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Role of Elastography in the Assessment of Benign and Malignant Breast Lesions with Histopathological Corelation - A Prospective Study

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Abstract:
Background: *Breast Cancer is the most common cancer in females, both in developed and developing countries and its incidence continues to escalate. Therefore, early detection to improve breast cancer outcomes remains the cornerstone of breast cancer control. Guidelines recommend screening for detecting breast cancer with mammography and ultrasonography. Strain elastography is a newer technique that can aid additional characterization of breast lesions.*
Objective: *The aim of this study was to determine the diagnostic accuracy of breast ultrasound elastography in differentiating benign from malignant breast lesions using histopathological diagnosis as gold standard.*
Materials and Methods: *The study was conducted at Department of Radio-Diagnosis, Medical College Kolkata. A total of 48 patients with breast lump were examined with B-mode sonography and subsequently with elastography. The study was conducted from 1st August 2020 to 31st January 2021. Conventional sonographic findings were classified according to the American College of Radiology Breast Imaging Reporting and Data System for sonography, and elastography images were assigned an elasticity score of 1 to 5 (1-3, benign; 4 and 5, malignant) according to the Ueno classification. Cytologic diagnoses obtained from fine-needle aspiration and histopathologic results from a core-needle biopsy or surgical biopsy were used as reference standards. Statistical analysis included sensitivity, specificity, and positive and negative predictive values.*
Results: *A total of 48 patients were included with a mean age of 36.7 years (range 17-61 years). On histopathological evaluation, 11(18.7%) lesions were malignant and 37(81.3%) were benign. Strain Elastography had sensitivity of 72.7% (95% confidence interval), specificity of 94.5%, a positive predictive value of 80% and a negative predictive value of 92.1% with an accuracy of 89.5%.*
Conclusion: *Our results show 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, thus reducing the false-positive rate. Use of elastography may increase malignancy detection rate by reducing the need for biopsy in benign breast lesions.*
Key word: *Sonoelastography (SE); Breast Cancer; Ultrasound; Benign and malignant breast lesions*

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I. Introduction

The rising incidence of breast cancer has led to tremendous research and innovations with consequent development of new diagnostic techniques. The recent development of breast ultrasound elastography (USE) has produced promising results in early diagnosis and differentiation of breast lesions. USE differentiates between benign and malignant lesions on the basis of elasticity of tissues with benign lesions having elasticity similar to adjoining normal tissues, while malignant lesions (being harder clinically) have lower elasticity as compared to adjoining normal tissues. In comparison, malignant tissues which have lower elasticity, display larger diameter in USE as compared to the B-mode sonography due to local infiltration and desmoplastic reaction. The purpose of this study was to evaluate the role of USE in the early diagnosis and differentiation of breast masses. Benign tissues appear similar to surrounding tissues and display smaller diameter on elastography.

II. Review of Literature

Ultrasound elastography is a new imaging mode that display tissue stiffness or hardness in real time as a colour map that translucently overlays the conventional B-mode image. The technique significantly improves the differentiation between benign and malignant tissues. This technique exploits the theory that benign and malignant breast lesions have inherent differences in firmness. Strain images display the relative stiffness of lesions compared with the stiffness of surrounding tissue. Stiffer areas deform less easily than do their surroundings and are depicted as dark on strain images, whereas softer areas deform more easily than do their surroundings and are depicted as light. Malignant masses typically appear dark and have high contrast with background breast tissue during deformation. Benign masses typically appear lighter and have lower contrast with background breast tissue during deformation. In addition, malignant lesions tend to be larger on US strain images than on corresponding B mode US images, perhaps because of the desmoplastic reaction commonly associated with malignancy. Walz et al., [10] in 1993 concluded that the elasticity characteristics in cancers, Fibroadenoma and normal breast parenchyma were different. Sarvazyan et al., in 1995 observed that neoplastic tissues were significantly harder than fibroadenoma and normal tissues. To use this property of elasticity of tissues, ultrasound equipped with elastography unit was developed in 2003-2004 for routine USE imaging. [11] For characterization of breast lesions, two elasticity scoring systems are widely used: The Tsukuba score developed by Itoh et al., [5] and other by Italian Research Group after Locatelli, Rizzatto. In a study conducted by Zahran., et al. in Egypt, strain elastography showed equal sensitivity but higher specificity than conventional sonography. Another study conducted by Navarro., et al. also showed that sonoelastography has higher specificity than conventional sonography. The ability of sonoelastography to evaluate the mechanical properties of different tissues is an useful diagnostic tool that provides further information about breast lesions in addition to the well-known morphological parameters such as shape, orientation, margins, internal structure and the presence of calcifications. These additional findings may be very useful in distinguishing malignant from benign solid lesions.

III. Materials and Methods

Patients:

The study was conducted at Department of Radio-Diagnosis, Medical College Kolkata. A total of 48 patients with breast lump were examined with B-mode sonography and subsequently with elastography. The study was conducted from 1st August 2020 to 31st January 2021. Patients mean age was 37 years, ranging from 17 years to 61 years. Sonoelastography was done in newly screened patients with breast lesions, before any biopsy and/or other interventional procedure.

Study design:

In each patient, bilateral whole breast sonography was done in radial and antiradial planes using GE logiq P9 ultrasound scanner equipped with 7.5-13 MHz linear array transducer. USE was simultaneously performed with the attached sonoelastography unit so that stiffness of lesion could be measured using colour mapping. The B-mode images were displayed alongside the elastography strain images to ensure that the elastography was done in the region of interest (ROI). We included the ROI, subcutaneous tissues, pectoralis muscles along with surrounding tissues in the scanning field. The patients were examined in supine position with arms behind the head. The ultrasound probe was lubricated with coupling gel on the skin surface. The probe was held lightly and perpendicular to the ROI during elastography.

Image Interpretation:

The elastography images were classified using the scoring system described by Itoh et al., which is as under:
The Tsukuba (Elasticity) score is a five-point scale that visually grades the stiffness of a mass

Score 1: Shows normal strain. The entire lesion presents with same colour pattern as normal breast. The lesion is more green in colour.

Score 2: Shows strain over most of the lesion so that hypoechoic lesion presents with mosaic colour pattern of blue and green.

Score 3: Shows strain at the periphery so that lesion appears green at the periphery and blue at the centre.

Score 4: Shows strain over entire hypoechoic lesion, the whole lesion appears blue in colour.

Score 5: Shows strain over entire lesion and the surrounding parenchyma so that both the lesion and surrounding area appear blue in colour.

On GE Logiq P9 Sonoelastography unit, green indicates medium tissue stiffness, red indicates soft tissues stiffness, and blue indicates harder tissue. The lesions with elastography score of 1, 2, 3 were considered benign and lesions with score of 4 and 5 were considered malignant.

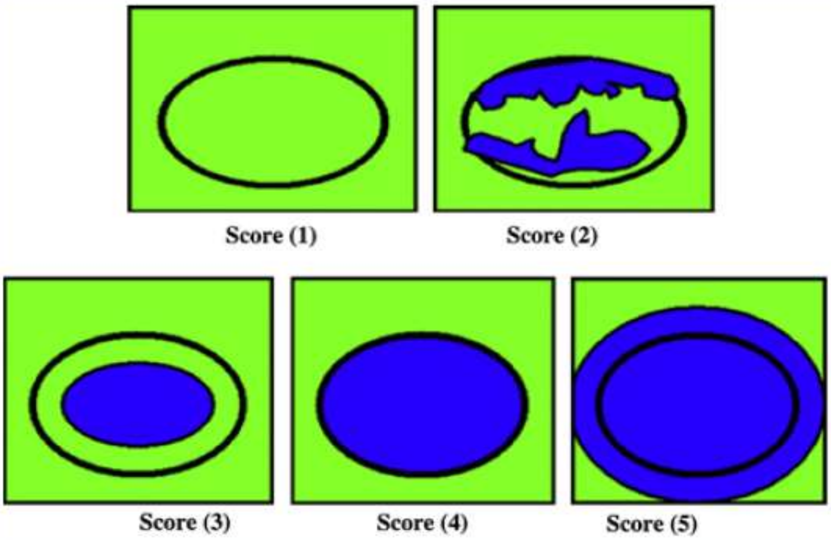

Figure 1: Elasticity scores [13].

Inclusion Criteria:
1. Patients with palpable breast lump.
2. Patients of all age groups.
3. Patients with informed consent for examination.

Exclusion Criteria:

1. Male Patients
2. Uncooperative patients.

Ethical Consideration:
The study was conducted after getting approval from Institutional Ethics Committee and other authority. Informed consent was taken from all participants

IV. Result

This study included 48 patients with palpable breast lumps. Their ages ranged from 17 years to 61 years with a mean age of 36.7 years (table 1 and figure 2).

Age(years)	No.	%
10-<20	5	10.4
20-<30	10	20.8
30-<40	16	33.3
40-<50	8	16.6
50-<60	7	14.5
>=60	2	4.1
Min-Max	17-61	
Mean+- SD	36.7 +- 12.1	
Median	36	

Table 1: Distribution of the studied cases according to age

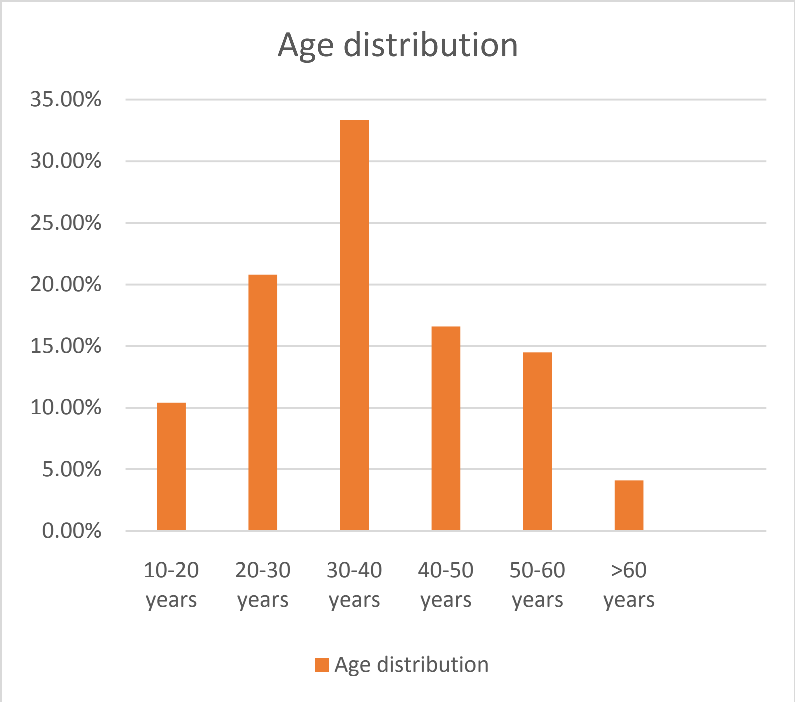

Figure 2: Distribution of patients according to age

All patients were evaluated by gray scale ultrasound and sonoelastography examination with a net total of 48 lesions being evaluated. All patients went for histopathological examination using Ultrasound (USG)-guided Fine needle aspiration cytology (FNAC) or tru-cut Biopsy or excisional biopsy. Considering the diagnosis, there were 48 breast lesions subdivided into 37 benign and 11 malignant lesions according to histopathology and follow-up. Fibroadenoma was the most common benign lesion while invasive ductal carcinoma was the most common malignant lesion (Table 2 and Figure 3).

Figure 3: Distribution of all breast lesions

Pathological Diagnosis	No. of lesions	%
Fibroadenoma	28	58.3
Simple cyst	1	2.1
Fibrocystic disease	2	4.1
Ductal Ectasia	1	2.1

Breast Abscess	3	6.25
Galactocele	1	2.1
Breast lipoma	1	2.1
Ductal carcinoma in situ	2	4.1
Invasive Ductal Carcinoma	8	16.6
Pagets disease	1	2.1
Total	48	100

Table 2: Final diagnosis of all breast lesions

Ultrasound elastography of breast lesions: Elastography was performed simultaneously on 48 patients with a total number of 48 lesions being classified according to modified Ueno and Ito elasticity score system.
Benign lesions took elastography score 1,2 ,3 and 4.
8 lesions (21.6%) had elastography score 1, 15 lesions (40.5%) had elastography score 2, 12 lesions (32.4%) had elastography score 3 and 2 lesions(5.4%) had elastography score 4.
However malignant breast lesions tool elastography score 3,4 and 5.
3 lesions (27.2%) had elastography score 3, 2 lesions (18.1%) had elastography score 4 and
6 lesions (54.5%) had elastography score 5. (Table 3 and Figure 4.)

None of the malignant lesions had score 1 or 2, while none of the benign lesions had score 5.

Elastography Score	Total (n=48)		Benign lesion (n=37)		Malignant lesion (n=11)	
	No.	%	No.	%	No.	%
1	8	16.66	8	21.6	0	0
2	15	31.25	15	40.5	0	0
3	15	31.25	12	32.4	3	27.2
4	4	8.33	2	5.4	2	18.1
5	6	12.5	0	0	6	54.5

Table 3: Relation between the elastography score and the diagnosis of breast lesions.

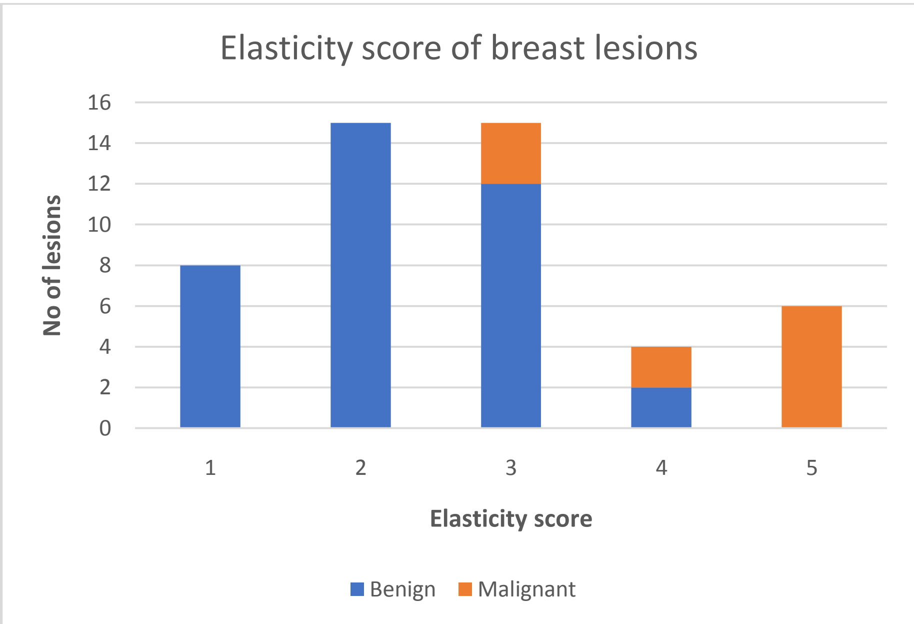

Figure 4: Elasticity score of benign and malignant breast lesions.

Sensitivity and specificity of the elastography test in breast lesions according to the elastography score: benign lesions according to the elastography score should have score 1,2 and 3. Malignant lesions should take score 4 and 5.

In our study 2 lesions out of 37 lesions took score 4 and 3 lesions out of 11 malignant lesions had score 3. So, sensitivity of the elastography test was 72.7% while specificity was 94.5% with Positive Predictive value (PPV) 80 % and Negative Predictive value (NPV) 92.1% and accuracy 89.5% (Table 4 and Figure 5).

Elastography score	**Histopathological Findings**		**Total**
	Malignant lesion	**Benign lesion**	
4+5(Malignant)	8 (a)	2(b)	10
1+2+3 (Benign)	3(c)	35(d)	38
Total	11	27	48

Table 4: Relation between the elastography score and pathological diagnosis.

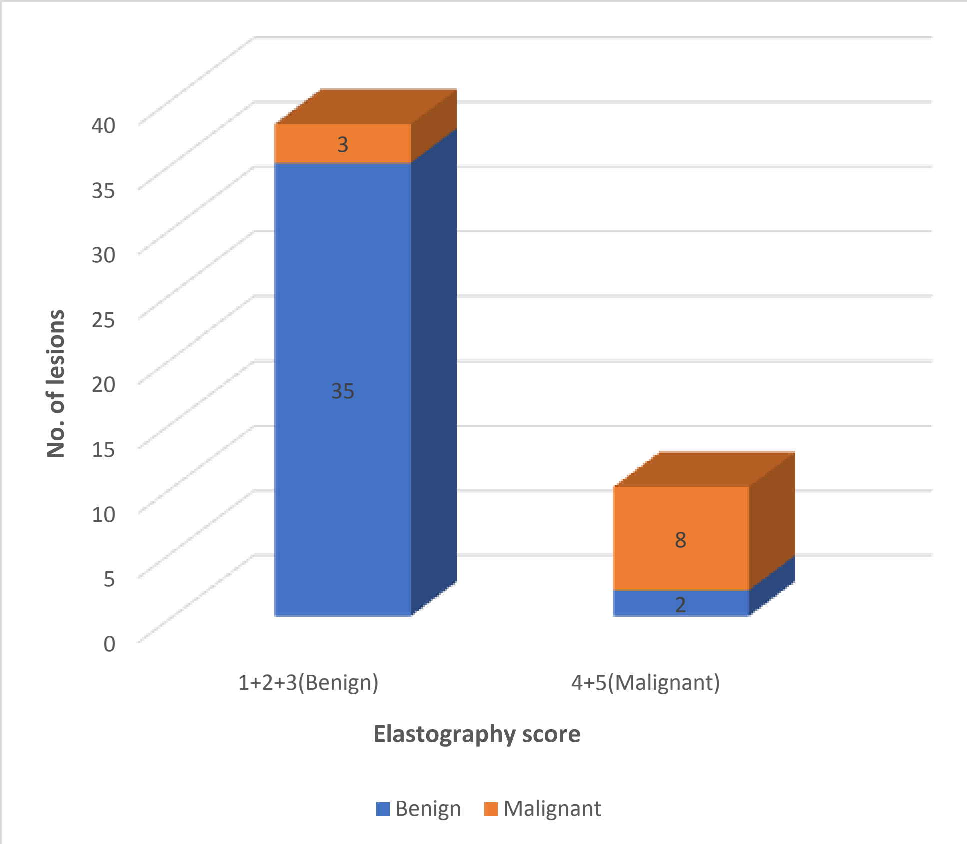

Figure 5: Showing relation between elastography score and pathological diagnosis.

Sensitivity= a/(a+c)*100 = 8/(8+3)*100 = 72.7%
Specificity= d/(b+d)*100 = 35/(2+35)*100 = 94.5%
Positive Predictive Value (PPV) = a/(a+b)*100 = 8/(8+2)*100 = 80%
Negative Predictive Value (NPV)= d/(c+d)*100 = 35/(3+35)*100 = 92.1%
Accuracy= (a+d)/(a+b+c+d)*100 = (8+35)/(8+2+3+35)=89.5%

Imaging

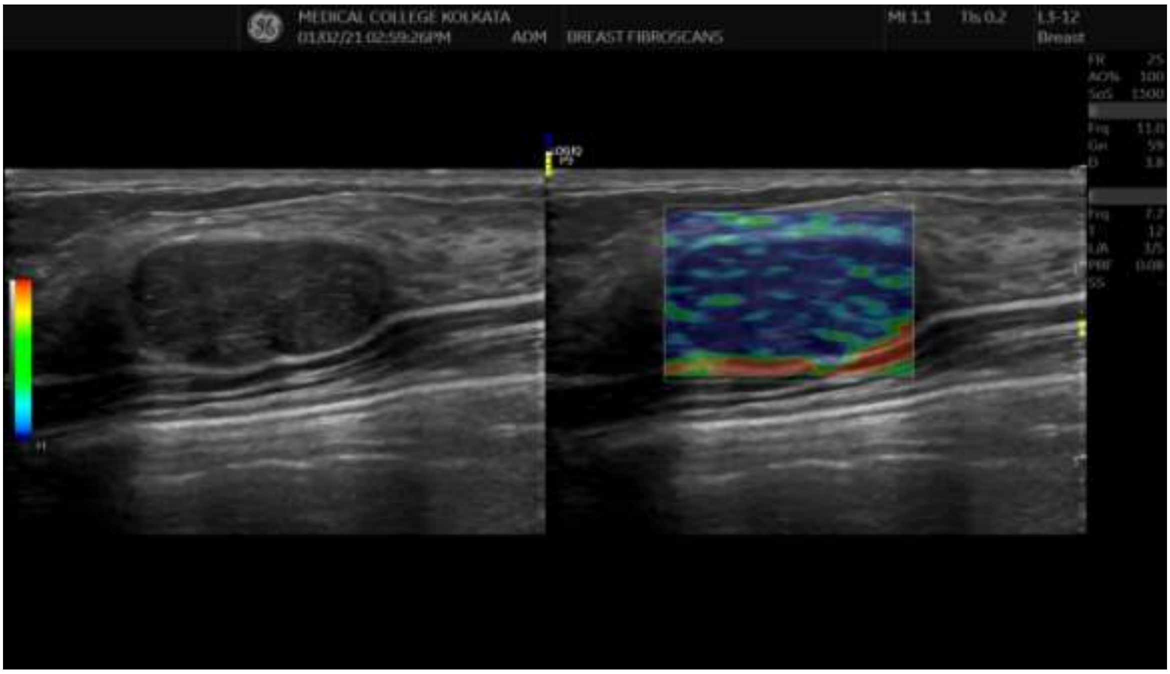

Figure 6: A 23 years old with right sided breast lump. (a) Conventional US showed well defined homogeneous hypoechoic lesion (b) on elastography the score was 3 (heterogenous but mostly blue and appears to be smaller than B mode image). US guided FNAC proved out to be fibroadenoma.

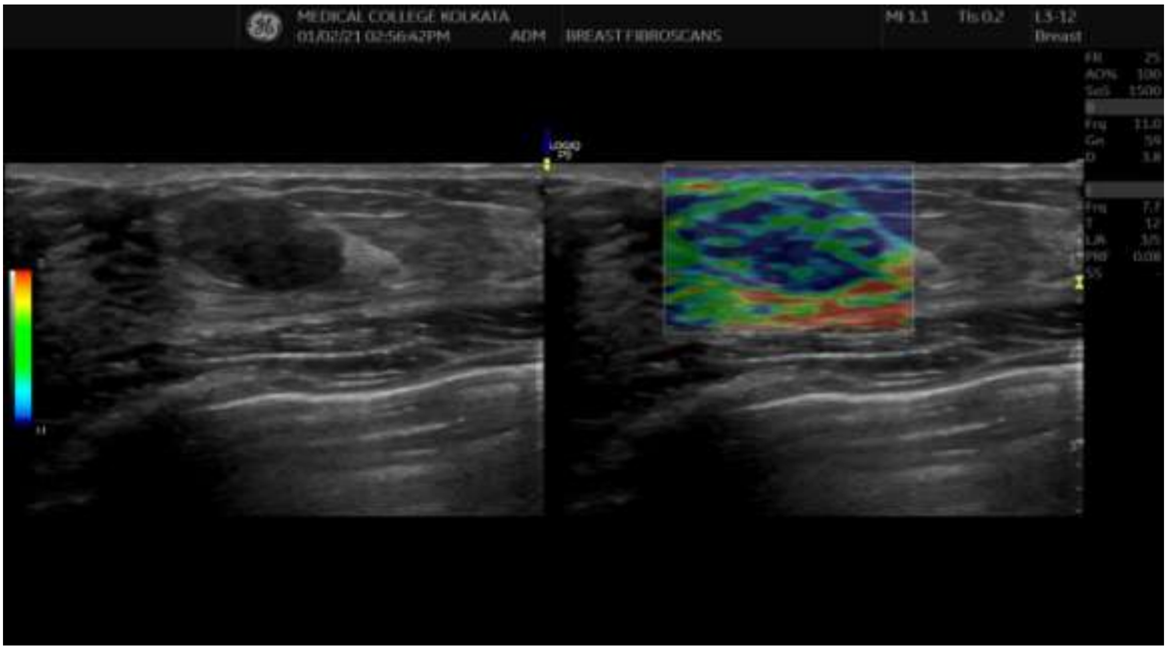

Figure 7: A 26 years old with left side breast lump. (a) Conventional US showed well defined homogeneous hypoechoic lesion (b) on elastography the score was 3 (heterogenous but mostly blue and appears to be smaller than B mode image). US guided FNAC proved out to be fibroadenoma.

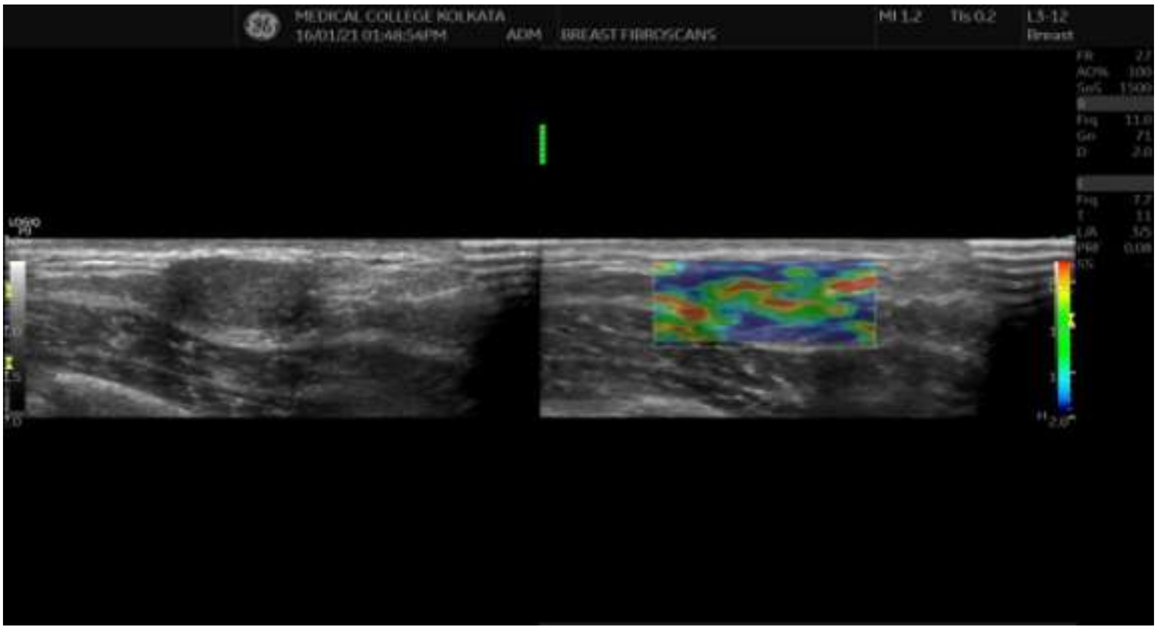

Figure 8: A 42 years old with a breast lump. .(a) Conventional US showed well defined homogeneous hypoechoic lesion (b) on elastography the score was 2 (heterogenous but mostly green and appears to be smaller than B mode image). US guided FNAC proved out to be fibroadenoma.

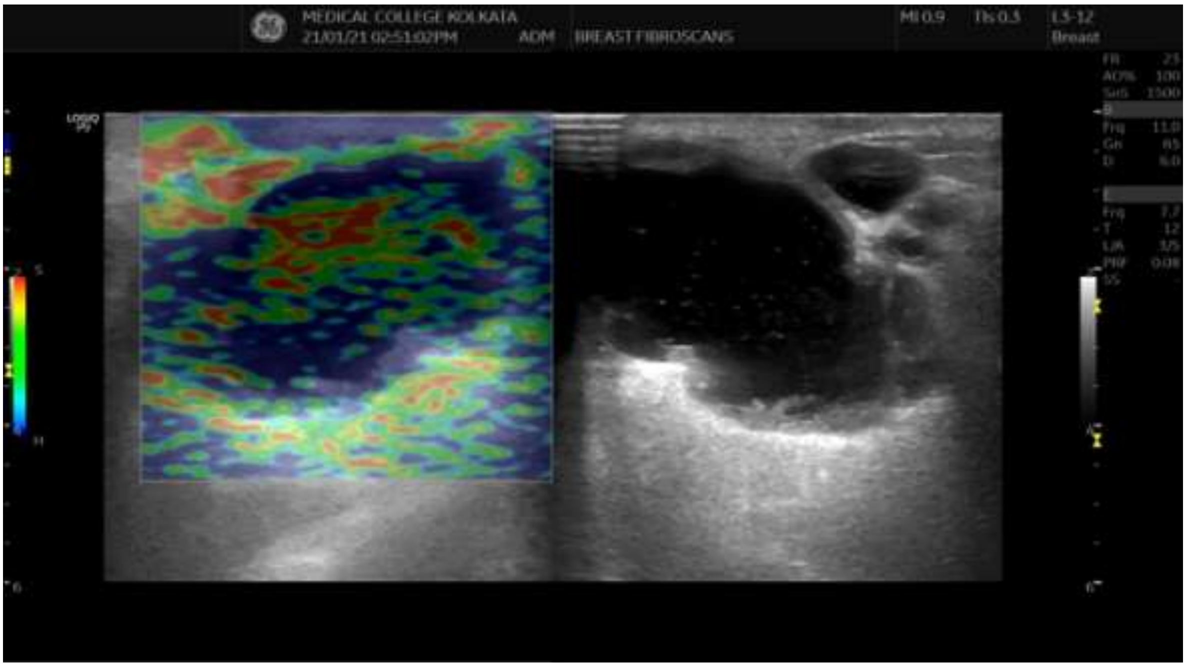

Figure 9: A 25-year-old with mastalgia and breast abscess on clinical examination.
(a) Conventional US showed thick-walled anechoic irregular lesion with echogenic debris inside. (b) on elastography the score was 4(low strain pattern and a uniform blue colour lesion confined to the visible margin of the lesion). On US guided Aspiration, pus was found, confirming it to be abscess. (FALSE POSITIVE CASE)

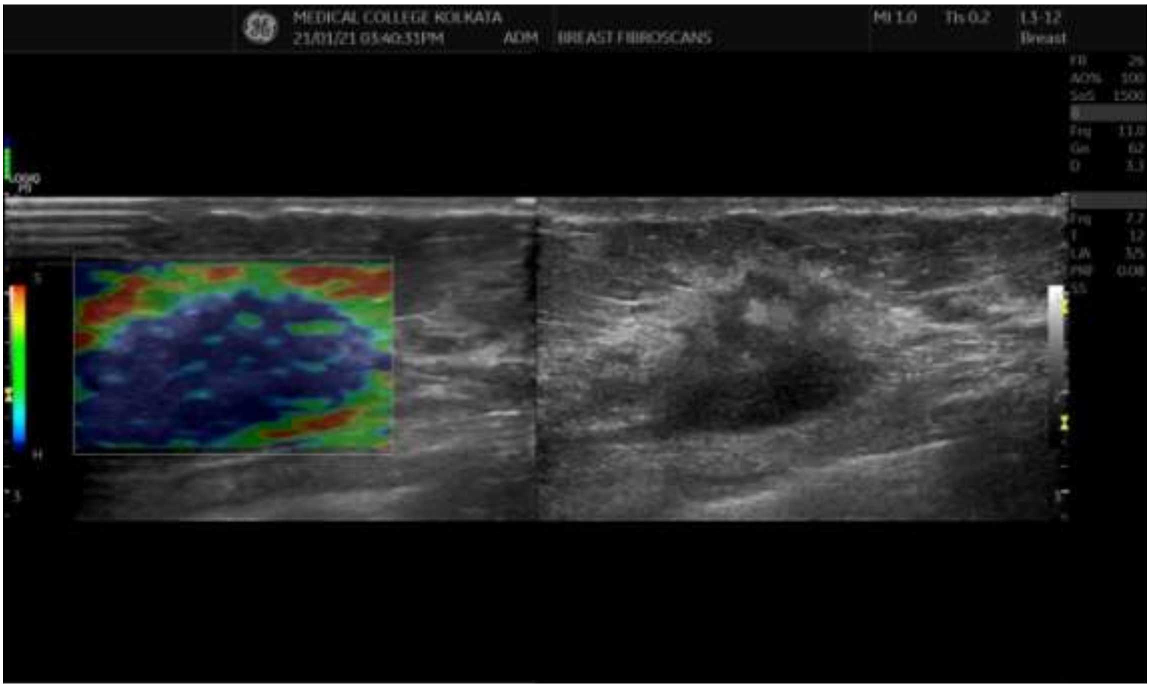

Figure 10: A 55-year-old woman with a right sided hard lump. (a) Conventional US showed a heterogenous hypoechoic lesion with spiculated margins. (b) On elastography the score was 5 (heterogenous mostly blue that extends beyond the lesion into the adjacent tissues. US guided tru-cut core needle biopsy was done which proved it to be invasive ductal carcinoma.

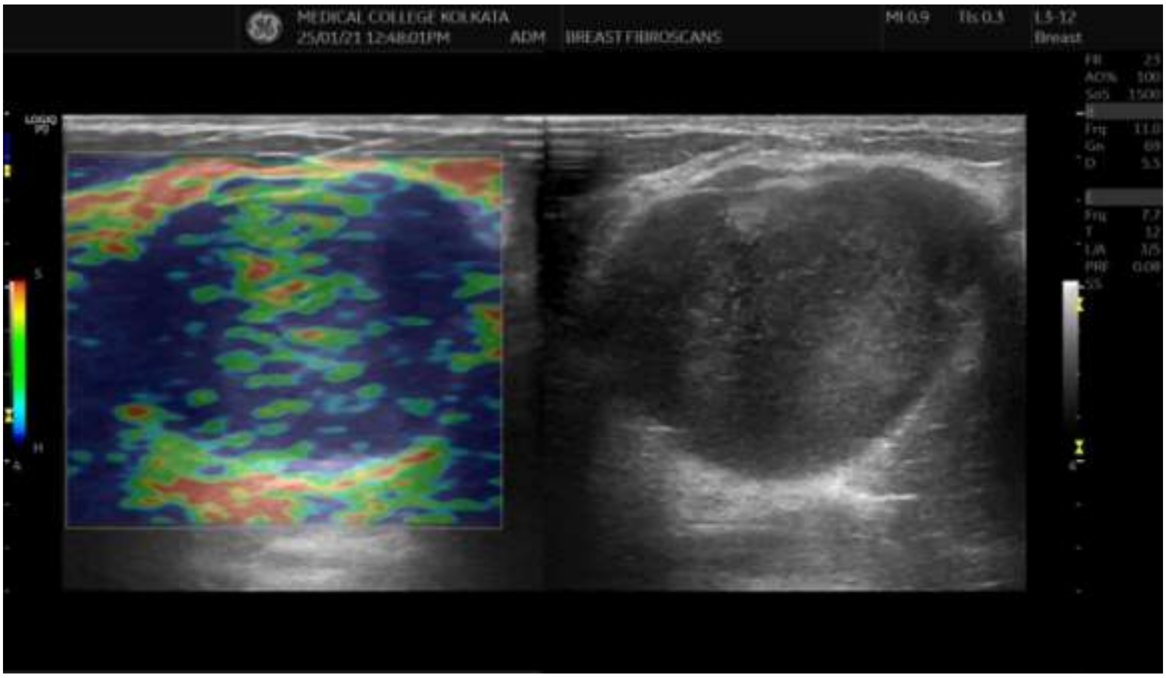

Figure 11: A 34-year-old woman with a left sided breast lump. (a) Conventional US showed a well-defined hypoechoic lesion which appears benign. (b) On elastography however, the score was 4(low strain pattern and a uniform blue colour lesion confined to the visible margin of the lesion). US guided tru-cut core needle biopsy was done which proved it to be invasive ductal carcinoma.

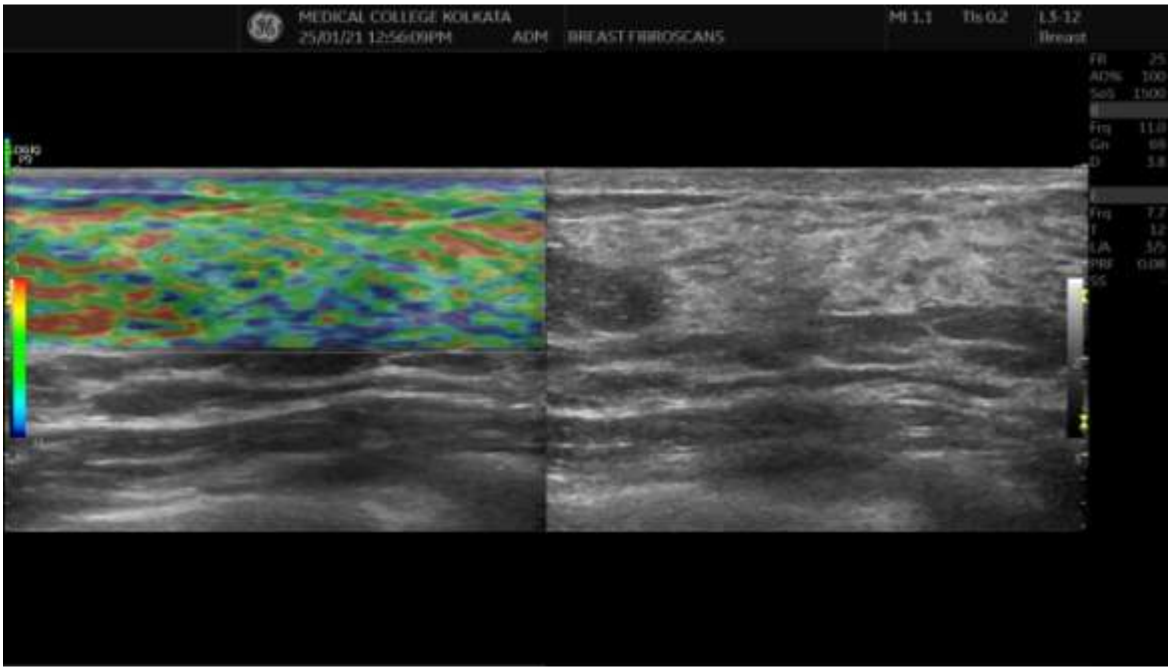

Figure 12: A 17-year-old with mastalgia and left sided breast lump. (a) Conventional US showed heterogenous hyperechoic fibrocystic changes. (b) On elastography the score was 1 (uniform pattern of high strain marked by an evenly distributed green colour throughout the lesion). USG guided FNAC was done which came out to be fibrocystic breast disease.

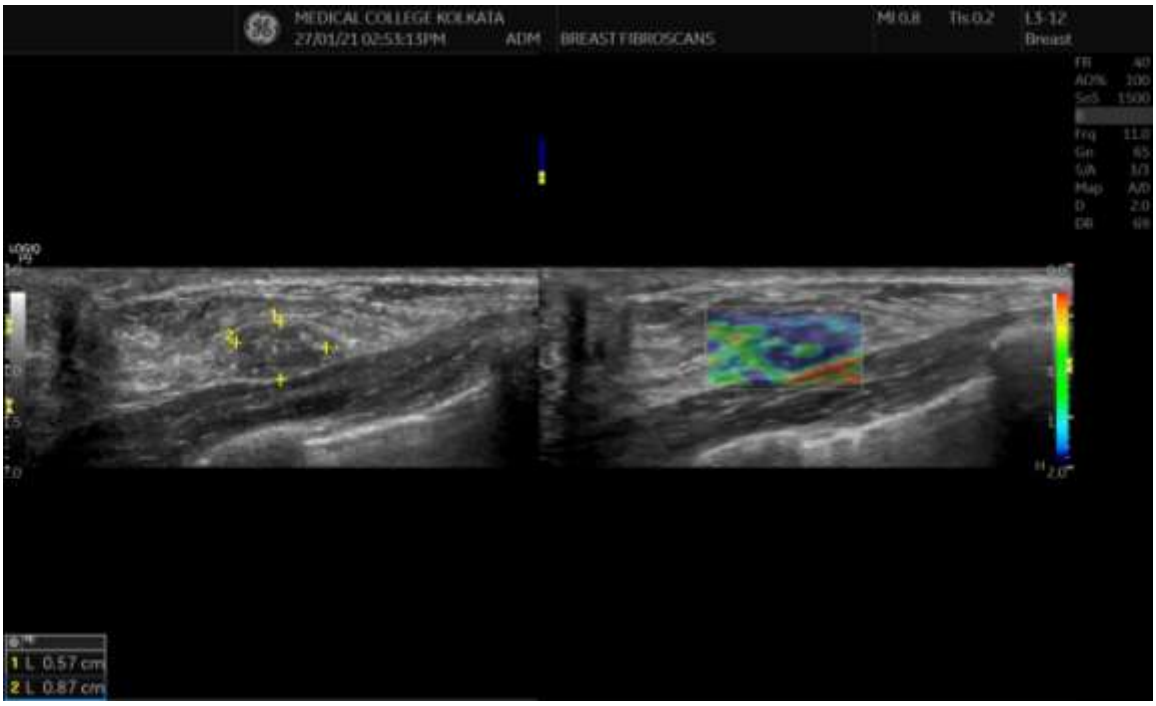

Figure 13: A 55-year-old woman with right sided breast lump. (a) Conventional US showed an irregular hypoechoic lesion with calcifications inside. (b) On elastography the score was 3 (heterogenous but mostly blue and appears to be smaller than B mode image). US guided tru-cut core needle biopsy was done and came out to be invasive ductal carcinoma. (FALSE NEGATIVE CASE).

V. Discussion

Breast cancer is one of the leading causes of malignancy worldwide and this has fuelled tremendous enthusiasm and research for early diagnosis of breast cancers. Early detection of cancer can reduce the morbidity and mortality arising out of breast malignancy. Ultrasound elastography (USE) was developed to help in the early detection and better differentiation of breast lesions.

The interpretation of breast lesions on B-mode USG relies mainly on morphological characteristics, whereas with the use of USE, differentiation of benign and malignant lesions was drastically increased due to variability in their firmness or elasticity. B-mode sonography mainly depends on shape, orientation, margin, internal echotexture, and presence of calcification. USG elastography additionally helps in determining the mechanical properties of tissues. The strain and stiffness can noninvasively be determined by using USE and can be colour-mapped with blue colour indicating region with low elasticity (harder tissue areas) and red colour indicating the region with higher elasticity (softer tissues).

In this study, 37 lesions (77 %) from 48 lesions were benign and 11 lesions(23%) were malignant. Considering the elastography score, a total number of 48 lesions were classified according to modified Ueno and Ito elasticity score system. According to our study, considering the benign lesion with elastography scores 1-3 and malignant lesion with elastography scores 4-5, the sensitivity and specificity of sonoelastography were 72.7%, 94.5% with PPV 80% and NPV 92.1% and accuracy 89.5%. Our results were slightly different from the studies of Thomas., et al. (Sensitivity of 91.8% and specificity of 78%) and Navarro., et al. (Sensitivity of 96.6% and specificity of 76.9%). These slight differences may be probably attributed to different prevelances of breast cancer, different patient selection criteria as well as difference in the number of the standard lesions and differences in the used equipment's.

The use of elastography has drastically increased the differentiation of benign and malignant breast lesions, but its use is limited in very dense breast parenchyma and in case of hamartoma or breast implants. USE has now also been used for differentiation of benign and malignant lesions in prostate, thyroid, lymph nodes, and liver lesions. As with B-mode imaging, there may be interobserver variability in interpretation of elastography images and to decrease that, adequate training and practice is required to learn the appropriate technique.

VI. Conclusion

Elastography should be used as an adjunct to the clinical B-mode examination of suspected breast cancer, and should not be used independently but as an additional role for conventional ultrasound examination assessed by the BIRADs scoring system and not as a separate examination.

Sonoelastography (SE) is widely available and easy to use in a clinical setting. The fact that SE is real time and can be done bedside along the B-mode examination makes the use of SE feasible in a lot of different anatomic areas. In breast cancer, SE has shown great potential and a good diagnostic performance in several studies.

Real-time elastography has shown the potential to provide additional characterization of breast lesions and to improve the specificity for low suspicion lesions achieved at conventional Ultrasonography.

Combined use of B-mode imaging with USE increases enhanced differentiation of benign and malignant lesions with higher specificity and accuracy and can decrease the use of unnecessary breast biopsies, thereby decreasing the morbidity and mortality arising out of breast malignancies.

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