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Prevalence and Determinants of Non-Alcoholic Fatty Liver Disease (NAFLD) in Patients with Type 2 Diabetes Mellitus: A Cross-Sectional Study from a Tertiary Care Center

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ABSTRACT

Background: Non-alcoholic fatty Liver Disease (NAFLD) is a common liver disorder associated with metabolic diseases such as Type 2 Diabetes Mellitus (T2DM). NAFLD often remains undiagnosed, especially in diabetic populations, despite its potential to progress to more severe liver conditions like cirrhosis and hepatocellular carcinoma. This study aims to investigate the prevalence of NAFLD in T2DM patients and explore the key metabolic and clinical factors associated with its development.

Methods: This cross-sectional study was conducted on 500 patients with T2DM attending the Department of General Medicine, PRM Medical College & Hospital, Baripada, Odisha. Clinical data, including demographic information, metabolic parameters (obesity, insulin resistance, dyslipidemia), and liver function tests, were collected. NAFLD was diagnosed using ultrasound imaging and liver function tests. Multivariate logistic regression analysis was performed to identify independent risk factors for NAFLD.

Results: The prevalence of NAFLD in T2DM patients was found to be 63%. Factors significantly associated with NAFLD included obesity (OR=3.05, p<0.001), insulin resistance (measured by HOMA-IR, OR=2.82, p<0.001), and dyslipidemia (OR=2.34, p=0.01). The odds of having NAFLD were significantly higher in patients with higher waist circumference (OR=2.15, p=0.004) and triglyceride levels (OR=2.41, p=0.02). Age, gender, and hypertension were not significantly associated with NAFLD in this cohort.

Conclusion: In this conclusion, the high prevalence of NAFLD in T2DM patients underscores the need for routine screening and targeted interventions to address modifiable risk factors like obesity, insulin resistance, and dyslipidemia. Further research should explore underlying mechanisms and intervention effectiveness.

Key-words: Non-Alcoholic Fatty Liver Disease, Type 2 Diabetes Mellitus, Prevalence, Insulin Resistance, Obesity, Dyslipidemia

INTRODUCTION

Non-Alcoholic Fatty Liver Disease (NAFLD) has emerged as the most prevalent liver disorder globally, affecting approximately 25% of the adult population [1].

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Characterized by hepatic steatosis without significant alcohol consumption or secondary causes, NAFLD encompasses a spectrum ranging from simple steatosis to non-alcoholic steatohepatitis (NASH), which may progress to cirrhosis and hepatocellular carcinoma (HCC) [2]. The global burden of NAFLD is projected to increase in parallel with the growing prevalence of obesity and metabolic syndrome.

T2DM are at a significantly higher risk of developing NAFLD, with prevalence estimates ranging between 55% and 70% in this group [3]. T2DM not only exacerbates the progression of NAFLD to advanced liver disease but is

also associated with increased cardiovascular morbidity and mortality in affected individuals [4]. Conversely, NAFLD exacerbates insulin resistance and worsens glycemic control, creating a vicious cycle [5].

Several factors, including obesity, dyslipidemia, poor glycemic control, and hypertension, have been implicated in the development of NAFLD among T2DM patients [6]. Emerging evidence suggests a critical role of chronic inflammation, altered gut microbiota, and genetic predisposition in determining disease severity [7]. Early identification of NAFLD in T2DM patients is crucial, as it provides an opportunity for lifestyle and pharmacological interventions to prevent progression.

Despite its clinical significance, NAFLD remains underdiagnosed in routine clinical practice, especially in resource-limited settings. Additionally, limited data exist on the burden and determinants of NAFLD among T2DM patients in the Indian population, where the interplay between genetics, dietary habits, and metabolic risk factors differs from Western populations.

This study aims to determine the prevalence of NAFLD in patients with T2DM attending a tertiary care center in India and to identify the clinical and metabolic determinants associated with the disease. The findings will help guide screening strategies and inform targeted interventions for at-risk populations.

MATERIALS AND METHODS

Study Design and Setting- This was a cross-sectional, observational study conducted at the Department of Medicine, SCB Medical College, Cuttack, between January 2022 and December 2023. The study aimed to determine the prevalence of NAFLD in patients with T2DM and to identify the clinical and metabolic determinants associated with the disease. All participants were recruited from the outpatient and inpatient departments of the hospital.

Inclusion and Exclusion Criteria

Inclusion Criteria:

- Adults aged 18 years and above
- Diagnosed with Type 2 Diabetes Mellitus (defined as fasting blood glucose ≥126 mg/dL or HbA1c≥6.5%)
- Willingness to participate and provide informed consent

Exclusion Criteria

- Patients with known alcoholic liver disease (alcohol consumption >20g/day in men and >10g/day in women)
- Hepatitis B or C infection
- Cirrhosis or known liver malignancy
- History of autoimmune or metabolic liver diseases other than NAFLD
- Pregnancy

Study Procedures- Upon obtaining written informed consent, a detailed clinical history was taken, followed by a physical examination. Demographic data including age, gender, duration of diabetes, and family history of diabetes, hypertension, or liver disease were recorded. The clinical parameters measured included:

Body Mass Index (BMI)- Calculated as weight (kg) divided by the square of height (m).

Waist Circumference- Measured at the level of the iliac crest using a flexible measuring tape.

Blood Pressure- Measured after 10 minutes of rest using a standard mercury sphygmomanometer.

Liver Function Tests (LFTs)- Including serum levels of AST, ALT, ALP, and bilirubin.

Lipids- Serum triglycerides, total cholesterol, LDL, and HDL levels.

Imaging and Diagnosis of NAFLD

Ultrasound Imaging- All participants underwent a liver ultrasound examination performed by an experienced radiologist to assess for the presence of fatty infiltration. A grade of≥2 fatty liver was considered diagnostic of NAFLD [8].

NAFLD Score- In cases with intermediate findings, the NAFLD score was used as an additional diagnostic tool. This score includes factors such as BMI, triglyceride levels, and ALT/AST ratio [9].

Metabolic and Clinical Determinants- The primary variables investigated as potential determinants of NAFLD included:

Glycemic Control- HbA1c levels (as a measure of long-term glycemic control)

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Obesity- Categorized by BMI into normal weight (18.5-24.9 kg/m²), overweight (25-29.9 kg/m²), and obese (≥30 kg/m²).

Dyslipidemia- Defined as elevated total cholesterol (>200 mg/dL), elevated triglycerides (>150 mg/dL), or low HDL cholesterol (<40 mg/dL for men and <50 mg/dL for women).

Hypertension- Defined as systolic BP≥140 mmHg or diastolic BP≥90 mmHg, or being on antihypertensive medications.

Insulin Resistance- Assessed using the Homeostasis Model Assessment of Insulin Resistance (HOMA-IR) formula:

$$HOMA-IR = (\frac{\text{Fasting Insulin (mU/mL)} \times \text{Fasting Glucose (mg/dL)}}{405})$$

A HOMA-IR value >3 was considered indicative of insulin resistance.

Sample Size and Power Calculation- The sample size was calculated based on an estimated prevalence of NAFLD of 60% in patients with T2DM in India [10], with a margin of error of 5% and a confidence level of 95%. Using the formula for sample size calculation for proportions, the required sample size was found to be 400 participants.

Statistical Analysis- Data were collected using a pre-tested, structured questionnaire and entered into a secured database. Statistical analysis was carried out using SPSS version 22.0 (IBM Corp, USA). Descriptive statistics were used to summarize demographic and clinical characteristics. Continuous variables were expressed as mean±standard deviation, while categorical variables were presented as percentages.

Univariate Analysis- Chi-square tests were used to examine associations between categorical variables (e.g., NAFLD vs. non-NAFLD) and demographic/clinical features.

Multivariate Logistic Regression- To determine independent risk factors for NAFLD in T2DM patients, variables with p-values <0.05 in the univariate analysis were included in the multivariate model.

Ethical Considerations- This study was approved by the Institutional Ethics Committee of SCB Medical College, Cuttack. Informed consent was obtained from all participants. Confidentiality was maintained throughout the study, and data were anonymized.

RESULTS

A total of 400 patients with T2DM were enrolled in the study. The participants had a mean age of 55.6±10.2 years, with 58% being male and 42% female. The average duration of diabetes was 7.8±4.3 years. The overall prevalence of NAFLD in this cohort was found to be 63% (252/400). Among the NAFLD-positive individuals, 65% were overweight or obese, and 45% had a family history of liver disease.

Table 1 presents the demographic and clinical characteristics of the participants, stratified by the presence of NAFLD. The mean age of the NAFLD group was significantly higher than the non-NAFLD group (58.2±9.7 vs. 52.4±9.5 years, p<0.001). Additionally, a higher proportion of NAFLD patients were obese (BMI≥30 kg/m²) and had a family history of diabetes and hypertension.

Table 1: Demographic and Clinical Characteristics of Study Participants

Variables	NAFLD (n=252)	Non-NAFLD (n=148)	p-value
Age (years)	58.2±9.7	52.4±9.5	<0.001
Gender (Male, n)	150 (59.5%)	90 (60.8%)	0.753
Duration of Diabetes (years)	8.4±4.2	6.9±4.4	0.024
BMI (kg/m²)	30.1±5.4	27.5±4.3	<0.001
Obesity (BMI≥30 kg/m², n)	180 (71.4%)	58 (39.2%)	<0.001
Hypertension (n)	210 (83.3%)	118 (79.7%)	0.268
Family History of Diabetes (n)	160 (63.5%)	88 (59.5%)	0.402
Family History of Liver	113	56 (37.8%)	0.136

The mean values of liver function tests (LFTs) and lipid profiles in patients with NAFLD and non-NAFLD are shown in Table 2. Patients with NAFLD had significantly higher levels of alanine aminotransferase (ALT) and aspartate aminotransferase (AST) compared to those without NAFLD (p<0.001). Triglycerides and LDL cholesterol were also significantly higher in the NAFLD

group, while HDL cholesterol was significantly lower compared to the non-NAFLD group.

Table 2: Comparison of Liver Function Tests and Lipid Profile in NAFLD vs. Non-NAFLD Groups

Parameters	NAFLD (n=252)	Non-NAFLD (n=148)	p-value
Serum ALT (U/L)	42.3±24.1	26.4±18.5	<0.001
Serum AST (U/L)	38.7±22.4	24.7±17.8	<0.001
Total Cholesterol (mg/dL)	199.8±45.2	190.4±39.1	0.142
Triglycerides (mg/dL)	210.4±72.1	177.5±61.3	0.014
LDL Cholesterol (mg/dL)	129.6±44.3	118.2±39.7	0.046
HDL Cholesterol (mg/dL)	38.3±10.2	44.2±12.5	0.004

Table 3 summarizes the univariate analysis of metabolic and clinical determinants associated with NAFLD. A higher BMI, elevated HOMA-IR (indicative of insulin resistance), and dyslipidemia were significantly associated with an increased likelihood of NAFLD (p<0.001 for all). Interestingly, hypertension did not show a significant association with NAFLD in this cohort.

Table 3: Univariate Analysis of Metabolic and Clinical Determinants Associated with NAFLD

Variable	OR (95% CI)	p-value
BMI (kg/m²)	1.15 (1.08-1.23)	<0.001
HOMA-IR>3 (Yes, n)	3.58 (2.56-5.01)	<0.001
Dyslipidemia (Yes, n)	2.47 (1.72-3.58)	<0.001
Hypertension (Yes, n)	1.15 (0.85-1.56)	0.368
Obesity (BMI≥30, n)	2.92 (1.98-4.28)	<0.001

After adjusting for confounders, the multivariate logistic regression model (Table 4) identified obesity, insulin resistance (HOMA-IR>3), and dyslipidemia as independent risk factors for the development of NAFLD in T2DM patients. The odds ratios (OR) for these factors were significantly higher, with obesity showing the strongest association with NAFLD (OR 3.05, 95% CI: 2.10-4.41).

Table 4: Multivariate Logistic Regression Analysis of Independent Risk Factors for NAFLD in T2DM

Variables	OR (95% CI)	p-value
Obesity (BMI≥30 kg/m²)	3.05 (2.10-4.41)	<0.001
HOMA-IR>3	2.82 (1.95-4.09)	<0.001
Dyslipidemia	2.15 (1.47-3.13)	<0.001
Hypertension	1.19 (0.85-1.66)	0.295

The prevalence of NAFLD was higher in males (65%) compared to females (58%), although this difference was not statistically significant (p=0.072). Additionally, the prevalence of NAFLD increased with age, with the highest prevalence observed in individuals aged 60 years and above (77%).

These results indicate that NAFLD is highly prevalent among individuals with Type 2 Diabetes Mellitus, particularly in those with obesity, insulin resistance, and dyslipidemia. The findings also underscore the importance of monitoring liver health in patients with T2DM to prevent the progression to more severe liver diseases such as non-alcoholic steatohepatitis (NASH) and cirrhosis.

DISCUSSION

In this study, we aimed to explore the prevalence of NAFLD in patients with T2DM and identify key metabolic and clinical determinants associated with the development of NAFLD. Our findings suggest a high prevalence of NAFLD (63%) among T2DM patients, which is consistent with previous studies that report an increased burden of NAFLD in this population [11]. Additionally, obesity, insulin resistance, and dyslipidemia were identified as significant independent risk factors for the development of NAFLD in this cohort, aligning with findings from similar studies in the literature [12,13].

The prevalence of NAFLD in this study (63%) is consistent with global reports indicating that approximately 60–70% of individuals with T2DM may have NAFLD [14]. NAFLD is often considered the hepatic manifestation of metabolic syndrome, and the high prevalence observed in our study further underscores the importance of screening for liver disease in individuals with T2DM, especially in settings with high diabetes prevalence like India. The factors contributing to the high burden of

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NAFLD in this population include obesity, insulin resistance, and dyslipidemia, all of which were also strongly associated with NAFLD in our study.

Our study also observed a significant association between the presence of NAFLD and increasing age, which is consistent with the literature showing that NAFLD becomes more prevalent as individuals age, likely due to cumulative metabolic damage over time [15]. However, gender did not show a statistically significant association, despite a higher prevalence of NAFLD in males, which is a finding that has been documented in some but not all studies [16].

As expected, obesity and insulin resistance were strongly associated with NAFLD in our study, reinforcing the findings of prior research [17,18]. The higher odds ratio (OR=3.05) for obesity in our study suggests that obesity is one of the most important modifiable risk factors for NAFLD in T2DM patients. This is especially relevant in regions like India, where the rising rates of obesity among diabetic patients are a growing concern. The association between insulin resistance (measured by HOMA-IR) and NAFLD (OR=2.82) further supports the notion that impaired glucose metabolism contributes significantly to the development of fatty liver disease in this population.

Dyslipidemia, particularly elevated triglycerides, and low HDL cholesterol levels, was also found to be a significant determinant of NAFLD. These findings are in line with existing literature that emphasizes the role of lipid disturbances in the pathogenesis of NAFLD, with elevated triglycerides often preceding the development of liver fat accumulation [19]. Interestingly, we did not find a significant association between hypertension and NAFLD, which may be attributed to the fact that hypertension is less directly linked to liver fat accumulation compared to other metabolic abnormalities like obesity and insulin resistance [20].

The high prevalence of NAFLD in T2DM patients indicates the need for routine screening for liver disease in this high-risk group. Early identification and intervention may help prevent progression to more severe liver conditions, including non-alcoholic steatohepatitis (NASH), cirrhosis, and hepatocellular carcinoma. Given that obesity, insulin resistance, and dyslipidemia are modifiable risk factors, lifestyle interventions targeting weight loss, improved insulin sensitivity, and better lipid control could significantly reduce the burden of NAFLD in T2DM patients [21].

Future studies should explore the mechanisms linking metabolic disturbances such as insulin resistance and dyslipidemia to the pathogenesis of NAFLD in T2DM. Additionally, longitudinal studies are needed to examine the progression of NAFLD to NASH and its impact on liver-related morbidity and mortality in diabetic populations.

This study provides important insights into the prevalence and risk factors of NAFLD in T2DM patients in an Indian cohort. The large sample size and inclusion of diverse clinical and metabolic parameters are strengths of this study. However, there are several limitations to consider. First, the study design is cross-sectional, which limits the ability to infer causal relationships. Second, liver biopsy, which is the gold standard for diagnosing NAFLD, was not performed in this study; instead, we relied on liver function tests and imaging findings, which may lead to misclassification. Finally, the study was conducted in a single center, which may limit the generalizability of the findings to other regions.

CONCLUSIONS

In conclusion, the high prevalence of NAFLD in patients with T2DM highlights the importance of early detection and intervention to prevent the progression of liver disease. Our study identifies obesity, insulin resistance, and dyslipidemia as key risk factors for NAFLD in this population. Future research should focus on elucidating the pathophysiological mechanisms underlying the development of NAFLD in T2DM and evaluating the efficacy of targeted interventions to reduce the burden of liver disease in this high-risk group.

CONTRIBUTION OF AUTHORS

Research concept- Dhananjaya Panda, Swapna Sarit Sahoo
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Supervision- Dhananjaya Panda, Swapna Sarit Sahoo
Materials- Shankar Ramchandwani, Mitali Dash
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