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Original Research Article

Comparative Evaluation of Ultrasound Elastography with Fine Needle Aspiration Cytology and Histopathological Examination of Breast Masses

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Abstract:

Background: Breast malignancies are the most common clinical condition diagnosed amongst women worldwide. Ultrasonic elastography is a non-invasive diagnostic technique for detecting the mechanical properties of tissues and seems to compensate for the shortcomings of conventional Ultra Sonography (USG). This study aimed to evaluate the accuracy of ultrasound elastography for determination and characterization of different breast masses and to investigate its role in distinguishing between benign and malignant breast masses with Fine Needle Aspiration Cytology (FNAC) and histopathological correlation.

Methods: A total of 252 patients with USG-confirmed breast lesions were included in this study, of which 12 were lost during follow-up and excluded. Finally 240 patients remain for the study.

Consecutive individuals with palpable breast lesions were evaluated using standard B-mode USG. The patients proven to have a breast lesion were next examined using Strain Elastography (SE). FNAC was employed for histopathological confirmation of malignant breast lesions. The benign lesions were identified by a combination of FNAC and biopsy and were monitored for next six months.

Results: Out of 240 suspected breast cancer 92 (38.3%) were malignant and 148 (61.7%) benign lesions. The mean stain ratio (SR) for benign lesions was 2.1, which was substantially less malignant lesions (4.2). When a cut-off value of 3.5 was utilized, the elasticity score showed 82.6% sensitivity and 92.8% specificity and the accuracy 88.2%. When a cut off of 2.95 was employed, SR scores showed 89.3% sensitivity and 89.6% specificity and accuracy 92.1%

Conclusions: Ultrasound elastography is a non-invasive, simple and quick procedure for improving the sensitivity, specificity and accuracy of USG and reducing the number of unwanted biopsies.

Keywords: Breast cancer, FNAC, Histopathology, Ultrasound elastography.

Introduction

Breast cancer is the most often diagnosed cancer and the main cause of cancer mortality in women globally. [1] As it affects an increasing number of women in their productive age group, it is critical to assist in the early diagnosis of the condition.

In current scenario, clinical examination like palpation, mammography and USG are the common diagnostic procedures performed to diagnose breast cancer, with different level of accuracy and predictive value. [2] Clinical palpation is the simplest assessment approach; however it has limited utility due to low sensitivity and accuracy. Breast cancer at early stage can be detected by Mammography through indirect signs, such as sand calcifications.

However, some studies have reported its limitations in detecting lobular cancer, intraductal cancer without characteristic microcalcifications, locally invasive cancer, multifocal cancer, and recurrent cancer after hormone replacement therapy (HRT). [3]

USG appears to be a better screening tool due to features such as simplicity, non-invasive nature and real time dynamic imaging procedure; but the

specificity is low because most solid tumours are benign. To achieve sufficient specificity, numerous tumor features must be categorized according to the Breast Imaging Reporting and Data System (BIRADS) standards score published by the American College of Radiology (ACR). [4]

Unfortunately, even reporting according to these criteria may not aid in the differentiation of certain tumors, resulting in an unnecessary rise in the number of breast lesion biopsies. [5,6] Ultrasound elastography is a non-invasive procedure for detecting mechanical properties of breast tissue. It appears to compensate for the shortcomings of traditional USG in the sense that it can clearly identify and pinpoint breast tumors in the E-mode (Elasticity mode).

The purpose of this study was to assess the sensitivity, specificity and accuracy of ultrasonic elastography in detecting and characterizing distinct breast masses, as well as to investigate its involvement in discriminating benign and malignant breast masses using FNAC and histological correlation.

Material and Methods

The present study was a hospital based observational prospective study. The study was conducted at Rama Medical College, Hospital & Research Centre, Kanpur, UP. The study period was three years (from January 2021 to December 2023). Patients referred from gynae department to the radiology department with complain of breast swelling which was diagnosed by USG considered as the study population. In all, a total of 240 patients were studied.

Inclusion Criteria

1. Patients with breast edema verified by USG were included.
2. Patients with incidentally found lesions on mammography were also included.

Exclusion Criteria

1. Patients who failed to follow-up were excluded.
2. Patients who did not give consent to USG, FNAC, or histopathology were also excluded.

Patients presenting with breast edema visiting the gynecology department were first clinically examined by palpation and then referred to the radiodiagnosis department for ultrasonic elastographic evaluation.

Consecutive individuals with palpable breast lesions were evaluated using standard B-mode USG. Those who were proven to have a breast lesion were then evaluated using Strain Elastography (SE) following informed written consent. Conventional USG pictures and real-time elastographic data sets were acquired utilizing a 12-MHz linear transducer.

Histological and Cytological diagnosis was performed by the co-investigator (pathologist) who was blinded to the radiological observations. The co-investigator had access to the clinical history of the patient provided with the requisition in the department of pathology, Rama Medical College, Hospital & Research Centre, Kanpur, U.P.

FNAC was used for histocytological confirmation of malignant lesions. The benign lesions were confirmed by a combination of FNAC and Histology and were followed up for next six months.

Statistical analysis was performed by calculating the sensitivity, specificity and accuracy for SR values and elasticity score. A p-value <0.05 indicated statistical significance. Microsoft Excel (2010) was used for data collection and statistical analysis.

Observation and Results

A total of 252 patients with enlarge breast masses diagnosed by USG were enrolled in current study, out of which 12 had to be excluded out of loss to follow-up. So, finally 240 patients were considered for subsequent statistical analysis.

Most (n=92; 38.4%) of the participants were belongs to the age group 31-40 years, followed by (n=62; 25.8%) belongs to age group 41-50 years, (n=43; 17.9%) belongs to age group 21-30 years, (n=27; 11.3%) belongs to age group 51-60 year and only 16 (6.6%) in the 61-70 age group. Mean age of patients was 40 (SD±2) years.

Table 1: Age wise distribution of participants.

Age Group	Number of participants	Percentage (%)
21-30	43	17.9
31-40	92	38.4
41-50	62	25.8
51-60	27	11.3
61-70	16	6.6
Total	240	100

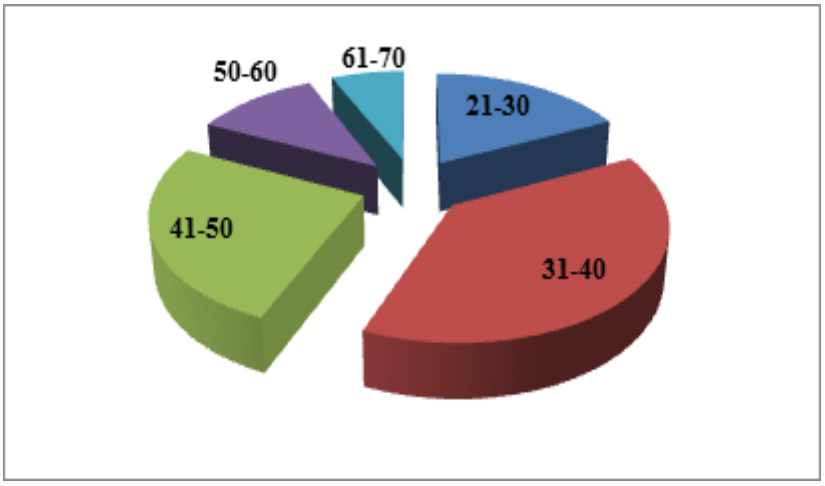

Chart No. 1: Age wise distribution of participants.

There were 98 (40.8%) malignant and 142 (59.2%) benign tumor. Most of the malignant breast lesions were diagnosed between 31-50 years of age where as most of the benign lesions was observed in the 41-70 years age group.

Out of 98 malignant cases, ductal carcinoma (invasive) (n=71; 29.5%) was most common lesion and second common lesion was ductal carcinoma in situ (n=37; 15.4%). Out of 142 benign nodular masses cases, fibroadenoma (n=46; 19.2%), fibrocystic disease (n=39, 16.3%) and benign cystic lesions (n=31, 12.9%) were the commonest benign cases (Table No. 2 and Graph No. 2).

Table 2: Histopathological Diagnosis of Breast masses (n=240)

Histopathological Findings	Number of cases	Percentage (%)
Infected benign cystic lesions	2	0.8
Fibroadenoma (calcified)	3	1.3
Lobular carcinoma (invasive)	4	1.6
Infiltrating ductal carcinoma	7	2.9
Benign cystic lesions	31	12.9
Ductal carcinoma in situ	37	15.4
Fibrocystic disease	39	16.3
Fibroadenoma	46	19.2
Ductal carcinoma (invasive)	71	29.5
Total	240	100

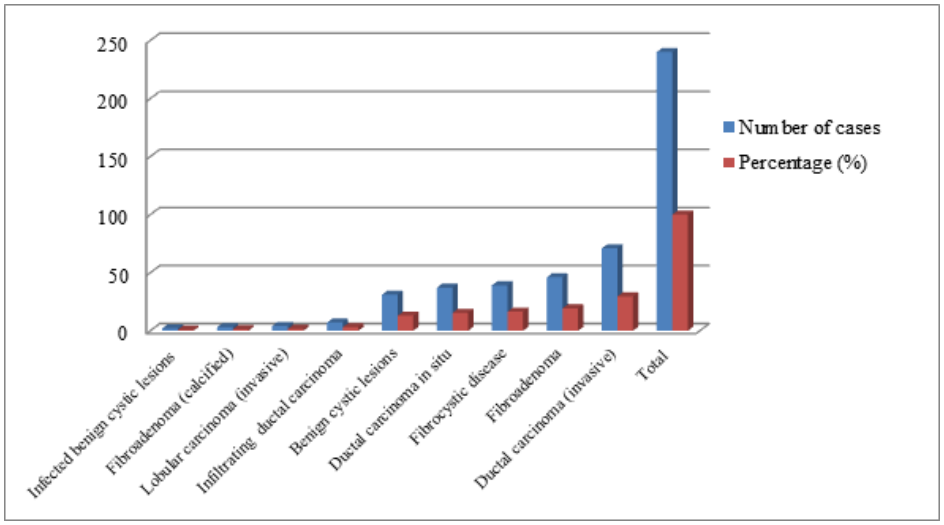

Chart 2: Histopathological Diagnosis of Breast masses (n=240)

The mean elasticity score for malignant lesions was 4.2. The average elasticity score for benign breast masses was 2.1 (Table no.3).

Table 3: Elasticity scores of malignant and benign lesion (n=240)

Type of lesion	Quantity	Elasticity Score					Total
		1	2	3	4	5	
Malignant	N	3	0	11	36	48	98
	%	3.0%	00%	11.2%	36.7%	48.9%	100%
Benign	N	53	49	19	12	9	142
	%	37.3%	34.5%	13.3%	8.4%	6.3%	100%

To determine the sensitivity and specificity of ultrasonic elastography, lesions with elasticity values of 1 to 3 were categorized as benign, whereas those with scores of 4 or 5 were classed as malignant.

The mean stain ratio (SR) for benign lesions was 2.1, which was substantially lower than that of malignant lesions (4.2). A receiver operator characteristic (ROC) analysis was used to evaluate Strain Elastography's usefulness in the differential identification of breast lesions.

When a cut-off value of 3.5 was utilized, the elasticity score showed 82.6% sensitivity and 92.8% specificity (area under the curve- 0.924, 95% CI- 0.871 to 0.983, p-0.0001) and the accuracy 88.2%. When a cut off of 2.95 was employed, SR scores showed 89.3% sensitivity and 89.6% specificity (area under the curve- 0.969, 95% CI- 0.951-0.982, p-0.0001) and accuracy 92.1% (Table no.4 and 5).

Table 4: Coordinates of ROC curve (Elasticity score).

Variables of test result: Elasticity score		
Positive if greater than or equal to	**Sensitivity**	**Specificity**
0	1	1
1.5	0.964	0.583
2.5	0.964	0.2
3.5	0.839	0.083
4.5	0.446	0.033
6	0	0

Table 5: Coordinates of ROC curve (Strain ratio).

Variables of test result: Strain ratio score		
Positive if greater than or equal to	**Sensitivity**	**Specificity**
0.05	1	1
1.75	1	0.979
1.94	1	0.536
2.13	1	0.481
2.65	0.954	0.132
2.81	0.921	0.134
2.96	0.922	0.117
2.97	0.924	0.12
2.99	0.896	0.14
3.0	0.885	0.13
3.47	0.877	0.13
4.54	0.841	0.084
5.16	0.851	0.085
5.96	0.589	0
6.24	0.564	0
6.81	0.127	0
7.21	0.089	0
7.45	0.028	0
8.65	0	0

The coefficient of Pearson correlation for elasticity scores and SR values was 0.936, showing excellent agreement (correlation) between the two approaches.

Discussion

The interpretation of a breast masses diagnosed by B-mode USG is mostly based on morphological factors. Additional approaches can be utilized to increase USG accuracy, including as Doppler and

harmonic imaging. [6,7] Strain Elastography (SE) can assist distinguish between benign and malignant breast lesions.

The clinical application of SE was first documented in 1990-91, but it wasn't until 2004-2005 that Ultra sonographic equipment was produced with some software for real-time analysis of Elastography pictures and routine USG exams. [8,9]

In this investigation, when a cut-off point of 3.5 was chosen, the elasticity score had a sensitivity of 82.6% and a specificity of 92.8%, which is comparable with existing literature on the use of real-time USG elastography. [10-14]

When a cut off of 2.95 was employed, SR scores showed 89.3% sensitivity and 89.6% specificity (area under the curve- 0.969, 95% CI- 0.951-0.982, p-0.0001) and accuracy 92.1%.

Although SR more than 3 is typically regarded suspicious for malignancy, there is extensive ongoing research to determine the right parameters for distinguishing between benign and malignant tumors. [15]

In the current study, the average SR for benign lesions was 2.3, whereas for malignant lesions it was 5.9, with a cut-off of 2.84. The sensitivity and specificity were 89.3% and 89.6%, respectively, which are comparable with previously reported statistics from similar investigations. [14-17]

Routine USG diagnosis reveals numerous non-palpable lesions and is insufficiently specific for screening patients. [18] The recent use of SE, particularly quantitative elastography with SR, has boosted USG specificity, allowing for early detection of sub-centimetre breast cancer and reducing the requirement for biopsies. [19] In the clinical diagnostic area, SE is important in choosing whether to follow-up patients with imaging or intervene. [20]

This study found a strong association between qualitative and quantitative elastography technique (elasticity score and SR), and using both approaches allows for a more reliable diagnosis. [21]

Some limitations of SE should be noted, such as the fact that it is less sensitive than regular USG when dealing with non- focused anomalies and is not recommended for evaluating postoperative alterations, diffuse lesions, or massive ones that surpass the probe's length or field of view. It is also of limited value in hematomas, breast implants and thick fibrous parenchyma.

Conclusion

Strain elastography technology is widely accessible and simple to apply in a therapeutic environment. SE is a real-time procedure that may be performed at the bedside with B-mode examination. In various investigations on breast cancer, SE has demonstrated remarkable promise and strong diagnostic performance. We conclude by stating that ultrasonic elastography is a simple and quick way for improving the sensitivity and specificity of USG and reducing the number of needless biopsies.

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Ethical approval: The study was approved by the Institutional Ethics Committee

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