

Original Article

Ultrasound Shear Wave Elastography for Hepatic Elasticity Assessment in Adults with and Without Chronic Liver Disease in Ethiopia: A Prospective Comparative Cross-Sectional Study

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Abstract

Background: Chronic liver disease (CLD) leads to development of fibrosis which results in increased stiffness of the hepatic parenchyma and decreased elasticity. Hepatic elasticity more than 5.4 kPa in Shear Wave Elastography (SWE) is considered as significant fibrosis. Early diagnosis of hepatic fibrosis has management implication among CLD patients as it may potentially be reversible. Measuring hepatic elasticity with SWE is one way of diagnosing and follow-up of patients with increased risk of having CLD. The relative accessibility, easy manipulation, and reliability make ultrasound a good diagnostic modality that allows early detection and intervention of fibrosis. However, there is relative lack of utilization of SWE to assess hepatic elasticity and no reference point set for Ethiopia.

Objective: The objective is to assess hepatic elasticity with real-time SWE in adult individuals with normal liver and among patients with clinical, laboratory and radiologic evidence of CLD.

Methods: A hospital based comparative cross-sectional study conducted from July to September 2021 at SPHMMC and Girum Hospital in Addis Ababa, Ethiopia. SWE was used to measure liver stiffness in 70 adults with normal livers and 80 with clinical or sonographic evidence of CLD. Data were collected using a structured checklist. Statistical analysis was performed using SPSS v26, including descriptive statistics, Kendall's tau-B correlation, independent t-tests, and ROC curve analysis. A p-value <0.05 was considered statistically significant.

Results: The mean value of liver stiffness (LS) measurements determined by SWE in patients without known liver pathology was 6.27 ± 1.33 kPa and in patients with liver pathology was 10.67 ± 6.22 kPa. No significant correlation was found between LS and age, gender, BMI, or steatosis.

Conclusion: SWE is useful for detecting significant fibrosis and early cirrhosis, but cutoff values should be tailored to disease etiology and laboratory findings by further research.

Keywords: CLD, Fibrosis, Shear Wave Elastography, Ethiopia

Introduction

Liver fibrosis is final common pathway for any chronic insult to the liver and is part of the structural and functional alterations in most chronic liver diseases. It is one of the main prognostic factors as the amount of fibrosis is correlated with the risk of developing cirrhosis, HCC and liver-related complications in viral and non-viral chronic liver diseases(1). Globally, liver diseases account for nearly two million deaths annually, with cirrhosis ranking among the top causes of morbidity and mortality worldwide. (2) In Ethiopia, although national prevalence data are lacking and most reports are institution-based, hepatitis B virus (HBV) infection is estimated to affect 8–10% of the population, while hepatitis C virus (HCV) affects approximately 1–3% (3). The major causes of fibrosis progression include chronic hepatitis B and C infections, alcoholic liver disease, and nonalcoholic fatty liver disease (4) (Table 1).

Table 1: Global mortality related to liver disease and liver cancer

	Cirrhosis and the liver			HCC	
	Global rank	Deaths (1,000)	% of total deaths	CDR (per 100,000 population)	Deaths (1,000)
World	11	1,162	2.1	15.8	788
East Asia & Pacific	13	328	2.0	14.4	547
Europe and central Asia	17	115	1.2	12.7	78
Latin America & Caribbean	9	98	2.7	15.6	33
Middle East & North Africa	8	77	3.5	18.2	24
North America	12	50	1.7	14.0	27
South Asia	10	314	2.5	18.0	38
Sub-Saharan Africa	16	179	1.9	17.9	42

CDR: Crude death rate

Importantly, liver fibrosis is a potentially reversible condition, even at the cirrhotic stage, particularly with effective antiviral therapy for hepatitis B and C. In addition, lifestyle modification such as reducing alcohol intake, achieving weight control, and managing diabetes and metabolic risk factors plays a critical role in slowing or reversing fibrosis progression in nonalcoholic fatty liver disease (5).

Regardless of the underlying etiology, timely prevention of variceal bleeding and early detection of hepatocellular carcinoma in patients with cirrhosis are essential strategies that significantly improve survival outcomes (6, 7).

So accurate staging of liver fibrosis is essential for guiding therapy, predicting treatment response, and monitoring disease progression. Although liver biopsy has long been

considered the gold standard for assessing fibrosis, it is invasive, prone to sampling error, and limited by inter-observer variability. Consequently, non-invasive imaging modalities have gained increasing importance in clinical practice and have been implemented in several guidelines for assessment of liver fibrosis (1,8).

Thus, non- invasive methods that are expected to replace liver biopsy have recently been developed, such as transient elastography (TE), acoustic radiation force impulse (ARFI), real-time tissue elastography (RTE) and real-time shear wave elastography (SWE). SWE is the newest of these methods and has better advantages like: real-time

two-dimensional (2-D) imaging, simple operation and quantitative measurements (9).

Several studies have demonstrated the reliability and diagnostic accuracy of real-time shear wave elastography (SWE), showing high sensitivity and specificity for differentiating significant and advanced fibrosis stages (9 – 13). According to the studies, the optimal cut-off for the diagnosis of significant fibrosis by ARFI was

- 5.4 kPa for the diagnosis of significant fibrosis;
- 7.2 kPa for the diagnosis of severe fibrosis and
- 9.7 kPa for the diagnosis of liver cirrhosis

Table 2 : Diagnostic accuracy and optimal cut-offs of ARFI for the diagnosis of liver fibrosis

ARFI	AUROC	Cut-off (m/s)	Sensitivity (%)	Specificity (%)	PPV (%)	NPV (%)	+LR
F≥2	0.87	1.34	79	85	91	66	5.07
F≥3	0.91	1.55	86	86	82	89	5.94
F=4	0.93	1.8	92	86	71	97	6.72

On the study of ultrasound shear wave elastography and liver biopsy to determine liver fibrosis in adult patients showed a direct and significant relationship between liver stiffness in different stages of fibrosis with ALT and AST levels. The highest levels of AST and ALT were seen in patients with F3 fibrosis and lowest levels were those with F0 (14).

Literatures suggest there are some limitations of SWE. According to ACR–SRU practice parameter for the performance of ultrasound elastography, the degree of liver fibrosis will be overestimated in the setting of markedly elevated liver function tests (>5x), non-fasting, congestive heart failure and pregnancy (15).

While magnetic resonance elastography (MRE) demonstrates superior diagnostic performance, its high cost, limited accessibility, and technical complexity make it less feasible in resource-limited settings like Ethiopia. In contrast, ultrasound-based methods, particularly SWE, provide a cost-effective, safe, and practical alternative for liver fibrosis assessment (16).

Despite these advantages, local experience with 2D shear wave elastography (SWE) remains limited. At the time of this study's initiation, there was no documented use of 2D-SWE and no established reference standards for its application in Ethiopia. Moreover, the technique has not been systematically evaluated for the follow-up of chronic liver disease (CLD) or incorporated into national clinical guidelines.

Therefore, this study aims to evaluate the diagnostic performance and clinical utility of 2D-SWE in assessing liver fibrosis among patients with chronic liver disease, thereby providing baseline evidence to support its integration into routine clinical practice and the development of local guidelines for liver fibrosis assessment in Ethiopian healthcare settings.

Methods and Materials

Study design, period and setting

This was an institutional based comparative cross-sectional study conducted from August 2021 to October 2021 at SPHMMC and Girum general hospital. St. Paul's Hospital Millennium Medical College (SPHMMC) is one of the tertiary referral hospitals directly under the Federal Ministry of Health. It is a teaching hospital for the health science

students enrolled in various undergraduate and postgraduate programs at Millennium Medical College. The college has more than 2800 clinical, academic and administrative and support staffs that provide medical specialty services to patients who are referred from all over the country, teaching medicine and nursing students and doing basic and applied researches. While the inpatient capacity is more than 700 beds, The College sees an average of 1200 emergency and outpatient clients daily (17). Girum Hospital is a private health facility established in 2007 G.C. by an American medical board certified physician Dr. Girum Berhane and his family with the main objective of introducing the art & science of medicine to Ethiopia by instituting an efficient hospital management system, a variety of medical specialties, investing on latest medical devices that enables to offer advanced quality healthcare services in nation to hold the patient referral abroad and hence to create a medical tourism center in Ethiopia in the short run (18).

Study Population

The source population for this study consisted of all adult clients visiting SPHMMC and Girum General Hospital. Specifically, the target population included those referred from various departments to the radiology units of both hospitals for sonographic examinations. The study population comprised all patients who underwent ultrasound scanning at SPHMMC and Girum General Hospital between August 1 and October 22, 2021.

Study Unit

The study population consists of two groups; Group A (patients with liver disease) attending radiology unit for sonography that meets the inclusion criteria while Group B (comparison group) consists of adults referred to sonography unit for reason other than a Hepatobiliary disease within the study period.

Inclusion and exclusion criteria

Inclusion criteria: Group A: These criteria include subjects with clinical or ultrasonographic evidence of Liver Disease and age of 18 or above. Group B: This includes adults with no clinical diagnosis or sonographic features suggesting the presence of Hepatobiliary disease had no Hepatobiliary surgery, or recent surgery for other reasons, and age of 18 or above.

Exclusion criteria: Group A: Pregnant women, Patients with congestive heart failure, Non-fasting

Group B which is the comparison group includes Alcohol consuming subjects, pregnant women, Subjects on hepatotoxic drugs such as anti-tuberculous and antiretroviral drugs and Ultrasonographic evidence of liver diseases.

Sample size determination

In the previous study of shear wave elastography in assessment of liver stiffness in normal and cirrhotic patients done in Egypt, they use 80 patients from which 60 had CLD and 20 are normal individuals. We used 50 patients with CLD, 25 patients with hepatic steatosis and 70 individuals with normal liver (19).

Data Collection Method

The data collection tool was a check list developed in English language. It was composed of socio-demographic data (age and sex, body mass index), laboratory parameters of liver disease (Liver enzymes, total bilirubin, Total protein), ultrasound parameters of liver disease (hepatic echogenicity, liver surface nodularity, ascites) and measurement parameters for hepatic elasticity (KPa). Data is gathered through face-to-face interview and on time measurement of the parameters. Ultrasound scanning is going to be done at Girum General Hospital by LOGIQ P9/P7 GE ultrasound machine with a C1-5-RS curvilinear probe. After making sure patient has fast for 6 hours; participants were asked for symptoms, physical examination were done, and review chart or laboratory data were undertaken. Then the Hepatobiliary system was scanned for inclusion and exclusion of subjects, before measuring hepatic elasticity. Then subjects were positioned in dorsal decubitus position, with the right arm elevated above the head for optimal intercostal access. ROI was placed on B-mode image of the liver; 2.0 cm deep beneath Glisson's capsule, to avoid reverberation artefacts and increased sub-capsular stiffness. Then patient were instructed to be at resting respiratory position (breath-hold without deep inspiration) and about 10 measurements were taken by pressing a button. Left lobe excluded and Measurement focuses mainly on segment V and VIII or VII. Measurements with IQR of > 30% were excluded from the sample.

Operational definition

Liver disease: defined as the presence of clinical features, abnormal liver function tests, or sonographic findings suggestive of hepatic pathology.

Chronic liver disease: Liver disease persisting for ≥ 6 months

Weight: the heaviness of a person.

Height: the part that rises or extends upward the greatest distance.

Data Quality Control

The data collection tool was pre-tested a week before the actual data collection days on subjects who are not included in the study at Girum General on 5% of the actual sample size. At the end of each data collection day, the principal investigator and supervisor checked the completeness and consistency of the data and whether recorded information makes sense to ensure the quality of data collected and the IQR of measured hepatic elasticity was checked for appropriateness.

Data Analysis

IBM-SPSS™ version 26 was used to code, enter, check the assumptions and analyze the data. The characteristics of the study population and hepatic elasticity were described using descriptive statistics of means, mode, standard deviations, frequencies, and proportions. The assumptions: normality of the outcome variable, linearity (between independent and dependent variables), and Homogeneity

were checked for continuous variables. Kendall's tau-b test was conducted to determine how hepatic elasticity is related continuous independent variables. Independent t-test will be conducted to determine a sex, steatosis, BMI, and CLD based Hepatic elasticity difference. A P value of less than 0.05 was considered significantly correlated for calculated Pearson's correlation and significance difference for the independent t-test and ANOVA. Receiver operating characteristics (ROC) curve was calculated to determine reference point for identification CLD in the applicable population. Then results were presented by text, figure, and tables by comparing the two groups of participants.

Results

Sociodemographic, laboratory and sonographic character of Participants: The study has included total of 150 adults of whom 78 (52%) were males and 72 (48%) were females. The age of participants ranged from 20-84years and mean age was 44.17 years with SD of 14.68, median 41.5 years. From the study participants; 10 (6.7%) were underweight, 113 (75.3%) were normal, 23 (15.3%) were overweight and 4 (2.7%) were obese in their body mass index. From the total of 150 participants; 60 (40%) have sonographic evidence of liver disease and 55 (35.9%) had laboratory abnormality suggesting liver disease. From the participants, 34 (22.7%) had chronic hepatitis B virus, 7 (4.7%) hepatitis C virus, 3 (2%) significant alcohol intake and 26 (16.7%) hepatic steatosis.

Table 3: Sociodemographic and clinical characteristics of participants

Characteristics	Finding	Characteristics	Finding
Gender		Liver Functions	
Male	78 (52.0%)	Total Bilirubin	0.92±1.38
Female	72 (48.0%)	Total Protein	7.22±7.07
Age	44.17±14.67 (20-85)	Steatosis	
BMI		Mild	19 (72%)
<18.4	10 (6.7%)	Moderate	7 (28%)
18.5-24.9	113 (75.3%)	Liver status	
>25	27 (18%)	Normal Liver	70 (46.6%)
Liver Enzymes		Diseased liver	80 (53.3%)
AST	49.78 ± 172.22	Hepatic Steatosis	26 (17.3%)
ALT	37.18±40.79	Chronic HBV infection	34 (22.7%)
ALP	72.65±50.50	Chronic HCV infection	
		Alcoholic liver disease	7 (4.7%)
			3 (2%)

Cause of Liver disease and Shear wave elastography results:

From a total of 80 individuals diagnosed to have liver disease by either clinical or radiological parameters, 34 (22.7%) had chronic hepatitis B virus, 26 (17.3%) had hepatic steatosis, 7 (4.7%) had chronic hepatitis C virus, and 3 (2%) alcoholic liver disease (Figure 1). Concerning severity of hepatic steatosis, 19 (73.08%) had mild steatosis, 7 (26.92%) had moderate steatosis and no participant was found with severe hepatic steatosis (Figure 2).

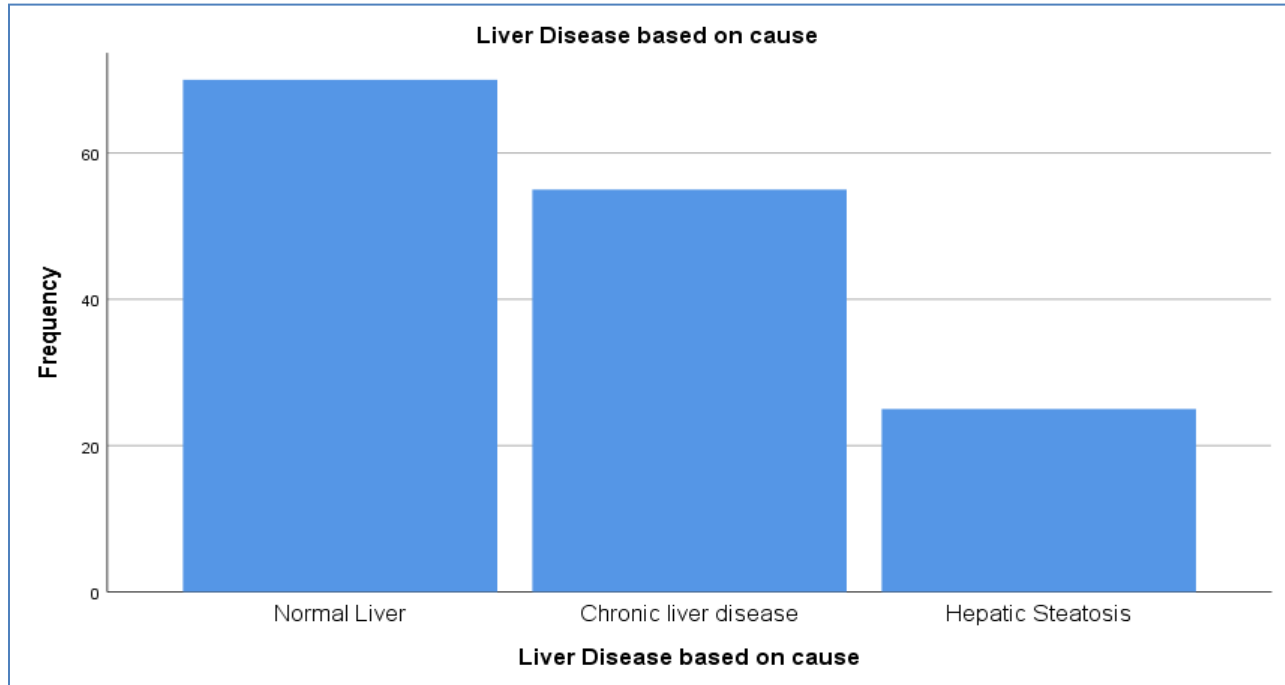


Figure 1: Status of liver in the study participants

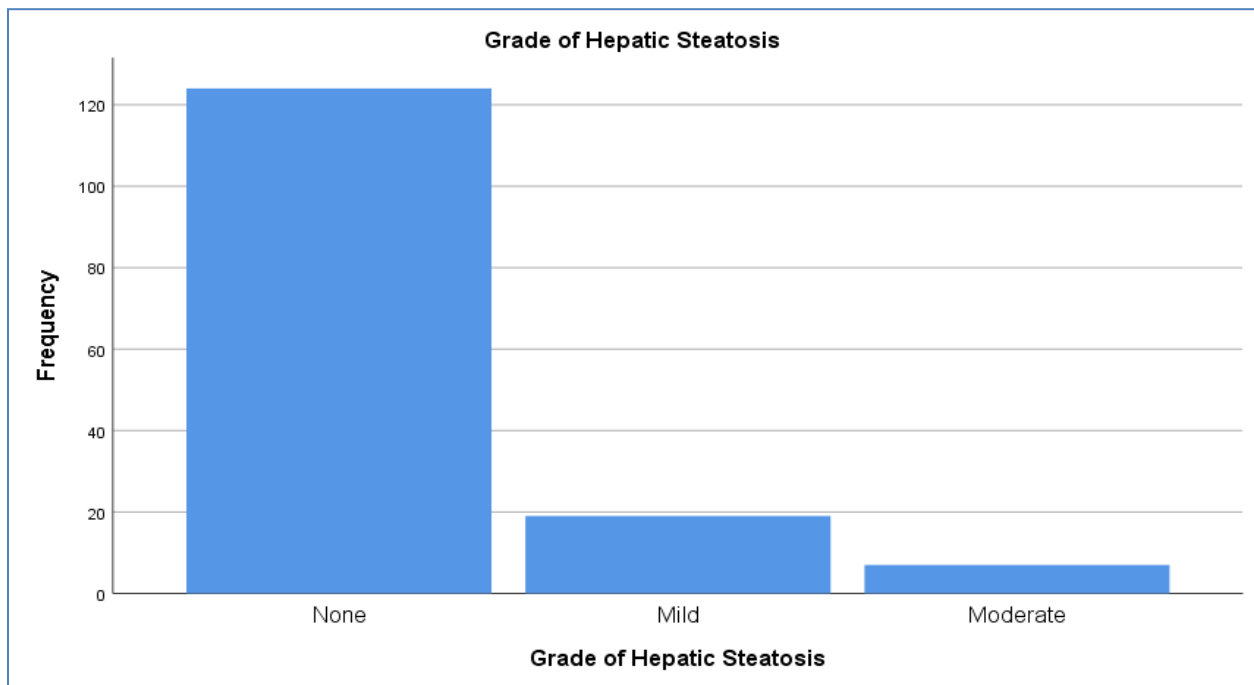


Figure 2: Grades of hepatic steatosis

The mean hepatic elasticity of individuals without clinical and sonographic evidence of CLD was 6.63kpa with maximum of 10.69KPa, minimum of 3.6KPa, standard deviation of 1.33 and the mean hepatic elasticity of individuals with clinical or sonographic evidence of CLD was 9.52 with maximum of 35.75 KPa, minimum of 4.08 KPa, standard deviation of 5.53 (Table 4 and Figure 3-6).

Table 4: Mean hepatic elasticity values in cases and controls

Mean hepatic elasticity (KPa)		
	Normal Liver	Liver Disease
N	70	80
Mean	6.2661	9.5197
Median	5.9250	8.0300
Std. Deviation	1.32706	5.53123
Minimum	3.60	4.08
Maximum	10.69	35.75

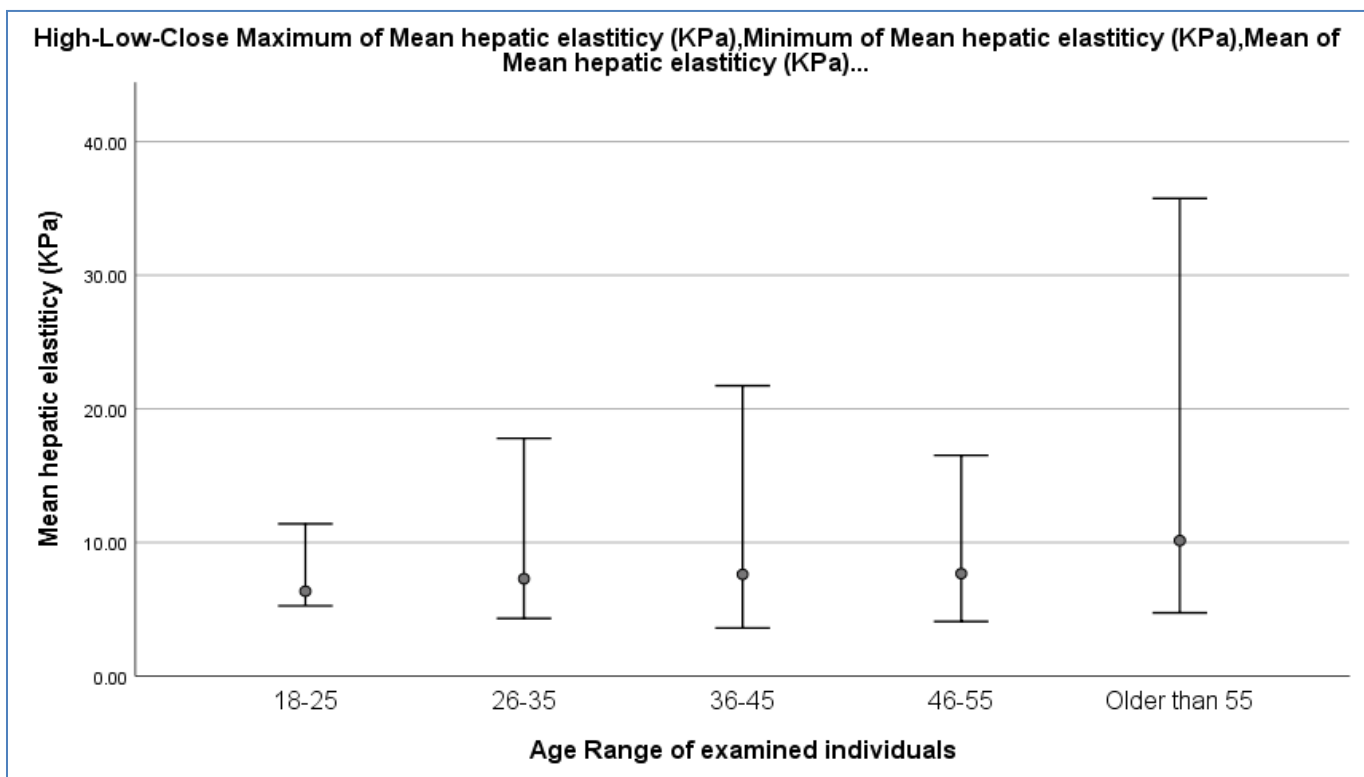


Figure 3: Mean Hepatic elasticity values in relation with age

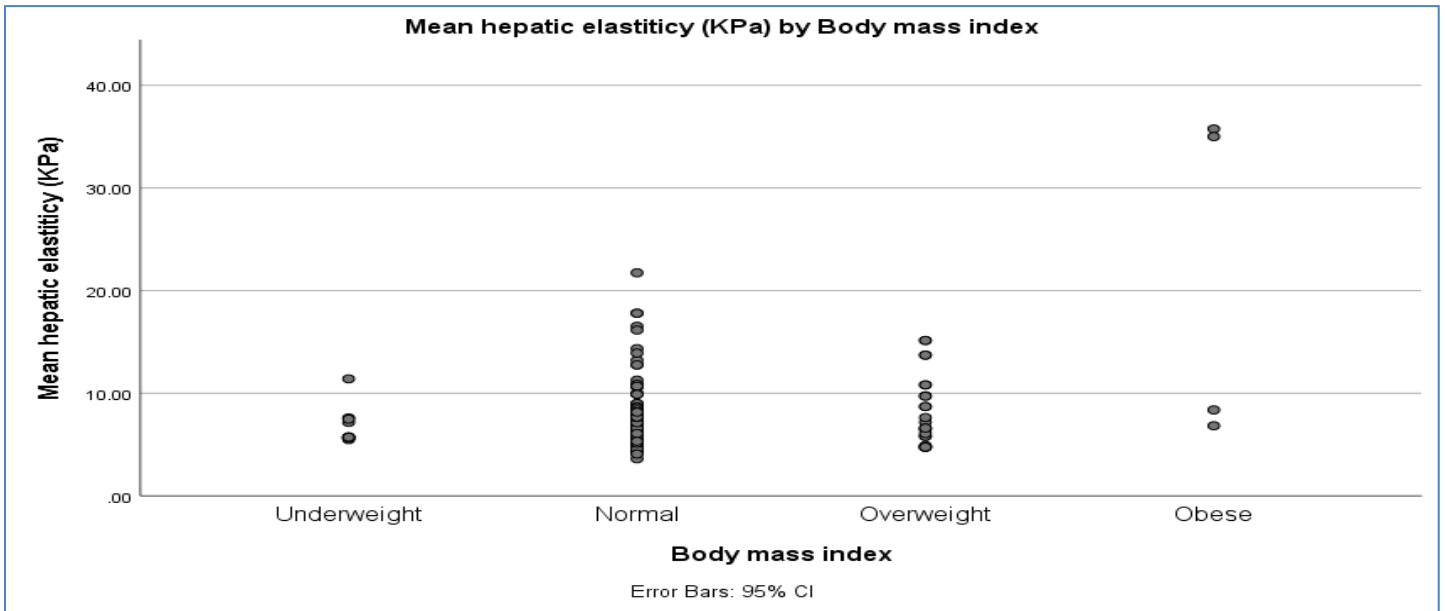


Figure 4: Distribution of Mean Hepatic elasticity values in relation with BMI

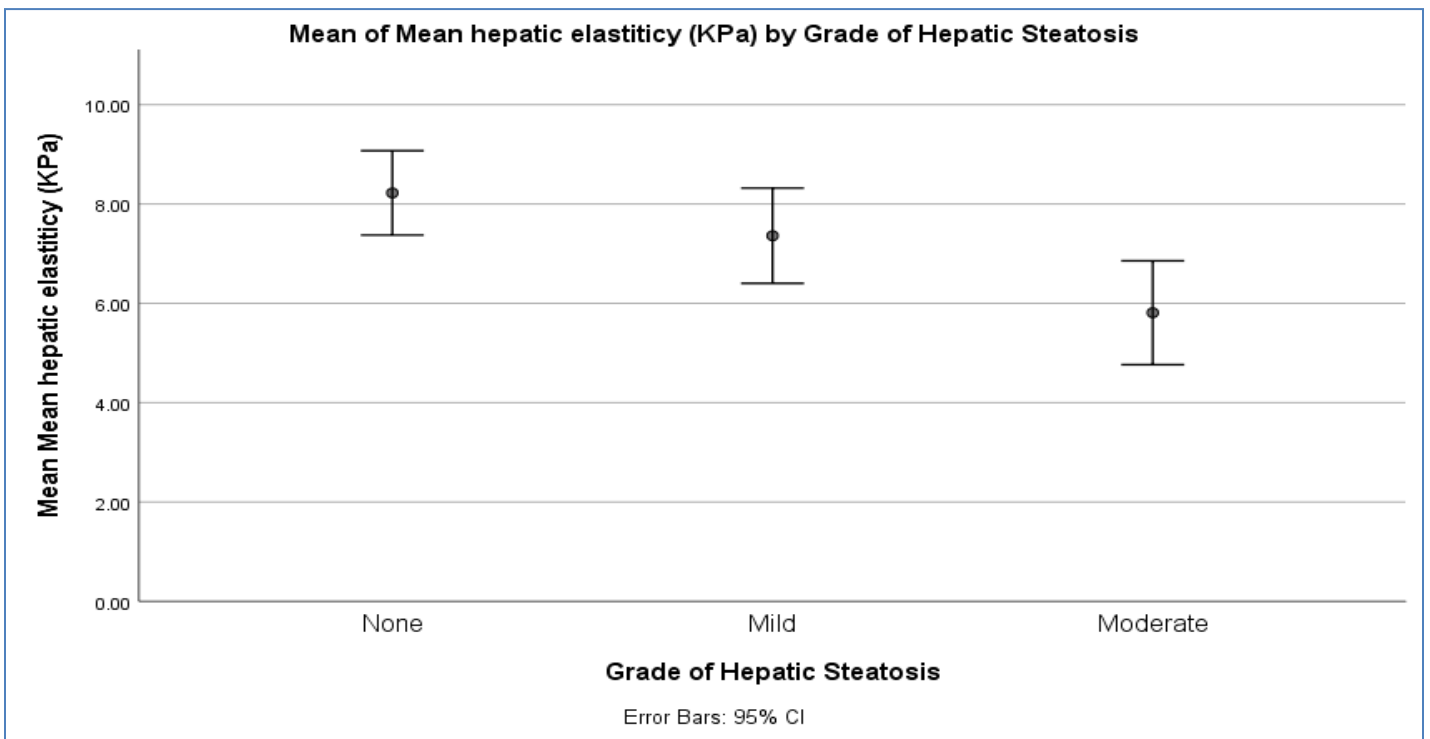


Figure 5: Distribution of Mean Hepatic elasticity values in relation of grade of hepatic steatosis

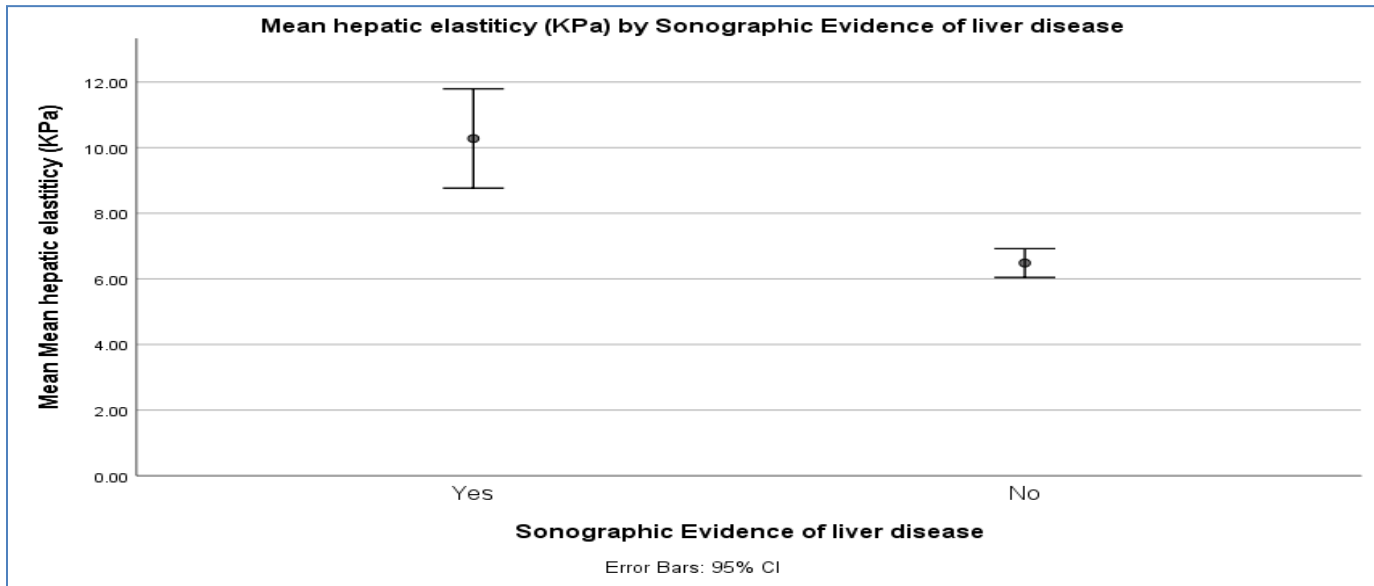


Figure 6: Distribution of Mean Hepatic elasticity values in relation of presence or absence of sonographic parameters of liver disease

The statistical significance for status of liver its correlation with mean hepatic elasticity was tested with students independent t-test with P-value of 0.000002 and CI (0.19, 0.45) where critical t-value of 5.09. The statistical significance for abnormal sonographic liver findings and its correlation with mean hepatic elasticity was tested with students independent t-test with P-value of 0.000008 and CI (0.22, 0.54) where critical t-value of 4.82. The statistical significance for abnormal laboratory findings and their correlation with mean hepatic elasticity was tested with kendall's tau-B test with Correlation coefficient of 0.22 for AST, 0.08 for ALT, 0.14 for ALP, 0.09 for Total bilirubin and -0.17 for total serum protein and CI (0.22, 0.54) where critical t-value of 4.82. Based on the above data, elevated levels of AST and ALP and decreased levels of total serum protein have statistically significant correlation with mean hepatic elasticity. The statistical significance for hepatic steatosis and its correlation with mean hepatic elasticity was

tested with students independent t-test with P-value of 0.57 and CI (-0.15, -0.24) where critical t-value of 4.82. No significant correlation was found between hepatic steatosis and mean hepatic elasticity. The relationship of participant gender and mean hepatic elasticity in clinically and sonographically normal liver was assessed with students independent t-test with P-value of 0.37 and CI (-0.34, 0.91) where critical t-value of 0.91. The test had confirmed no significant difference between mean hepatic elasticity between male and female participants. The statistical significance of BMI and mean hepatic elasticity was tested with students independent t-test with P-value of 0.33 and CI (-0.04, 0.11) where critical t-value of 0.99. The test had confirmed that there is no significant relation between BMI and mean hepatic elasticity in individuals without of CLD.

Discussion

Non-invasive methods are used to detect fibrosis such as transient elastography but it was not so accurate and has limitations in obesity and ascites. By now, real-time shear wave elastography was used to detect the degree of liver stiffness due to fibrosis which is resulted from liver injury by virus. So, there is a decrease in the need for an invasive method such as liver biopsy (19).

Our study has several unique features. First, to our knowledge, this research is the first study of SWE in Ethiopia and our results provide an initial detection criterion for Ethiopia and east Africa populations, and in future studies of chronic liver disease, our results may be used as a reference value for assessing the shear modulus with SWE. Second, this study appears to be the first to evaluate factors that are associated with LS values.

Our study revealed that there is no statistically significant difference in mean SWE values between men and women. However, the influence of gender on LS is controversial. A large sample (923 subjects) Chinese study that used SWE reported that the median stiffness in men was significantly higher than in women (9). A different study that used ARFI among 137 healthy subjects found no statistically significant difference in mean ARFI values between men and women (20). These inconsistencies may be a result of different sample sizes, geographic differences, and racial differences.

The age and BMI of the subjects did not affect the SWE results, which is consistent with previous studies (9, 11, 20).

In our study there is no statistically significant difference in mean 2D-SWE values and hepatic steatosis which is consistent with previous studies (11).

This study has shown significant SWE difference between the normal and CLD individuals with mean 2D-SWE difference between the normal and CLD liver of 4.24 with standard error of difference 0.85 , P-value of <0.001 and confidence interval CI (0.0253-0.05945).

Table 5: Comparison of mean hepatic elasticity values with previous studies

Study	Control		Case	
	SWE±SD	N	SWE±SD	N
Z. Haung et.al. (2014)	5.1KPa±1.02	512		
C. Suh et.al. (2014)	4.4KPa±0.9	126	9.6KPa±3.2	22
M. Zaki et.al (2019)	10.4KPa±2.65 91	20	45.65±10.54 13	60
Our study (2021)	6.27KPa±1.33	55	10.69KPa±6. 22	70

Our study revealed that the mean LS value of livers without Sonographic or laboratory evidence CLD was 6.27KPa. This value is close to the reports from studies done by different authors like Z. haung et.al. which found mean value of 5.1KPa(9), C. Suh et.al. which found mean value of 4.4 KPa(11), M. Zaki et.al. which found mean value of 10.4KPa(19).

Our study included 80 patients with chronic liver disease and 70 normal controls; with significantly higher mean liver stiffness values observed in patients with chronic liver

disease compared to controls. Similar findings have been reported in the literature. *Mohamed et al.* reported higher liver stiffness values in patients with high-grade fibrosis (12.6 kPa) compared to controls (3.1 kPa). Comparable results have also been described in African settings; a study from Lomé, Togo by *Dagbe M et al.* demonstrated increased liver stiffness in patients with chronic liver disease using two-dimensional shear wave elastography (21, 22).

This study has some limitations. First, the absence of histologic confirmation limited the establishment of reference cut off values for both controls and cases. Second, we did not compare SWE findings with other non-invasive imaging modalities, such as FibroScan, for liver stiffness assessment. Third, the potential influence of confounding factors may have been underestimated. In addition, the analysis involved a relatively small number of participants with hepatic steatosis. Finally, the study did not evaluate the prognostic value of SWE in predicting morbidity and mortality among patients with liver cirrhosis. Despite these limitations, this is the first study in our locality to emphasize the value of real-time SWE as a non-invasive tool for liver fibrosis assessment. Further large-scale studies are warranted to validate and expand upon these findings.

Conclusion

Our study demonstrates that two-dimensional shear wave elastography is a feasible and non-invasive method for measuring hepatic elasticity in adults with and without chronic liver disease. Mean liver stiffness values were significantly higher in individuals with chronic liver disease compared to those with normal liver findings.

As this study did not assess histologic fibrosis stages or establish diagnostic cut-off values, further large-scale studies incorporating histopathology correlation and comparative non-invasive methods are required to validate fibrosis stage-specific thresholds.

Abbreviations

CLD: Chronic Liver Disease; KPa: Kilopascal; IQR/M: Ratio of the Interquartile range to the Median; SWE: Shear wave elastography; SPHMMC: St. Paul's Hospital Millennium Medical Collage; TE: Transient Elastography

Declarations of Consent for publication

Not applicable

Ethical declaration

A formal ethical approval letter was issued from the Institutional Review Board of SPHMMC. After taking permission from the hospital and department of radiology the data collection was started. Informed consent was obtained from the respondents before proceeding to data collection. The respondents' right to refuse or withdraw from participating in the study at any time was fully respected, and the information provided by each respondent was kept confidential by putting the collected data in a secure room and the patients' name is omitted from the checklist.

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Competing interest

The authors declare that they have no competing interests.

Availability of data and materials

The datasets used in the current study or data collection tool are available from the corresponding author with a reasonable request.

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