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Research Article

A Study of Metabolic Dysfunction -Associated Steatotic liver disease in Type 2 Diabetes Mellitus in Accordance with Real Time Hepatic Elastography

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ABSTRACT

Background: Metabolic dysfunction associated steatotic liver disease (MASLD) has emerged as one of the most common liver disorders worldwide and is particularly frequent among patients with Type 2 Diabetes Mellitus (T2DM). In people with diabetes, fatty changes in the liver often develop silently and may progress to fibrosis or advanced liver disease without obvious symptoms. Early identification of liver involvement in this high-risk group is therefore clinically important.
Aim: To assess the prevalence and severity of MASLD in patients with T2DM using conventional ultrasonography, with special emphasis on liver fibrosis assessment through Real Time Hepatic Elastography (RTHE), and to compare these findings with biochemical fibrosis scoring.
Materials and Methods: This cross-sectional study included 150 patients with T2DM evaluated at a tertiary care hospital over a two-year period. Patients with significant alcohol intake, viral hepatitis, or known hepatotoxic drug exposure were excluded. All participants underwent clinical evaluation, routine laboratory investigations, abdominal ultrasonography to detect fatty liver, calculation of the MASLD fibrosis score, and liver stiffness assessment using RTHE. Fibrosis was graded from F0 to F4 based on Liver Fibrosis Index values. Statistical analysis was performed to determine associations between imaging and fibrosis scoring results.
Results: MASLD was identified in 58.7% of patients on conventional ultrasonography. On RTHE, more than half of the patients (53.3%) showed no evidence of fibrosis; however, a significant proportion (36.7%) demonstrated advanced fibrosis (F3–F4), including 26.7% with severe fibrosis. Biochemical fibrosis scoring classified 74% of patients as having definite fibrosis. A significant association was observed between ultrasonographic findings and RTHE grading ($p = 0.002$), whereas the correlation between RTHE and fibrosis scoring was not statistically significant ($p = 0.41$).
Conclusion: A substantial number of patients with T2DM have underlying MASLD, and many already exhibit advanced fibrosis despite minimal symptoms. Real Time Hepatic Elastography offers valuable non-invasive insight into liver stiffness and may help identify high-risk individuals early. Routine liver assessment in diabetic patients could facilitate timely intervention and potentially reduce long-term hepatic complications.

Keywords: *Metabolic Dysfunction Associated Steatotic Liver Disease (MASLD), Type 2 Diabetes Mellitus (T2DM), Real-Time Hepatic Elastography (RTHE), Liver Fibrosis, Ultrasonography.*

INTRODUCTION

Metabolic dysfunction associated steatotic liver disease (MASLD) has become one of the most common chronic liver disorders worldwide and is increasingly recognised as the hepatic manifestation of metabolic syndrome [1,2]. It

encompasses a spectrum ranging from simple steatosis to non-alcoholic steatohepatitis (NASH), which is characterised by hepatocellular injury and inflammation and may progress to fibrosis, cirrhosis, and hepatocellular carcinoma [3,4]. Because most patients remain asymptomatic until advanced stages, MASLD is frequently detected incidentally during evaluation for metabolic disorders.

The global rise in obesity and Type 2 Diabetes Mellitus (T2DM) has paralleled the increasing burden of MASLD [5]. Insulin resistance plays a central role in the pathogenesis of hepatic steatosis by promoting increased lipolysis, enhanced free fatty acid flux to the liver, and altered hepatic lipid metabolism [6]. Consequently, individuals with T2DM demonstrate a markedly higher prevalence of MASLD compared to the general population [7]. In diabetic patients, MASLD is not merely a coincidental finding; it is associated with accelerated fibrosis progression and increased risk of liver-related as well as cardiovascular morbidity [8,9].

T2DM is a chronic metabolic disorder characterised by impaired insulin secretion and/or action, leading to persistent hyperglycaemia and multisystem complications [10]. The coexistence of MASLD in patients with T2DM significantly worsens clinical outcomes and adversely affects quality of life [11]. Advanced hepatic fibrosis in this group is a major predictor of liver-related mortality [12]. Therefore, early detection of hepatic involvement in diabetic patients is essential for timely intervention and prevention of long-term complications.

Accurate assessment of liver fibrosis is crucial for prognostication and therapeutic decision-making in chronic liver disease [13]. Although liver biopsy has traditionally been considered the reference standard for fibrosis staging, its invasive nature, sampling variability, and potential complications limit its routine use [14]. This has led to growing interest in non-invasive imaging techniques that can reliably assess liver parenchymal changes.

Ultrasonography remains the first-line modality for detecting fatty infiltration due to its accessibility and cost-effectiveness [15]. However, conventional ultrasound cannot reliably quantify fibrosis. Real Time Hepatic Elastography (RTHE), a strain-based elastographic technique integrated with ultrasound systems, provides qualitative and semi-quantitative assessment of liver stiffness by analysing tissue deformation in response to mechanical stress [16]. By mapping variations in tissue elasticity, RTHE offers a non-invasive method to evaluate hepatic fibrosis and monitor disease progression without exposing patients to procedural risks [17].

The clinical relevance of assessing liver stiffness in T2DM patients lies in identifying those at higher risk of progressive liver disease. Glycaemic control, duration of diabetes, and associated metabolic risk factors may influence hepatic steatosis and fibrosis severity [18]. Understanding this relationship can aid clinicians in adopting a more comprehensive and targeted management strategy for diabetic individuals.

In this context, the present study was undertaken to evaluate the prevalence and severity of MASLD in patients with T2DM using ultrasonography, with specific emphasis on Real Time Hepatic Elastography for assessment of liver stiffness. The study aims to highlight the importance of early, non-invasive detection of hepatic involvement in diabetic patients and to explore its clinical implications for risk stratification and management.

METHODOLOGY

Study Design and Setting

This cross-sectional observational study was conducted at Dept. of Medicine, Dr. D. Y. Patil Medical College and Hospital, Pimpri, Pune, a tertiary care teaching hospital catering to a large urban and semi-urban population. The study was carried out over a period of two years, from October 1, 2016 to September 30, 2018. Patient recruitment and data collection were completed during this period, followed by data analysis and compilation of results.

A cross-sectional design was chosen to evaluate the prevalence and severity of Metabolic dysfunction associated steatotic liver disease (MASLD) in patients with Type 2 Diabetes Mellitus (T2DM) and to assess hepatic fibrosis using Real Time Hepatic Elastography (RTHE). Such a design is appropriate for estimating disease burden and identifying associations between metabolic parameters and liver involvement at a given point in time [19].

Study Population

A total of 150 patients with T2DM attending the outpatient and inpatient services were enrolled after applying predefined inclusion and exclusion criteria. All participants provided voluntary written informed consent prior to enrolment.

Inclusion Criteria

- Diagnosed cases of Type 2 Diabetes Mellitus.

Exclusion Criteria

- History of alcohol consumption exceeding 40 g/week in males and 20 g/week in females.
- Positive serology for Hepatitis B surface antigen (HBsAg) or Hepatitis C virus (HCV).
- History of use of potentially hepatotoxic medications.

These criteria were adopted to ensure that fatty liver changes, if present, were attributable to metabolic causes rather than alcohol or other chronic liver diseases [20,21].

Clinical and Laboratory Evaluation
All patients underwent detailed clinical evaluation including history, anthropometric measurements (age, body mass index), and relevant biochemical investigations. Routine laboratory tests included liver function tests (ALT, AST), platelet count, and serum albumin levels.

The MASLD Fibrosis Score (NFS) was calculated for each patient using established parameters such as age, BMI, presence of impaired fasting glucose/diabetes, AST/ALT ratio, platelet count, and serum albumin. The NFS is a validated, non-invasive scoring system used to identify patients at risk of advanced fibrosis in MASLD [22].

Ultrasonographic Assessment
All participants underwent abdominal ultrasonography to evaluate liver size, echotexture, and degree of fatty infiltration. Conventional ultrasonography remains the first-line imaging modality for detecting hepatic steatosis due to its accessibility and cost-effectiveness [23].

Fatty liver was graded based on echogenicity patterns:

- **Grade I (Mild):** Slight increase in hepatic echogenicity with normal visualization of diaphragm and intrahepatic vessel borders.
- **Grade II (Moderate):** Moderate increase in echogenicity with partial impairment of visualization of intrahepatic vessels and diaphragm.
- **Grade III (Severe):** Marked increase in echogenicity with poor penetration of posterior liver segments and poor or absent visualization of vessels and diaphragm.

This grading system has been widely used in clinical studies for semi-quantitative assessment of hepatic steatosis [24].

Real Time Hepatic Elastography (RTHE)
To evaluate hepatic fibrosis, Real Time Hepatic Elastography (RTHE) was performed in all patients using the Aloka Arietta S60 ultrasound system in strain wave mode. RTHE is a non-invasive imaging technique that assesses tissue elasticity by analysing deformation patterns generated by intrinsic mechanical stress within the liver parenchyma [25].

Unlike conventional ultrasound, elastography provides additional information regarding liver stiffness, which correlates with the degree of fibrosis [26].

The Liver Fibrosis Index (LFI) was calculated using parameters derived from strain elastography. Fibrosis grading was performed according to established cut-off values:

- **F0:** < 1.92
- **F1:** 1.92–2.05
- **F2:** 2.05–2.28
- **F3:** 2.28–2.56
- **F4:** > 2.56

These grading thresholds have been described in previous elastographic validation studies and provide a semi-quantitative assessment of fibrosis severity [25,27].

All examinations were performed by experienced radiologists to minimize inter-observer variability. Patients were examined in the supine position with appropriate breath-hold instructions to improve image acquisition and reproducibility.

Data Management and Statistical Analysis
Data collected from clinical, laboratory, and imaging assessments were entered into a structured master chart using Microsoft Excel. All records were cross-verified to ensure completeness and accuracy prior to statistical analysis.
Statistical analysis was performed using:

- Microsoft Excel
- Epi Info online

Descriptive statistics were used to summarize demographic and clinical characteristics. Categorical variables were expressed as frequencies and percentages. The Pearson chi-square test was applied to assess associations between categorical variables.

For dichotomous outcomes, the Mantel–Haenszel Odds Ratio (OR) with 95% Confidence Interval (CI) was calculated to determine the strength of association between T2DM-related factors and presence or severity of MASLD and fibrosis. A p-value of <0.05 was considered statistically significant.

Ethical Considerations
The study protocol was reviewed and approved by the Institutional Scientific and Ethical Committee. All participants (or their relatives where applicable) were informed about the study objectives, procedures, potential benefits, and minimal risks involved.

Written informed consent was obtained in English, Hindi, or Marathi as per participant preference. For illiterate participants, consent was obtained in the presence of an impartial witness not directly involved in the study.

Confidentiality of patient information was strictly maintained throughout the study period. Data were anonymized during analysis to ensure privacy and ethical compliance in accordance with biomedical research guidelines [28].

RESULTS
A total of 150 patients with Type 2 Diabetes Mellitus (T2DM) were evaluated for Metabolic dysfunction associated steatotic liver disease (MASLD) using conventional ultrasonography and Real Time Hepatic Elastography (RTHE).

Baseline Characteristics
Most patients were in the middle to older age groups. Nearly two-thirds (62%) were between 46 and 65 years of age, reflecting the typical demographic profile of T2DM.

Table 1: Age Distribution of Study Participants (n = 150)

Age Group (Years)	Number	Percentage
36–45	35	23.3%
46–55	47	31.3%
56–65	46	30.7%
≥66	22	14.7%
Total	**150**	**100%**

A male predominance was observed, with males constituting 58.7% of the study population.

Regarding duration of diabetes, the majority (65.3%) had diabetes for less than 5 years, suggesting that hepatic involvement may begin early in the course of T2DM.

Body Mass Index (BMI) analysis showed that 60.6% of patients were either overweight or obese, reinforcing the metabolic link between adiposity and MASLD.

Prevalence of MASLD on Conventional Ultrasonography

Table 2: MASLD on Ultrasonography

MASLD on USG	Number	Percentage
Present	88	58.7%
Absent	62	41.3%
Total	**150**	**100%**

MASLD was detected in **58.7%** of diabetic patients on conventional ultrasound. This highlights the high burden of fatty liver among individuals with T2DM.

Fibrosis Assessment by Real Time Hepatic Elastography (RTHE)
RTHE was used to assess liver stiffness and grade fibrosis.

Table 3: Fibrosis Staging on RTHE

RTHE Grade	Number	Percentage
F0	80	53.3%
F1	6	4.0%
F2	9	6.0%
F3	15	10.0%
F4	40	26.7%
Total	**150**	**100%**

More than half of the patients (53.3%) had no fibrosis (F0). However, a significant proportion showed advanced fibrosis: 26.7% were classified as F4, indicating severe fibrosis. When combined, stages F3 and F4 accounted for 36.7% of the study population, suggesting a substantial burden of advanced liver disease in diabetic patients.

MASLD Fibrosis Score
Laboratory-based fibrosis scoring showed that the majority of patients had biochemical evidence suggestive of fibrosis.

Table 4: MASLD Fibrosis Score Distribution

Fibrosis Score Category	Number	Percentage
No fibrosis	4	2.7%
Indeterminate	35	23.3%
Definite fibrosis	111	74.0%
Total	**150**	**100%**

Based on fibrosis scoring, 74% of patients fell into the definite fibrosis category, while only 2.7% showed no evidence of fibrosis.

Association Between Conventional USG and RTHE

Table 5: Association Between MASLD on USG and RTHE

RTHE Grade	USG Present	USG Absent	Total
F0	37	43	80
F1–F4	51	19	70
Total	**88**	**62**	**150**

Chi-square = 16.86, p = 0.002
A statistically significant association was observed between findings on conventional ultrasonography and RTHE (p = 0.002).

Notably, some patients classified as F0 on RTHE still showed fatty changes on ultrasound, indicating that steatosis can be present without measurable fibrosis. Conversely, higher RTHE grades were more frequently associated with positive ultrasound findings.

Association Between RTHE and MASLD Fibrosis Score
When RTHE findings were compared with the MASLD fibrosis score, no statistically significant association was observed (Chi-square = 8.27, p = 0.41).

Although most patients with higher RTHE grades were categorized as having definite fibrosis on scoring, considerable overlap existed across categories. This suggests that biochemical scoring systems and elastography may reflect different aspects of liver pathology.

DISCUSSION
The present study highlights the substantial burden of Metabolic dysfunction associated steatotic liver disease (MASLD) among patients with Type 2 Diabetes Mellitus (T2DM), reinforcing the concept that MASLD represents the hepatic manifestation of metabolic dysfunction. In our cohort, 58.7% of diabetic patients demonstrated fatty liver changes on conventional ultrasonography. This prevalence is consistent with global data reporting MASLD in 50–70% of individuals with T2DM [29,30]. The close association between insulin resistance, hyperglycaemia, and hepatic lipid accumulation explains this high coexistence [31].

Demographic and Metabolic Profile
The majority of our patients were between 46 and 65 years of age, reflecting the peak age group for T2DM and its metabolic complications. Previous epidemiological studies have shown that MASLD prevalence increases with age, particularly in patients with long-standing metabolic risk factors [32]. A male predominance (58.7%) was observed in our study, which aligns with earlier observations suggesting higher MASLD prevalence in men, possibly due to differences in fat distribution and hormonal influences [33].

More than 60% of our patients were overweight or obese, further supporting the strong relationship between adiposity and hepatic steatosis. Obesity contributes to increased free fatty acid flux to the liver, mitochondrial dysfunction, and oxidative stress, thereby accelerating disease progression from simple steatosis to fibrosis [34,35]. This metabolic background likely explains the significant burden of advanced fibrosis seen in our cohort.

Prevalence of MASLD in T2DM
The detection of MASLD in nearly three-fifths of our diabetic population underscores the importance of routine hepatic evaluation in T2DM. Several longitudinal studies have shown that T2DM not only increases the risk of developing MASLD but also accelerates its progression to advanced fibrosis and cirrhosis [36]. Targher et al. demonstrated that diabetic patients with MASLD have a significantly higher risk of liver-related mortality compared to non-diabetic individuals [37].

In our study, MASLD was detected using conventional ultrasonography, which remains a practical screening tool in clinical settings. Although ultrasound is operator-dependent and less sensitive for mild steatosis, it provides a reliable first-line assessment in resource-limited environments [38].

Fibrosis Assessment by Real Time Hepatic Elastography
A notable finding in our study was the distribution of fibrosis grades on Real Time Hepatic Elastography (RTHE). While 53.3% of patients were classified as F0, a concerning 36.7% demonstrated advanced fibrosis (F3–F4), including 26.7% in the F4 category. This proportion is clinically significant, as advanced fibrosis is the strongest predictor of liver-related morbidity and mortality in MASLD [39].

Diabetes has been independently associated with faster fibrosis progression. Hyperglycaemia promotes hepatic stellate cell activation and collagen deposition, while chronic inflammation further drives fibrogenesis [40]. Large cohort studies have confirmed that T2DM is a key determinant of advanced fibrosis, independent of obesity and other metabolic factors [41]. The high percentage of severe fibrosis observed in our population may reflect delayed diagnosis, poor glycaemic control, or prolonged metabolic stress. It emphasizes the need for early, non-invasive fibrosis assessment in diabetic patients, even when they are asymptomatic.

Comparison Between Conventional Ultrasonography and RTHE
A statistically significant association ($p = 0.002$) was found between conventional ultrasonography and RTHE findings. Patients with higher elastography grades were more likely to have fatty liver detected on ultrasound. However, discrepancies were observed, with some patients demonstrating steatosis on ultrasound but no fibrosis on RTHE. This is expected, as steatosis and fibrosis represent different stages within the MASLD spectrum [42].

Ultrasound detects fatty infiltration but cannot reliably stage fibrosis. In contrast, elastography evaluates liver stiffness, which correlates with fibrotic changes [43]. The significant correlation in our study supports the complementary role of these modalities in comprehensive liver assessment.

MASLD Fibrosis Score and Its Correlation
The MASLD fibrosis score categorized 74% of patients as having definite fibrosis. However, when compared with RTHE findings, no statistically significant association was observed ($p = 0.41$). This lack of strong correlation may be attributed to the inherent differences between biochemical scoring systems and imaging-based stiffness measurements.

Serum-based fibrosis scores rely on indirect markers such as platelet count, transaminases, and albumin levels. These parameters may be influenced by factors unrelated to fibrosis severity, including systemic inflammation and glycaemic status [44]. Several studies have noted that while fibrosis scores are useful for ruling out advanced disease, they may overestimate fibrosis in certain populations [45].

Our findings suggest that RTHE may provide additional structural information beyond biochemical indices, particularly in diabetic patients where metabolic abnormalities may confound laboratory parameters.

Clinical Implications
The coexistence of T2DM and MASLD significantly increases the risk of cardiovascular disease, liver-related complications, and overall mortality [46]. Advanced fibrosis, rather than steatosis alone, is the critical determinant of prognosis [47]. The identification of nearly one-third of patients with advanced fibrosis in our study highlights an urgent need for systematic screening strategies in diabetic clinics.

Early detection allows for aggressive risk factor modification, including weight reduction, improved glycaemic control, lipid management, and lifestyle intervention [48]. Studies have shown that sustained weight loss and optimal metabolic control can reduce hepatic fat content and may even lead to regression of fibrosis in early stages [49,50].

Strengths and Limitations
A key strength of this study is the combined use of conventional ultrasonography, RTHE, and biochemical fibrosis scoring in a defined diabetic population. This multi-modal approach provides a more comprehensive assessment of hepatic involvement.

However, the cross-sectional design limits causal inference. Liver biopsy, the reference standard for fibrosis staging, was not performed due to ethical and practical considerations. Nonetheless, non-invasive techniques are increasingly recognized as acceptable alternatives for fibrosis assessment in clinical practice [51].

CONCLUSION OF DISCUSSION
In conclusion, our study demonstrates a high prevalence of MASLD among patients with Type 2 Diabetes Mellitus, with a significant proportion showing advanced fibrosis on Real Time Hepatic Elastography. The findings reaffirm that T2DM is not only a metabolic disorder but also a strong driver of progressive liver disease.

Routine screening for MASLD and fibrosis in diabetic patients should be considered, particularly in those with obesity or long-standing disease. Incorporating non-invasive modalities such as RTHE into clinical practice may help identify high-risk individuals early and guide timely intervention to prevent long-term hepatic complications.

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