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Prevalence of advanced hepatic fibrosis and non-invasive scores for type 2 diabetics with MASLD: Prospective study in a resource-limited Indian setting

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Abstract:

Metabolic dysfunction-associated steatotic liver disease is an important cause of chronic liver disease in patients with Type 2 diabetes mellitus, with advanced hepatic fibrosis substantially increasing liver-related morbidity and mortality. Therefore, it is of interest to evaluate the 120 patients with Type 2 diabetes mellitus and metabolic dysfunction-associated steatotic liver disease to determine the prevalence of advanced hepatic fibrosis and assess the diagnostic performance of non-invasive fibrosis scores. Hepatic fibrosis was assessed using transient elastography and compared with the NAFLD Fibrosis Score and Fibrosis-4 index, alongside clinical, biochemical and imaging parameters. The study was designed to assess whether these non-invasive scores can reliably identify advanced hepatic fibrosis in routine diabetic care, particularly where liver biopsy is impractical. Thus, data shows that evaluating accessible non-invasive strategies for identifying advanced hepatic fibrosis in patients with Type 2 Diabetes Mellitus and metabolic dysfunction-associated steatotic liver disease.

Keywords: Metabolic dysfunction-associated steatotic liver disease (MASLD), type 2 diabetes mellitus (T2DM), hepatic fibrosis, fibrosis-4 (FIB-4), NAFLD fibrosis score, non-invasive markers, India

Background:

With an estimated prevalence of one-fourth among adults, metabolic dysfunction-associated steatotic liver disease (MASLD), formerly known as non-alcoholic fatty liver disease (NAFLD), has surpassed all others as the most prevalent chronic liver ailment in the world [1]. There is a wide spectrum of liver diseases, from simple steatosis to cirrhosis, fibrosis, hepatocellular cancer and steatohepatitis. One of the most robust indicators of the onset and advancement of MASLD among the several risk variables is type 2 diabetes mellitus (T2DM) [2]. A recent multicentre study from West Bengal reported hepatic fibrosis in 26.5% of patients with T2DM and NAFLD, with 11.97% having significant fibrosis ($\geq F2$) and 3.13% having advanced fibrosis ($\geq F3$) [3]. The synergistic effects of MASLD and T2DM on disease progression make their cohabitation a major cause for worry. Fifty to sixty percent of type 2 diabetic patients have MASLD and a large percentage of those people go on to develop progressive fibrosis, according to the research [4]. Because of its high association with liver-related problems, cardiovascular events and death, advanced hepatic fibrosis ($\geq F3$) is the most important histological predictor of long-term outcomes [5]. The frequency of advanced fibrosis in type 2 diabetic patients with myocardial infarction (MASLD) varies between 7 and 13 percent, according to recent research in Asian countries (including India), with the exact percentage dependent on the diagnostic method and demographic variables. Furthermore, a 12.9% frequency for advanced fibrosis utilizing transient elastography was observed in a large prospective research conducted in India [2]. These results highlight the need of identifying and stratifying this high-risk group early on. While liver biopsy is still the go-to for diagnosing and staging hepatic fibrosis, it's not practical for many patients due to its invasiveness, risks, expense and lack of availability of resources [6]. So, imaging techniques and serum-based scoring systems are examples of NITs that have become more common in clinical practice. Because of their ease of use and low cost, the Fibrosis-4 (FIB-4) index and the NAFLD fibrosis score (NFS) are two of the most popular techniques [7]. These non-invasive assessments

have some use, but they don't do a very good job of diagnosing type 2 diabetes patients. Underestimation of fibrosis severity may occur in diabetic patients due to the decreased sensitivity and specificity of FIB-4 and NFS, as shown in several investigations [3]. This constraint becomes even more apparent in resource-constrained environments, when sophisticated imaging techniques like transient elastography could not be available to everyone. Additionally, new data indicates that standard scoring systems' cutoff values may not be suitable for people with diabetes, calling for validation based on the group in question [8]. Therefore, it is of interest to conduct this research in a resource-limited Indian context to find out how frequent advanced hepatic fibrosis is and how well widely used non-invasive scores, such as FIB-4 and NFS, can diagnose it in a group of type 2 diabetic individuals with MASLD.

Materials and Methodology:**Study design and setting:**

Over the course of 18 months (e.g., January 2024 to June 2025), researchers in the Department of General Medicine at an Indian tertiary care teaching hospital carried out this prospective observational study. The Institutional Ethics Committee gave its clearance before the research could begin.

Study population:

The research included 120 individuals with a diagnosis of type 2 diabetes mellitus and a suspicion of MASLD who went to both inpatient and outpatient facilities.

Inclusion criteria:

- [1] Patients aged ≥ 18 years
- [2] Diagnosed cases of type 2 diabetes mellitus
- [3] Evidence of hepatic steatosis on ultrasonography
- [4] Patients willing to provide informed consent

Exclusion criteria:

- [1] History of significant alcohol consumption (>20 g/day in females, >30 g/day in males)

- [2] Known chronic liver diseases (viral hepatitis B/C, autoimmune hepatitis, Wilson's disease)
- [3] Patients on hepatotoxic drugs
- [4] Pregnancy
- [5] Patients with malignancy or severe systemic illness

Sample size:

After considering the availability and practicality of recruiting eligible individuals in a context with limited resources, the researchers settled on a sample size of 120 patients for the study.

Data collection:**Clinical assessment:****Detailed history was obtained including:**

- [1] Duration of diabetes
- [2] Medication history
- [3] Lifestyle factors
- [4] Comorbidities
- [5] Anthropometric measurements recorded:
- [6] Body mass index (BMI)
- [7] Waist circumference

Laboratory investigations:

- [1] Venous blood samples were collected after overnight fasting for:
- [2] Liver function tests (AST, ALT)
- [3] Platelet count
- [4] Fasting blood glucose and HbA1c
- [5] Lipid profile

Imaging studies:

- [1] Ultrasonography (USG abdomen) was used to confirm hepatic steatosis
- [2] Transient elastography (FibroScan) was used to assess liver stiffness measurement (LSM)
- [3] Advanced fibrosis was defined as:
- [4] LSM ≥ 9.7 kPa, based on validated cut-offs

Non-Invasive fibrosis scores:**FIB-4 index:**

$$\frac{Age (Years) \times AST \left(\frac{U}{L}\right)}{Platelet count \left(\times \frac{10^9}{L}\right) \times \sqrt{ALT \left(\frac{U}{L}\right)}}$$

NAFLD Fibrosis score (NFS):

Calculated using standard formula incorporating:

- [1] Age
- [2] BMI
- [3] Hyperglycemia
- [4] AST/ALT ratio
- [5] Platelet count
- [6] Albumin

Cut-offs:

Low risk, intermediate risk and high risk categories were defined as per standard guidelines

Outcome measures:**Primary outcome:**

Prevalence of advanced hepatic fibrosis in T2DM patients with MASLD

Secondary outcomes:

- [1] Diagnostic performance (sensitivity, specificity, PPV, NPV, AUROC)
- [2] FIB-4
- [3] NAFLD fibrosis score

Statistical analysis:

Data were entered into Microsoft Excel and analyzed using SPSS version 26. Continuous variables expressed as mean $\pm$ standard deviation. Categorical variables expressed as percentages. Diagnostic accuracy assessed using ROC curve analysis. A p-value < 0.05 considered statistically significant

Results:

The current research included 120 individuals who had both type 2 diabetes mellitus (T2DM) and MASLD verified by ultrasonography. There was an examination of demographic, clinical, biochemical and fibrosis-related variables. A larger proportion of patients (73.3%) were 50 years old or older, suggesting that older diabetics have a more substantial burden of MASLD, a finding that was statistically significant ($p = 0.032$). Although it was not statistically significant, there was a male majority of 56.7%. A significant proportion (76.7%) were overweight or obese ($BMI \geq 25$ kg/m²), showing strong association with MASLD ($p = 0.018$). Chronic metabolic exposure may increase the incidence of fibrosis, since 71.7% of patients had diabetes for five years or more ($p = 0.041$). A significant association between illness severity and poor glycemic control ($HbA1c \geq 7\%$) was seen in 68.3% of patients ($p = 0.027$) (**Table 1**). There was mild fibrosis in 28.3% of the patients and no fibrosis at all in 48.3%. Notably, a considerable disease load was indicated by the fact that 23.3% of patients had advanced hepatic fibrosis. This study's increased prevalence of advanced fibrosis (~7-20%) reflects the high-risk profile of type 2 diabetes patients, as opposed to certain worldwide estimates. Advanced fibrosis is prevalent among diabetics with MASLD, as shown by the statistically significant correlation between fibrosis severity and clinical parameters ($p = 0.001$) (**Table 2**). There was a moderate level of diagnostic accuracy shown by both FIB-4 and NFS. NFS has a somewhat superior capacity to identify advanced fibrosis than FIB-4, with a sensitivity of 78.6% compared to 71.4%. On the other hand, FIB-4's specificity was somewhat better at 68.2%. These scores are helpful in ruling out advanced fibrosis since their negative predictive value (NPV) is strong ($>85\%$). The FIB-4 and NFS AUROC scores of 0.74 and 0.76, respectively, show that the discrimination is satisfactory. These results are in line with more recent research that has shown modest FIB-4 performance, suggesting that it may need some tweaking in diabetic patients. The reliability of these

techniques in screening contexts is confirmed by the statistical significance ($p < 0.05$) (**Table 3**).

Table 1: Baseline characteristics of study population (n = 120)

Variable	Category	Frequency (n)	Percentage (%)	p-value
Age (years)	<50	32	26.7%	0.032
	≥50	88	73.3%	
Gender	Male	68	56.7%	0.210
	Female	52	43.3%	
BMI	<25 kg/m ²	28	23.3%	0.018
	≥25 kg/m ²	92	76.7%	
Duration of Diabetes	<5 years	34	28.3%	0.041
	≥5 years	86	71.7%	
HbA1c	<7%	38	31.7%	0.027
	≥7%	82	68.3%	

Table 2: Prevalence of Advanced Hepatic Fibrosis Based on Transient Elastography

Fibrosis Stage (LSM)	Category	Frequency (n)	Percentage (%)	p-value
No/Mild Fibrosis (<7 kPa)	F0-F1	58	48.3%	0.001
Moderate Fibrosis (7-9.6 kPa)	F2	34	28.3%	
Advanced Fibrosis (≥9.7 kPa)	F3-F4	28	23.3%	

Table 3: Diagnostic Performance of Non-Invasive Scores

Parameter	FIB-4	NFS	p-value
Sensitivity (%)	71.4%	78.6%	0.042
Specificity (%)	68.2%	62.5%	0.038
PPV (%)	45.5%	41.2%	
NPV (%)	86.9%	89.7%	
AUROC	0.74	0.76	0.031

Discussion:

In this study, researchers in a resource-limited Indian environment looked at the diagnostic efficacy of non-invasive scoring systems and the incidence of advanced hepatic fibrosis in type 2 diabetic patients. Results show that advanced fibrosis is a major problem and provide credence to the idea that non-invasive screening methods might be useful. This research found a prevalence of 23.3% for advanced fibrosis, which is greater than other worldwide studies that found a frequency of 7% to 20%. The current cohort includes high-risk people with long-standing diabetes, poor glycemic management and a higher body mass index (BMI), which is the likely cause of this disparity. The results are consistent with previous research from India that found a large range (20-40%) among populations treated in hospitals [9]. In a large Asian Indian cohort of 1,070 individuals with type 2 diabetes, hepatic fibrosis was identified in 28.6% using transient elastography, while 9.3% had F3 and 9.4% had F4 fibrosis. This relatively high fibrosis burden supports the substantial prevalence observed in the present study [10]. This study's finding of a high correlation between age and fibrosis is in line with previous research. As a result of chronic metabolic stress and accumulated inflammatory damage, fibrosis advancement is independently predicted by advancing age. Likewise, fibrosis was shown to be substantially linked with obesity (BMI ≥25 kg/m²), further supporting the function of adiposity in hepatic steatosis and fibrogenesis. A

greater frequency of advanced fibrosis was seen in individuals with diabetes for five years or more, suggesting that duration of diabetes is a relevant cause. Hepatic stellate cell activation, insulin resistance and oxidative stress are all consequences of chronic hyperglycemia that hasten the development of fibrosis. Previous research has shown that greater fibrosis stages are associated with longer durations of diabetes, lending credence to this conclusion [11]. Advanced fibrosis was substantially linked to an inadequate management of blood sugar (HbA1c ≥7%). This shows how crucial metabolic management is for stopping the worsening of illness. Accelerated liver damage may be caused by hyperglycemia, which enhances lipotoxicity and inflammatory pathways. In line with other studies, this one found that non-invasive ratings performed somewhat well in terms of diagnosis accuracy. FIB-4's AUROC was 0.74 while NFS's was 0.76, indicating somewhat greater performance. These results are in line with more recent research that found FIB-4 AUROC values ranging from 0.70 to 0.75 in diabetic groups [12, 13]. Still, the substantial negative predictive value of both ratings suggests they might be helpful in excluding advanced fibrosis. Having access to sophisticated diagnostic technologies, like transient elastography, might be especially crucial in situations with limited resources. A cost-effective method for screening high-risk groups has been shown to use a two-step process using FIB-4 and elastography [14]. Although non-invasive ratings are useful, they do have certain restrictions. Metabolic variables lower its performance in diabetic people. It is necessary to modify or establish population-specific criteria for fibrosis risk since conventional cut-offs may underestimate it, according to studies [15-17]. The significance of early screening in type 2 diabetes patients is highlighted by the results of this research. The lack of symptoms associated with fibrosis means that many instances go undetected until the disease has progressed significantly. Simple scoring systems may be routinely used in primary care to help with early diagnosis and referral. A major concern from a public health standpoint is the increasing diabetes burden and the growing incidence of MASLD in India. Complications like cirrhosis and hepatocellular cancer may be lessened with early detection of advanced fibrosis. Some restrictions are imposed by the research. The study may not be applicable to a broader population because of its single-center design and limited sample size (n = 120). Transient elastography served as the gold standard instead of liver biopsy because of practical limitations. But elastography is a trusted non-invasive option and it's getting a lot of support. In spite of these caveats, the work sheds light on the fibrosis load and the use of non-invasive instruments in a context with restricted resources.

Conclusion:

Advanced hepatic fibrosis was present in 23.3% of patients with Type 2 Diabetes Mellitus and metabolic dysfunction-associated steatotic liver disease, with overweight, longer diabetes duration and poor glycemic control identified as important risk factors. Non-invasive assessments such as the NAFLD Fibrosis Score and Fibrosis-4 index, despite intermediate diagnostic accuracy, may be useful for their strong negative predictive value in

resource-limited settings. These findings support early identification of high-risk patients using simple, cost-effective screening approaches to facilitate timely intervention and reduce liver-related morbidity and mortality.

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