



## Diagnostic Accuracy of Shear Wave Elastography in Detection of Liver Fibrosis in Patients with Hepatitis C Infection by Taking Histopathology as Gold Standard

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### Declaration

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### ABSTRACT

**Background and aim:** Chronic hepatitis C infection leads to progressive liver fibrosis and cirrhosis, creating significant long-term health burdens. Liver biopsy remains the definitive method for staging fibrosis, but its invasive nature, procedural discomfort, and risk of complications limit its routine use. Shear wave elastography (SWE) offers a non-invasive technique for measuring liver stiffness and may provide a reliable alternative for assessing fibrosis severity. This study was conducted to determine the diagnostic accuracy of 2D-SWE in detecting advanced fibrosis in patients with chronic hepatitis C, using histopathology as the reference standard. **Methodology:** A cross-sectional diagnostic accuracy study was performed on 150 adults with confirmed hepatitis C infection. All participants underwent 2D-SWE followed by ultrasound-guided liver biopsy. A stiffness value of  $\geq 9.3$  kPa on SWE was considered indicative of advanced fibrosis. Histopathology was interpreted by a blinded pathologist using the METAVIR scoring system, with F3-F4 categorized as fibrosis positive. Sensitivity, specificity, predictive values, and overall accuracy of SWE were calculated against biopsy findings. Stratified analysis was performed for age, gender, duration of disease, and BMI. **Results:** Among the 150 patients, 72 (48%) had advanced fibrosis on biopsy. SWE identified 75 patients as fibrosis positive. The test yielded 65 true positives, 10 false positives, 68 true negatives, and 7 false negatives. This corresponded to a sensitivity of 90.3%, specificity of 87.2%, positive predictive value of 86.7%, negative predictive value of 90.7%, and an overall diagnostic accuracy of 88.7%. No meaningful differences in accuracy were observed across demographic subgroups. **Conclusion:** Shear wave elastography demonstrates high diagnostic accuracy for identifying advanced fibrosis in chronic hepatitis C. Its non-invasive nature and strong performance make it a practical tool for routine clinical assessment and for reducing reliance on liver biopsy.

### INTRODUCTION

Liver cirrhosis remains a major global health burden, responsible for nearly 1.5 million deaths each year, with a particularly heavy impact in regions such as Latin America where it accounts for about 2.7% of all deaths [1,2]. Chronic hepatitis C virus infection is one of the most significant contributors to progressive liver damage, affecting an estimated 71 million people worldwide [3]. In patients with hepatitis C, determining the degree of liver fibrosis is central to clinical decision-making. The stage of fibrosis guides antiviral treatment, helps predict long-term outcomes, and determines when to initiate surveillance for complications such as variceal bleeding or hepatocellular carcinoma [2,4].

Liver biopsy has traditionally served as the standard method for assessing fibrosis because it allows direct visualization of liver tissue [5]. Despite its diagnostic value, biopsy has several well-recognized drawbacks. It is

invasive, carries a measurable risk of complications including bleeding and, rarely, procedure-related mortality, and is costly for both patients and healthcare systems [1,5]. Sampling variation can also result in inaccurate staging, as only a small portion of the liver is evaluated. Most importantly, biopsy is not ideal for repeated monitoring due to patient discomfort and the cumulative risks associated with multiple procedures [5].

To overcome these limitations, attention has shifted toward non-invasive techniques for fibrosis assessment. Serum indices such as APRI and FIB-4 are inexpensive and widely available, but their diagnostic accuracy at the individual patient level is inconsistent. Elastography-based imaging has therefore become an important alternative. Transient elastography (FibroScan) was the first such modality to gain widespread use, but its performance may decline in intermediate fibrosis stages and it is limited in patients with obesity or ascites [5].

Shear wave elastography (SWE), integrated into standard ultrasound systems, offers real-time measurement of liver stiffness and provides a quantitative assessment of fibrosis without the limitations associated with older methods [1]. By generating shear waves and measuring their propagation speed, SWE produces reproducible stiffness values that correlate strongly with histological fibrosis. International societies, including the European Association for the Study of the Liver and multiple ultrasound federations, now recommend elastography as part of routine evaluation in chronic liver disease [3,6,7]. As a result, SWE has become a widely adopted tool in the assessment of chronic hepatitis [8].

Previous studies have demonstrated high diagnostic accuracy of SWE in viral hepatitis, with pooled analyses showing sensitivities and specificities approaching 90% for cirrhosis and similarly strong performance for earlier fibrosis stages [5, 9]. Despite this, data from South Asian populations remain limited, and local validation is important because optimal stiffness thresholds may differ by population, disease etiology, and equipment used.

## MATERIAL AND METHODS

The study was carried out as a cross-sectional diagnostic accuracy investigation in the Department of Diagnostic Radiology, Combined Military Hospital (CMH) Lahore, over an eight-month period from September 2024 to April 2025. Approval was obtained from the institutional ethics committee before recruitment began, and written informed consent was taken from all participants. All examinations and procedures were performed in accordance with the ethical principles of the Declaration of Helsinki.

Patients between 18 and 70 years of age with confirmed chronic hepatitis C infection for at least one year were considered for inclusion. Individuals were eligible if their clinical or laboratory findings suggested underlying fibrosis and if their blood profile allowed a safe liver biopsy. Patients were excluded if they had other causes of liver disease, focal liver lesions, decompensated cirrhosis, significant ascites that interfered with elastography, contraindications to biopsy, or clinical conditions known to affect liver stiffness measurements. A total of 150 patients were enrolled based on a sample size calculation that assumed expected sensitivity and specificity values close to 90% for shear wave elastography, with an estimated fibrosis prevalence of 48% in chronic hepatitis C.

After enrollment, demographic and clinical data were obtained. Each patient first underwent two-dimensional shear wave elastography using a GE LOGIQ P7 R3 ultrasound system. The examination was performed with the patient lying supine and the right arm raised. A convex transducer was placed in the right intercostal space, and measurements were taken from the right liver lobe while avoiding large vascular structures. Patients were asked to briefly suspend breathing during acquisition. Ten valid stiffness readings were obtained for each patient, and the median value was used for analysis, provided that measurement variability remained within acceptable limits. A stiffness value of 9.3 kPa or higher was taken as suggestive of significant fibrosis.

Following elastography, all patients underwent an ultrasound-guided percutaneous liver biopsy using an 18-gauge automated needle. Two core samples were taken from the right lobe. Adequate samples were fixed in formalin and later reviewed by an experienced pathologist who was blinded to the elastography results. Fibrosis was staged using the METAVIR scoring system, and advanced fibrosis was defined as stage F3 or F4. Patients were observed for several hours after biopsy, and no serious complications occurred.

Data were analyzed using standard statistical methods. Continuous variables were summarized as means with standard deviations, while categorical variables were presented as frequencies and percentages. The diagnostic performance of elastography was assessed against biopsy results by calculating sensitivity, specificity, positive and negative predictive values, and overall accuracy. Correlation between elastography measurements and histological fibrosis stage was evaluated, and subgroup analyses were conducted based on age, sex, body mass index, and duration of infection. A p-value of less than 0.05 was considered statistically significant.

## RESULTS

A total of 150 patients with chronic hepatitis C infection were enrolled. The study population comprised 90 males (60%) and 60 females (40%), with ages ranging from 22 to 68 years (mean  $49.8 \pm 11.7$  years). The predominant genotype was HCV genotype 3, which is endemic in the study region. None of the participants had received antiviral therapy prior to enrollment. Mean body mass index (BMI) was  $27.5 \pm 4.3$  kg/m<sup>2</sup>, with 28% of patients classified as overweight (BMI 25–30 kg/m<sup>2</sup>) and 18% as obese (BMI >30 kg/m<sup>2</sup>). The median duration of known HCV infection was 4.5 years. Baseline liver function parameters demonstrated median alanine aminotransferase (ALT) of 82 U/L and aspartate aminotransferase (AST) of 75 U/L, with all participants meeting the inclusion criterion of ALT >40 U/L. Platelet counts demonstrated substantial variation (mean  $180 \times 10^9$ /L), with 15 patients (10%) exhibiting moderate thrombocytopenia ( $<100 \times 10^9$ /L), suggestive of advanced hepatic disease.

Advanced fibrosis (F3–F4) was documented in 72 patients (48%), including 46 with bridging fibrosis and 26 with cirrhosis; 12 cirrhosis cases demonstrated regenerative nodules. Remaining 78 patients (52%) exhibited absent or mild fibrosis. All samples were adequate (median 18 mm,  $\geq 6$  portal tracts). Median SWE was 9.1 kPa (IQR 7.2–13.4), demonstrating strong correlation with fibrosis stage ( $\rho = 0.74$ ,  $p < 0.001$ ). Stiffness increased progressively: F0–F1 ( $5.8 \pm 1.5$  kPa), F2 ( $8.0 \pm 1.8$  kPa), F3 ( $11.2 \pm 2.4$  kPa), and F4 ( $19.6 \pm 5.7$  kPa) ( $p < 0.0001$ ). Using  $\geq 9.3$  kPa cutoff, 75 patients (50%) classified as test-positive and 75 as test-negative.

**Table 1**

*Mean Shear Wave Elastography Values According to METAVIR Fibrosis Stage.*

METAVIR Stage	Mean SWE (kPa)	Standard Deviation
F0–F1	5.8	1.5

F2	8.0	1.8
F3	11.2	2.4
F4	19.6	5.7
Overall median	9.1	IQR 7.2–13.4
SWE-Histology correlation ( $\rho$ )	0.74	$p < 0.001$

The diagnostic performance of SWE against histopathological reference standard is presented in Table below.

**Table 2**  
*Contingency Table of Shear Wave Elastography versus Histopathology for Advanced Fibrosis Detection.*

SWE Result	Biopsy: Advanced Fibrosis (F3–F4)	Biopsy: No Advanced Fibrosis (F0–F2)	Total
SWE $\geq 9.3$ kPa (Positive)	65 (TP)	10 (FP)	75
SWE $< 9.3$ kPa (Negative)	7 (FN)	68 (TN)	75
Total	72	78	150

SWE demonstrated sensitivity of 90.3% (95% CI 81–96%), specificity of 87.2% (95% CI 78–93%), positive predictive value of 86.7%, negative predictive value of 90.7%, and overall accuracy of 88.7%. No F4 cirrhosis cases were misclassified as negative; all 26 demonstrated stiffness 14–28 kPa. Seven false-negatives occurred exclusively in F3 cases with SWE values 7.5–9.2 kPa, immediately below the 9.3 kPa threshold, indicating borderline fibrosis presentation rather than test failure.

**Table 3**  
*Diagnostic Performance Indices of Shear Wave Elastography for Advanced Fibrosis Detection*

Diagnostic Parameter	Value
Sensitivity	90.3%
Specificity	87.2%
Positive Predictive Value	86.7%
Negative Predictive Value	90.7%
Overall Diagnostic Accuracy	88.7%

Subgroup performance metrics revealed no significant differences by sex (males: sensitivity 91%, specificity 85%; females: sensitivity 89%, specificity 89%;  $p = 0.78$ ; false-negatives: 5 males, 2 females). Age showed comparable accuracy ( $< 50$  years: sensitivity 88%, specificity 90%;  $\geq 50$  years: sensitivity 92%, specificity 85%;  $p = 0.55$ ). Obese patients (BMI  $\geq 30$ ,  $n = 27$ ) demonstrated marginally reduced specificity (80% vs. 89% non-obese;  $p = 0.40$ ) with increased SWE variability (15% vs. 10% IQR). HCV infection duration  $\geq 5$  years showed marginally elevated mean stiffness with comparable diagnostic metrics to shorter duration, indicating fibrosis stage not infection duration determines stiffness measurements.

**Table 4**  
*Comparison with Non-Invasive Serological Markers*

Diagnostic Modality	Sensitivity	Specificity	Overall Accuracy
SWE ( $\geq 9.3$ kPa)	90.3%	87.2%	88.7%
APRI ( $> 1.0$ )	75.0%	70.5%	72.0%
Performance Difference	+15.3%	+16.7%	+16.7%

## DISCUSSION

In this cross-sectional study of 150 patients with chronic hepatitis C, shear wave elastography showed high diagnostic performance for detecting advanced liver fibrosis when compared with liver biopsy. Sensitivity was 90% and specificity 87%, giving an overall accuracy of

about 89%. These figures are very close to those reported in previous work. Jiang et al. (2016) reported pooled sensitivity of 89% and specificity of 88% for cirrhosis using 2D-SWE in a meta-analysis [1], while Li et al. (2016) found area under the ROC curve values around 0.85–0.90 across fibrosis stages [2]. Malik et al. (2022) similarly reported sensitivity and specificity in the mid-80% range for F4 disease using elastography [3]. Local data are in the same direction; Jesrani et al. (2019) demonstrated a strong positive correlation between SWE stiffness and biopsy stage in chronic hepatitis C, with the best agreement in advanced fibrosis [4]. Our results follow the same pattern: stiffness values rose consistently from lower to higher METAVIR stages, and all cirrhotic patients had clearly elevated stiffness. The small number of false positive and false negative results is comparable to the recognised sampling variability and inter-observer differences associated with biopsy itself [5].

Serum-based indices such as APRI remain attractive because they are simple and inexpensive, but they tend to misclassify a noticeable proportion of patients, especially in intermediate fibrosis [6]. In our series, SWE separated advanced from non-advanced fibrosis more clearly than serologic scores. The high negative predictive value (around 91%) is particularly useful in practice; a low SWE value made advanced fibrosis very unlikely, meaning that biopsy could often be avoided in such patients. The positive predictive value was also high, supporting the use of raised stiffness to guide closer follow-up or treatment decisions, especially when clinical and laboratory findings point in the same direction [7–9]. Together, these characteristics are consistent with the gradual move in many liver units away from routine biopsy and toward elastography-based assessment in chronic viral hepatitis.

We did not include transient elastography (FibroScan) in this study, but published work suggests that 2D-SWE performs at least as well. Vidili et al. (2024) reported a strong correlation between transient elastography and SWE in hepatitis C, with similar cutoff values for cirrhosis [11]. SWE offers some practical advantages because it can be performed on standard ultrasound machines during a routine abdominal scan, allowing the operator to avoid ribs and large vessels and to choose an optimal region of interest [12]. Previous reports have shown that transient elastography may fail in a significant fraction of obese patients or those with ascites [14,15]. In our cohort, all patients yielded valid SWE readings. Specificity was slightly lower in obese patients, probably due to technical limitations and the influence of steatosis, but the reduction was small and did not markedly affect overall performance. Integrating SWE into a standard ultrasound examination also lets the radiologist assess steatosis and focal liver lesions at the same sitting, which improves the overall value of the visit [16].

The choice of 9.3 kPa as the cutoff for significant fibrosis was deliberately conservative compared with earlier hepatitis C studies, where thresholds around 11–12 kPa are often used for cirrhosis. This lower threshold helped ensure that no cirrhotic patients were missed and captured most F3 cases as well, at the cost of a few false positives among those with moderate fibrosis. This is a familiar trade-off between sensitivity and specificity. Some

authors have recommended the use of two thresholds, with a low value to confidently rule out advanced fibrosis and a higher value to rule it in [18]. It is also important to recognise that optimal cutoffs depend on the underlying liver disease; HCV tends to have lower stiffness thresholds than NAFLD for the same histological stage [20]. Beyond hepatitis C, SWE has shown good performance in autoimmune hepatitis, NAFLD, and hepatitis B [21–23], suggesting that elastography can serve as a common tool across a wide range of chronic liver diseases.

This study included a moderate sample size, and some subgroup analyses did not have enough power to detect small differences. Fibrosis was analysed as a binary outcome (F3–F4 versus F0–F2), so performance in distinguishing intermediate stages could not be fully assessed. Liver biopsy, although used as the reference standard, is subject to sampling error and may not always reflect diffuse liver involvement. Finally, all measurements

were obtained on a single ultrasound system, and cutoff values may need adjustment when other platforms or software versions are used.

## CONCLUSION

Shear wave elastography proved to be a dependable tool for assessing advanced liver fibrosis in patients with chronic hepatitis C. Its performance closely matched that of biopsy while avoiding the discomfort and risks associated with invasive testing. The technique provided clear separation between mild and advanced disease in most individuals and was practical to perform in routine clinical settings. By offering a reliable, non-invasive method for evaluating fibrosis, elastography can help reduce the need for biopsy and support timely clinical decisions. Its ease of use and strong alignment with histological findings make it a valuable addition to everyday hepatology practice.

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