

CLINICAL, RADIOLOGICAL AND BIOCHEMICAL PROFILE OF METABOLIC DYSFUNCTION ASSOCIATED STEATOTIC LIVER DISEASE IN OBESE PATIENTS WITH AND WITHOUT TYPE 2 DIABETES MELLITUS: A COMPARATIVE OBSERVATIONAL STUDY

Gajanan Jagtap Patil¹, Jithin Prakash^{2*}, Sunil Rana³

^{1,3}Department of Medicine, Sarvodaya Hospital and Research Centre, Faridabad, India.

²Department of Medicine, Kasturba Medical College, Manipal Academy of Higher Education, Manipal, India.

Corresponding Author: Jithin Prakash

ORCID ID: 0009-0006-4044-5022

Email ID: jithinprakash2014@gmail.com jithin.prakash@manipal.edu

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ABSTRACT

Background and Aims: Metabolic dysfunction-associated steatotic liver disease (MASLD) and type 2 diabetes mellitus (T2DM) frequently coexist and share overlapping cardiometabolic pathways. We compared the clinical, biochemical and radiological profile of MASLD in obese patients with and without T2DM. **Methods:** This hospital-based comparative observational study enrolled 100 newly detected MASLD subjects, comprising 50 obese patients with T2DM and 50 obese patients without T2DM. Participants underwent clinical assessment, anthropometry, laboratory investigations, abdominal ultrasonography and transient elastography. Continuous variables were compared using independent-samples t tests and categorical variables using chi-square or Fisher's exact tests. **Results:** The T2DM group was older (51.96 ± 7.88 vs 47.03 ± 7.14 years; $p = 0.039$) and had a higher BMI (37.17 ± 3.63 vs 35.05 ± 2.40 kg/m²; $p = 0.044$). Triglycerides (234.99 ± 67.27 vs 183.62 ± 70.03 mg/dL; $p = 0.005$) and HbA1c ($7.89 \pm 0.71\%$ vs $5.63 \pm 0.77\%$; $p = 0.001$) were higher, whereas ALT (63.80 ± 31.06 vs 77.25 ± 33.92 U/L; $p = 0.009$) and LDL cholesterol (115.30 ± 32.86 vs 129.08 ± 34.84 mg/dL; $p = 0.008$) were lower in the T2DM group. Hypertension was more prevalent (69% vs 47%; $p = 0.026$), and platelet count was lower (226.62 ± 93.84 vs $247.07 \pm 88.48 \times 10^3/\mu\text{L}$; $p = 0.042$). Metabolic dysfunction-associated steatohepatitis (MASH) was reported in 81% versus 65% ($p = 0.004$), and advanced fibrosis in 43% versus 19% ($p = 0.002$) of the T2DM and non-T2DM groups, respectively. Ferritin was lower in the T2DM group (210.43 ± 96.58 vs 255.19 ± 101.60 ng/mL; $p = 0.054$). **Conclusions:** Among obese patients with MASLD, those with T2DM demonstrated older age, greater adiposity, a less favourable metabolic profile, and higher reported prevalence of MASH and advanced fibrosis. These findings support systematic non-invasive assessment of liver disease in obese patients, particularly those with T2DM.

Keywords: Metabolic dysfunction-associated steatotic liver disease; MASLD; type 2 diabetes mellitus; obesity; transient elastography; liver fibrosis; India

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1. INTRODUCTION

Metabolic dysfunction-associated steatotic liver disease is a common chronic liver disease characterized by hepatic steatosis in the absence of significant alcohol exposure or another dominant secondary cause [1]. Its spectrum ranges from isolated steatosis to

steatohepatitis, progressive fibrosis, cirrhosis and hepatocellular carcinoma [2]. The burden is particularly high among people with obesity and T2DM [3,4]. MASLD and T2DM share insulin resistance, visceral adiposity, dyslipidaemia and pro-inflammatory pathways [5], and diabetes is

associated with a greater risk of progression to advanced fibrosis [7,8]. Indian data demonstrate a substantial burden of fatty liver disease among patients with T2DM, with reported prevalence estimates ranging from 12.5% to 87.5% across regions [8,9]; comparative data specifically examining obese patients with and without diabetes remain limited. We therefore compared the clinical, biochemical and radiological profile of obese patients with MASLD according to the presence or absence of T2DM.

2. MATERIALS AND METHODS

2.1 Study Design and Setting

This comparative observational study was conducted in a tertiary care hospital over a planned 15-month period. The study protocol was approved by the Institutional Ethics Committee, ethical clearance was obtained and written informed consent was taken from all participants.

2.2 Participants

A total of 100 participants were enrolled, with 50 participants in each group: Group 1, obese patients with T2DM; and Group 2, obese patients without T2DM.

2.3 Eligibility and Exclusion Criteria

Adults aged >18 and <75 years with MASLD according to the study definition were eligible. Exclusion criteria were significant alcohol consumption (>20 g/day), pre-existing liver dysfunction, HBsAg or HCV positivity, haematological malignancy, and pre-existing coronary artery disease, chronic kidney disease, stroke or cirrhosis.

2.4 Sample Size

The sample size was calculated using a prevalence-based formula for a single proportion. The thesis used an expected MASLD prevalence of 56.5% among patients with T2DM, $q = 43.5\%$, $Z\alpha = 1.96$ at a 5% significance level, and a 10% margin of error, yielding a calculated sample size of 94.37; the final sample was set to 100 participants, with 50 in each group.

2.5 Clinical and Laboratory Assessment

History, anthropometry and clinical examination were performed using

standardized methods. BMI was calculated as weight (kg) divided by height in metres squared. Waist and hip circumferences and blood pressure were recorded. Laboratory investigations included complete blood count, renal function, liver function, lipid profile, glucose, viral markers, HbA1c, INR and ferritin.

2.6 Radiological Assessment

Abdominal ultrasonography was performed by a radiologist using a high-resolution B-mode ultrasonography system. Fatty liver was identified by a “bright liver” pattern and graded from grade 0 to grade 3 according to hepatic echogenicity and visualization of the diaphragm and intrahepatic vessels[10]. The study also used transient elastography (Fibro Scan) for MASLD assessment[11] with CAP thresholds of 248/268/280 dB/m for S1,S2,S3 respectively and LSM thresholds of 7–8 kPa (F2), 9.6–10 kPa (F3) and 13–14 kPa (F4).

2.7 Statistical Analysis

Data were tabulated in Microsoft Excel and analysed using SPSS version 22.00 for Windows (SPSS Inc., Chicago, USA). Categorical and continuous variables were compared using chi-square and t tests, respectively. Statistical significance was set at $p < 0.05$.

3. RESULTS

3.1 Demographic and Clinical Characteristics

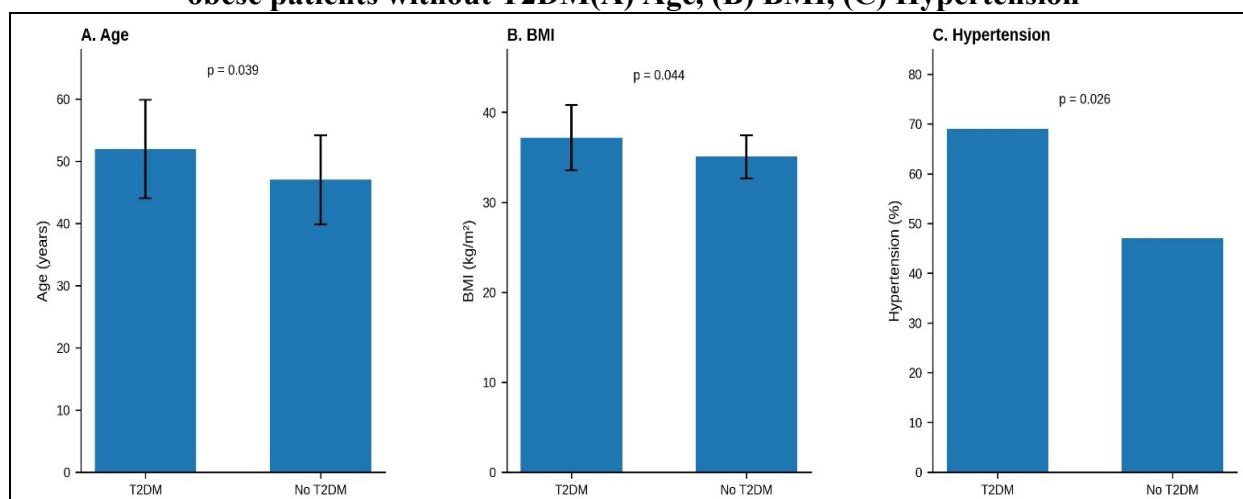
The T2DM group was older and had a higher mean BMI than the non-diabetic group. Females predominated in both groups. The differences in age, BMI, Hypertension between two groups are illustrated in figure 1.

Table 1. Demographic and clinical characteristics of the study groups.

Variable	Obese + T2DM (n = 50)	Obese without T2DM (n = 50)	p
Male (%)	36	43	0.13
Female (%)	64	57	0.13
Age (years), mean $\pm$ SD	51.96 $\pm$ 7.88	47.03 $\pm$ 7.14	0.039
BMI (kg/m ²), mean $\pm$ SD	37.17 $\pm$ 3.63	35.05 $\pm$ 2.40	0.044
Hypertension (%)	69	47	0.026

Values are mean $\pm$ SD or percentage; p from independent-samples t tests (continuous variables) and chi-square tests (categorical variables)

Figure 1 -Comparison of Age, BMI, Hypertension between obese patients with T2DM and obese patients without T2DM(A) Age, (B) BMI, (C) Hypertension



3.2 Biochemical Profile

Bilirubin, AST, albumin, total cholesterol, HDL and INR were similar between groups. Triglycerides were higher in the T2DM group, whereas ALT and LDL cholesterol were lower. HbA1c was substantially higher

and ferritin significantly lower in the T2DM group; platelet count was numerically but not significantly lower (Tables 2 and 3). Comparison of biochemical profiles between two study groups are illustrated in Figure 2.

Table 2. Liver function and lipid profile of the study groups.

Variable	Obese + T2DM (n = 50)	Obese without T2DM (n = 50)	p
Bilirubin (mg/dL)	0.69 ± 0.38	0.65 ± 0.34	0.61
AST (U/L)	54.16 ± 32.04	60.11 ± 36.28	0.43
ALT (U/L)	63.80 ± 31.06	77.25 ± 33.92	0.009
Albumin (g/dL)	4.23 ± 0.44	4.31 ± 0.52	0.17
Total cholesterol (mg/dL)	193.10 ± 48.78	202.70 ± 51.56	0.08
Triglycerides (mg/dL)	234.99 ± 67.27	183.62 ± 70.03	0.005
HDL (mg/dL)	41.04 ± 9.81	43.86 ± 8.77	0.10
LDL (mg/dL)	115.30 ± 32.86	129.08 ± 34.84	0.008

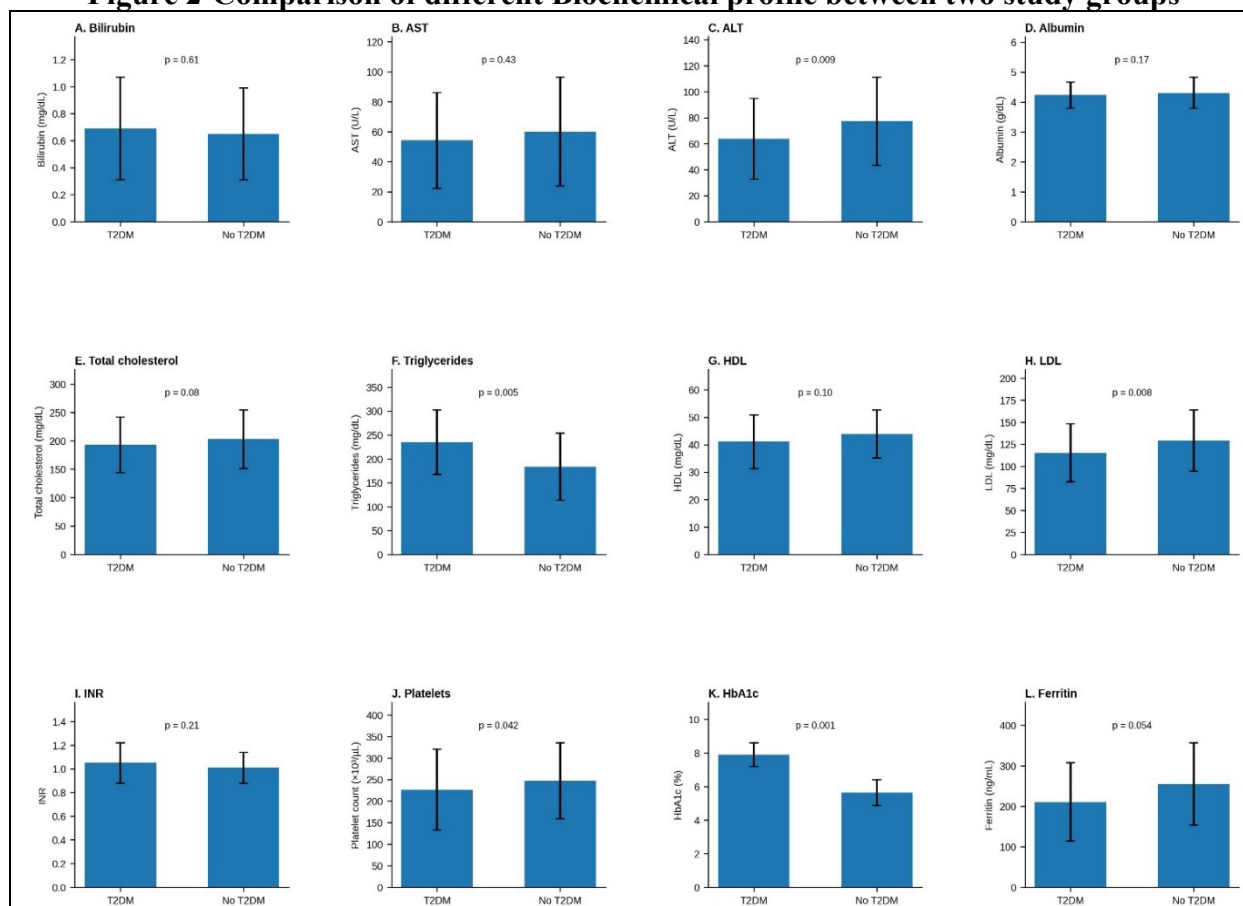
Values are mean ± SD; p from independent-samples t tests.

Table 3. Haematological, glycaemic and iron indices of the study groups.

Variable	Obese + T2DM (n = 50)	Obese without T2DM (n = 50)	p
INR	1.05 ± 0.17	1.01 ± 0.13	0.21
Platelet count (×10 ³ /μL)	226.62 ± 93.84	247.07 ± 88.48	0.042
HbA1c (%)	7.89 ± 0.71	5.63 ± 0.77	0.001
Ferritin (ng/mL)	210.43 ± 96.58	255.19 ± 101.60	0.054

Values are mean ± SD; p from independent-samples t tests.

Figure 2-Comparison of different Biochemical profile between two study groups



3.3 Radiological and Non-invasive Liver Outcomes

MASLD was diagnosed using Fibro Scan in the study population, with ultrasonography also used for radiological assessment and grading. MASH was reported in 81% of participants in the T2DM group and 65% in the non-T2DM group ($p = 0.004$) (Table 4). Advanced fibrosis was reported in 43% and 19%, respectively ($p = 0.002$) (Table 5). Figure 3 shows the radiological and non-invasive outcomes-MASH and advanced fibrosis compared between two groups.

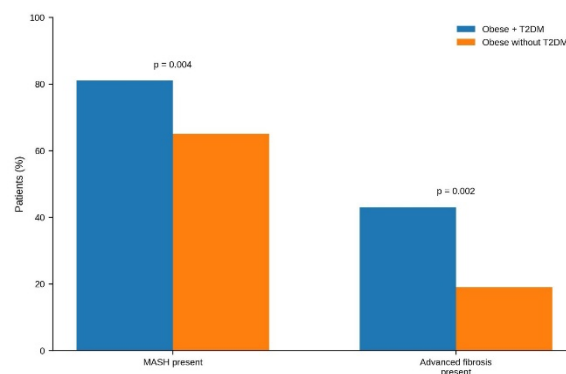
Table 4. MASH status by study group

MASH	Obese + T2DM (n = 50)	Obese without T2DM (n = 50)	p
Present (%)	81	65	0.004
Absent (%)	19	35	

Table 5. Advanced fibrosis status by study group

Advanced fibrosis	Obese + T2DM (n = 50)	Obese without T2DM (n = 50)	p
Present (%)	43	19	0.002
Absent (%)	57	81	

Figure 3 -Comparison of Radiological and non-invasive liver outcomes- MASH and Advanced fibrosis between obese patients with T2DM and obese patients without T2DM



4. DISCUSSION

In this comparative cohort of obese patients with MASLD, those with T2DM were older, had a higher BMI and exhibited a less favourable metabolic profile than those without diabetes. Higher triglycerides and HbA1c, together with lower platelet counts, are biologically consistent with the greater metabolic burden associated with T2DM.

The lower ALT concentration in the diabetic group is noteworthy but should not be interpreted as evidence of less severe liver disease: aminotransferases are normal in a substantial proportion of patients with diabetes-associated MASLD, and have limited sensitivity for clinically important fibrosis[12,13]. The cross-sectional design does not allow the mechanism of this finding to be established.

MASH was reported in 81% of participants with T2DM and 65% without T2DM ($p = 0.004$), while advanced fibrosis was reported in 43% and 19%, respectively ($p = 0.002$). These findings indicate a greater reported burden of advanced liver disease among obese participants with T2DM, consistent with evidence that diabetes is associated with more severe MASLD and fibrosis [7,14]. At the same time, severe liver disease was present in a substantial proportion of obese patients without T2DM, supporting non-invasive assessment of liver disease severity irrespective of diabetes status.

Age and BMI differed between the groups. Although the thesis describes age-, sex-, and weight-matching of the non-diabetic obese group, the reported group means differed in age and BMI. The observed associations should therefore not be interpreted as independent causal effects of diabetes.

4.1 Strengths

The study addresses a clinically relevant comparison within an exclusively obese MASLD population, isolating diabetes status as the contrast of interest, and combines standardized anthropometry, laboratory assessment and non-invasive liver imaging in

a North Indian hospital setting where such comparative data remain scarce.

4.2 Limitations

The study was single-centre and observational, with a relatively small sample, and no liver biopsy was performed. MASH and advanced fibrosis were therefore defined by non-invasive criteria, which may misclassify disease severity. In addition, the groups differed in age and BMI, and the analysis did not include multivariable adjustment.

CONCLUSION

Among obese patients with MASLD, those with T2DM were older, had greater adiposity, more hypertension, higher triglycerides and HbA1c, lower ALT and LDL cholesterol, and a higher reported prevalence of MASH and advanced fibrosis than obese patients without T2DM. Severe MASLD was also present in a substantial proportion of obese patients without T2DM, supporting the need for non-invasive assessment of liver disease severity irrespective of diabetes status.

DECLARATIONS

Ethics Approval and Consent to Participate: This study was conducted in accordance with the principles of the Declaration of Helsinki. The study protocol was approved by the Institutional Ethics Committee on 09 May 2023. Written informed consent was obtained from all participants in their vernacular language prior to enrolment.

Consent for Publication: Not applicable. This manuscript does not contain any individual person's data in any form (images, videos, or voice recordings).

Availability of Data and Materials: The datasets generated and analyzed during the current study are available from the corresponding author on reasonable request, subject to institutional requirements.

Competing Interests: The authors declare that they have no competing interests.

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