Original Article

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Evaluation of Fibrinogen Level in Type 2 Diabetic Patients

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Abstract

Background: The incidence of cardiovascular disease due to thrombosis is 2–4 folds greater in diabetic patients. High fibrinogen concentration enhances therisk. To evaluate fibrinogen concentration in type 2 diabetic patients to see coagulation status.

Materials and methods: This comparative cross-sectional study was conducted at Chittagong Medical College and Hospital (CMCH) from January 2022 to December 2022. This study include 35 patients with Type 2 DM (Group-A) and 35 age- and sex matched non diabetic healthy subjects (Group-B) from the outpatient and Inpatient Department of Medicine and Endocrinology Department of CMCH. A structured questionnaire was used to collect socio-demographic and clinical data. After interview, 5 ml of blood was collected to determine fibrinogen level and platelet count from both groups. This data was entered into SPSS version 23.0 and analyzed. Statistical tests like unpaired student's t-test and Chi-square test were used. Values less than 0.05 was considered as statistically significant.

Results: Significantly increase fibrinogen level in Type 2 DM patients (Group-A) in comparison to non diabetic healthy individuals (Group-B).

Conclusion:The results of this study conclude T2DM had altered coagulation status.

Key words: Diabetes Mellitus; Fibrinogen level; Platelet count.

Introduction

Diabetes Mellitus (DM) is a crucial global health problem.[1] It considerably affect human life and health expenditures.[2] According to World Health Organisation (WHO) incidence of diabetes increased from 108 million (1980) to 422 million (2014).[3] In 2019 International Diabetic Federation (IDF) reported an estimated 463 million adults are living with DM. Highest incidence mostly occurs in developing countries due to westernization and urbanization.[3] A recent study in Bangladesh showed that the prevalence of diabetes among adults had increased substantially from 4% to 9% from 1995 to 2010.[4]

Diabetes Mellitus (DM) is characterized by hyperglycemia accompanied with the biochemical alterations in carbohydrate protein and lipid metabolism.[5] 75% deaths in diabetic patients are due to cardiovascular complications and among them 80% are due to thrombosis.[6] The main causes of morbidity and mortality in the diabetes results from thrombosis and related complications.[7]

Diabetes mellitus itself is a pro-coagulant state.[8] Hypercoagulability in diabetes may accelerate atherosclerosis and acts as a risk factor of cardiovascular disease.[5] The prevalence of risk factors for atherosclerosis is hypertension and hypercholesterolemia.[6] Diabetic subjects suffers from premature atherosclerosis and more extensive vascular disease, predisposing them to plaque rupture and thrombus formation.

Plasma fibrinogen is a major determinant of blood viscosity and blood flow.[1] It influences thrombogenesis, blood rheology and platelet aggregation. Epidemiological studies have found a significant positive relation between fibrinogen levels and insulin levels.[9]

Markers of fibrinolysis were found abnormal in people with metabolic syndrome. In addition, chronic hyperglycemia and tissue glycation had marked effects on fibrin structure, clot generation and resistance to fibrinolysis.[6]

Data on coagulation status in T2DM patients is scarce in Bangladesh. This study result can help to provide information regarding fibrinogen level of type 2 diabetic patient which help to determine coagulation status of these patients.

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Materials and methods

A comparative cross-sectional study was carried out in Department of Physiology, Chittagong Medical College in collaboration with Department of Medicine and Department of Endocrinology, Chittagong Medical College Hospital, Chattogram.

Sampling technique: Purposive sampling.

Based on the presence or absence of diabetes, participants will be grouped into the following two groups:

Group A: Type 2 Diabetic patient (35 patient)

Group B: Healthy non diabetic subjects (35 apparently healthy persons)

Group A: Total 35 male and female subject having diabetes more than 1 year,age 33- 50 yrs, FPG ≥6.1-10.0 mmol/Land are on oral hypoglycemic drugs or on insulin.

Group B: Apparently healthy 35individuals without diabetes.Age 33-50 years. FPG ≤6.1mmol/L.

Voluntarily willing to participate.

Inclusion criteria for Group-A

- Diagnosed case of T2DM patient.
- Age 33-50 years
- BMI 18.5- 27.5kg/m^2
- $HbA_{1C=}$ 5.6%-10.5%.

Exclusion criteria for Group-A

- Type I Diabetes mellitus
- Age <33yrs and 50 years
- History of thromboembolism,stroke and bleeding disorder.

Inclusion criteria for Group-B

- Apparently healthy individuals without diabetes.
- Age 33-50 years
- BMI =18.5- 27.5Kg/m^2
- HbA_{1C} 5.5%.

Exclusion criteria for Group B

≥ BMI ≥27.6 kg/m^2

≥ Diagnosed case of type I or type II DM.

≥ Age <33yrs, 50 years

≥ History of thromboembolism, stroke and bleeding disorder.

Participants underwent physical examination and provided sociodemographic data in a structured questionnaire.All data were recordedin a predesigned Case Record Form (CRF). Aim, objective and detail procedure was explained to all subjects separately. Clinical data and anthropometric data was collected through interviewing and measurements. Information about age of the patient, general health, occupation, history of present or past disease, food habits, alcohol consumption, duration of diabetes mellitus, use of any drugs or insulin for diabetes was collected. ID number was given to each subject.After screening of inclusion andexclusion criteria, 35 diabetic patients were recruited in this study. 35apparently healthy non diabetic subjects in Group-B from attendant in hospital and office workers were taken.

Blood samples was collected from 8 am to 2 pm after studying case record form on the same day. Each day blood samples was collected approximately from 3 to 5 subjects. The blood containing tubes was kept in a cold box (4^0C) immediately. It was transported to the laboratory with minimum vibration within 2 hours of venipuncture and procedure was completed within 4 hours.

THROMBIN REAGENT was used to determine fibrinogen level. The enzyme thrombin converts the soluble plasma protein fibrinogen into it's insoluble polymer, fibrin. The clotting time for diluted plasma is inversely proportional to the fibrinogen concentration of the plasma. By using this principle, fibrinogen based on measuring clotting time of diluted plasma after addition of thrombin was used.

Data were recorded in the form of an Excel worksheet. After data collection, these were processed and analyzed by SPSS version 23.The difference in percentage values werecompared using the Chi-square test between two groups. The unpaired student's t-test compared the difference in the mean values of quantitative variables between two groups. $p < 0.05$ was considered statistically significant.

Before start the study eithical consideration was obtained.

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Results

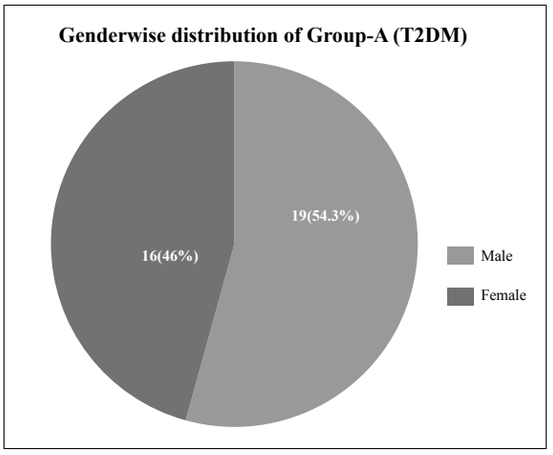

Figure 1 Gender-wise distribution of subjects in Group-A (T2DM distribution of subjects in Group-A (T2DM)

Figure 1 shows 19 (54.3%) subjects is male and 16 (46%) subjects is female

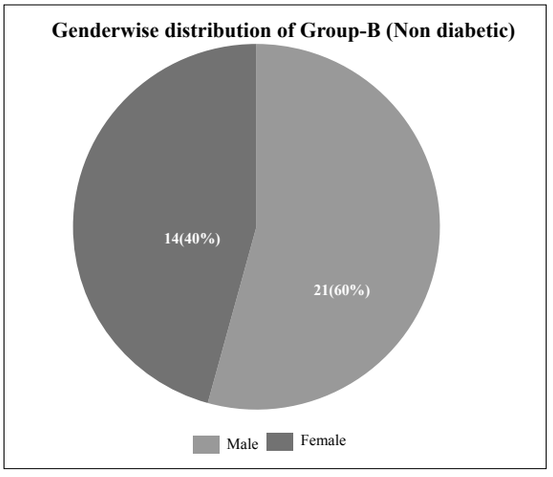

Figure 2 Gender-wise distribution of subjects in Group-B (Non diabetic)

Figure 2 shows 14 (40%) subjects is male and 21 (60%) subjects is female in Group-B (Non diabetic)

Table I showing sociodemographic characteristics of the study subjects. No significant difference was observed in terms of religion, educational status, occupation and monthly income between both groups. (p> 0.05).

Table I Demographic characteristics of the subjects in Group-A(T2DM) and Group-B (Non-diabetic) (n=70)

Attribute		Group-A (T2DM) Person (%) (n=35)	Group-B (Nondiabetic) Person (%) (n=35)	p value (Teststatistics)
Educational level	Below SSC	9 (25.7)	2 (5.7)	p=0.002 S
	SSC to HSC	9 (25.7)	2 (5.7)	χ^2=12.99
	HSC above	17 (48.6)	31 (88.6)	
Occupation	Housemaker	9 (25.7)	6 (17.1)	p=0.118 NS
	Service	21 (60.0)	28 (80.0)	χ^2=4.27
	Business	5 (14.3)	1 (2.9)	
Monthly income	≤20,000Tk	10 (28.6)	5 (14.3)	p=0.346 NS
	20,000--50,000Tk	19 (54.3)	23 (65.7)	χ^2=2.13
	>50,000 Tk	6 (17.1)	7 (20.0)	

Chi- square test was done. Data were expressed as frequency (%).

Group-A= Type 2 Diabetic patient. Group-B= non diabetic subjects. S= Statistically significant. (p<0.05). NS= Statistically not significant. (p>0.05).

Table I shows that Group-A (T2DM) and Group-B (Nondiabetic) subjects are similar in terms of their occupational status and monthly income (p>0.05). Group-B (Nondiabetic) subjects have comparatively better educational status than Group-A (T2DM) (p<0.05).

Table II Serum fibrinogen of Group-A (T2DM) and Group-B (non-diabetic) (n=70)

Attributes	Group-A (T2DM) Mean ±SD (Range) (n=35)	Group-B (Non diabetic) Mean±SD (Range) (n=35)	p value (Teststatistics)
Fibrinogen (g/l)	3.3±0.6 (2.0-4.6)	2.9±0.7 (1.1-3.9)	0.009S (t=2.676)

Unpaired student's t test was done.
Group-A= Type 2 DM patient. Group-B=Nondiabetic subjects. SD= Standard deviation. NS= Statistically not significant (p 0.05), S= Statistically significant. p(<0.05).

Table II shows mean fibrinogen was significantly higher in Group-A(T2DM)(p>0.05).

Discussion

In present study demographic characteristics of Group-A (T2DM) and Group-B (Non diabetic) were assessed. It was similar in terms of their occupational status and their monthly income. Educational status of Group-A (T2DM) were significantly lower than Group-B (non diabetic) (p<0.05)(Table I). Akhter S et al. hypothetised

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inverse association between education and poverty with diabetes. But in present study less educated people were more in diabetic group. It indicates less educated people are less health conscious and there is chance of undiagnosed diabetic patient hidden in lesseducated poor people. So routine screening test may be done to detect diabetes in general population above 30 years.

There was significantly higher fibrinogen level in T2DM patients. It is consistent with previous researchers and is inconsistent with Abdelrhman A H et al.[10-12]

Agarwal C et al. supposed that hyperglycemia in diabetes contribute to hyperfibrinogenemia that activate coagulation cascade.[1] Increasing thrombin formation and fibrinogen degradation products may stimulate hepatic fibrinogen synthesis.[13] Zhao et al. supposed that increased fibrinogen levels are strong and independent cardiovascular risk factor.[10] Hyperglycemic environment causes hyperglycosylated fibrinogen. It predisposes clot formation and resistant to fibrinolysis. Hence there is increased fibrinogen in Diabetes.[10]

Limitation

Due to financial matter we have conducted this study in a selective area and small number of samples were taken. This study population may not representative of whole community.

Conclusion

In this study significantly raised fibrinogen was observed in T2DM subjects.

Recommendation

Further longitudinal study with large sample can be conducted in different hospitals. Fasting and post prandial blood glucose test can be done in similar type of study. D-dimer and vWF can be done for further evaluation. Other coagulation factors can be studied. Similar study on large sample female subjects can be done.

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Contribution of authors

FBT- Conception, collection of data, drafting & final approval.

MB- Interpretation of data, critical revision & final approval.

SA-Conception, critical revision, manuscript writing & final approval

SA-Design, data collection, drafting & final approval

MHC-Data analysis, drafting & final approval.

Disclosure

All the authors declared no conflict of interest.

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