# 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**

NAFLD, Clinical Profile, Biological Profile, NASH.

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#### BACKGROUND

Non-alcoholic fatty liver disease is a type of chronic liver disease seen in patients who do not consume significant amounts of alcohol. It is also referred to as fatty liver, hepatitis steatonecrosis and pseudo-alcoholic liver disease. NAFLD includes two entities namely fatty liver disease and Non-Alcoholic Steatohepatitis (NASH).

NAFLD is a common condition. Some of the factors associated with non-alcoholic liver diseases are obesity, hyperlipidaemia and hyperglycaemia. NAFLD is associated with metabolic syndrome and represents a spectrum of disorders characterised by predominantly macrovesicular

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hepatic steatosis that occur in individuals even in the absence of consumption of alcohol.<sup>1</sup> Other factors that have been implicated in causation of NAFLD are protein-calorie malnutrition, total parental nutrition and drugs like steroids, tamoxifen and amiodarone.

The other causes of NAFLD includes drugs and toxins like amiodarone, diltiazem, antiretroviral therapy, petrochemicals, total parenteral nutrition, severe anaemia, metabolic syndrome, disorders of lipid metabolism, toxin exposure at work place and environmental causes. Some other surgical causes like jejunocolic bypass, jejunoileal bypass, gastroplasty and extensive bowel resection have been implicated as aetiological causes for NAFLD.

**Risk Factors of NAFLD**- AST/ALT ratio >1, diabetes mellitus, obesity and age >45 years.

A study conducted at Mayo Clinic (1999) suggested that age, obesity, diabetes mellitus and a serum AST/ALT ratio greater than one can help identify a subset of patients with NAFLD who are most likely to have severe fibrosis as indicated by liver biopsy.

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### Original Research Article

Pathogenesis of NAFLD- The two stages have been proposed in the development of NAFLD.<sup>2</sup>



#### 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.<sup>3</sup>

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.<sup>4</sup>

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

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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.

Presenting Complaints	Frequency	%			
Generalised weakness (GW)	35	61.4			
Right upper quadrant discomfort (RUQD)	per quadrant discomfort 16 (RUQD)				
Right upper quadrant pain (RUQP)	14	24.56			
Anorexia (AN)	11	19.29			
Pruritus (PR)	8	14.05			
Table 1. Percentage Distribution of Diabetic Patients with NAFLD Based on Presenting Complaints					

The graphical representation of diabetic patients with NAFLD based on presenting complaints were shown below.



Figure 1. Percentage Distribution of Diabetic Patients Based on Presenting Complaints

## Distribution of Diabetic Patients Based on with/Without NAFLD and Gender

The whole sample were subjected to percentage analysis based on with/without NAFLD and tabulated as shown below.

Category	Frequency	Percentage			
With NAFLD	57	57			
Without NAFLD	43	43			
Male	47	47			
Female 53 53					
Table 2. Percentage Distribution of Diabetic Patients with/without NAFLD					

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.

Category Frequency		Mean	SD	`ť′		
With NAFLD	57	9.614	4.4027			
Without NAFLD	43	7.186 3.14		3.2		
Table 3. Result of Significance of Duration of Disease among Diabetic Patients with/without NAFLD						

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.

Frequency	Mean	SD	`ť			
57	96.91	6.057	E 102			
43	84.23	15.283	-5.105			
Table 4. Result of Significance of Circumference of     Waist among Diabetic Patients with/without						
	57 43 It of Significa ng Diabetic H NAFA	57 96.91 43 84.23 It of Significance of a ng Diabetic Patients NAFLD	57 96.91 6.057   43 84.23 15.283   It of Significance of Circumfering Diabetic Patients with/wite NAFLD			

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.

Category	Frequency	Mean	SD	`ť′		
With NAFLD	57	25.677	4.509	-		
Without NAFLD	43	23.767	3.084	2.347		
Table 5. Result of Significance of BMI among Diabetic patients with/without NAFLD						

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.

### 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.

Aspect	Category	Frequency	Mean	SD	`ť
Systolic blood pressure	With NAFLD	57	129.16	19.169	2 020*
	Without NAFLD	43	121.35	15.819	-2.029**
Diastolic blood pressure	With NAFLD	57	87.211	10.245	-1.139**
	without NAFLD	43	84.33	9.67	
Table 6. Result of Significance of Blood Pressure among Diabetic Patients with/without NAFLD					

\*- Significant at 0.05 level.

\*\*- Not 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.

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.

## 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.

Aspect	Category	Frequency	Mean	SD	`ť
Fasting blood sugar	With NAFLD	57	156.45	24.839	11.009*
	Without NAFLD	43	127.96	25.79	
Postprandial blood sugar	With NAFLD	57	179.47	24.66	11 002*
	Without NAFLD	43	128.88	27.20	11.005
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 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.

#### 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%.

The presenting complaints in which most common was general weakness and least common was pruritus.

- 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.

 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.

It is found that there exist a significant difference in waist circumference between diabetic patients with/without NAFLD.

 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.
It is found that there exist a significant difference in BMI

between diabetic patients with/without NAFLD.

- 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. It is found that there exist a significant difference in systolic blood pressure between diabetic patients with/without NAFLD.
- 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.

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It is found that there exist no significant difference in systolic blood pressure between diabetic patients with/without NAFLD.

 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.<sup>5</sup> 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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