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ORIGINAL ARTICLE

Role of 2-D Shear Wave Splenic Elastography in Predicting Esophageal Varices in Patients with Chronic Liver Disease: A Validation Study from North India

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Abstract

Background: The term Chronic Liver Disease (CLD) refers to continuous worsening of liver function over a period of 6 months. Major complication of CLD is portal hypertension (PH), often leading to esophageal varices (EV), which pose a risk of life-threatening gastrointestinal (GI) bleeding. Current guidelines of regular endoscopic screening are resource intensive and inconvenient for these patients. The objectives of this study were to determine the splenic stiffness values in patients of CLD with documented EV using 2D-shear wave elastography (2D-SWE) and to predict the severity of EV in patients of CLD. **Methods:** This cross-sectional study was conduced in a tertiary care hospital in North India. All Patients with CLD and esophageal varices (EV), referred for splenic stiffness measurement, over a period of one year were included in the study. Splenic stiffness was measured using 2D-SWE and its correlation with the severity of EV was analyzed. **Results:** Mean splenic stiffness measurement (SSM) on (2D-SWE) were 22.67, 31.5 and 40.08 kPa in grade I, II and III EV respectively. The mean difference between the splenic stiffness in high grade (Grade II & II) and low-grade (Grade I) EV was 13.1 kPa which was statistically significant ($p<0.05$). On ROC curve analysis, a cutoffvalue of 32 kPa was established for distinguishing high-grade from low-gradeEV, with area under the ROC curve (AUROC) of 0.93, sensitivity of 75%, and specificity of 100%. **Conclusion:** 2-D SWE of spleen is a reliablenon-invasive tool to predict high-grade EV in patients with CLD.

Key Words

Chronic Liver Disease, Portal hypertension, Esophageal varices, Splenic elastography, Endoscopy

Introduction

The term Chronic Liver Disease (CLD) refers to continuous worsening of liver function over a period of 6 months, including production of clotting factors, essential proteins, detoxification of harmful products of metabolism, and biliary excretion.[1] Major complication of CLD is portal hypertension (PH) which occurs as a result of increased intrahepatic vascular resistance due to the dysregulation of liver sinusoidal endothelial cells and hepatic stellate cells.[2]Portal Hypertension (PH) is associated with complications such as gastrointestinal varices, ascites, and hypersplenism.

Esophageal varices (EV) areamajor complication of PH and result in significant morbidity and mortality in these patients, requiring timely identification and

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intervention.[3] Upper Gastrointestinal Endoscopy (UGE) is the accepted gold standard method of identifying EV, howeverits application is limited due to higher cost and invasiveness, thus promoting increasing interest in non-invasive diagnostic techniques. Baveno VII consensus recommendation advocates adoption of non-invasive techniques for diagnosing EV amd limit unnecessary UGE in low-risk patients.[4]

Nowadays, Ultrasound elastography has emerged as a non-invasive diagnostic techniqueto evaluate liver disease and its complications. Elastography is based on the basic principle of physics that the abnormal tissue tends to be stiffer and less elastic than surrounding healthy tissue. There are two main types of elastography: strain elastography (SE) and shear wave elastography (SWE). SWE includes transient elastography (TE), point shear wave elastography (pSWE), and two-dimensional shear wave elastography (2D-SWE). TE, commonly known as FibroScan, is widely used in hepatology and has limitations in patients with ascites or obesity whereas pSWE and 2D-SWEallow for a more comprehensive liver assessment.

As liver stiffness may be influenced by various hepatic changes besides fibrosis, SSM may serve as a more direct indicator of PH than liver stiffness measurement (LSM). SSM has also been proposed as a potential marker for predicting esophageal varices and assessing the risk of bleeding, thus making it a valuable tool for non-invasive evaluation of PH. Recent studies have documented the role of SSM as a promising tool in the non-invasive evaluation of PH severity.[5-9] However, majority of these studies are from western world and limited literature is available from South East Asia, where the prevalence of CLD and PH is very high. The objectives of this study were to determine the splenic stiffness values in patients of CLD with documented EV using 2D-shear wave elastography (2D-SWE) and to predict the severity of EV in patients of CLD.

Material and Methods

Study Design and Setting

This cross-sectional observational study was conducted in the department of Radio-Diagnosis and Imaging and Department of Gastroenterology in a tertiary care institute over a period of one year (July 2023 to August 2024). Ethical clearance was obtained from Institutional Ethical Committee of the institute (No: IEC/GMCJ/2023/1528 dated 21/09/2023). Written informed consent was obtained from each patient before participating in the study.

Inclusion and Exclusion Criteria

All Patients of CLD and documented EV on UGE, referred to the department of Radio-Diagnosis and Imaging, for measurement of splenic stiffness using 2-D SWE over a period of one year were included in the study. Patients with known focal liver or splenic lesions, patients with congestive heart failure, patients with chronic kidney disease, patients with documented portal vein thrombosis, pediatric patients and pregnant women were excluded from the study.

Study Protocol

Registration of the anthropometric data was done for all patients and blood examination results were recorded. Elastography was performed by a single operator using the ESAOTE MYLAB 9 ultrasound machine with a curvilinear probe after at least six hours of fasting. The patient was positioned supine and rested for 10 minutes before the scan to avoid falsely elevated stiffness measurements. A B-mode scan was performed to assess liver size, echogenicity, spleen size, and portal venous system. Splenic elastography was performed using 2-D SWE conducted via the left intercostal approach, with the region of interest placed 2 cm below the splenic capsule. During the examination, patients held their breath for at least 15 seconds during measurement. Ten elastography readings were recorded in each patient, and the mean value was calculated.

Grading of EV was done according to the Baveno VI consensus[10]

Grade I: varices that flatten on insufflation.

Grade II: non-confluent varices protruding into the lumen upon insufflation.

Grade III: confluent varices that do not flatten upon insufflation.

Patients with grade II and III EV are at high risk of bleeding and were considered as high-risk EV.

Statistical Analysis

Data was entered into Microsoft excel and spread sheet made. Percentages were used to express categorical variables whereas mean and standard deviations were used for numerical variables. The mean difference between the SSM in high grade and low-grade EV was assessed using independent t-test. The correlation between splenic stiffness and EV severity was assessed using ROC curve analysis. The area under the receiver operating characteristic (AUROC) curve was used to evaluate the sensitivity and specificity for SSM. A cutoff value for differentiating low-risk and high-risk EV was determined based on AUROC, sensitivity, and

specificity.All statistical analyses were performed using Jamovi version 2.3.28 software.

Results

A total of 107 patients were included in the study based on the defined inclusion and exclusion criteria. Out of these, 7 patients were excluded from final analysis as 2-D SWE could not be adequately performed in these patients due to lack of breath hold or massive ascites. So, a total of 100 patients were available for final analysis.

In the present study, 64 patients were males and 36 were females with male to female ratio of 1.77. Majority of patients were seen in 40-49 years age group (37%) followed by 60-69 years age group (21%). Alcohol abuse was the commonest cause of CLD in our study (53 %) followed by chronic hepatitis (21%) and Non-Alcoholic Steatohepatitis (26%). On UGE, the distribution of EV according to Baveno VI consensus is depicted in Table 1. Grade I varices were seen in 25% patients whereas Grade II and III varices were seen in 33% and 42% patients respectively.

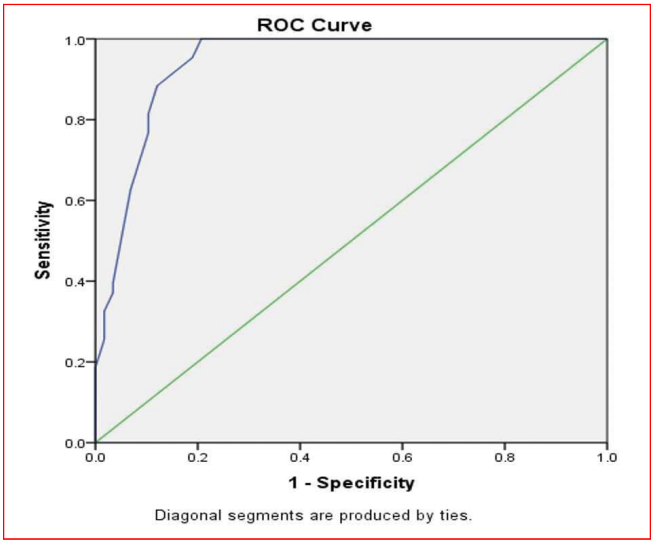

Figure 1: ROC Curve Analysis between Splenic Stiffness and Esophageal Varices Severity.

Table 1: Distribution of Esophageal Varices (EV) according to Baveno VI recommendations.

Grade of EV	Number	Percentage
Grade 1	25	25.0
Grade II	33	33.0
Grade III	42	42.0
Total	100	100.0

Mean SSM in patients in our study was 32.901 ±8.48 kPa. The distribution of SSM in various grades of EV is depicted in Table 2. Mean values of splenic stiffness were 22.67, 31.5 and 40.08 kPa in grade I, II and III EV

Table 2: Splenic Stiffness (kPa) in patients with different Grades of Esophageal Varices EV).

Grade of EV	Splenic Stiffness (kPa)					
	Minimum	Maximum	Mean	Standard deviation	Median	Range
I	17	44	22.67	6.11	20	17-44
II	20	42	31.50	5.02	31	20-42
III	33	46	40.08	3.73	40	33-46

Table 3: Independent t-test between Low Grade and High-Grade Esophageal Varices (EV).

	Severity of varices	N	Mean SSM	Standard Deviation	Standard Error of Mean	p-value
Splenic stiffness (kPa)	Low grade varices	25	22.676	6.110	1.2607	<0.0001
	High grade varices	75	36.309	6.086	0.7020	

Table 4: ROC analysis between Splenic Stiffness and Esophageal Varices Severity.

Cut-off	AUROC	Sensitivity	Specificity	Positive Predictive Value	Negative Predictive Value
32	0.93	75	100	100	75

respectively. Range of splenic stiffness was 17-44 kPa in Grade I varices, 20-42 kPa in Grade II varices and 33-46 kPa in grade III varices respectively. Grade II and III EV were considered high risk varices in our study. The mean difference between the SSM in high grade and low-grade EV was 13.1 kPa and this was statistically significant ($p<0.05$) using independent t-test (Table 3). On ROC analysis between SSM and EV severity, a cut off value of 32 kPa showed maximum AUROC of 0.93 for differentiating high risk and low risk EV, with a sensitivity of 75.8%, specificity of 100%, positive predictive value of 100% and negative predictive value of 75% (Table 4 and Figure 1).

Discussion

Measurement of hepatic and splenic stiffness are becoming useful non-invasive tools in evaluating patients with CLD and PH.[11] Liver stiffness values correlate well with PH and HVPG and it has already been established as a essential diagnostic technique in segregating patients at risk for EV varices and decompensated liver disease.[12-14] Increased portal venous pressure leads to increased liver andsplenic stiffness and any alteration in both liver and splenic stiffness reflects a single pathology. As compared to liver, abnormalities in splenic stiffness are more severe and so mean cutoff values in predicting EV and its grading are notably higher for splenic stiffness than liver stiffness.[15]

EV are porto-systemic collaterals that develop in patents with CLD to bypass high resistance portal flow. Standard guidelines advocate UGE screening in all patients with CLD to identify EV, however UGE requires dedicated technical expertise (performed by a gastroenterologist) and is an invasive procedure. So, a non-invasive alternative modality to screen high risk patients with EV is the need of hour to stratify them for definitive endoscopic management.[15]

2021 Baveno VII Guidelines have formally included SSM in the evaluation of CLD and PH.[11] This has been done with the primary objective to reduce unnecessary UGE in patients with low-risk EV. However, the data determining the optimal cut off values for SSM in patients with EV is very limited, particularly in South Asia and in case of non-viral liver diseases. So, the objectiveof this study was to determine the usefulness of splenic 2D-SWE as anaccurate, simple and non-invasive predictor of EV in patients with CLD.

In our study, significant correlation ($p<0.05$) using independent t-test was observed in the SSM between low-grade and high-grade EV, supporting the evidence that splenic stiffness increases with portal hypertension. The results were similar to previous studies published in the literature.[6-9,11,16,17] On ROC analysis between SSM and EV severity, a cut off value of 32 kPa showed maximum AUROC of 0.93 for differentiating high risk and low risk EV, with specificity and positive predictive value of 100%, sensitivity of 75.8 % and negative predictive value of 75% (Table 4). So, our results demonstrate that SSM of 32 kPa be taken as cut off value in predicting low risk EV and endoscopic screening may be deferred in patients with SSM <32 kPa. The results were similar to study by Muzika C *et al*[11] who observed that splenic stiffness value of 32.8 kPa demonstrated a higher likelihood of EV and values above 40.4 kPa were associated with more advanced grades of EV. Giuffrè M *et al*[18] also reported a similar cutoff value (31 kPa) in predicting EV severity. So according to recent Baveno VII guidelines, SSM can serve asa valuable non-invasive diagnostic tool in risk stratification of PH and avoid unnecessary endoscopies in low-risk patients.

Our study had a few limitations. Liver stiffness measurements (LSM) were not included in the study and only results of SSM were incorporated in our study. LSM is an essential component in non-invasive assessment of PH and combining both LSM with SSM improves the predictive value for grading the severity of EV. Further, sample size in our study was comparatively smaller and this may limit the generalizability of the results. Also, interobserver variability was not assessed in our study as reading were obtained by a single radiologist. So similarprospective studies need to be carried out to validate these findings across multiple centers with diverse etiologies and racial groups.

Conclusion

SSM using splenic elastography is a new and non-invasive tool in predicting EV in patients with CLD. With AUROC of 0.93 and cut off of 32 kPa, splenic elastography demonstrates excellent diagnostic accuracy, helping to optimize patient selection for endoscopic screening. More multi-center prospective studies with larger sample size and varied clinical settings are warranted to validate the effectiveness of SSM in predicting EV.

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