

Correlation of Liver Elastography with Biochemical Parameters in Patients of Type II Diabetes Mellitus

Surabhi Kumari¹, Rahul Arya², Diksha Mahajan³, Meraj Rasool⁴

¹Senior Resident, Department of General Medicine, Indira Gandhi Institute of Medical Science (IGIMS), Patna, Bihar, India

²Associate Professor, Department of General Medicine, T.S. Misra Medical College and Hospital, Lucknow, U.P. India

³Junior resident, Department of General Medicine, T.S. Misra Medical College and Hospital, Lucknow, U.P. India

⁴Associate Professor, Department of General Medicine, T.S. Misra Medical College and Hospital, Lucknow, U.P. India

Received: 14-07-2025 / Revised: 08-08-2025 / Accepted: 14-09-2025

Corresponding Author: Dr. Meraj Rasool

Conflict of interest: Nil

Abstract:

Background: Particularly in those without conventional risk factors for cirrhosis, non-alcoholic fatty liver disease (NAFLD) is becoming more widely acknowledged as a major contributor to chronic liver problem. It is widely known that T2DM increases the risk of developing non-alcoholic fatty liver disease (NAFLD). Non-invasive assessment of liver stiffness using elastography offers the potential for early detection of liver disease in diabetic patients with fatty liver. The purpose of this study was to investigate the relationship between several biochemical markers and liver stiffness as determined by elastography in patients with type 2 diabetes mellitus.

Methods: 305 patients with T2DM, aged above 18 years, participated in a cross-sectional study. All of the patients qualified for both liver elastography and biochemical analysis. Liver stiffness measurements obtained via elastography were analysed in relation to clinical and laboratory findings.

Results: A considerable proportion of patients with T2DM and fatty liver demonstrated advanced fibrosis on elastography. Higher stages of fibrosis (F3/F4) were significantly associated with increased BMI, AST, ALT, fasting blood glucose, and triglyceride levels.

Conclusion: A notable prevalence of advanced liver fibrosis was observed among diabetic patients with NAFLD. Liver elastography proved to be a reliable, non-invasive modality for evaluating fibrosis severity in patients with T2DM, supporting its use as a screening tool in this high-risk population.

Keywords: Type II Diabetes Mellitus, Fatty liver, Fibrosis, Liver Elastography.

This is an Open Access article that uses a funding model which does not charge readers or their institutions for access and distributed under the terms of the Creative Commons Attribution License (<http://creativecommons.org/licenses/by/4.0>) and the Budapest Open Access Initiative (<http://www.budapestopenaccessinitiative.org/read>), which permit unrestricted use, distribution, and reproduction in any medium, provided original work is properly credited.

Introduction

Type 2 diabetes mellitus (T2DM) accounts for 90 % of all diabetes cases and affects more than 23 million Americans and 250 million people worldwide [1]. By 2030, prevalence is predicted to increase from 31.7 million to 79.4 million in India alone [2]. Beyond the classic triad of neuropathy, retinopathy and nephropathy, hepatic sequelae have come into focus. About 25% of adults worldwide and up to 30% in developed countries are currently afflicted with non-alcoholic fatty liver disease (NAFLD), which includes simple steatosis, non-alcoholic steatohepatitis (NASH), fibrosis, cirrhosis, and hepatocellular cancer [3]. Metabolic comorbidities such as obesity, dyslipidemia and T2DM both drive and are driven by NAFLD, with each condition doubling the risk of the other [4].

Prognosis hinges on fibrosis progression rather than steatosis alone. Yet ultrasonography lacks sensitivity for early fibrosis, while liver biopsy—although definitive—is invasive, costly and unsuitable for large-scale screening [5]. Vibration-controlled transient elastography (TE) offers a rapid, non-invasive alternative and achieves an area under the receiver-operating-characteristic curve of 0.93 for detecting advanced fibrosis [6]. Several guidelines now propose universal TE screening for T2DM, but limited availability and cost constrain uptake, especially in resource-limited settings. Biochemical scores such as the NAFLD fibrosis score combine age, body-mass index, transaminases, glucose status, platelets and albumin to triage patients, yet their accuracy remains inconsistent [7].

Clarifying how routine laboratory indices correlate with TE-measured stiffness could focus scarce elastography resources on those most likely to harbour significant disease. Accordingly, we assessed the association between liver stiffness (measured by TE) and standard biochemical parameters in adults with T2DM attending a tertiary-care centre in Lucknow, India, and identified independent predictors of advanced fibrosis.

Methods

Study Design: This investigation employed a hospital-based, cross-sectional observational design.

Study Setting: Research activities were carried out in the Department of General Medicine, T. S. Misra Medical College & Hospital, Lucknow, Uttar Pradesh, a tertiary-care center that offers comprehensive diabetes and hepatology services.

Study Duration: Enrolment and data collection spanned 12 months, from January 2024 to January 2025.

Participants: A total of 305 adults (≥ 18 years) with confirmed T2DM were consecutively recruited. Sample size was calculated assuming a 27 % prevalence of advanced fibrosis among diabetics, 5 % absolute precision, and $\alpha = 0.05$.

Inclusion Criteria

- Diagnosed T2DM (per ADA criteria).
- Willingness to provide written informed consent.

Exclusion Criteria

- Significant alcohol intake (> 20 g/day for women, > 30 g/day for men).
- Hepatitis B surface antigen or anti-HCV positivity.
- Pregnancy.
- Known chronic systemic illness (e.g., CHF, CKD).
- Current use of hepatotoxic drugs (e.g., methotrexate, tamoxifen).
- Ultrasonographic evidence of cirrhosis or portal hypertension.

Bias Control: Consecutive sampling minimized selection bias. All vibration-controlled transient elastography (VCTE) examinations were

performed by a single certified operator using the same FibroScan® device and probe (M or XL as appropriate) to limit measurement bias. Potential confounders—age, sex, BMI, and diabetes duration—were adjusted for in multivariable analyses.

Data Collection: Demographic data, anthropometry, diabetes duration, medication history, and fasting laboratory values (glucose, HbA1c, lipid profile, ALT, AST) were recorded on a structured pro-forma.

Procedure: Each participant underwent a standardized assessment protocol that included measurement of height, weight, and blood pressure using calibrated instruments, followed by fasting venous blood collection under aseptic conditions for biochemical analysis in the hospital's NABL-accredited laboratory. Liver stiffness was evaluated by transient elastography after a minimum 3-hour fast, with measurements performed in the supine position over the right lobe. For reliability, at least ten valid measurements with an interquartile range $\leq 30\%$ of the median were required. The liver stiffness cut-off values applied to define fibrosis stages were: F1 > 5.6 kPa, F2 > 6.65 kPa, F3 ≥ 8 kPa, and F4 ≥ 17 kPa.

Statistical Analysis: Data were entered in Microsoft Excel and analysed with SPSS v23.0. Results are presented as mean $\pm$ SD for continuous variables and frequency (%) for categorical variables. Group comparisons employed the independent-samples t-test or one-way ANOVA (continuous data) and χ^2 test (categorical data). Pearson correlation coefficients assessed linear associations between liver stiffness and biochemical parameters. A two-tailed $P < 0.05$ denoted statistical significance.

Baseline and demographic variables: The study enrolled 305 adults with T2DM (mean [SD] age, 54.7 [17.1] years), comprising 169 men (55.4%) and 136 women (44.6%). Age distribution showed 73 participants (23.9%) were 30–45 years, 147 (48.2%) were 46–60 years, and 85 (27.9%) were older than 60 years. Nearly half were obese (BMI ≥ 25 kg/m², 48.9%), whereas 55 (18.0%) were overweight, 68 (22.3%) had normal BMI, and 33 (10.8%) were underweight.

Table 1: Baseline and demographic variables

Variables		No. of cases (n = 305)	Percentage
Age in years	30-45	73	23.9%
	46-60	147	48.2%
	>60	85	27.9%
Mean Age		54.7±17.1 years	
Gender	Male	169	55.4%
	Female	136	44.6%
BMI (kg/m ²)	<18.5 underweight	33	10.8%
	18.5-22.9 Normal	68	22.3%
	23.0-24.9 Overweight	55	18.0%
	≥25 Obese	149	48.9%

Liver Fibrosis Staging by Transient Elastography: Liver-stiffness distribution was: F0 (no fibrosis), 126 patients (41.3%); F1, 73 (23.9%);

F2, 48 (15.7%); F3, 37 (12.2%); and F4 (cirrhosis), 21 (6.9%). Thus, 58 participants (19.0%) had advanced fibrosis (F3 + F4).

Table 2: Liver Fibrosis Staging by Transient Elastography

Fibrosis	No. of cases (n=305)	Percentage
No fibrosis (F0)	126	41.3%
Mild fibrosis (F1)	73	23.9%
Moderate Fibrosis (F2)	48	15.7%
Severe Fibrosis (F3)	37	12.2%
Cirrhosis (F4)	21	6.9%

Association With Duration of Diabetes and Body Mass Index: Advanced fibrosis increased with longer diabetes duration: among those with >10

years of T2DM, 29.7% were staged F3 and 47.6% F4.

Table 3: Cross-tabulation of the duration of diabetes with liver stiffness

Duration of Diabetes	Liver Stiffness					p- value
	F0 (n=126)	F1 (n=73)	F2 (n=48)	F3 (n=37)	F4 (n=21)	
Newly Diagnosed	10 (7.9%)	2 (2.7%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	
<1 year	16(12.7%)	4 (5.5%)	7 (14.5%)	0 (0.0%)	0 (0.0%)	
1 to 5 years	58 (46.0%)	29 (39.7%)	15 (31.3%)	17 (45.9%)	4 (19.0%)	<0.001
5 to 10 years	30 (23.8%)	26 (35.6%)	15 (31.3%)	9 (24.3%)	7 (33.3%)	
>10 years	12 (9.5%)	12(16.4%)	11(22.9%)	11(29.7%)	10(47.6%)	

Biochemical Differences (Group I: F0–F2 vs Group II: F3–F4): Compared with patients in Group I (F0–F2), those in Group II (F3–F4) showed markedly higher liver-enzyme activities—ALT 56.4 ± 7.3 U/L vs 37.1 ± 6.2 U/L and AST

46.8 ± 8.4 U/L vs 33.9 ± 5.4 U/L—together with poorer glycemic control, reflected by a mean HbA1c of 9.1 ± 2.0% vs 6.3 ± 1.2% and a greater proportion of fasting plasma glucose > 125 mg/dL (87.9% vs 73.7%).

Table 4: Comparison of the liver function test Between Group 1 and Group 2

Variables		Groups I (F0, F1, F2)	Group II (F3 and F4)	p-value
Liver Function test	Serum ALT (U/L)	37.1±6.2	56.4±7.3	<0.001
	Serum AST (U/L)	33.9±5.4	46.8±8.4	<0.001

Table 5: Comparison of the Glycemic control Between Group 1 and Group 2

Variables		Groups I (F0, F1, F2) (n=247)	Group II (F3 and F4) (n=58)	p-value
Glycemic control	FBS<100mg/dl	11 (4.5%)	0 (0.0%)	0.047
	FBS: 100-125mg/dl	54 (21.9%)	7 (12.1%)	
	FBS>125mg/dl	182 (73.7%)	51 (87.9%)	
HbA1c		6.3±1.2	9.1±2.02	<0.001

Correlation of advanced fibrosis with BMI, age, duration of diabetes and HbA1c: Liver stiffness correlated positively with multiple metabolic and clinical factors: HbA1c ($r = 0.873$), duration of diabetes ($r = 0.681$), age ($r = 0.547$), AST ($r =$

0.632), BMI ($r = 0.412$), ALT ($r = 0.314$), and fasting plasma glucose ($r = 0.297$); by contrast, lipid parameters (HDL-C, LDL-C, total cholesterol) showed no significant association with stiffness.

Table 6: Correlation of advanced fibrosis with BMI, age, duration of diabetes and HbA1c

Parameters	Correlation coefficient	p-value
Age	0.547	<0.001
BMI	0.412	<0.001
HbA1c	0.873	<0.001
Duration of diabetes	0.681	<0.001
AST	0.632	0.012
ALT	0.314	0.006
FBS	0.297	<0.001
HDL	0.093	0.847
TC	0.015	0.398
LDL	0.164	0.494

Discussion

Significant fibrosis as assessed by TE and a high frequency of NAFLD were seen in this research of 305 patients with T2DM. Among all participants, 58.7% exhibited some degree of fibrosis, with 23.9% classified as mild (F1), 15.7% as moderate (F2), 12.1% as severe (F3), and 6.9% as cirrhosis (F4). Advanced fibrosis (F3/F4) was present in 19.0% of cases. These findings are consistent with both Indian and international research utilizing non-invasive assessment techniques, with previous studies reporting advanced fibrosis rates of 27.2% and proportions of F2, F3, and F4 at 17.1%, 12.7%, and 7.8%, respectively [8, 9]. The TE cut-offs in this investigation align closely with those established in prior studies, enabling robust cross-study comparison [9, 10]. Minor differences in advanced fibrosis rates could be attributed to variations in population BMI, glycemic status, and region.

The data emphasize that NAFLD and advanced fibrosis are highly prevalent among Indian patients with T2DM. Nationwide research has found NAFLD prevalence among diabetic patients ranging from 54.3% in males to 60.0% in females, with regional variability between 44.1% and 72.4% [11]. Urban South Indian populations have shown a prevalence of 32.0% [12]. These rates are generally higher than those reported in older studies using ultrasonography, which often underestimates mild steatosis due to lower sensitivity. For example,

previous studies based on abdominal ultrasound have shown NAFLD in 32–62% of T2DM patients [20,30,31]. The higher rates observed in TE-based studies, including ours, likely reflect the greater sensitivity of TE in detecting early and mild steatosis, which can be present when as little as 10% of hepatocytes are infiltrated [24].

Key components of the metabolic syndrome, including increased BMI, longer duration of diabetes, and suboptimal glycemic control, emerged as independent predictors of higher liver stiffness and fibrosis. Nearly half of the cohort was obese, and advanced fibrosis was most frequently observed in those with longer diabetes duration and higher BMI. Among individuals with cirrhosis (F4), 81.0% were classified as obese. These associations are well-documented in previous literature, highlighting obesity, advancing age, poor glycemic control (higher HbA1c), and longer diabetes duration as principal risk factors for fibrosis progression [8, 13]. Additionally, this study found significant correlations between liver stiffness and BMI, age, HbA1c, and diabetes duration, consistent with prior reports [14, 15]. Collectively, these findings reinforce the central role of insulin resistance and metabolic syndrome in the pathogenesis of NAFLD.

Liver enzymes (ALT, AST) were considerably elevated in individuals with advanced fibrosis, according to biochemical study; however, their diagnostic precision was restricted on their own.

Prior research has shown that, while there is a correlation between transaminase levels and fibrosis, normal liver enzyme values do not exclude significant disease [16, 17]. The results here suggest that ALT, despite being independently associated with fibrosis in multivariate models, lacks adequate sensitivity and specificity to serve as a sole screening test for NAFLD or advanced fibrosis, confirming observations from additional studies [18, 19]. Therefore, as recommended in the literature [20, 21], ALT should be interpreted alongside non-invasive imaging modalities such as TE for optimal risk stratification.

This analysis represents one of the few Indian studies to systematically assess both moderate (F2) and advanced (F3/F4) fibrosis in type 2 diabetes using TE. The identification of moderate fibrosis is clinically important, as patients with F2 or greater fibrosis are at elevated risk for liver disease progression and require specialist management [22]. Conversely, individuals with no fibrosis or F1 fibrosis are generally suitable for follow-up in primary care settings. This approach aligns with growing international consensus that moderate fibrosis, especially in the presence of metabolic syndrome and diabetes, warrants referral to a hepatologist.

Some limitations should be acknowledged. As a cross-sectional study based in a tertiary care setting, there is potential for selection bias, as participants may have a higher burden of metabolic risk factors compared to the general population. Liver biopsy, while the gold standard for diagnosis, was reserved for selected cases due to ethical and logistical reasons, which may have resulted in underrepresentation of milder fibrosis. Nevertheless, all patients underwent validated non-invasive assessment using TE and CAP, providing a strength to this study, and our findings remain highly comparable to other regional and global investigations. The rate of unsuccessful TE measurements in our cohort was low and in line with published data.

Conclusion

Older age, a higher body mass index, a longer duration of diabetes, poor glycemic control, and elevated transaminase levels are all strongly linked to an increased risk of liver fibrosis in individuals with type 2 diabetes and non-alcoholic fatty liver disease (NAFLD). Timely diagnosis and management of these risk factors depend on their recognition. Transient elastography may help with early liver fibrosis identification and lessen the need for invasive biopsy when used in clinical settings. In this high-risk group, broader implementation of focused screening techniques may aid in halting the development of severe liver disease.

References

1. Cannon A, Handelsman Y, Heile M, Shannon M. Burden of Illness in Type 2 Diabetes Mellitus. *J Manag Care Spec Pharm*. 2018;24(9-a Suppl):S5-s13.
2. Adams LA, Lymp JF, Sauver JS, Sanderson SO, Lindor KD, Feldstein A, et al. The natural history of nonalcoholic fatty liver disease: a population-based cohort study. *Gastroenterology*. 2005;129(1):113-21.
3. Younossi ZM, Koenig AB, Abdelatif D, Fazel Y, Henry L, Wymer M. Global epidemiology of nonalcoholic fatty liver disease—meta-analytic assessment of prevalence, incidence, and outcomes. *Hepatology*. 2016;64(1):73-84.
4. Younossi ZM, Golabi P, de Avila L, Paik JM, Srishord M, Fukui N, et al. The global epidemiology of NAFLD and NASH in patients with type 2 diabetes: a systematic review and meta-analysis. *Journal of hepatology*. 2019;71(4):793-801.
5. Mantovani A, Petracca G, Beatrice G, Tilg H, Byrne CD, Targher G. Non-alcoholic fatty liver disease and risk of incident diabetes mellitus: an updated meta-analysis of 501 022 adult individuals. *Gut*. 2021;70(5):962-9.
6. Browning JD, Szczepaniak LS, Dobbins R, Nuremberg P, Horton JD, Cohen JC, et al. Prevalence of hepatic steatosis in an urban population in the United States: impact of ethnicity. *Hepatology*. 2004;40(6):1387-95.
7. Bedogni G, Miglioli L, Masutti F, Tiribelli C, Marchesini G, Bellentani S. Prevalence of and risk factors for nonalcoholic fatty liver disease: the Dionysos nutrition and liver study. *Hepatology*. 2005;42(1):44-52.
8. TEWARI A, TEWARI V, TEWARI J. Screening for Non-alcoholic Liver Disease in Type 2 Diabetic Patients and its Association with Age, BMI and Duration of Diabetes Mellitus-A Cross-sectional Study. *Journal of Clinical & Diagnostic Research*. 2021;15(4).
9. Kumar R, Rastogi A, Sharma MK, Bhatia V, Tyagi P, Sharma P, et al. Liver stiffness measurements in patients with different stages of nonalcoholic fatty liver disease: diagnostic performance and clinicopathological correlation. *Digestive Diseases and Sciences*. 2013;58(1):265-74.
10. Eddowes PJ, Sasso M, Allison M, Tsochatzis E, Anstee QM, Sheridan D, et al. Accuracy of FibroScan controlled attenuation parameter and liver stiffness measurement in assessing steatosis and fibrosis in patients with nonalcoholic fatty liver disease. *Gastroenterology*. 2019;156(6):1717-30.
11. Kalra S, Vithalani M, Gulati G, Kulkarni C, Kadam Y, Pallivathukkal J, et al. Study of prevalence of nonalcoholic fatty liver disease (NAFLD) in type 2 diabetes patients in India

- (SPRINT). The Journal of the Association of Physicians of India. 2013;61(7):448-53.
12. Mohan V, Farooq S, Deepa M, Ravikumar R, Pitchumoni C-e. Prevalence of non-alcoholic fatty liver disease in urban south Indians in relation to different grades of glucose intolerance and metabolic syndrome. Diabetes research and clinical practice. 2009;84(1):84-91.
 13. Snehalatha C, Viswanathan V, Ramachandran A. Cutoff values for normal anthropometric variables in Asian Indian adults. Diabetes care. 2003;26(5):1380-4.
 14. Yen Y-H, Chang K-C, Tsai M-C, Tseng P-L, Lin M-T, Wu C-K, et al. Elevated body mass index is a risk factor associated with possible liver cirrhosis across different etiologies of chronic liver disease. Journal of the Formosan Medical Association. 2018;117(4):268-75.
 15. Kumar S. Assessment of liver involvement in type 2 diabetes mellitus using fibroscan® and correlation with risk factors. 2019.
 16. Sanyal D, Mukherjee P, Raychaudhuri M, Ghosh S, Mukherjee S, Chowdhury S. Profile of liver enzymes in non-alcoholic fatty liver disease in patients with impaired glucose tolerance and newly detected untreated type 2 diabetes. Indian journal of endocrinology and metabolism. 2015;19(5):597-601.
 17. Pratyush DD, Tiwari S, Singh S, Singh SK. Waist circumference cutoff and its importance for diagnosis of metabolic syndrome in Asian Indians: A preliminary study. Indian Journal of Endocrinology and Metabolism. 2012;16(1):112-5.
 18. Chandel S, RAVI TEJA K. 1303-P: Screening for Metabolic Dysfunction–Associated Fatty Liver Disease (MAFLD) in Asian-Indians with Type 2 Diabetes Using Vibration-Controlled Transient Elastography—A Cross-Sectional Observational Study. Diabetes. 2023;72(Supplement_1):1303-P.
 19. Mosaad A, Elalfy H, Amer T, Arafa M. Transient Elastography and its Correlation with Biochemical Scores in patients with Metabolic associated fatty liver disease. Medical Journal of Viral Hepatitis. 2022;6(3):22-8.
 20. Pozzan R, Pena RG, Palma CCSSV, Abi-Abib RdC, Terra C, Cobas RA. Risk factors associated with nonalcoholic fatty liver disease evaluated by elastography in patients with type 2 diabetes. Archives of Endocrinology and Metabolism. 2022;66:452-8.
 21. Lallukka S, Sädevirta S, Kallio MT, Luukkonen PK, Zhou Y, Hakkarainen A, et al. Predictors of Liver Fat and Stiffness in Non-Alcoholic Fatty Liver Disease (NAFLD)—an 11-Year Prospective Study. Scientific reports. 2017;7(1):14561.
 22. Kumar NA, Das S. Fibroscan of liver in type 2 diabetes mellitus and its correlation with risk factors. Journal of Diabetes Mellitus. 2019;9(02):62.