International Journal of Research in Medical Sciences
Gour K et al. Int J Res Med Sci. 2024 Mar;12(3):840-845
www.msjonline.org
pISSN 2320-6071 | eISSN 2320-6012

DOI: https://dx.doi.org/10.18203/2320-6012.ijrms20240527

Original Research Article

Sonomammographic and sonoelastographic evaluation of benign and malignant breast lesions and its correlation with fine needle aspiration cytology

Khushboo Gour*, Rikta Mallik, Anisha Mondal, Abhishek Mondal

Department of Radio-diagnosis, Bankura Sammilani Medical College, Bankura, West Bengal, India

Received: 07 January 2024
Revised: 05 February 2024
Accepted: 08 February 2024

***Correspondence:**
Dr. Khushboo Gour,
E-mail: gourkhushboo19@gmail.com

ABSTRACT

Background: Breast cancer affects 25.8% of women worldwide. Mammography and ultrasound have sensitivity, but invasive breast biopsies and aggressive biopsies are essential. Sonoelastography is a non-invasive imaging method that can measure tissue stiffness related to different pathologic conditions, such as cancer. Objective is to assess the diagnostic accuracy of sonomammography and sonoelastography in diagnosing breast lesions as benign or malignant in correlation with fine needle aspiration cytology (FNAC) as gold standard.
Methods: This study was conducted on 52 female patients with breast mass and sensitivity, specificity, negative predictive value (NPV), positive predictive value (PPV), kappa and p value of conventional gray scale ultrasound and ultrasonography (USG) elastography were calculated and compared with that of FNAC. Ultrasound was performed using grayscale and elastography mode on GE LOGIQ P9 ultrasound equipment with a 7-12 MHz linear-array transducer. All cases with breast lesions identified on ultrasound elastography underwent FNAC.
Results: The sensitivity, specificity, PPV, NPV of sonoelastography were 78.5, 94.7, 84.6, 92.3 with kappa 0.75 and p value <0.0001. Similarly, sensitivity and specificity for strain ratio were 85.7 and 97.4, and that for size ratio were 85.7 and 100 respectively. These results are comparable to or better than results for conventional ultrasound.
Conclusions: Breast elastography makes it easier to classify BIRADS 3 category lesions which are benign but still confused as malignant on conventional USG. BIRADS category 3 and 4 lesions with benign findings on sonoelastography can be downgraded to category 2 and 3 respectively thus reducing the number of false positive malignancy cases and biopsy.

Keywords: Breast cancer, Elastography, FNAC, Ultrasound

INTRODUCTION

Breast cancer affects 25.8% of women worldwide, and early identification is crucial for controlling the disease. Mammography and ultrasound have sensitivity, but invasive breast biopsies and aggressive biopsies are essential. Trustworthy diagnostic techniques are needed to reduce unnecessary invasive procedures and improve patient outcomes.

Breast cancer diagnosis methods include palpation, mammography, and ultrasonography (USG), with varying accuracy and predictive value.[2] Clinical palpation has weak sensitivity and imperfect accuracy, while mammography can detect early breast cancer by sand-like calcifications but has limited role in detecting cancers without calcification.[3] USG is more suitable due to its simplicity, real-time dynamic imaging, and non-invasiveness. However, its specificity is weak due to majority of tumors being benign. breast imaging reporting and data system (BI-RADS), a quality control and risk assessment tool, helps assess different aspects of tumors but some tumors may be difficult to distinguish, leading to an excessive increase in breast lesion biopsies.[4-6]

Greyscale ultrasonography has been used for evaluating symptomatic breast masses for a long time. The sonographic BI-RADS lexicon was used to help report breast sonography and mammography results and assess risk.[10] Ultrasound has advantages over mammography in diagnosing breast cancer, such as being non-invasive and radiation-free.[11] It is suitable for young breasts, pregnant women, and breastfeeding women, and has good lateral resolution.[12] Sonographic approaches have been developed to improve sensitivity in identifying malignant breast lesions, including ultrasound elastography assessment and palpation. Ultrasonic elastography has 86.5% sensitivity, 89.8% specificity, and 88.3% accuracy in differentiating benign from malignant solid breast lesions.[1] However, it has drawbacks, such as interobserver variability during data collection and interpretation.[13] Ultrasonic elastography is a non-invasive imaging method that can measure tissue stiffness related to different pathologic conditions, such as cancer and hepatobiliary disorders. It has been used for the identification and classification of breast lesions, and its precise identification and pinpointing in the B mode make it a promising alternative to conventional ultrasound elastography.

Ultrasound elastography, first described by Ophir et al in the early 1990s, is a non-invasive imaging technique used for diagnosing cancer, hepatobiliary disorders, and breast lesions.[2] It is based on the idea that malignant tumors are stiffer under compression than benign ones.[1-3] Most countries now adopt a triple evaluation strategy, with FNAC as the first-line pathological investigation. Pathologists with a focus on cytopathology are ideal for collecting and evaluating FNAC samples. Radiological imaging techniques are crucial for diagnosing and monitoring confirmed cases. BIRADS encourages collaboration between surgeons, pathologists, and radiologists to minimize errors and enhance communication with patients and medical professionals.[14,15]

Objective

Objective of the study was to assess the diagnostic accuracy of sonomammography and sonoelastography in diagnosing breast lesions as benign or malignant in correlation with FNAC as gold standard.

METHODS

This prospective analytical study of cross-sectional design was carried out in the radiodiagnosis and pathology department of Bankura Sammilani Medical College and Hospital after receiving the necessary institutional ethical clearance, from June 2021 to November 2022, in West Bengal, India. Every participant's free and informed permission was obtained. Each woman had her sociodemographic, personal, and medical history recorded. Prior to FNAC, all patients underwent clinical examination of the breast mass conventional ultrasound and sonoelastography examinations. The study involved 52 female patients with breast lumps in total. Individuals under the age of 18, not willing to participate in the study, unfit for FNAC, post-operative bilateral mastectomy patients, who have already been diagnosed, cases which were not differentiated by FNAC as benign or malignant, and those who did not give their informed consent were eliminated. Patients underwent ultrasonography examinations in a room with moderately low lighting, using a GE LOGIQ P9 ultrasound equipment with a 7-12 MHz linear-array transducer, a traditional B-mode grayscale ultrasound, and color Doppler integrated with real-time elastography software. All cases with breast lesions identified on ultrasound elastography underwent FNAC.

Conventional B-mode ultrasonography (sonomammography)

Patients were examined in supine position. Grid technique is widely adopted for routine breast ultrasound. Other adopted technique for breast USG is radial scanning pattern. The US lexicon of sonomammogram includes six morphologic features of the solid breast masses such as shape of the lesion, orientation of the lesion, margin of the lesion, boundary of the lesion, echotexture of the lesion and posterior acoustic features of the mass.

Details of BIRADS criteria for breast mass characterization through conventional USG is given as follows- category 1: negative findings, category 2: benign findings, category 3: probably benign findings, category 4: findings suspicious for malignancy, category 4a: low level suspicious for malignancy, category 4b: intermediate level suspicious for malignancy, category 4c: moderate suspicious for malignancy, and category 5: findings highly suggestive of malignancy.[8]

Strain elastography of the breast lesion

Strain elastography was performed on the patient in supine position, and with the probe-oriented perpendicular to the chest wall.[7] The probe is applied to the breast and is moved slightly inferior and superior, and normal breast tissue is included to obtain the elasticity images. The probe is applied with just a light pressure in order to obtain the images, which are appropriate for analysis and a higher level of pressure is simply passed up. Before and after soft compression of tissues, an image will be taken in which colour coding which is used to evaluate deformation. Moderate vertical compressions will be applied with the probe, three to five times, over the lump and elasticity images will be displayed in a computer monitor. A chromatic scale assigns tissues that undergo strain (soft tissues) a different colour from those that are not deformed by the compressions. The B-mode grey scale image and the elastography image will be displayed side by side.

Elasticity score (Tsukuba score)

A visual representation of how tissues deform under compression. A five-point score system is used to categorize the lesion. A strain score cut off ≥4 indicates malignancy. All cases having elasticity score of 1-3 will be considered benign. Score 1, complete deformability of lesion score 2, deformability of large amount of lesion with little stiff areas score 3, presence of stiff area in center with peripheral deformability of lesion score 4, completely stiff lesion Score 5, entire lesion and surrounding area are stiff.[3,8,9]

Colours on the Figure 1 correspond to- blue: tissue with the greatest strain (hardest component), red: tissue with no strain (softest component), and green: tissue with intermediate strain.[8]

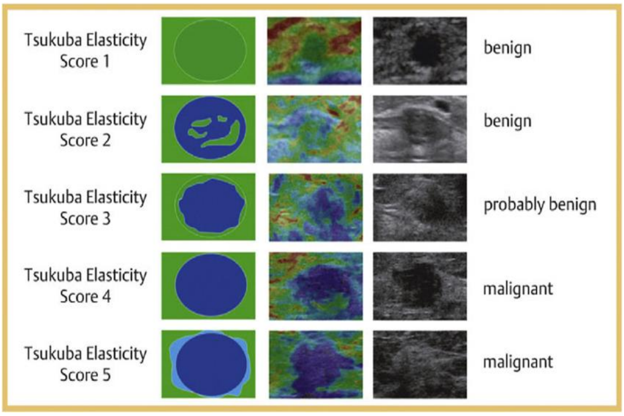

Figure 1: Tsukuba score.

Size ratio (E/B ratio)

Malignant lesions are known to appear larger in size on elastograms than on B-mode images. The width ratio, also known as the EI/B ratio (EI=elastography image size, B=B-mode size), can be calculated by measuring the largest diameter of a lesion on both the matching elastogram and the B-mode picture. Hard lesions with decreased elasticity appear larger on elastography than on B-mode ultrasound due to a desmoplastic response of tumors.[16] The size change between the B-mode image and sonoelastography image is evaluated. Cut off point ≥1.2 is considered as malignant in this study.[8]

Strain ratio

The strain ratio (also known as the fat lesion ratio when applied to the breast) can be used to differentiate benign breast lesions from malignant. The stiffness of a discrete mass lesion is often assessed using the strain ratio. The strain in the region of interest (ROI) can be compared to a ROI in the reference tissue that is going through a similar stress, presuming that the stress is evenly distributed throughout the field of view. This gives a semi-quantitative evaluation of the tissue stiffness that is relative as opposed to absolute. It is used to measure how stiff the lesion is in comparison to the tissue around it. First, a ROI that best encircles the lesion's interior (A) is chosen and placed. Second, the reference region (B) is measured and situated in the fatty tissue around it. The strain ratio (SR), which is determined as the average strain in the reference (B) divided by the average strain in the "lesion" (A), is given as a percentage (%) for the mean strain in both of these locations.

Strain ratio (B/A) =Mean strain of fat area (B) /mean strain in lesion of interest.[16]

A malignancy is predicted by a strain ratio of more than 4.5 in this study.[8]

USG-guided FNAC

Following optimum, steady visibility of the lesion, fine-needle aspiration cytology investigation was done without any local anaesthesia, under ultrasound guidance with linear probe. After cleaning the skin, the needle (21-27 gauge) was placed close to one of the transducer's short sides and progressed along a trajectory parallel to the transducer's long axis. On the monitor, the needle's progress could be seen plainly, and it was unmistakably confirmed that the tip was inside the lesion. Aspiration was used once the needle had entered the lesion and for the purpose of gathering several samples, the tip is moved in various directions. The needle was not aspirated when it was being removed. Aspirated material was placed, smeared and fixed on glass slides and then sent to the pathology department for cytological analysis by pathologist. The cytopathological results (benign/malignant) was compared with sonological findings based on BIRADS and with sonomammography findings.

RESULTS

A total of 52 lesions diagnosis, Bankura Sammilani were selected for the study between the time period of June 2021 to November 2022. The results of our investigation were evaluated using proportion and chi squared test. The level of sign Decision criterion: We compare p value with level of significance. If $p<0.05$, we accept the null hypothesis.

The most common breast lesion was found to be fibroadenoma (44.2%). Other benign lesions include duct ectasia and fibroadenosis, Intraductal papillomas, granuloma and mastitis, complex cyst) and phylloides tumour. The most common malignant breast lesion was ductal ca in situ (7.6%), followed by invasive ductal carcinoma (7.6%). Other malignant lesions found in this study include medullary carcinoma and mucinous carcinoma with 1.9% each.

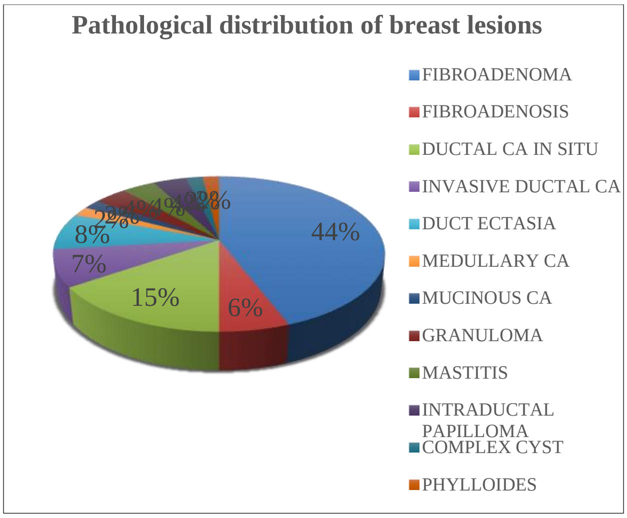

Figure 2: Pathological distribution of breast lesions.

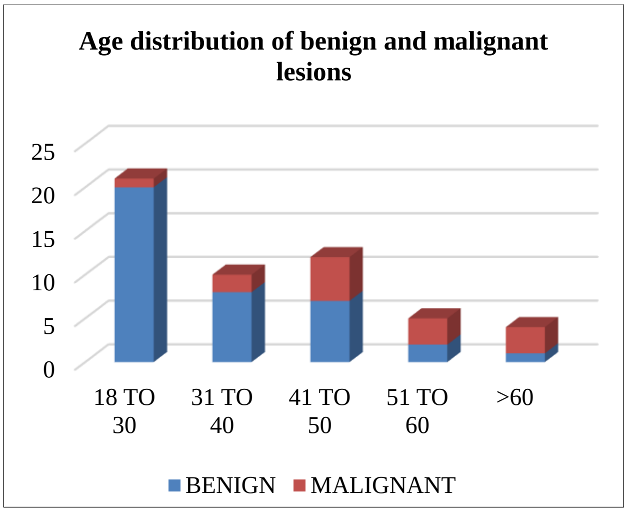

Figure 3: Age distribution of benign and malignant lesions.

Table 1: Elasticity (Tsukuba) score wise distribution of cases.

Elasticity score (Tsukuba)	1 (one)	2 (two)	3 (three)	4 (four)	5 (five)
No. of cases	5	25	9	4	9
No. of benign case (FNAC)	5	25	6	2	0
No. of malignant case (FNAC)	0	0	3	2	9

Mean elasticity score for benign lesions: 82/39=2.10 mean elasticity score for malignant lesions: 61/13=4.69

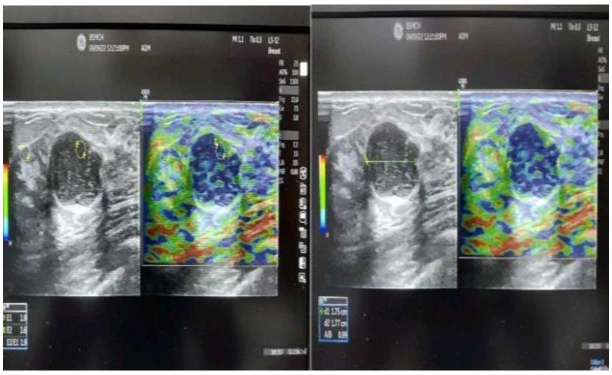

Figure 4: Fibroadenoma on strain elastography with tsukuba score 2, strain ratio of 1.9 and size ratio of 0.99.

Table 2: Strain ratio wise distribution of cases.

Strain ratio	<4.5	>4.5
No. of cases	39	13
No. of benign cases	38	1
No. of malignant cases	1	14

Mean strain ratio for benign lesions=2.58 mean strain ratio for malignant lesions=8.54

In our study most of the patients were in the age group of 18-30 years (40.3%). The incidence of benign breast lesions was higher in younger population, while the incidence of malignant breast lesions was higher in older population.

Table 3: Size ratio wise distribution of cases.

Strain ratio	<1.2	>1.2
No. of cases	40	12
No. of benign cases (histopathology)	38	0
No. of malignant cases (histopathology)	2	12

Mean strain ratio for benign lesions=0.97 mean strain ratio for malignant lesions=1.35

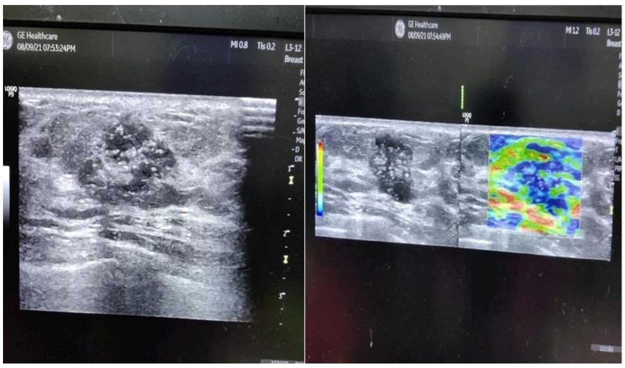

Figure 5: DCIS with BIRADS score 4 and Tsukuba score 5.

Table 4: Correlation of sonomammography (BIRADS) and sonoelastrography with FNAC accuracy.

Modality	Sensitivity	Specificity	PPV	NPV	Accuracy	PLR	NLR	%FP	%FN
BIRADS	85.7	86.8	70.5	94.2	86.5	6.51	0.17	13.2	14.3
Elastography score	78.5	94.7	84.6	92.3	90.3	14.9	0.23	5.3	21.4
Strain ratio	85.7	97.4	92.3	94.8	94.2	32.5	0.15	2.6	14.3
E/B (size) ratio	85.7	100	100	95	96.1	--	0.14	0	14.3

All of the modalities have p value of <0.0001

DISCUSSION

In this study we compared sonomammography BIRADS score and elastography interpretation i.e. elastography score, strain ratio, size ratio with the gold standard FNAC amongst 52 patients to distinguish between benign and malignant breast lesion, out of which overall 38 (73%) were benign in FNAC. In 18–40-year, age group 28 cases (90.3%) were found to be benign while in >40 years age group 47.6% (10 cases) were benign and 52.3% (i.e. 11 cases) were found to be malignant.

The most common breast lesion was found to be fibroadenoma 23 (44.2%) cases. Amongst benign lesions ductal ectasia 4 (7.6%) cases, fibroadenosis were 3 (5.7%) cases, least common were found to be phylloids 1 (1.9%) case and complex cyst. Ductal ca in situ 8 (15.3%) cases was found to be most common malignant lesion followed by invasive ductal carcinoma 4 (7.6%) cases out of 52 patients.

Elasticity score (Tsukuba) of 1-3 which was taken as benign for 39 (75% of 52) cases of which 3 cases with score of 3 turned out to be malignant on FNAC. 13 cases with score of 4-5 were taken as malignant of which 2 cases with score of 4 were diagnosed benign on FNAC. In this study the mean elasticity score for benign lesions is 2.10 and 4.69 for malignant lesions (Table 1) which are similar to a study conducted by Itoh and colleagues in 2004 their mean elasticity score for malignant lesion was 4.2 and 2.1 for benign (p<0.001).[1]

Strain ratio of <4.5 is classified as benign while >4.5 is malignant. Out of 52cases 39 cases were given strain ratio <4.5 of which 1 case was found to be malignant in FNAC. And amongst 13 cases with strain ratio >4.5, 1 case was diagnosed as benign in FNAC. Mean strain ratio for benign was 2.58 and 8.54 for malignant lesions which is much higher (Table 2). These are in concordance to study by Singh et al in 2020.[12]

Size ratio of <1.2 is considered benign and >1.2 as malignant. Here 40 (76.9%) cases with size ratio <1.2 out of which 02 (3.8%) cases were diagnosed as malignant in FNAC. And of 12 (23%) cases with size ratio >1.2, all were found to be malignant in FNAC. Mean size ratio for benign lesions was 0.97 and 1.35 for malignant. These values are similar to study by Singh et al in 2020 which shows mean size ratio for benign lesions to be 0.86 and 1.35 for malignant (Table 3).[8] Accuracy of BIRADS in diagnosing benign in diagnosing benign vs malignant lesions was 86.5% which is lower as compared to elastography score with accuracy of 90.3%.

In our study the positive likelihood ratio and negative likelihood ratio for BIRADS was 6.51 and 0.16 respectively and the same for elastography scores was 14.9 and 0.23 respectively.

Percentage of false positive and false negetive for BIRADS was 13.2% and 14.3% respectively while the same for elastography scores was 5.3% and 21.4%. Thus, there is 7.2% increase in false positives. The p value was <0.0001 for both which is significant.

The sensitivity of strain ratio was 85.7% which was similar to sensitivity of size ratio and that of BIRADS indicating no significant difference between these tests. These findings were in concordance with a study by Zhao in 2012 which showed sensitivity of strain ratio to be 87.7% when a cut-off value of 3.06 was considered.[17]

Limitations

Measurements impacted by variations in density of breast tissues close to breast lesions, inter or intra-observer variability, radiologist's experience level, small sample volume, lack of follow up in surgically removed malignant breast mass. Some cases could not be differentiated by FNAC as benign or malignant. False negative in benign FNAC cases with clinical suspicion of malignancy should be monitored.

CONCLUSION

This study shows that breast elastography can reach highest specificity and fairly high negative predictive value when used in combination with conventional USG. It makes it easier to classify BIRADS 3 category lesions which are benign but still confused as malignant on conventional USG, leading to further patient suffering, cost and resource wastage. BIRADS category 3 & 4 lesions with benign findings on sonoelastography can be downgraded to category 2 and 3, BIRADS category 3 lesions with malignant findings on sonoelastography can be upgraded to category 4. Thus, the predictive accuracy of conventional USG increases when used in combination with elastography and it may reduce the need for FNAC and further invasive and expensive diagnostic procedures in breast lesions classified as BI-RADS 3 (probably benign) on USG and postpone follow-up. In conclusion, breast sonoelastography is a very quick and easy approach that can raise the specificity and sensitivity of USG. It is the most easily accessible and accurate non-invasive imaging technique. It is painless, safe and inexpensive tool. Elastography is ideal for rural locations where other facilities are occasionally unavailable and could spare countless women from the suffering, wait, costs, discomfort, and anxiety associated with a biopsy.

ACKNOWLEDGEMENTS

The authors would like to acknowledge the radio-diagnosis department and department of pathology of Bankura Sammilani Medical College and Hospital and other supportive staffs who were involved in imaging, tissue sample collection, processing and examinations.

Funding: No funding sources
Conflict of interest: None declared
Ethical approval: The study was approved by the Institutional Ethics Committee

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Cite this article as: Gour K, Mallik R, Mondal A, Mondal A. Sonomammographic and sonoelastographic evaluation of benign and malignant breast lesions and its correlation with fine needle aspiration cytology. Int J Res Med Sci 2024;12:840-5.