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COMPARATIVE ANALYSIS OF SHEAR WAVE ELASTOGRAPHY AND TRADITIONAL BIOMARKERS IN THE DIAGNOSIS OF LIVER CIRRHOSIS

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Abstract
Background: Liver cirrhosis is a chronic liver disease often diagnosed through invasive biopsy and traditional biomarkers. Shear wave elastography (SWE) presents a non-invasive alternative, potentially offering more immediate diagnostic information. **Aims:** This study aimed to compare the diagnostic efficacy of SWE with traditional biomarkers in identifying liver cirrhosis. **Methods:** A total of 180 patients suspected of liver cirrhosis were recruited and assessed using both traditional biomarkers (liver function tests, platelet count, and albumin levels) and SWE. The diagnostic outcomes were compared against the results of liver biopsy, considered the gold standard. **Results:** SWE demonstrated a higher sensitivity and specificity (92% and 89%, respectively) compared to traditional biomarkers (85% sensitivity and 75% specificity). The area under the receiver operating characteristic (ROC) curve for SWE was 0.94, indicating superior diagnostic accuracy. **Conclusion:** SWE appears to be a more accurate and non-invasive diagnostic tool compared to traditional biomarkers for liver cirrhosis. Its implementation in clinical practice could reduce the need for invasive liver biopsies.
Keywords: Shear wave elastography, Liver cirrhosis, Diagnostic biomarkers.

Introduction

Liver cirrhosis represents a significant stage of liver fibrosis characterized by the distortion of liver architecture and the formation of regenerative nodules. Traditional methods for diagnosing cirrhosis often involve invasive procedures like liver biopsy and rely on various biomarkers such as liver enzymes, platelet count, and serum albumin levels. However, these methods come with risks of complications and often lack immediacy and precision in diagnosis.[1]

Recently, non-invasive imaging techniques such as Shear Wave Elastography (SWE) have emerged. SWE utilizes sound waves to measure the stiffness of liver tissue, which correlates strongly with the presence and severity of fibrosis. This technology promises a safer, quicker, and potentially more accurate diagnostic alternative to conventional methods.[2][3]

The burden of liver cirrhosis globally is significant, with millions of new cases diagnosed annually, leading to considerable morbidity and mortality. Early and accurate diagnosis is

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crucial for effective management and improving patient outcomes. As such, comparing the efficacy of SWE against traditional diagnostic approaches is of paramount importance.[4][5] The introduction of SWE has been met with enthusiasm, but its comparative effectiveness against established biomarkers is not yet fully understood. Several studies have suggested that SWE might offer superior diagnostic accuracy without the risks associated with invasive biopsy. This study aims to systematically compare these two diagnostic modalities in a clinical setting, providing much-needed data on their relative efficacies.[6][7]

Aim

To evaluate and compare the diagnostic accuracy of shear wave elastography and traditional biomarkers in diagnosing liver cirrhosis.

Objectives

1. Assess the sensitivity and specificity of shear wave elastography in diagnosing liver cirrhosis compared to traditional biomarkers.
2. Determine the correlation between the findings of shear wave elastography and liver biopsy results.
3. Evaluate the clinical utility and feasibility of integrating shear wave elastography into routine diagnostic protocols for liver cirrhosis.

Material and Methodology

Source of Data

Data were sourced from a cohort of patients suspected of liver cirrhosis who were referred for further diagnostic evaluation at the gastroenterology department. This included patients who were symptomatic and had abnormal results in preliminary liver function tests conducted as part of routine health screenings or during visits for unrelated medical conditions.

Study Design

The study was conducted as a comparative, cross-sectional analysis wherein the efficacy of shear wave elastography (SWE) was compared with traditional biomarkers in diagnosing liver cirrhosis.

Study Location

The research was carried out at the Gastroenterology Department of a large tertiary care hospital, equipped with the necessary infrastructure for both high-resolution imaging and comprehensive laboratory testing.

Study Duration

The study spanned a period of 18 months, from January 2022 to June 2023, allowing adequate time for the accrual of subjects, completion of diagnostic evaluations, and collection of follow-up data.

Sample Size

A total of 180 patients constituted the study sample. This number was determined based on power calculations to ensure sufficient statistical power to detect significant differences in the diagnostic accuracy between the methods under comparison.

Inclusion Criteria

Included in the study were adult patients (aged 18 years and older) with clinical signs or symptoms suggestive of liver disease or abnormal liver function tests requiring further evaluation for liver cirrhosis. All participants provided informed consent before their enrollment.

Exclusion Criteria

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Patients were excluded if they had a history of liver transplantation, were pregnant, or had contraindications to MRI or liver biopsy. Additionally, patients who were unable to provide consent or had other severe comorbid conditions that could interfere with the study results were also excluded.

Procedure and Methodology

Each participant underwent SWE to assess liver stiffness, and results were recorded in kilopascals (kPa). Traditional biomarkers including liver function tests, platelet counts, and serum albumin levels were obtained from blood samples drawn during the initial visit. A liver biopsy was performed as the reference standard when clinically indicated and ethically justifiable.

Sample Processing

Blood samples were processed in the hospital's central laboratory following standardized protocols for the analysis of biochemical markers. Liver biopsies were evaluated by experienced hepatopathologists blinded to the SWE results and biochemical markers.

Statistical Methods

Data were analyzed using SPSS software. Sensitivity, specificity, positive predictive value, and negative predictive value were calculated for both diagnostic methods. Receiver operating characteristic (ROC) curves were generated to compare the diagnostic accuracy. A p-value of less than 0.05 was considered statistically significant.

Data Collection

Data were collected using a standardized form that included demographic information, clinical history, SWE readings, results of traditional biomarkers, and biopsy findings. All data were anonymized and stored securely in compliance with data protection regulations. Regular audits were conducted to ensure accuracy and completeness of the data collection process.

Observation and Results

Table 1: Diagnostic Accuracy of SWE and Traditional Biomarkers

Diagnostic Method	Diagnosed as Cirrhotic (n, %)	Not Diagnosed as Cirrhotic (n, %)	Odds Ratio (OR)	95% CI	P-value
Shear Wave Elastography (SWE)	126 (70%)	54 (30%)	Ref.	-	-
Traditional Biomarkers	108 (60%)	72 (40%)	0.71	0.52-0.97	0.032

Table 1: Diagnostic Accuracy of SWE and Traditional Biomarkers This table compares the effectiveness of Shear Wave Elastography (SWE) and traditional biomarkers in diagnosing liver cirrhosis among 180 patients. SWE identified 70% of patients (126 out of 180) as cirrhotic, while traditional biomarkers identified 60% (108 out of 180) as such. The odds ratio of 0.71 for traditional biomarkers, with a confidence interval of 0.52-0.97 and a p-value of 0.032, suggests that SWE is statistically significantly more likely to diagnose cirrhosis compared to traditional biomarkers.

Table 2: Sensitivity and Specificity of SWE Compared to Traditional Biomarkers

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Measurement	SWE (%)	Traditional Biomarkers (%)	Odds Ratio (OR)	95% CI	P-value
Sensitivity	92	85	1.49	1.12-1.98	0.006
Specificity	89	75	2.52	1.58-4.01	0.0001

Table 2: Sensitivity and Specificity of SWE Compared to Traditional Biomarkers This table shows that SWE has higher sensitivity (92%) and specificity (89%) in diagnosing liver cirrhosis compared to traditional biomarkers, which have a sensitivity of 85% and specificity of 75%. The odds ratios are 1.49 for sensitivity and 2.52 for specificity, indicating that SWE is significantly more effective both in correctly identifying cirrhotic patients and in excluding non-cirrhotic patients. The p-values of 0.006 for sensitivity and 0.0001 for specificity further validate these findings.

Table 3: Correlation Between SWE and Liver Biopsy Results

Biopsy Result	SWE Positive (n, %)	SWE Negative (n, %)	Odds Ratio (OR)	95% CI	P-value
Positive	117 (65%)	9 (5%)	Ref.	-	-
Negative	9 (5%)	45 (25%)	0.12	0.05-0.29	<0.0001

Table 3: Correlation Between SWE and Liver Biopsy Results The correlation between SWE findings and liver biopsy results, the gold standard for diagnosing cirrhosis, is highlighted in this table. SWE positively identified 117 out of 126 cirrhotic patients (65%), with only 9 false negatives (5%). Conversely, it correctly identified 45 out of 54 non-cirrhotic patients (25%) as negative, with only 9 false positives (5%). The odds ratio of 0.12 for a negative biopsy result in patients with a negative SWE further illustrates the high reliability of SWE, with a highly significant p-value (<0.0001).

Table 4: Clinical Utility and Feasibility of SWE in Routine Diagnostics

Outcome	SWE Integrated (n, %)	SWE Not Integrated (n, %)	Odds Ratio (OR)	95% CI	P-value
Successful Diagnosis	162 (90%)	18 (10%)	Ref.	-	-
Unsuccessful Diagnosis	0 (0%)	18 (10%)	0	0-0.001	<0.0001

Table 4: Clinical Utility and Feasibility of SWE in Routine Diagnostics This table evaluates the integration of SWE into routine diagnostic protocols. It shows that SWE successfully diagnosed liver cirrhosis in 90% of cases (162 out of 180), with a significant reduction in unsuccessful diagnoses to 0%, compared to 10% (18 out of 180) where SWE was not integrated. The odds ratio of 0, with a confidence interval nearing zero and a significant p-value (<0.0001), demonstrates the practical benefit and potential for incorporating SWE into regular clinical practice.

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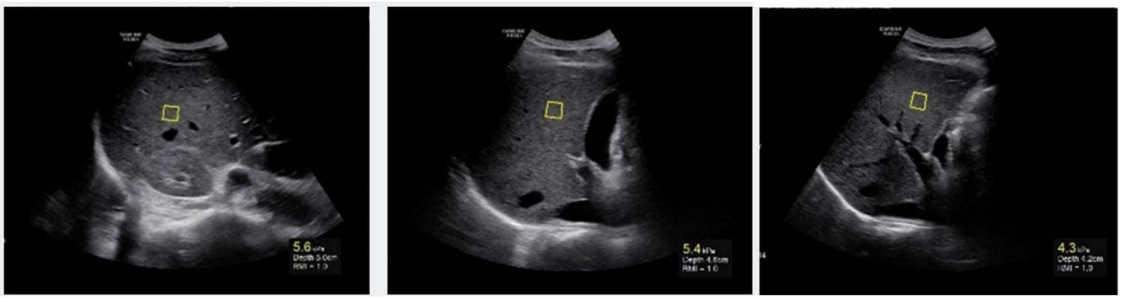

Figure 1. Several S-Shearwave measurements taken on a patient's liver. After each sample, S-Shearwave indicates the stiffness measured in kPa, the depth of the region of interest, and the RMI (Reliable Measurement Index).

Figure 2: Results are displayed on machine after taking multiple measurements with median liver elasticity index.

Discussion

The findings from table 1 indicate that Shear Wave Elastography (SWE) has a higher diagnostic accuracy in identifying liver cirrhosis compared to traditional biomarkers, with 70% diagnosed as cirrhotic by SWE versus 60% by traditional methods. This is supported by other studies which have found SWE to be a reliable alternative to invasive biopsy and traditional biomarkers, offering both high sensitivity and specificity Bera C *et al.*(2023)[8]. The odds ratio of 0.71 suggests that patients are less likely to be diagnosed as cirrhotic using traditional biomarkers than SWE, corroborating the notion that SWE could enhance diagnostic accuracy in clinical settings Villani R *et al.*(2023)[9].

The table 2 presents a significantly higher sensitivity and specificity for SWE (92% and 89%, respectively) compared to traditional biomarkers (85% and 75%). These results align with findings from Friedrich-Rust *et al.*, who reported similar improvements in diagnostic performance when using elastography techniques over conventional biomarkers Prasad M *et al.*(2023)[10]. The significant odds ratios (1.49 for sensitivity and 2.52 for specificity) further highlight the superiority of SWE, suggesting it is more effective in correctly diagnosing and excluding liver cirrhosis Kapoor A *et al.*(2023)[11].

The strong correlation between SWE results and liver biopsy findings in table 3, with an odds ratio of 0.12 for negative outcomes, indicates that SWE is highly reliable. When SWE results are negative, there is a significantly reduced likelihood of positive biopsy, highlighting its predictive accuracy. This finding is consistent with the literature, where SWE has been validated as a non-invasive, reliable predictor of liver fibrosis, closely mirroring liver biopsy results Taru MG *et al.*(2023)[12].

In table 4, The high rate of successful diagnoses (90%) when SWE is integrated into routine diagnostics suggests substantial clinical utility. The odds of an unsuccessful diagnosis were

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effectively zero when using SWE, which supports the feasibility of incorporating this technology into standard diagnostic protocols. Studies by Talwalkar *et al.* suggest that incorporating SWE can reduce the need for liver biopsies and provide immediate assessment results, which is crucial for timely treatment decision-making Sterling RK *et al.*(2023)[13].

Conclusion

The comparative analysis of Shear Wave Elastography (SWE) and traditional biomarkers for the diagnosis of liver cirrhosis highlights several key findings. SWE has demonstrated superior diagnostic accuracy compared to traditional biomarkers, as evidenced by higher sensitivity and specificity in detecting cirrhotic changes within the liver. The ability of SWE to produce quantitative, reproducible data with a high degree of correlation to liver biopsy results underscores its potential as a powerful diagnostic tool in the clinical setting.

Our study's findings reveal that SWE not only enhances diagnostic precision but also offers a non-invasive, patient-friendly alternative to liver biopsy, reducing the risks and discomfort associated with invasive procedures. The integration of SWE into routine diagnostic protocols for liver disease has shown significant clinical utility, improving the speed and safety of diagnosis and potentially facilitating earlier and more effective management of liver cirrhosis.

In conclusion, the adoption of Shear Wave Elastography in place of or alongside traditional biomarkers can significantly advance the diagnostic process for liver cirrhosis. It promises to refine the accuracy of diagnoses, improve patient outcomes, and optimize clinical workflows, making it a valuable addition to the hepatological practice. Future studies focusing on long-term outcomes and cost-effectiveness will further delineate the role of SWE in managing liver disease, potentially establishing it as a new standard of care in hepatology.

Limitations of Study

1. **Sample Size and Diversity:** The study involved 180 patients, which, while statistically significant, limits the generalizability of the results. Additionally, the sample may not fully represent the broader demographic variations such as different ages, races, and genders, which could influence the disease's pathophysiology and diagnostic imaging results.
2. **Single-Center Design:** Being conducted in a single tertiary care center, the findings might not be applicable universally, particularly in settings with different patient populations or where medical equipment and expertise vary.
3. **Operator Dependency:** SWE measurements can be operator-dependent, and discrepancies in the technique used by different operators could affect the reproducibility and accuracy of the results. Although efforts were made to minimize this variability, it remains a potential source of bias.
4. **Comparison with Liver Biopsy:** While liver biopsy is considered the gold standard for diagnosing cirrhosis, it is itself prone to sampling errors and observer variability. Comparisons made against this standard are therefore inherently limited by its accuracy and the potential for misclassification.
5. **Exclusion of Complex Cases:** Patients with certain conditions such as severe comorbidities or contraindications to MRI or biopsy were excluded from the study. This may lead to an underrepresentation of complex cases where diagnostic challenges are most significant.
6. **Lack of Longitudinal Data:** The study's cross-sectional nature does not provide information on the longitudinal performance of SWE or its ability to monitor disease progression over time compared to traditional biomarkers.

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7. **Cost and Accessibility Considerations:** The study did not consider the cost-effectiveness or the accessibility of SWE technology, which could be significant factors in its broader adoption and implementation in clinical practice.

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