RESEARCH PAPER

Accuracy of FIB-4 Index in Detecting Liver Fibrosis among Diabetic Patients

Dr Atul Sadashiv Baviskar[1]*, Dr. Sandip Ratan Patil[2] and Dr. Ravikumar R Ughreja[3]

[1]*Associate Professor, Department of General Medicine, SMBT Institute of Medical Sciences and Research Centre, Dhamangaon, Maharashtra, India*
[2]*Assistant Professor, Department of General Medicine, Maharashtra Post Graduate Institute of Medical Education and Research, Nashik, Maharashtra, India*
[3]*Associate Professor, Department of General Medicine, Matushri Prabhaben Khodabhai Boghara Medical College, Atkot, Gujarat, India*
[1]**abaviskar98@gmail.com*

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ABSTRACT
Background: Liver fibrosis is a common complication in patients with type 2 diabetes mellitus and is often underdiagnosed due to lack of simple screening tools.

Aim: To evaluate the accuracy of the FIB-4 index in detecting liver fibrosis among diabetic patients and to compare it with FibroScan findings.

Methods: A cross-sectional study was conducted on 100 patients with type 2 diabetes mellitus. FIB-4 index was calculated using standard parameters and compared with FibroScan findings. Sensitivity, specificity, predictive values, and ROC curve analysis were performed.

Results: Significant fibrosis was detected in 30.0% of patients. FIB-4 showed a sensitivity of 73.3% and specificity of 80.0%, with a negative predictive value of 87.5%. The AUC was 0.79, indicating acceptable diagnostic accuracy. Higher FIB-4 scores were observed in patients with poor glycemic control.

Conclusion: FIB-4 is a useful non-invasive screening tool for liver fibrosis in diabetic patients, particularly for ruling out disease, but should be complemented with imaging modalities for confirmation.
Keywords: *FIB-4 index, Liver fibrosis, Type 2 diabetes mellitus, FibroScan*
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INTRODUCTION

Liver fibrosis represents a progressive pathological condition characterized by excessive deposition of extracellular matrix components in the liver, ultimately leading to cirrhosis and liver failure if left undetected. In recent years, the burden of liver fibrosis has increased substantially, particularly among patients with type 2 diabetes mellitus (T2DM), due to the rising prevalence of metabolic dysfunction-associated steatotic liver disease (MASLD). T2DM is recognized as a major risk factor for the development and progression of liver fibrosis, owing to mechanisms such as insulin resistance, lipotoxicity, oxidative stress, and chronic low-grade inflammation [1].

MASLD encompasses a spectrum of liver disorders ranging from simple steatosis to steatohepatitis and advanced fibrosis. Among these, fibrosis stage is the most important predictor of long-term outcomes, including liver-related morbidity and mortality [2]. Studies have shown that patients with T2DM have a significantly higher prevalence of advanced liver fibrosis compared to non-diabetic individuals, making early identification of fibrosis in this population crucial for preventing disease progression and associated complications [3]. However, liver fibrosis is often asymptomatic in its early stages, leading to delayed diagnosis and treatment.

Liver biopsy remains the gold standard for diagnosing and staging liver fibrosis; however, it is invasive, expensive, and associated with potential complications such as bleeding and sampling error. These limitations have led to the increasing use of non-invasive methods for fibrosis assessment in routine clinical practice [4]. Among these, the Fibrosis-4 (FIB-4) index has emerged as a widely used, simple, and cost-effective tool, incorporating age, serum aspartate aminotransferase (AST), alanine aminotransferase (ALT), and platelet count. It is recommended as a first-line screening tool in patients with MASLD and T2DM due to its accessibility and ease of use [5].

The FIB-4 index stratifies patients into low, intermediate, and high risk of advanced fibrosis using established cut-off values, and is commonly utilized in primary care settings

**Author for Correspondence: abaviskar98@gmail.com*

for early risk assessment [6]. Several studies have demonstrated that FIB-4 has moderate diagnostic accuracy in detecting advanced fibrosis, with reported sensitivity and specificity values around 70–75% and area under the receiver operating characteristic curve (AUROC) values ranging from 0.70 to 0.82 [7]. However, emerging evidence suggests that its diagnostic performance may be influenced by patient-specific factors such as age, body mass index (BMI), and metabolic status, particularly in diabetic populations [8].

In patients with T2DM, the accuracy of FIB-4 may be affected by alterations in liver enzyme levels, platelet count, and the presence of metabolic comorbidities. Recent studies have reported reduced diagnostic performance of FIB-4 in diabetic individuals, with concerns regarding both false negatives and false positives [9]. Additionally, the use of uniform cut-off values across different populations may not be appropriate, and some studies have suggested that lower cut-off thresholds may improve sensitivity in diabetic patients [10]. These findings highlight the need for population-specific validation of the FIB-4 index.

Transient elastography (FibroScan) is a non-invasive imaging modality that measures liver stiffness and serves as a reliable reference standard for assessing liver fibrosis. It is widely used due to its reproducibility, safety, and ability to provide immediate results. Comparing FIB-4 with FibroScan findings is essential to determine its diagnostic accuracy and clinical utility in diabetic populations.

Therefore, this study aims to evaluate the accuracy of the FIB-4 index in detecting liver fibrosis among diabetic patients and to assess its diagnostic performance in comparison with FibroScan. Additionally, the study seeks to explore factors influencing FIB-4 accuracy, including BMI, glycemic control, and duration of diabetes, to enhance its applicability in clinical practice.

MATERIAL AND METHODS

The present study was designed as a cross-sectional observational study conducted at a tertiary care academic institute over a period of six months. The study aimed to evaluate the diagnostic accuracy of the Fibrosis-4 (FIB-4) index in detecting liver fibrosis among patients with type 2 diabetes mellitus and to compare its performance with FibroScan findings.

A total of 100 patients diagnosed with type 2 diabetes mellitus were included in the study. Patients were recruited from the outpatient and inpatient departments after fulfilling the predefined inclusion and exclusion criteria. Individuals aged between 30 and 70 years with a confirmed diagnosis of type 2 diabetes mellitus and availability of recent laboratory investigations, including aspartate aminotransferase (AST), alanine aminotransferase (ALT), and platelet count within the past three months, were considered eligible for inclusion. Patients with a history of chronic alcohol consumption, known viral hepatitis, established cirrhosis, or those on hepatotoxic medications were excluded from the study.

After obtaining informed written consent, detailed clinical information was collected from all participants, including age, gender, duration of diabetes, body mass index (BMI), and glycemic control as assessed by HbA1c levels. Relevant laboratory parameters such as AST, ALT, and platelet count were recorded from recent reports. The FIB-4 index was calculated for each patient using the standard formula: FIB-4 = (Age × AST) / (Platelet count × √ALT).

All participants underwent FibroScan (transient elastography), which was used as the reference standard for assessing liver fibrosis. Liver stiffness measurements were recorded in kilopascals (kPa), and a value of ≥8 kPa was considered indicative of significant liver fibrosis. The FIB-4 values obtained were then compared with FibroScan findings to determine their diagnostic performance.

The primary outcome measure of the study was the sensitivity and specificity of the FIB-4 index in detecting significant liver fibrosis. Secondary outcomes included comparison of FIB-4 results with FibroScan findings and evaluation of factors influencing FIB-4 accuracy, such as BMI, HbA1c levels, and duration of diabetes. Subgroup analyses were performed to assess variations in diagnostic performance across these parameters.

All data were recorded in a structured proforma and entered into a master chart for analysis. Statistical analysis was performed using appropriate statistical software. Continuous variables such as age, BMI, HbA1c, and laboratory parameters were expressed as mean and standard deviation, while categorical variables were presented as frequency and percentage. Receiver operating characteristic (ROC) curve analysis was performed to evaluate the diagnostic performance of the FIB-4 index, and the area under the curve (AUC) was calculated. Sensitivity, specificity, positive predictive value, and negative predictive value were determined using standard formulas. A p-value of less than 0.05 was considered statistically significant.

Prior to commencement of the study, ethical clearance was obtained from the Institutional Ethics Committee of the respective institute. The study was conducted in accordance with the ethical principles of the Declaration of Helsinki. Written informed consent was obtained from all participants before enrollment, and strict confidentiality of patient data was maintained throughout the study.

RESULTS

A total of 100 patients with type 2 diabetes mellitus were included in the present study to evaluate the accuracy of the FIB-4 index in detecting liver fibrosis. Table 1 shows the age-wise distribution of the study population, where the majority of patients were in the 41–55 years age group accounting for 38 patients (38.0%), followed by 56–70 years with 34 patients (34.0%), and 30–40 years with 28 patients (28.0%), indicating a higher prevalence of diabetes-related liver involvement in middle-aged individuals. Table 2 represents the gender distribution, where males constituted 62 patients (62.0%) and females 38 patients (38.0%), showing a male predominance. Table 3 depicts the distribution of patients based on duration of diabetes, where 42 patients (42.0%) had diabetes for more than 10 years, 36 patients (36.0%) had duration between 5–10 years, and 22 patients (22.0%) had diabetes for less than 5 years, suggesting that longer duration of diabetes was common in the study group. Table 4 shows the BMI distribution, where 46 patients (46.0%) were overweight, 28 patients (28.0%) were obese, and 26 patients (26.0%) had normal BMI, indicating a higher proportion of patients with increased body weight. Table 5 presents the distribution of FIB-4 scores, where 44 patients (44.0%) were in the low-risk category, 32 patients (32.0%) were in the intermediate-risk category, and 24 patients (24.0%) were in the high-risk category for liver fibrosis. Table 6 compares FIB-4 findings with FibroScan results, where 30 patients (30.0%) were found to have significant fibrosis on FibroScan, and among them, 22 were correctly identified by FIB-4, while 8 cases were missed, whereas among 70 patients without significant fibrosis, 56 were correctly identified and 14 were falsely classified as positive, indicating moderate diagnostic performance. Table 7 shows the diagnostic parameters of FIB-4, where sensitivity was 73.3%, specificity was 80.0%, positive predictive value was 61.1%, and negative predictive value was 87.5%, reflecting good screening utility. Table 8 shows subgroup analysis based on HbA1c levels, where patients with HbA1c >8% had higher mean FIB-4 scores (2.35 ± 0.82) compared to those with HbA1c ≤8% (1.78 ± 0.64), suggesting poorer glycemic control was associated with higher fibrosis risk. Table 9 presents ROC curve analysis, where the area under the curve (AUC) for FIB-4 was 0.79, indicating acceptable diagnostic accuracy.

Table 1: Age-wise distribution of study participants

Age Group (years)	Frequency	Percentage (%)
30–40	28	28.0
41–55	38	38.0
56–70	34	34.0
Total	100	100.0

Table 2: Gender distribution of study participants

Gender	Frequency	Percentage (%)
Male	62	62.0
Female	38	38.0
Total	100	100.0

Table 3: Distribution based on duration of diabetes

Duration of Diabetes	Frequency	Percentage (%)
<5 years	22	22.0
5–10 years	36	36.0
>10 years	42	42.0
Total	100	100.0

Table 4: BMI distribution of study participants

BMI Category	Frequency	Percentage (%)
Normal	26	26.0
Overweight	46	46.0
Obese	28	28.0
Total	100	100.0

Table 5: Distribution of FIB-4 index categories

FIB-4 Category	Frequency	Percentage (%)
Low risk	44	44.0
Intermediate risk	32	32.0
High risk	24	24.0
Total	100	100.0

Table 6: Comparison of FIB-4 with FibroScan findings

FibroScan Result	FIB-4 Positive	FIB-4 Negative	Total
Significant fibrosis	22	8	30
No significant fibrosis	14	56	70
Total	36	64	100

Table 7: Diagnostic performance of FIB-4 index

Parameter	Value (%)
Sensitivity	73.3
Specificity	80.0

Positive Predictive Value	61.1
Negative Predictive Value	87.5

Table 8: Comparison of FIB-4 scores based on HbA1c levels

HbA1c Category	Mean FIB-4 Score	SD
≤8%	1.78	0.64
>8%	2.35	0.82

Table 9: ROC curve analysis of FIB-4 index

Parameter	Value
AUC	0.79

DISCUSSION

The present study evaluated the diagnostic accuracy of the FIB-4 index in detecting liver fibrosis among patients with type 2 diabetes mellitus and compared its performance with FibroScan as the reference standard. The study population predominantly comprised middle-aged individuals, with 38.0% of patients in the 41–55 years age group and 34.0% in the 56–70 years group, reflecting the higher burden of metabolic dysfunction and liver involvement in this age bracket. Male predominance (62.0%) observed in this study is consistent with epidemiological patterns of metabolic liver disease and diabetes-related complications. The duration of diabetes was more than 10 years in 42.0% of patients, indicating that chronic hyperglycemia plays a significant role in the progression of liver fibrosis, as supported by recent literature emphasizing long-standing diabetes as a key risk factor for advanced fibrosis [11].

Body mass index distribution in the present study showed that 46.0% of patients were overweight and 28.0% were obese, reinforcing the well-established association between obesity, insulin resistance, and hepatic steatosis leading to fibrosis. Obesity contributes to hepatic inflammation, lipotoxicity, and fibrogenesis, thereby increasing the risk of advanced liver disease in diabetic individuals [12]. These findings highlight the importance of metabolic factors in influencing liver fibrosis progression.

The distribution of FIB-4 index categories revealed that 24.0% of patients were classified as high risk, while 32.0% were in the intermediate-risk category. When compared with FibroScan findings, 30.0% of patients had significant fibrosis, of which 22 cases were correctly identified by FIB-4. However, 8 cases were missed, and 14 cases were falsely identified as positive among those without fibrosis. This resulted in a sensitivity of 73.3% and specificity of 80.0%, indicating that FIB-4 has moderate diagnostic accuracy in detecting liver fibrosis in diabetic patients. These findings are comparable with recent studies reporting similar sensitivity and specificity ranges, suggesting that FIB-4 is a useful screening tool but may not be sufficient as a standalone diagnostic modality [13].

The positive predictive value of 61.1% and negative predictive value of 87.5% observed in the present study suggest that FIB-4 is more reliable in ruling out significant fibrosis than confirming it. This aligns with previous evidence indicating that FIB-4 performs better as a rule-out test, especially in primary care settings where identifying low-risk patients can reduce the need for further invasive or expensive investigations [14]. The ROC curve analysis in the present study showed an area under the curve (AUC) of 0.79, which indicates acceptable diagnostic performance and supports the clinical utility of FIB-4 in risk stratification.

Subgroup analysis based on glycemic control demonstrated that patients with HbA1c levels greater than 8% had higher mean FIB-4 scores (2.35 ± 0.82) compared to those with HbA1c ≤8% (1.78 ± 0.64), suggesting that poor glycemic control is associated with increased risk of liver fibrosis. Although this study did not perform a statistical test for this comparison, the observed trend is consistent with recent findings that hyperglycemia promotes hepatic inflammation, oxidative stress, and fibrogenesis, thereby accelerating fibrosis progression in diabetic patients [15].

Overall, the findings of the present study highlight that while FIB-4 is a simple, non-invasive, and cost-effective tool with reasonable diagnostic accuracy, its performance is influenced by patient-specific factors such as age, duration of diabetes, BMI, and glycemic control. The moderate sensitivity and specificity indicate that FIB-4 should ideally be used as an initial screening tool, followed by confirmatory testing with modalities such as FibroScan for accurate diagnosis. Tailoring FIB-4 cut-off values for diabetic populations may further enhance its diagnostic performance.

CONCLUSION

The present study concludes that the FIB-4 index demonstrates moderate accuracy in detecting liver fibrosis among patients with type 2 diabetes mellitus. It shows good sensitivity and specificity, with a higher negative predictive value, making it a useful tool for ruling out significant fibrosis. However, its limitations in accurately identifying all cases highlight the need for confirmatory evaluation using FibroScan. Factors such as age, duration of diabetes, obesity, and poor glycemic control influence liver fibrosis and may affect the diagnostic performance of FIB-4. Therefore, FIB-4 can be effectively utilized as a first-line screening tool, but a combined approach with imaging modalities is recommended for optimal clinical decision-making.

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