Diagnostic performance of FibroScan in liver fibrosis staging in a tertiary care hospital of Nepal

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ABSTRACT

Introduction: Liver fibrosis is the excessive accumulation of extracellular matrix proteins resulting from chronic liver injury caused by viral hepatitis, non-alcoholic fatty liver disease, or alcoholism. If undiagnosed, it can progress to cirrhosis, liver failure, and hepatocellular carcinoma, emphasizing the need for early detection. Although liver biopsy was once the gold standard for fibrosis assessment, it is invasive and prone to complications and sampling errors. To overcome these limitations, non-invasive imaging methods such as FibroScan have been developed. This research aimed to study the diagnostic performance of FibroScan in liver fibrosis staging in a tertiary care hospital of Nepal. **Methods:** A hospital-based cross-sectional study was conducted among 60 adult patients with chronic liver disease. All participants underwent liver stiffness measurement using FibroScan and liver biopsy. Fibrosis was staged according to the METAVIR scoring system. Cut-off values of ≥7.1 kPa and ≥9.5 kPa were used to define significant (≥F2) and advanced fibrosis (≥F3), respectively. Diagnostic performance metrics including sensitivity, specificity, positive predictive value (PPV), negative predictive value (NPV), accuracy, and area under the ROC curve (AUC) were calculated. Mean liver stiffness was compared across fibrosis stages. **Results:** Histopathology revealed F0–F1 in 30%, F2 in 20%, F3 in 23.3%, and F4 in 26.7% of patients. For significant fibrosis (≥F2), elastography showed sensitivity 88.6%, specificity 89.2%, PPV 81.6%, NPV 93.5%, accuracy 89%, and AUC 0.93. For advanced fibrosis (≥F3), sensitivity was 90%, specificity 83.3%, PPV 84.4%, NPV 89.3%, accuracy 86.7%, and AUC 0.91. Mean liver stiffness increased significantly with fibrosis stage (F0–F1: 5.8±1.2 kPa to F4: 12.5±1.5 kPa; p=0.01). **Conclusions:** FibroScan is a reliable non-invasive tool for detecting significant and advanced liver fibrosis, demonstrating high diagnostic accuracy and good correlation with histopathological findings.

Keywords: Chronic liver disease, diagnostic accuracy, liver fibrosis, METAVIR Score, non-invasive assessment, ultrasound elastography.

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INTRODUCTION

Liver fibrosis is a progressive accumulation of extracellular matrix proteins in response to chronic liver injury. It occurs due to viral hepatitis, non-alcoholic fatty liver disease, alcoholic liver disease, or other etiologies.[1] If left undiagnosed, fibrosis can progress to cirrhosis, portal hypertension, liver failure, and hepatocellular carcinoma, making early detection and staging crucial for patient management.[2] Previously, liver biopsy was the gold standard for assessing fibrosis. But it is invasive, associated with procedural risks like bleeding and infection, and subject to sampling errors and inter-observer variability.[3] These limitations prompted the development of non-invasive diagnostic methods. FibroScan is a non-invasive imaging technique that measures liver stiffness, which correlates with the degree of fibrosis.[4] Techniques like transient elastography (TE), point shear wave elastography (pSWE), and two-dimensional shear wave elastography (2D-SWE) were validated in various chronic liver diseases.[5] Elastography provides rapid, repeatable, and reliable assessment of fibrosis, allowing for early detection, monitoring of

disease progression, and evaluation of treatment response.[6] This study aimed to evaluate the accuracy of FibroScan in staging liver fibrosis, using histopathological assessment from liver biopsy as the reference standard.

METHODS

This hospital-based analytical cross-sectional study was conducted in the Department of Radiology and Gastroenterology at the College of Medical Sciences and Teaching Hospital, Bharatpur-10, Chitwan, Nepal, from October 2023 to March 2025. Patients with suspected liver disease who presented to the Emergency or Gastroenterology Outpatient Department (OPD) and were referred to Radiology department for ultrasonography (USG) were included. Those diagnosed with chronic liver disease on USG were further evaluated for fibrosis using FibroScan and underwent liver biopsy at other centers. Information from the FibroScan and liver biopsy was obtained through patient follow-up visit.

A total of 60 adult patients (≥18 years) with chronic liver disease of any etiology who consented to undergo both liver biopsy and elastography were enrolled using consecutive sampling. Patients with coagulopathy contraindicating biopsy, pregnant women, or those with liver masses were excluded. Demographic and clinical data, including age, sex, residence, etiology of liver disease, body mass index (BMI), and duration of illness, were collected using a structured questionnaire.

Liver stiffness measurement was performed using FibroScan machine, with patients fasting for at least six hours before the procedure. The median of at least 10 valid measurements was recorded, and cut-offs of ≥7.1 kPa and ≥9.5 kPa were used to define significant fibrosis (≥F2) and advanced fibrosis (≥F3), respectively. Percutaneous liver biopsy was performed under ultrasound guidance using a 16–18 gauge core needle, and fibrosis staging was assessed by a blinded pathologist according to the METAVIR scoring system (F0–F1: no/mild fibrosis, F2: significant fibrosis, F3: advanced fibrosis, F4: cirrhosis).

Ethical approval was obtained from the Institutional Review Committee of the College of Medical Sciences (Ref. No. COMSTH_IRC/2023-123-45). Written informed consent was obtained from all participants before data collection. Statistical analysis was performed using Statistical Package for the Social Sciences (SPSS) version 17.0. Data were analyzed using both descriptive and inferential Statistical tools. In the descriptive statistics for categorical variables frequency and percentage were calculated while for continuous variable mean and standard deviation were calculated. Cross-tabulation had been done among FibroScan with biopsy findings. Sensitivity, specificity, positive predictive value (PPV), negative predictive value (NPV), accuracy, and area under the receiver operating characteristic (ROC) curve (AUC) were calculated. In the inferential statistics Mean liver stiffness across fibrosis stages was compared using ANOVA, with $p<0.05$ considered statistically significant.

RESULTS

The study included 60 patients with chronic liver disease, predominantly males (61.7%) and mostly from urban areas (70%). The participants' ages ranged from 18 to over 60 years, with the majority between 31 to 45 years (36.7%) and 46 to 60 years (33.3%). The most common etiology was Alcoholic Liver Disease, accounting for 35 cases (58.33%). Non-Alcoholic Fatty Liver Disease (NAFLD) was the second most frequent cause, observed in 17 patients (28.33%). Hepatitis B Virus (HBV) infection was identified in 5 patients (8.33%), while Hepatitis C Virus (HCV) infection was seen in 3 patients (5%). Most patients had a normal body mass index (58.3%), while 26.7% were overweight, 8.3% obese, and 6.7% underweight. The duration of illness varied, with nearly half (46.7%) experiencing disease for 3 to 5 years, 30% for more than 5 years, and 23.3% for ≤2 years. (Table 1)

Table 1: Demographic and clinical characteristics of study participants (n=60)

Categories	Frequency (%)
Age (years)	
18 to 30	8(13.3%)
31 to 45	22(36.7%)
46 to 60	20(33.3%)
>60	10(16.7%)
Mean ± SD (years)	42.89±4.76
Sex	
Male	37(61.7%)
Female	23(38.3%)
Etiology of Chronic Liver Disease	
Alcoholic Liver Disease	35(58.33%)
Hepatitis B Virus (HBV)	5(8.33%)
Hepatitis C Virus (HCV)	3(5%)
Non-alcoholic Fatty Liver Disease (NAFLD)	17(28.33%)
Residence	
Urban	42(70%)
Rural	18(30%)
Body Mass Index (BMI)	
<18.5 (Underweight)	4(6.7%)
18.5 to 24.9 (Normal)	35(58.3%)
25.0 to 29.9 (Overweight)	16(26.7%)
≥30 (Obese)	5(8.3%)
Duration of Illness (years)	
≤2	14(23.3%)
3 to 5	28(46.7%)
>5	18(30%)

Based on histopathological examination of liver biopsy specimens, the distribution of fibrosis stages among the 60 patients showed that 30% had no or mild fibrosis (F0–F1), 20% had significant fibrosis (F2), 23.3% had advanced fibrosis (F3), and 26.7% had cirrhosis (F4). The mean liver stiffness measured by FibroScan increased progressively with the severity of fibrosis. Patients with F0–F1 fibrosis had a mean stiffness of 5.8±1.2 kPa, those with F2 fibrosis had 7.5±1.0 kPa, F3 fibrosis 9.8±1.1 kPa, and F4 cirrhosis 12.5±1.5 kPa. The differences in mean liver stiffness across fibrosis stages were statistically significant (p=0.01), demonstrating a strong correlation between elastography measurements and histopathological fibrosis severity. (Table 2)

Table 2: Distribution of liver fibrosis stages based on histopathological findings (n=60)

Fibrosis Stage (METAVIR)	Frequency (%)	Mean Liver Stiffness ± SD (kPa)
F0–F1 (No or mild fibrosis)	18(30%)	5.8±1.2
F2 (Significant fibrosis)	12(20%)	7.5±1.0
F3 (Advanced fibrosis)	14(23.3%)	9.8±1.1
F4 (Cirrhosis)	16(26.7%)	12.5±1.5

FibroScan demonstrated good diagnostic performance in detecting significant fibrosis (≥F2) when compared with liver biopsy. Among the 35 patients with biopsy-proven ≥F2 fibrosis, 31 were correctly identified as positive by elastography (true positives), while four patients were missed (false negatives). Of the 25 patients with biopsy <F2, 18 were correctly identified as negative (true negatives) and seven were incorrectly classified as positive (false positives). (Table 3)

Table 3: FibroScan vs. liver biopsy (≥F2 fibrosis)

Biopsy / Fibrosis Stage	Elastography Positive (≥F2)	Elastography Negative (<F2)	Total
Biopsy ≥F2	31 (True Positive, TP)	4 (False Negative, FN)	35
Biopsy <F2	7 (False Positive, FP)	18 (True Negative, TN)	25
Total	38	22	60

For advanced fibrosis (≥F3), FibroScan also showed strong diagnostic performance. Among 30 patients with biopsy-proven ≥F3 fibrosis, 27 were correctly identified as positive (true positives), while three patients were missed (false negatives). Of the 30 patients with biopsy <F3, 25 were correctly classified as negative (true negatives) and five were incorrectly labeled as positive (false positives). (Table 4)

Table 4: FibroScan vs. liver biopsy (≥F3 fibrosis)

Biopsy (Reference Standard)	Elastography Positive (≥F3)	Elastography Negative (<F3)	Total
Biopsy ≥F3	27 (TP)	3 (FN)	30
Biopsy <F3	5 (FP)	25 (TN)	30
Total	32	28	60

The diagnostic performance of FibroScan at different liver stiffness cut-offs was evaluated against biopsy findings. For significant fibrosis (≥F2) at a cut-off of 7.1 kPa, elastography showed a sensitivity of 88.6%, specificity of 89.2%, positive predictive value (PPV) of 81.6%, negative predictive value (NPV) of 93.5%, accuracy of 89%, and an area under the ROC curve (AUC) of 0.93. For advanced fibrosis (≥F3) at a cut-off of 9.5 kPa, the sensitivity was 90%, specificity 83.3%, PPV 84.4%, NPV 89.3%, accuracy 86.7%, and AUC 0.91. (Table 5)

Table 5: Diagnostic performance of FibroScan at different cut-offs

Parameter	≥F2 (7.1 kPa)	≥F3 (9.5 kPa)
Sensitivity	88.6	90
Specificity	89.2	83.3
Positive Predictive Value (PPV)	81.6	84.4
Negative Predictive Value (NPV)	93.5	89.3
Accuracy	89	86.7
Area Under the ROC Curve (AUC)	0.93	0.91

DISCUSSION

In this study involving 60 patients with chronic liver disease, males comprised 61.7% of the. Most patients (70%) were from urban areas and the predominant age groups were 31 to 45 years (36.7%) and 46 to 60 years (33.3%). Our research showed that the mean±SD of age was 42.89±4.76 years. Study conducted by Nand et al. showed mean age of patient's to be 46.2±9.86, similar to our study.[7] The most common etiology was Alcoholic Liver Disease, accounting for 35(58.33%) cases. Non-Alcoholic Fatty Liver Disease (NAFLD) was the second most frequent cause, observed in 17(28.33%) patients. HBV infection was identified in 5(8.33%) patients, while HCV infection was seen in 3(5%) patients.

Regarding the BMI of patients, 58.3% had a normal BMI, 26.7% were overweight, 8.3% were obese, and 6.7% were underweight.

Also, 30% had no or mild fibrosis (F0–F1), 20% had significant fibrosis (F2), 23.3% had advanced fibrosis (F3), and 26.7% had cirrhosis (F4). Study conducted by Sah et al. showed that majority of patients on ultrasound grading were mild 64.28%, 25.72% were moderate and only 10 % were in severe groups.[8]

The duration of illness varied, with 46.7% having the disease for 3–5 years, 30% for more than 5 years, and 23.3% for ≤2 years. For significant fibrosis (≥F2), elastography showed a sensitivity of 88.6%, specificity of 89.2%, positive predictive value of 81.6%, negative predictive value of 93.5%, and overall accuracy of 89%, with an AUC of 0.93. For advanced fibrosis (≥F3), the sensitivity was 90%, specificity 83.3%, PPV 84.4%, NPV 89.3%, and accuracy 86.7%, with an AUC of 0.91. Our findings showed that liver stiffness values increased progressively across fibrosis stages. Castera et al. reported optimal cut-offs of 8.7 kPa for ≥F2 and 14.5 kPa for F4 in chronic hepatitis C, with AUROCs of 0.79, 0.91, and 0.97 for ≥F2, ≥F3, and F4 respectively.[9] One meta-analysis by Friedrich-Rust et al. confirmed this performance, showing pooled AUROCs of 0.84 for significant fibrosis (≥F2), 0.89 for severe fibrosis (≥F3), and 0.94 for cirrhosis (F4).[10] In chronic hepatitis B, Liu et al. reported pooled AUROCs of 0.85 for F2, 0.887 for F3, and 0.929 for F4, showing its reproducibility in HBV population.[11]

The mean liver stiffness measured by FibroScan showed a progressive increase with the severity of fibrosis. Patients with F0–F1 fibrosis had a mean stiffness of 5.8±1.2 kPa, those with F2 fibrosis 7.5±1.0 kPa, F3 fibrosis 9.8±1.1 kPa, and F4 cirrhosis 12.5±1.5 kPa. The differences in mean liver stiffness across fibrosis stages were statistically significant (p=0.01), indicating a strong relationship between elastography values and histopathological grading. This finding confirms that liver stiffness measured by FibroScan reliably reflects fibrosis severity and can serve as a non-invasive surrogate for biopsy in staging chronic liver disease.

While Sah et al. mention that for moderate grade mean fibrosis 8.22 kpa and for severe grade mean fibrosis was 18.16 kpa.[8] These published benchmarks are consistent with our data, where mean stiffness increased stepwise across fibrosis stages, and cut-offs near 7–9 kPa for detecting ≥F2–F3 offered strong discrimination. This proves the reliability of our results and supports the broader clinical utility of non-invasive liver stiffness measurement.

CONCLUSIONS

FibroScan is a reliable, non-invasive tool for assessing liver fibrosis in patients with chronic liver disease. It demonstrates good agreement with histopathological findings and can accurately distinguish between mild, significant, and advanced fibrosis. By providing a safe, rapid, and reproducible method for liver stiffness assessment, elastography offers a valuable alternative to invasive liver biopsy, facilitating timely diagnosis, monitoring of disease progression, and informed clinical decision-making. Its use in routine practice can improve patient care while minimizing the risks and limitations associated with traditional biopsy methods. Further large-scale studies are recommended to validate its performance across different populations and etiologies of liver disease.

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AUTHORS' CONTRIBUTIONS

VNP contributed to the concept, study design, intellectual content, literature review, data acquisition, manuscript preparation, editing, and finalization.

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