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Original Research Article

SONOELASTOGRAPHIC STUDY OF FOCAL AND DIFFUSE LIVER DISEASES AND ITS COMPARISON WITH LIVER FNAC/BIOPSY

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ABSTRACT

Background: Chronic liver disease (CLD) and focal liver lesions (FLLs) are major causes of morbidity and mortality worldwide. Liver biopsy is the gold standard for diagnosis but is invasive and limited by sampling errors. Acoustic Radiation Force Impulse (ARFI) elastography offers a non-invasive alternative for assessing liver stiffness and differentiating lesion types. The objective is to evaluate the role of ARFI-based point shear wave elastography (pSWE) in focal and diffuse liver diseases and correlate findings with histopathology.

Materials and Methods: This prospective hospital-based study was conducted from September 2017 to August 2018 in 102 subjects (59 with liver disease, 43 controls). All underwent routine abdominal ultrasound and ARFI elastography using PHILIPS Affinity 70 (C 1–5 MHz probe). Stiffness values were measured in kilopascals (kPa) and compared with FNAC/biopsy results. Diagnostic accuracy was assessed using ROC analysis.

Results: The caudate lobe/right lobe ratio significantly differentiated cirrhosis from controls (AUC=0.990; cutoff=0.65; sensitivity 78.9%, specificity 100%). Liver stiffness significantly differentiated cirrhosis (AUC=0.888; cutoff 8–22 kPa) and haemangiomas (AUC=0.936; cutoff <8 kPa). Malignant lesions (HCC, metastases) had significantly higher stiffness than benign lesions (AUC=0.80; cutoff >22 kPa; sensitivity 82.8%, specificity 80%). Differentiation between HCC and metastases was not statistically significant.

Conclusion: ARFI elastography is a reliable, non-invasive modality for assessing fibrosis in CLD and characterising FLLs, with high accuracy for distinguishing malignant from benign lesions. While histopathology remains definitive, ARFI can reduce biopsy rates, guide management, and aid in early diagnosis.

Keywords: Acoustic Radiation Force Impulse, Elastography, Liver Stiffness, Chronic Liver Disease, Focal Liver Lesions.

INTRODUCTION

Chronic diseases accounts for 46% of global diseases and 59% of mortality, killing about 35 million people annually, according to the WHO.[1,2] Cirrhosis alone has killed 771,000 people worldwide in 2001, ranking 14th and 10th in developed nations.[3] Cirrhosis could be the 12th greatest cause of death by 2020.[4] Chronic liver diseases (CLDs) have different causes but share clinicopathological characteristics; however, their development rate and clinical course vary.[5-7] As one-third of cirrhosis patients are asymptomatic, the prevalence may be underestimated. With non-invasive diagnostic tools like transient elastography, epidemiology is becoming increasingly accurate.[8,9]

HBV, HCV, HIV, excessive alcohol use, hepatotoxic medications, non-alcoholic fatty liver disease, autoimmune hepatitis, and cryptogenic hepatopathy are all causes of CLDs. Fibrosis in CLD is a wound-healing response to repeated liver injury, causing collagen deposition and structural modification.[10,11]

Cirrhosis is the final stage, marked by fibrosis, regenerating nodules, hepatic architecture distortion, and lobar atrophy –hypertrophy complex leads to various clinical symptoms and consequences.

Diagnostic, monitoring and treatment decisions for CLD and focal liver lesions depend on ultrasound. It is used to diagnose lesions, assess liver parenchyma morphology, dysmorphism, portal hypertension, therapy monitoring (e.g., after radiofrequency ablation), and treatment response. Conventional ultrasound does not measure tissue stiffness, even though mechanical qualities vary greatly with disease.[12]

METAVIR scoring (F0–F4) is used to grade liver biopsy histologically, which is the gold standard for fibrosis assessment. However, biopsy has limitations, including sample error due to tissue size, intra- and inter-observer variability in fibrosis grading, and procedural invasiveness with hazards such as post-biopsy haemorrhage.[13-16] Hepatitis C non-invasive biochemical assays are validated, although they often misclassify intermediate fibrosis phases.[17]

Non-invasive ultrasound-based elastography measures tissue elasticity quantitatively or qualitatively.[18] Strain imaging and shear-wave elastography (SWE) are the main approaches for tissue elastic modulus estimation.[19-21] Transient elastography was the first validated liver stiffness assessment tool in CLD patients, correlating well with fibrosis staging.[22] Elastography improves FLL diagnosis and patient treatment by distinguishing benign from malignant lesions.[23]

Advanced SWE methods include ARFI and SSI. These systems generate shear waves using short-duration, high-intensity acoustic pulses instead of mechanical vibration. ARFI uses a single "pushing" beam along with conventional pulse-echo ultrasonography to measure shear-wave propagation at multiple off-axis locations in order to calculate velocity.[22]

New imaging methods like real-time elastography (ES) aim to increase diagnosis accuracy.[24] Real-time ARFI elastography (ElastoPQ) has been used to quantify tissue stiffness in diffuse liver disorders.[25] Assessment of localized and diffuse hepatic disease is radiation-free, cost-effective, and reproducible with this technology.

Given the limitations of liver biopsy and the benefits of elastography, this study examined ARFI ElastoPQ's ability to diagnose liver stiffness in healthy people and CLD patients and distinguish benign from malignant focal liver lesions using histopathology (FNAC/biopsy) as the reference standard. This study will assess elastography's role in focal and diffuse liver disorders and its histological correlate.

MATERIALS AND METHODS

This prospective hospital-based interventional investigation was carried out in the Department of Radiodiagnosis at Gandhi Memorial and Associated Hospital, King George's Medical University, Lucknow, spanning one year, from September 2017 to August 2018. Ethical approval was secured from the Institutional Ethical Committee before initiation. A total of 112 people referred for routine abdominal ultrasonography from outpatient and inpatient treatments were initially included. Ten people were eliminated due to inadequate breath-holding or significant ascites, resulting in 102 participants for analysis. Among these, 43 were healthy controls with no history of liver disease, while 59 were patients diagnosed with either localized or diffuse liver disease.

Patients were eligible if they had a clinical diagnosis or suspicion of localized or diffuse liver disease, regardless of sex, and supplied written informed consent. The exclusion criteria included post-transjugular intrahepatic portosystemic shunt (TIPS) status, acute or chronic pancreatitis, a history of major abdominal surgery, history of liver injury/laceration, gross ascites, previous radiation therapy, chemoembolization, or radiofrequency ablation, cholelithiasis or cholecystitis, cardiac congestion, pregnancy, and fatty liver. Individuals who declined to participate were also omitted.

All subjects underwent abdominal ultrasonography and shear wave elastography using PHILIPS Affinity 70 ultrasound equipment equipped with a C1–5 MHz convex probe. Patients were directed to abstain from food for 4–6 hours prior to the scan. Participants were positioned in the left lateral decubitus posture with the right arm elevated above the head during the evaluation. The Acoustic Radiation Force Impulse (ARFI) ElastoPQ technique, a point shear wave elastography (pSWE) method, was utilised via an intercostal route to evaluate liver stiffness. The target area was delineated using grayscale imaging, confirming a vessel-free zone of liver parenchyma at least 2 cm under the capsule. A designated region of interest (ROI) sized 1.0 × 0.5 cm was utilised. Minimal probe pressure was exerted, and patients were instructed to hold their breath momentarily during each acquisition to reduce motion artifacts. For each lesion, three distinct measurements were taken, and the average shear wave velocity, denoted in kilopascals (kPa), was documented. In diffuse liver disease, parenchymal echotexture was classified as fine, slightly coarse, or severely coarse, while portal vein diameter was evaluated to assess the occurrence of portal hypertension.

Patients with focal or diffuse hepatic lesions underwent ultrasound-guided fine-needle aspiration cytology (FNAC) or biopsy in the interventional radiology department. Specimens were dispatched to the Department of Pathology for histological evaluation, which acted as the reference standard.

Statistical Analysis: Data were analysed utilising SPSS version 21.0 for Windows. Continuous variables were presented as mean ± standard deviation (SD) or median with range, as applicable, whilst categorical variables were represented as

frequencies and percentages. The chi-square test was utilised to compare categorical variables. The Wilcoxon rank-sum test was utilised for nonparametric comparisons. Receiver operating characteristic (ROC) curves were generated for each elastographic parameter, and their diagnostic efficacy was evaluated in comparison to FNAC/biopsy outcomes. A p-value less than 0.05 was deemed statistically significant.

RESULTS

[Table 1] explores the demographic characteristics of patients (n = 59) and controls (n = 43). The average age was marginally greater in the case group (45.10 ± 16.49 years) than in the control group (42.11 ± 14.36 years), although this disparity was not statistically significant (p = 0.339). The gender distribution indicated a greater percentage of males in the control group (61.12%) compared to the cases (50.85%); still, the difference was not statistically significant (p = 0.217).

[Table 2] shows the CL/RL ratio across several illness categories and control groups. The ratio was greatest in cirrhosis absent of portal hypertension (0.81 ± 0.26) and in cirrhosis with portal hypertension (0.76 ± 0.22), indicating the hypertrophy of the caudate lobe observed in chronic liver disease. Benign lesions, including haemangiomas (0.45 ± 0.06), and malignant lesions, such as hepatocellular carcinoma (0.52 ± 0.16) and metastases (0.46 ± 0.06), exhibited lower ratios, approaching control values (0.43 ± 0.06).

[Table 3] shows the mean, maximum, minimum, and median stiffness values (in kPa) obtained using ARFI elastography. The controls exhibited modest stiffness values, with a mean of 6.25 ± 0.98 kPa. In cases of chronic liver disease (CLD), cirrhosis accompanied by portal hypertension had the greatest stiffness (25.41 ± 12.11 kPa), whereas cirrhosis without portal hypertension demonstrated lower stiffness (18.70 ± 9.22 kPa). Benign lesions, exemplified by haemangiomas, exhibited modest stiffness (5.71 ± 1.54 kPa), whereas malignant lesions demonstrated significantly elevated stiffness—HCC (43.86 ± 22.33 kPa) and metastases (44.26 ± 29.08 kPa).

[Table 4] indicates the sensitivity, specificity, positive predictive value (PPV), and negative predictive value (NPV) of stiffness thresholds for various hepatic diseases. For chronic liver disease, stiffness values ranging from 8 to 22 kPa demonstrated a sensitivity of 85% and a specificity of 56.2%. Haemangiomas (<8 kPa) exhibited exceptional diagnostic accuracy, with a sensitivity of 97.7% and a specificity of 80%. Malignant lesions (>22 kPa) had comparable sensitivity (82.8%) and specificity (80.0%). HCC had great specificity (90.0%) but low sensitivity (44.4%), probably because of variability in tumor stiffness.

[Figure 1] shows the ROC analysis of the CL/RL ratio in distinguishing cirrhosis from control subjects. The AUC was 0.990 (95% CI: 0.969–1.011; p < 0.001) with an ideal cutoff of 0.65, resulting in 78.9% sensitivity and 100% specificity. This illustrates the significant diagnostic value of the CL/RL ratio, especially in identifying cirrhosis.

[Figure 2] shows ROC analysis pertaining to hepatic stiffness in chronic liver disease (CLD). The AUC was 0.888 (95% CI: 0.771–1.005; p < 0.001) with an optimum cutoff of 8–22 kPa, yielding 85% sensitivity and 56.2% specificity. Although marginally less precise than the CL/RL ratio, stiffness assessment continues to serve as a robust non-invasive indicator for chronic liver disease (CLD).

[Figure 3] shows ROC analyses for various localized liver lesions. Haemangiomas demonstrated superior discrimination (AUC 0.936; p < 0.001) at a cutoff of <8 kPa. HCC demonstrated moderate diagnostic accuracy (AUC 0.697; p = 0.062) with a cutoff of >28 kPa, whereas metastases exhibited an AUC of 0.749 (p = 0.002) at a cutoff of >22 kPa. When hepatocellular carcinoma (HCC) and metastases were classified as malignant lesions, diagnostic accuracy enhanced (AUC 0.80; p = 0.038) with a threshold of >22 kPa, attaining over 80% sensitivity and specificity.

Table 1: Demographic Characteristics of Study Participants (Cases and Controls)

		Cases (n=59)	Controls (n = 43)	1p-Value
Age (years)	Mean±SD	45.10±16.49	42.11±1436	0.339
Gender	Female (%)	29 (49.15%)	15 (38.88%)	0.217
	Male (%)	30 (50.85%)	28 (61.12%)	

Table 2: Caudate Lobe Width/Right Lobe Width Ratio in Various Liver Conditions and Controls

	n	Mean ±SD	Maximum	Minimum	Median
Cirrhosis with portal hypertension	6	0.76±0.22	1.15	0.54	0.79
Cirrhosis without portal hypertension	10	0.81±0.26	1.37	0.52	0.71
Haemangioma	14	0.45±0.06	0.60	0.38	0.43
HCC	10	0.52±0.16	0.90	0.39	0.48
Metastasis	19	0.46±0.06	0.60	0.38	0.45
Controls		0.43±0.06	0.64	0.30	0.42

Table 3: Liver Stiffness Values (kPa) in Different Liver Conditions Measured by ARFI ElastoPQ

	Mean ±SD (kPa)	Maximum (kPa)	Minimum (kPa)	Median (kPa)
Cirrhosis with portal hypertension	25.41±12.11	43.15	10.81	20.38
Cirrhosis without portal hypertension	18.70±9.22	38.13	5.35	17.81

Haemangioma	5.71±1.54	8.37	3.45	5.98
HCC	43.86±22.33	72.13	13.47	45.75
Metastasis	44.26±29.08	78.54	4.15	39.42
Controls	6.25±0.98	8.10	4.30	6.19

Table 4: Diagnostic Performance of Liver Stiffness Cutoff Values in Various Liver Conditions

	Sensitivity	Specificity	PPV	NPV
CLD	85	56.2	82.9	60.0
Haemangioma	97.7	80.0	93.5	92.3
HCC	44.4	90.0	44.4	90.0
Metastasis	63.2	57.5	41.4	76.7
Malignant	82.8	80.0	80.0	82.8

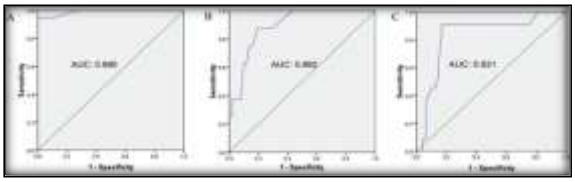

Figure 1: Receiver operating characteristic (ROC) Curve Analysis of Caudate Lobe Width/Right Lobe Width Ratio for Differentiating Cirrhosis and Controls

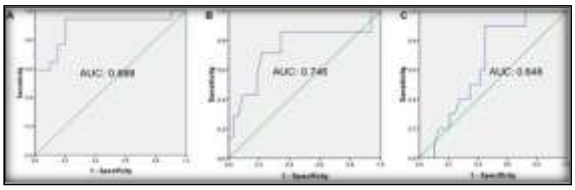

Figure 2: Receiver operating characteristic (ROC) Curve Analysis of Liver Stiffness Values for Chronic Liver Disease and its Subtypes

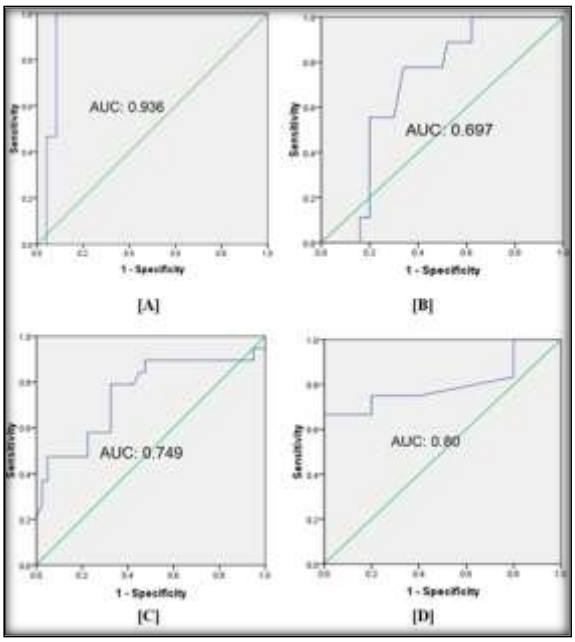

Figure 3: Receiver operating characteristic (ROC) curve analysis of [A] stiffness for Haemangioma, [B] stiffness for HCC, [C] stiffness for Metastasis and [D] stiffness for malignant lesions

DISCUSSION

This study examined the utility of acoustic radiation force impulse (ARFI) elastography in assessing liver fibrosis in chronic liver disease (CLD) and in characterising focal liver lesions (FLLs), utilising histology as the gold standard. The precise evaluation of fibrosis is essential for prognosis and treatment strategies in chronic liver disease, while the dependable distinction between benign and malignant focal liver lesions might avert unwarranted invasive procedures. Liver biopsy, while the gold standard for fibrosis staging and tumor characterisation, is invasive, prone to sample errors, and not always practical in everyday practice.[13-16] In this setting, non-invasive imaging modalities like ARFI present potential alternatives.[18-22]

The study comprised 102 participants (59 with focal/diffuse liver lesions and 43 healthy controls) who underwent ARFI Point Shear Wave Elastography (pSWE) with the PHILIPS Affinity 70 system. The results were associated with fine needle aspiration cytology (FNAC) or biopsy, fulfilling all four objectives of the study.

The relationship between the Caudate Lobe to Right Lobe Width Ratio and cirrhosis is significant.

The caudate lobe/right lobe (C/RL) width ratio strongly distinguished cirrhosis from controls, with an AUC of 0.990 (95% CI: 0.969–1.011, $p<0.001$) at a cutoff of 0.65, resulting in 78.9% sensitivity and 100% specificity. This aligns with an earlier study that established a high C/RL ratio exhibits low sensitivity (43%) but exceptional specificity (100%) in histologically confirmed cirrhosis.[26] Volumetric studies have similarly shown hypertrophy of the caudate lobe and lateral segment with atrophy of the right lobe in cirrhosis, which supports our observations.

Our investigation demonstrated that liver stiffness values effectively distinguished cirrhosis, achieving an AUC of 0.888 (95% CI: 0.771–1.005, $p<0.001$) with an optimum range of 8–22 kPa. An earlier study established a robust association between ARFI values and fibrosis stage (Spearman rho = 0.848, $p < 0.001$), identifying predictive cutoffs for cirrhosis at 1.78 m/s (AUROC 0.951) at a depth of 2–3 cm beneath the capsule.[27] Another study additionally reported an AUROC greater than 0.8 for ARFI in differentiating cirrhosis in chronic hepatitis C.[19] A further report similarly indicated that ARFI had strong concordance with METAVIR grading, achieving a sensitivity and specificity of more than 80% for severe fibrosis ($F\geq2$).[28] Taken together with these reports, our findings lend further support to the use of ARFI as a non-invasive method for staging fibrosis.

Our study revealed that ARFI effectively distinguishes malignant lesions (HCC and metastases) from benign lesions, achieving an AUC of 0.80 (95% CI: 0.635–0.965, p=0.038) and an optimum cutoff of >22 kPa (sensitivity 82.8%, specificity 80.0%). These results coincide with earlier reports indicating considerably greater stiffness in malignant lesions compared to benign ones (p<0.001),[19] with a reported sensitivity and specificity of 68% and 69% for this distinction.[29] Another study observed that malignant lesions exhibited considerably greater stiffness (60.41 kPa) than benign lesions (22.05 kPa), with a threshold of 30.8 kPa resulting in an AUC of 0.74.[30]

We noted an overlap between hepatocellular carcinoma (HCC) and metastases. A similar lack of separation was reported in previous studies, neither of which found a significant difference in stiffness between these two malignant subtypes.[19,31] This overlap highlights that although ARFI is beneficial for distinguishing between benign and malignant conditions, it is less dependable for subclassifying malignant tumors.

In the case of haemangiomas, our threshold of <8 kPa demonstrated significant diagnostic precision (AUC 0.936, sensitivity 97.7%, specificity 80.0%), aligning with earlier findings that reported varying stiffness values in haemangiomas attributable to differing fibrotic septa composition.[32] Another study also observed reduced stiffness in haemangiomas relative to malignant focal liver lesions, underscoring the utility of ARFI as an adjunctive diagnostic instrument.[33]

Metastases exhibited significantly elevated stiffness values (>22 kPa) in contrast to benign lesions (AUC 0.749, p=0.002). An earlier study documented analogous findings employing SWV with a threshold of 2.5 m/s (88% sensitivity, 83% specificity) to distinguish metastatic from non-metastatic nodules.[34] Another report identified ARFI as effective for metastasis detection; however, lesion size and necrosis may influence the readings.[35]

FNAC/biopsy functioned as the reference standard in our research. A robust connection was identified between elastography-derived stiffness and histological diagnosis for both widespread and localized liver lesions, in keeping with earlier reports that likewise found ARFI stiffness to be unaffected by the surrounding parenchymal condition and to correlate strongly with disease.[29,36]

Our findings indicate that ARFI elastography can function as a quick, non-invasive, and reproducible instrument for the preliminary evaluation of fibrosis in chronic liver disease, tracking disease advancement, and assisting in focal liver lesion characterisation. Due to its elevated specificity for haemangiomas and robust efficacy in distinguishing benign from malignant lesions, ARFI can inform the necessity for biopsy, especially in resource-constrained environments.

The main limitations of our study were the relatively small sample size and short study duration (<1 year), which limited long-term prognostic evaluation. Patients with ascites or inability to hold breath were excluded, introducing selection bias. Background liver stiffness in focal lesion cases was not assessed, and inter-observer variability was not evaluated. Lesion depth, necrosis, and technical factors may have influenced ARFI measurements.

CONCLUSION

ARFI-based shear wave elastography is a valuable, non-invasive tool for assessing liver stiffness in both focal and diffuse liver diseases, with good diagnostic accuracy when correlated with histopathology. In chronic liver disease, ARFI reliably differentiated cirrhosis from non-cirrhotic cases, and in focal liver lesions, it demonstrated significant potential in distinguishing malignant from benign lesions, particularly metastatic nodules. While not a substitute for liver biopsy in all cases, ARFI can significantly reduce the need for invasive procedures, guide clinical decision-making, and enable early diagnosis and management.

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