A STUDY OF ELECTROCARDIOGRAPHY AND TREADMILL TEST IN TYPE 2 DIABETIC PATIENTS WITHOUT CARDIAC SYMPTOMS

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INTRODUCTION

Coronary artery disease is more common in diabetic population, but can be asymptomatic in many patients and may present with sudden death, myocardial infarction, arrhythmia, silent myocardial ischaemia or heart failure. Early detection of asymptomatic coronary artery disease in Type 2 Diabetes may prevent catastrophic cardiac events. However, periodical thorough clinical examination and resting Electrocardiogram (ECG) may fail to detect coronary artery disease. Noninvasive tests like exercise electrocardiography should then be proposed for early detection of asymptomatic CAD in these patients.

AIM AND OBJECTIVES

Aim and objectives of the present study is to assess the prevalence of Coronary Artery Disease (CAD) in Type 2 Diabetic patients without any clinical evidence of CAD and to evaluate the patients with normal ECG by Treadmill Test.

MATERIALS AND METHOD

The present study was conducted in 100 consecutive Type 2 Diabetes mellitus patients, who attended Outpatient Department or were admitted in the Department of Internal Medicine at Silchar Medical College and Hospital, Silchar, for the period of 1 year from 1st July, 2014 to 30th June, 2015.

RESULTS AND OBSERVATIONS

50 patients in the study were in the age group 35-44 years, of these 40 were male and 10 were female; 33 patients were in the age group 45-54 of which 23 were male and 10 were female; 11 male and 6 female were in the age group 55-64. More number of subjects, i.e. 61 patients (61%) were having diabetes equal to or less than 5 years followed by 28 patients (28%) with the disease duration of more than 5 to 10 years, next 9 patients (9%) between more than 10 to 15 years and only 2 patients (2%) between more than 15 to 20 years of duration. The averages of glycosylated haemoglobin (HbA1C) was 7.98, 7.66, 8.66 and 10.65, for the duration of diabetes equal to or less than 5 years, more than 5 to 10 years, more than 10 to 15 years and more than 15 to 20 years of disease duration respectively. Among 100 patients of our study, TMT result was positive in 27 patients (27%) and was negative in 73 patients (73%). Among the 27% of the TMT positive cases, 22.97% cases (17 patients) were males and 38.46% cases (10 patients) were females. The results of the specified duration of the disease, i.e. TMT positive were 16.39% (10/61 cases), 32.14% (9/28 cases), 66.66% (6/9 cases) and 100% (2/2 cases) with the duration of diabetes ≤5 years, >5-10 years, >10-15 years and >15-20 years respectively.

CONCLUSION

It can be inferred that early screening of patient with Type 2 Mellitus for the evidence of asymptomatic coronary artery disease is essential and the TMT positivity, i.e. possibility of Asymptomatic Coronary Artery Disease increases with longer duration of the disease.

KEYWORDS

Treadmill Test, Electrocardiography, Diabetes, Glycosylated Haemoglobin.

periodical thorough clinical examination and resting Electrocardiogram (ECG) may fail to detect coronary artery disease. Hence, sophisticated cardiovascular non-invasive tests should then be proposed for early detection of asymptomatic CAD in these patients. Exercise electrocardiography can identify the majority of patients likely to have significant ischaemia during their daily activities and remains the most important screening test for significant CAD.\textsuperscript{1,6,7}

In diabetes mellitus, there is greater prevalence of painless sudden death particularly during sleep. Silent myocardial ischaemia is evidenced during treadmill. Incidence of painless ST depression is twice in diabetics (75\%) versus non-diabetics (35\%).\textsuperscript{8}

Koistinen et al\textsuperscript{9} conducted a study of 136 asymptomatic diabetics and 80 symptomatic controls with exercise ECG and found positive results in 29\% diabetics and 5\% controls. Ahluwalia G et al\textsuperscript{10} from India evaluated 20 male diabetic patients (age range, 40-60 years) with normal autonomic function to determine the prevalence of silent myocardial ischaemia on exercise electrocardiography. A cohort of 20 matched non-diabetic patients was also included in the study. Silent myocardial ischaemia was detected in 50\% of the diabetic patients on exercise electrocardiography compared with 10\% in non-diabetics. Garg PK et al\textsuperscript{11} conducted a study in India to evaluate silent myocardial ischaemia in Type 2 Diabetes mellitus by treadmill test. The result showed the prevalence of silent myocardial ischaemia was 3.3 times higher in Type 2 Diabetes mellitus patients. Motoji et al\textsuperscript{12} found 31\% treadmill test positive in diabetics without prior evidence of coronary artery disease and silent myocardial ischaemia was 2.2 times more common in diabetics as compared with non-diabetics.

AIM AND OBJECTIVES
To assess the prevalence of Coronary Artery Disease (CAD) in Type 2 Diabetes Mellitus patients without clinical evidence of CAD with normal ECG and to evaluate them by Treadmill Test.

MATERIAL AND METHODS
The present study was conducted in 100 consecutive Type 2 Diabetes Mellitus patients, who attended Outpatient Department or were admitted in the Department of Internal Medicine at Silchar Medical College and Hospital, Silchar, for the period of 1 year from 1\textsuperscript{st} July, 2014 to 30\textsuperscript{th} June, 2015.

Study Design
The present study is a clinical observational study on the patients of Type 2 Diabetes Mellitus without clinical evidence of coronary artery disease.

Inclusion Criteria
1. Patients of Type 2 Diabetes Mellitus (diagnosed according to the American Diabetes Association Criteria) without any symptoms of coronary artery disease.
2. Age: 35 years and above.
3. No past history of ischaemic heart disease, cerebrovascular accident or hypertension.
4. Both sexes.

Exclusion Criteria
1. Patients with type 1 Diabetes Mellitus (excluded by the absence of past history of DKA).
2. Age < 35 years.
4. Patient of type 2 DM with diagnosed CAD.
5. Renal disorders.
6. Febrile illnesses.
7. Patients with severe Osteoarthritis or other disabilities.

All Patients were Subjected to the following Investigations at the Time of Inclusion into the Study

- Routine complete blood counts.
- Glycosylated haemoglobin (HbA1c).
- Fasting and post prandial blood sugar.
- Fasting lipid profile (total cholesterol, triglycerides, LDL, HDL).
- Renal function test (blood urea, serum creatinine).
- Urine routine and microscopic examination.

Diagnosis of Diabetes was Established according to ADA Criteria:\textsuperscript{13}

- Symptoms of diabetes plus random blood glucose concentration ≥11.1 mmol/L (200 mg/dL), or
- Fasting plasma glucose ≥ 7 mmol/L (126 mg/dL), or
- HbA1c >6.5\%, or
- Two-hour plasma glucose >11.1 mmol/L (200 mg/dL) during an oral.

12-Lead ECG (Machine, Cardiart 108t-DIGI)
Every patient who were included in the study group underwent 12-lead electrocardiography and those subjects without evidence of prior myocardial infarction were included into the study.

Technique of Treadmill Test (Machine, RMS - Treadmill)
The patient was instructed not to eat or drink caffeinated beverages three hours prior to testing and to wear comfortable shoes and loose fitting clothes. A brief physical examination was performed prior to the test and a written informed consent was taken. A standard 12-lead electrocardiogram was taken. Blood pressure was recorded in both supine and sitting or standing positions and hypertensives were excluded. After that the patient was instructed on how to perform the test. The entire procedure was explained to the patient in detail. Patients were instructed to report immediately when they experience unusual or significant symptoms (e.g. chest pain, dizziness, etc) during exercise. Furthermore, patients were also assured that they may request termination of exercise prematurely whenever necessary.\textsuperscript{14} Standard multistage maximal exercise test was done on a motorised treadmill according to Modified Bruce protocol.\textsuperscript{15} The heart rate, blood pressure and electrocardiograms were recorded at the end of each stage of exercise, immediately before and after stopping the exercise and for each minute for at least 5 to 10 minutes in the recovery phase. Exercise test was terminated in all patients following the achievement of target heart rate or an abnormal ischaemic response. ECG was recorded every minute and blood pressure was measured at rest and at the end of each step during exercise. The test was stopped when one of the following endpoints was reached:

- Target heart rate, 85\% of the predicted heart rate (220 beats/min, age in years);
- Severe fatigue;
- Systolic blood pressure reduction;
Hypertensive response (systolic blood pressure increase 250 mmHg and/or diastolic blood pressure 115 mmHg). If the patient developed dyspnoea, fatigue or chest pain.

The following ST-Segment Changes were Considered Positive:

- Horizontal or down-sloping ST-segment depression of 0.1 mV or greater persisting at least 80 msec in the absence of pre-existing ST-segment abnormalities and in the absence of any drug or electrolyte disturbance known to induce such changes.
- ST-segment elevation of 0.1 mV or more than the control tracing in any lead except aVR.

Ethical Clearance

The study required non-invasive investigations to be conducted on both outpatients and indoor patients. Hence, an ethical clearance has been obtained from the institution, Silchar Medical College and Hospital, Silchar.

Statistical Analysis

All the relevant data were entered in Microsoft Excel. Continuous variables were presented as mean and standard deviation and categorical variables were presented as absolute numbers and percentages. The comparison of normally distributed continuous variables between the groups was performed using Student’s “t” test. The prevalence rate was expressed in terms of percentage. A “P” - value < 0.05 was considered statistically significant.

RESULTS AND OBSERVATIONS

We studied a total number of 100 cases of Type 2 Diabetes Mellitus without clinical symptoms of ischaemic heart disease in Silchar Medical College and Hospital, Silchar and following observations were noted.

<table>
<thead>
<tr>
<th>Age Group</th>
<th>Total</th>
<th>Male</th>
<th>Female</th>
</tr>
</thead>
<tbody>
<tr>
<td>35-44 (years)</td>
<td>50</td>
<td>40</td>
<td>10</td>
</tr>
<tr>
<td>45-54 (years)</td>
<td>33</td>
<td>23</td>
<td>10</td>
</tr>
<tr>
<td>55-64 (years)</td>
<td>17</td>
<td>11</td>
<td>6</td>
</tr>
</tbody>
</table>

Table 1: Age and Sex Distribution

<table>
<thead>
<tr>
<th>BMI (kg/m²)</th>
<th>Number of Patients</th>
</tr>
</thead>
<tbody>
<tr>
<td>Normal (18.5 – 24.9)</td>
<td>33</td>
</tr>
<tr>
<td>Overweight (25 – 29.9)</td>
<td>30</td>
</tr>
<tr>
<td>Obese (30 and above)</td>
<td>37</td>
</tr>
</tbody>
</table>

Table 3: Body Mass Index

The above table and graph shows the age and sex distribution of our present study group; 50 patients in the study were in the age group of 35 – 44 years. Of these 40 were males and 10 were females; 33 patients were in the age group of 45 - 54 years. Of these 23 were males and 10 were females; 17 patients in the study were in the 55-64 age group, of these 11 were males and 6 were females.

Most patients in our study population were in the age group between 35-44 years followed by age group 45-54 years.

<table>
<thead>
<tr>
<th>Duration of DM (Years)</th>
<th>Total</th>
<th>Male</th>
<th>Female</th>
</tr>
</thead>
<tbody>
<tr>
<td>≤ 5</td>
<td>61</td>
<td>51</td>
<td>10</td>
</tr>
<tr>
<td>&gt; 5 – 10</td>
<td>28</td>
<td>20</td>
<td>8</td>
</tr>
<tr>
<td>&gt; 10 – 15</td>
<td>9</td>
<td>3</td>
<td>6</td>
</tr>
<tr>
<td>&gt; 15 – 20</td>
<td>2</td>
<td>0</td>
<td>2</td>
</tr>
</tbody>
</table>

Table 2: Showing Duration of Diabetes

This table and graph shows distribution of our study populations in certain periods of duration of diabetes mellitus that our study subjects have been suffered/suffering from, (including males and females in that particular period).

It is found that in our study more number of subjects, i.e. 61 patients (61%) were having diabetes equal to or less than 5 years followed by 28 patients (28%) with the disease duration of more than 5 to 10 years, next 9 patients (9%) between more than 10 to 15 years and only 2 patients (2%) between more than 15 to 20 years of duration.
The above given table gives the idea about the glycosylated haemoglobin, i.e. HbA1c, among our study populations with respect to the duration of diabetes.

The averages of glycosylated haemoglobin (HbA1C) was 7.98, 7.66, 8.66 and 10.65, for the duration of diabetes equal to or less than 5 years, more than 5 to 10 years, more than 10 to 15 years and more than 15 to 20 years of disease duration respectively.

These values of HbA1c show that all patients in our study population were having poor glycaemic control.

<table>
<thead>
<tr>
<th>Sex</th>
<th>Male (n=74)</th>
<th>Female (n=26)</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>+ve</td>
<td>%</td>
<td>-ve</td>
</tr>
<tr>
<td>Male</td>
<td>17</td>
<td>22.97</td>
<td>57</td>
</tr>
<tr>
<td>Female</td>
<td>10</td>
<td>38.46</td>
<td>16</td>
</tr>
<tr>
<td>Total</td>
<td>27</td>
<td>27</td>
<td>73</td>
</tr>
</tbody>
</table>

**Table 5: TMT Results**

The above given table and graph shows the percentage of TMT results of our study populations of having type 2 diabetes without cardiac symptoms to whom the TMT was conducted. It shows the prevalence of asymptomatic coronary artery disease in the study population.

Among 100 patients of our study, TMT result was positive in 27 patients (27%) and was negative in 73 patients (73%).

Among the 27% of the TMT positive cases, 22.97% cases (17 patients) were males and 38.46% cases (10 patients) were females.

<table>
<thead>
<tr>
<th>Duration of Diabetes (Years)</th>
<th>TMT +ve</th>
<th>%</th>
<th>TMT -ve</th>
<th>%</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td>≤ 5</td>
<td>10</td>
<td>16.39</td>
<td>51</td>
<td>83.6</td>
<td>61 (100%)</td>
</tr>
<tr>
<td>&gt; 5 - 10</td>
<td>9</td>
<td>32.14</td>
<td>19</td>
<td>67.85</td>
<td>28 (100%)</td>
</tr>
<tr>
<td>&gt; 10 - 15</td>
<td>6</td>
<td>66.66</td>
<td>3</td>
<td>33.33</td>
<td>9 (100%)</td>
</tr>
<tr>
<td>&gt; 15 - 20</td>
<td>2</td>
<td>100</td>
<td>0</td>
<td>0</td>
<td>2 (100%)</td>
</tr>
<tr>
<td>Total</td>
<td>27</td>
<td>27</td>
<td>73</td>
<td>73</td>
<td>100 (100%)</td>
</tr>
</tbody>
</table>

**Table 6: TMT Results and Duration of Diabetes Mellitus**

This table shows the relation of asymptomatic coronary artery disease (i.e. TMT positivity) with respect to the duration of diabetes mellitus among our study population.

In the present study, TMT was positive in 27% cases and in the same population it was negative in 73% of cases.

The results of the specified duration of the disease, i.e. TMT positive were 16.39% (10/61 cases), 32.14% (9/28 cases), 66.66% (6/9 cases) and 100% (2/2 cases) with the duration of diabetes ≤5 years, > 5-10 years, > 10-15 years and >15-20 years respectively.

It can be inferred that TMT positivity, i.e. possibility of Asymptomatic Coronary Artery Disease increases with longer duration of the disease.

**DISCUSSION**

India leads the world today with the largest number of diabetics in any given country. Although Coronary Artery Disease (CAD) and diabetes mellitus have been recognised as distinct entities for many decades, but their correlation was established only in 1870 after the work of Seegen J. De, who emphasised higher incidence and mortality of CAD among diabetics. A recently observed and focused aspect of coronary artery disease is its silent and asymptomatic presentation.

The present study was aimed at the asymptomatic presentation of coronary artery disease in diabetes mellitus patients. It consisted of assessing the prevalence of asymptomatic coronary artery disease in type 2 diabetic patients without clinical evidence of CAD and to evaluate them by Treadmill Test.

In this study, 74 were males and 26 were females with mean age of 45.5 years. Of the total 30 patients (30%) were overweight, 37 patients (37%) were obese and remaining were with normal BMI. Thus, the greater number of patients were seen to belong to obese group.

In our study population more number of patients, i.e. 61 patients (61%) were having diabetes equal to or less than 5 years followed by 28 patients (28%) with the duration of >5 to 10 years, next 9 patients (9%) between >10 to 15 years and only 2 patients (2%) between >15 to 20 years.

Amongst the 100 patients TMT was positive in 27 (27%), of them 17 were male and 10 were female. Motoji M et al reported treadmill test positive in 31% of patients of diabetes mellitus without evidence of coronary artery disease. Gupta SB et al found treadmill test positive in 38.3% of diabetics without clinical evidence of coronary artery disease. Achari V et al from India reported treadmill test positive in 50% of diabetics who had no symptoms of CAD. In a study of prevalence of asymptomatic coronary artery disease in patients with diabetes mellitus by treadmill test conducted by Jayashankar CA et al found prevalence of silent CAD as 31.37% in Type 2 Diabetes Mellitus patients. Achari V et al reported silent myocardial ischaemia Type 2 Diabetes Mellitus patient as high as 42.5%.

Duration of Type 2 Diabetes Mellitus and coronary artery disease:- In the present of the 61 patients with Type 2 Diabetes Mellitus of duration equal to or less than 5 years, TMT was positive in 10 (16.39%). Of the 28 patients with Type 2 Diabetes Mellitus of duration >5 to 10 years, TMT was positive in 9 (33.1%). TMT was positive in 6 (66.66%) of 9 patients with diabetes for duration >10 to 15 years. TMT was positive in 100%, that is 2 out of 2 patients who had diabetes for more than 15 years. High incidence of TMT positive in patients with longer duration of diabetes mellitus was also reported by Ahluwalia V et al.
CONCLUSION
From the present study, it is concluded that prevalence of silent myocardial ischaemia is high (27%) amongst Type 2 Diabetes Mellitus patients. The prevalence is higher in female (38.46%) than male (22.97%); and longer the duration of Diabetes greater is the risk of CAD. An aggressive and early screening of patients with Type 2 Diabetes Mellitus patients for the evidence of coronary artery disease is essential.

REFERENCES