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Original Article

Radiology Section

Validation of Shear Wave Elastography as a Non Invasive Procedure to Detect and Grade Oesophageal Varices in Chronic Liver Disease: A Cross-sectional Study

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ABSTRACT

Introduction: Chronic Liver Disease (CLD) is characterised by progressive liver dysfunction. The most serious consequence of CLD is portal hypertension, which can lead to ascites, Gastroesophageal Varices (GEV) and hepatic encephalopathy. Of these, the development of GEV is a major complication. Given the high mortality associated with variceal bleeding, screening for GEV is recommended for all patients with diagnosed CLD. Shear Wave Elastography (SWE) is a novel imaging modality that can measure Liver Stiffness (LS) and Splenic Stiffness (SS) in real time. Most studies have assessed Transient Elastography (TE) and Acoustic Radiation Force Impulse (ARFI); however, only a few have evaluated SWE. Moreover, appropriate cut-off values to categorise the severity of varices are not available for liver.

Aim: To evaluate SWE as a non invasive method to detect and grade Oesophageal Varices (EV) in CLD.

Materials and Methods: A cross-sectional study was conducted in the Department of Gastroenterology at Believers Church Medical College Hospital, Thiruvalla, Kerala, India, from April 2023 to March 2024. All individuals aged 18 years or older, of any gender, with diagnosed CLD of any aetiology who consented to participate were eligible. The diagnosis of CLD was based on clinical, biochemical and radiological features. The study evaluated the role of SWE in conjunction with endoscopy in CLD and assessed variables such as age, Body Mass Index (BMI), aetiology and the grading of EV. The study estimated SWE's ability to demonstrate associations between LS and SS with the presence and severity of EV. Sensitivity, specificity, Positive Predictive Value (PPV) and Negative Predictive Value (NPV) were calculated for validation of SWE. To assess SWE, Receiver Operating Characteristics (ROC) curves were plotted and optimal cut-off values were estimated using Youden's index.

Results: Of 96 patients evaluated, 76% were male, with a mean age of 45±13.42 years. Alcoholic cirrhosis emerged as the most prevalent aetiology, accounting for 54 (56.25%) cases. EV was detected in 59 patients (61.46%). The area under the ROC curve (AUC) values were 0.855 for Liver Stiffness, measurement (LSM) and 0.938 for Splenic Stiffness Measurement (SSM). LSM had a specificity of 97.03%, while SSM had a sensitivity of 91.5% and a specificity of 91.9%, indicating that SWE offers robust diagnostic capability for detecting and grading EV.

Conclusion: The study underscores the clinical significance of SWE as a non invasive tool for assessing and grading EV in CLD.

Keywords: Endoscopy, Liver stiffness, Splenic stiffness

INTRODUCTION

The liver is the largest solid organ in the human body and carries out numerous essential functions, including detoxification, metabolism of various substances and synthesis. Liver diseases are among the leading causes of morbidity and mortality in the Indian subcontinent [1]. Liver cirrhosis is the end stage of CLD. The most serious consequence of CLD is portal hypertension, which can lead to ascites, GEV and hepatic encephalopathy. Of these, the development of GEV is a major complication [2]. Given the high mortality associated with variceal bleeding, screening for GEV is recommended for all patients with diagnosed CLD [3].

Oesophagogastroduodenoscopy (EGD) is the diagnostic procedure used to detect varices and other stigmata of variceal bleeding, such as red colour signs and the size of the varices. Moreover, therapeutic interventions can be performed during the same procedure [4]. It is considered the gold standard for diagnosing varices. Unfortunately, EGD is expensive, invasive and uncomfortable and frequently requires sedation [5]. Therefore, there is a clinical need for a non invasive and sensitive method to assess and grade GEV, particularly high-risk varices. Three commonly used non invasive methods are TE, AFRI and SWE. Of these, SWE is the most novel method. As the earliest elastography technique to be applied in clinical practice, TE has been used to classify hepatic fibrosis and to predict the occurrence of EV and portal hypertension. However, this method is prone to measurement errors in patients with obesity, severe ascites and narrow intercostal spaces. Moreover, the failure rate can be as high as about 19% in some patient groups [6].

By contrast, SWE has two-dimensional imaging capabilities, unlike TE and is based on shear waves that are implemented in diagnostic ultrasound (US) systems, while also providing a quantitative estimate of tissue stiffness [7]. SWE has the advantage of being able to image LS in real time, unlike TE, which yields only a single stiffness value [8]. Moreover, SWE may provide a more accurate assessment of liver tissue stiffness due to the availability of B-mode imaging on the same probe and a higher frame rate [9].

Only a small number of studies have investigated the novel SWE, which has suggested a role for 2D elastography and potential benefit in detecting EV [8,10]. The appropriate cut-off values to categorise the severity of EV are not available for LS or SS. Their ability to predict the severity of EV has not been compared. This study aimed to compare the effectiveness of LS with SS in detecting and grading the severity of EV.

MATERIALS AND METHODS

A cross-sectional study was conducted in the Department of Gastroenterology at Believers Church Medical College Hospital, Thiruvalla, Kerala, India, from April 2023 to March 2024. Prior clearance for the study was obtained from the Institutional Ethics Committee (IEC) (IEC study No. IEC/2023/03/331). The sampling method used was simple random sampling. The study population included 96 patients.

Inclusion criteria:

1) Individuals aged 18 years or older, irrespective of gender or liver disease aetiology, diagnosed with CLD who consented to participate.
2) The diagnosis of CLD was based on clinical, biochemical and radiological features. Signs of liver disease (e.g., jaundice, hepatomegaly, splenomegaly, ascites, spider naevi, palmar erythema, gynaecomastia) were assessed and associated investigations, which included Liver Function Tests (LFTs), Prothrombin Time (PT) and International Normalised Ratio (INR), Complete Blood Count (CBC) and imaging studies (abdominal US, CT or MRI as appropriate) were performed and evaluated for features favouring CLD.

EGD was performed in all patients included in the study.

Exclusion criteria:

1) History of endoscopic treatment for GEV, including endoscopic injection or ligation, that might affect portal haemodynamics.
2) Patients on propranolol or other pharmacologic treatment for EV prior to recruitment.
3) Transjugular Intrahepatic Portosystemic Shunt (TIPS).
4) Presence of Portal Vein (PV) thrombus confirmed by US with colour Doppler.
5) History of liver surgery or partial splenic embolisation or splenectomy.
6) Presence of Hepatocellular Carcinoma (HCC) or splenic tumors.
7) Presence of hepatic encephalopathy grade 3 or 4, severe ascites, left-sided portal hypertension (this entity is due to pancreatic disease with a normal liver), or contraindication to undergoing upper gastrointestinal endoscopy (EGD).
8) Concomitant renal failure or severe life-threatening co-morbidities including congestive heart failure NYHA class III or IV, acute asthmatic attack, or recent Myocardial Infarction (MI).
9) Pregnancy or lactation.

Study Procedure

All patients were examined in the morning after a fasting state of at least four hours, with 10 minutes of prior rest, using the Mindray DC-80 SC6-1E convex array probe (Shenzhen Mindray Bio-medical Electronics Co., Ltd., Shenzhen, China). Patients were placed in the supine position and the SWE examination was performed using brightness (B)-mode ultrasound. The elasticity image box was set 1.5-3 cm deeper than the Glisson capsule and the splenic capsule and vessels were avoided during measurement. Measurements of LS were performed on the right lobe of the liver through the intercostal space, with the patient's right upper limb in maximal abduction. The probe was placed on the right side of the 7th to 9th intercostal spaces along the midclavicular or anterior axillary line. When the target area of the liver was located, the B-mode US was switched to SWE mode for LS measurement. The patient was asked to hold a breath for about 5 seconds during measurement. The maximum penetration depth was 8 cm and the Region of Interest (ROI) was a rectangle measuring 5×15 mm. Measurements were repeated 5-10 times and the results were reported as mean, standard deviation (SD) and median values expressed in kilopascals (kPa) for each organ. Measurements of splenic length and SS were performed between the 9th and 11th intercostal spaces, with the patient's left upper limb in maximal abduction. About 5-10 measurements were obtained and averaged.

Child Turcot Pugh score classification [11]: Child-Pugh (also referred to as Child-Turcotte-Pugh, CTP) score was used to assess the severity of liver disease. The classification uses five parameters: bilirubin, albumin, prothrombin time (PT) or INR, ascites and hepatic encephalopathy. Each parameter is assigned a score from 1 to 3 and the total score (5-15) classifies patients into three classes: Class A (5-6), Class B (7-9), or Class C (10-15).

Grading of EV [12]: Varices were categorised into three groups: Grade 1 - small (minimally elevated above the surface), Grade 2 - medium (tortuous veins occupying < 1/3 of the esophageal lumen) and Grade 3 - large (tortuous veins occupying > 1/3 of the esophageal lumen).

Outcomes measured: LSM and SSM values for all patients with CLD included in the study were measured. Specific cut-offs for LSM and SSM for detecting the grading and severity of EV in CLD were determined.

STATISTICAL ANALYSIS

Comparison of the sensitivity and specificity of LS with SS was performed. Statistical Package for the Social Sciences (SPSS) software version 24.0 was used. Sensitivity, specificity, positive and negative predictive values and likelihood ratios with their respective 95% confidence intervals were calculated for validation of SWE. To grade SWE, ROC curves were drawn and appropriate cut-off values were estimated using Youden's J statistic.

RESULTS

Of the 96 patients, the largest proportion (43.8%) belonged to the 36-50 years age group The majority were male, comprising 73 (76.0%) of the total population, while females accounted for 23 (24.0%) [Table/Fig-1]. A seemingly healthy majority 54 (56.3%) had normal weight (BMI < 24.9 kg/m^2). Conversely, smaller portions fell into the overweight 13 (13.5%) and obese 8 (8.3%) categories [Table/Fig-2].

Age group (years)	n (%)
18-35	19 (19.8)
36-50	42 (43.8)
>50	35 (36.5)

[Table/Fig-1]: Age distribution.

BMI (kg/m^2)	n (%)
Underweight (<18.5)	21 (21.9)
Normal (18.5 to 24.9)	54 (56.3)
Overweight (24.9 to 29.9)	13 (13.5)
Obese (>30)	8 (8.3)

[Table/Fig-2]: BMI distribution.

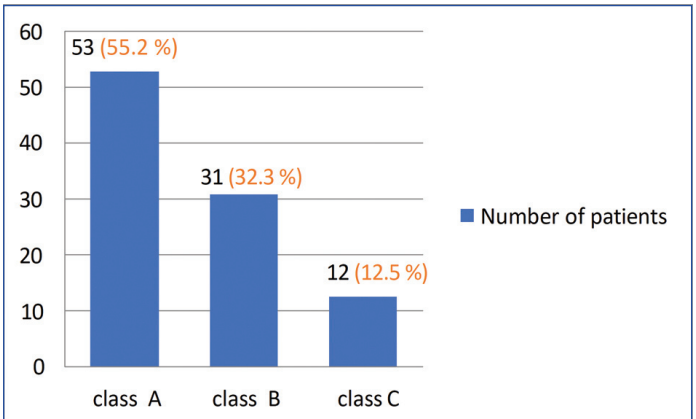
Alcoholic cirrhosis emerged as the most prevalent cause, accounting for 54 patients (56.25%) of the study population [Table/Fig-3]. [Table/Fig-4] shows the representation of patients in the study under different CTP classes.

Among the 96 patients evaluated, EV was detected in 59 patients (61.46%), while the remaining 37 patients (38.54%) showed no evidence of EV on EGD. The difference in liver stiffness LSM between patients with and without EV was statistically significant (p -value < 0.0001), indicating that LSM by 2D SWE is a potential marker for the presence of EV. The difference in spleen SSM between patients with and without EV was also statistically significant (p<0.0001) [Table/Fig-5,6]. Among the patients with LSM < 15 kPa, 23 had EV

while 36 did not. For patients with LSM ≥ 15 kPa, 36 had EV and only one did not. For patients with SSM < 17 kPa, 12 had EV while 34 did not have EV [Table/Fig-7].

Aetiology of cirrhosis	n (%)
Alcohol	54 (56.25)
Non Alcoholic Fatty Liver Disease (NAFLD)	23 (23.96)
Hepatitis B virus (HBV)	8 (8.33)
Hepatitis C virus (HCV)	3 (3.13)
Autoimmune	5 (5.21)
Haemochromatosis	2 (2.08)
Wilson's disease	1 (1.04)

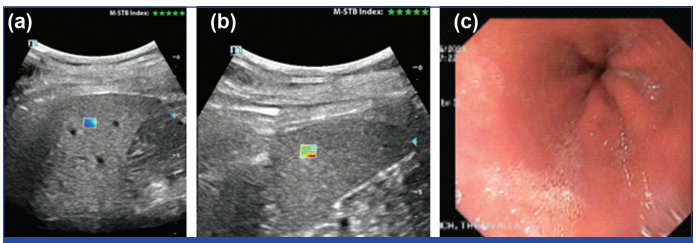
[Table/Fig-3]: Aetiology of CLD.



[Table/Fig-4]: CTP classification.

Examination	All	Oesophageal Varices (EV)		p-value
		Present	Absent	
LSM	14.76±3.18	16.14±3.1	12.4±1.6	<0.0001
SSM	16.45±3.59	18.53±1.4	13.81±3.2	<0.0001

[Table/Fig-5]: Comparison of Shear Wave Elastography (SWE) and endoscopy results.



[Table/Fig6]: Patient with Chronic Liver Disease (CLD). a. LSM - 12.35 kPa; b. SSM - 13.36 kPa; c. Endoscopy showing no varices.

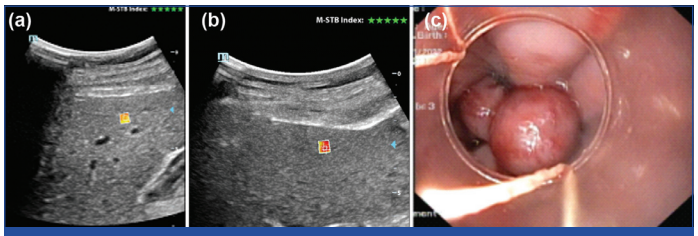
	SWE (Kpa)	Oesophageal Varices (EV)		Corrected Chi-square	p-value
		Present	Absent		
LSM	<15	23	36	30.22	<0.00001
	≥15	36	1		
SSM	<17	12	34	43.82	<0.00001
	≥ 17	47	3		

[Table/Fig-7]: Association between EV and SWE cut-offs.

Variceal grades were categorised into three groups: G1 (17 patients), G2 (28 patients) and G3 (14 patients). For variceal grade 1 (G1), the mean LSM was 12.365±1.17 kPa and the mean SSM was 17.04±0.60 kPa. For variceal grade 2 (G2), LSM was 15.90±1.28 kPa and SSM 18.38±0.40 kPa. In variceal grade 3 (G3), LSM rose to 19.87±1.69 kPa, while SSM reached 20.52±1.02 kPa. These findings indicate a progressive escalation in both liver and spleen stiffness measurements as variceal grades advance [Table/Fig-8,9].

Variceal grade	No. of patients	LSM	SSM	p-value
		Mean±SD	Mean±SD	
G1	17	12.365±1.17	17.04±0.60	<0.0001
G2	28	15.90±1.28	18.38±0.40	<0.0001
G3	14	19.87±1.69	20.52±1.02	0.2289

[Table/Fig-8]: Association between variceal grade and LSM, SSM.

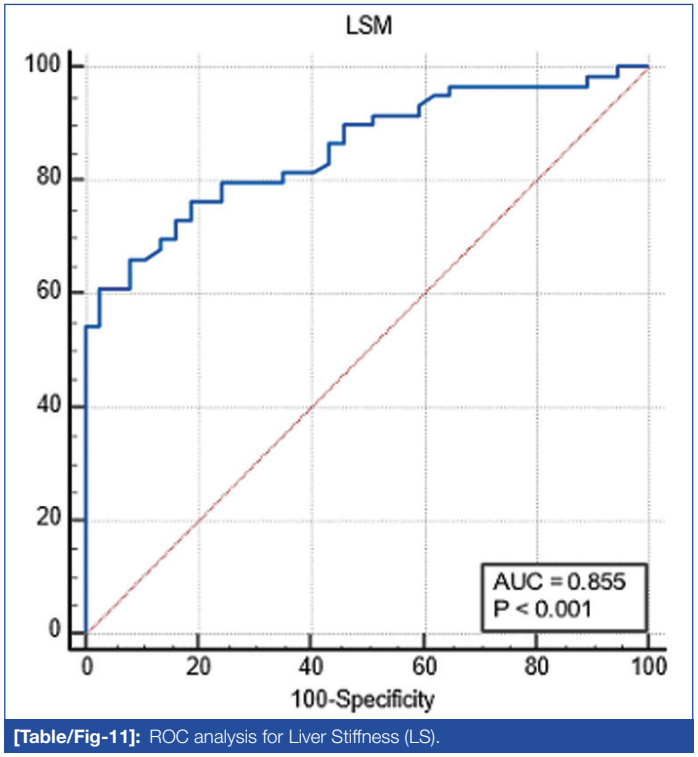


[Table/Fig-9]: Patient with Chronic Liver Disease (CLD).
a. LSM - 22.3 kPa; b. SSM - 30.4 kPa; c. Endoscopy showing grade 3 varices

Using a cut-off value of >15.07 kPa for LSM, the sensitivity was 61.02% [Table/Fig-10]. The Area Under the Curve (AUC) for LSM reached 0.855 [Table/Fig-11], highlighting the robust discriminative ability of SWE in distinguishing between patients with and without EV. The Youden index, a composite measure of sensitivity and specificity, was 0.58, indicating balanced diagnostic accuracy at the chosen cut-off point.

Cut-off Value (kPa)	Sensitivity	Specificity	AUC (Liver Stiffness)	Youden index	Z stat	p-value
>15.07	61.02%	97.03%	0.855	0.58	9.529	<0.0001

[Table/Fig-10]: ROC analysis for Liver Stiffness (LS).

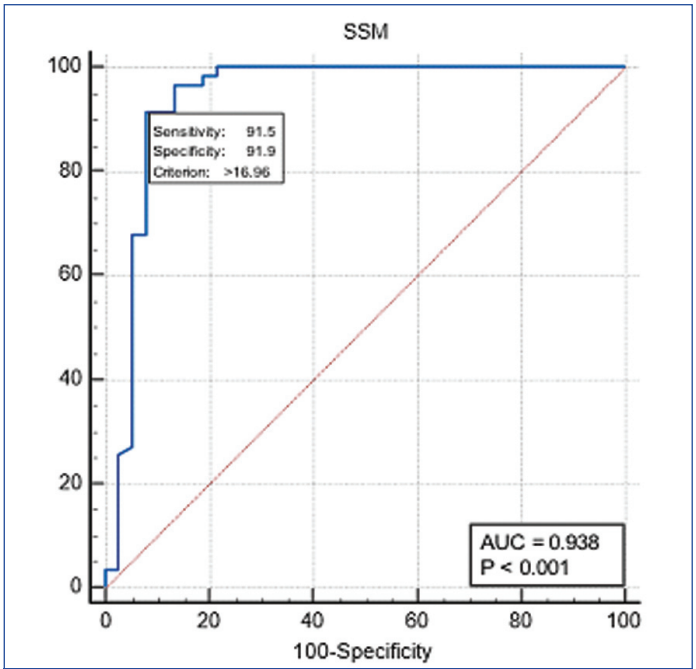


[Table/Fig-11]: ROC analysis for Liver Stiffness (LS).

The ROC analysis for SWE in assessing and grading EV in CLD reveals a critical cut-off value of >16.9 kPa for spleen stiffness. This threshold yielded a sensitivity of 91.5% and specificity of 91.9% [Table/Fig-12]. The AUC for SS was 0.938 [Table/Fig-13].

Cut-off Value (kPa)	Sensitivity	Specificity	AUC (Liver Stiffness)	Youden index	Z stat	p-value
>16.9	91.5%	91.9%	0.938	0.8342	13.04	<0.0001

[Table/Fig-12]: ROC analysis for spleen stiffness.



[Table/Fig-13]: ROC analysis for spleen stiffness.

DISCUSSION

The SWE offers several advantages over traditional invasive methods like EGD. As a non invasive technique [13], SWE reduces patient discomfort, eliminates the risks associated with sedation and endoscopy and can be performed more frequently, facilitating ongoing monitoring. Zaki M et al., [9], study involving 60 patients, demonstrated the high diagnostic accuracy of SWE in detecting varices in cirrhotic patients. Their findings showed significantly higher SWE values in cirrhotic patients compared with controls, with a sensitivity and specificity of 100% at a cut-off value of 13.1 kPa. This suggests that SWE could be a reliable tool for identifying varices in this patient population. In the study by Guo HY et al., all participants underwent TE and 2D SWE on the same day and they concluded that 2D SWE may be more reliable than TE in detecting liver stiffness [13].

Heilani MW et al., showed that in patients with an LSM < 10 kPa, EV or clinically significant portal hypertension can be reliably excluded and that patients with an LSM > 20 kPa are at high-risk of clinically significant portal hypertension and EV [14]. The high prevalence of EV (61.46%) in present study highlights the significant risk faced by patients with CLD, where the development of varices is a common and serious complication. Danish M et al., in a larger study of 204 patients, reported modest results [15]. The liver elastography showed a sensitivity of 44.90% and specificity of 51.90%, with an overall poor diagnostic accuracy of 51.86% in detecting varices in cirrhotic patients. This discrepancy highlights the need for further investigation and standardisation of SWE techniques across different clinical settings. Namikawa S et al., provided valuable insights into the correlation between SWE measurements and both liver fibrosis and EV complication rates [16], though their study did not specify sample size or patient characteristics. The high AUROC of 0.901 for EV prediction suggests that SWE could be a promising tool for assessing the risk of varices in CLD patients. Present study, involving 96 patients, aligns more closely with the findings of Zaki M et al. and Namikawa S et al., [9,16]. The high AUC values for both LSM (0.855) and SSM (0.938), along with the impressive specificity for LSM (97.03%) and the sensitivity and specificity for SSM (91.5% and 91.9%, respectively), indicate that SWE offers robust diagnostic capability for variceal detection and grading.

Future research should also focus on the role of confounding factors and the potential for SWE to replace or complement current invasive diagnostic procedures.

Limitation(s)

Present study had several limitations, including a smaller sample size, a less homogeneous distribution of the various aetiologies of CLD and a lack of age-matched controls.

CONCLUSION(S)

SWE could be a valuable tool in the routine surveillance of EV, enabling healthcare providers to identify patients at high-risk and initiate appropriate prophylactic measures. Furthermore, the implementation of SWE could enhance the overall management of CLD by integrating a reliable, non invasive diagnostic method into standard care protocols. This would support a more proactive approach to patient care, reducing the incidence of acute variceal bleeding events and improving clinical outcomes.

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