DOI: 10.7860/IJARS/2017/26373:2275

Original Article

Radiology Section

Role of Real Time Elastography Combined with Ultrasound for the Characterisation of Breast Masses

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ABSTRACT

Introduction: Real time elastography is a relatively new imaging technique which acts as a complimentary tool in improving the diagnostic ability of ultrasound for evaluating patients with breast masses. They provide information on tissue stiffness, thereby differentiating benign from malignant lesions and hence avoiding unwanted biopsies on benign lesions.

Aim: To evaluate the role of real time elastography combined with ultrasound for the differentiation of breast masses using histological analysis as a reference standard.

Materials and Methods: The study was done in 116 patients presented to the Department of Radiology with palpable breast masses using GE Health care LOGIQ F8 ultrasound machine. All patients with focal breast mass, who gave consent to all the imaging modalities were included. Ultrasound followed by real time elastography was done and the lesions were given BIRADS score and elastography score. These patients were then subjected to breast biopsy and the results of biopsy were correlated with ultrasound and elastography.

Results: Fibroadenoma was the commonest benign lesion and ductal carcinoma was the commonest malignant lesion in our study. The sensitivity, specificity of real time elastography was 89.03%, 90.7% and sensitivity, specificity of ultrasound combined with elastography was 98.63%, 90.70% in this study.

Conclusion: Ultrasound combined with real time elastography has higher sensitivity and can avoid unnecessary breast biopsies in BIRADS III/IV lesions. Elastography can guide the exact site for biopsies and improve the number of positive breast biopsies.

Keywords: Biopsy, Ductal carcinoma, Fibroadenoma, Histology, Imaging

INTRODUCTION

Mammography and sonography are the important sensitive imaging modalities available in the detection of breast cancer [1]. Ultrasonography is the first imaging modality used in any case of breast mass. Mammography is useful as a diagnostic tool and screening procedure for detection of breast malignancy. Sonoelastography is a relatively new imaging technique which acts as a complementary tool in improving the diagnostic ability of Ultrasound for evaluating the patients with breast masses [2]. Palpation is the standard screening method for detecting breast masses in breast abnormalities [3]. Clinical palpation is based on the principle that cancer tissue is harder than the normal surrounding tissue. However, palpation has poor sensitivity and limited accuracy in terms of different locations of lesions [4]. Hence ultrasound is useful in cases where masses are not palpable. Elastography was discovered as a complimentary tool for ultrasound in understanding the soft tissue elasticity and other characteristics of the lesion [5]. With this technique the lesion is compressed and the tissue strain resulting from the compression is imaged [2]. Elastography with ultrasonography improves the characterization and differentiation of benign and malignant breast lesions [6]. Manual compression of the lesion using an ultrasound probe produces a strain with which the hardness of the tissues are evaluated by assessing the level of strain [7]. Malignant lesions are usually harder than the benign lesions. Approximately 70-90% of benign lesions in breast are subjected to biopsy and this results in unnecessary discomfort, anxiety and cost consumption to the patients. Elastography helps in reducing the rate of unwanted biopsies performed in benign lesions [8,9].

Currently, two methods of elastography are available. They are Strain elastography and Shear Wave elastography. They provide information on tissue stiffness thereby differentiating the benign from malignant lesions, hence avoiding unwanted biopsies on benign lesions [9,10]. Harder tissue recovers at a different speed than softer tissue after compression and the resulting time differences is measured using mathematical algorithm and displayed as a colour coded elastogram [11]. Elastography allows evaluation of soft tissue by elastic

deformation because mechanical properties of the tissues are needed for identification of malignancy, bearing in mind that breast carcinomas are harder than the adjacent tissues. Although, there are innumerable studies available on elastography in the literature, only very few studies are available in which real time elastography and Ultrasound combined with real time elastography were used to characterize breast lesions. It is in this context, this study was performed. In this study we used stress or real time elastography.

MATERIALS AND METHODS

This prospective study was conducted in the Department of Radiology, SRM Medical College and Research Centre, Kattangulathur, Kancheepuram, Tamil Nadu, India, between the period of March 2015 to July 2016 on 116 patients. The study was conducted after getting clearance from institutional ethical committee. Written informed consent was obtained from all patients prior to the study procedure or data collection. All focal breast lesions referred to Radiology Department for ultrasound examinations who gave consent to the imaging modalities were included in this study. In case of multiple breast lesions, only the lesion suspicious for malignancy were included in the study and in cases of multiple benign lesions, largest lesion were included in the study. Post traumatic and post inflammatory breast swellings and patients who did not give consent for undergoing biopsies were excluded from the study. All cases were evaluated initially by gray scale ultrasound using GE Healthcare LOGIQ F8 ultrasound machine and doppler ultrasound to assess the nature and vascularity of the lesion followed by real time elastography. The gray scale characteristics of the lesions which were evaluated include shape, echogenicity, margins, surrounding tissues, whether taller than wider, presence of micro lobulations, micro calcifications, posterior acoustic shadowing and adjacent skin thickening. Color Doppler imaging was done and the vascularity of the lesion assessed. The presence or absence of axillary and intramammary lymph nodes was also assessed. Depending on gray scale and color Doppler, axillary lymph nodal status the lesion was classified according to BIRADS classification.

Elastographic assessment was done using linear 6-12 Mhz ultrasound transducer probe. Interpretation of the lesions were based on the Tsukuba Scoring system. It is a qualitative assessment. The images were displayed in shades of gray. The softer tissue represents light shade of gray. The harder component and the tissue with higher strain in darker shade of gray. The intermediate component represents intermediate shade of gray.

The Qualitative evaluation is based on 5 point scoring system

Score-1: Deformability of the entire lesion, Evenly shaded in lighter shade of gray.

Score-2: Deformability of most of the lesion with some small stiff areas, mosaic pattern of dark and light shade of gray.

Score-3: Deformability of the peripheral portion of the lesion with stiff tissue in the center, lesion with darker shade central part and lighter shade in the periphery.

Score-4: The entire lesion is stiff, Indicate a lesion with darker shade of gray.

Score-5: Entire lesion and surrounding tissue are stiff, Entire lesion in darker shades of gray with central part and periphery.

The score of three and less than three were considered benign and four and more than four were considered malignant.

The lesions are classified as benign and malignant using –

1. Real time elastography alone and;

2. Using combined imaging features of gray scale, Doppler ultrasound and real time elastography.

All focal breast lesions were subjected to image guided Fine Needle Aspiration Cytology (FNAC) or biopsy whichever was feasible. The various breast biopsy techniques used were ultrasound guided FNAC, ultrasound guided biopsy and surgical biopsy. Using image guidance the hardest part of the lesion on elastography was biopsied. The histopathological results were compared with the imaging findings.

RESULTS

A total of 116 patients who presented to the Department of Radiology, SRM Medical College Hospital with symptomatic breast masses were enrolled in the study. The age group range of the patients was from 15-70 years. The youngest patient was 15 years and oldest patient was 70 years [Table/Fig-1]. Maximum number of breast lesions was seen in the age group of 31-50 years accounting for 26% of the total cases. Low incidence of malignancy was encountered in less than 30 years of age. The minimum size of the breast lesions encountered was 5 mm and maximum size was 9.1 cm. Both solid and cystic lesions were included in the study and solid lesions contributed to 84.48% of the total cases and cystic lesions for 15.51% of the total cases.

Out of 116 patients, maximum number of lesions was seen in the right breast accounting for 53.44% and 7.75% of lesions were seen bilaterally. Benign lesions were common in the right breast accounting for 69% of total lesions. Malignant lesions

Age (in years)	Number of Cases	Percentage
15-20	9	7.75%
21-30	25	21.55%
31-40	30	25.86%
41-50	30	25.86%
51-60	10	8.62%
61-70	12	10.3%

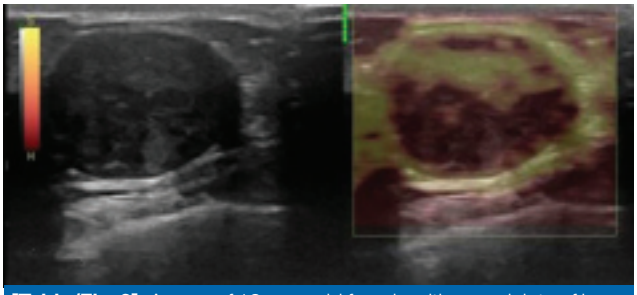
[Table/Fig-1]: Age group distribution of patients.

were common in the left breast accounting for 53.3 % of cases. Out of the 116 cases enrolled in the study, 73 were benign breast lesions and 43 were malignant lesions. Benign lesions accounted for 63% of cases and malignant lesions for 37% of total cases [Table/Fig-2]. Both benign and malignant lesions were commonly seen in upper outer quadrant of right breast, benign lesions accounting for 30.2% and malignant lesions for 31.57% in upper outer quadrant of right breast. Malignant lesions were most commonly encountered in left breast accounting for 55.8% of lesions in left breast and they were mostly seen in upper outer quadrant of left breast accounting for 33.33%. In total number of 116 patients, 90 cases underwent FNAC and 26 cases underwent biopsy.

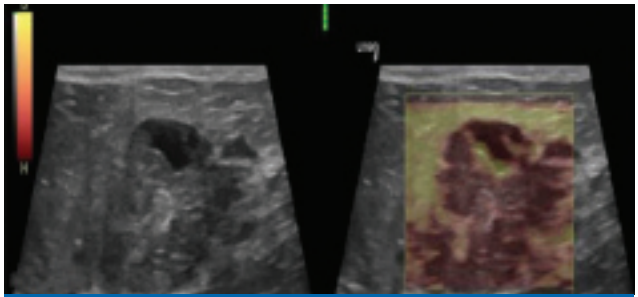
	Number of Cases	Percentage
Benign	73	62.93%
Malignant	43	37.06%

[Table/Fig-2]: Classification of lesions.

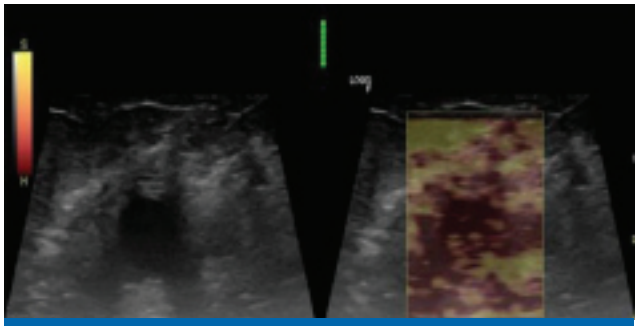
Fibroadenoma was the most common benign breast lesion accounting for 78% of total benign lesions followed by fibrocystic breast diseases accounting for 19% of total benign lesions [Table/Fig-3]. Two cases of intraductal papilloma were also encountered during this study accounting for 2.73% [Table/Fig-4]. Of the malignant lesions, ductal carcinoma was the most common malignant lesion contributing to 54 % of cases followed by infiltrating ductal carcinoma accounting for 21% of total malignant lesions [Table/Fig-5]. Only single



[Table/Fig-3]: A case of 18-year-old female with complaints of lump in right breast. Grey scale ultrasound revealed BIRADS III lesion of right breast. On elastography the lesion has score III. FNAC of the lesion turned out to be fibroadenoma.



[Table/Fig-4]: A 65-year-old female presented with complaints of lump in right breast. Grey scale ultrasonography revealed a BIRADS IV lesion and elasticity score was IV. Biopsy of the lesion turned out to be intraductal papilloma which is benign entity.



[Table/Fig-5]: A 48-year-old female with complaints of lump in right breast. Gray scale ultrasonography of the lesion was BIRADS IV. The elasticity score of the lesion was Score III which was benign. However FNAC turned out to be malignant.

case of Intra cystic papillary neoplasm was seen in this study accounting for 2.32% of malignant lesions. In 116 patients, oval shaped lesions were seen in 73 cases accounting for 62.9%, irregular lesions were seen in 24 cases accounting for 20.7% and round lesions were seen in 19 cases accounting for 16.4%. Oval shaped lesions were most commonly benign lesions accounting for 93.1% and irregular, round shaped lesions were most commonly malignant accounting for 100% cases. Most (53.4%) of the breast lesions were hypoechoiec and malignancy was most commonly seen in lesions with complex echo pattern (90.7%). Out of 116 patients, circumscribed margins were seen in 58 lesions accounting for 50%, indistinct margins in 20 cases accounting for 17.2%, lobulated margins in 20 lesions accounting for 20%, 8 cases with microlobulated margins accounting for 6.9%, spiculated margins in 10 cases accounting for 8.6%. All (100%) lesions with indistinct and spiculated margins were found to be malignant. Most (87.5%) of the lesions with microlobulated margins were malignant. Most of the benign lesions showed circumscribed and lobulated margins accounting for 93.1% and 90%.

Posterior acoustic enhancement were more commonly seen in benign lesions accounting for 66.1% and combined pattern (shadowing and enhancement) were more commonly seen in the malignant lesion accounting for 100%. Internal vascularity was most commonly encountered in malignant lesions. Of 116 cases, 42 cases were vascular and 34 lesions out of 42 with vascularity were found to be malignant. Seventy four lesions did not show any vascularity and out of them, 65 were benign and 9 were malignant. Most (87.8%) benign lesions were not showing any vascularity and minimal internal vascularity were encountered in few lesions. Of 116 patients, no calcifications were seen in 75.9% of cases, micro calcifications were seen in 7.8% of cases, macro calcifications were seen in 15.5% of cases and calcified wall was seen in 0.9% of cases. Malignancy was mostly associated with calcifications (61.11%) and micro calcifications (100%). Most of the benign lesions were not showing any calcifications. Surrounding architectural distortion was seen in 23.3% of total cases and in 100% of

malignant masses.

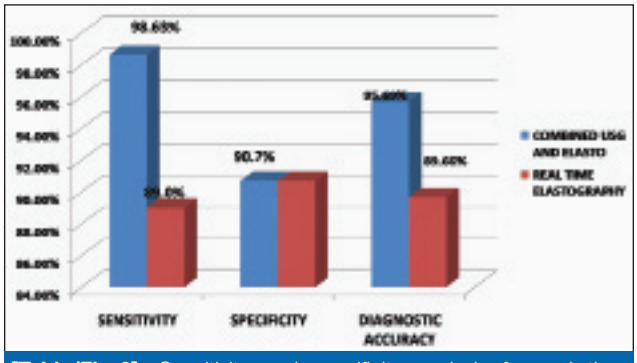
Enlarged axillary lymphnodes were seen in 20 malignant lesions accounting for 94.8%. Most of the benign lesions did not show enlarged axillary lymphnodes accounting for 75.8%. In this study with 116 patients, mammography was done for 40 patients aged above 40 years. Out of 40 patients who underwent mammography, 6 lesions were benign and 34 lesions were malignant. Mammography showed additional findings in the form of scattered micro calcifications in 3 cases and did not show any positive findings in 6 cases of malignant masses diagnosed by ultrasound due to small size of the mass.

Of the 116 patients in which the lesions were characterized using Tsukuba Elasticity scoring, there were 13 cases which showed score II accounting for 11.2%, 52 cases with score III accounting for 44.8%, 36 score IV lesions accounting for 31.0%, 15 score V lesions accounting for 12.9%. In 116 patients, 65 lesions were compressible, 10 lesions were firm and 41 lesions were hard. Benign lesions were compressible and firm and hard lesions were commonly encountered in malignancy.

Overall diagnostic performance of breast elastography to characterize benign and malignant breast lesions from this study was excellent and statistically significant with a p-value of <0.0001. Sixty one of the 75 cases of breast lesions which were compressible on elastography were found to be benign and 35 out of 41 cases which were hard were found to be malignant.

Real time elastography had 4 false positive and 8 false negative cases whereas, combined ultrasound and elastography had 4 false positive and 1 false negative cases.

The sensitivity, specificity, positive, negative predictive value and diagnostic accuracy of real time elastography alone in this study was 89.03%, 90.7%, 94.20%, 82.98% and 89.66% respectively. The sensitivity , specificity, positive, negative predictive value and diagnostic accuracy of real time elastography combined with ultrasound in this study was 98.63%, 90.7%, 94.74%, 97.50% and 95.69% [Table/Fig-6].



[Table/Fig-6]: Sensitivity and specificity analysis for real time elastography and combined ultrasonography with elastography.

Combined ultrasonography and real time ultrasonography technique was more sensitive, equally specific and had more diagnostic accuracy than real time elastography alone.

DISCUSSION

Breast ultrasonography is easy, relatively cheap, non-invasive evaluation of breast with no exposure to radiation risk [1]. It can be easily performed without pain or discomfort to the patients. Breast cancers tend to be harder than normal fibroglandular tissues and breast is readily accessible to compression. Real time elastography is a relatively newer diagnostic method compared to conventional ultrasonography for evaluation of breast pathologies and acts as a complementary tool to gray scale ultrasound in the evaluation of breast masses.

Elastography is one of the imaging technology available to measure tissue stiffness. The common elastographic approach involves stress and strain imaging [12]. In this study we used stress imaging. Several clinical studies demonstrated that sonoelastography was useful for differentiating between benign and malignant breast lesions with 70.1–100% sensitivity and 41.0–98.5% specificity similar to this study [9].

Combined use of gray scale ultrasonography and real time elastography has higher diagnostic accuracy. The literature has cited significant increase in sensitivity from 71.2% to 89.7% when elastography is added to conventional ultrasonography which is similar to this study. The mean age of women with benign lesions in this study was 32.3 and the malignant lesions was 51.4 years which were similar to the study conducted by Dobruch-Sobczak K et al., in which the mean age of women with malignant neoplasms was 55.07 years [12].

In this study with 116 patients, 100% micro calcifications were seen in malignancy. Our results are similar to the study conducted by Hashimoto Y et al., which concluded that presence of microcalcifications on ultrasound, serves as an useful prediction to evaluate the degree of malignancy for patients with invasive breast carcinoma [13].

This study showed very low incidence of breast cancer in young women less than 30 years of age and this is consistent with the study conducted by Ha R et al., which concluded that low incidence of breast cancer in women less than 30 years of age [14].

In this study with 116 patients, 73 lesions were benign and 43 were malignant confirmed by histopathology. In all 68(93.1%) benign lesions were oval in shape and 54(73.9%) of benign lesions had circumscribed margin. This is consistent with the study conducted by Ha R et al., which proved the benign nature of lesions as oval shape, circumscribed margins and parallel orientation [14]. These findings support that Ultrasound features can distinguish benign lesions from malignancy and only follow-up can be performed rather than invasive needle biopsy.

Itoh A et al., used ultrasound elastography to detect breast

lesions and proposed 5 point Tsukuba scoring system. They concluded that breast elastography has higher sensitivity than conventional ultrasonography. The authors concluded that real time elastography achieved a sensitivity, specificity and accuracy of 86.5%, 89.8% and 88.3% [15]. In this study ultrasound elastography had a sensitivity of 89.0%, specificity of 90.7%, and positive predictive value of 94.2% and diagnostic accuracy of 89.7%.

Aly AM et al., in Egypt reported sensitivity of 82%, specificity 90.6%, accuracy of 90% for real time elastography and thus concluded that ultrasound elastography can facilitate improved classification of benign and malignant breast masses [16]. In this study ultrasound elastography had a sensitivity of 89.0%, specificity of 90.7% and accuracy of 89.7% with slightly increased sensitivity when compared to the latter study.

Overall diagnostic performance of breast elastography to characterize benign and malignant breast lesions from this study was excellent and statistically significant with a $p<0.0001$. In this study ultrasound elastography had a sensitivity of 89.0%, specificity of 90.7%, positive predictive value of 94.2%, negative predictive value of 83% and accuracy of 89.7%. Our results were close to the study conducted by Parajuly SS et al., in China [17] with increased sensitivity in this study.

According to Stonian D et al., real time elastography is superior to ultrasonography in the diagnosis of malignant breast masses. They reported real time elastography has a sensitivity of 82.4%, specificity of 81.9%, positive predictive value of 80.3%, negative predictive value of 83.9% and diagnostic accuracy of 82.2% [1]. In this study ultrasound elastography had a sensitivity of 89.0%, specificity of 90.7%, positive predictive value of 94.2% and diagnostic accuracy of 89.7% with improved sensitivity and specificity.

This study concluded that size of the lesion is not predictive of malignancy, risk of malignancy is same regardless of size of the lesions. In ultrasound elastography, size of the lesion did not affect the benign or malignant nature of the lesion. This was similar to the study conducted by Mutala TM et al., which concluded that size of the lesion did not affect the diagnostic performance of the elastography [8].

Multiple studies have shown that ultrasound elastography acts as an additional diagnostic information to characterize breast lesions and it improves the specificity of suspicious lesions detected on gray scale ultrasound.

In this study with 116 patients, 73 lesions were benign. Fibroadenomas were the most common benign lesion accounting for 78.08%. About 14% of fibroadenomas were hard on elastographic assessment and 9.3% of cystic malignancies were soft on elastographic assessment. Thus, concluding that elastography has poor specificity in detecting malignancy in cystic lesions. This is consistent with study conducted by Fleury Ede F et al., describing the complex appearance of fibroadenoma in elastography, which exhibits a variable presentation of both soft and hard on elastographic assessment. They concluded that fibroadenomas (hypocellular with collagen) appear softer, whereas, complex and hypercellular fibroadenomas were harder [18].

Addition of elastographic findings to BIRADS lexicon acts as an additional tool to improve the sensitivity, specificity, negative predictive value and diagnostic accuracy in characterization of breast masses.

In this study with 116 patients, of 73 benign and 43 malignant lesions confirmed by histopathology, with the combined use of ultrasonography and elastography, sensitivity specificity, negative predictive value, positive predictive value and diagnostic accuracy were improved compared when real time elastography alone in characterization of breast masses. In this study the sensitivity, Specificity, positive predictive value, negative predictive value and diagnostic accuracy of combined ultrasound and elastography was 98.6%, 90.7%, 94.74%, 97.50% and 95.69%. These results were similar to study conducted by Fluery Ede F et al., which concluded that addition of elastographic findings to the BIRADS lexicon improve the diagnostic efficacy of ultrasound in characterization of breast masses with sensitivity of 95.90%, specificity of 80.65% and diagnostic accuracy of 91.38% [19].

Mutala TM et al., conducted a study to evaluate the diagnostic accuracy of qualitative and semiquantitative strain elastography in breast lesions in 112 patients . They reported combined ultrasound with elastography has a sensitivity of 86%, specificity of 96%, positive predictive value of 89% and negative predictive value of 96% [8]. In this the sensitivity, specificity, positive predictive value, negative predictive value and diagnostic accuracy of combined ultrasound and elastography was 98.6%,90.7%,94.74%,97.50% and 95.69%.

When we combined the ultrasound and elastography together, the results are best for the detection of breast malignancy. The negative predictive value was higher 97.50% when we combined the modalities together. This combination reflects the morphological features and properties of the lesions and they reflect whether the lesion is benign or malignant. This combination did not affect the positive predictive value which is only slightly higher than the ultrasound elastography. This combination was the optimal diagnostic modality.

LIMITATIONS

Strain ratio was not calculated in this study which would have still improved the sensitivity and specificity of elastography. Elastography is influenced by the extent of tissue compression. Strong pressure can lead to misdiagnosis, hence light pressure should be maintained for tissue diagnosis. Large malignant lesions can cause necrosis, hemorrhage or sarcomatous components which can affect the elasticity score. These are

the few of the limitations of elastography encountered in this study.

CONCLUSION

Elastography is the most crucial supplementary tool for B-mode ultrasound. Elastography can aid in guiding the exact site for biopsies and can improve the number of positive breast biopsies. False negatives may occur in soft breast cancers (mucinous carcinoma, carcinoma with an inflammatory stroma etc.,) and false positives may be seen with poorly deformable benign lesions such as hypercellular fibroadenoma. Ultrasound combined with elastography can avoid unnecessary biopsies in BIRADS III/IV lesion.

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FINANCIAL OR OTHER COMPETING INTERESTS: None.

Date of Publishing: **Apr 01, 2017**