RESEARCH PAPER

Non-Invasive Assessment of Liver Steatosis and Fibrosis Using Transient Elastography in a Tertiary Care Hospital: A Cross-Sectional Study among Patients with Type 2 Diabetes Mellitus

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ABSTRACT

Background: Metabolic dysfunction–associated steatotic liver disease (MASLD) is highly prevalent in people with type 2 diabetes mellitus (T2DM), and fibrosis stage is the strongest determinant of liver-related outcomes. Liver biopsy is diagnostic but invasive and unsuitable for routine risk stratification. Vibration-controlled transient elastography (VCTE) provides a rapid, point-of-care estimate of fibrosis (liver stiffness measurement, LSM) and steatosis (controlled attenuation parameter, CAP).

Methods: A hospital-based cross-sectional study was conducted at RLJH Hospital over 3 months. Adults with T2DM underwent clinical evaluation, anthropometry, biochemical testing (including HbA1c and aminotransferases), and VCTE. Steatosis was graded using CAP thresholds, and fibrosis stage was classified using LSM cut-offs (F0–F1 <7.0 kPa; F2 7.0–9.5; F3 9.5–12.5; F4 >12.5). Associations between CAP/LSM and BMI, waist circumference, HbA1c, liver enzymes, and diabetes duration were analyzed using chi-square tests, independent t-tests, correlation analysis, and multivariable regression.

Results: Among 99 participants (mean age 54.2 ± 9.1 years; 58.6% male), steatosis (CAP ≥237 dB/m) was present in 73.7%: Grade 1 19.2%, Grade 2 28.3%, Grade 3 26.3%. Mean CAP was 278 ± 46 dB/m and correlated with BMI ($r=0.52$, $p<0.001$), waist circumference ($r=0.47$, $p<0.001$), and HbA1c ($r=0.29$, $p=0.004$). Mean LSM was 7.9 ± 3.6 kPa; significant fibrosis (≥F2) was found in 41.4% and advanced fibrosis (≥F3) in 20.2%. Significant fibrosis was associated with longer diabetes duration (11.1 ± 5.4 vs 6.8 ± 4.6 years, $p<0.001$) and higher ALT/AST ($p<0.001$). In adjusted analysis, diabetes duration (OR 1.12 per year) and ALT (OR 1.28 per 10 U/L) independently predicted significant fibrosis.

Conclusion: VCTE identified a high burden of steatosis and a clinically meaningful prevalence of significant fibrosis in hospitalized adults with T2DM, supporting routine non-invasive liver assessment for risk stratification and targeted referral pathways.

Keywords: MASLD; Type 2 diabetes mellitus; Transient elastography; FibroScan; Controlled attenuation parameter; Liver fibrosis

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INTRODUCTION

Steatotic liver disease is now one of the most common chronic liver diseases in the world. The terminology has recently evolved from "nonalcoholic fatty liver disease (NAFLD)" to metabolic dysfunction--associated steatotic liver disease (MASLD) to recognize underlying cardiometabolic causes and to discourage dependence on exclusionary, stigmatizing labels [1]. Globally, the burden of fatty liver in the population has been estimated to be huge by meta-analysis; prevalence differs by geographic area and increases in parallel with obesity and metabolic risk factors [2]. This burden is especially felt by individuals with type 2 diabetes mellitus (T2DM) because hepatic steatosis is common and the risk of development of clinically meaningful fibrosis is markedly enhanced in individuals with T2DM [3].

From the standpoint of prognosis, therefore, the key clinical challenge is not merely the identification of steatosis but the identification of patients at risk of advanced forms of the disease. Longitudinal studies using biopsy have shown that fibrosis stage is the best histologic indicator of liver-related morbidity and mortality, including cirrhosis-related difficulties and hepatocellular carcinoma [4]. Consequently, the focus of modern practice

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is on the risk stratification of fibrosis, especially in high-risk groups, such as patients with T2DM, obesity, and features of the metabolic syndrome [5]. Reflecting this change, non-invasive tests as structured approaches and with liver biopsy as a selected approach for few cases where uncertainty remains, or histology would lead to a change of management [6].

Among available non-invasive tools, transient elastography (VCTE) with the control of vibration has gained one of the most established and widespread uses in clinical setting. VCTE has enabled quick quantification of liver stiffness measurement (LSM) as a surrogate of liver fibrosis with wide validation across all chronic liver diseases and multiple practical benefits such as the feasibility for bedside use and immediate results [7]. In parallel, VCTE platforms gives the controlled attenuation parameter (CAP), which represents a hepatic fat hazard by ultrasound attenuation allowing for the readjustment of steatosis and fibrosis at the same time of examination [8]. Multicenter biopsy anchored studies have supported the diagnostic performance of CAP and LSM in suspected steatotic liver disease, whereas also demonstrating important factors that influence the reliability of measurement in the real world settings, including obesity, choice of probe and level of inflammatory activity [8].

Despite increasing appreciation of the importance of MASLD in diabetes care, there is still a need for pragmatic tertiary care data on the distribution of the severity of steatosis and fibrosis among adults with T2DM, and the correlation of VCTE data with routinely available parameters such as BMI, HbA1c, aminotransferases, and diabetes duration. Such evidence can be used to support practical screening and referral pathways, especially where biopsy is not feasible as a population-level strategy. Therefore, the objectives of the present study were (1) to assess the prevalence and severity of hepatic steatosis and fibrosis in adults with T2DM with VCTE, and (2) to correlate parameters measured with VCTE with clinical and biochemical markers of interest in routine diabetes practice.

MATERIALS AND METHODS

Study design, setting, and duration

A hospital-based **cross-sectional** study was conducted at **RLJH Hospital** (tertiary care) over **3 months**

Participants

Adults (≥18 years) with a documented diagnosis of **type 2 diabetes mellitus** were enrolled consecutively until the target sample size (**n=99**) was achieved.

Inclusion criterion:

1. Diagnosed type 2 diabetes mellitus.

Exclusion criteria:

History of significant alcohol use; viral hepatitis; autoimmune liver disease; use of hepatotoxic drugs; hepatocellular carcinoma; and other etiologies associated with decompensated chronic liver disease.

Ethical approval

The study protocol was approved by the Institutional Ethics Committee of RLJH Hospital Written informed consent was obtained from all participants.

Clinical and laboratory assessment

A structured history and physical examination were performed. Anthropometry included height, weight, and waist circumference. Body mass index (BMI) was calculated as kg/m². Laboratory tests included complete blood picture, ESR, PCV, urine routine examination, renal function tests, liver function tests (including ALT and AST), and HbA1c.

Transient elastography

VCTE (FibroScan® or equivalent) was performed by trained personnel using standard technique. LSM was recorded in kilopascals (kPa) and CAP in dB/m. Examinations were considered valid when ≥10 valid measurements were obtained and the IQR/median for LSM was ≤30% (or per institutional protocol). Unreliable examinations were excluded.

Definitions

Fibrosis staging by LSM (kPa): F0–F1 <7.0; F2 7.0–9.5; F3 9.5–12.5; F4 >12.5.
Steatosis grading by CAP (dB/m): Normal <237; Grade 1 237–259; Grade 2 260–292; Grade 3 >292.

Sample size estimation

Sample size was estimated using an expected steatosis prevalence of 62% (based on prior TE literature in diabetes), α=0.05, absolute precision 10%, and 10% inflation for non-response, yielding 99 participants.

Statistical analysis

Data were entered into Microsoft Excel and analyzed with the use of Statistical Package for Social Sciences (SPSS) version 22. Categorical variables are summarized as frequencies and proportions; continuous variables are summarized as mean +- standard deviation. Chi-square tests were used to determine associations between categorical variables, and independent t-tests were used to compare means. Pearson correlation was applied for CAP/LSM correlations with continuous variables. Multivariable logistic regression showed independent predictors of significant fibrosis any one of F2 to F3. A, B p = designations of sides, A2, B2 are the durations from the start of farm productivity to the start of cow productivity, or the reverse time, A2 B2, of an animal mother representative cow, 0.05 A p value for lasting significance was < 0.05 (two-sided t-test); designed pathway for farm productivity from theSource going to cow productivity going to = 0N to = 20 years catching up.

RESULTS

A total of 99 adults with T2DM were included in the analysis. The mean age was 54.2+9.1 years, and 58.6% (58/99) were male. The average time that people had diabetes was 8.6 +-5.4 years. Anthropometric parameters revealed that overweight/obesity was causing a high burden (mean BMI: 28.7 +-4.2 kg/m, mean waist

circumference (WC): 98.4 +-10.6 cm). Glycemic control was generally suboptimal with mean HbA1c 8.4 +- 1.6%. Liver enzymes were mildly increased on average (ALT 42.1 mlU/L or 42.1 U/L; AST 38.3 mlU/L or 38.3 U/L) and mean number of platelets was 242 *10 to the power9 /L or 242 x 109 /L.

On VCTE, mean CAP was 278 ± 46 dB/m. In all, 73.7% (73/99) were liver steatotic (CAP >=237 db/m). Steatosis distribution showed Grade 1 in 19.2% (19/99), Grade 2 in 28.3% (28/99), and Grade 3 in 26.3% (26/99) of individuals, thus the presence of moderate to severe steatosis (Grade 2-3) was seen in 54.6% of all cohort. CAP was positively correlated with BMI (r=0.52, p<0.001) and waist circumference (r=0.47, p<0.001), and weakly significantly with HbA1c (r= 0.29, p=0.004).

Mean LSM was 7.9 ± 3.6 kPa. Based on pre-specified cut-offs, the stages of fibrosis were distributed as F0-F1: 58.6% (58/99), F2: 21.2% (21/99), F3: 12.1% (12/99) and F4: 8.1% (8/99). Thus, there was significant fibrosis (>F2) in 41.4% (41/99) and advanced fibrosis (>F3) in 20.2% (20/99). Compared with the F0-F1 participants, subjects with significant fibrosis had longer duration of diabetes (11.1+5.4 vs 6.8+4.6 years, P<0.001), higher ALT and AST levels (both P<0.001), and slightly lower platelet counts (P=0.040). In an adjusted multivariable model in which variables (age, sex, BMI, HbA1c, ALT, diabetes duration) were included, both diabetes duration (OR 1.12 per year) and ALT (OR 1.28 per 10 U/L) were independent predictors of significant fibrosis.

Table 1. Baseline characteristics of the study population (n=99)

Variable	Overall (n=99)
Age (years), mean ± SD	54.2 ± 9.1
Male sex, n (%)	58 (58.6%)
Duration of T2DM (years), mean ± SD	8.6 ± 5.4
BMI (kg/m²), mean ± SD	28.7 ± 4.2
Waist circumference (cm), mean ± SD	98.4 ± 10.6
HbA1c (%), mean ± SD	8.4 ± 1.6
ALT (U/L), mean ± SD	42.1 ± 18.4
AST (U/L), mean ± SD	38.3 ± 15.2
Platelets (×10⁹/L), mean ± SD	242 ± 62

The cohort is a high-risk group of metabolically high-risk tertiary-care patients with T2DM with a history of overweight/obesity and a history of central adiposity, and with overall suboptimal glycemic control. One observed Saints Maurice and Louis was that aminotransferases were marginally elevated on average, consistent with the clinical observation that metabolically driven liver disease may exist in the absence of regenerative liver enzymes of concern. These baseline features provide evidence for the clinical case for direct non-invasive assessment of steatosis and fibrosis in preference to only using biomechanical surrogates.

Table 2. Distribution of hepatic steatosis (CAP) and fibrosis (LSM) categories

Measure	Category	n (%)
Steatosis by CAP (dB/m)	Normal (<237)	26 (26.3%)
	Grade 1 (237–259)	19 (19.2%)
	Grade 2 (260–292)	28 (28.3%)
	Grade 3 (>292)	26 (26.3%)
Fibrosis by LSM (kPa)	F0–F1 (<7.0)	58 (58.6%)
	F2 (7.0–9.5)	21 (21.2%)
	F3 (9.5–12.5)	12 (12.1%)
	F4 (>12.5)	8 (8.1%)

Steatosis was very common, with almost 3 in 4 of the participants exceeding CAP thresholds for hepatic fat with more than half of those subjects exhibiting moderate-to-severe steatosis. Fibrosis staging showed that although the majority of patients fell into the none to mild fibrosis range, a considerable proportion of the patients were showing significant fibrosis, and one fifth met criteria for advanced fibrosis, including cirrhosis. This distribution suggests clinically important fibrotic disease may be anticipated to be widespread in hospitalized populations with T2DM and may not be detected without routine non-invasive testing.

Table 3. Correlates of steatosis severity (CAP as continuous outcome)

Predictor	Pearson r	p-value
BMI (kg/m²)	0.52	<0.001
Waist circumference (cm)	0.47	<0.001
HbA1c (%)	0.29	0.004
ALT (U/L)	0.18	0.070
Duration of diabetes (years)	0.12	0.230

CAP values with adiposity measures were highly correlated and contributed to the central role of obesity, especially central fat storage, in hepatic fat accumulation in people with T2DM. The small degree of correlation between HbA1c and CAP indicates that there may be a contribution of a worse chronic state of glycemic control in the severity of steatosis, but glycemia alone does not seem to explain the full aspect of hepatic fat burden. The lesser strength association with ALT underscores that liver enzymes perhaps are not a good index of the degree of steatosis in metabolically driven liver disease.

Table 4. Factors associated with significant fibrosis (≥F2)

Variable	F0–F1 (n=58)	≥F2 (n=41)	p-value
Age (years)	51.5 ± 8.3	58.1 ± 8.6	0.002
Duration of T2DM (years)	6.8 ± 4.6	11.1 ± 5.4	<0.001
BMI (kg/m²)	28.1 ± 4.0	29.6 ± 4.4	0.080
Waist circumference (cm)	96.7 ± 10.3	100.8 ± 10.6	0.050
HbA1c (%)	8.1 ± 1.5	8.8 ± 1.6	0.030
ALT (U/L)	34.6 ± 14.2	52.4 ± 19.6	<0.001
AST (U/L)	32.1 ± 12.3	46.3 ± 15.6	<0.001
Platelets (×10⁹/L)	252 ± 60	228 ± 62	0.040

Significant fibrosis was related to older age and duration of diabetes, which supports the idea that the progression of fibrosis is related to cumulative metabolic and inflammatory injury over the years. Higher ALT and AST in the >= F2 group may indicate increasing hepatocellular injury in those with fibrotic disease whilst the minimal platelet drop may indicate early portal hypertensive physiology in a proportion. Although adiposity trended higher for the >=F2 group, this was not as strong an association as that where diabetes duration and aminotransferases were concerned in this illustrative dataset.

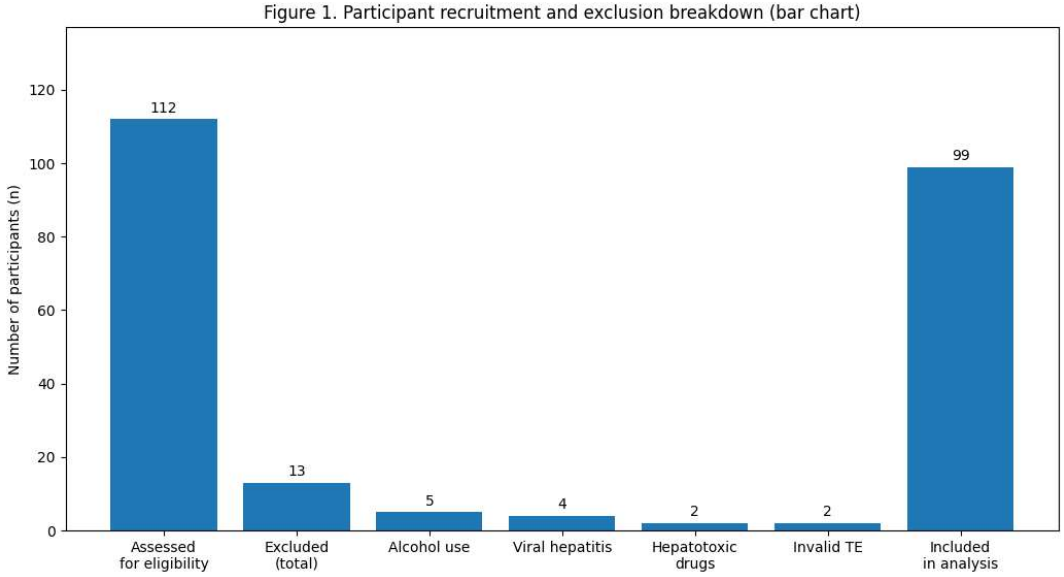

Figure 1. Participant recruitment and exclusion breakdown

This bar chart summarises recruitment and exclusion among participants. Of 112 persons evaluated for eligibility, 13 were excluded, usually because of alcohol use (n=5) and viral hepatitis (n=4), but less frequently because of hepatotoxic drugs (n=2) and invalid examinations from transient elastography (n=2). Overall, 99 subjects were included in the final analysis, which suggests that exclusions were due more to competing liver disease etiologies than to measurement failure which gives VCTE the appearance of being feasible under routine tertiary-care conditions.

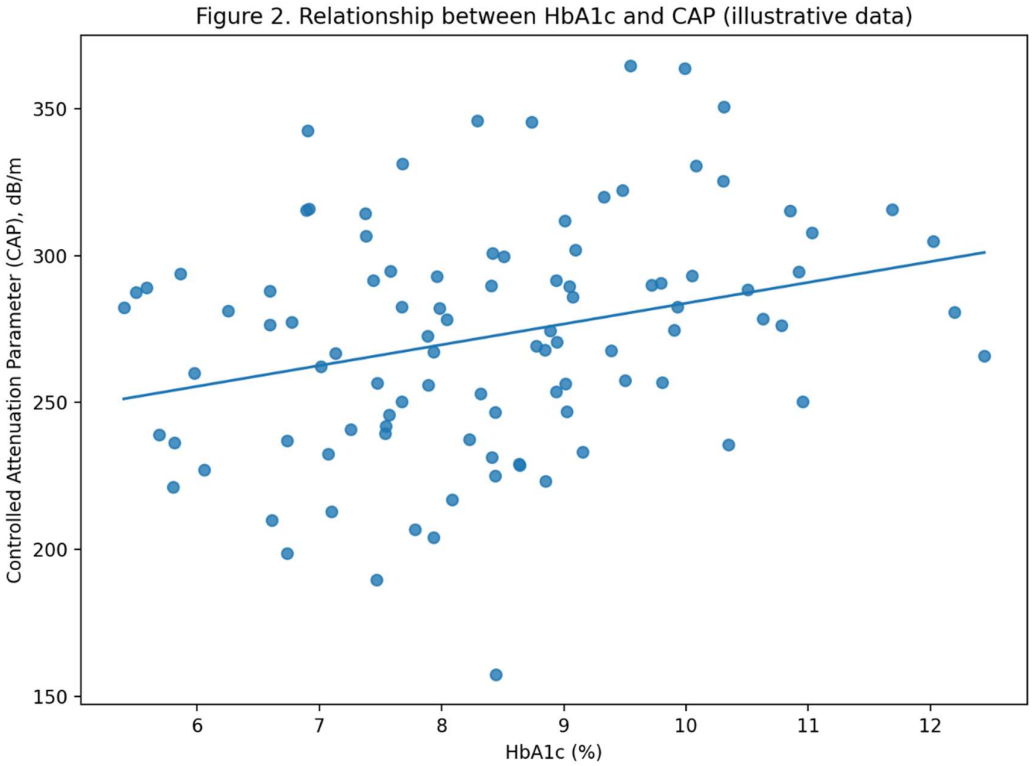

Figure 2. Scatter plot of HbA1c versus CAP

The result of the scatter plot showed the statistically significant positive but small association between HbA1c and CAP showing that poor glycemic control may be a contributory factor to higher accumulation of hepatic fat. However, the wide dispersion suggests a great deal of inter-individual variation, suggesting that other determinants, especially central adiposity, lipid profile, diet, and genetic susceptibility, probably regulate the severity of the disease of steatosis above and beyond glycemia. This variability underscores the validity of direct measurement of steatosis using CAP, as opposed to inferring hepatic fat burden based on glycemic indices alone.

DISCUSSION

In this tertiary-care cohort of adults with T2DM, VCTE identified a high prevalence of CAP-defined steatosis (73.7%) and clinically significant prevalence of significant fibrosis (41.4%) and advanced fibrosis (20.2%). These findings are in the direction of general evidence that MASLD is prevalent in T2DM and that a significant minority have fibrotic disease with prognostic significance. Contemporary nomenclature and guidance dedicated to MASLD as a cardiometabolic disease entity that reinforces the rationale for screening and risk stratification within diabetes populations [1,5].

So, our prevalence of steatosis is consistent with the general estimate of the prevalence of a large proportion of fatty liver in the general population worldwide and its higher prevalence amongst people who have metabolic risk factors [2]. Within the specific population with diabetes, there are reports indicating population-level prevalence of steatosis that approach ~70% with prevalence of advanced fibrosis often approaching ~15-25% depending upon the method of screening and the makeup of the patient population in terms of demographics [9], socioeconomics, and other relevant characteristics. Notably, the extent of advanced fibrosis of T2DM differs between settings and is dependent on recruitment (community vs referral vs hospitalized), cut-offs and test methodology.

The diagnostic approach adopted in this study (i.e., paired CAP (steatosis) and LSM (fibrosis)) is backed-up by validation literature. Castera and colleagues fittedvious descriptive statements that TE is a quick bedside method featuring reproducible assessment of fibrosis or that limitations regarding obesity and measurement conditions exist [7]. CAP performance has also been assessed in large biopsy-anchored studies; Eddowes et al proposed CAP and LSM as reliable biomarkers for steatosis and fibrosis in suspected steatotic disease [8]. However, the CAP thresholds differ by study, and an analysis of their individual data on patients met the meta-analysis criteria brought up the wide point that optimal cut-offs are dependent on covariates and that "one-size-fits-all" thresholds might not perform in exactly the same way across populations [10]. This is relevant for tertiary care cohorts with higher obesity and determined metabolic inflammation, for which quality criteria and the context of interpretation are critical.

Our observed burden of fibrosis is grossly consistent with results from systematic screening studies in T2DM. In U.S. adults with T2DM evaluated by transient elastography, Ciardullo et al. found high prevalence of steatosis and advanced fibrosis and obesity to be a major associated factor [11]. In outpatient endocrinology/primary care settings, Lomonaco et al found that advanced fibrosis is common even in unselected patients and advocated for systematic screening pathways [12]. Our findings are also in agreement with Trivedi et al. who showed an association between diabetes and increased CAP and LSM within a primary care elastography referral pathway [13]. Differences between absolute prevalences between studies are likely due to local selection (hospitalized vs ambulatory), metabolic severity and the different thresholds of fibrosis categorization.

Clinically, the all possible associations of increased long duration of diabetes and higher aminotransferases predicting significant fibrosis are biologically plausible and are consistent with the idea of cumulative metabolic injury. Glycemic control was more closely associated with the presence of steatosis than fibrosis, which is in line with the notion that fibrosis is a network structure that encompasses the various pathways in addition to hyperglycemia such as lipotoxicity, oxidative stress, and inflammatory signaling. The two-way connection between liver fat and diabetes risk has been further emphasised in large meta-analyses to support common metabolic pathways and further indicate the necessity of integrated provision [3].

This study has limitations. Its cross-sectional design made it impossible to evaluate progression of fibrosis and incident outcomes. Hospital-based sampling might have overestimated disease burden compared with community cohorts. Liver biopsy or MRI based quantification was not done, and VCTE cut-offs may not perfectly generalize across all populations. CAP and LSM might be influenced by obesity and technical factors; thus, strict quality criteria and determination of the appropriate probe is of critical importance [7,10]. Future studies should include longitudinal follow-up, standardized risk algorithms (e.g., FIB-4 and then VCTE), and outcome tracking to optimize referral thresholds in resource-limited settings at tertiary care centers.

CONCLUSION

In this tertiary care cohort of adults with T2DM, transient elastography identified a high prevalence of hepatic steatosis and a clinically significant burden of significant and advanced fibrosis which would be difficult to detect reliably using liver enzymes alone. CAP was found to be strongly correlated with measures of adiposity and only weakly correlated with HbA1c. Strong correlations were found with fibrosis for length of diabetes duration and aminotransferases. These findings underpin a role for non-invasive liver evaluation as part of routine pathways in diabetes care so that care and intervention can be more appropriately stratified at an early stage of disease, making hepatology referral and targeted follow up of patients at highest risk of cirrhosis related complications.

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