Evaluation of Coagulation Profile in Type-1 Diabetes Mellitus Patients: A Hospital Based Prospective Study

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Abstract

Background: Type-1 Diabetes Mellitus (T1DM) can affect the coagulation factors which in turn may form abnormal clots. The present study conducted to evaluate the coagulation profile in patients suffering from T1DM.

Materials and Methods: This study was conducted in the Institute of Biochemistry, Madras Medical College, Tamil Nadu in the period of Sept 2008 to Oct 2008. A total of 75 peoples were included in the study. It was divided into two groups. Group-I (n=25) was considered control group. Group-II (n=50) had T1DM. All the patients demographic data was collected. Blood was collected from all the patients and used for estimation of glucose, lipid profile and coagulation profile. The data was expressed in mean standard deviation. Unpaired t test was applied to find the statistical significant between the groups.

Results

There was no significant difference observed in the age and gender between the groups. Significant difference was observed in FBS, PBS, HbA1c, urea, creatinine, lipid profile and coagulation profile (Fibrinogen, prothrombin time, INR, aPTT, platelet count) compared group-I with group-II.

Conclusion

It was observed that significant changes in coagulation profile in T1DM compared to control group. Knowledge about these changes is useful in the prevention and treatment of T1DM patients suffering from various coagulation and cardiovascular disorders.
Keywords: Diabetes mellitus, Lipid profile, coagulation profile, glucose, platelet count, insulin

INTRODUCTION
Diabetes Mellitus (DM) is one of the major causes for the death in present era. Recent studies showed that 80% of patients with DM die due to cardiovascular problems [1, 2]. Based on the insulin secretion DM is classified into two types. Insulin Dependent Diabetes Mellitus (IDDM) or Type-1DM and Non Insulin Dependent Diabetes Mellitus (NIDDM) or Type-2DM [3]. Type-1DM can develop due to the destruction of pancreatic beta cells and it can develop from childhood [4]. Type-2DM is mainly due to insulin resistance and it will develop as age progresses. In both DM hyperglycemia is common [5]. Long time exposure to hyperglycemic state causes glycation of various proteins in the body. Long term hyperglycemia can affect the levels of coagulation factors and other parameters involved in the coagulation. Patients with hypercoagulation state have high risk of thrombosis. Uncontrolled T1DM patients can develop this condition and increase the risk of mortality due to abnormal clotting mechanism [6,7].

Studies have proposed that hyperglycemia can stimulate the coagulation factors, platelets and thrombin, which can lead to formation of abnormal clots. T1DM patients showed alteration in platelet aggregation and fibrinolysis process also [8]. With this background the present study was conducted to evaluate the coagulation profile in patients with T1DM.

MATERIALS AND METHODS
Study setting and period
This study was conducted in the Institute of Biochemistry, Madras Medical College, Tamil Nadu in the period of Sept 2008 to Oct 2008. This study was ethically cleared from Institutional Human Ethics Committee.

A total of 25 healthy subjects were selected for group-I. They were considered as control group. Group II had (n=50) T1DM patients without any complications.

Selection of patients (n=50) for group-II

Inclusion criteria
- Patients with T1DM without any complications
- Not on any drug therapy which affect the coagulation factors
- Minimum of 5 years history of T1DM
Exclusion criteria

- Acute illness
- Liver disorders
- On the therapy of hepatotoxic drugs
- Any DM complications
- On anti-coagulant, anti-platelet and fibrinolytic drug therapy
- Recent trauma and surgery

Study groups

Group-I (Control): healthy subjects (n=25)
Group-II (Cases): T1DM patients without any complications (n=50)

Procedure

All the patients were included in the study based on inclusion and exclusion criteria. Study protocol was explained to all the study population and informed consent was taken from individuals. Demographic data (Age and gender) was collected. All the subjects were advised for overnight 12 hr fasting prior to the blood collection. The required amount of blood was collected from each subject and used for the estimation of fasting and postprandial glucose, HbA1c, Urea Creatinine, Lipid profile, Fibrinogen, Prothrombin Time-PT, International Normalised Ratio for Prothombin time (INR), aPTT-activated partial thromboplastin time, and Platelet count by standard methods [9-11].

STATISTICAL ANALYSIS

Statistical Package for Social Sciences (SPSS 16.0) version used for analysis, Unpaired t test was applied to find the statistical significant between the groups. P value less than 0.05 considered statistically significant at 95% confidence interval. The data was expressed in mean and standard deviation.

RESULTS

The mean age in the control group is 24.84 and in T1DM group is 27.12 years. 12 males and 13 females in Group-I and more males (31) and fewer females (19) were observed in T1DM group. Significant increase in fasting, post prandial glucose, HbA1c, total cholesterol, triglycerides, LDL was observed in T1DM patients compared with control group. Increased urea and creatinine levels were observed in group-II compared to group-I and it was statistically significant (p<0.001). Significant change was observed in HbA1c levels between control (4.28±0.46) and case groups (7.88±1.74), it was statistically significant (p<0.001). Significant increase in
fibrinogen was observed in group-II. Significant changes (p<0.001) were observed in all parameters compared group-I with group-II.

Table-1: Comparison of demographic data between the groups

<table>
<thead>
<tr>
<th>Demographic data</th>
<th>Group-I (MEAN±SD)</th>
<th>Group-II (MEAN±SD)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age (MEAN±SD) (Y)</td>
<td>24.84±2.47</td>
<td>27.12±7.23</td>
</tr>
<tr>
<td>Gender</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Male</td>
<td>12</td>
<td>31</td>
</tr>
<tr>
<td>Female</td>
<td>13</td>
<td>19</td>
</tr>
<tr>
<td>Duration of DM (MEAN±SD) (Y)</td>
<td>-</td>
<td>7.88±3.05</td>
</tr>
</tbody>
</table>

Table-2: Comparison of blood glucose, HbA1c, urea and creatinine levels between the groups

<table>
<thead>
<tr>
<th>Observation</th>
<th>Group-I (MEAN±SD)</th>
<th>Group-II (MEAN±SD)</th>
<th>p value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Fasting glucose (mg/dL)</td>
<td>83.21±10.19</td>
<td>139.27±30.89*</td>
<td>0.001</td>
</tr>
<tr>
<td>Postprandial glucose (mg/dL)</td>
<td>122.42±6.86</td>
<td>196.88±52.83*</td>
<td>0.001</td>
</tr>
<tr>
<td>HbA1c (%)</td>
<td>4.28±0.46</td>
<td>7.88±1.74*</td>
<td>0.001</td>
</tr>
<tr>
<td>Urea (mg/dL)</td>
<td>24.57±5.29</td>
<td>27.36±7.69*</td>
<td>0.04</td>
</tr>
<tr>
<td>Creatinine (mg/dL)</td>
<td>0.80±0.14</td>
<td>0.92±0.20*</td>
<td>0.04</td>
</tr>
</tbody>
</table>

(*p<0.05 significant compared group-I with group-II)

Table-3: Comparison of lipid profile levels between the groups

<table>
<thead>
<tr>
<th>Observation</th>
<th>Group-I (MEAN±SD)</th>
<th>Group-II (MEAN±SD)</th>
<th>p value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Triglyceride (mg/dL)</td>
<td>114.88±18.16</td>
<td>188.15±57.36*</td>
<td>0.001</td>
</tr>
<tr>
<td>Total cholesterol (mg/dL)</td>
<td>147.68±15.20</td>
<td>188.25±36.51*</td>
<td>0.03</td>
</tr>
<tr>
<td>HDL (mg/dL)</td>
<td>43.27±3.62</td>
<td>37.43±5.38*</td>
<td>0.001</td>
</tr>
<tr>
<td>LDL (mg/dL)</td>
<td>81.44±15.46</td>
<td>113.20±34.87*</td>
<td>0.03</td>
</tr>
</tbody>
</table>

(*p<0.05 significant compared group-I with group-II)
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Table-4: Comparison of coagulation profile levels between the groups

<table>
<thead>
<tr>
<th>Observation</th>
<th>Group-I (MEAN±SD)</th>
<th>Group-II (MEAN±SD)</th>
<th>p value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Fibrinogen (mg/dL)</td>
<td>307.64±43.10</td>
<td>493.98±38.72*</td>
<td>0.01</td>
</tr>
<tr>
<td>Prothrombin time (Seconds)</td>
<td>12.46±0.66</td>
<td>10.12±0.45*</td>
<td>0.04</td>
</tr>
<tr>
<td>International Normalised Ratio (INR) for prothrombin time</td>
<td>1.56±0.05</td>
<td>1.00±0.08*</td>
<td>0.04</td>
</tr>
<tr>
<td>aPTT (Seconds)</td>
<td>25.00±2.91</td>
<td>22.18±2.27*</td>
<td>0.04</td>
</tr>
<tr>
<td>Platelet count (Lacs/µL)</td>
<td>2.19±0.68</td>
<td>2.33±0.45</td>
<td>1.34</td>
</tr>
</tbody>
</table>

(*p<0.05 significant compared group-I with group-II)

DISCUSSION

DM is associated with increased risk of various cardiovascular disorders. That can lead to atherosclerosis and coagulation abnormalities because DM is a procoagulation state. A few studies observed changes in coagulation profile in T1DM patients. In this present study a total of 75 subjects were included. 25 were in group-I and remaining in group-II. Acang et.al study reported that decreased PTs and aPPT in DM [12]. In the present study also similar results were observed. Increased fibrinogen levels were observed in T1DM patients compared to control group in the present study. Collier et.al and Carmassi F et.al study also observed increased fibrinogen levels in DM patients [13]. Cigdem B et.al observed a significant relationship between T1DM and changes in coagulation profile [14]. A similar change in coagulation profile was observed in the present study in patients with T1DM. Long term hyperglycemia can alter the platelet function and enzymes involved in the coagulation mechanism and abnormal clots can develop. This can increase the risk of micro and macro vascular complications. Early detection and maintenance of good glyceamic control can reduce the risk mortality due to abnormal clots in patients with T1DM.

CONCLUSION

From this study observations it can be concluded that, patients with more than 5 years suffering with T1DM is required more medical attention while using drugs which may influence coagulation process, because there is a significant change in the coagulation profile in T1DM compared to healthy population.

Conflict of interest: Nil
REFERENCES


