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Evaluation of ultrasound elastography for differentiating benign and malignant focal liver lesions: A prospective study

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Abstract
Background: Ultrasound elastography is a non-invasive diagnostic modality that quantifies tissue stiffness, aiding in the characterization of focal liver lesions (FLLs). This study evaluates its efficacy by correlating Elastography parameters with histopathologic findings.
Materials and Methods: This prospective study was conducted at Tagore Medical College, Chennai, over one year. A total of 100 patients aged 20–80 years with FLLs identified by imaging underwent ultrasound elastography using strain elastography and shear wave elastography. Elastographic parameters—stiffness value, stiffness ratio, shear wave velocity (SWV), and strain ratio—were recorded and compared against histopathologic results.
Results: Malignant lesions were predominant in older males (mean age: 62 years), while benign lesions were common in younger patients (mean age: 38 years). Strain ratio emerged as the most reliable diagnostic parameter, achieving 100% sensitivity and specificity at a cutoff of 2.34. Other parameters, including stiffness value (cutoff: 16.51 kPa, sensitivity: 79.54%, specificity: 81.82%) and SWV (cutoff: 1.96 m/s, sensitivity: 82.10%, specificity: 81.81%), also demonstrated strong diagnostic accuracy. Lesion-specific analysis revealed significantly higher stiffness and SWV for metastatic lesions compared to hemangiomas ($P < 0.05$).
Conclusion: Ultrasound elastography is a valuable non-invasive tool for differentiating benign and malignant liver lesions, with strain ratio being the most discriminatory parameter. These findings support elastography's integration into routine diagnostic protocols to enhance clinical decision-making.

Keywords: Ultrasound elastography, focal liver lesions, strain ratio, stiffness value, shear wave velocity, diagnostic accuracy

Introduction

The accurate characterization of focal liver lesions (FLLs) is critical in clinical practice, particularly for guiding appropriate therapeutic strategies and monitoring disease progression. Conventional imaging modalities, including ultrasound (US), computed tomography (CT), and magnetic resonance imaging (MRI), have proven invaluable in identifying and assessing liver lesions; however, they are sometimes limited in their ability to differentiate benign from malignant lesions with high specificity and sensitivity [1].

Ultrasound elastography has emerged as a promising non-invasive imaging technique that provides quantitative assessment of tissue stiffness, offering additional insights into the mechanical properties of liver lesions [2]. This method capitalizes on the principle that malignant tumors often exhibit increased stiffness compared to benign lesions, thereby enabling improved diagnostic accuracy [3].

Strain elastography and shear wave elastography (SWE) are the two main techniques utilized in ultrasound elastography, each with unique advantages. Strain elastography measures relative tissue stiffness based on manual compression, while SWE provides quantitative measurements of stiffness through the propagation of shear waves generated by acoustic radiation force impulses [4]. The integration of these techniques with B-mode ultrasound allows for real-time imaging and non-invasive evaluation, enhancing their clinical applicability [5]. Moreover, studies have demonstrated that elastography is particularly effective when used in conjunction with histopathologic correlation, allowing for precise differentiation of FLLs such as hepatocellular carcinoma (HCC), metastases, and benign entities like hemangiomas [6].

Histo-pathologic correlation remains the gold standard for confirming the diagnosis of FLLs, serving as a benchmark to validate the diagnostic performance of elastography parameters

[7]. Several studies conducted prior to 2017 highlight the significant diagnostic utility of elastography in this context, underscoring its potential to reduce unnecessary biopsies and streamline patient management [8]. This study aims to evaluate the efficacy of ultrasound elastography in assessing the prevalence of focal liver lesions and its correlation with histopathological features.

Materials and Methodology

This prospective study was conducted at the Department of Radio-diagnosis, Tagore Medical College, Chennai, from January 2017 to December 2017, following approval from the Institutional Ethics Committee. Written informed consent was obtained from all participants in accordance with institutional guidelines.

The study followed a prospective design to evaluate the efficacy of ultrasound elastography in characterizing focal liver lesions (FLLs) with histopathologic correlation.

Patients aged between 20 and 80 years, of both sexes, referred for imaging or biopsy with a diagnosis of FLLs on ultrasound, conventional CT, or MRI, were included. The sample consisted of 100 patients selected based on inclusion and exclusion criteria.

Inclusion criteria: Patients aged 20–80 years, irrespective of sex; presence of FLLs detected by ultrasound, CT, or MRI.

Exclusion criteria: Pregnant or lactating women, irrespective of gestational age; patients with previously treated FLLs, gross ascites, or simple hepatic cysts; uncooperative patients or those unable to hold their breath during imaging.

All patients underwent a detailed abdominal ultrasound examination followed by elastography using a Hitachi Aloka Arietta S70 machine with a 3.5 MHz convex probe. Two elastography techniques—Shear Wave Elastography (SWE) and Strain Elastography—were employed.

For SWE, patients were positioned supine with their right arm in maximum abduction. The probe was aligned parallel to the intercostal space to minimize rib shadowing, and stiffness measurements were taken at a depth of 4 cm. Five measurements were obtained for each lesion and averaged. Lesion stiffness (kPa), stiffness ratio, and shear wave velocity (m/s) were recorded for analysis.

For strain elastography, strain values were calculated by applying vertical pressure with the probe, ensuring consistent depth and placement of regions of interest within lesions and adjacent liver parenchyma. Strain ratios were calculated as the strain of the lesion compared to normal liver parenchyma.

Biopsies or surgical specimens were collected for histopathologic analysis. For patients with hemangiomas, imaging modalities served as the confirmatory method. The elastography values were correlated with histopathologic findings to differentiate benign from malignant lesions.

Data were analyzed using SPSS software. Descriptive statistics were used for continuous and categorical variables. A p-value < 0.05 was considered statistically significant.

Results

Out of the 100 patients, benign liver lesions were more common in individuals aged up to 40 years (63%), whereas malignant lesions were predominantly seen in those aged between 60 and 80 years (66%). The mean age of patients with malignant lesions was 62 years, while it was 38 years for benign lesions. The predominance of malignant lesions in older patients aligns with the age-related increase in liver malignancies, likely due to cumulative exposure to risk factors such as chronic liver disease or carcinogens. Conversely, the higher prevalence of benign lesions in younger individuals suggests that these lesions may be incidental findings unrelated to underlying systemic conditions.

Regarding gender distribution, 74% of the participants were males, and 26% were females. Among malignant lesions, 77% of the cases were males, and 23% were females. Benign lesions occurred in 64% males and 36% females. The gender disparity, with a higher proportion of males in both malignant and benign groups, could reflect gender-specific risk factors, such as higher rates of alcohol consumption or viral hepatitis among males.

Table 1: Distribution of focal liver lesions

Type	Malignant	Benign
Metastasis	42%	-
HCC	30%	-
Cholangiocarcinoma	6%	-
Hemangioma	-	18%
FNH	-	4%
Total	78%	22%

Elastography parameters demonstrated significant variations, with malignant lesions showing markedly elevated values compared to benign lesions. The mean stiffness value for malignant lesions was 32.49 ± 17.01 kPa, significantly higher than the 11.04 ± 4.81 kPa observed for benign lesions ($p < 0.01$). Similarly, the mean stiffness ratio for malignant lesions was 3.62 ± 2.84, compared to 1.51 ± 0.64 in benign lesions ($p < 0.01$). Strain ratio, the most discriminatory parameter, achieved a perfect diagnostic performance, with a cutoff of 2.34 yielding 100% sensitivity and specificity. These findings underscore the superior diagnostic potential of strain ratio in distinguishing malignancies.

Table 2: Elastography parameters

Parameter	Malignant (Mean ± SD)	Benign (Mean ± SD)	P-value
Stiffness Value (kPa)	32.49 ± 17.01	11.04 ± 4.81	<0.01
Stiffness Ratio	3.62 ± 2.84	1.51 ± 0.64	<0.01
SWV (m/s)	2.52 ± 0.52	1.55 ± 0.42	<0.01
Strain Ratio	3.41 ± 0.52	1.13 ± 0.44	<0.01

ROC analysis confirmed the diagnostic efficacy of elastography parameters. For instance, a stiffness value cutoff of 16.51 kPa achieved 79.54% sensitivity and 81.82% specificity, while a SWV cutoff of 1.96 m/s demonstrated 82.10% sensitivity and 81.81% specificity. Lesion-specific profiles revealed metastatic lesions with a mean stiffness value of 27.9 kPa and SWV of 2.6 m/s ($p < 0.01$), highlighting their invasiveness. In contrast, hemangiomas had lower stiffness (11.4 kPa) and SWV (1.5 m/s) but were still significantly different from the background liver ($p < 0.05$). These quantitative distinctions emphasize elastography's value in guiding non-invasive, precise diagnostic decisions.

Table 3: Diagnostic performance of elastographic parameters

Parameter	Cutoff Value	Sensitivity (%)	Specificity (%)
Stiffness Value (kPa)	16.51	79.54	81.82
Stiffness Ratio	1.76	66.71	63.63
SWV (m/s)	1.96	82.10	81.81
Strain Ratio	2.34	100.0	100.0

Table 4: Elastographic parameters of lesions

Lesion Type	Stiffness Value (kPa)	SWV (m/s)	P-value
Metastasis	27.9	2.6	<0.01
Hemangioma	11.4	1.5	<0.05
HCC	37.7	2.2	>0.05
Cholangiocarcinoma	38.3	2.5	>0.05
FNH	9.0	2.3	>0.05

Discussion

This study was undertaken to evaluate the diagnostic accuracy of ultrasound elastography in differentiating benign from malignant focal liver lesions (FLLs). Liver lesions often present diagnostic challenges, necessitating a non-invasive, reliable modality for their characterization. Elastography offers a unique approach by quantifying tissue stiffness, a critical factor in distinguishing malignancies. By assessing elastographic parameters such as stiffness value, stiffness ratio, shear wave velocity (SWV), and strain ratio, this study aimed to establish cutoff values to enhance diagnostic precision.

The findings align with previous studies, highlighting elastography's potential. For instance, Ferraioli *et al.* [9] demonstrated that stiffness values were significantly higher in malignant lesions, with a mean stiffness value exceeding 30 kPa, similar to the 32.49 ± 17.01 kPa observed in this study. Likewise, Barr *et al.* [10] reported strain ratio as a highly reliable parameter, with diagnostic performance comparable to the perfect sensitivity and specificity achieved here. The cutoff value of 16.51 kPa for stiffness value, with 79.54% sensitivity and 81.82% specificity, is consistent with earlier research by Friedrich-Rust *et al.* [11], who suggested cutoff values between 15-17 kPa for differentiating liver malignancies.

However, some variations exist. This study reported a mean SWV of 2.52 ± 0.52 m/s for malignant lesions, which is slightly lower than the 2.8 m/s observed in the study by Cosgrove *et al.* [12] This discrepancy could be attributed to differences in population demographics or imaging equipment. Additionally, the strain ratio cutoff of 2.34, with 100% sensitivity and specificity, exceeds the diagnostic performance reported by Bamber *et al.* [13], where specificity was slightly lower.

The lesion-specific profiles also corroborate earlier findings, with metastases showing higher stiffness values than benign lesions. Hemangiomas, while stiffer than the background liver, displayed lower elastographic parameters than malignant lesions, consistent with observations by Piscaglia *et al.* [14] These differences further emphasize the role of elastography in guiding targeted diagnostics and clinical decisions.

Conclusion

This study highlights the diagnostic value of ultrasound elastography in differentiating benign and malignant liver lesions. Strain ratio proved to be the most reliable parameter, achieving 100% sensitivity and specificity, while other parameters like stiffness value and SWV also demonstrated high diagnostic accuracy. Elastography's non-invasive nature and precision underscore its potential to guide clinical management, minimizing invasive procedures. The significant differences in elastographic profiles between lesion types further emphasize its utility in personalized diagnostic strategies.

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Conflicts of Interest

None declared.

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