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Original Research Article

Role of 2D shear wave elastography in differentiating malignancy from focal liver lesions as compared to multiphasic contrast enhanced computed tomography

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ABSTRACT

Background: Liver cancer is the third most common cause of cancer mortality worldwide. A precise evaluation of benign and malignant liver lesions is very important for the patients. In the present study, we aim to evaluate the use of SWE in the differentiation of malignant from benign focal liver lesions and to determine the SWE characteristics of common liver lesions as compared to multiphasic computed tomography (CT) scan.
Methods: Diagnostic test evaluation observational study where sensitivity, specificity, PPV and NPV of both modalities 2D SWS and multiphase contrast-enhanced-computed tomography (CECT) are compared. 63 patients with focal liver lesions were evaluated by both modalities with HPE as gold standard.
Results: Overall sensitivity, specificity, PPV, NPV and accuracy of multiphasic CECT is 89.74%, 50.00%, 10.28%, 99.39% and 98.71% respectively. Overall sensitivity, specificity, PPV, NPV and accuracy of 2D SWS is 94.59%, 56.25%, 12.13%, 99.39% and 58.55% respectively.
Conclusions: 2D SWS is a useful modality and is capable of evaluating stiffness changes in the liver associated with solid focal liver lesions, which helps in distinguishing benign from malignant lesions and also in their sub-categorization, i.e., differentiating focal nodular hyperplasia from hemangioma and differentiating hepatocellular carcinoma, with high sensitivity and accuracy. Overall performance of both CECT and 2D SWS did not show much difference statistically. However, both modalities complement each other and shortcoming of one modality can be overcome with the help of other thereby leading to better diagnostic evaluation.

Keywords: 2D SWS, Multiphasic CECT, HCC, FNH, Hemangioma, Metastasis

INTRODUCTION

Liver cancer is the third most common cause of cancer mortality worldwide.[1] There are many risks factors predisposing to liver malignancy including most commonly being infection of hepatitis virus, exposure to aflatoxin, alcohol, and cigarette consumption.[2] A precise evaluation of benign and malignant liver lesions is very important for the patients. Liver biopsy has been used to differentiate malignant lesions from the benign ones. Yet, biopsy can lead to several complications, including bleeding, owing to liver dysfunction, challenges in tumour targeting, and tumour seeding.[3] Consequently, certain non-invasive methods are used worldwide in the evaluation of

liver lesions. Imaging techniques, such as ultrasound (US), CT, magnetic resonance imaging (MRI), and enhanced ultrasound (EUS) have been used to detect liver lesions, recent days. Multiphasic CECT is the most commonly used imaging modality to characterize and define extent of disease in liver. Side effects are need to administer iodine contrast and radiation exposure which may be the limiting factor in patients with deranged renal profile. MRI a non-radiation modality can also characterize liver lesions but limitations include long imaging times and motion artifacts. Owing to the technological and clinical limitation of these methods, it is still an unknown problem to develop a method to diagnose liver cancer non-invasively, practically, and easily.[4] Compared with normal surrounding liver tissues, the malignant tissues are generally harder. Utilizing this very property of malignant tissue measuring, tissue elasticity measurement might contribute to the diagnosis of different pathologic changes.[6,7] Elastography, is a non-invasive method, which can reveal this property of a tissue, has been developed as an alternative to liver biopsy. Conventional imaging techniques do not provide information on tissue mechanical properties, although its stiffness may vary considerably. Elastography which is also known as virtual palpation was developed in the 1990s to map tissue stiffness, and replaces the palpation performed by clinicians. Nowadays, it is widely used for diagnostics of different diseases.[7] Elastography gives a new aspect in the diagnostic algorithm of the conventional ultrasound examination, by adding the liver stiffness quantification.[8-11] Tumors, especially malignant ones, are generally stiffer than the normal surrounding tissue. Several elastographic approaches have been developed, such as transient elastography, strain imaging, magnetic resonance elastography (MRE) and SWE.[12-15] The last one includes point shear wave elastography (pSWE) and 2D-SWE. SWE measures the speed of the shear waves generated into the tissue when an external force is applied. It assesses a tissue's inherent tendency to revert to its original shape and size following deformation. Two-dimensional shear-wave elastography technique allows real-time measurements of liver stiffness over a larger region of interest, resulting in a significantly larger sampling volume and in which a color-coded elastogram is obtained.[16-19] SWE generates shear waves at a tissue focal point, where wave velocity estimates tissue stiffness. It delivers an organ's local kilopascal evaluation (kPa). Its key advantages are reproducibility, operator independence, greater spatial resolution, and quantitative stiffness evaluation without human compression artifacts.[20-23] In the last few years, pSWE and 2D SWE have become more popular. It has been initially used to detect not only for lesions of superficial organs, such as the thyroid gland, breast, and prostate gland, but also for staging of liver fibrosis.[24,25] Liver lesions are a common finding in sonography sometimes even on routine abdominal sonography and there is need of non-invasive, non-radiation technique to differentiate benign from malignant lesions. Recently, a series of studies have assessed the accuracy of elastography in the differential diagnosis of benign and malignant liver lesions and compared it to liver biopsy, with sensitivity ranging from 68-95.5% and specificity ranging from 69-92.2%.[26,27] In the present study, our objective is to evaluate the use of SWE in the differentiation of malignant from benign focal liver lesions and to determine the SWE characteristics of common liver lesions which may help to differentiate malignant from benign lesions as compared to multiphasic CT scan.

Aim

The aim of this study is to assess the ability of ultrasound SWE, which is a type of stiffness-based imaging, to differentiate focal liver lesions into malignant or benign as compared to multiphasic CT scan with histopathology (HPE) as gold standard.

Objectives

Primary objectives were to differentiate benign from malignant hepatic lesions on ultrasound elastography as compared to multiphasic CT scan with HPE as gold standard as compared to HPE.

Secondary objectives were to identify various cut-off values on USG elastography in differentiating benign from malignant masses as compared to HPE.

METHODS

Study type

Prospective observational study in a tertiary care teaching hospital (Command Hospital Kolkata). The study was done for a period of 02 years from April 2023-March 2025.

Patients are selected based on inclusion and exclusion criteria as mentioned below.

Inclusion criteria

Feasibility of ultrasound elastography in a focal liver lesion detected using conventional ultrasound and with following characteristics, distance from skin surface to centre of lesion <8 cm, lesion diameter >1 cm, in patient with multiphasic liver CT as part of routine diagnostic evaluation were included in the study.

Exclusion criteria

History of chemotherapy or local treatment, such as trans catheter arterial chemoembolization and ablation, distance of lesion from heart or large vessels <0.5 cm and in patients with confirmed HPE report not available were excluded from the study.

Procedure of study in detail

All studied patients were subjected to the following: 2D Grey-scale ultrasound; Ultrasound elastography using a

semi quantitative technique to compare the stiffness of the lesion to that of the surrounding liver parenchyma. A green signal on the right side of the image is an indicator of adequate tissue sampling. Triphasic MDCT of the liver to further characterize the hepatic lesions; Patient undergoing biopsy as part of diagnostic evaluation and in whom a definite HPE report is available.

Ethical clearance

The study proposal along with other relevant documents would be submitted to the institutional ethical committee for review and approval. The study commenced only after obtaining the approval of Institutional ethical committee the approval is obtained in writing. Written informed consent was taken from all the patients prior to their participation in study. The patient has the right to refuse in participation in study without affecting his clinical management in any form.

Statistical analysis

Sample size formula $n=[z^2 \times p \times (1-p)]/e^2$

Z is the z score (Z for CI of 95% is 1.96), e is the margin of error (for CI of 95% margin of error is taken as 5%), n is the sample size, p is the population proportion (proportion of liver lesions in global population was 15%).

As per the statistical calculation the sample size calculated from the WHO formula is 59.

For statistical analysis data were entered into a Microsoft excel spreadsheet and then analyzed by SPSS (version 27.0; SPSS Inc., Chicago, IL, USA) and GraphPad Prism version 5. Data had been summarized as mean and standard deviation for numerical variables and count and percentages for categorical variables. Two-sample t-tests for a difference in mean involved independent samples or unpaired samples. Paired t-tests were a form of blocking and had greater power than unpaired tests. A chi-squared test ($\chi 2$ test) was any statistical hypothesis test wherein the sampling distribution of the test statistic is a chi-squared distribution when the null hypothesis is true. Without other qualification, 'chi-squared test' often is used as short for Pearson's chi-squared test. Unpaired proportions were compared by Chi-square test or Fischer's exact test, as appropriate. The 2×2 table is also used to determine sensitivity and specificity, PPV and NPV of both tests.

RESULTS

In our study comprising of 63 patients, 10 patients (15.9%) were in the age group of 31-40 years. The 41-50 years age group comprised 9 patients (14.3%). A total of 13 patients (20.6%) belonged to the 51-60 years age group, while the largest proportion was observed in the 61-70 years age group with 21 patients (33.3%). Patients aged more than 70 years accounted for 10 individuals (15.9%). In our study, 18 patients (28.6%) were female, while 45 patients (71.4%) were male.

Table 1: Frequency of focal lesions in the study.

CT scan	N
Abscess	5
Hemangioma	3
Metastasis	15
CLD with HCC	10
CLD with regenerative nodule	1
FNH	2
Giant hemangioma	1
Unifocal HCC in normal liver	18
Multifocal HCC	3
Complex cyst	4
Simple cyst	1
Total	63

Multiphasic CECT could detect lesions in all 63 patients. Based on the imaging criteria 44 lesions were characterized as malignant and 19 lesions as benign. Most commonly characterized lesion is HCC in 31 patients (unifocal HCC in normal background liver in 18 patients, multifocal HCC in 3 patients, HCC in the setting of cirrhotic liver in 10 patients) followed by metastasis in 15 patients. In the benign category the most common being liver abscess in 05 patients followed by complex cyst in 04 patients and hemangioma in 04 patients, FNH in 02 patients, CLD with regenerative nodule in 01 patient and simple cyst in 01 patient (Table 1). Multiphasic CECT mis-diagnosed a total of 09 benign cases as malignant, namely 03 cases of atypical hemangioma as HCC, 02 cases of chronic granulomatous lesions as malignant, 02 cases of FNH as malignant and 02 cases of complex cysts as malignant. Overall sensitivity, specificity, PPV, NPV and accuracy of multiphasic CECT is 89.74%, 50.00%, 10.28%, 99.39% and 98.71% respectively (Table 2 and 3).

Table 2: 2×2 table of CECT in focal liver lesions malignant vs benign.

Negativity	Disease present	Disease absent	Total
Positive	35	9	44
Negative	4	9	13
Total	39	18	57

*Prevalence of disease is 6%.

Table 3: 2×2 table of 2D SWS in focal liver lesions malignant vs benign.

Negativity	Disease present	Disease absent	Total
Positive	35	7	42
Negative	2	9	11
Total	37	16	53

In 2D SWE the lesion characterization into benign and malignant is done on the basis of elastography values with a cut off of 16 kPa (taken from published study done in the past). On the basis of data 2D SWE characterized 37 lesions as malignant (based on values in the range from 17 to 53.8 kPa with median value of 31 kPa) and 26 lesions as benign where values were below 16 Kpa (range 2 to 16 kPa and median value being 7.3 kPa). Based on available HPE diagnosis, 2D SWS misdiagnosed 7 benign lesions as malignant due to high elasticity values (01 hepatic hemangioma, 03 FNH, 01 regenerative nodule and 02 chronic granulomatous etiology). 02 cases of metastasis were missed on 2D SWS and labeled as benign which turned out to be cystic metastasis.

Overall sensitivity, specificity, PPV, NPV and accuracy of 2D SWS is 94.59%, 56.25%, 12.13%, 99.39% and 58.55% respectively (Table 4 and 5).

Table 4: Result of 2×2 tables for CT scan and 2D SWS.

Statistics	CT scan (95% CI) values (%)	2D SWS (95% CI) values (%)
Sensitivity	89.74 (75.78-97.13)	94.59 (81.81-99.34)
Specificity	50 (26.02-73.98)	56.25 (29.88-80.25)
PPV	10.28 (6.66-15.54)	12.13 (7.3-19.47)
NPV	98.71 (96.44-99.54)	99.39 (97.54-99.85)
Positive likelihood ratio	1.79 (1.12-2.88)	2.16 (1.23-3.79)
Negative likelihood ratio	0.21 (0.07-0.58)	0.10 (0.02-0.40)
Accuracy	52.38 (38.73-65.78)	58.55 (41.19-71.92)

*Disease prevalence (6%)

Table 5: Lesion distribution as malignant and benign in various tests.

Pathology	CT scan	2D SWS	Histopathology
Malignant	44	37	28
Benign	19	26	09
Total	63	63	37

In cases of HCC, provided there was liver cirrhosis or chronic HBV without cirrhosis, the guidelines of the American association society of liver disease (AASLD) were followed for the diagnosis in association with Liver imaging reporting and reporting data system version 2018 (LI-RADS v2018) on CT/MRI.[19,20] In all other malignant lesions biopsy was taken for 37 lesions (in 07 focal lesions showed typical imaging features of HCC biopsy was not done) where diagnosis need to be confirmed either because of diagnostic dilemma or tissue sample was warranted to guide chemo/immunotherapy. Out of 37 lesions HCC was detected in 13 lesions, FNH in 03 lesions, regenerative nodule in 02 cases, metastasis was detected in 15 lesions, 02 cases as hemangioma, 02 cases as chronic granulomatous pathology) (Table 6).

Table 6: Lesion elasticity in benign and malignant lesions with background liver as comparative value.

Variables	Malignant lesion, (n=37)	Benign lesion, (n=26)	P value
Focal lesion median	31 (17-53.8)	7.3 (2-16)	<0.001
Background liver median	17 (12.5-25.4)	08 (4.3- 16)	<0.001

The mean lesion elasticity for patients with malignant pathology on histopathological was 31. The mean lesion elasticity for patients with benign histopathological examination was 7.3. This difference was statistically significant (p<0.0001).

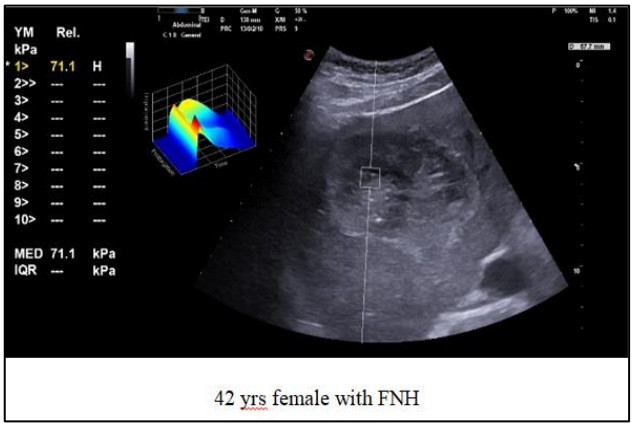

Figure 1: The 42 years old female patient with focal nodular hyperplasia showing elevated elasticity values of 71.1 (this patient underwent liver biopsy and turned out to ne FNH on HPE).

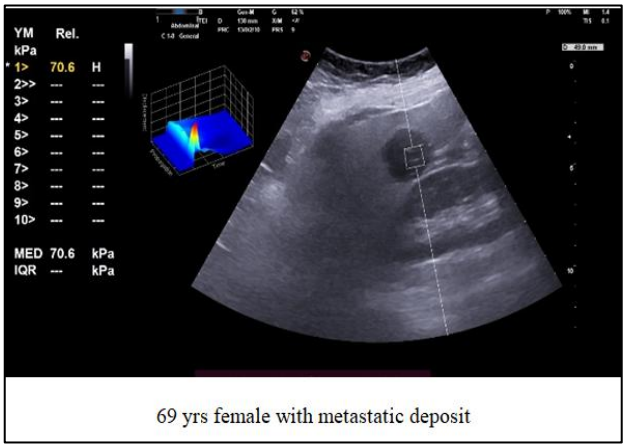

Figure 2: The 69 years old female with metastatic deposit showing elevated elasticity values, 70.6 kPa (it turned out to be deposit from adeno carcinoma of ascending colon on work up).

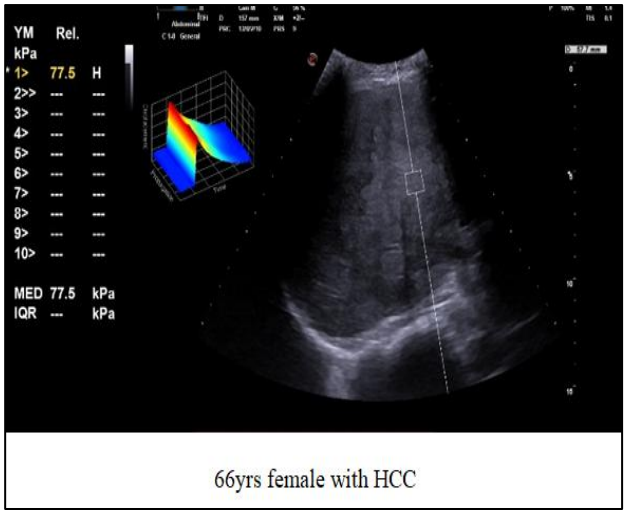

Figure 3: The 66 years old female with HCC and showing elevated elasticity values of 77.5kPa.

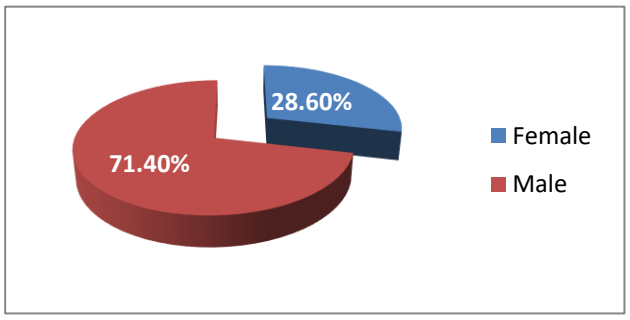

Figure 4: Distribution of male and female population in the study in pie chart form.

DISCUSSION

Hemangioma, focal nodular hyperplasia, hepatic adenoma, localized fatty change, chronic granulomatous lesions, regenerative and dysplastic nodules, lipoma, angiomyolipoma, focal hepatic fibrosis, and hematoma are solid benign FLLs (post-abdominal trauma). Simple cyst, hydatid cyst, liver abscess (pyogenic or amoebic), Caroli's illness, biloma, biliary cystadenoma, and peliosis hepatis are cystic FLLs. FLLs can be primary (from the liver) or secondary (originating elsewhere like metastases and lymphomas). Except for cystic and necrotic metastases, most malignant liver lesions are solid. Colon, stomach, pancreatic, breast, and lung are common metastasis locations. Hepatocellular carcinoma, cholangiocarcinoma, fibrolamellar carcinoma, hepatoblastomas, and angiosarcomas are primary lesions. Gray-scale ultrasonography, colour Doppler, MRI, CT, and PET are utilised to diagnose FLLs. Angiography and percutaneous biopsies are invasive. The widespread use of imaging modalities with an emphasis on non-invasive imaging techniques has increased the detection of incidental FLLs over the last two decades, preventing the unnecessary use of painful biopsy, especially in the diagnosis of benign touch-me-not lesions, reducing the risk of bleeding and anxiety among patients. Liver hemangiomas, the most frequent benign liver tumour, are accurately diagnosed by imaging 7-9. Characterizing liver tumours and distinguishing benign from malignant lesions is crucial for planning treatment. We found that malignant hepatic lesions demonstrated significantly higher mean lesion elasticity values compared with benign lesions ($p<0.0001$). Malignant lesions showed high stiffness, including hepatocellular carcinoma (43±7.49), carcinoma gallbladder with hepatic metastasis (47±7.61), carcinoma rectum with liver metastasis (43.00±1.41), and carcinoma pancreas with hepatic metastasis (38.00±0.00). In contrast, benign lesions had much lower elasticity values, such as simple cyst (2.00±0.00), giant hemangioma (5.00±0.00), atypical hemangioma (4.54±1.81), focal nodular hyperplasia (16.27±3.72), and abscess (6.54±2.25). It is also noted that the malignant lesions showing degeneration/necrotic changes owing to large size or metastasis having mixed appearance showed elastography values lower than the solid lesions with similar malignant pathology. This can be attributable to less densely packed cellular structure and heterogeneous intercellular milieu in the malignant lesions.[28] Of all the benign lesions 2D SWI could not identify FNH and hepatic adenomas from malignant lesions owing to densely packed cellular components thereby increasing elastography values and falsely being labelled as malignant. One more important observation noted in the study is that the background liver elasticity is an important confounding factor in cases where the malignant lesions have borderline raised elasticity. In cirrhotic liver due to generalized increased liver stiffness focal dysplastic nodules may not show differential elevation of elasticity. In such cases multiphasic CECT/MRI holds the key to diagnosis.

In this study, the SWE values of metastases varied widely depending on the primary tumor type; for example, metastases from GIT cancers had lower stiffness (median value=21.5 kPa) than metastases from breast cancer (median value=36.2 kPa). Similar findings were reported by Abdel-Latif et al who found that the stiffness of colorectal metastases (median value=20.11 kPa) was lower than that of breast cancer metastases (median value=28.44 kPa), and Guibal et al who found that the stiffness of carcinoid tumor metastases (mean value=27.8 kPa) was higher than that of metastases from gastro-intestinal tract adenocarcinomas (median value=19.81 kPa).[23,29]

This study has demonstrated that 2D SWS is a useful modality and is capable of evaluating stiffness changes in the liver associated with solid focal liver lesions, which helps in distinguishing benign from malignant lesions and also in their sub-categorization, i.e., differentiating focal nodular hyperplasia from hemangioma and differentiating hepatocellular carcinoma, with high sensitivity and accuracy. Thus, it can be added to routine grey-scale sonographic examinations for rapid, cost-effective, non-invasive, and non-contrast assessments to aid in the diagnosis and further management. It is more useful in

patients with compromised renal function where iodine contrast cannot be used. In the study both multiphasic CECT and USG 2D SWS detected lesions in all 63 patients however the overall sensitivity, specificity, PPV, NPV and accuracy of 2D SWS is 94.59%, 56.25%, 12.13%, 99.39% and 58.55% respectively and of multiphasic CECT is 89.74%, 50.00%, 10.28%, 99.39% and 98.71% respectively. This leads us to the conclusion that the overall performance of both CECT and 2D SWS did not show much difference. However, both modalities complement each other and shortcoming of one modality can be overcome with the help of other thereby leading to better diagnostic evaluation.

Limitations

The study has a small sample size thereby more studies with larger sample size needs to be planned in future for more stronger statistical correlation. Another limitation is attrition of patients during follow up. To better study change in elasticity of malignant lesions post chemotherapy patients should be included.

CONCLUSION

2D SWS is a useful modality and is capable of evaluating focal changes in the stiffness of liver associated with solid focal liver lesions, which helps in distinguishing benign from malignant lesions and also in their sub-categorization, i.e., differentiating focal nodular hyperplasia from hemangioma and differentiating hepatocellular carcinoma, with high sensitivity and accuracy. Overall performance of both CECT and 2D SWS did not show much difference statistically. However, both modalities complement each other and shortcoming of one modality can be overcome with the help of other thereby leading to better diagnostic evaluation. Although the advantage of 2D SWS remains in being non-invasive, non-radiation involving and can be repeated without any risk to the patients.

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Ethical approval: The study was approved by the Institutional Ethics Committee

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