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Original Research Article

Diagnostic Accuracy of Non-invasive Fibrosis Scores Compared with Fibro Scan for Assessment of Liver Fibrosis in Patients with Type 2 Diabetes Mellitus and Non-Alcoholic Fatty Liver Disease: A Prospective Cross-Sectional Study

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Abstract:

Background: Type 2 diabetes mellitus (T2DM) is strongly associated with non-alcoholic fatty liver disease (NAFLD), increasing the risk of progressive liver fibrosis, cirrhosis, and hepatocellular carcinoma. Liver biopsy remains the gold standard for fibrosis assessment but is invasive and unsuitable for routine clinical practice. Several serum-based fibrosis scores have been developed as non-invasive alternatives; however, their diagnostic performance varies across different populations. This study compared the diagnostic accuracy of APRI, FIB-4, BARD, and NAFLD Fibrosis Score (NFS) using FibroScan as the reference standard in diabetic patients with NAFLD.

Methods: A prospective cross-sectional study was conducted among 378 adult patients with T2DM and ultrasonographically diagnosed NAFLD attending a tertiary care centre. Clinical characteristics, anthropometric measurements, biochemical parameters, and FibroScan findings were recorded. APRI, FIB-4, BARD, and NFS were calculated using standard formulae. Diagnostic performance was assessed by sensitivity, specificity, positive predictive value (PPV), negative predictive value (NPV), diagnostic accuracy, and receiver operating characteristic (ROC) analysis.

Results: Among the 378 patients, 272 (71.96%) were male and 106 (28.04%) were female. The mean HbA1c was 7.72 ± 1.06%, and most patients had diabetes for 2–5 years. FibroScan demonstrated no fibrosis in 29.36%, significant fibrosis in 56.35%, and advanced fibrosis in 14.29% of patients. FIB-4 showed the highest diagnostic performance with an AUC of 0.627, followed by APRI (0.606), NFS (0.572), and BARD (0.468). BARD demonstrated the highest sensitivity (92.88%) but the lowest specificity (5.45%), whereas FIB-4 showed the highest specificity (60.00%) and PPV (78.11%).

Conclusion: FIB-4 demonstrated the best overall diagnostic performance among the evaluated non-invasive fibrosis scores and appears to be the preferred first-line screening tool for diabetic NAFLD patients. APRI may serve as an acceptable alternative where FibroScan is unavailable. BARD and NFS should not be used as standalone diagnostic tests because of their limited specificity.

Keywords: Type 2 diabetes mellitus, NAFLD, MASLD, FibroScan, FIB-4, APRI, Liver Fibrosis, Transient Elastography.

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Introduction

Non-alcoholic fatty liver disease (NAFLD), recently redefined as metabolic dysfunction-associated steatotic liver disease (MASLD), is the most common chronic liver disease worldwide and affects nearly one-third of the adult population. Individuals with type 2 diabetes mellitus (T2DM) are particularly susceptible, with reported prevalence rates ranging from 50% to 70%. Diabetes not only increases hepatic fat accumulation but also accelerates progression to steatohepatitis, advanced fibrosis, cirrhosis, and hepatocellular carcinoma.

The degree of liver fibrosis is the most important determinant of liver-related and overall mortality in patients with NAFLD. Consequently, early identification of significant fibrosis has become a major objective in the management of patients with metabolic liver disease.

Although liver biopsy remains the gold standard for fibrosis assessment, its invasive nature, sampling variability, potential complications, and high cost limit routine clinical use. Therefore, several non-invasive methods have been developed, including serum fibrosis scores such as AST-to-Platelet Ratio Index (APRI), Fibrosis-4 Index (FIB-4), BARD score, and NAFLD Fibrosis Score (NFS), as well as imaging techniques such as vibration-controlled transient elastography (FibroScan).

Among these methods, FibroScan has emerged as a reliable non-invasive modality for evaluating liver stiffness and has been increasingly recommended by international liver societies. However, the limited availability and relatively high cost of FibroScan restrict its use in many developing countries. In contrast, serum fibrosis scores are inexpensive, readily available, and can be calculated from routine laboratory investigations. Their diagnostic accuracy, however, varies among different ethnic and clinical populations.

India bears one of the world's largest burdens of T2DM, making early detection of liver fibrosis particularly important. Comparative studies evaluating the performance of different fibrosis scores in Indian diabetic patients remain limited. Identifying the most reliable screening tool would facilitate timely referral for FibroScan and optimize resource utilization in routine clinical practice.

The present study was undertaken to compare the diagnostic accuracy of APRI, FIB-4, BARD score, and NAFLD Fibrosis Score using FibroScan as the reference standard in patients with T2DM and NAFLD. Secondary objectives included comparison of clinical and biochemical characteristics associated with liver fibrosis and assessment of the overall diagnostic performance of these commonly used non-invasive fibrosis scores.

Table 1: Baseline Characteristics of Study Participants

Variable	Value
Total patients	378
Male	272 (71.96%)
Female	106 (28.04%)
Mean HbA1c	7.72 ± 1.06%
Mean duration of diabetes	4.10 ± 1.41 years
Grade I NAFLD	222 (58.73%)
Grade II NAFLD	147 (38.89%)
Grade III NAFLD	9 (2.38%)

Materials and Methods

Study design and participants: This prospective cross-sectional study was conducted in the Department of Gastroenterology at a tertiary care teaching hospital over one year. A total of 378 consecutive adult patients with Type 2 diabetes mellitus (T2DM) and ultrasonographically diagnosed non-alcoholic fatty liver disease (NAFLD) were enrolled after obtaining written informed consent. Patients with significant alcohol intake, chronic viral hepatitis, autoimmune liver disease, Wilson's disease, hemochromatosis, drug-induced liver disease, hepatic malignancy, pregnancy, or incomplete clinical data were excluded.

Data Collection

Demographic characteristics, duration of diabetes, clinical presentation, anthropometric measurements, laboratory investigations, abdominal ultrasonography, Tissue Attenuation Imaging (TAI), and transient elastography (FibroScan) were recorded. APRI, FIB-4, BARD, and NAFLD Fibrosis Score (NFS) were calculated using standard published formulae.

FibroScan served as the reference standard. Diagnostic performance of the fibrosis scores was assessed by sensitivity, specificity, positive predictive value (PPV), negative predictive value (NPV), accuracy, and area under the receiver operating characteristic (ROC) curve.

Results

Patient characteristics: A total of 378 patients were included. Males constituted 71.96%, while females accounted for 28.04%. The majority of patients presented with abdominal pain (76.46%), followed by dyspepsia (62.44%) and abdominal distension (23.28%). Most patients had no documented diabetic complications (83%), while urinary tract infection (10%), neuropathy (4%), and nephropathy (3%) were less common.

The mean HbA1c was 7.72 ± 1.06%, and 95.2% of patients had HbA1c ≥6.5%. The mean duration of diabetes was 4.10 ± 1.41 years, with 58.2% having diabetes for 2–5 years. Most patients were overweight according to Asian BMI criteria.

Liver steatosis and fibrosis: Ultrasonography demonstrated Grade I steatosis in 58.73%, Grade II in 38.89%, and Grade III in 2.38% of patients. The mean TAI value was 228.80 ± 24.39 dB/m. FibroScan identified no fibrosis in 29.36%, significant fibrosis in 56.35%, and advanced fibrosis in 14.29% of patients.

Performance of non-invasive fibrosis scores: Among the evaluated scores, FIB-4 demonstrated the best diagnostic performance, followed by APRI. BARD showed excellent sensitivity but poor specificity, whereas NFS demonstrated moderate sensitivity with limited specificity.

Table 2: Distribution of Fibrosis by Different Non-invasive Methods

Method	Low risk (%)	Intermediate (%)	High risk (%)
FibroScan	29.36	56.35	14.29
APRI	31.74	54.24	14.02
BARD	6.62	49.46	43.92
FIB-4	46.29	37.04	16.67
NFS	20.37	42.59	37.03

Table 3: Diagnostic Performance of Fibrosis Scores

Score	Sensitivity (%)	Specificity (%)	PPV (%)	NPV (%)	Accuracy (%)
APRI	73.41	43.24	75.68	40.34	64.55
FIB-4	58.80	**60.00**	**78.11**	37.50	59.15
BARD	**92.88**	5.45	70.45	24.00	**67.37**
NFS	77.53	15.45	69.00	22.08	59.42

Table 4: ROC Analysis

Fibrosis Score	Area Under Curve (AUC)
FIB-4	**0.627**
APRI	0.606
NFS	0.572
BARD	0.468

Table 5: Comparison of Patients with and Without Fibrosis (FibroScan)

Parameter	Fibrosis	No Fibrosis
HbA1c (%)	7.74	7.68
Platelet count (/mm³)	219,865	206,216
AST/ALT ratio	1.07	1.01
TAI (dB/m)	239.33	203.47
Hemoglobin (g/dL)	11.60	12.66
BMI (kg/m²)	29.58	29.65
Albumin (g/dL)	3.60	3.53

Key findings

- **FIB-4 had the highest AUC (0.627)** and the highest specificity, making it the most reliable overall fibrosis score in this study.
- **APRI** showed acceptable sensitivity and can be used as a practical screening tool.
- **BARD** had excellent sensitivity but an unacceptably low specificity, leading to many false-positive results.
- **NFS** demonstrated only modest diagnostic performance.
- FibroScan identified significant or advanced fibrosis in more than **70%** of diabetic NAFLD patients, highlighting the need for routine fibrosis assessment in this high-risk population.

Discussion

In this prospective cross-sectional study involving 378 patients with T2DM and NAFLD, we compared the diagnostic performance of four widely used non-invasive fibrosis scores using FibroScan as the reference standard. The principal finding was that FIB-4 demonstrated the best overall diagnostic performance, whereas APRI showed acceptable screening utility. Although the BARD score exhibited excellent sensitivity, its extremely low specificity substantially limited its clinical usefulness. The NAFLD Fibrosis Score (NFS) showed only modest diagnostic discrimination.

The majority of patients were middle-aged males, consistent with previous Indian hospital-based studies. More than 95% had HbA1c ≥6.5%, reflecting poor glycaemic control and emphasizing the close relationship between diabetes and progression of NAFLD. Persistent insulin resistance promotes hepatic fat accumulation, oxidative stress, inflammation, and progressive fibrosis, making patients with T2DM a particularly high-risk population.

FibroScan identified significant or advanced fibrosis in more than 70% of participants, highlighting the considerable burden of liver fibrosis among diabetic NAFLD patients attending tertiary care centres. This finding supports recent recommendations that patients with T2DM should undergo routine assess-

ment for advanced fibrosis using validated non-invasive tools.

Among the evaluated scores, FIB-4 achieved the highest AUC (0.627) together with the highest specificity and positive predictive value, indicating the best balance between sensitivity and specificity. These findings support current international recommendations that advocate FIB-4 as the preferred first-line fibrosis assessment tool because it is inexpensive, easily calculated from routine laboratory investigations, and suitable for primary care screening.

APRI demonstrated moderate sensitivity and acceptable diagnostic accuracy. Although initially developed for chronic viral hepatitis, our findings indicate that APRI remains a useful screening tool in diabetic NAFLD, particularly where FibroScan is unavailable. However, its lower specificity suggests that positive cases should undergo confirmatory assessment by transient elastography.

The BARD score showed the highest sensitivity but generated a large number of false-positive results because of extremely poor specificity. Consequently, BARD should not be used as a standalone diagnostic test despite its ability to detect most patients with fibrosis.

Similarly, NFS demonstrated reasonable sensitivity but limited specificity and only modest overall diagnostic performance. Therefore, NFS should be interpreted cautiously and preferably in combination with imaging-based modalities.

Strengths

- Large prospective cohort (378 patients).
- Direct comparison of four commonly used fibrosis scores in the same population.
- Use of FibroScan as the reference standard.
- Real-world data from a tertiary care centre in India.

Limitations

- Single-centre study.
- Cross-sectional design.
- Liver biopsy was not performed as the reference standard.
- External validation in larger multicentre cohorts is required.

Conclusion

FIB-4 demonstrated the best overall diagnostic performance among the evaluated non-invasive fibrosis scores for detecting liver fibrosis in patients with T2DM and NAFLD. APRI may be considered an acceptable alternative screening tool where FibroScan is unavailable. BARD and NFS exhibited limited specificity and should not be used independently for fibrosis diagnosis. A stepwise approach using FIB-4 followed by FibroScan may improve early identification of clinically significant fibrosis while reducing unnecessary referrals and healthcare costs.

Highlights

- FIB-4 demonstrated the highest diagnostic accuracy among evaluated fibrosis scores.
- APRI remains a practical screening tool in resource-limited settings.
- BARD had high sensitivity but very poor specificity.
- NFS showed limited standalone diagnostic utility.
- FibroScan confirmed a high burden of liver fibrosis among diabetic NAFLD patients.

Declarations

Ethics approval: Approved by the Institutional Ethics Committee. Written informed consent was obtained from all participants.

Funding: None.

Conflict of interest: The authors declare no conflict of interest.

Author contributions: Study conception and design, data collection, analysis, interpretation, and manuscript preparation were performed by the authors.

Data availability: Available from the corresponding author upon reasonable request.

References

1. Rinella ME, Neuschwander-Tetri BA, Siddiqui MS, Abdelmalek MF, Caldwell S, Barb D, et al. AASLD Practice Guidance on the clinical assessment and management of metabolic dysfunction–associated steatotic liver disease. Hepatology. 2024.
2. European Association for the Study of the Liver (EASL), European Association for the Study of Diabetes (EASD), European Association for the Study of Obesity (EASO). EASL–EASD–EASO Clinical Practice Guidelines on the management of metabolic dysfunction–associated steatotic liver disease (MASLD). J Hepatol. 2024.
3. American Diabetes Association Professional Practice Committee. Standards of Care in Diabetes—2025. Diabetes Care. 2025.
4. Younossi ZM, Golabi P, Paik JM, Henry L, Van Dongen C, Henry Z. Global epidemiology of NAFLD and MASLD. Nat Rev Gastroenterol Hepatol. 2024.
5. Targher G, Byrne CD, Tilg H. NAFLD and type 2 diabetes mellitus: pathophysiological mechanisms and clinical implications. Lancet Diabetes Endocrinol. 2023.
6. Eslam M, Sanyal AJ, George J. MAFLD: A consensus-driven proposed nomenclature for

metabolic fatty liver disease. Gastroenterology. 2020;158:1999–2014.
7. Eslam M, Sarin SK, Wong VW, Fan JG, Kawaguchi T, Ahn SH, et al. The Asian Pacific Association for the Study of the Liver clinical practice guidelines for metabolic dysfunction-associated steatotic liver disease. Hepatol Int. 2024.
8. Castera L. Non-invasive evaluation of steatotic liver disease using transient elastography. J Hepatol. 2023.
9. Siddiqui MS, Vuppalanchi R, Van Natta ML, Hallinan E, Kowdley KV, Abdelmalek MF, et al. Vibration-controlled transient elastography in NAFLD. Hepatology. 2019.
10. Sterling RK, Lissen E, Clumeck N, et al. Development of a simple non-invasive index (FIB-4) to predict liver fibrosis. Hepatology. 2006;43:1317–1325.
11. Wai CT, Greenson JK, Fontana RJ, et al. A simple non-invasive index can predict fibrosis in chronic hepatitis C. Hepatology. 2003;38:518–526.
12. Angulo P, Hui JM, Marchesini G, et al. The NAFLD Fibrosis Score: A non-invasive system that identifies liver fibrosis. Hepatology. 2007;45:846–854.
13. Harrison SA, Oliver D, Arnold HL, et al. Development and validation of the BARD score. Gut. 2008;57:1441–1447.
14. McPherson S, Hardy T, Henderson E, et al. Evidence of the diagnostic accuracy of FIB-4 in NAFLD. Gut. 2017.
15. Shah AG, Lydecker A, Murray K, et al. Comparison of non-invasive fibrosis markers in NAFLD. Clin Gastroenterol Hepatol. 2009.
16. Eddowes PJ, Sasso M, Allison M, et al. Accuracy of FibroScan in NAFLD. Gastroenterology. 2019.
17. Newsome PN, Sasso M, Deeks JJ, et al. FibroScan for liver fibrosis assessment in NAFLD. Lancet Gastroenterol Hepatol. 2020.
18. Younossi ZM, Corey KE, Lim JK. Clinical assessment of MASLD in practice. Hepatology. 2024.
19. Loomba R, Lim JK, Patton H. Clinical management of NAFLD and MASLD. N Engl J Med. 2024.
20. Adams LA, Anstee QM, Tilg H, Targher G. NAFLD and diabetes: current concepts. J Hepatol. 2017.
21. Chalasani N, Younossi Z, Lavine JE, et al. The diagnosis and management of nonalcoholic fatty liver disease. Hepatology. 2018.
22. Cusi K. Treatment of NAFLD in patients with type 2 diabetes. Diabetologia. 2022.
23. Mantovani A, Petracca G, Beatrice G, Tilg H, Byrne CD, Targher G. Non-invasive fibrosis assessment in type 2 diabetes. Diabetes Metab. 2023.
24. Bril F, Cusi K. Management of metabolic dysfunction-associated steatotic liver disease in diabetes. Clin Liver Dis. 2023.
25. Ajmera V, Loomba R. Advances in non-invasive assessment of liver fibrosis. Clin Gastroenterol Hepatol. 2023.
26. Wong VW, Adams LA, de Lédinghen V, Wong GL, Sookoian S. Non-invasive biomarkers in MASLD. Nat Rev Gastroenterol Hepatol. 2023.
27. Powell EE, Wong VW, Rinella M. Recent advances in MASLD. Lancet. 2024.
28. Singh S, Allen AM, Wang Z, et al. Fibrosis progression in NAFLD: A systematic review and meta-analysis. Clin Gastroenterol Hepatol. 2015.
29. Estes C, Razavi H, Loomba R, Younossi ZM, Sanyal AJ. Modeling the global burden of NAFLD. Hepatology. 2018.
30. Younossi ZM, Stepanova M, Ong J, et al. Global burden of metabolic dysfunction-associated steatotic liver disease. J Hepatol. 2024.