinical and biochemical parameters rather than as an isolated marker. Optimal glycemic control, appropriate management of hypertension and dyslipidemia, weight optimization, and regular follow-up remain important components of comprehensive diabetes care [25].

The present study has certain limitations. The sample size was relatively small, and the hospital-based nature of the study may limit the generalizability of the findings to the wider population. Plasma fibrinogen levels were estimated at a single point in time; serial measurements could have provided a better understanding of temporal variations and the effect of changes in glycemic control. Larger prospective studies would be useful to further clarify the clinical significance of plasma fibrinogen in relation to diabetic vascular complications.

Overall, the present study demonstrated significantly elevated plasma fibrinogen levels in patients with type 2 diabetes mellitus compared with non-diabetic controls. Higher fibrinogen levels were associated with poor glycemic control and several adverse cardiovascular risk factors. These findings support the role of hyperfibrinogenemia as an important component of the procoagulant state associated with type 2 diabetes mellitus and highlight the importance of optimal metabolic control in reducing the overall vascular risk profile.

CONCLUSION

The present study demonstrated significantly higher plasma fibrinogen levels in patients with type 2 diabetes mellitus compared with non-diabetic controls. Elevated plasma fibrinogen levels were associated with poor glycemic control and adverse cardiovascular risk factors, including increased body mass index, hypertension, and dyslipidemia.

Plasma fibrinogen showed a significant positive association with fasting blood glucose, postprandial blood glucose, and HbA1c levels in diabetic participants. Patients with poor glycemic control had markedly higher plasma fibrinogen levels than those with good glycemic control. These findings suggest that hyperfibrinogenemia may reflect the altered procoagulant state associated with inadequate metabolic control in type 2 diabetes mellitus.

The increased cardiovascular morbidity and mortality associated with diabetes emphasize the importance of identifying potentially modifiable cardiovascular risk factors. Assessment of plasma fibrinogen, along with conventional metabolic and cardiovascular risk parameters, may help identify individuals at increased risk. Emphasis on optimal glycemic control, appropriate management of associated risk factors, lifestyle modification, and regular follow-up may

contribute to reducing future cardiovascular complications.

Declarations

Ethics Approval

The study was conducted in accordance with the principles of the Declaration of Helsinki and after obtaining approval from the Institutional Ethics Committee of SVS Medical College and Hospital, Mahabubnagar, Telangana, India.

Informed Consent

Written informed consent was obtained from all participants before their inclusion in the study.

Conflict of Interest

The authors declare that they have no conflict of interest related to this study.

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Author Contributions

All authors contributed to the conception and design of the study, data collection, analysis and interpretation of the findings, and preparation and critical revision of the manuscript. All authors approved the final version of the manuscript and agree to be accountable for all aspects of the work.

Data Availability

The data supporting the findings of this study are available from the corresponding author upon reasonable request, subject to appropriate ethical and institutional restrictions.

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