ORIGINAL RESEARCH

Accuracy of Ultrasound Elastography in Characterization of Breast Lesions

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ABSTRACT

Background: The paper reviews elastography's importance in distinguishing benign from malignant breast lesions. Breast cancer accounts for 27% of all cancers among women in India, according to NICPR. Breast lumps can be benign cysts or malignant lesions.4Incidence rises in early 30s and peaks in 50s-64s.

Martial and Methods: This prospective, cross-sectional, diagnostic study was done at NRI General Hospital, Guntur, and Andhra Pradesh, India. 82 individuals were excluded from ultrasound electrography using PHILIPS AFFINITY 70. November 2019-October 2021 was the study's duration.

Results: 53 of 82 research participants had benign lesions. USG found 29 women with malignant lesions. HPE found 45 benign and 27 malignant tumours. In the current study, most women had a bump and mastalgia. Malignancies often cause nosebleeds. Benign instances show mastalgia, lump, swelling. 13 asymptomatic patients. 2 had malignant lesions. 9 were benign. One case of malignant nipple ulcer was found.

Conclusion: Dense breasts reduce mammogram detection of breast cancer. Ultrasonography shows dense glandular tissue as hyperechoic, but breast tumours are hypoechoic and easily recognised. Ionizing radiation limits mammography's age and frequency. Ultrasound elastography is risk-free.

Keywords: Ultrasound, electrography, characterization, breast lesions.

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INTRODUCTION

The paper reviews elastography's importance in distinguishing benign from malignant breast lesions. Breast tumours are the most prevalent among all females. Breast lumps can be benign or cancerous. Differentiating malignant from benign tumours is crucial for patient care. Malignant lesions are most often invasive ductal carcinomas.[1] Breast cancer accounts for 27% of all cancers among women in India, according to NICPR. Incidence rises in early 30s, peaks in 50s-64s.[2] In metropolitan environments, 1 in 22 women acquire breast cancer. 1 in 60 in rural areas. Breast cancer mortality varies by stage, thus early diagnosis is crucial. Stage 0 has a 99% 5-year survival probability, stage l 92%, 2a 82%, 2b 65%, 3a 47%, 3b 44%, and 4 14%. Early diagnosis means early treatment and greater survival chances. Treatment varies by stage. Mammography, Ultrasound, and MRI assist examine breast tissue. Elastography has boosted ultrasound's specificity and helped diagnose breast cancer early. In cases with equivocal Stavros criteria, quantitative elastography with strain ratio enhances diagnostic accuracy (stages 3 and 4 BIRADS).[2-5]

SE identifies benign from malignant breast lesions based on tissue flexibility. Malignant lesions have decreased flexibility and are more complicated than benign ones. Due to nearby desmoplastic reactions, they exhibit higher dimensions on elastography, but benign lesions have a smaller diameter on elastography than on B mode. Elasticity allows a substance to be

deformed by an external force and return to its original shape or size.[1] Strain imaging or shear wave imaging include ARFI and RSV.[3] Applying manual compression/decompression along the longitudinal axis with typical transducers creates strain. Manual compression deformation is transformed into elastic modulus to create elastogram. Real-time elastography evaluates a lesion's size and stiffness. Malignant lesions look larger on elastograms due to desmoplastic response or expansion into surrounding tissue. Strain ratios show lesion rigidity. It's calculated by comparing a lesion's average strain to that of a similar area of breast fat.[4,5] A cutoff between 3 and 4 was suggested to identify benign from malignant breast lesions. Several investigations found that a cut-off point between elasticity scores 1 and 2 or 2 and 3 improved diagnostic performance and reduced interobserver variability.[6,7] Itoh et al,[8] provided a common grading method for strain elastography colour maps.

Aims and objectives of the study

To detect and characterize various breast lesions using ultrasound elastography, a non-invasive technique and determine the sensitivity and specificity of ultrasound elastography.

To find a correlation between strain ratios on Elastography with HPE or FNAC wherever possible.

MATERIALS & METHODS

We have done this study on 82 patients who came to the Radiodiagnosis Department with breast lesions. As per the inclusion and exclusion criteria, we have chosen 82 patients for our study after taking informed consent from them.

Study type, duration, and place: This prospective, cross-sectional, diagnostic study was done at a tertiary care hospital -NRI General Hospital, Guntur, Andhra Pradesh, India - equipped with all necessary facilities. Intervention is in the form of establishing an accurate diagnosis.

Sample size: Around 130 patients visited the Radiodiagnosis dept. NRIMC had breast lesions, requiring USG for diagnosis during the study period. After considering the exclusion criteria, 40 patients were excluded from the study basing on exclusion criteria and 8 patients didn't provide informed consent. So, we have included 82 patients in our study. Ultrasound elastography using –Philips Affinity 70 was done for 82 patients.

Duration of the study: November 2019 to October 2021.

Inclusion Criteria

1. Asymptomatic women undergoing screening mammography.
2. Patients with symptoms related to the breast such as breast lumps, mastalgia, nipple discharge, nipple retraction etc.
3. Physical examination suggestive of palpable lump in the breast.

Exclusion Criteria

1. Pregnant and lactating women.
2. Asymptomatic women less than 25yrs of age.
3. Normal findings on Ultrasonography of the breast.

Materials

The main equipment used in this study is Ultrasound elastography affinity-70 Philips machine.

Figure 1: Philips Affinity 70–Ultrasound equipment

Elasticity scores of 3 and 4 were suggested to differentiate benign from malignant breast lesions. But, a cut-off point between 1 and 2 or 2 and 3 found to achieve better diagnostic performance with less interobserver variability, as per previous studies. A color scale that ranges from 0(dark blue, soft) to +180 kPa (red, hard) is used for detecting breast masses.

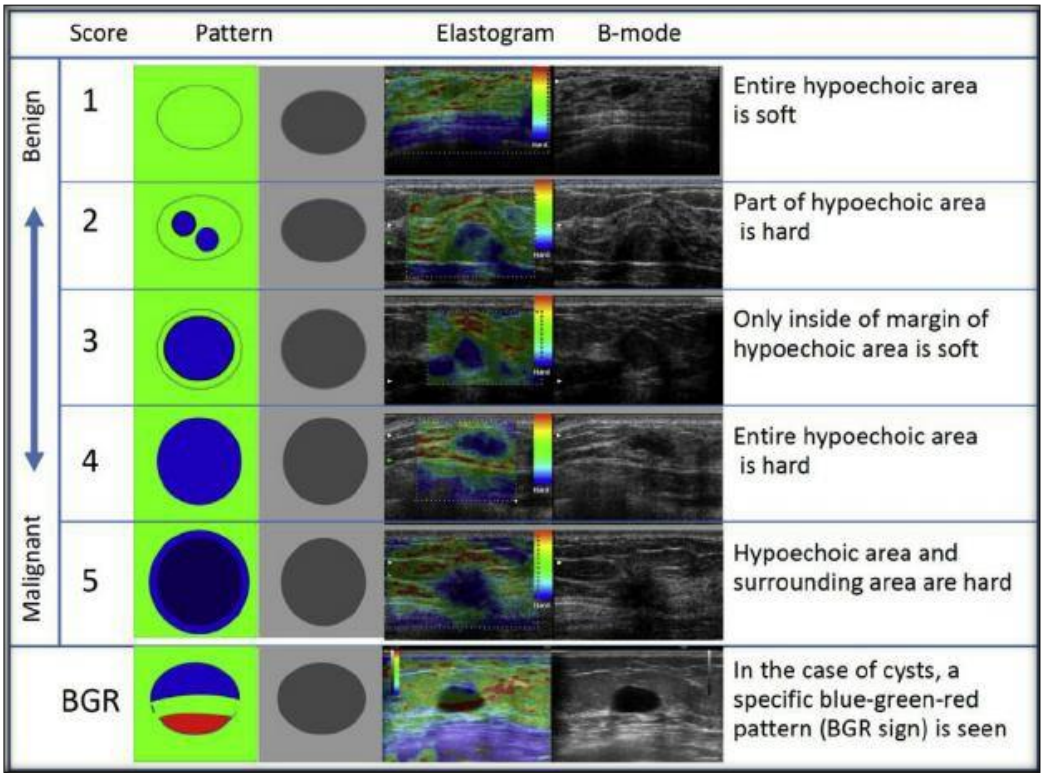

Figure 2: Elastography scoring system

Score of 1: Even strain throughout the entire lesion-benign;
Score of 2: Strain in most of the hypoechoic lesion with some areas of no strain- benign;
Score of 3: Strain at the periphery of the hypoechoic lesion with sparing of the center of the lesion-probably benign
Score of 4: No strain throughout the entire hypoechoic lesion-malignant;

Score of 5: No strain throughout the entire hypoechoic lesion or in the surrounding area- malignant.

RESULTS

Statistical analysis was done using statistical software named Statistical Package for the Social Science version 20.0.0 (SPSS Inc., Chicago, Illinois, USA). The categorical variables or qualitative data were expressed in frequency or number and percentage.

Demographic details:

Age: Age of the women participated in this study ranged from 31 years to 80 years. Most of the women belonged to the age group 41-50 years, indicating breast lesions are common in this age group.

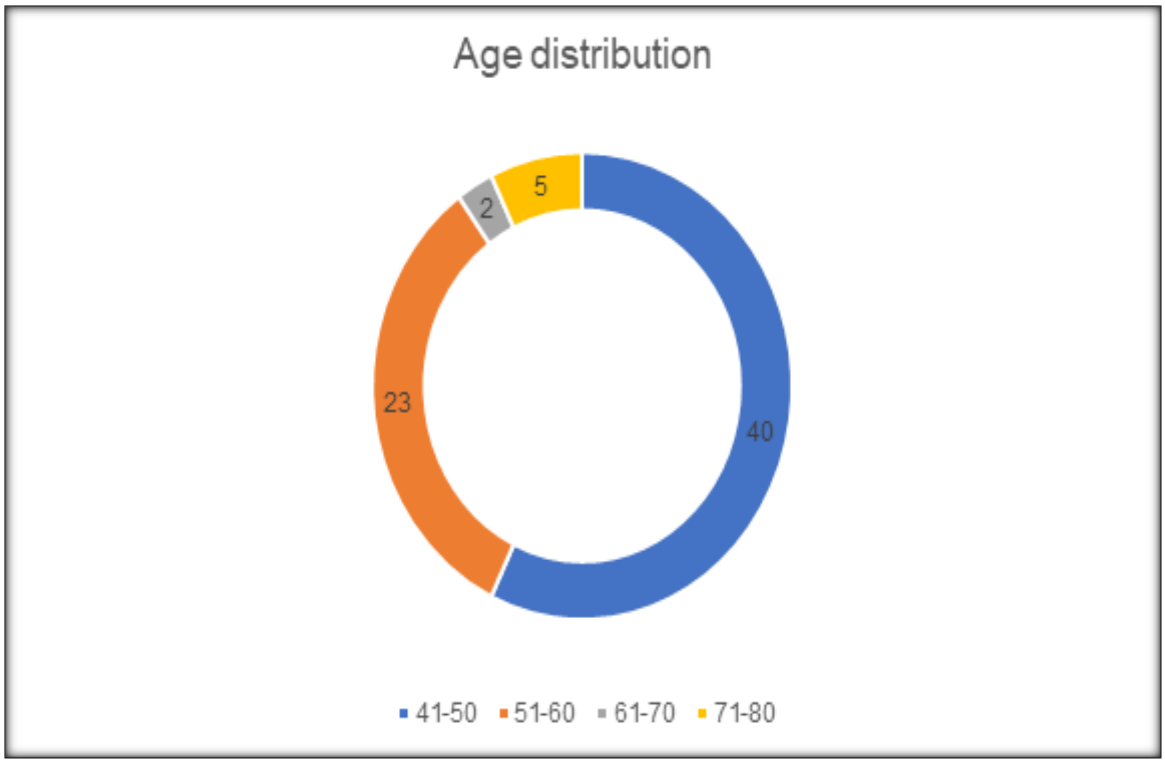

Figure 3: Age distribution of women

Table 1: Age distribution of women

Age in years	No of women	% of women
31-40	12	14.6%
41-50	40	48.7%
51-60	23	28%
61-70	2	2.4%
71-80	5	6.0%
Mean age ± SD	49.30 ± 9.56	

Malignant and benign lesions:

In the current study, 53 women out of 82 had benign lesions. 29 women had malignant lesions, as per USG findings. 45 patients had benign lesions and 27 had malignant lesions as per HPE findings.

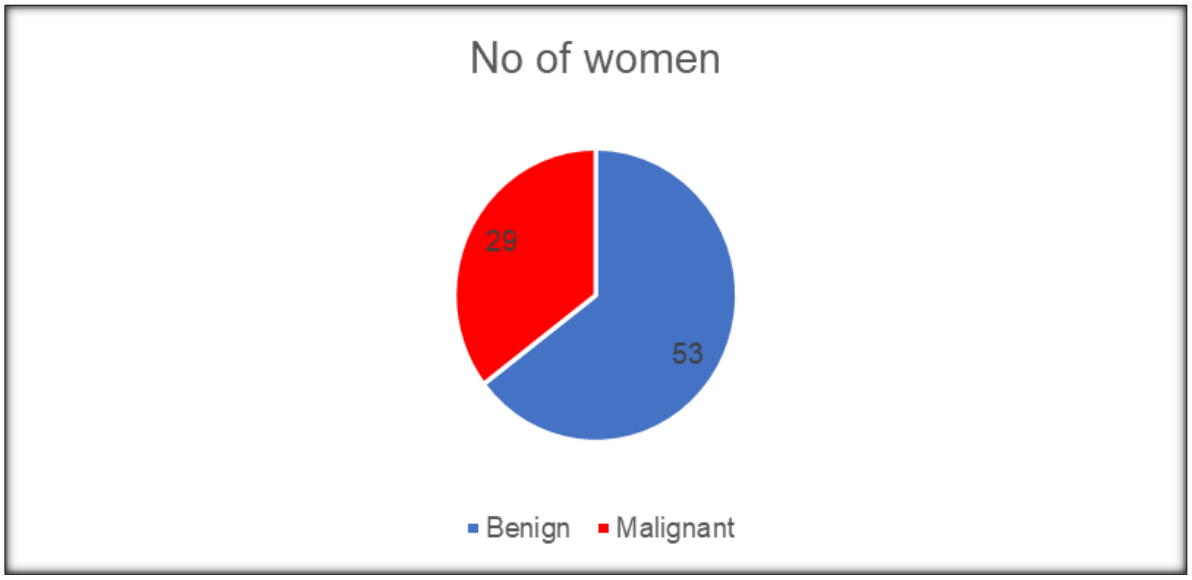

Figure 4: No of benign and malignant lesions

Table 2: Mean age of patients with benign and malignant lesions

Nature of lesion	Mean age ± SD	P value
Benign	50.2± 10.3	0.49
Malignant	48.72 ±8.9	

As per the above table, there are no significant differences in mean ages of women with benign and malignant lesions as evident from the p value of 0.49.

Complaints: Most of the women presented with lump followed by mastalgia in the current study. Nipple discharge is commonly seen in malignant cases. Mastalgia, lump, swelling are seen in benign cases 13 patients are asymptomatic. Among them, 2 women had malignant lesions. 9 had benign lesions. Nipple ulcer is seen in only 1 case, who had a malignant lesion.

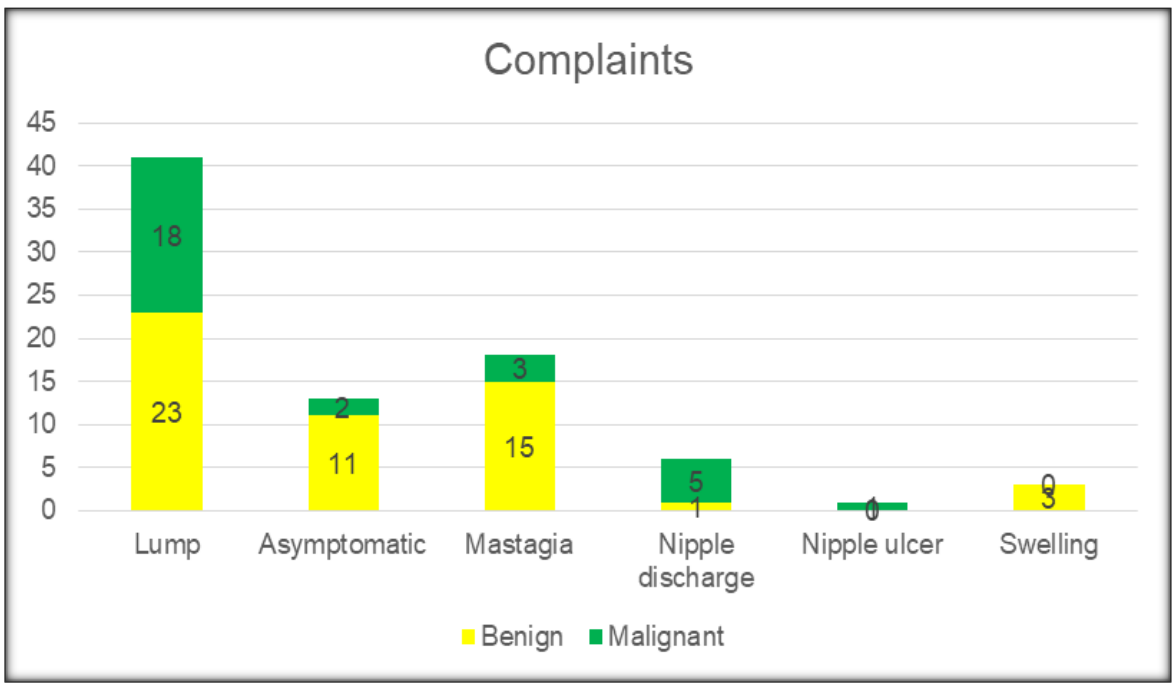

Figure 5: Complaints of patients with benign and malignant lesions

Side of the lesion:
Most of the women had a breast lesion on the right side, followed by left side. Only 9 women had bilateral lesions.

Table 3: Involved side of the lesion

Side	Malignant lesions	Benign lesions	Total and %
Right	15	27	52(63.4%)
Left	13	18	31(37.8%)
Bilateral	1	8	9(10.9%)

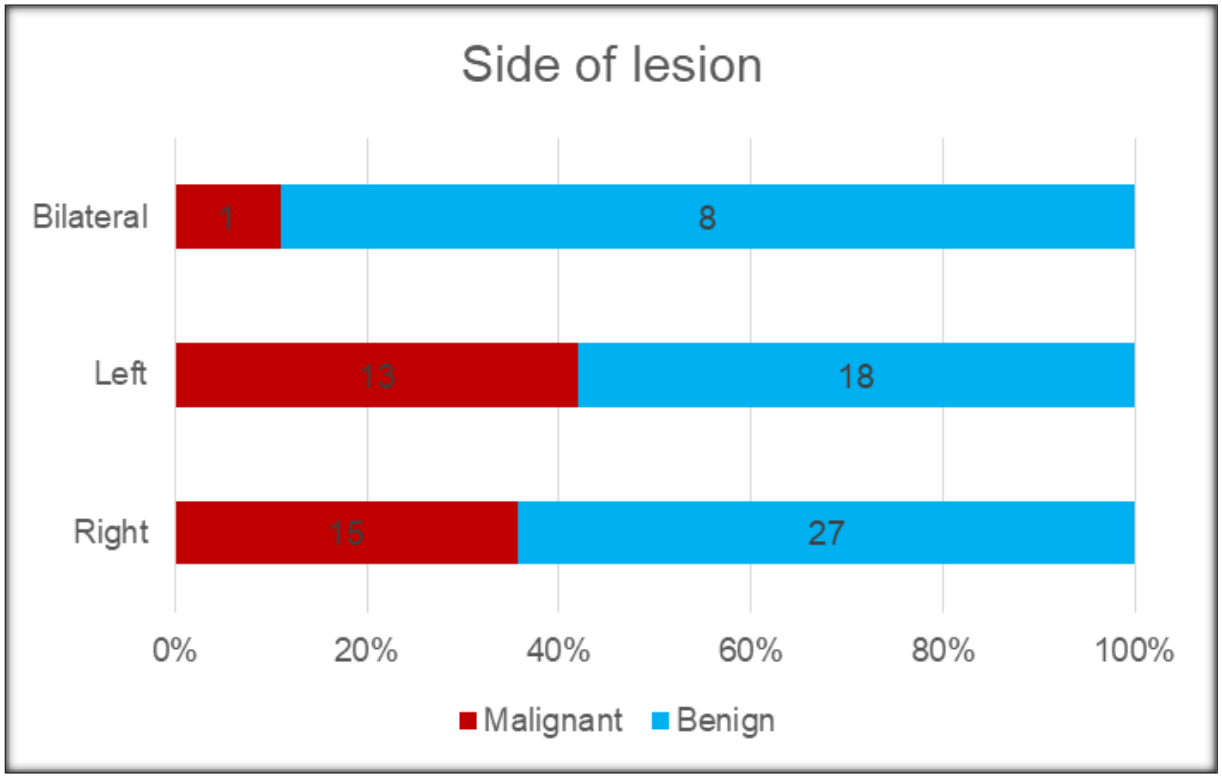

Figure 6: Involved side of the lesion

Quadrant involved:
In 41(50%) women, upper outer quadrant is involved in the current study, indicating that upper outer quadrant is most common site of breast lesions. Upper inner quadrant is involved in only 3 women.

Table 4: Quadrant involved in lesions

Quadrant	Malignant lesions	Benign lesions	Total lesions and %
Upper outer	24	27	41(62.1%)
Upper inner	1	2	3(3.6%)
Central	2	12	14(17%)
Lower outer	1	6	7(8.5%)
Lower inner	1	6	7(8.5%)

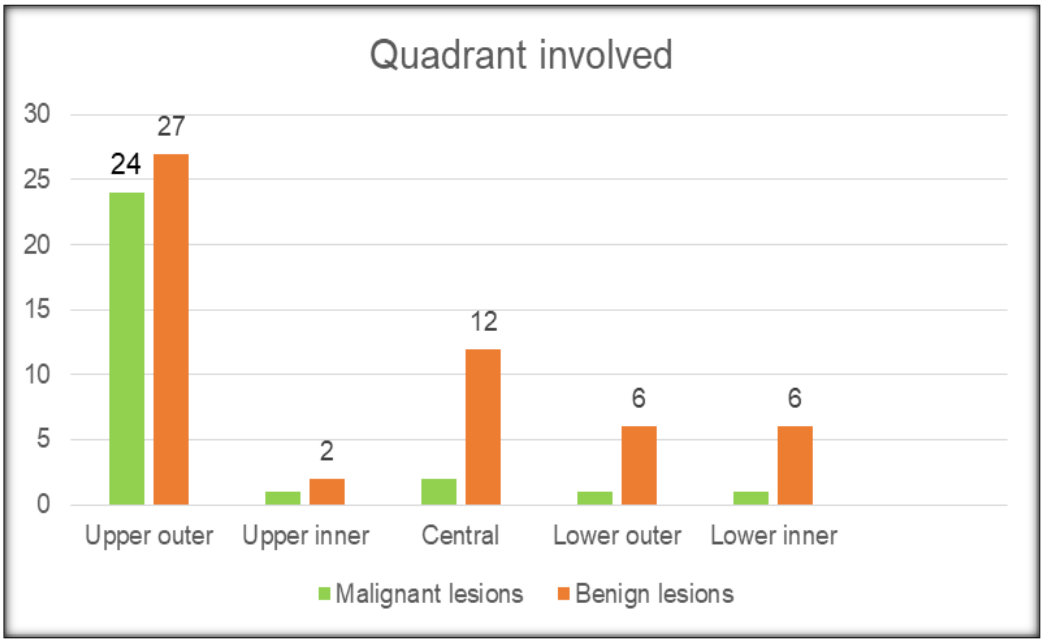

Figure 7: Quadrant involved in lesions

Margins:
Most of the women had well defined (29.2%) margins followed by spiculated margins in the current study. All spiculated margins are seen in malignant lesions. Most of the indistinct margins are seen in malignant lesions.

Table 5: Status of margins in lesions

Margins	No of malignant lesions	No of benign lesions	Total lesions and %
Well defined	0	24	24(29.2%)
Spiculated	14	0	14(17%)
Indistinct	6	3	9(10.9%)
Lobulated	3	19	22(26.8%)
Obscured	6	7	13(15.85%)

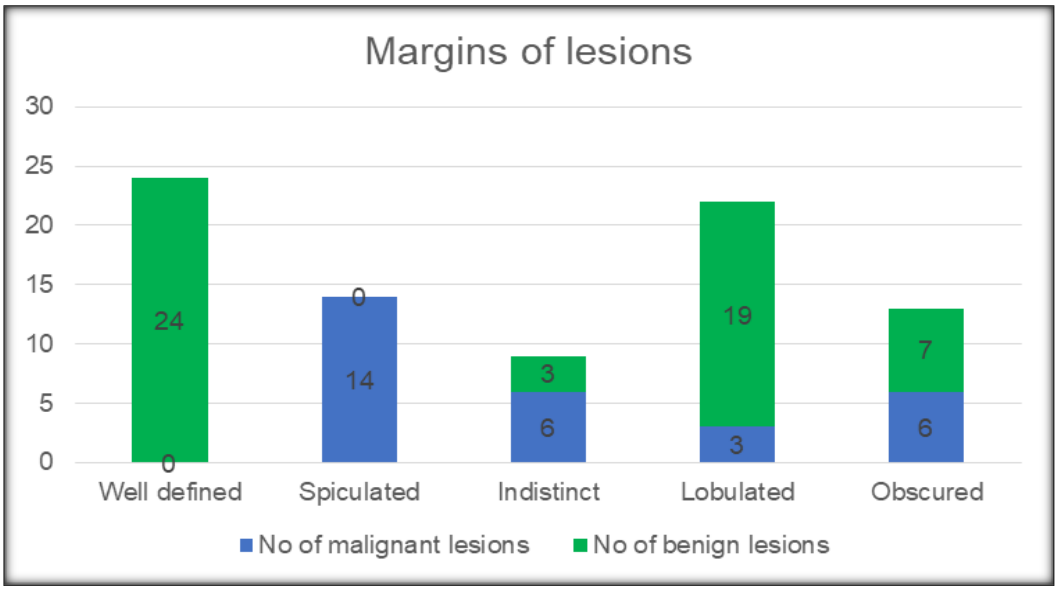

Figure 8: Margins in lesions

BIRADS Staging:
Most of the patients had stage III in BIRADS classification.

Table 6: BIRADS staging in lesions

BIRADS Stage	No of malignant lesions	No of benign lesions	Total lesions and %
II	0	25	25(30.4%)
III	0	28	28(34.1%)
IV	19	0	19(23.1%)
V	10	0	10(12.1%)

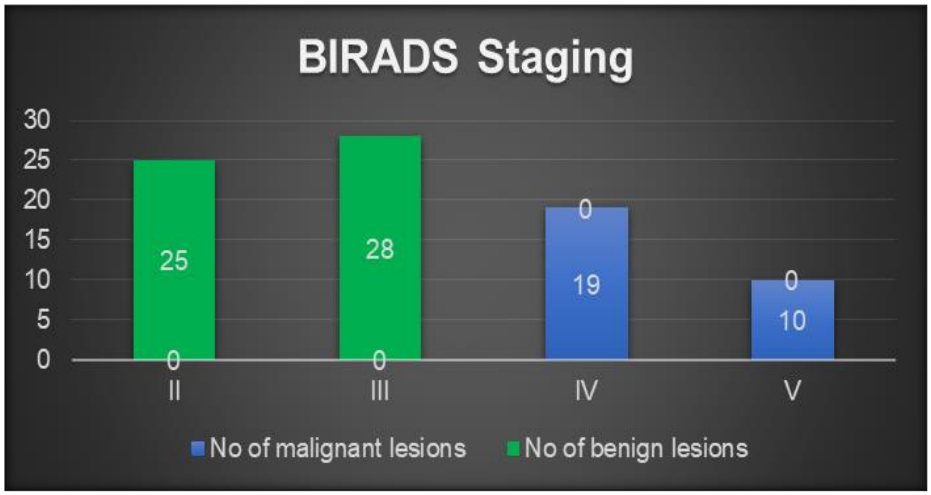

Figure 9: BIRADS staging in lesions

Elastography strain:
The mean strain of all lesions found to be 2.43. In the current study, the mean strain for benign lesions was found to be less than malignant lesions. The difference is very significant as evident by the p value. $P < 0.0001$.

Table 7: Mean strain of lesions

	Mean Strain	P value
Benign	1.5±0.72	P < 0.0001
Malignant	4.58±1.11	

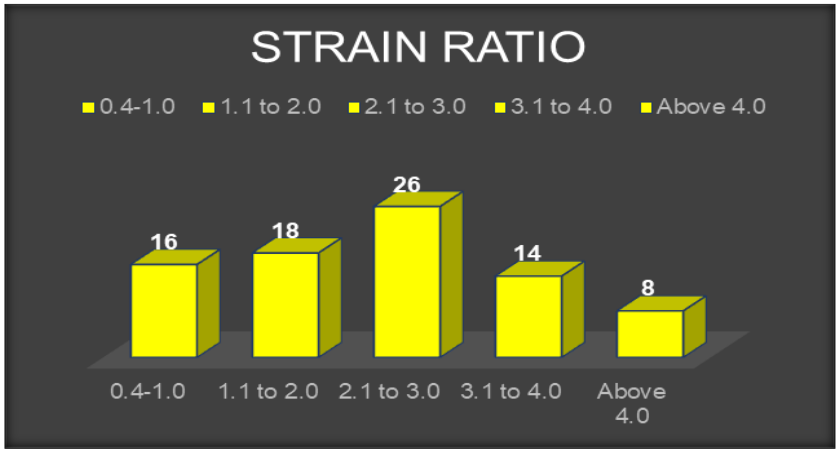

Figure 10: Strain Ratios of lesions on US elastography:

Most of the lesions are wider than taller.Malignant lesions are usually found to be wider than taller in the current study.

Table 8: USG Findings of lesions

	No of benign lesions	No of malignant lesions	Total lesions and %
Wider than Taller	34	16	50 (60.9%)
Taller than wider	19	13	32(39.1%)

DISCUSSION

The high prevalence of breast cancer and a need for early treatment prompts an accurate and early diagnosis. Non-invasive diagnosis of the breast masses with imaging modalities remains one of the major areas of interest. Mammography and USG are the diagnostic methods with the highest sensitivity in detecting breast cancer. Elastography is a new screening modality for characterizing lesions in the breast. A biopsy is an indispensable method to confirm malignancy. Increased numbers of aggressive biopsies performed for benign abnormalities is an additional problem due to the risk of infection, resultant anxiety, discomfort, and increased costs. USE is a new modality that provides details on the stiffness of the lesion. This study is carried out to evaluate the role of elastography in evaluating various breast lesions. We evaluated 82 patients in this prospective study. Age of the women participated in this study ranged from 31 years to 80 years. Most of the women belonged to the age group 41-50 years, indicating breast lesions are common in this age group. In the current study, 53 women out of 82 had benign lesions. 29 women had malignant lesions, as per USG findings. 45 patients had benign lesions and 27 had malignant lesions as per HPE findings. There are no significant differences in mean ages of women with benign and malignant lesions as evident from the p value of 0.49. Most of the women presented with lump followed by mastalgia in the current study. Nipple discharge is commonly seen in malignant cases. Mastalgia, lump, swelling are seen in benign cases 13 patients are asymptomatic. Among them, 2 women had malignant lesions. 9 had benign lesions. Nipple ulcer is seen in only 1 case, who had a malignant lesion.

Most of the women had a breast lesion on the right side, followed by left side. Only 9 women had bilateral lesions. In 41(50%) women, upper outer quadrant is involved in the current study, indicating that upper outer quadrant is most common site of breast lesions. Upper inner quadrant is involved in only 3 women. Most of the women had well defined (29.2%) margins followed by spiculated margins in the current study. All spiculated margins are seen in malignant lesions. Most of the indistinct margins are seen in malignant lesions. Most of the patients had stage III in BIRADS classification, followed by stage II.

Elastography strain:

The mean strain of all lesions found to be 2.43. In the current study, the mean strain for benign lesions was found to be less than malignant lesions. The difference is very significant as evident by the p value. $P < 0.0001$ It was found that all the lesions above 3.1 are found to be malignant in the current study. Most of the lesions are wider than taller. Malignant lesions are usually found to be wider than taller in the current study.

We have compared our elastography results with HPE results to differentiate benign from malignant lesions. Sensitivity was 83.78%, specificity was found to be 95.56%

Side of the lesion

In our study, breast lesions are found to be more common on the right side. The studies of Srivastav,[32] et al and Dixit,[33] et al. showed similar right-sided preponderance in 53% and 61 % cases. Wynder,[34] et al. and Haagensen,[35] et al. noted breast masses more on left side.

Table 9: Comparison with Farooq's study:

Parameters	Farooq' study	Current study
Study period	2019	2020-2021
Lesions studies	Breast lesions	Breast lesions
Sample size	155	82
Age	20-70 years	31-80 years
More lesions	More lesions are malignant	More lesions are benign
Sensitivity	92.17%	83.7%
Specificity	90.4%	95.7%
PPV	96.36%	93.9%
NPV	80%	87.76%
Accuracy	91.61%	90.24%

Comparison with the study of Hui,[36] et al:

This study evaluated 296 lesions. Out of them, 87 were histologically malignant, and 209 were benign. Ultrasound elastography was most specific (95.7%) and had the lowest false-positive rate in this study. In our study, 33 lesions are malignant out of 82 lesions. Ultrasound elastography was found to have a specificity of 95.56%.

Table 10: Comparison with sidigh's meta-analysis:

Parameters	Sidigh's meta-analysis	Current study
Study period	2012	2020-2021
Lesions studies	Breast lesions	Breast lesions
Sample size	2087 masses	82
More lesions	More lesions are benign	More lesions are benign
Sensitivity of SR	88%	83.7%
Specificity of SR	83%	95.7%

Comparison with Ioana Andreea,[22]s study:

In loana's study, 58 patients diagnosed with breast lesions were evaluated. All the patients were examined in supine position and the B-mode USG image was displayed alongside the elastography strain image. They used EUS Hitachi EUB 8500 ultrasound system with a 6.5-MHz linear probe. Results showed that USE had a sensitivity of 86.7%, a specificity of 92.9% for elasticity score, a sensitivity of 93.3%, and a specificity of 92.9% for SR. In this study, the cut-off point of 3.67 was used. In our study, we didn't evaluate elasticity score. Our cut-off point was found to be 3.1 for malignant lesions. In our study, the sensitivity was found to be 83.7% for strain ratio.

Table 11: Comparison with Gheonea's study:

Parameters	Gheonea's study	Current study
Study period	2009-2010	2020-2021
Lesions studies	Breast lesions	Breast lesions
Sample size	58	82
Sensitivity of SR Cut off 3.67	93.3%	83.78%
Specificity of SR	92.9%	95.7%

Nariya Cho,[37] et al's study:

In this study, ninety-nine nonpalpable breast masses were evaluated. Out of 99, 79 are benign, and 20 are malignant. The strain index was calculated by dividing the strain value of the subcutaneous fat by that of the mass. The diagnostic performance of the strain index and B-mode USG were compared by receiver operating characteristic curve analysis. Results show that the mean strain index values as 6.57 +/- 6.62 in malignant masses and 2.63 +/- 4.57 in benign masses.

Table 12: Comparison of our study results with Hyun Jin:[38]

The following table shows the comparison of our elastography results with Hyun Jin's study:

	Current study	**Hyun jin's study**
Total lesions	82	110
Benign/ malignant	53/29	67/43
Strain ratio cut off value	3.1	4.21
Sensitivity	83%	86%
Specificity	95%	85%

Table 13: Comparison of our study results with Hasan Yerli:[39]

The following table shows the comparison of our elastography results with Hasan's study:

Parameters	**Current study**	**Hasan's study**
Total lesions	82	78
Benign/ malignant	53/29	62/16
Strain ratio cut off value	3.1	3.52
Sensitivity	83%	80%
Specificity	95%	93%

The sensitivity and specificity of elastography obtained in our study is more compared to Hasan's study. But the strain ratio in our study is less than hasan's study.

Table 14: Comparison of our study results with Lee,[40] et al:

The following table shows the difference of our elastography results with Lee's study:

Parameters	**Current study**	**Lee's study**
Total lesions	82	315
Benign/ malignant	53/29	267/48
Sensitivity	83%	93%
Specificity	95%	51%

The specificity of elastography obtained in our study is more compared more compared to Lee's study. Lee didn't analyse the strain ratio cut off value.

Study of Hyo Jin Kim:[42]

In this study, 108 breast masses were evaluated with strain and shear wave elastography. The diagnostic performance was compared. Out of the 108 masses, 64 were benign- more benign masses similar to our study. The areas under the curves or AUCs were found to be significantly higher for strain and shear wave elastography-supplemented ultrasonography compared to the ultrasonography alone. We didn't asses AUC in our study. The performances of strain and elasticity ratios were found to be same in differentiating benign from malignant masses. The study concluded that both elastographies improved the diagnostic performance of conventional ultrasonography in the qualitative and quantitative assessment of breast masses.

CONCLUSION

We conclude that breast cancer was less likely to be detected by mammography in women with dense breasts. Dense glandular tissue usually has a hyperechoic appearance on ultrasonography, and mostly breast cancers are hypoechoic and hence easily detected on ultrasonography. Mammography uses ionizing radiation, thus limiting the age and frequency. But, there is no such risk seen with ultrasound elastography. Though conventional B-mode US is more sensitive in picking up breast lesions, elastography based on strain ratios is more specific in differentiating lesions into benign and malignant. Thus, it aids in reducing the number of biopsies in BIRADS III and BIRADS IV categories. When Elastography was combined with the B-mode US, the diagnostic performance was significantly improved compared with the B-mode US alone. Thus, Elastography should be used as an add-on to conventional B-mode US.

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