ORIGINAL RESEARCH PAPER
Volume - 10 | Issue - 04 | April - 2021 | PRINT ISSN No. 2277 - 8179 | DOI : 10.36106/ijsr
INTERNATIONAL JOURNAL OF SCIENTIFIC RESEARCH

ROLE OF ULTRASONOGRAPHIC ELASTOGRAPHY IN THE DIFFERENTIAL DIAGNOSIS OF BREAST MASSES AND ITS CONTRIBUTION TO CLASSICAL ULTRASONOGRAPHIC EVALUATION

Radiodiagnosis

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ABSTRACT

Introduction: India is experiencing an unprecedented rise in the number of breast cancer cases across all sections of society. Breast cancer is now the most common malignancy in women and the second leading cause of cancer- related mortality. Breast cancer is quite easily and effectively treated, provided it is detected in it's early stages. There is a drastic drop in the survival rates when women present with advanced stage of breast cancer, regardless of the setting. Unfortunately, women in resource-poor and developing countries, like India, generally present at a later stage of disease than women elsewhere, partly due to the absence of effective awareness programs and partly due to the lack of proper mass screening programs **Aims And Objectives:** The diagnostic performance of elastography in differentiating benign from malignant breast lesions. To assess whether elastography has the potential to reduce the need for breast biopsy /FNAC. Cut off value of Strain Ratio for benign versus malignant breast lesions. Further characterize BI-RADS 3 lesions using elastography **Materials And Methods:** The study was approved by the GSVM MEDICAL COLLEGE AND LLR HOSPITAL Ethics Committee. All patients that presented to the Radiology and Imaging Department of LLR HOSPITAL for diagnostic work up for breast pathology were included in the study. After obtaining a written and signed informed consent from all patients, they were subjected to conventional B-Mode ultrasonography followed by elastography. All diagnostic breast imaging was done with Samsung RS80A ultrasound machine using linear array transducer of frequency 5-12MHz.**Observations & Results:** The elastography patterns for each lesion were assessed and documented in color scale. Color images were constructed automatically and displayed as a color-overlay on the B-mode image. The color pattern of each lesion was then evaluated on a scale of 1-5 according to the Tsukuba elasticity scoring system. **Conclusion:** Strain Ratio cutoff of 3.3 is a sensitive parameter to differentiate benign and malignant breast lesions. Elastography is a specific test for differentiating benign and malignant breast lesions. The combined use of elasticity score, strain ratio and B- Mode sonographyincreases the diagnostic performance in distinguishing benign from malignant breast masses.

KEYWORDS

Ultrasonographic Elastography, Differential Diagnosis , Breast Masses

INTRODUCTION

India is experiencing an unprecedented rise in the number of breast cancer cases across all sections of society. Breast cancer is now the most common malignancy in women and the second leading cause of cancer- related mortality.

Breast cancer is quite easily and effectively treated, provided it is detected in it's early stages. There is a drastic drop in the survival rates when women present with advanced stage of breast cancer, regardless of the setting. Unfortunately, women in resource-poor and developing countries, like India, generally present at a later stage of disease than women elsewhere, partly due to the absence of effective awareness programs and partly due to the lack of proper mass screening programs

Currently, the triad of palpation, mammography, and ultrasound are performed for the assessment of breast masses.[1]

Elastography is an emerging imaging technique, and a relatively unexplored tool, used to map the elastic properties of the examined soft tissues, i.e, it quantifies the "stiffness" of a lesion compared to the surrounding adipose and fibroglandular tissues of the breast. Elastography can visualize tissue elasticity or stiffness in vivo and can be thought of as an imaging substitute to palpation by physical examination for differentiating benign and malignant breast lesions.

The principle of elastography is based on the fact that malignant lesions are significantly stiffer than fibroadenomas and other benign breast lesions, and their transverse dimension is larger on the elastograms than the size estimates on the conventional sonogram.[2]

For the elastographic examination, the region of interest is superimposed semi-transparently on the B-mode ultrasound image ensuring that the lesion occupies less than one-third of this area so that there is enough surrounding breast tissue. Following this, a brief mechanical stimulus (compression or vibrations) is propagated through the tissue. The results of the tissue compression are displayed as a color image called anelastogram.[3]

Breasts are both superficial as well as readily compressible. Also, most breasts contain adequate and easily identifiable adipose tissue which serves as an ideal internal control. These physical properties of the breasts allows for ideal practical application of elastography in assessment of breast lesions [4].

Thus, the aim of this study is to prospectively differentiate benign and malignant breast masses based on conventional B-mode ultrasonography and elastography, with cytological / histopathological findings being the reference standard.

1. To assess the diagnostic performance of elastography in differentiating benign from malignant breast lesions.
2. To assess whether elastography has the potential to reduce the need for breast biopsy /FNAC.
3. To calculate the cut off value of Strain Ratio for benign versus malignant breast lesions.
4. To further characterize BI-RADS 3 lesions using elastography

MATERIALS AND METHODS

The study was approved by the GSVM MEDICAL COLLEGE AND LLR HOSPITAL

Ethics Committee.

All patients that presented to the Radiology and Imaging Department of LLR HOSPITAL for diagnostic work up for breast pathology were included in the study. After obtaining a written and signed informed consent from all patients, they were subjected to conventional B-Mode ultrasonography followed by elastography.

All diagnostic breast imaging was done with Samsung RS80A ultrasound machine using linear array transducer of frequency 5-12MHz.

Histopathology was used as the standard reference.

Study Design: Prospective study.

Time Frame: December 2018 to September 2020.

Inclusion Criteria:

1. Patients with clinically palpable breast masses.
2. Patients who are willing to give consent for elastography, FNAC/ biopsy
3. Patients who are referred because of a positive physical palpation and/or positive mammograms and/or positive ultrasound and/or positive MRI

Exclusion Criteria:

1. Patients who are unwilling or unable to provide informed consent.
2. Women with breast implants.
3. Patients with superficial skin lesions
4. Case of trauma

OBSERVATIONS & RESULTS

Our study showed that in a total of 100 breast lesions of 100 female patients were included at the beginning of the study, 98 lesions of 98 patients were confirmed by histopathology. They underwent B-mode ultrasonography followed by elastography in the same visit. Final diagnosis of all cases was confirmed with histopathology (fine needle aspiration cytology, FNAC). The prevalence of benign lesions was 71.4% (70/98). The distribution of the types is depicted in our study. The prevalence of malignant lesions was 28.57% (28/98). Out of the 70 histopathologically proven benign cases, 29 were assigned a BIRADS category 2 (benign),31 were assigned as BIRADS category 3 (probably benign) and 10 were assigned category 4(false positive) . These false positive cases included 8 cases of fibroadenoma and 2 case of fibroadenosis.

We found out of the 28 histopathologically proven malignant cases, 11 cases were BIRADS 4 on B-mode ultrasonography, 16were BIRADS 5 (high suspicion of malignancy) and 1 was assigned category 3(false negative).False negative case was of invasive lobular carcinoma. Out of 28 malignant cases 17 were infiltrating duct carcinoma,9 were invasive lobular carcinoma and 2 were mucinous carcinoma. The distribution of benign and malignant lesions into the BIRADS stages. The elastography patterns for each lesion were assessed and documented in color scale. Color images were constructed automatically and displayed as a color-overlay on the B-mode image. The color pattern of each lesion was then evaluated on a scale of 1-5 according to the Tsukuba elasticity scoring system.

We showed that the scores of 1 to 3 were considered benign lesions and 4 to 5 as malignant. Out of the 70 benign cases, 32 had elasticity score (ES) of 1, 22 had elasticity score of 2 ,14 had a ES of 3 and 3 had a ES of 4. Out of the 28 malignant cases, 11 had a score of 4, 14 had a score of 5, 2 lesions had a score of 3 and 1 had a score 2. The three false positive cases with the ES of 4 was case of fibroadenoma. The 3 lesions with the false negative ES of 3 and 2 respectively, were both cases of infiltrating duct carcinoma and mucinous carcinoma.

In our study showed that the strain ratio (SR) was calculated as an independent parameter, automatically by the software within the ultrasound machine. The Youden's Index was used in the MedCalc software. The data obtained on applying the software basically calculated the sensitivity and specificity for each cut off value and generated the appropriate value which offered optimum sensitivity, without loss of specificity. We got a sensitivity of 96.43 %, specificity of 92.86%, accuracy of 93.88%, PPV of 81.82% and NPV of 98.46% when a cut off value of 3.3 was used.

We found in although B-Mode ultrasound (BIRADS classification) shows accuracy (88.78%), and 96.43% sensitivity, it has poor specificity of 85.7%. Hence, it can be used as an excellent tool for screening, but cannot be considered as a good diagnostic tool. Elasticity score (ES) shows accuracy (93.88%). This scoring system is highly subjective and can lead to high degree of errors due to inter-observer bias. Therefore, ES also cannot be considered as a gold standard diagnostic tool. Strain ratio calculation has an optimum accuracy of 93.88%. And also show a very good sensitivity of 96.43and specificity of 92.86%. Hence of the three tools described above, strain ratios together with elasticity score would be the most appropriate tool for differentiating benign from malignant lesions.

DISCUSSION

Breast ultrasound has proved to be useful not only in the differentiation between solid and cystic masses but also benign and malignant masses. However, because of considerable overlap between the sonographic features of benign and malignant breast lesions, there was always a need for a more confirmative test. Therefore, biopsy is presently used to supplement other diagnostic methods in the evaluation of breast lesions, but again the rates of cancer detection in biopsies are only 10–30%. Elastography proved to be a saviour as a quick, easy and a non- invasive method of revealing the physical properties of a tissue, as a supplement to B-Mode sonography and as an alternative to biopsy. The interpretation criteria in elastography consist of the qualitative parameter, **“Elasticity Score”** (ES) and the quantitative parameter, **“Strain Ratio”** (SR).

Elasticity score (ES) was calculated after obtaining the elastogram. The elastogram was displayed as a color-overlay on the B-mode image. These color images were constructed automatically with the same image processing settings. The color pattern of each lesion was evaluated on a scale of 1-5 according to the Tsukuba elasticity scoring system and scores of 1 to 3 were considered benign and 4 to 5 as malignant, based on the relative stiffness of the lesion.

Most of the benign lesions showed ES of 1, 2 or 3 but three histopathologically proven benign cases of fibroadenoma showed ES of 4. None of the benign lesions had a score of 5. Most of the malignant lesions showed ES of 4 or 5. And three lesions, of which 1 was infiltrating duct carcinomas and 2 were mucinous carcinoma on histopathology, showed ES of 2 and 3 respectively.

Based on the elastographic patterns and scores the **sensitivity, specificity** and **diagnostic accuracy** of **89.29%**, **95.71%** and **93.88%** was found in our study. A study conducted by **YasuakiHirooka et al**, [5] to compare the diagnostic performance of B-mode ultrasonography and elasticity scores found a sensitivity, specificity and diagnostic accuracy for elasticity scores of 77.5%, 100% and 91.1%, respectively. Our study showed a better sensitivity and better accuracy compared to the study conducted by **Yasuaki et al** [5] but the specificity was lower. The three false positive (benign) cases of fibroadenoma in our study which showed ES of 4, on histopathology showed overgrowth of both epithelial elements i.e. ducts and lobules, and varying amounts fibrous stroma in differing proportions with extensive sclerosis. Thus the hardness of this lesion can be attributed to the increased amount of fibrous stroma as well as sclerosis.

Another similar study conducted by **Xia Gong et al** [3] found the sensitivity, specificity, and diagnostic accuracy of elastography to be 92.65%, 73.39%, and 81.25%, respectively having the same criteria of elasticity score cut off of more than or equal to 4 for malignant lesions. The specificity in our study was better, suggesting that elastography scores can be used for additional confidence when used along with B-Mode elastography.

In a study elastography had 86.5% sensitivity, 89.8% specificity and 88.3% accuracy with ES cut off between 3 and 4. Elastography had higher sensitivity than conventional ultrasound (71.2%) whereas the accuracy of elastography was equivalent to that of conventional ultrasound (84.7%).

Beatriz Navarro et al [6] carried out a similar study which stated that elasticity showed lesser sensitivity (69.5%) but a higher specificity (83.1%) than conventional sonography (which showed a sensitivity of 96.6% and specificity of 76.9%), same as our study. Once again proving that elastography may be useful as a complementary technique in addition to conventional sonography in the characterization of breast lesions because it increases the diagnostic specificity and reduces the false-positive rate.

In a prospective study performed by **SughraRaza et al**,[7] the sensitivity of elasticity score was found to be 92.7% and specificity was 85.8%, concluding that elastography may provide additional characterization of breast lesions and improve specificity, particularly for low-suspicion lesions.

Table 8 enlists a comparative analysis of findings of elasticity scores of various studies and our study at a glance.

Since **Stavros et al**[8] proposed using 2-dimensional conventional ultrasonography for distinguishing benign and malignant breast tumors, it has been widely accepted and used. Many researchers showed that sonography had a high sensitivity, specificity, and accuracy and was very useful for differential diagnosis between benign and malignant breast tumors. Some studies also showed that sonography showed a good sensitivity but a poor specificity.

Differentiation between benign and malignant breast lesions can be made even with conventional B-mode sonography in many cases with certain degree of confidence. However, elastography has enabled ultrasonologists to judge in a more reliable manner, especially due to the visual impact by color. Elastography is very useful as a subsidiary diagnostic tool for all workers including the less-experienced medical technologists and skillful clinical radiologists or breast specialists. There have been several studies conducted over the recent years that have concluded that elastography has a better diagnostic performance when combined with B- Mode ultrasound rather than when used individually.

In our study, when used alone, elastographic strain ratio had almost equal **sensitivity (96.43%)** but **good specificity (92.86%)** compared to conventional sonography (sensitivity 96.4% and specificity 85.7%). As mentioned earlier, conventional sonography can only be a screening tool, but with the help of additional data from elastography, it can prove to be a better diagnostic tool as well. When used together the sensitivity of elastographic strain ratio can be increased without compromising the specificity.

BIRADS 3 breast lesions fall in the category of probably benign, i.e, on conventional B-Mode sonography, the lesion cannot be confidently diagnosed to be either benign or malignant. These lesions are suggested a closer watch and a short-term follow-up but very often are subjected to biopsy / FNAC for confirmation due to patient or clinician concern. Elastography proves to be in an important tool in these lesions to avoid unnecessary intervention, especially in benign cases.

CONCLUSION

1. Strain Ratio cutoff of 3.3 is a sensitive parameter to differentiate benign and malignant breast lesions.
2. Elastography is a specific test for differentiating benign and malignant breast lesions.
3. The combined use of elasticity score, strain ratio and B- Mode sonographyincreases the diagnostic performance in distinguishing benign from malignant breast masses.

Table: Comparison Of Strain Ratio, Elasticity Scoring And Ultrasound On The Basis Of Their Sensitivity, Specificity And Accuracy

CRITERION	SENSITIVITY	SPECIFICITY	ACCURACY
STRAIN RATIO > 3.3	96.43	92.86	93.88%
ELASTICITY SCORE > 3	89.29	95.71	93.88%
BIRADS > 3	96.43	85.7	88.78%

Table: Strain Ratios In The Study Population

TYPE	RANGE OF STRAIN RATIOS (SR)	MEAN SR
Benign	0.75 - 3.2	1.923
Malignant	2.8- 7.9	6.427
Total	0.75 – 7.9	3.725

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