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Comparing shear wave elastography with liver biopsy in the assessment of liver fibrosis at King Hussein Medical Center

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Abstract

Background and study aims: The aim of this prospective study is to compare the sensitivity and specificity of the liver shear wave elastography to the golden standard liver biopsy in staging liver fibrosis.

Patients and methods: Ninety-five patients were included in this study. These patients were sent for liver biopsy as a possible living liver donor or because of different pathologies including viral and autoimmune hepatitis and congenital liver diseases. A shear wave elastography and US-guided liver biopsy were done at the same setting by one experienced radiologist. One experienced histopathologist, blinded to SWE results, read the specimens.

Results: We included 95 patients in the study with a mean age of 30 years (range 3–65 years). We had 15/95 (16%) patients with hepatitis B/C, 61/95 (64%) patients with another liver disease, and 19/95 (20%) were donors. The mean of liver stiffness measured by elastography in patients was 6.5±0.19 kPa. The mean liver stiffness measured by elastography in patients with F0–F1 fibrosis was 5.39 ± 0.62 kPa, F2 was 7.32 ± 0.41, at stage F3 was 8.46 ± 0.33, and in the F4 stage, it was 11.42 ± 2.8 kPa. We found a significant difference in the mean level of liver stiffness in different degrees of fibrosis ($p = 0.0001$).

Conclusion: The shear wave elastography could be used to assess liver fibrosis regardless of the cause.

Keywords: Shear wave elastography, Liver fibrosis

Introduction

Chronic liver disease (CLD) is a widespread health problem that is a result from a wide range of inciting factors, where increasing deposition of fibrous tissue within the liver parenchyma leads to end-stage cirrhosis. Fibrosis is a continuum; the higher stage of fibrosis (F3–F4), the higher the risk for clinical complications; portal hypertension; hepatic insufficiency (e.g., ascites, variceal hemorrhage, and hepatic encephalopathy); and hepatocellular carcinoma (HCC).

From hepatology point of view, for patients with severe fibrosis or liver cirrhosis who are asymptomatic, the term "compensated advanced chronic liver disease" (cACLD) has been proposed [1–5]. Decompensated cirrhosis is an important cause of morbidity and mortality so, assessing the stage of the liver is a cornerstone in the strategy of management of many liver diseases [6–8], as an early clinical intervention may slow down the progression to end-stage decompensated cirrhosis.

Therefore, the availability of noninvasive tools to exclude or diagnose cACLD in these patients is of the utmost importance.

For many years, the liver biopsy was and still is the golden method for verification of fibrosis and inflammation. Lately, many non-invasive methods were approved for the staging of liver fibrosis, as liver biopsy carries

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a certain percentage of morbidity and mortality that increases with the advanced stages of fibrosis [9–13].

Liver stiffness, which is supposed to result mainly from fibrosis, can be measured noninvasively by quantitative elastography. In both children and adults, several clinical ultrasound-based techniques are currently used for quantitative elastography measurements such as transient elastography (TE) and acoustic radiation force impulse (ARFI), which includes point elastography (pSWE) and two-dimensional shear wave elastography (2-D SWE) [14].

2-D SWE is a sonographic-based elastography method for noninvasive measurement of liver stiffness, through mechanical wave excitation from ultrasound transducer towards human tissue which propagates with speed correlating to tissue stiffness level. In concept, lower speed propagation of (2-D) shear waves is an indication for softer tissue medium while higher speed propagation of (2-D) shear waves indicates stiffer tissue medium.

With increasing fibrosis, the liver becomes stiffer, which can be monitored using 2-D SWE.

The aim of this study is to assess the accuracy, sensitivity, and specificity of SWE in comparison to the gold standard liver biopsy in the assessment of liver fibrosis at KHMC.

Patients and methods

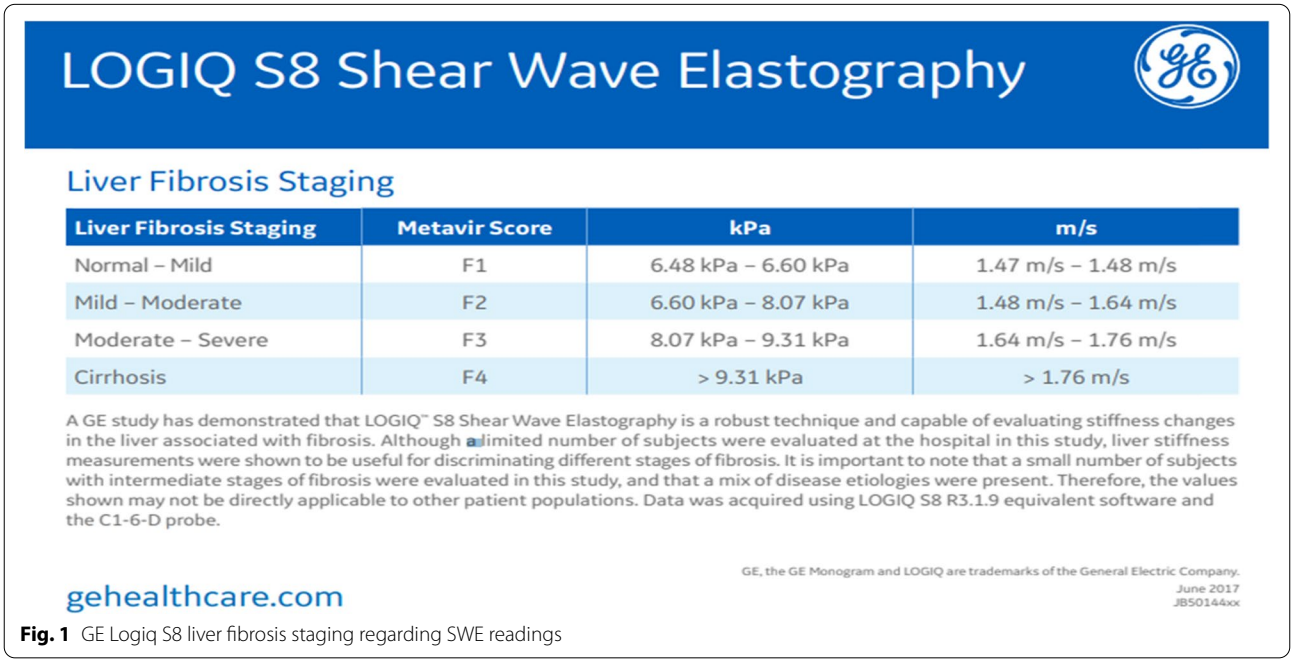
Ninety-five patients were enrolled in this prospective single-institution study. Ethical committee approval and informed consent from all patients were obtained.

All patients scheduled for liver biopsy in the Radiology Department from August 2017 till December 2019 were eligible for the study and underwent 2-D SWE examination at the same setting for the liver biopsy. Patients were fasting for at least 8 h.

In this study, the liver stiffness measurement (LSM) was assessed by a single experienced radiologist using the 2-D SWE imaging (GE LOGIQ™ S8 XDclear; C1-6-D convex transducer 1–6 MHz, GE Healthcare, Milwaukee, WI, USA), where LSM was acquired using 2-D SWE (kPa) Young's Modulus measurements representing the liver tissue stiffness within a defined region of interest (ROI) superimposed on the conventional B-mode image, with the ability to adjust 2-D SWE ROI location and size.

With this technique, during an ultrasound exam, a ROI is placed over an area of the liver, at least 1 cm below the liver capsule, taking care not to include large vasculature or biliary structures. Patients were in supine or slightly left decubitus position with right arm overhead, an intercostal imaging approach targeting right liver lobe, segments 7 or 8 of the liver. Serial measurements, at least ten, are taken through multiple scans while the patient suspends respiration. Measurements were collected, and a statistical summary was shown automatically on the machine. The median was measured, and the IQR/median ratio should be less than 30% (Fig. 1).

The cause for a biopsy varies from normal possible living liver donors, viral hepatitis, NAFLD, and suspected congenital liver diseases.


LOGIQ S8 Shear Wave Elastography

Liver Fibrosis Staging

Liver Fibrosis Staging	Metavir Score	kPa	m/s
Normal – Mild	F1	6.48 kPa – 6.60 kPa	1.47 m/s – 1.48 m/s
Mild – Moderate	F2	6.60 kPa – 8.07 kPa	1.48 m/s – 1.64 m/s
Moderate – Severe	F3	8.07 kPa – 9.31 kPa	1.64 m/s – 1.76 m/s
Cirrhosis	F4	> 9.31 kPa	> 1.76 m/s

A GE study has demonstrated that LOGIQ™ S8 Shear Wave Elastography is a robust technique and capable of evaluating stiffness changes in the liver associated with fibrosis. Although a limited number of subjects were evaluated at the hospital in this study, liver stiffness measurements were shown to be useful for discriminating different stages of fibrosis. It is important to note that a small number of subjects with intermediate stages of fibrosis were evaluated in this study, and that a mix of disease etiologies were present. Therefore, the values shown may not be directly applicable to other patient populations. Data was acquired using LOGIQ S8 R3.1.9 equivalent software and the C1-6-D probe.

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Fig. 1 GE Logiq S8 liver fibrosis staging regarding SWE readings

Biopsy was done by the same radiologist immediately after the 2-D SWE, under local anesthesia. Two core biopsies using 18 G automated needle biopsy were taken from the right liver lobe.

One experienced pathologist, blinded to 2-D SWE results read the specimens, using the METAVIR scoring system.

Statistical analysis

SAS software version 9.4 was used for statistical analysis. The sensitivity, specificity, positive predictive value (PPV), negative predictive value (NPV), and accuracy of 2-D SWE in detecting the different stages of liver fibrosis were calculated. The chi-square test was used to analyze the relationship between the stages of fibrosis as assessed by the two methods (2-D SWE and liver biopsy). Categorical variables are presented as percentages and continuous variables are reported as means, medians, and standard deviations (SD). Univariate analysis was performed, and box and whisker plots were created to investigate the association between mean liver stiffness (kPa) measured by elastography at different stages of fibrosis. *P* values under 0.05 were considered statistically significant.

Table 1 Demographic and clinical characteristics of the subjects

Variable	*N* = 95
Age (mean ± SE)	30 ± 1.6
Aspartate transaminase (AST) (mean ± SE) U/L (normal <37)	104 ± 22
Alanine transaminase (ALT) (mean ± SE) U/L (normal < 40)	124.2 ± 21.2
Alkaline phosphatase (AKP) (mean ± SE) U/L (normal 40–129)	173.5 ± 17.5
Elastography liver stiffness (kPa) (mean ± SE)	6.5 ± 0.19
Diagnosis	
Hepatitis B/C	15 (16%)
Other liver disease	61 (64%)
Donor	19 (20%)

Results

Ninety-five patients were enrolled in the study, with a mean age of 30 years (range: 3–65 years). Fifteen out of 95 patients (16%) had hepatitis B/C, 61 patients (64%) had another liver disease, and 19 (20%) were donors for a liver transplants. The basic characteristics of the study patients are presented in Table 1.

The mean liver stiffness measured by elastography in patients was 6.5 ± 0.19 kPa. The mean liver stiffness measured by elastography in patients with F0–F1, F2, F3, and F4 stage fibrosis was 5.39 ± 0.62 kPa, 7.32 ± 0.41 kPa, 8.46 ± 0.33 kPa, and 11.42 ± 2.8 kPa, respectively. We found a significant difference in the mean level of liver stiffness between the different stages of fibrosis ($p < 0.0001$, Table 2 and Figs. 2 and 3).

Additionally, the assessment of the accuracy of elastography in determining different stages of liver fibrosis showed that there is a significant relationship between the results from 2-D SWE and liver biopsy ($p = 0.0001$). Regarding the 2-D SWE fibrosis score, there are 57 patients (60%) with F0–F1 stage fibrosis, followed by F2 (23%) and F3 (11%). The sensitivity was 89.7%, 32.4%, 20.0%, and 33.3% for fibrosis stages F0–F1, F2, F3, and F4, respectively. The specificity was 60.7% for F0–F1, 82.7% for F2, 90.5% for F3, and 96.5% for F4. The accuracy was 72.6%, 63.1%, 83.1%, and 90.5%, respectively (Tables 3 and 4).

Hepatitis B/C

The mean liver stiffness measured by elastography in patients with F0–F1 fibrosis was 5.44 ± 0.43 kPa, in F2 was 7.18 ± 0.48 kPa, and at stage F3 was 8.57 ± 0.35 kPa. The median stiffness was F0–F1: 5.49 kPa (IQR = 5.10–5.60 kPa), F2: 7.45 kPa (IQR = 6.66–7.57 kPa), and F3: 8.57 (IQR = 8.30–8.82 kPa) (Table 5).

Additionally, an assessment of the accuracy of elastography in determining different stages of liver fibrosis in patients with hepatitis B/C was performed. The sensitivity was 62.5% and 28.5% for fibrosis stages F0–F1 and F2, respectively. The specificity was 57.1% for F0–F1 and 62.5% for F2, and the accuracy was 60% and 46.6%, respectively (Table 6 and Fig. 4).

Table 2 Analysis of liver stiffness measured by elastography at different fibrosis stages

SWE fibrosis score	*N*	Mean (Kpa)	Std. dev	Minimum	Maximum	Range	IQR (75th–25th)
F0–F1	57	5.39	0.61	3.49	6.52	3.03	0.75
F2	22	7.33	0.41	6.66	7.88	1.22	0.58
F3	10	8.46	0.33	8.14	9.17	1.03	0.39
F4	6	11.42	2.79	9.35	16.65	7.3	2.73

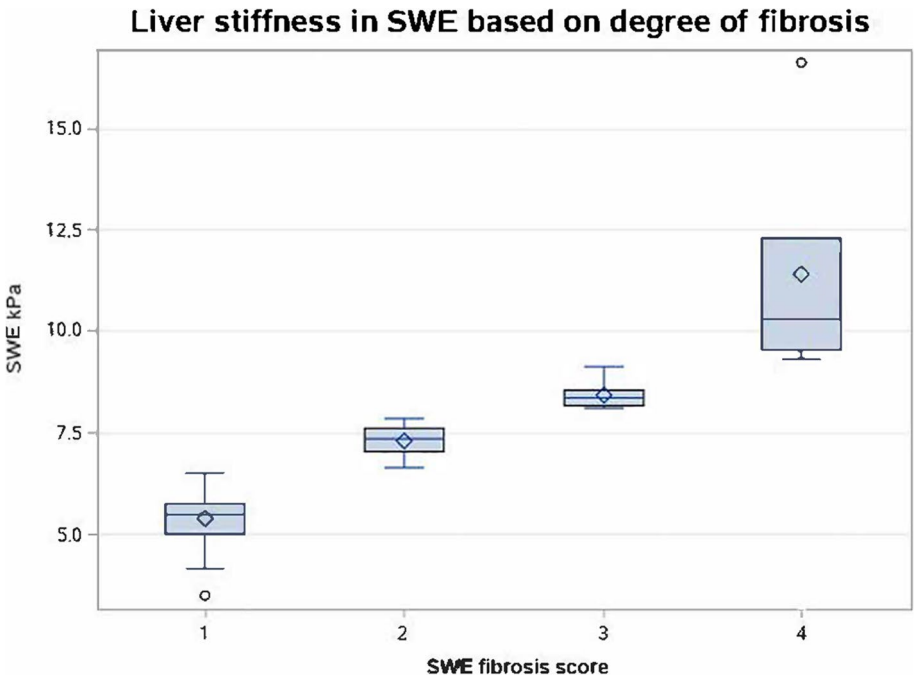

Fig. 2 Box and whisker plot of liver stiffness measured by elastography based on the stage of fibrosis. Each box represents the interquartile range (from the 25th to the 75th percentile). The line horizontally crossing each box represents the median. The median stiffness (kPa) for F0–F1: 5.49 (IQR = 5.02–5.77), F2: 7.38 (IQR = 7.06–7.64), F3: 8.39 (IQR = 8.2–8.59), and F4: 10.3 (IQR = 9.5–12.3)

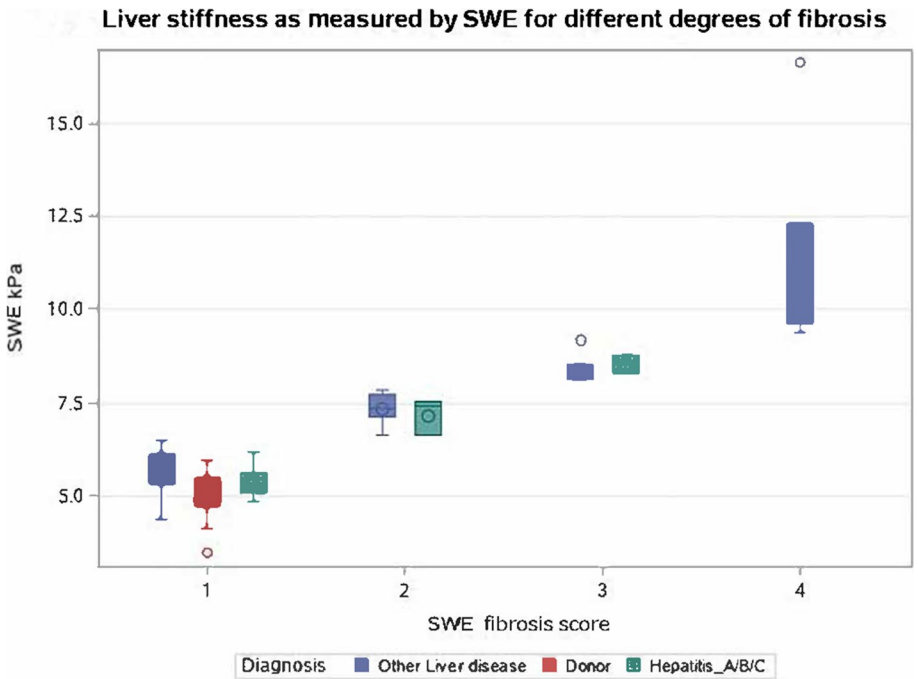

Fig. 3 Box and whisker plot of liver stiffness measured by elastography based on the stage of fibrosis, plotted by diagnosis. Each box represents the interquartile range (25th to 75th percentile). The line crossing each box horizontally represents the median

Table 3 The results of the elastography fibrosis score compared to the tissue biopsy

	Shear wave elastography fibrosis score				
		F0–F1	F2	F3	F4	Total
Biopsy fibrosis score	**F0–F1**	35	3	1	0	39 (41%)
	F2	20	12	4	1	37 (39%)
	F3	2	4	2	2	10 (11%)
	F4	0	3	3	3	9 (9%)
	Total	57 (60%)	22 (23.2%)	10 (10.5%)	6 (6.3%)	95 (100%)

Table 4 Diagnostic accuracy of SWE for detecting different stages of liver fibrosis compared to liver biopsy

	F0–F1	F2	F3	F4
Sensitivity	89.7	32.4	20.0	33.3
Specificity	60.7	82.7	90.5	96.5
PPV	61.4	45.4	20.0	50.0
NPV	89.4	65.7	90.5	93.2
Accuracy	72.6	63.1	83.1	90.5

Other liver diseases

The mean liver stiffness measured by elastography in patients with F0–F1, F2, F3, and F4 fibrosis was 5.59 ± 0.59 kPa, 7.37 ± 0.39 kPa, 8.43 ± 0.34 kPa, and 11.42 ± 2.8 kPa, respectively. The median values (in kPa) were for F0–F1: 5.65 (IQR = 5.33–6.15), F2: 7.38 (IQR = 7.15–7.76), F3: 8.35 (IQR = 8.2–8.6), and F4: 10.3 (IQR = 9.6–12.3) (Table 7).

The assessment of the accuracy of elastography in determining the different stages of liver fibrosis in patients with other liver diseases showed that there is a significant relationship between the results of 2-D SWE and liver biopsy ($p = 0.0005$). The sensitivity was 92.8%, 35.7%, 20.0%, and 33.3% for fibrosis stages F0–F1, F2, F3, and F4, respectively. The specificity was 63.8% for F0–F1, 78.7% for F2, 88.2% for F3, and 94.2% for F4. The accuracy was 70.4%, 59%, 77%, and 85.2%, respectively (Table 8 and Fig. 5).

Donor

The mean liver stiffness measured by elastography in patients with F0–F1 fibrosis was 5.06 ± 0.61 kPa. The median value for F0–F1 was 5.23 kPa (IQR = 4.72–5.52 kPa) (Table 9).

The assessment of the diagnostic accuracy of elastography in determining different stages of liver fibrosis was not performed in donor patients, as all patients were had a F0–F1 fibrosis score.

Discussion

Imaging-based techniques have been developed to assess the stage of liver fibrosis, ultrasound elastography, and MR elastography have both shown good results in several clinical studies [15–18], with US elastography providing the advantage of lower cost and better availability than MR elastography [3, 5, 11, 12].

The use of 2-D SWE as a noninvasive method to assess liver fibrosis has grown rapidly, and new information regarding disease-specific liver stiffness is available since

Table 6 The results of the elastography fibrosis score compared to the tissue biopsy in hepatitis B/C patients

	SWE fibrosis score				
Biopsy fibrosis score		F0–F1	F2	F3	Total
	F0–F1	5	3	0	8
	F2	3	2	2	7
	Total	8	5	2	15

Table 5 Univariate analysis of liver stiffness measured by elastography at different fibrosis stages

SWE fibrosis score	*N*	Mean	Std. dev	Minimum	Maximum	Range	IQR (75th–25th)
F0–F1	8	5.44	0.43	4.87	6.21	1.34	0.54
F2	5	7.18	0.48	6.66	7.57	0.91	0.91
F3	2	8.57	0.35	8.33	8.82	0.49	0.49

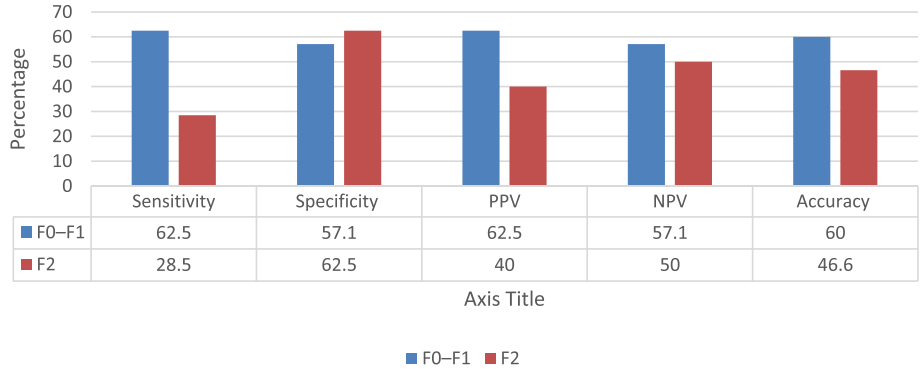

Fig. 4 Diagnostic accuracy of SWE for detecting different stages of liver fibrosis compared to liver biopsy in hepatitis B/C patients. Stratified analysis based on diagnosis

Table 7 Univariate analysis of liver stiffness measured by elastography at different fibrosis stages

SWE fibrosis score	*N*	Mean	Std. dev	Minimum	Maximum	Range	IQR (75th–25th)
F0–F1	30	5.59	0.59	4.39	6.52	2.13	0.82
F2	17	7.37	0.39	6.66	7.88	1.22	0.61
F3	8	8.43	0.34	8.14	9.17	1.03	0.39
F4	6	11.42	2.79	9.35	16.65	7.30	2.73

Table 8 The results of the elastography fibrosis score compared to the tissue biopsy in patients with other liver diseases

	SWE fibrosis score					
Biopsy		**F0–F1**	**F2**	**F3**	**F4**	**Total**
	F0–F1	13	0	1	0	14
	F2	15	10	2	1	28
	F3	2	4	2	2	10
	F4	0	3	3	3	9
	Total	30	17	8	6	61

the consensus statement of the SRU in September 2015 [1, 2].

Despite this benefit, the use of noninvasive tests is favored due to the need for longitudinal monitoring and to safely extend screening to larger populations.

SWE is an acceptable noninvasive method for the diagnosis and staging of liver fibrosis and a more accurate than serum fibrosis panels (e.g., aspartate aminotransferase [AST] to platelet ratio index or FIB-4) in predicting significant or advanced fibrosis, and it can replace liver biopsy in certain situations.

Previous research has studied 2-D SWE liver fibrosis staging in patients with CLD, patients with HCV [19, 20], and patients with hepatitis B [21]. These studies vary on the accuracy of elastography; however, the sensitivity, specificity, and diagnostic accuracy of SWE are comparable to biopsy results [22].

Ferraioli et al. [23] showed that SWE is a reliable and reproducible noninvasive method for the assessment of liver elasticity. Expert operators had a higher reproducibility of measurements over time than novice operators.

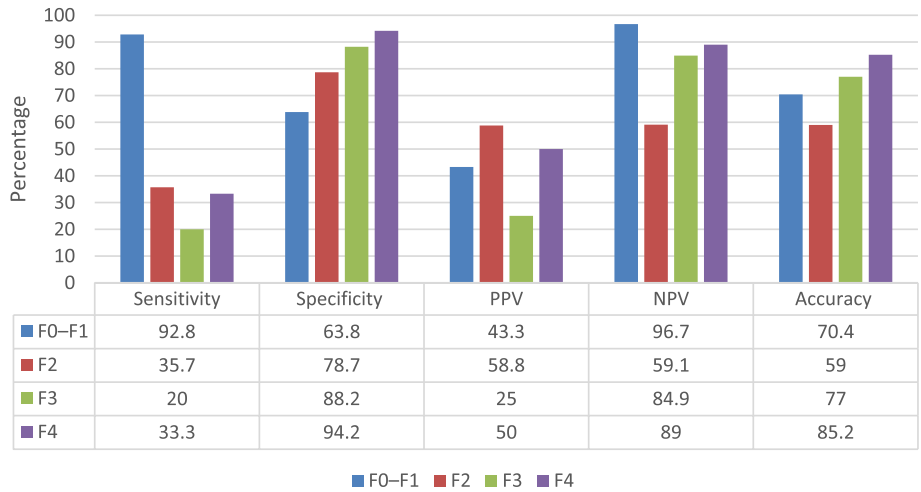

Fig. 5 Diagnostic accuracy of SWE for detecting different stages of liver fibrosis compared to liver biopsy in patients with other liver diseases

Table 9 Univariate analysis of liver stiffness measured by elastography at different fibrosis stages

SWE fibrosis score	*N*	Mean	Std. dev	Minimum	Maximum	Range	IQR (75th–25th)
F0–F1	19	5.06	0.61	3.49	5.98	2.49	0.80

Zeng et al. [24] concluded that the ALT-adapted dual cut-offs of LSMs showed high accuracy for diagnosis of the presence or absence of significant fibrosis and cirrhosis in patients with chronic HBV infection.

Ma et al. [7] studied SWE in patients with chronic HBV and compare it with pathology. They found comparable results to our study, where F1 (5.60 ± 2.55 kPa), F2 (7.44 ± 3.43 kPa) ($p = 0.01 < 0.05$), F3 (8.71 ± 3.14 kPa), and F4 (10.87 ± 5.25 kPa) ($p = 0.01 < 0.05$). In this study, we combined chronic HBV and HCV due to a small number of patients and our results were as follows: F0–F1 fibrosis was 5.44 ± 0.43 kPa, F2 was 7.18 ± 0.48, and at stage F3 was 8.57 ± 0.35 kPa. The median stiffness (in kPa) for F0–F1 are as follows: 5.49 (IQR = 5.1–5.60), F2: 7.45 (IQR = 6.66–7.57), and F3: 8.57 (IQR = 8.3–8.82)

In addition, Tada et al. [25] studied SWE in patients with chronic HCV only and concluded that: SWE has an excellent ability for diagnosing significant liver fibrosis in CHC even when patients with cirrhosis are excluded, odds ratio, 2.52; 95% confidence interval, 1.49–4.28; $P < 0.001$.

The stage of fibrosis is important to determine prognosis, surveillance, and prioritizing the treatment [1, 2, 7–9, 19, 21, 26–30], by the new direct-acting antiviral (DAA) therapy for hepatitis C, and the decision to start treatment for hepatitis B in the absence of other indications, since F2 score of fibrosis in healthy-looking individuals indicates treatment which can be decided without liver biopsy [7].

Furthermore, Stasi et al. [31] concluded that liver stiffness before treatment is useful in predicting the response to treatment in HCV patients.

It is also a helpful tool in assessing donors for liver transplantation, as in some cases, many potential donors may present for donation, and noninvasive methods would be time-saving with a convenient cost-benefit outcome.

The wider disease causes in this study are a homogenous representation of chronic liver disease.

From a clinical perspective, it is more important to rule in or rule out significant disease than it is to provide an exact stage by using the METAVIR scoring system.

In this study, we conclude that 2-D SWE is a noninvasive method that can be used in assessing liver stiffness and can replace biopsy to assess liver fibrosis regardless of the cause.

Limitations

This study population sample has a wide range of causes of liver disease beyond viral hepatitis that may cause heterogeneity in elasticity readings; however, a clear correlation between fibrosis stage and elasticity readings suggests that this method is likely valid in fibrosis measurements.

In addition, most of our sample is in the normal/mild fibrosis, therefore low power of the study in advanced fibrosis.

Also, different pathologies make the relative number of patients in each group which is relatively small.

Authors' contributions

The authors read and approved the final manuscript.

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Declarations

Competing interests

The authors declare that they have no competing interests.

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