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Diagnostic Accuracy of Shear Wave Elastography to Differentiate Solid Hepatic Lesions in Benign and Malignant Lesions

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Author`s Contribution

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ABSTRACT

Objective: To determine the diagnostic accuracy of shear wave elastography (SWE) to differentiate solid hepatic lesions in benign and malignant lesions using triphasic computed tomography (CT) scan and histopathology as standard methods.

Methodology: This descriptive cross-sectional study was conducted in Radiology Department, Dr Ruth K.M. Pfau Civil Hospital Karachi from March to September 2023. Elastography was performed on 96 patients with at least single solid hepatic lesion >1cm in diameter within depth of <5cm from hepatic capsule. Elastography findings were compared with triphasic CT scan and histopathology. The primary performance outcome of SWE were determined in term of sensitivity, specificity, positive predictive value (PPV), negative predictive value (NPV) and accuracy against triphasic CT scan and histopathology.

Results: Out of 96 patients, 51 (53.1%) were males and 45 (46.9%) were females with a mean age of 50.31±11.29 years (Range: 18-70 years). The mean size and depth of the focal hepatic lesion was 4.3 ± 0.92 cm and 3.5 ± 1.2 cm. Cholangiocarcinoma was the stiffest malignant lesion with mean stiffness of 30.5±8.53kPa while the focal nodular hyperplasia was the stiffest benign lesion with mean stiffness of 13.65 ± 5.36kPa. Overall sensitivity, specificity, PPV, NPP and diagnostic accuracy of SWE in diagnosis of focal hepatic lesions were 93.9%, 83.3%, 92.5%, 86.2% and 90.6% respectively with cutoff value of 14.0 kPa.

Conclusion: SWE found to be a useful and easy non-invasive imaging modality to distinguish between benign and malignant focal hepatic lesions with high sensitivity, specificity and NPV, which aid in reliable exclusion of malignancy.

Keywords: Benign Lesion, Biopsy, Diagnostic Accuracy, Focal Hepatic Lesions, Malignant lesion, Shear Wave Elastography.

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Introduction

Focal hepatic lesions are commonly seen in clinical practice and create a challenge to characterize them.[1] Liver cancer is the 2nd commonest cause of cancer-related mortality in men and 6th cause in female globally.[2] Various imaging modalities are available to characterize the hepatic lesion like ultrasound including Doppler, computed tomography (CT) and Magnetic resonance imaging (MRI). Ultrasound is the base-line imaging modality for evaluation of hepatic lesions due to advantages of real-time imaging, low cost, radiation free and widespread availability.[2,3] Whenever a focal hepatic lesion is identified on ultrasound, then it is considered an indication for other imaging modalities like contrast enhanced CT/MRI but these imaging have certain limitations like CT is costly and has radiation exposure as well as risk of contrast side effect while MRI is radiation free and use safe contrast but it is time consuming, expensive and limited available.[2] Although biopsy of lesion is gold standard to differentiate and diagnose focal hepatic lesion but it also has certain drawbacks like invasive nature, procedural related complications and sampling variability.[3]

Elastography is an emerging imaging modality that assess the tissue stiffness and doesn't require an intravenous

contrast. The basis of elastography depends on alteration of tissue elasticity in pathological conditions like neoplasm or inflammation. Shear wave elastography (SWE) is the latest technique of elastography in which 2-D elastographic map overlaid on a gray-scale anatomic image that provides a quantitative estimate of tissue stiffness which measured in kilopascals (kPa) and displayed as color mapping within the region of interest (ROI).[4] Its role is well documented in diagnosis of malignant lesions of the breast, thyroid and prostate but limited data is available on SWE assessment on focal hepatic lesions.[5] It is a user friendly version, have high spatial resolution and can measure the tissue stiffness automatically with an adequate ROI.[2,5] A number of international studies and reviews have established about SWE as a very useful imaging technique but most of these reported different sensitivity, specificity and accuracy as well as different values of tissue stiffness of focal hepatic lesions either due to variable lesion size, different proportion of benign and malignant lesions in the study population, different cut-off value for malignancy, use of different vendor's SWE equipment or combination of these factors.[1,2,6,7]

There is paucity of literature and local data regarding the use of shear wave elastography for differentiating liver lesions into benign and malignant masses in Pakistani population. In the present study, our purpose is to evaluate the use of SWE in the differentiation of malignant from benign focal hepatic lesions and their characterization using triphasic CT scan and histopathology as reference methods. This would facilitate to reduce the further imaging and decrease the biopsy of benign hepatic lesions.

Methodology

This was a Descriptive Cross-Sectional study conducted in the Radiology Department, Dr. Ruth K.M. Pfau Civil Hospital Karachi from March to September 2023 after the approval from Research Evaluation Unit, CPSP/REU/RAD-2020-183-3090.

Written informed consent for the enrollment in the study was obtained from each patient. The data was collected prospectively and sampling technique was non-probability. Inclusion criteria comprised individuals of any gender aged between 18-70 years exhibiting single or multiple focal hepatic lesions > 1cm in diameter and maximum depth of < 5cm to hepatic capsule on Gray scale ultrasound. Patients with already diagnosed hepatic lesion or history of intervention to hepatic lesion, patients with perihepatic ascites, obese and non-cooperative patients were excluded from the study. Sample size was calculated by taking prevalence of benign lesion 30.7%,[1] expected sensitivity 98.1% and specificity 78.3% of shear wave sono-elastography,[1] desired precision of 10% and confidence interval of 95%. The estimated sample size was 96.

Demographic data including age and gender were calculated. All patients underwent gray-scale ultrasound and shear wave elastography with six-hour fasting using Aixplorer Multiwave Ultrasound System (France) with a curved array transducer of 3.5 MHz by consultant radiologist. Gray-scale ultrasound was performed for evaluation of focal hepatic lesion in term of number, size, margin, echogenicity and distance from hepatic capsule. Then shear wave elastography was performed by keeping built-in region of interest over the targeted hepatic lesion and surrounding normal hepatic parenchyma. The hepatic lesion was analyzed as benign and malignant according to mean elasticity (Emean) value measured in kPa (kiloPascal) with reference of mean elasticity of normal tissues. In case of multiple hepatic lesions, the largest or most accessible lesion was analyzed. Focal liver lesion on SWE will be labelled as malignant with Emean value > 14 kPa and benign with Emean value of ≤ 14 kPa based on lesion stiffness displayed as color map ranging from dark blue (lowest stiffness) to dark red (highest stiffness).1 Triphasic CT scan of abdomen was performed in all patients on Toshiba Activion Scanner (TSX-037A) with scanning parameters of 120KV, 150mA, 1mm collimation and 3mm slice thickness. Following plain scan, images acquisition done in the arterial phase (35 seconds), portovenous phase (70 seconds) and delayed phase (5 minutes). Then biopsy of lesion was performed when inaccuracy was observed in the results of SWE and CT findings. The average time period between SWE and standard methods was 2-3 weeks. SWE diagnosis was compared with findings of contrast enhanced computed tomography (CECT - triphasic protocol) and biopsy report to estimate sensitivity, specificity, PPV, NPPV and accuracy.

A database was developed on SPSS version 26.0. Mean and standard deviation were calculated for age, hepatic lesion size, lesion depth from liver surface and lesion stiffness. Frequency and percentage were calculated for gender, shear wave elastography diagnosis and histopathological diagnosis. The diagnostic accuracy of shear wave elastography was determined in terms of sensitivity, specificity, PPV, NPP and diagnostic

accuracy against triphasic CT scan and biopsy. p-value ≤ 0.05 was considered to be statistically significant.

Results

Ninety-six patients were enrolled to determine the diagnostic accuracy of shear wave elastography in differentiating solid focal hepatic lesions in benign and malignant lesions keeping the triphasic CT scan and histopathology as reference methods. There were 51 (53.1%) males and 45 (46.9%) females with overall mean age of 50.22 ± 6.4 years (Range: 18-70 years). The mean age of 45.2 ± 5.4 years for the benign lesions and 52.5 ± 5.5 years for the malignant lesions. The malignant lesions presented more among the male patients aged 50-60 years. The mean size and depth of the hepatic lesion was 4.3 ± 0.92 cm and 3.5 ± 1.2 cm. (Table I)

Table I: Diagnostic accuracy of SWE in focal hepatic lesions. (n=96)

SWE	Triphasic CT / Histopathology		Total	P-value
	Malignant	Benign		
Malignant (n=67)	62	5	67	< 0.001*
Benign (n=29)	4	25	29	
Total	66	30	96	
Sensitivity	**Specificity**	**PPV**	**NPV**	**Accuracy**
93.9%	83.3%	92.5%	86.2%	90.6%

Chi square test was applied; P-value <0.05 considered as significant.

Table II: Shear Wave Elastography Analysis of Focal Hepatic lesion. (n= 96)

Lesion	Focal Lesion	N	Mean Stiffness Value (kPa)
Benign	Hemangioma	15	9.75 ± 4.8
	Focal nodular hyperplasia	5	13.65 ± 5.36
	Adenoma	2	11.57 ± 5.5
	Focal Fatty Infiltration	3	10.78 ± 3.5
	Focal Fatty Sparing	3	8.1 ± 6.2
	Regenerating Nodule	2	12.01 ± 2.5
Malignant	Hepatocellular Carcinoma	31	16.8 ± 6.2
	Cholangiocarcinoma	9	30.5 ± 8.53
	Metastasis	26	20.1 ± 7.4

Out of 96 patients, 67 (69.8%) patients were diagnosed as malignant lesions while 29 (30.2%) patients as benign lesions by SWE. All patients underwent triphasic CT scan; however, about 55 (56.2%) patients out of 96 underwent biopsy. Sixty-two patients out of 67 (92.5%) who labelled as malignant lesions by SWE were proven malignant while other (7.5%) were came out to be benign. Twenty-five patients out of 29 (86.2%) who were labelled as benign lesion by SWE were came out benign while the rest (13.8%) were found malignant. The sensitivity, specificity, PPV, NPV and accuracy of SWE were 93.9%, 83.3%, 92.5%, 86.2% and 90.6% respectively with cutoff value of 14.0 kPa (Table 1). Mean stiffness of benign and malignant lesion was 10.1 ± 5.12 kPa and 18.3 ± 7.34 kPa. Table II shows the SWE analysis of focal hepatic lesions.

Discussion

Focal hepatic lesions are commonly encountered in clinical and radiological practice. These lesions can sometimes be challenging to characterize, yet early and accurate diagnosis is crucial for appropriate treatment and improved patient outcomes. Shear wave elastography (SWE) is a relatively new imaging technique that provides a convenient and quantitative method to assess tissue stiffness in the evaluation of focal solid hepatic lesions.

In Pakistan, only a few studies have evaluated the diagnostic accuracy of SWE, and the results have been variable. This variability may be attributed to differences in the types of hepatic focal lesions included or the use of different stiffness cut-off values.[2–8]

In our study, we assessed the diagnostic accuracy of SWE in distinguishing between benign and malignant hepatic lesions and in characterizing various types of focal hepatic lesions based on tissue stiffness in a cohort of 96 Pakistani patients. We found SWE to be highly accurate. The mean stiffness values observed were 18.3 ± 7.34 kPa for malignant lesions and 10.1 ± 5.12 kPa for benign lesions. These findings are comparable to those reported by Park et al,[6] Serag et al,[9] and Awadallah et al,[10] who also noted higher stiffness values in malignant hepatic lesions.

However, some studies did not find a significant difference in stiffness between benign and malignant lesions.[11–13] The variability in sensitivity and specificity reported in previous studies on SWE may be due to differences in study populations, sample sizes, SWE equipment used, stiffness cut-off values, or a combination of these factors.[6,7,13]

This study showed that SWE exhibited the sensitivity of 93.9%, specificity of 83.3%, PPV of 92.5% and NPV of 86.2% with overall accuracy of 90.6% at cutoff value of 14.0kPa in differentiating solid hepatic lesions in benign and malignant lesions. These results are comparable with the studies done by Abdel-Latif *et al.*[1] and Shahid *et al.*[2] These results disagree with some studies such as Park *et*

al.[6] who reported the sensitivity and specificity of 82.4% and 70.6% respectively at cut-off value of 30.8kPa, and Gerber *et al.*[7] who reported sensitivity of 79.9%, specificity 62%, PPV 67% and NPV 76% at an optimal cut-off of 20.7kPa. Additionally, among the benign focal hepatic lesions, FNH has significantly higher lesion stiffness on SWE due to vascular malformation, fibrous septations of central scar and tortuous feeding arteries, as explained by Abdel-Latif *et al.*[1] as well as El-Gazzarah *et al.*[13] and this copes with the result of current study (13.65 ± 5.36 kPa).

The current study there were 16 cases of hemangiomas with mean stiffness of 9.75 ± 4.8 kPa. This was close to the result reported by Shahzad *et al.*[8] and Serag *et al.*[9] Guibal *et al.*[14] explained in his study that the tissue stiffness of hemangioma was due to presence of fibrous septa between the blood-filled spaces. The mean stiffness of adenoma was 11.57 ± 5.5kPa which was comparable to the studies done by Keskin *et al.*[15] but higher than Gerber *et al.*[7] and Guibal *et al.*[14] We had 3 cases of focal fatty infiltration with mean stiffness of 10.78 ± 3.5 kPa.

This result was comparable to the study conducted by Serag et al.[9] but was higher than the value reported by Awadallah et al.[10] Ronot et al.[11] also reported similar findings regarding the mean stiffness of diffuse hepatic steatosis, which was 9.6 kPa. Although we found only two studies that included cases of focal fatty sparing, they reported tissue stiffness values of 6.6 ± 0.3 kPa and 11.3 ± 4.3 kPa, respectively.[11],[14] Our result for focal fatty sparing (8.1 ± 6.2 kPa) did not match either of these, indicating a need for further research.

The current study also included two cases of regenerating nodules, which showed a mean stiffness of 12.90 ± 2.5 kPa. However, we did not find any existing studies reporting tissue stiffness values for regenerating nodules, highlighting another area that warrants further investigation.

It is worth mentioning that among the malignant focal hepatic lesions, cholangiocarcinoma was the stiffest lesion reported by Guibal *et al.*[14] The mean stiffness of cholangiocarcinoma was 30.5 ± 8.53 kPa in the current study which closely matches with studies by Shahid *et al.*[2] Shazad *et al.*[8] and Ronot *et al.*[11] who elaborated that elevated stiffness value of cholangiocarcinoma was due to its highest fibrous component. In the current study, the mean stiffness of HCC was 16.8 ± 6.2 which corresponds to the studies,[2,8,14] however it is lower than Awadallah *et al.*[10] and Ronot *et al.*[11] The mean stiffness of hepatocellular carcinoma (16.8 ± 6.2 kPa) was lower than cholangiocarcinoma in the current study which is in agreement to the studies who reported a mean stiffness of HCC as 15.4 ± 7.2 kPa and 14.86 ± 10 kPa respectively.[9,14] Gurber *et al.*[7] and Gad *et al.*[16] enumerated the important role of SWE in malignant lesions was to differentiate between HCC and CCC, as found in current study. According to Shahzad *et al.*[8] and Awadallah *et al.*[10] the stiffness value of metastasis is varied depends on the type of primary tumor, cellular architecture and vascular permeability. This study reported 26 cases of metastasis with mean stiffness of 20.1 ± 7.4kPa which was copping with findings of studies.[2,8,9] unfortunately we didn't further analysis the type of metastasis in the current study.

In our part of the world, contrast-enhanced computed tomography (CECT) and/or biopsy are commonly used for the diagnosis of focal hepatic lesions. However, these methods can be costly and resource-intensive, particularly in healthcare settings that are already resource-constrained. Therefore, through this study, we aimed to highlight the significance of shear wave elastography (SWE) as a supportive, non-invasive tool in the accurate diagnosis of focal hepatic lesions.

Given the limited availability of local data regarding the role of SWE in the diagnosis and characterization of focal hepatic lesions, this study represents a valuable contribution to the existing body of local evidence. A major limitation of our study was that not all focal hepatic lesions were confirmed by histopathological biopsy. Other limitations include the relatively small sample size and the single-center study design. Additionally, certain infective lesions, such as hydatid cysts and liver abscesses, were not represented, and some lesion categories such as hepatic adenomas and regenerative nodules were underrepresented.

Further multicenter studies with larger sample sizes are recommended to validate these findings and better assess the role of SWE in differentiating benign from malignant solid focal hepatic lesions in the local population.

Conclusion

SWE observed to a better, reliable, non-invasive and radiation free imaging modality to differentiate between benign and malignant focal hepatic lesion with high sensitivity, specificity and accuracy due to significant difference of tissue stiffness. Where available, SWE should be used to complement routine ultrasound of liver,

especially in cases where contrast imaging is contraindicated and this will help to reduce unnecessary further imaging as well as intervention especially of benign lesions.

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