Int. j. adv. multidisc. res. stud. 2025; 5(2):604-608

Received: 25-01-2025
Accepted: 05-03-2025

International Journal of Advanced Multidisciplinary Research and Studies

ISSN: 2583-049X

Assessment of Point Shear Wave Elastography as a Diagnostic Tool in Comparison to Biochemical Indices in patients with Alcohol Associated Acute Pancreatitis

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DOI: https://doi.org/10.62225/2583049X.2025.5.2.3878
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Abstract

Background

The gold standard for assessing liver fibrosis is liver biopsy, which is a painful, invasive technique. Point Shear Wave Elastography (P-SWE) imaging is an advanced and new promising ultrasound based diagnostic method that analyses the wave propagation speed and helps in the assessment of tissue stiffness. Our study is first study from North India wherein we have tried to assess the liver stiffness (P-SWE using Esaote MyLab9 Exp Ultrasound) in patients with alcohol associated acute pancreatitis (AA-AP), and therein tried to evaluate the diagnostic performance of P-SWE against biochemical index (APRI index).

Objective

The objective of this study was to assess the effectiveness of P-SWE as a diagnostic tool, in comparison to biochemical indices in patients with AA-AP.

Material and Method

73 patients with alcohol related acute pancreatitis (cases) and 67 patients with non-alcohol related acute pancreatitis (controls) was recruited in this study. P-SWE was done in all 140 patients and utilized for grading of liver fibrosis.

Observation and Result

Mean P-SWE measurement in cases was 1.68 ± 0.17 m/s, and controls was 1.30 ± 0.14 m/s. Cut off value of 1.4 m/s had sensitivity of 93.2%, specificity of 88.1%, positive predictive value of 89.5%, negative predictive value of 92.2%, diagnostic accuracy of 90.7% and area under ROC curve = 0.911. There was positive correlation between amount of alcohol intake (g/day) and P-SWE (m/s). P-SWE positively correlated [Pearson correlation (r): +0.76] with APRI results in our study.

Conclusion

P-SWE can provide valuable information about liver stiffness in patients with AA-AP and help to predict the stage of liver fibrosis. Ultimately, early diagnosis plays a crucial role in patient management, since there is high chance of regression or reversal of liver fibrosis in early stage. The available cut off values of P-SWE was also validated in this study with high diagnostic performance for significant fibrosis (F2), severe/advanced fibrosis (F3) and cirrhosis (F4).

Keywords: Liver Stiffness, Point Shear Wave Elastography, Fibrosis, Cirrhosis

Introduction

Acute pancreatitis is an inflammatory condition involving the pancreas, in which auto-digestion of pancreas occurs by its digestive enzymes, leading to functional impairment and morphological changes [1]. There are several factors that predispose a person to acute pancreatitis, such as alcoholism, gallstone, exposure to certain drugs, abdominal trauma, cystic fibrosis, sepsis, etc.

Alcohol abuse is commonly related with pancreatitis [2]. The liver and pancreas are closely related developmentally along with structural and functional similarities. Furthermore, the diseases associated with alcohol intake in these organs exhibit striking similarities. The diseases in these organs are related to parenchymal cell destruction, activation of stellate cells, aberrant wound

healing and fibrosis.

Chronic alcohol abuse is an important cause of liver fibrosis, acute pancreatitis as well as chronic liver disease. Hepatic fibrosis is a pathologic condition that shows signs of liver function deterioration during early stage; if ignored, structural deformation and cirrhosis result [3]. The value of a non-invasive test, which can help in picking liver fibrosis in early stage, cannot be overstated. The gold standard is liver biopsy, which is a painful, invasive technique (with a 33% error rate due to sample error and inter-observer variability). Elastography is a newly introduced, non-invasive, quantitative method for assessing liver fibrosis [4, 5, 6, 7, 8, 9, 10].

Non-invasive methods for evaluation of liver fibrosis using ultrasound wave includes transient elastography (TE), P-SWE and 2D-Shear Wave Elastography (2D-SWE). The advantages of ultrasound-based approaches for assessing liver stiffness are that they are non-invasive, well-tolerated by patients, and provide a quick assessment of severity of condition. Currently available high end ultrasound equipment have an integrated Shear wave elastography module.

P-SWE imaging is an advanced and new promising ultrasound based diagnostic method that analyses the wave propagation speed, and helps in assessment of tissue stiffness. By short acoustic radiation forces (less than 1 ms), localized displacements are developed in specific region of interest (without any external compression), and thereby decreasing the operator dependency. The quantitative (wave velocity values measured in m/s or kilopascal) or qualitative (imaging) response can be evaluated from the generated wave, by virtual touch tissue imaging and virtual touch tissue quantification.

AST – platelet ratio index (AST level and platelet count) or APRI index is also used to predict liver fibrosis, which is graded as no fibrosis (F0), mild to moderate fibrosis (F1), significant fibrosis (F2), severe/advanced fibrosis (F3) and cirrhosis (F4). Our study is first study from North India wherein we have tried to assess the liver stiffness (P-SWE using Esaote MyLab9 Exp Ultrasound) in patients with AA-AP, and therein tried to evaluate the diagnostic performance of P-SWE against biochemical index (APRI index).

Material and Method

Patient profile

This diagnostic validation study was conducted in a tertiary care hospital in North India for a duration of 18 months, and after Institutional Ethical Clearance. 140 patients presenting with a history of acute pancreatitis, and aged >18 years were selected for this study. 73 patients with alcohol-related acute pancreatitis (alcohol consumption: >40 g/day, for a cumulative period of more than 5 years); and 67 patients with non-alcohol related acute pancreatitis was recruited in this study. Written informed consent was taken from all patients and the patient's proforma was filled. All patients were evaluated for their demographic profile (age & sex), and clinical symptoms. Patients with liver trauma, gross ascites, established cases of cirrhosis, a known history of chronic liver diseases of various other etiologies (viral hepatitis, autoimmune hepatitis, extrahepatic cholestasis, hepatic venous congestion, and other liver diseases) were excluded from this study.

Technique of P-SWE

We used high-end ultrasound system (Esaote MyLab9 Exp) with curvilinear transducer (3-5 MHz) and P-SWE software, to obtain shear wave velocities. The P-SWE procedure was done as per WFUMB Guideline/Guidance on Liver Multiparametric Ultrasound [11].

Patients were instructed to arrive in a fasting state (6 hours), and P-SWE was done after patient abstained from alcohol for atleast 5 days. They were trained to adopt a resting respiratory position, neither fully inhaling nor exhaling, during elastography examination. P-SWE was performed with patient lying on their back, with the right arm positioned above the head, to facilitate intercostal access. The patients were instructed to hold their breath in neutral position, during each measurement. Prior to elastography, routine grayscale ultrasonography of liver was performed. Then, the mode was switched to elastography. A region of interest (ROI), represented by a 0.5 × 1.0 cm box, was placed perpendicular to centre of the transducer, approximately 1.5-2.0 cm beneath Glisson's capsule, while avoiding major liver vessels and bile ducts. Ten measurements were taken in right lobe of liver, with IQR/M ≤15%. The median SW velocity of measured values was displayed on result screen, (along with IQR/M), and utilized for grading of liver fibrosis (Fig 1).

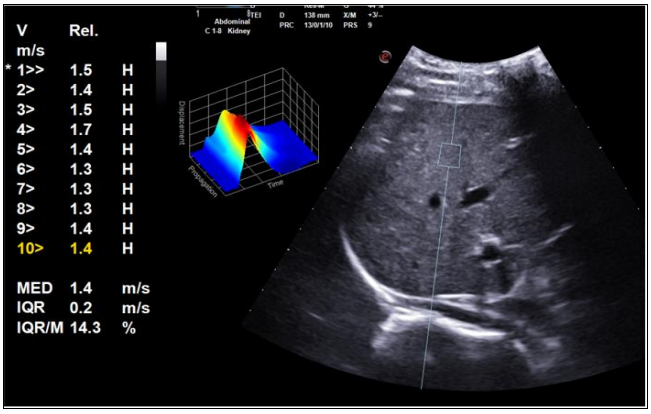

Fig 1: 40-year-old male patient diagnosed with Acute Pancreatitis P-SWE measurement was 1.4 m/s, and IQR/M 14.3%

Biochemical indices

The APRI index was computed using age, liver function test, and platelet count, that were collected on same day when liver P-SWE was done.

Statistical Analysis

All calculations were done using available "Statistical Package for Social Sciences (SPSS) version 24 software". Data was entered in Microsoft Excel spreadsheet. Frequency analysis for categorical variables, descriptive statistics, mean and standard deviation were obtained for all continuous variables. AUROC curve analysis was done to assess the diagnostic performance of each test (P-SWE and APRI index) separately, and results were compared for each test. Kruskal–Wallis test was performed for analysis of normal variance of shear wave velocity, and Pearson correlation coefficient was derived to correlate APRI with P-SWE result.

Observation and Result

140 patients with acute pancreatitis and fulfilling the inclusion criteria were recruited in this study. Out of these, 73 had alcohol related acute pancreatitis (cases) and 66 had non-alcohol related acute pancreatitis (controls). Maximum patients in case group were between age group of 18-40 years, whereas in control group maximum patients were in age group of 41-60 years (Fig 2). The mean age (years) in cases was 41.10 $\pm$ 13.04 and controls was 44.36 $\pm$ 13.49. In case group, 66 patients (90.4%) were male and 7 patients (9.6%) were female. In control group, 38 patients (56.7%) were male and 29 patients (43.3%) were female (Fig 3).

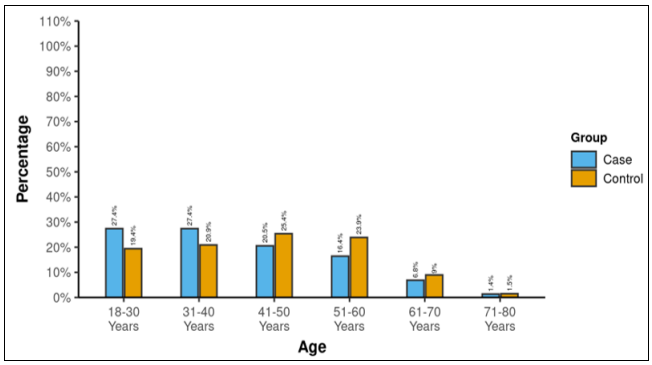

Fig 2: Association between group and age

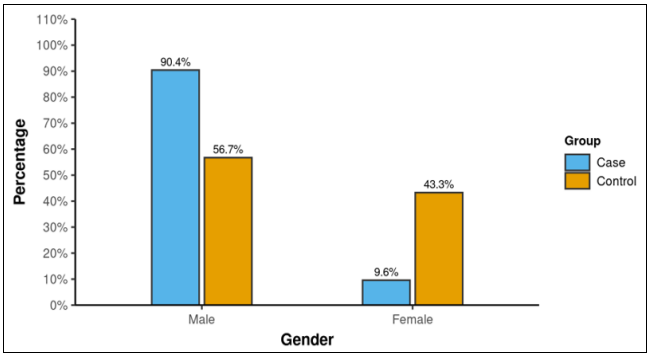

Fig 3: Association between group and gender

In case group, Modified Marshal score was 1 in 3 patients (4.1%), 2 in 28 patients (38.4%) and 3 in 42 patients (57.5%). In control group, Modified Marshal score was 1 in 1 patient (1.5%), 2 in 28 patients (41.8%) and 3 in 38 patients (56.7%). AST/ALT ratio in cases was 1.72 $\pm$ 0.94, and in controls was 1.68 $\pm$ 0.78. APRI index in cases was 1.53 $\pm$ 0.22, and in controls was 0.40 $\pm$ 0.40.

Mean P-SWE measurement in cases was 1.68 $\pm$ 0.17 m/s, and controls was 1.30 $\pm$ 0.14 m/s (Fig 4). In cases, 5 (6.8 %) patients had severe/advanced fibrosis (F = 3), 16 (21.9%) patients had significant fibrosis (F = 2), and 52 (71.2 %) patients had mild to moderate fibrosis (F =1), as shown in Table 1 and Fig 5. In controls, 0 (0 %) patients had severe/advanced fibrosis (F = 3), 2 (3%) patients had significant fibrosis (F = 2) and 65 (97%) patients had mild to moderate liver fibrosis (F =1).

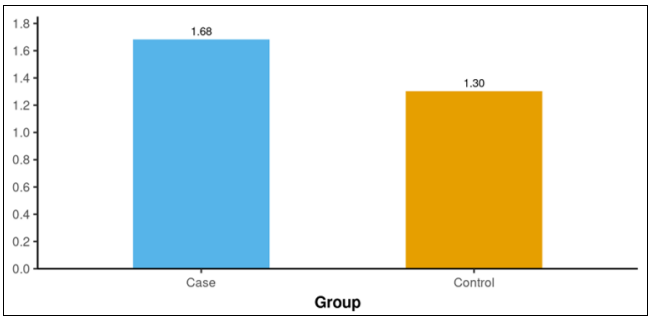

Fig 4: Association between group and P-SWE (m/s)

Table 1: P-SWE measurement in cases and control

P-SWE measurement	Case	Control	Total
< 1.48 m/s (F = 1): Mild to moderate fibrosis	52 (71.2%)	65 (97%)	117 (83.6%)
1.48 – 1.76 m/s (F = 2): Significant fibrosis	16 (21.9%)	2 (3.0%)	18 (12.9%)
>1.76 m/s (F = 3): Severe/advanced fibrosis	5 (6.8%)	0 (0%)	5 (3.6%)
Total	73	67	140

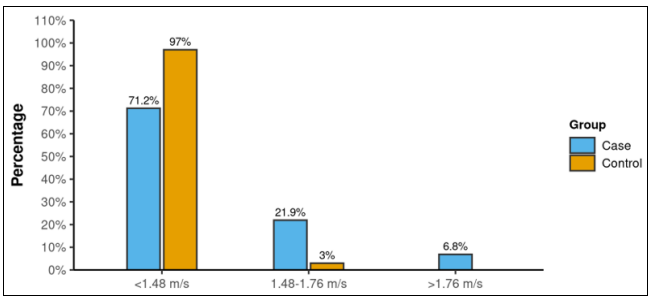

Fig 5: The density plot below depicts the distribution of P-SWE (m/s) in the 2 different groups

ROC curve analysis showing diagnostic performance of P-SWE is shown in Fig 6. Cut off value of 1.4 m/s had sensitivity of 93.2%, specificity of 88.1%, positive predictive value of 89.5%, negative predictive value of 92.2%, diagnostic accuracy of 90.7% and area under ROC curve = 0.911. P-SWE positively correlated [Pearson correlation (r): +0.76] with APRI index in our study. There was positive correlation between the amount of alcohol intake (g/day) and P-SWE as shown in Fig 7.

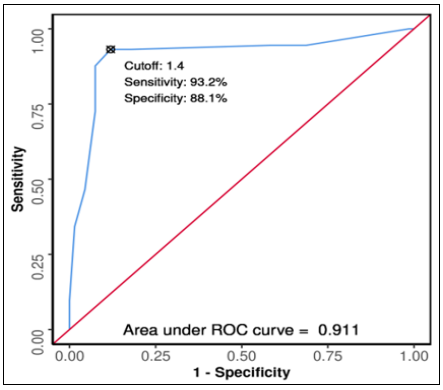

Fig 6: ROC curve analysis showing diagnostic performance of P-SWE (m/s) in predicting group: Case vs control (n=140)

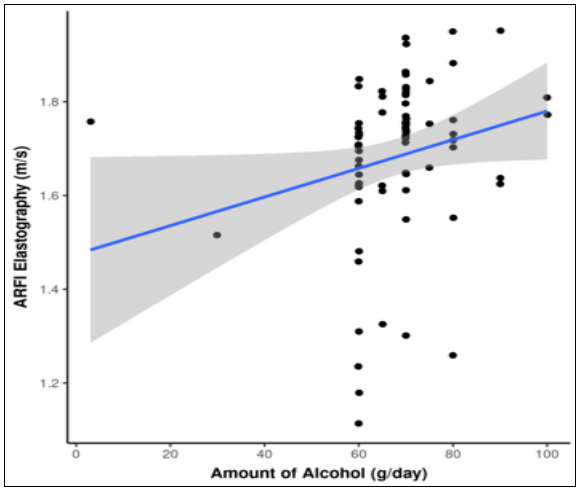

Fig 7: Scatterplot depicting the positive correlation between P-SWE (m/s) and amount of alcohol (g/day) in case group

Discussion

Alcoholism is associated with acute pancreatitis, hepatic steatosis, steato-hepatitis, and steato-fibrosis, ultimately causing cirrhosis [12, 13, 14]. Therefore, assessment of liver fibrosis is very important in patients with AA-AP. Classically, biochemical markers are used, such as ratio of serum aspartate to alanine amino-transferase levels (AST/ALT), to predict the aetiology of underlying liver disease. This ratio is usually less than 1.0 in patients with chronic hepatitis & chronic cholestatic syndrome, and greater than 2.0 in alcoholic liver disease. APRI (AST – platelet ratio) index is also a commonly used biochemical marker to grade and monitor, stage of liver fibrosis. Early diagnosis may prevent progression of steato-fibrosis in alcoholic liver disease, by alcohol abstinence and by lifestyle changes.

The purpose of this study was to assess, a more accurate, simple and non-invasive alternative method of monitoring progression of liver fibrosis in AA-AP. The ability of elastography to stage the liver fibrosis is well established in literature [15, 16, 17, 18]. Currently, transient elastography (TE), P-SWE, and 2D-SWE are three main ultrasound based elastography techniques, which help in direct and indirect quantification of liver stiffness.

In a meta-analysis published in 2013, Bota S *et al*, compared TE and Acoustic radiation force impulse elastography (ARFI elastography) using information from significant research database [15] They concluded that ARFI elastography is a good evaluation method, with higher rate of reliable measurements and similar predictive value to TE, for significant fibrosis and cirrhosis, and that without invasive biopsy.

Alcohol damages the liver at cellular level, and leads to fibrosis. Fibrosis generally advances, and leads to scarring and parenchymal damage. As tissue stiffness increases as a result of liver fibrosis, ARFI imaging results in higher ARFI readings. The second benefit of ARFI imaging is that it does not have the limitations of transient elastography (obesity, limited window for evaluation, ascites).

However, ultrasound systems for elastography are manufactured by different manufacturers, and standard values for Shear wave elastography vary among different ultrasound systems. In P-SWE, small region of interest (0.5 x 1 cm) can be selected, making it easier to choose the parenchymal region devoid of blood vessels and bile ducts.

Losurdo G, *et al* concluded that P-SWE shows Liver Stiffness measurement estimation in agreement with Transient Elastography in most cases, and the best concordance was observed for Hepatitis C and Alcoholic liver disease, and for higher ranges of Liver Stiffness.

In our study, we used the optimal cut off value for significant fibrosis (F2) as 1.48 m/s (AUROC=0.87), for severe/advanced fibrosis (F3) as 1.76 m/s (area under ROC curve = 0.91), as suggested by Friedrich-Rust *et al* [10] When these cut off value were used, we observed that area under ROC curve for significant fibrosis was 0.91 and for severe/advanced fibrosis was 0.85. We have also compared the diagnostic accuracy of P-SWE with APRI index (area under ROC curve = 0.85 for significant fibrosis and area under ROC curve = 0.83 for severe/advanced fibrosis). Therefore, area under ROC curve of P-SWE & diagnostic accuracy of P-SWE with APRI index was slightly higher in significant fibrosis (F2) as compared to severe/advanced fibrosis (F3). Additionally, in our study we also evaluated the severity of acute pancreatitis in relation with duration of alcohol intake, and amount of alcohol intake, and this showed a positive correlation. Our findings are in agreement with study done by Cofaru FA *et al* [8], that evaluated acute pancreatitis with dose and duration of alcohol intake.

P-SWE can be integrated with conventional B mode ultrasound and Doppler. Moreover, this procedure is painless and requires only few extra minutes, with no separate patient preparation. Using a ROI, P-SWE can be assessed for many sample areas as possible, and for as many repetitions as required noninvasively, contrary to invasive liver biopsy. Altered coagulation factors is also not a contraindication for P-SWE.

Conclusion

P-SWE can provide valuable information about liver stiffness in patients with alcohol-related acute pancreatitis and help to predict the stage of liver fibrosis. Ultimately, early diagnosis plays a crucial role in patient management, since there is high chance of regression or reversal of liver fibrosis in early stage.

The available cut off values of P-SWE in AA-AP was also validated in this study with high diagnostic performance for significant fibrosis (F2), and severe/advanced (F3) fibrosis.

Limitations and Future Direction

There are certain limitations in our study.

1. Ours was a single centre study, with limited sample size, which would limit the statistical power of the study. Also, our control group had more female to male ratio, as compared to case group.
2. In our study, liver stiffness was measured using P-SWE in patients with acute pancreatitis, due to various aetiologies, in control group. These varied aetiologies of acute pancreatitis may have variable effect on measurement of liver stiffness by P-SWE.
3. The findings of P-SWE from different ultrasound vendors may vary. It is unclear whether the findings of this study can be applied to other vendor's equipment; therefore, more comparative studies on different vendors' equipment are required.
4. Liver biopsy was not done in all patients in our study as Gold standard.
5. Recent developments have revealed that Magnetic Resonance Elastography (MRE) can produce

encouraging outcome, so it must be compared to P-SWE, and its diagnostic efficacy and practicability must be investigated.

Ethical approval
All procedures performed in the studies involving human participants were in accordance with the Ethical Standards of the Institutional and /or National Research Committee and with the 1964 Helsinki Declaration and its later amendments or comparable Ethical Standards.

Informed consent
Informed consent was obtained from all the individual participants included in this study.

Financial support and sponsorship
None.

Conflicts of interest
None declared.

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