COMPARISON OF CLINICAL PROFILE OF DIABETES MELLITUS PATIENTS WITH OR WITHOUT NON-ALCOHOLIC FATTY LIVER DISEASES

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ABSTRACT

BACKGROUND
Non-alcoholic fatty liver disease represents a spectrum of conditions, which is characterised histologically by significant macrovesicular hepatic steatosis that occurs in those who do not consume alcohol in amounts considered to be harmful to liver and in the absence of known toxins, drugs, viral disease, etc. This disease is quite frequently seen in diabetes especially type 2 diabetes mellitus, which is probably related to altered glucose metabolism. The spectrum of non-alcoholic fatty liver disease is quite variable from mild alteration of transaminases, which is a benign disease to one with high morbidity and mortality. Type 2 diabetes mellitus is a risk factor for NAFLD and the prevalence of NAFLD in diabetic patients have been shown to be between 30-80%.

MATERIALS AND METHODS
In this study, normative survey technique was selected. Duration of the study was one year. The sample comprised of 100 diabetic patients age ranged 31-70 years. The sample was selected on the basis of inclusion and exclusion criteria. The tools such as clinical profile and checklist were administered.

RESULTS
The study found out that NAFLD is very common in diabetes mellitus. Diabetic patients with NAFLD has a longer duration of diabetes compared to that of diabetic patients without NAFLD diabetic patients with NAFLD had higher BMI, waist circumference and systolic blood pressure than that of patients without NAFLD.

CONCLUSION
All the patients within the spectrum of NAFLD should be considered potentially affected not only by a liver disease, but by a multisystem disease. Clinicians should be aware of the importance of a complete clinical evaluation for early diagnosis and treatment of liver disease as well as the different manifestations. All type 2 diabetic patients should be monitored for the development of NAFLD. Early diagnosis of NAFLD can prevent the progression to NASH and its complications.

KEYWORDS
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Pathogenesis of NAFLD- The two stages have been proposed in the development of NAFLD.2

\[
\begin{array}{c}
\text{Normal Liver} \\
\quad \text{Increase in fatty acid influx} \\
\quad \text{Decreased fatty acid oxidation} \\
\quad \text{Increased fatty acid synthesis} \\
\quad \text{Decreased VLDL assembly} \\
\quad \text{Insulin resistance} \\
\hline
\text{Fatty Liver} \\
\quad \text{Endotoxin} \\
\quad \text{Immune factors} \\
\quad \text{Oxidative stress} \\
\quad \text{TNF alpha} \\
\quad \text{Leptin} \\
\hline
\text{Non alcoholic steatohepatitis} \\
\quad \text{Other factors} \\
\quad \text{Fibrosis}
\end{array}
\]

Need and Significance of the Study
NAFLD is a common condition affecting millions of people. It is the most common liver disorder in western industrialised countries affecting 20-40% of the general population. It is mostly seen in patients with obesity (60-95%), type 2 diabetes mellitus (28-55%) and hyperlipidaemia (27-92%). By the year 2020, there will be approximately 100 million patients with diabetes; of these, 60 million (60%) will be in the Asian western substrates of non-alcoholic fatty liver disease. It is not restricted to the west as witnessed by their increasingly universal distribution.3

The last two or three decades have seen the evolution of western style life of near complete inactivity, energy dense food choices and lack of physical activity and thus obesity and metabolic syndrome is expected to become a serious social problem in Asia.

NAFLD is a reversible condition. The progression of NAFLD to NASH can lead to the progression to cirrhosis and liver failure. Hence, the importance of early diagnosis of NAFLD, which can prevent the progression to NASH and its complications. The combinations of findings of obesity, hyperglycaemia, insulin resistance, diabetes, hypertriglyceridaemia and hypertension is seen in large number of NAFLD patients. This complex association is also seen in NASH patients. Several studies have shown that controlling the various components of metabolic syndrome can lead to regression of fatty liver and delay the progression to NASH.4

All patients within the spectrum of NAFLD should be considered potentially affected not only by a liver disease, but by a multisystem disease. This suggestion could be even stronger in the presence of higher insulin resistance, which is a sensitive predictor of both progressive liver disease and severe extrahepatic disease. Diabetic patients with NAFLD have increased risk of mortality due to cardiovascular and liver-related events. In the absence of biopsy or of an adequate score able to identify subjects at risk, these patient could miss careful follow-up and might be scarcely motivated toward lifestyle modifications that are potentially able to cure their liver disease and the extrahepatic manifestations of the metabolic syndrome. Clinicians should be aware of the importance of a complete clinical evaluation for early diagnosis and treatment of liver disease as well as the different manifestations.

In this context, the investigator conducted the study.

Objectives
1. To evaluate general and clinical profile of NAFLD in diabetic patients.
2. To study the prevalence of NAFLD among diabetes mellitus patients.
3. To compare the clinical profile of diabetes mellitus patients with/without NAFLD.

Hypothesis- There will be no significant difference in the clinical profile of diabetes mellitus patients with/without NAFLD.

MATERIALS AND METHODS
In the present study, normative survey technique cum experiment method were used. One group post-test, only design were selected for the study. Duration of the study was one year. The sample comprised of 100 diabetic patients age ranged 31-70 years. The sample were selected on the basis of inclusion and exclusion criteria. NAFLD was the dependent variable and independent variables include age, gender, duration of DM, hepatomegaly and splenomegaly.

The tools such as clinical profile and checklist were used. Initially, the general profile, checklist for fatigue, heaviness of right upper abdomen, pain right upper abdomen, anorexia and itching was given to patients. The patients were subjected to undergo examination of the gastrointestinal system, cardiovascular, respiratory and central nervous system. The patients were made to undergo the routine examination of blood, FBS, PPBS, RBS, HbA1c, blood urea, serum creatinine and urine routine.

Inclusion Criteria
- Patients attending the diabetic clinic of Medical College, Kottayam, Kerala.
- Be able to communicate meaningfully with the investigator and be legally competent to provide written informed consent.
- Subjects of both genders with an age average between 31 to 70 years (inclusive).
- Have type 2 diabetes mellitus as defined by the American Diabetes Association Guidelines.
- Female patients must be non-lactating and must either be at least one year postmenopausal or be using
adequate mechanical contraceptive precautions or be surgically sterilised. Eligible only if having a negative pregnancy test throughout the study period.

Exclusion Criteria
- Any cause of chronic liver disease other than NASH.
- Any clinical evidence or history of ascites, bleeding varices or spontaneous bacterial encephalopathy.
- History of alcohol abuse.
- Prior surgical procedures including gastroplasty, jejunoileal or jejunocolic bypass.
- Prior exposure to organic solvents such as carbon tetrachloride.
- Total Parental Nutrition (TPN) within the past months.
- Subjects with type 1 diabetes mellitus.

Analytical Methods
- Plasma glucose was measured by glucose oxidase method.
- Blood pressure was measured using a standardised sphygmomanometer.
- General data sheet was used to collect details of demographic data (session I), case history (session II) and presenting complaints (session III).

Analysis and Interpretation: Distribution of diabetic patients with NAFLD based on presenting complaints.
The total diabetic patients were subjected to percentage analysis based on the presenting complaints and tabulated as shown below.

<table>
<thead>
<tr>
<th>Presenting Complaints</th>
<th>Frequency</th>
<th>Percentage</th>
</tr>
</thead>
<tbody>
<tr>
<td>Generalised weakness (GW)</td>
<td>35</td>
<td>61.4</td>
</tr>
<tr>
<td>Right upper quadrant discomfort (RUQD)</td>
<td>16</td>
<td>28.07</td>
</tr>
<tr>
<td>Right upper quadrant pain (RUQP)</td>
<td>14</td>
<td>24.56</td>
</tr>
<tr>
<td>Anorexia (AN)</td>
<td>11</td>
<td>19.29</td>
</tr>
<tr>
<td>Pruritus (PR)</td>
<td>8</td>
<td>14.05</td>
</tr>
</tbody>
</table>

The table shows that out of 100 diabetic patients, 57% belonged to diabetic group with NAFLD, while 43% belonged to diabetic patients without NAFLD. Among the total sample, 47% were males and 53% were females.

Comparison of Clinical Profile of Diabetes Mellitus Patients With/Without NAFLD
Comparison of diabetic patients with/without NAFLD based on duration of disease.
The mean, SD and 't' were calculated for the duration of disease of diabetic patients with/without NAFLD and tabulated as shown below.

<table>
<thead>
<tr>
<th>Category</th>
<th>Frequency</th>
<th>Mean</th>
<th>SD</th>
<th>'t'</th>
</tr>
</thead>
<tbody>
<tr>
<td>With NAFLD</td>
<td>57</td>
<td>9.614</td>
<td>4.4027</td>
<td></td>
</tr>
<tr>
<td>Without NAFLD</td>
<td>43</td>
<td>7.186</td>
<td>3.14</td>
<td>3.2</td>
</tr>
</tbody>
</table>

The patients with NAFLD had a longer duration of diabetes compared to those without NAFLD. The 't' value obtained is 3.2, which is significant at 0.01 level. It is inferred that there exist significant difference in the duration of disease between diabetic patients with/without NAFLD.

Comparison of Diabetic Patients with/without NAFLD Based on Waist Circumference
The mean, SD and 't' were calculated for waist circumference of diabetic patients with/without NAFLD and tabulated as shown below.

<table>
<thead>
<tr>
<th>Category</th>
<th>Frequency</th>
<th>Mean</th>
<th>SD</th>
<th>'t'</th>
</tr>
</thead>
<tbody>
<tr>
<td>With NAFLD</td>
<td>57</td>
<td>96.91</td>
<td>6.057</td>
<td>-5.103</td>
</tr>
<tr>
<td>Without NAFLD</td>
<td>43</td>
<td>84.23</td>
<td>15.283</td>
<td></td>
</tr>
</tbody>
</table>

The patients with NAFLD had higher mean waist circumference compared to those without NAFLD. The 't' value obtained is -5.103, which is significant at 0.01 level. It is inferred that there exist significant difference in waist circumference between diabetic patients with/without NAFLD.
Comparison of Diabetic Patients with/without NAFLD Based on BMI

The mean, SD and ‘t’ were calculated for BMI of diabetic patients with/without NAFLD and tabulated as shown below.

<table>
<thead>
<tr>
<th>Category</th>
<th>Frequency</th>
<th>Mean</th>
<th>SD</th>
<th>‘t’</th>
</tr>
</thead>
<tbody>
<tr>
<td>With NAFLD</td>
<td>57</td>
<td>25.677</td>
<td>4.509</td>
<td></td>
</tr>
<tr>
<td>Without NAFLD</td>
<td>43</td>
<td>23.767</td>
<td>3.084</td>
<td>2.347</td>
</tr>
</tbody>
</table>

Table 5. Result of Significance of BMI among Diabetic patients with/without NAFLD

Comparison of Diabetic Patients with/without NAFLD Based on Blood Pressure

The mean, SD and ‘t’ were calculated for blood pressure of diabetic patients with/without NAFLD and tabulated as shown below.

<table>
<thead>
<tr>
<th>Aspect</th>
<th>Category</th>
<th>Frequency</th>
<th>Mean</th>
<th>SD</th>
<th>‘t’</th>
</tr>
</thead>
<tbody>
<tr>
<td>Systolic blood pressure</td>
<td>With NAFLD</td>
<td>57</td>
<td>129.16</td>
<td>19.16</td>
<td>-2.029</td>
</tr>
<tr>
<td></td>
<td>Without NAFLD</td>
<td>43</td>
<td>121.35</td>
<td>15.81</td>
<td></td>
</tr>
<tr>
<td>Diastolic blood pressure</td>
<td>With NAFLD</td>
<td>57</td>
<td>87.211</td>
<td>10.245</td>
<td></td>
</tr>
<tr>
<td></td>
<td>without NAFLD</td>
<td>43</td>
<td>84.33</td>
<td>9.67</td>
<td>-1.139**</td>
</tr>
</tbody>
</table>

Table 6. Result of Significance of Blood Pressure among Diabetic patients with/without NAFLD

Comparison of Diabetic Patients with/without NAFLD Based on Blood Sugar

The mean, SD and ‘t’ were calculated for blood sugar of diabetic patients with/without NAFLD and tabulated as shown below.

<table>
<thead>
<tr>
<th>Aspect</th>
<th>Category</th>
<th>Frequency</th>
<th>Mean</th>
<th>SD</th>
<th>‘t’</th>
</tr>
</thead>
<tbody>
<tr>
<td>Fasting blood sugar</td>
<td>With NAFLD</td>
<td>57</td>
<td>156.45</td>
<td>24.839</td>
<td>11.009*</td>
</tr>
<tr>
<td></td>
<td>Without NAFLD</td>
<td>43</td>
<td>127.96</td>
<td>25.79</td>
<td></td>
</tr>
<tr>
<td>Postprandial blood sugar</td>
<td>With NAFLD</td>
<td>57</td>
<td>179.47</td>
<td>24.66</td>
<td>11.803*</td>
</tr>
<tr>
<td></td>
<td>without NAFLD</td>
<td>43</td>
<td>128.88</td>
<td>27.20</td>
<td></td>
</tr>
</tbody>
</table>

Table 7. Results of Significance of Blood Sugar among Diabetic patients with/without NAFLD

**- Significant at 0.05 level.

* The patients with NAFLD had a higher mean systolic blood pressure and diastolic blood pressure compared to those without NAFLD. The ‘t’ value obtained is -2.029, which is significant at 0.05 level and -1.139, which is not significant at 0.05 level.

Findings

1. NAFLD is very common in diabetes mellitus. The generalised weakness was present in 61.40%, right upper quadrant discomfort 28.07%, right upper quadrant pain 24.56%, anorexia 19.29% and pruritus 14.03%.
2. Diabetic patients with NAFLD had a longer duration of diabetes compared to that of diabetic patients without NAFLD.
3. Diabetic patients with NAFLD had higher BMI, waist circumference, systolic blood pressure than that of patients without NAFLD.
4. In the clinical profile, the ‘t’ value obtained for waist circumference among patients with/without NAFLD is -5.103, which is significant at 0.05 level.
5. In the clinical profile, the ‘t’ value obtained for BMI among patients with/without NAFLD is -2.347, which is significant at 0.05 level.
6. In the clinical profile, the ‘t’ value obtained for systolic blood pressure between diabetic patients with/without NAFLD is -2.209, which is significant at 0.05 level.
7. In the clinical profile, the ‘t’ value obtained for diastolic blood pressure between diabetic patients with/without NAFLD is -1.139, which is not significant at 0.05 level.

The patients with NAFLD had a higher body mass index compared to those without NAFLD. The ‘t’ value obtained is -2.347, which is significant at 0.05 level. It is inferred that there exist a significant difference in BMI between diabetic patients with/without NAFLD.

It is inferred that there exist a significant difference in systolic blood pressure, but not in diastolic blood pressure between diabetic patients with/without NAFLD.

The patients with NAFLD had a higher mean fasting blood sugar and postprandial blood sugar compared to those without NAFLD. The ‘t’ value obtained is 11.009 and 11.803, which is significant at 0.05 level.

It is inferred that there exist a significant difference in fasting blood sugar and postprandial blood sugar between diabetic patients with/without NAFLD.

**The finding of generalised weakness is not significant at 0.05 level.

**The finding of anorexia is not significant at 0.05 level.
It is found that there exist no significant difference in systolic blood pressure between diabetic patients with/without NAFLD.

8. The 't' value obtained for fasting blood sugar between diabetic patients with/without NAFLD is 11.009, which is significant at 0.05 level.

It is found that there exist a significant difference in fasting blood sugar and postprandial blood sugar between diabetic patients with/without NAFLD.

9. The 't' value obtained for postprandial blood sugar between diabetic patients with/without NAFLD is 11.803, which is significant at 0.05 level.

It is found that there exist a significant difference in postprandial blood sugar between diabetic patients with/without NAFLD.

CONCLUSIONS AND SUGGESTIONS

All the patients within the spectrum of NAFLD should be considered potentially affected not only by liver disease, but by multisystem disease. This suggestion could be even stronger in the presence of higher insulin resistance, which is a sensitive predictor of both progressive liver disease and severe extrahepatic disease. Clinicians should be aware of the importance of a complete clinical evaluation for early diagnosis and treatment of liver disease as well as the different manifestations. All type 2 diabetic patients should be monitored for the development of NAFLD.

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