FIB-4, APRI, and AST/ALT Ratio Compared to FibroScan for the Assessment of Hepatic Fibrosis in Patients with Non-Alcoholic Fatty Liver Disease: A Cross-Sectional Study

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ABSTRACT

Background: Non-alcoholic fatty liver disease (NAFLD) is now the most prevalent chronic liver disorder globally. Liver fibrosis stage is the primary determinant of prognosis in NAFLD patients. FibroScan (transient elastography) is a validated non-invasive method for fibrosis assessment, but its availability remains limited in resource-constrained settings. Simple serum-based indices offer a potentially cost-effective alternative.

Objectives: To evaluate and compare the diagnostic performance of FIB-4 score, APRI score, and AST/ALT ratio against FibroScan for the assessment of hepatic fibrosis in NAFLD patients.

Methods: This hospital-based cross-sectional observational study enrolled 150 consecutive NAFLD patients at a tertiary care centre in Jaipur, India over 18 months (March 2024 – August 2025). All participants underwent FibroScan assessment and calculation of FIB-4, APRI, and AST/ALT ratio from standard biochemical parameters. Fibrosis was staged F0–F4 by transient elastography. Statistical analysis was performed using SPSS 29.0; a p-value <0.05 was considered significant.

Results: The mean age was 51.41 ± 10.46 years; 62.67% were male. FibroScan-determined fibrosis distribution: F0 (40%), F4 (18%), F0–F1 (17.33%), F2–F3 (16.67%), F3–F4 (8%). All three serum indices — FIB-4, APRI, and AST/ALT ratio — showed statistically significant progressive increases with advancing fibrosis stage (all $p < 0.001$). In advanced fibrosis (F3–F4 and F4), 100% of patients exceeded the established high-risk thresholds for each index (FIB-4 ≥ 3.4; APRI > 1.5; AST/ALT ≥ 0.8). Mean FIB-4 scores rose from 1.16 ± 0.50 in F0 to 7.92 ± 1.03 in F4; APRI from 0.47 ± 0.16 to 2.62 ± 0.24; and AST/ALT ratio from 0.61 ± 0.15 to 1.50 ± 0.19.

Conclusions: FIB-4, APRI, and AST/ALT ratio are reliable, low-cost, and widely accessible non-invasive markers that correlate strongly with FibroScan-determined fibrosis severity in NAFLD patients. FIB-4 demonstrated the greatest discriminative power for advanced fibrosis. These indices are recommended as initial fibrosis triage tools, with FibroScan reserved for patients in the indeterminate risk range.

Keywords: *NAFLD; non-alcoholic fatty liver disease; liver fibrosis; FIB-4; APRI; AST/ALT ratio; FibroScan; transient elastography; non-invasive markers*

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1. INTRODUCTION

Non-alcoholic fatty liver disease (NAFLD) has emerged as the most prevalent chronic liver disorder worldwide, affecting an estimated 25–30% of the adult population. Its rising burden is strongly associated with the global epidemics of obesity, metabolic syndrome, and sedentary lifestyles. NAFLD encompasses a pathological spectrum from simple hepatic steatosis to non-alcoholic steatohepatitis (NASH), progressive fibrosis, cirrhosis, and hepatocellular carcinoma. A global meta-analysis estimated NAFLD prevalence at 25.2%, with the highest rates in the Middle East (31.8%) and South America (30.4%), followed by Asia (27.4%), North America (24.1%), and Europe (23.7%).[1]

In India, NAFLD prevalence ranges from 9% to 32% in the general population, with higher rates in urban communities.[2] Among patients with type 2 diabetes mellitus, prevalence may reach 70%.[3,4] Notably, the Indian subcontinent also experiences a significant burden of "lean NAFLD", where hepatic steatosis develops in individuals with a normal or low body mass index, likely reflecting specific genetic and metabolic predispositions.[5]

Liver fibrosis stage is now recognised as the most critical prognostic determinant in NAFLD, correlating with overall mortality, liver-specific outcomes, and extrahepatic complications including cardiovascular disease.[6] Timely and accurate fibrosis assessment is therefore essential for appropriate risk stratification, treatment decisions, and monitoring. Although liver biopsy remains the historical reference standard, it is invasive, costly, and subject to sampling error and interobserver variability, rendering it impractical for population-level screening in a disease with such high prevalence.

Transient elastography (FibroScan) has achieved broad clinical validation as a non-invasive standard for fibrosis assessment, offering rapid, reproducible liver stiffness measurements in kilopascals (kPa) that correlate with fibrosis stage. However, FibroScan requires specialised equipment, trained operators, and entails significant cost — limiting its availability in resource-constrained settings. Simple serum-based indices, including the Fibrosis-4 (FIB-4) score, the AST-to-Platelet Ratio Index (APRI), and the AST/ALT ratio, offer universally available and low-cost alternatives derived from standard blood tests routinely performed in clinical practice.[7,8]

The present study was designed to evaluate and compare the diagnostic performance of FIB-4, APRI, and the AST/ALT ratio against FibroScan for hepatic fibrosis assessment in NAFLD patients at a tertiary care centre in North India — a setting where comparative data remain relatively sparse.

2. MATERIALS AND METHODS

2.1 Study Design and Setting

This was a hospital-based cross-sectional observational study conducted in the Department of General Medicine, Mahatma Gandhi Medical College and Hospital, Jaipur, India, over 18 months (March 2024 to August 2025) following Institutional Ethics Committee approval. Patients admitted to the medical wards and ICU, as well as those attending outpatient services, were screened for eligibility.

2.2 Participants

A total of 150 consecutive adult patients (age > 18 years) diagnosed with NAFLD or NASH who provided written informed consent were enrolled. Patients with other chronic liver diseases (hepatitis B or C, autoimmune hepatitis, Wilson's disease, alcoholic liver disease), hepatotoxic drug use, decompensated liver disease, congestive heart failure, or conditions precluding reliable FibroScan assessment (severe obesity, ascites, pregnancy) were excluded.

2.3 Clinical and Biochemical Assessment

All participants underwent detailed clinical evaluation including history, anthropometric measurements (height, weight, BMI, waist circumference), and standard laboratory investigations: complete blood count, liver function tests (AST, ALT, ALP, GGT, bilirubin, albumin), lipid profile (total cholesterol, LDL, HDL, triglycerides), fasting glucose/HbA1c, renal function tests, PT/INR, PTT, and viral markers (HBsAg, anti-HCV) to exclude other aetiologies.

2.4 Calculation of Serum Fibrosis Indicesc[7,8]

The three serum-based indices were calculated using the following validated formulae:

APRI = [(AST / upper limit of normal AST) × 100] / platelet count (×10⁹/L)

FIB-4 = (Age [years] × AST [U/L]) / (Platelet count [×10⁹/L] × √ALT [U/L])

AST/ALT ratio = AST (U/L) / ALT (U/L)

2.5 FibroScan Assessment

All enrolled patients underwent transient elastography (FibroScan, Echosens, France) performed by trained personnel using the standard protocol. Liver stiffness measurement (LSM) in kilopascals was recorded. Fibrosis stage was categorised as: F0 (no fibrosis), F1 (mild fibrosis), F2 (significant fibrosis), F3 (advanced fibrosis), and F4 (cirrhosis).

2.6 Statistical Analysis

Data were entered in Microsoft Excel and analysed using SPSS version 29.0. Continuous variables were expressed as mean ± standard deviation; categorical variables as frequencies and percentages. Comparisons across fibrosis stages were made using one-way ANOVA for continuous variables and chi-square test for categorical variables. A p-value < 0.05 was considered statistically significant.

3. RESULTS

3.1 Demographic and Clinical Characteristics

A total of 150 patients were enrolled. The mean age was 51.41 ± 10.46 years, with the majority of patients in the 51–60 years age group (n = 74; 49.3%), followed by those above 61 years (n = 37; 24.7%). Males constituted 62.67% (n = 94) and females 37.33% (n = 56) of the study population.

Table 1. Demographic and fibrosis stage distribution of study participants (n = 150)

Characteristic	Value
Age (years), mean ± SD	51.41 ± 10.46
Male sex, n (%)	94 (62.67%)
Female sex, n (%)	56 (37.33%)
F0 – No fibrosis, n (%)	60 (40.00%)
F0–F1 – Mild fibrosis, n (%)	26 (17.33%)
F2–F3 – Significant/advanced fibrosis, n (%)	25 (16.67%)
F3–F4 – Advanced fibrosis, n (%)	12 (8.00%)
F4 – Cirrhosis, n (%)	27 (18.00%)

3.2 Biochemical Parameters Across Fibrosis Stages

Table 2 summarises the key biochemical parameters stratified by fibrosis stage. AST levels increased progressively from 38.82 ± 5.99 U/L in F0 to 92.00 ± 4.94 U/L in F4 ($p < 0.001$). ALT levels peaked at F3–F4 (83.92 ± 3.55 U/L) before declining in F4 (62.22 ± 5.74 U/L), a pattern consistent with the burnt-out NASH phenomenon. Serum albumin declined progressively (4.75 ± 0.66 g/dL in F0 to 3.78 ± 0.23 g/dL in F4; $p < 0.001$), while bilirubin (0.87 to 2.83 mg/dL), ALP (134.38 to 149.22 U/L), glucose (95.6 to 121.44 mg/dL), INR (1.17 to 1.73), and PTT (29.77 to 43.85 seconds) all increased significantly with advancing fibrosis (all $p < 0.001$). Platelet count showed a marked progressive decline (228.05 ± 65.01 to 87.78 ± 4.27 × 10⁹/L; $p < 0.001$). Total cholesterol, LDL, and triglycerides all declined significantly with advancing fibrosis (all $p < 0.001$), while GGT and HDL did not show significant associations ($p = 0.09$ and $p = 0.62$, respectively).

Table 2. Key biochemical parameters by fibrosis stage (mean ± SD)

Parameter	F0 (n=60)	F0–F1 (n=26)	F2–F3 (n=25)	F3–F4 (n=12)	F4 (n=27)	p-value
AST (U/L)	38.82 ± 5.99	41.73 ± 4.86	59.24 ± 6.50	92.42 ± 4.01	92.00 ± 4.94	< 0.001
ALT (U/L)	65.83 ± 12.78	66.88 ± 16.06	69.48 ± 11.99	83.92 ± 3.55	62.22 ± 5.74	< 0.001
AST/ALT Ratio	0.61 ± 0.15	0.67 ± 0.21	0.88 ± 0.22	1.10 ± 0.07	1.50 ± 0.19	< 0.001
Albumin (g/dL)	4.75 ± 0.66	4.35 ± 0.64	4.07 ± 0.61	3.85 ± 0.35	3.78 ± 0.23	< 0.001
Bilirubin (mg/dL)	0.87 ± 0.49	1.19 ± 0.60	1.52 ± 0.76	1.95 ± 0.81	2.83 ± 1.71	< 0.001
Platelets (×10⁹/L)	228.05 ± 65.01	191.35 ± 43.71	148.08 ± 20.95	111.00 ± 18.06	87.78 ± 4.27	< 0.001
INR	1.17 ± 0.36	1.19 ± 0.39	1.25 ± 0.29	1.38 ± 0.11	1.73 ± 0.15	< 0.001
Glucose (mg/dL)	95.6 ± 4.66	98.0 ± 4.83	112.08 ± 10.48	118.5 ± 10.1	121.44 ± 10.46	< 0.001
ALP (U/L)	134.38 ± 15.91	138.23 ± 5.91	142.16 ± 8.66	147.17 ± 6.09	149.22 ± 12.15	< 0.001

3.3 Non-Invasive Fibrosis Scores Across Fibrosis Stages

All three serum indices demonstrated statistically significant progressive increases with advancing fibrosis stage (Table 3). Mean APRI rose from 0.47 ± 0.16 in F0 to 2.62 ± 0.24 in F4 ($p < 0.001$). FIB-4 showed the steepest gradient, rising from 1.16 ± 0.50 in F0 to 7.92 ± 1.03 in F4 ($p < 0.001$). The AST/ALT ratio increased from 0.61 ± 0.15 to 1.50 ± 0.19 ($p < 0.001$).

Table 3. Non-invasive fibrosis scores by fibrosis stage (mean ± SD)

Score	F0 (n=60)	F0–F1 (n=26)	F2–F3 (n=25)	F3–F4 (n=12)	F4 (n=27)	p-value
APRI	0.47 ± 0.16	0.56 ± 0.13	1.01 ± 0.18	2.13 ± 0.36	2.62 ± 0.24	< 0.001
FIB-4	1.16 ± 0.50	1.34 ± 0.45	2.49 ± 0.84	5.05 ± 1.15	7.92 ± 1.03	< 0.001
AST/ALT Ratio	0.61 ± 0.15	0.67 ± 0.21	0.88 ± 0.22	1.10 ± 0.07	1.50 ± 0.19	< 0.001

3.4 Categorical Threshold Performance

The distribution of each index by established categorical thresholds is presented in Tables 4–6. Using APRI > 1.5 as the threshold for advanced fibrosis, 100% of F3 and F4 patients exceeded this cut-off, while 46.67% of F0 patients had APRI < 0.5. For FIB-4, using the high-risk threshold of ≥ 3.4, 100% of F3–F4 and F4 patients were correctly classified, while 75.00% of F0 patients had FIB-4 < 1.45. For the AST/ALT ratio, using ≥ 0.8 as the advanced fibrosis cut-off, 100% of F3 and F4 patients exceeded this threshold, while 91.67% of F0 patients had a ratio < 0.8.

Table 4. APRI categories by fibrosis stage, n (%)

APRI Grade	F0 (n=60)	F1 (n=26)	F2 (n=25)	F3 (n=12)	F4 (n=27)
< 0.5	28 (46.67)	5 (19.23)	0	0	0
0.5 – 1.5	32 (53.33)	21 (80.77)	25 (100.00)	0	0
> 1.5	0	0	0	12 (100.00)	27 (100.00)
p-value	< 0.001				

Table 5. FIB-4 categories by fibrosis stage, n (%)

FIB-4 Score	F0 (n=60)	F1 (n=26)	F2 (n=25)	F3 (n=12)	F4 (n=27)
< 1.45	45 (75.00)	14 (53.85)	2 (8.00)	0	0
1.45 – 3.39	15 (25.00)	12 (46.15)	20 (80.00)	0	0
≥ 3.4	0	0	3 (12.00)	12 (100.00)	27 (100.00)
p-value	< 0.001				

Table 6. AST/ALT ratio categories by fibrosis stage, n (%)

AST:ALT Ratio	F0 (n=60)	F1 (n=26)	F2 (n=25)	F3 (n=12)	F4 (n=27)
< 0.8	55 (91.67)	19 (73.08)	15 (60.00)	0	0
≥ 0.8	5 (8.33)	7 (26.92)	10 (40.00)	12 (100.00)	27 (100.00)
p-value	< 0.001				

4. DISCUSSION

4.1 Demographic Profile

The mean age of 51.41 ± 10.46 years and male predominance (62.67%) observed in the present study are consistent with published epidemiological data on NAFLD in India and globally. NAFLD-associated fibrosis characteristically becomes clinically manifest in middle-aged to elderly individuals, and advancing age is an independent predictor of fibrosis progression — a phenomenon attributable to prolonged metabolic burden, reduced hepatic regenerative capacity, and cumulative oxidative injury. This demographic context is clinically relevant because age is a direct parameter in the FIB-4 formula, amplifying its discriminative power in older cohorts.

The male predominance likely reflects differences in body fat distribution, sex hormonal profiles, and lifestyle-related metabolic risk factors. Notably, the F4 stage showed a higher female representation (44.44%) than earlier stages, consistent with post-menopausal loss of oestrogen's hepatoprotective effects and accelerated fibrosis progression in older women — a pattern reported in prior literature on sex-specific fibrosis trajectories in NAFLD.

4.2 Biochemical Parameters and Fibrosis

The statistically significant progressive escalation in AST levels with advancing fibrosis, alongside the paradoxical decline in ALT at the F4 stage, is mechanistically well-characterised. In early and moderate fibrosis, hepatocellular injury drives parallel elevations in both transaminases. However, in end-stage disease, progressive hepatocyte loss reduces the ALT-producing cellular pool — a manifestation of the "burnt-out NASH" phenomenon. This divergence in AST and ALT trajectories provides the pathophysiological basis for the AST/ALT ratio as a fibrosis biomarker.

The inverse relationships between fibrosis severity and serum albumin, platelet count, total cholesterol, LDL, and triglycerides reflect the progressive loss of hepatic synthetic capacity as functional hepatocyte mass is replaced by fibrotic tissue.[9,10] Conversely, rising bilirubin, ALP, INR, PTT, and glucose levels mirror the progressive impairment of hepatic excretory, coagulatory, and metabolic functions. These findings are consistent with prior reports from Al Danaf et al.[9] and Aggarwal et al.[11]

4.3 AST/ALT Ratio

The AST/ALT ratio showed a statistically significant stepwise rise from 0.61 ± 0.15 in F0 to 1.50 ± 0.19 in F4 ($p < 0.001$). Its categorical performance was particularly compelling: 100% of patients with advanced fibrosis (F3 and F4) had an AST/ALT ratio ≥ 0.8, while 91.67% of F0 patients were below this threshold, demonstrating high specificity for advanced fibrosis at this cut-off. These findings corroborate those of Mansour et al.,[12] Aggarwal et al.,[11] and Al Danaf et al.,[9] who validated this index in NAFLD cohorts using FibroScan or real-time elastography as the comparator. The principal advantage of the AST/ALT ratio lies in its universal availability from routine liver function testing, rendering it applicable at no additional cost in any clinical laboratory setting worldwide.

4.4 APRI Score

APRI demonstrated a progressive increase from 0.47 ± 0.16 in F0 to 2.62 ± 0.24 in F4, with a highly significant association across all fibrosis stages ($p < 0.001$). The categorical threshold analysis was definitive for advanced disease: 100% of F3 and F4 patients exceeded APRI > 1.5, while 46.67% of F0 patients had APRI < 0.5. APRI's mechanistic basis — incorporating both AST as a hepatocellular injury marker and thrombocytopenia as a surrogate of portal hypertension and reduced hepatic thrombopoietin synthesis — provides complementary information about fibrosis-related pathophysiology.

These results are consistent with Aggarwal et al.[11] (2024), who reported an AUROC of 0.747 for APRI in detecting F2 or higher fibrosis, with sensitivity of 70.83% and specificity of 79.55% at an optimal cut-off of 0.276 in a 68-patient NAFLD cohort. Al Danaf et al.[9] (2022) similarly confirmed APRI's utility as a screening tool for fibrosis assessment in NASH and NAFLD/NASH populations.

4.5 FIB-4 Score

FIB-4 demonstrated the most dramatic escalation across fibrosis stages, rising from 1.16 ± 0.50 in F0 to 7.92 ± 1.03 in F4 — an approximately 6.8-fold increase from no fibrosis to cirrhosis. The categorical analysis was definitive: 75.00% of F0 patients had FIB-4 < 1.45, and 100% of F3–F4 and F4 patients had FIB-4 ≥ 3.4. This complete separation at established thresholds demonstrates excellent specificity for advanced fibrosis in the present cohort.

The incorporation of age into the FIB-4 formula is a key advantage in the present study's predominantly older demographic. Shamseya et al.[13] (2022) reported FIB-4 sensitivity of 90%, specificity of 93.3%, and overall accuracy of 93% for advanced fibrosis detection using real-time elastography as the reference standard — among the highest reported for non-invasive serum indices. These findings are further corroborated by Mansour et al.[12] (2024) and Al Danaf et al.[9] (2022).

4.6 Comparative Advantages and Limitations

All three indices achieved complete discriminative performance at their established thresholds for advanced fibrosis (F3–F4) in the present cohort. Their practical advantages over FibroScan include universal availability from standard blood tests, freedom from the technical limitations of transient elastography (including failure rates up to 20% in severely obese patients and unreliable measurements in biliary obstruction or active hepatitis), low cost, and suitability for serial monitoring of fibrosis progression or regression.

However, these indices share limitations: they rely on categorical cut-offs that may misclassify patients in the indeterminate range (FIB-4 1.45–3.39; APRI 0.5–1.5), and they are influenced by non-fibrotic factors such as acute hepatitis, haematological disorders, or congestive heart failure. FibroScan, in contrast, offers continuous quantitative liver stiffness measurement with greater precision across the full fibrosis spectrum. Mansour et al. (2024) concluded that combined FibroScan and controlled attenuation parameter (CAP) assessment remains the most comprehensive simultaneous screening approach for fibrosis and steatosis in NAFLD.[12]

The optimal clinical strategy, supported by both the present findings and prior literature, is a stepwise approach: serum indices for initial risk stratification, with FibroScan reserved for patients in the indeterminate risk range. This framework maximises diagnostic accuracy while minimising cost and

procedural burden — a strategy particularly valuable in resource-limited healthcare settings.

5. CONCLUSION

FIB-4, APRI, and the AST/ALT ratio are reliable, cost-effective, and universally accessible non-invasive markers for hepatic fibrosis assessment in NAFLD patients, demonstrating statistically significant correlations with FibroScan-determined fibrosis severity across the full disease spectrum. FIB-4 demonstrated the strongest discriminative performance for advanced fibrosis, particularly in the older patient population that characterised the present study. APRI showed comparable discriminative ability with well-validated categorical thresholds, and the AST/ALT ratio offered high specificity for advanced fibrosis at a simple, universally calculated cut-off.

These findings support the integration of FIB-4, APRI, and AST/ALT ratio as initial triage tools in clinical pathways for NAFLD management, with FibroScan reserved for patients in the indeterminate risk category. This stepwise, resource-conscious approach optimises diagnostic accuracy while reducing patient burden and healthcare costs — a strategy of particular relevance for North Indian and resource-limited settings. Multicentre prospective studies incorporating liver biopsy as the reference standard and formal AUROC-based comparisons are warranted to further validate these findings and define optimal cut-off thresholds for diverse populations.

6. LIMITATIONS

The cross-sectional design precluded assessment of fibrosis progression over time. The relatively modest sample size (n = 150) may limit statistical power for subgroup analyses. Liver biopsy was not performed as a reference standard; FibroScan was used as the comparator. Lifestyle factors, dietary intake, physical activity levels, and treatment compliance were not systematically quantified. The single-centre design at a tertiary referral hospital may introduce referral bias, limiting generalisability to primary care settings.

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