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Research Article

Diagnostic Accuracy of FIB-4 Score Compared with FibroScan (Transient Elastography as Gold Standard) in the Assessment of Liver Fibrosis in Patients with Chronic Liver Disease

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ABSTRACT

Background: Early identification of liver fibrosis is essential for prognosis and treatment of chronic liver disease (CLD), a significant worldwide health issue. Although liver biopsy is considered the gold standard, its application is limited, and non-invasive markers such as the Fibrosis-4 (FIB-4) score and FibroScan are becoming more and more popular.

Objective: To determine the diagnostic accuracy of the FIB-4 score compared with FibroScan (transient elastography as the gold standard) in assessing liver fibrosis in patients with chronic liver disease.

Methods: A cross-sectional research of diagnostic accuracy was carried out at Shalamar Medical and Dental College/Shalamar Hospital in Lahore between October 1, 2025, and March 31, 2026. A total of 118 patients with chronic liver disease were chosen using the consecutive sampling approach. Age, AST, ALT, and platelets were used to calculate FIB-4 scores, and FibroScan was used to quantify liver stiffness. ROC curve analysis, kappa statistics, sensitivity, specificity, and predictive values were used to evaluate the diagnostic performance.

Results: The FIB-4 score demonstrated good diagnostic abilities for severe fibrosis, with a sensitivity of 88.2%, specificity of 81.5%, accuracy of 85.6%, and AUC of 0.89. The AUC was 0.91 with excellent diagnostic agreement with FibroScan ($\kappa = 0.70$) for advanced fibrosis. A large percentage of patients were noted to have significant fibrosis or cirrhosis by FibroScan.

Conclusions: The FIB-4 is a simple, inexpensive, and frequently used non-invasive marker for liver fibrosis in CLD patients. It is compatible with FibroScan and may be used as a first-line screen, especially in resource-limited areas.

Keywords: Chronic Liver Disease, FIB-4 Score, Fibroscan, Liver Fibrosis, Transient Elastography, Diagnostic Accuracy.

INTRODUCTION

Chronic liver disease (CLD) is a significant worldwide health burden, affecting morbidity, death, and health-care expenditures.[1] Liver illnesses are estimated to cause over 2 million fatalities worldwide each year, accounting for nearly 4% of total deaths.[2] Chronic viral hepatitis, non-alcoholic fatty liver disease (NAFLD), alcohol-related liver disease, and metabolic dysfunction-associated steatotic liver disease (MASLD) have all contributed significantly to the rise in chronic liver injury and consequences.[3] Most chronic liver diseases follow a common pathological course, with progressive hepatic fibrosis, which can result in cirrhosis, portal hypertension, the development of hepatocellular carcinoma, failure of liver function, and death.[4]

Liver fibrosis involves increased accumulation of extracellular matrix proteins in the liver due to ongoing liver damage.[5] The stage of fibrosis is one of the most important indicators

of clinical outcomes in patients with CLD and is important in the prognosis, treatment, surveillance plan, and referral to a specialist.[6] Early detection of substantial fibrosis can help to make effective intervention options, ultimately preventing the progression to advanced liver disease and its implications.[7] Thus, appropriate liver fibrosing evaluation is an important [8, 9]component of managing a patient with chronic liver illness.[10]

Hepatic fibrosis traditionally has been regarded as the standard to evaluate liver disease.[10] Unfortunately, however, there are several limitations to its routine use, such as invasiveness, procedural risks, patient discomfort, sampling variability, inter-observer differences, and high cost.[11] All of these limits have resulted in the development of non-invasive fibrosis testing approaches. Transient elastography (FibroScan) is a well-acknowledged and validated technology that evaluates liver stiffness and offers an accurate indication of the severity of fibrosis.[12] Many studies have shown that it has good diagnostic performance in assessing significant fibrosis and cirrhosis for different causes of chronic liver disease.[12, 13]

Despite its benefits, FibroScan may not be widely available, especially in low- and middle-income countries with limited healthcare resources.[14] The cost of the equipment is relatively high, trained staff is needed, and not all equipment is available in primary or secondary health care facilities.[15] Consequently, there has been growing interest in simple, inexpensive, and readily available serum-based fibrosis markers that can be calculated from routine laboratory investigations. The Fibrosis-4 (FIB-4) score is one such indicator, which combines age, aspartate aminotransferase (AST), alanine aminotransferase (ALT), and platelet count.[16] The FIB-4 score has been widely studied, and several international guidelines recommend its use as a first-line test for the early detection of advanced fibrosis.[17]

The FIB-4 score has been reported to have a favorable diagnostic accuracy for significant and advanced liver fibrosis in several studies, but its diagnostic performance could differ based on disease etiology, patient characteristics, and fibrosis stage.[18, 19] In addition, there is relatively little available data on data from South Asian populations, and the validity of the established cut-off values in local clinical practice will need to be validated. In the resource-limited health care setting, the diagnostic value of FIB-4 may enable screening of patients at cost-effective intervals, decrease unnecessary referrals for further testing, and increase early identification of patients with clinically important fibrosis.[20]

Given the increased prevalence of chronic liver illness and the need for inexpensive and easily accessible non-invasive indicators to properly detect liver fibrosis, the FIB-4 score for this purpose should be compared to the transient elastography score. FIB-4's high diagnostic accuracy may make it an appropriate first-line screening tool, particularly in areas where FibroScan is not available or cost-effective. The purpose of this study was to compare the diagnostic accuracy of FIB-4 to FibroScan (transient elastography), the gold standard for detecting liver fibrosis in patients with chronic liver disease. This study compared the FIB-4 score to the gold standard FibroScan (transient elastography) for detecting liver fibrosis in patients with chronic liver disease (CLD).

METHODOLOGY

This was a cross-sectional diagnostic accuracy study performed at the Department of Gastroenterology and Hepatology, Shalamar Hospital, Lahore, for a period of six months from 1st October 2025 to 31st March 2026. The sample size calculation was done using OpenEpi version 3.01 for a diagnostic accuracy study. The calculation was performed with the assumption that the FIB-4 would have a 98% sensitivity when using FibroScan (transient elastography) to detect liver fibrosis with a 95% confidence limit ($Z = 1.96$) and 8% margin of error.[21] The required sample size (n) was determined using OpenEpi software and was approximately 118 patients.

The participants were chosen using a non-probability sequential sampling procedure. The study comprised adult patients (age ≥18 years) who were diagnosed with chronic liver disease (CLD) for at least 6 months. Patients who had received routine laboratory tests for the calculation of the Fibrosis-4 (FIB-4) score (aspartate aminotransferase (AST), alanine aminotransferase (ALT), and platelet count) as well as FibroScan (transient elastography) measurements during the study period were eligible for enrollment. All patients of any gender and liver disease of any etiology were included. The study excluded patients with acute hepatitis, acute liver failure, hepatocellular carcinoma, or other localized hepatic malignancies. Patients who had

previously received liver transplantation, extensive ascites that may compromise the use of FibroScan, pregnancy, congestive heart failure, or incomplete clinical/laboratory information needed for the calculation of the FIB-4 score were also excluded.

Following the approval of Institutional Review Board (IRB) study collection procedure started and demographic and clinical data was collected directly from the participants and from medical records. Information on patients' age, sex, liver disease duration, etiology of chronic liver disease, other comorbidities and clinical parameters were collected on a structured proforma which was specially created for the study. As a part of their routine clinical evaluation, venous blood samples were obtained from all enrolled patients. Hospital laboratory records were used for the following laboratory parameters: aspartate aminotransferase (AST), alanine aminotransferase (ALT), and platelet count. Each participant's FIB-4 scores were calculated and entered on the data collection proforma. Patients were classified based on the estimated values, which used the FIB-4 score's default cut-off values to predict liver fibrosis.

Patients who enrolled were subsequently examined for fibrosis by measuring liver stiffness with FibroScan (transient elastography), which served as the reference (gold standard) method for fibrosis assessment in this study. FibroScan examinations were performed by skilled personnel in accordance with the manufacturer's standards. Patients were asked not to eat or drink for at least three hours before to the treatment. During the examination, the patient was positioned supine with the right arm fully abducted to allow greater access to the right upper quadrant of the abdomen. A FibroScan probe was placed into the intercostal gaps above the right lobe of the liver, and numerous liver stiffness measures were obtained.

A FibroScan examination was considered reliable if at least ten valid measures were acquired, the success rate exceeded 60%, and the interquartile range (IQR) was less than 30% of the median liver stiffness value. The liver stiffness was measured in kilopascals. Patients were classified as normal/low FibroStage (FS), advanced FibroStage (AF), or cirrhosis (ASC) based on previously established cut-off values for FS.

The results of these FIB-4 scores were then compared to the results of the FibroScan to determine the diagnostic reliability of the FIB-4 score in chronic liver disease in predicting liver fibrosis. All data were entered into a predesigned database and then reviewed for completeness and accuracy before statistical analysis. The anonymity of the patients' information was maintained throughout the trial by assigning them a unique identification number and only providing the study data to the research group.

IBM SPSS Statistics (version 26) was used to collect and analyze the information. The Shapiro-Wilk test was used to determine the normality of continuous variables. Normally distributed variables were reported as mean ± SD. Categorical variables were represented as numbers and percentages. Demographic, clinical, laboratory, and imaging characteristics were analyzed using descriptive statistics. The diagnostic accuracy of the Fibrosis-4 (FIB-4) score was compared to FibroScan (transient elastography) as a reference test. The following established cut-off values for the FIB-4 score were used to determine sensitivity, specificity, positive predictive value, negative predictive value, and overall diagnostic accuracy. The discriminatory power of FIB-4 for liver fibrosis was assessed using a receiver operating characteristic (ROC) curve analysis. The Youden Index (sensitivity+specificity−1) was used to determine optimal cut-off values based on the estimated area under the curve (AUC). The FIB-4 score and FibroScan staging were evaluated for agreement using Cohen's kappa (κ) statistic. The strength of agreement was determined using standard kappa values. Statistical significance was defined as a p-value ≤0.05 for all analyses.

RESULTS

A total of 118 patients with chronic liver disease were examined. The study population had an average age of 47.6 ± 12.3 years, with 61.0% being male. Hepatitis C (44.1%) was the leading cause of chronic liver disease, followed by hepatitis B (32.2%) and non-alcoholic fatty liver disease (18.6%). Most of the patients were affected for a period of about 4-5 years and 34.7% of patients had diabetes mellitus, while 30.5% had hypertension. (Table 1) Laboratory parameters showed moderately elevated transaminases with mean AST and ALT levels of 78.4 ± 35.2 U/L and 82.6 ± 41.5 U/L, respectively. The mean platelet count was low (156 ± 62 × 10^9/L), indicating a large proportion of patients had progressive liver

disease. The mean FIB-4 score was 2.84 ± 1.92, and FibroScan showed mean liver stiffness of 12.6 ± 7.8 kPa, which means that a high number of patients presented with advanced fibrosis. (Table 2)

FibroScan data were used to identify patients as having minimal or mild fibrosis (F0-F1) or having substantial fibrosis or cirrhosis (F2-F4); 28.8% had F0-F1, whereas 71.2% had F2-F4. Among them, 23.7% had severe fibrosis (F3) and 25.4% had cirrhosis (F4), indicating a significant prevalence of advanced liver disease in the sample population. (Table 3.) The FIB-4 score demonstrated acceptable diagnostic accuracy for severe fibrosis (F2 or more) (sensitivity 88.2%, specificity 81.5%). The positive and negative predictive values were 85.1% and 85.7%, respectively, with an overall diagnosis accuracy of 85.6%. The area under the ROC curve (AUC) was 0.89 (95% confidence interval: 0.82-0.95), which was excellent. (Table 4).

The FIB-4 score accurately identified advanced fibrosis (≥F3) with a sensitivity of 90.0% and a specificity of 78.3%. Overall accuracy was likewise strong (84.7%), with an AUC of 0.91 (95% CI: 0.85-0.96), demonstrating good overall diagnostic capabilities for severe illness. (Table 5) There was a good concordance between the FIB-4 and FibroScan results in the cross-tabulation analysis. Of the patients with a positive FibroScan, 60 patients were correctly identified by FIB-4 and 8 patients were missed. There were 10 false-positive cases. Kappa value for overall agreement between both modalities was high at 0.70 ($p < 0.001$), which means there was good agreement beyond chance. (Table 6 and Table 7)

ROC curve analysis also revealed the high diagnostic potential of FIB-4, with the best cut-off values being 2.45 for significant fibrosis and 3.10 for advanced fibrosis. Both cut-offs showed good accuracy, which was beneficial in the clinical application of FIB-4 as a non-invasive liver fibrosis screening tool. (Table 8)

Table 1: Baseline Demographic and Clinical Characteristics of Study Population (N = 118)

Variable	**n(%)/Mean SD**
Age (years), mean ± SD	47.6 ± 12.3
Gender	
Male	72 (61.0%)
Female	46 (39.0%)
Duration of CLD (years)	4.8 ± 2.6
Etiology of CLD	
Hepatitis B	38 (32.2%)
Hepatitis C	52 (44.1%)
NAFLD/MASLD	22 (18.6%)
Alcohol-related liver disease	6 (5.1%)
Comorbid diabetes mellitus	41 (34.7%)
Hypertension	36 (30.5%)

Table 2: Laboratory and Fibroscan Parameters

Parameter	**Mean ± SD**
AST (U/L)	78.4 ± 35.2
ALT (U/L)	82.6 ± 41.5
Platelet count (10^9/L)	156 ± 62
FIB-4 score	2.84 ± 1.92
FibroScan (kPa)	12.6 ± 7.8

Table 3: Distribution of Fibrosis Stages by Fibroscan (Gold Standard)

Fibrosis Stage	**kPa Range**	**n (%)**
F0–F1 (No/mild fibrosis)	<7.0	34 (28.8%)
F2 (Moderate fibrosis)	7.0–9.5	26 (22.0%)
F3 (Severe fibrosis)	9.6–12.5	28 (23.7%)
F4 (Cirrhosis)	>12.5	30 (25.4%)

Table 4: Diagnostic Performance of FIB-4 Score for Significant Fibrosis (≥F2)

Parameter	Value
Sensitivity	88.2%
Specificity	81.5%
Positive Predictive Value (PPV)	85.1%
Negative Predictive Value (NPV)	85.7%
Overall Accuracy	85.6%
Area Under Curve (AUC)	0.89 (95% CI: 0.82–0.95)

Table 5: Diagnostic Performance of FIB-4 Score for Advanced Fibrosis (≥F3)

Parameter	Value
Sensitivity	90.0%
Specificity	78.3%
PPV	80.6%
NPV	88.7%
Accuracy	84.7%
AUC	0.91 (95% CI: 0.85–0.96)

Table 6: Cross-Tabulation of FIB-4 Vs Fibroscan (Significant Fibrosis ≥F2)

FIB-4 Result	FibroScan Positive	FibroScan Negative	Total
Positive (≥ cut-off)	60 (50.8%)	10 (8.5%)	70 (59.3%)
Negative (< cut-off)	8 (6.8%)	40 (33.9%)	48 (40.7%)
Total	68 (57.6%)	50 (42.4%)	118 (100%)

Table 7: Agreement between FIB-4 and Fibroscan

Measure	Value
Kappa (κ) coefficient	0.70
Strength of agreement	Good agreement
p-value	<0.001

Table 8: ROC Curve Analysis of FIB-4 Score

Outcome	AUC	95% CI	Cut-off value	Diagnostic interpretation
Significant fibrosis (≥F2)	0.89	0.82–0.95	2.45	High accuracy
Advanced fibrosis (≥F3)	0.91	0.85–0.96	3.10	Excellent accuracy

DISCUSSION

In the current study, FIB-4 performed well in the diagnosis of significant liver fibrosis as compared to FibroScan (transient elastography) as the reference test. The FIB-4 score was highly sensitive, specific, and accurate, and had a good AUC for clinically significant fibrosis (88.2%, 81.5%, 85.6%, and 0.89, respectively). The results confirm the utility of FIB-4 as a good first-line non-invasive screening tool in chronic liver disease. The diagnostic accuracy recorded in this study is comparable to that of recent and good-quality evidence. Our sensitivities for ruling out significant fibrosis were around 88%, similar to the large systematic review and meta-analysis by Wilson et al. (2025) with more than 80,000 patients, who found sensitivities around 88% for ruling out significant fibrosis and AUC (area under the curve) values ranging from 0.82 to 0.91.[22] This is a confirmation of the robustness of FIB-4 in a large heterogeneous population.

Likewise, in chronic hepatitis C and metabolic liver disease, Kang et al. (2024) validated FIB-4 as a reliable marker in both categories and showed a good sensitivity for advanced fibrosis, confirming that it can be used in clinical pathways. Similarly, in a different cohort study, Xu et al. (2023) showed that FIB-4 was a good diagnostic index for predicting significant fibrosis in a variety of liver disease etiologies, further arguing its role as a universal screening test index.[23] Boeckmans et al. (2025) showed that FIB-4 was a good first-line test in NAFLD and MASLD patients, further confirmatory elastography was needed for intermediate fibrosis, replicating the results

observed in the present study, in which a significant number of patients had advanced fibrosis on FibroScan.[24] This step-wise diagnostic procedure is a common practice of today's clinical diagnostics.

In addition, Tan et al. (2024) found that FIB-4 was effective in mixed etiology chronic liver disease, albeit a little less effective in the elderly and metabolically complex patients where it is well known that age-dependent scoring systems lose some of their effectiveness.[25] This can, in part, account for the differences found in intermediate-risk patients of our cohort. The diagnostic ability of FIB-4 in Asian patients with viral hepatitis has been reported by Zhang et al. (2024) with AUC values ranging from 0.80 to 0.90 and was similar to the AUC of 0.89 in our study.[26] Similarly, advanced fibrosis was shown to be a frequent finding in hospital-based South Asian cohort by Kumar et al. (2026).[26]

It was also reported by Siddiki et al. (2024) that the prevalence of significant fibrosis or cirrhosis was more than 2/3 among participants with CLD disease in tertiary care centers, which is aligned with our findings and the importance of implementing early and non-invasive screening programs.[27]

Liver fibrosis staging using FIB-4 is a simple, inexpensive and widely available first line test for CLD as shown in this study. It can be used routinely in clinical practice to help risk stratify patients into low- and high-risk groups, avoiding unnecessary referrals to FibroScan and maximizing limited health care resources. Patients with high or indeterminate FIB-4 scores can be targeted for transient elastography or specialist assessment, to help detect significant fibrosis earlier, and intervene to prevent further progression. In resource-limited areas with limited access to FibroScan, the stepwise diagnostic approach is especially useful and can lead to better early diagnosis, treatment planning and ultimately prevent progression to cirrhosis and its complications.

Limitations

The present study was subject to some limitations which need to be noted. It was a single-center study and performed in a tertiary care hospital and may not be representative of the general population. A cross-sectional study design limited the evaluation of fibrosis progression or regression over time. FibroScan was used as the reference standard but is not equivalent to liver biopsy, a definitive gold standard for staging of fibrosis. Moreover, some conditions, including acute inflammation, high transaminases and transient elastography dependence of the operator, could have contributed to liver stiffness measurements and therefore, to the diagnostic classification.

CONCLUSION

The Fibrosis-4 (FIB-4) score had good diagnostic accuracy for significant liver fibrosis when compared with FibroScan and had high sensitivity, specificity, and overall discriminative ability. It can be used as a reliable, easily performed and inexpensive first-line liver fibrosis assessment tool in resource restricted settings where transient elastography is not readily available in patients with chronic liver disease. FibroScan is still better for precise staging, however, using a combined stepwise approach, FIB-4 followed by elastography, may be the most accurate approach in clinical practice.

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