# **Original Research**

# Shear-wave Elastography and Its Correlation with Gray-scale Sonographic Grades of Fatty Liver in Non-alcoholic Fatty Liver Disease Patients: An Observational Study

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### **ABSTRACT**

**Background:** Non-alcoholic fatty liver disease (NAFLD) is now one of the most common causes of chronic liver disease worldwide. Early detection and accurate grading are essential to prevent progression to cirrhosis and hepatocellular carcinoma, highlighting the need for reliable, non-invasive diagnostic tools.

**Objectives:** The objectives are to assess the role of gray-scale sonographic grading and point shear-wave elastography (pSWE) in the evaluation of NAFLD, and to establish quantitative cutoff values for different grades of fatty liver by pSWE.

Materials and Methods: A cross-sectional observational study was conducted on 245 patients referred for ultrasonography at the department of radiodiagnosis, in a tertiary teaching hospital of north India. All patients underwent gray-scale sonography and pSWE using EsoateMyLab Eight eXP with a 1–8 MHz curvilinear transducer. Ten elastographic measurements were obtained from the right lobe of the liver and averaged. Fatty liver was graded sonographically into Grade 1, Grade 2, and Grade 3. Statistical analysis was performed using Statistical Package for the Social Sciences v21.

**Results:** On gray-scale sonography, 118 patients (48.2%) were classified as Grade 1, 101 (41.2%) as Grade 2, and 26 (10.6%) as Grade 3 fatty liver. Mean liver stiffness values on elastography increased progressively with severity:  $4.5 \pm 1.3$  kilopascals (kPa) (Grade 1),  $6.3 \pm 1.5$  kPa (Grade 2), and  $8.9 \pm 1.9$  kPa (Grade 3). A cutoff value of 5.45 kPa for differentiating between Grade 2 and Grade 1 yielded 93.1% sensitivity and 98.3% specificity, while a cutoff value of 7.45 kPa for differentiating between Grade 3 and Grade 2 yielded 96.2% sensitivity and 94.1% specificity, respectively.

**Conclusion:** pSWE is a reliable, non-invasive, and quantitative imaging tool for diagnosing and grading NAFLD. Increasing liver stiffness values correlate strongly with higher sonographic grades. Larger, multicentric studies with histopathological confirmation are recommended to validate these cutoff values.

Keywords: Fatty liver grading, liver stiffness, non-alcoholic fatty liver disease, shear-wave elastography, sonography

### INTRODUCTION

Non-alcoholic fatty liver disease (NAFLD) encompasses a spectrum of hepatic disorders ranging from simple steatosis to non-alcoholic steatohepatitis, progressive fibrosis, cirrhosis, and hepatocellular carcinoma (HCC).<sup>[1]</sup> With a global prevalence of 25–30%, NAFLD has emerged as the leading cause of chronic liver disease worldwide.<sup>[2,3]</sup> In India, prevalence rates range from 9 to 32% in the

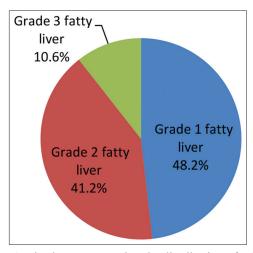
general population, with substantially higher rates among individuals with obesity, metabolic syndrome, and type 2 diabetes mellitus.<sup>[4]</sup>

The diagnostic gold standard for NAFLD remains liver biopsy. However, biopsy is invasive, costly, and carries the risk of complications such as bleeding, pain, and sampling errors, limiting its use for widespread screening and longitudinal follow-up.<sup>[5]</sup> In clinical practice, several

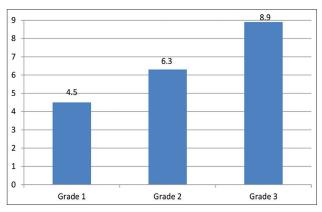
non-invasive imaging modalities—ultrasonography (USG), computed tomography (CT), and magnetic resonance imaging—have been employed as alternatives. [6] Among these, gray-scale USG is the most commonly used due to its wide availability, affordability, and ease of use. Nonetheless, conventional sonography is subjective, operator-dependent, and demonstrates limited sensitivity in detecting early or mild hepatic steatosis. [7]

Advances in ultrasound-based techniques, particularly point shear-wave elastography (pSWE), now enable quantitative measurement of liver stiffness expressed in kilopascals (kPa). Elevated stiffness values have been correlated with the degree of hepatic steatosis, fibrosis, and progression toward cirrhosis.<sup>[8,9]</sup> Several international studies have shown elastography to be a reliable and reproducible non-invasive method for assessing NAFLD severity.<sup>[10-12]</sup>

Given the rising burden of NAFLD in India, there is an urgent need to validate imaging-based diagnostic approaches that are accurate, affordable, and widely accessible. This study was therefore undertaken to



**Figure 1:** Pie chart representing the distribution of subjects in various grades of fatty liver, showing frequency and percentage



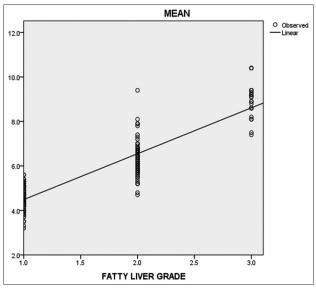
**Figure 2:** Mean liver stiffness (kilopascals [kPa]) on shearwave elastography with interquartile range (kPa) in various grades of fatty liver

evaluate the role of gray-scale sonographic grading and pSWE in patients with NAFLD and to establish objective, quantitative cutoff values for differentiating grades of fatty liver in an Indian cohort.

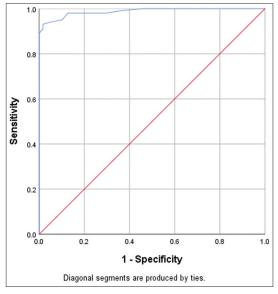
### MATERIALS AND METHODS

### Study design and setting

This was a cross-sectional observational study conducted in the department of radiodiagnosis, in a district-level tertiary teaching hospital of north India.



**Figure 3:** Statistical correlation between liver stiffness (in kilopascals) on the Y-axis and gray-scale sonographic grades of fatty liver on X-axis



**Figure 4:** Receiver operating characteristic curve for the fatty liver grade 2

## Study population

Patients referred by physicians for abdominal USG and meeting the inclusion criteria were consecutively recruited after obtaining informed written consent.

### Inclusion criteria

- a. Adults aged ≥18 years
- Patients referred for abdominal USG with suspected fatty liver
- c. Patients with no history of significant alcohol consumption (defined as <20 g/day for men and <10 g/day for women)
- d. Patients are willing to provide informed written consent.

#### **Exclusion criteria**

- a. History of alcoholic liver disease
- b. Known cases of viral hepatitis (HBV, HCV) or other chronic liver diseases
- c. Patients with hepatic malignancy, cirrhosis, or portal hypertension
- d. Patients with cardiac failure, renal disease, or systemic illnesses affecting liver stiffness
- e. Pregnant women
- f. Patients in whom shear-wave elastography could not be performed due to technical limitations (e.g., morbid obesity, poor acoustic window).

# Sample size and sampling

A total of 245 patients who fulfilled the inclusion criteria were recruited consecutively during the study period.

### Data collection tools and procedure

All examinations were performed using the EsoateMyLab Eight eXP ultrasound system equipped with a curvilinear transducer (frequency range: 1–8 MHz).

Fatty liver was graded on gray-scale sonography according to hepatic echogenicity, intrahepatic vessel clarity, and diaphragm visualization into three categories:

- Grade 1 (Mild): Slight, diffuse increase in hepatic parenchymal echogenicity with normal visualization of intrahepatic vessels and diaphragm
- Grade 2 (Moderate): Moderate, diffuse increase in hepatic parenchymal echogenicity with mild impairment in visualization of intrahepatic vessels and diaphragm
- Grade 3 (Severe): Marked increase in hepatic parenchymal echogenicity with poor or absent visualization of intrahepatic vessels, diaphragm, and posterior right lobe due to acoustic attenuation.

For pSWE, ten measurements of liver stiffness were taken from different sites in the right lobe of the liver,

avoiding large vessels and biliary structures. The mean liver stiffness value was calculated and expressed in kPa [Figures 7-9].

# Data analysis

All data were compiled using Microsoft Excel 2010 and analyzed with SPSS version 21.

- Categorical variables were expressed as frequencies and percentages
- Continuous variables were presented as mean ± standard deviation
- Diagnostic performance of elastography was assessed using sensitivity, specificity, positive predictive value (PPV), and negative predictive value (NPV) for various stiffness cutoff values.

# **RESULTS**

# Distribution of patients by gray-scale sonographic grading

Out of the 245 patients included in the study, 55.9% (n = 137) were females and 44.1% (n = 108) were males, hence it shows female dominance. The most common form was Grade 1 (48.2%), followed by Grade 2 (41.2%), while Grade 3 (10.6%) was the least frequent [Table 1 and Figure 1].

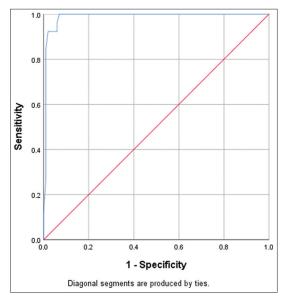
# Liver stiffness measurements by shear-wave elastography

On objective assessment by shear wave elastography, mean liver stiffness for grade 1, 2, and 3 was found to be  $4.5 \pm 1.3$  kPa, $6.3 \pm 1.5$  kPa, and  $8.9 \pm 1.9$  kPa respectively suggesting the increase in mean liver stiffness value with increasing grade of fatty liver [Table 2 and Figure 2]. Quantitative elastography assessment showed a progressive increase in mean liver stiffness values with higher grades of fatty liver [Figure 3]. Differences between successive grades were statistically significant (P < 0.05).

On comparative analysis between subjective assessment (by gray-scale sonographic grading) and objective assessment of liver stiffness (by pSWE), a significant correlation was found with a correlation coefficient of  $0.819 \ (P < 0.0001)$ .

### Diagnostic accuracy of elastography cutoffs

On statistical analysis of liver stiffness by pSWE in various grades of fatty liver, the maximum accuracy for differentiating Grade 1 and Grade 2 was found at a cutoff value of 5.45 kPa as determined by receiver operating characteristic (ROC) curve. ROC curve analysis was performed to assess the diagnostic accuracy of pSWE in differentiating between various grades of fatty liver. The area under curve (AUC) was calculated as 0.899 with a P < 0.001 [Figure 4].



**Figure 5:** Receiver operating characteristic curve for the fatty liver Grade 3

For a cutoff value of 5.45 kPa, the sensitivity was 93.07%, specificity was 98.31%, PPV was 97.92%, and NPV was 94.31% for the diagnosis of Grade 2 fatty liver, as shown in Table 3.

On statistical analysis of liver stiffness by pSWE in various grades of fatty liver, the maximum accuracy for differentiating Grade 2 and Grade 3 was found at a cutoff value of 7.45 kPa as determined by the ROC curve. The AUC was calculated as 0.988 with a P < 0.001 [Figures 5 and 6].

For a cutoff value of 7.45 kPa, the sensitivity was 96.15%, specificity was 94.06%, PPV was 80.65 %, and NPV was 98.96% for the diagnosis of Grade 3 fatty liver, as shown in Table 4.

# Correlation between sonographic grades and elastography values

A strong correlation was observed between higher sonographic grades and rising elastography stiffness values. Patients with mild fatty liver (Grade 1) had significantly lower stiffness compared to those with moderate or severe grades, confirming elastography as an objective, quantitative supplement to subjective sonographic grading.

# Key observations

- The majority of patients presented with mild NAFLD (Grade 1)
- Elastography values increased consistently with disease severity
- High sensitivity and specificity support elastography as a reliable, non-invasive alternative to biopsy
- High NPV values (94–99%) highlight its utility in ruling out advanced fatty liver in borderline cases.

**Table 1:** Distribution of subjects in various grades of fatty liver, showing frequency and percentage

Sonographic grade of fatty liver	Frequency	Percentage
Grade 1	118	48.16
Grade 2	101	41.22
Grade 3	26	10.61
Total	245	100%

**Table 2:** Mean liver stiffness (kPa) on shear-wave elastography with interquartile range (kPa) in various grades of fatty liver

Sonographic grade of fatty liver	Mean liver stiffness (kPa)	Interquartile range (kPa)
Grade 1	4.5	1.3
Grade 2	6.3	1.5
Grade 3	8.9	1.9

kPa: Kilopascals

**Table 3:** Statistical measure of performance at cutoff of 5.45 kPa for the diagnosis of Grade 2 fatty liver

Statistical measure	Value (%)	95% Confidence interval
Sensitivity	93.07	86.24-97.17
Specificity	98.31	94.01-99.79
Positive predictive value	97.92	92.24-99.47
Negative predictive value	94.31	89.02-97.13
Accuracy	95.89	92.34–98.10

kPa: Kilopascals

**Table 4:** Representing the statistical measure of performance at cutoff of 7.45 kPa for the diagnosis of Grade 3 fatty liver

Statistical measure	Value (%)	95% Confidence interval
Sensitivity	96.15	80.36 - 99.90%
Specificity	94.06	87.52 - 97.79%
Positive predictive value	80.65	65.64 - 90.09%
Negative predictive value	98.96	93.28 - 99.85%
Accuracy	94.49	88.97 – 97.76%

kPa: Kilopascals

### **DISCUSSION**

This study demonstrates that shear-wave elastography is a reliable, non-invasive, and reproducible modality for grading NAFLD, with high sensitivity and specificity values. The progressive increase in mean liver stiffness across grades 1, 2, and 3 highlights a strong correlation between elastographic findings and disease severity. These results reinforce elastography as a valuable adjunct

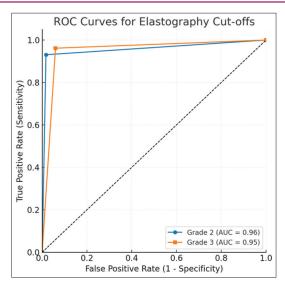


Figure 6: Receiver operating characteristic curves illustrate the discriminative ability of elastography thresholds for Grade 2 and Grade 3 fatty liver

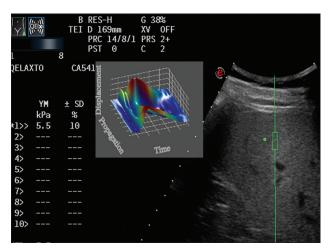


Figure 7: Elastographic measurement of the liver with a AQ3,7stiffness value of 5.5 kilopascals

to gray-scale sonography, offering an objective and quantitative approach for staging fatty liver disease.

The prevalence pattern observed in our cohort, with the majority of patients presenting with Grade 1 NAFLD and relatively fewer with Grade 3, is consistent with global epidemiological data showing early stages to be more common.<sup>[2,3]</sup> This reflects the increasing burden of metabolic risk factors such as obesity and diabetes, but also highlights the opportunity for early intervention.

Although gray-scale USG remains the most widely used screening tool for NAFLD because of its availability and cost-effectiveness, it is limited by operator dependence and reduced sensitivity in detecting mild steatosis.<sup>[7,13]</sup> Our findings support the role of shear-wave elastography in overcoming these limitations by providing reproducible and quantitative measures of liver stiffness.

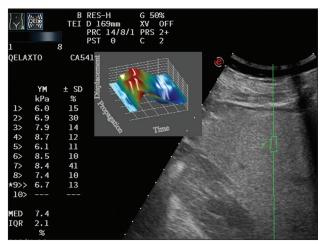


Figure 8: Elastographic measurement of liver with a AQ3,7 stiffness value of 6.7 kilopascals (kPa). Mean liver stiffness for the represented case came out to be  $7.2 \pm 2.0$  kPa



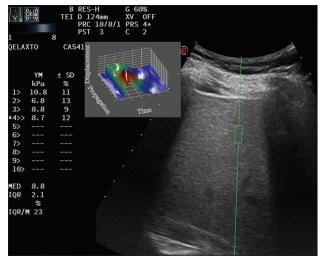


Figure 9: Elastographic measurement of liver with a AO3.7 stiffness value of 8.7 kilopascals (kPa). Mean liver stiffness for the represented case came out to be  $8.2 \pm 1.2$  kPa

The elastography cutoff values identified in this study (5.45 kPa for Grade 2 and 7.45 kPa for Grade 3) are comparable to international reports, where thresholds of 5-6 kPa have been associated with moderate disease and >8 kPa with advanced disease. [10,14] Such consistency across different populations strengthens the case for developing standardized cutoff values for global clinical practice.

Beyond hepatology, NAFLD carries significant extrahepatic implications, being strongly associated with type 2 diabetes mellitus, cardiovascular disease, and hepatocellular carcinoma.<sup>[1,15]</sup> Thus, accurate non-invasive grading tools such as elastography are vital not only for disease monitoring but also for guiding comprehensive metabolic risk reduction strategies.

#### Limitations

This study has several limitations. First, histopathological confirmation was not performed, which remains the gold standard for NAFLD diagnosis and staging. Second, as a single-center study, the findings may not be fully generalizable to wider populations with diverse demographic and metabolic profiles. Finally, potential confounding factors such as dietary habits and duration of comorbidities were not assessed.

Future studies should aim to validate these findings in larger, multicentric cohorts with biopsy correlation and explore the integration of elastography into risk prediction models combining clinical, biochemical, and imaging markers.

# CONCLUSION

Shear-wave elastography emerges as a robust, non-invasive, and quantitative tool for the diagnosis and grading of NAFLD. The progressive rise in liver stiffness values with advancing sonographic grades confirms its reliability in disease staging. When combined with conventional USG, elastography enhances diagnostic accuracy, facilitates earlier detection, and supports timely intervention. Its use has the potential to improve disease monitoring and reduce progression to advanced fibrosis, cirrhosis, and hepatocellular carcinoma.

#### Recommendations

- Routine incorporation of shear-wave elastography in the evaluation of patients with suspected NAFLD
- Standardization of global cutoff values for elastography to ensure consistency and comparability across populations
- Larger, multicentric studies with histopathological correlation to validate diagnostic thresholds and improve clinical applicability
- Integration into primary care and metabolic screening programs, particularly for patients with obesity, diabetes, or metabolic syndrome, to enable early identification and risk stratification.

# **ACKNOWLEDGMENT**

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# **CONFLICTS OF INTEREST**

The authors declare that they have no conflicts of interest related to this study.

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