



## Study of ultrasound elastography in the evaluation of breast lumps with FNAC/ histopathological correlation

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### Abstract

**Background:** Breast cancer is one of the most prevalent cancers among women worldwide, making early detection crucial for effective treatment and improved survival rates. Diagnostic imaging plays a pivotal role in the early identification and characterization of breast lesions. Ultrasound elastography represents a significant advancement in the evaluation of breast lumps. By providing detailed information on tissue stiffness, it enhances the diagnostic accuracy of conventional ultrasound and aids in the differentiation between benign and malignant lesions.

**Objectives:** To study the sensitivity and specificity of ultrasound elastography in the detection and characterization of various breast lumps and to study the role of ultrasound elastography in differentiating benign and malignant breast lesions.

**Methods:** A prospective study was conducted for a period of 2 years, where patients presenting with palpable breast lumps and with incidentally detected lesions on imaging modalities like mammography were included. They were subjected to the ultrasound imaging and elastography and FNAC/histopathology for confirmation and establishment of final diagnosis. The sonographic and elastographic parameters for benign and malignant lesions were compared relative to the histopathological diagnosis.

**Results:** Among the 100 patients in our study, majority (47%), were between 36-45 years old and the mean age of the participants was  $40.63 \pm 6.872$  years. In terms of mass location, 39% of the masses were found in the left breast, and 61% were in the right breast. The BIRADS scores ranged from a minimum of 2 to a maximum of 4, with a mean score of  $2.97 \pm 0.577$  and its classification showed that 38% of the masses were benign, 37% were indeterminate, and 25% were malignant. Elastography score interpretations revealed that 67% of the masses were classified as benign, while 33% were classified as malignant. Strain interpretation results indicated that 67% of the masses were benign, and 33% were malignant. FNAC/Histopathology results showed that 65% of the masses were benign and 35% were malignant. A p-value of 0.001 was found showing a significant correlation between elastography and FNAC/Histopathology and between strain analysis and FNAC/Histopathology respectively.

**Conclusion:** Ultrasound elastography is a valuable tool in the evaluation of breast lumps, providing additional information on tissue stiffness that complements traditional imaging and diagnostic methods. Its non-invasive nature, real-time imaging capabilities, and potential to reduce unnecessary biopsies make it an attractive option for clinicians. When used in conjunction with FNAC and histopathological examination, elastography can enhance the accuracy and efficiency of breast lump diagnosis, ultimately improving patient care and outcomes. Advancements in ultrasound elastography technology hold promise for improving its diagnostic accuracy and clinical utility.

**Keywords:** Breast cancer, ultrasound elastography, strain elastography, shear wave elastography, histopathology

### Introduction

Breast cancer is one of the most prevalent cancers among women worldwide, making early detection crucial for effective treatment and improved survival rates. Diagnostic imaging plays a pivotal role in the early identification and characterization of breast lesions. Among various imaging modalities, ultrasound is widely used due to its accessibility, cost-effectiveness, and non-ionizing nature. Traditional B-mode ultrasound provides valuable information about the size, shape, and internal structure of breast lumps, but it often lacks specificity in differentiating between benign and malignant lesions. To enhance diagnostic accuracy, advanced techniques such as ultrasound elastography have been developed.

Ultrasound elastography is an innovative imaging technique that evaluates tissue stiffness by measuring the deformation of tissues under applied mechanical stress. It provides a non-invasive method to assess the mechanical properties of breast lesions, offering additional information that

complements conventional B-mode ultrasound. There are two main types of elastography: strain elastography and shear wave elastography. Both techniques have shown promise in improving the characterization of breast lumps, aiding in the differentiation between benign and malignant lesions.

Strain Elastography measures the relative deformation of tissue when an external force is applied. This technique compares the strain in a lesion to the strain in surrounding normal tissue, resulting in a strain ratio. Studies have shown that strain elastography can effectively distinguish between benign and malignant breast lesions. For instance, a study by Zhi *et al* <sup>[1]</sup>, demonstrated that strain elastography significantly improves the diagnostic accuracy of breast ultrasound by providing additional information about tissue stiffness. The strain ratio, a key parameter in strain elastography, has been found to be particularly useful, with a cutoff value typically around 3.0 to 4.5 indicating malignancy <sup>[2]</sup>.

Shear Wave Elastography (SWE), on the other hand, measures the speed of shear waves propagating through tissue. Malignant tissues, being stiffer, have higher shear wave velocities compared to benign tissues. SWE provides quantitative measurements of tissue stiffness, which can be displayed as color-coded maps superimposed on the B-mode images. Research has shown that SWE is highly effective in differentiating benign from malignant breast lesions, with studies indicating high sensitivity and specificity [3]. A meta-analysis by Zhang *et al.* confirmed the diagnostic superiority of SWE over conventional B-mode ultrasound, highlighting its potential as a valuable tool in breast cancer diagnostics<sup>4</sup>. The integration of elastography into routine breast ultrasound examinations has the potential to revolutionize breast cancer diagnostics. By providing additional information on tissue stiffness, elastography enhances the specificity and sensitivity of ultrasound, reducing the number of unnecessary biopsies and ensuring that malignant lesions are promptly identified and treated. This non-invasive technique is particularly valuable in settings where access to advanced imaging modalities like MRI is limited. Moreover, elastography can be used in conjunction with fine-needle aspiration cytology (FNAC) and histopathological examination to further validate its findings. FNAC is a minimally invasive procedure that involves using a thin needle to extract cells from a breast lump for microscopic examination. Histopathology, considered the gold standard, involves the examination of surgically removed tissue to provide a definitive diagnosis. By correlating elastography findings with FNAC and histopathological results, clinicians can achieve a more comprehensive and accurate diagnosis.

A study by Barr *et al* [5], demonstrated the high diagnostic accuracy of elastography when combined with FNAC and histopathology. The research highlighted that elastography could effectively guide biopsy decisions, ensuring that suspicious lesions are adequately sampled while avoiding unnecessary procedures for benign lesions [5]. This correlation not only improves diagnostic confidence but also enhances patient management and outcomes.

The primary advantage of ultrasound elastography lies in its ability to provide additional, non-invasive information about breast tissue stiffness. This capability significantly enhances the diagnostic accuracy of conventional ultrasound, particularly in cases where B-mode ultrasound findings are inconclusive. Additionally, elastography is relatively quick to perform and can be easily integrated into routine ultrasound examinations without the need for extensive training or additional equipment.

Ultrasound elastography represents a significant advancement in the evaluation of breast lumps. By providing detailed information on tissue stiffness, it enhances the diagnostic accuracy of conventional ultrasound and aids in the differentiation between benign and malignant lesions. Studies have shown that elastography, when combined with FNAC and histopathological correlation, offers a comprehensive and reliable approach to breast cancer diagnosis. In view of this, the present study was undertaken.

### Objective of the study

This study was conducted to study the sensitivity and specificity of ultrasound elastography in the detection and characterization of various breast lumps and to study the role of ultrasound elastography in differentiating benign and malignant breast lesions.

### Methodology

We conducted a prospective study for a period of 2 years, where we enrolled patients presenting with palpable breast lumps in the department of Radiodiagnosis at Al Ameen medical college and hospital, Vijayapura and also included patients with incidentally detected lesions on imaging modalities like mammography.

Patients coming to Department of Radiodiagnosis, Al-Ameen hospital with palpable breast lumps, a minimum of 100 cases who fulfilled our inclusion and exclusion criteria from Al-Ameen medical college and hospital Vijayapura, were included in the study, after obtaining approval by ethical committee.

Informed consent was taken from all enrolled patients after detailed counselling. After a detailed history of the cases who presented with palpable breast lumps, they were subjected to the ultrasound imaging and elastography. LOGIQ P9 GE ultrasound machine having capability of high frequency small part probe (L 5-13) was used for assessment and sonoelastography evaluation of the breast lumps. All the patients were subjected to FNAC/histopathology for confirmation and establishment of final diagnosis.

Each lesion was assigned a BI-RADS category using conventional ultrasound features like shape, echotexture, margin, orientation, and posterior acoustic characteristics. It was followed by elastography. The Elastography score was determined on a five-point Tsukuba classification proposed by Itoh *et al* [6]. Histopathological results obtained were used as the reference standard for comparison of conventional ultrasound and elastography findings. The sonographic and elastography parameters for benign and malignant lesions were compared relative to the histopathological diagnosis.

The data was collected and compiled in MS Excel. Descriptive statistics has been used to present the data. To analyse the data SPSS (Version 26.0) was used. Significance level was fixed as 5% ( $\alpha = 0.05$ ). Qualitative variables are expressed as frequency and percentages and Quantitative variables are expressed as Mean and Standard Deviation. To compare the proportion between variables, chi-square test was used.

### Results

This study included 100 patients presenting with palpable breast lumps in our hospital. The age distribution of the patients in this study shows that the majority, 47%, are between 36-45 years old. Those aged 25-35 years constitute 22% of the study population, while 31% are between 46-55 years old. The mean age of the participants is  $40.63 \pm 6.872$  years.

In terms of mass location, 39% of the masses are found in the left breast, and 61% are in the right breast. The size of the masses ranges from a minimum of 1.2 cm to a maximum of 3 cm, with a mean size of  $2.167 \pm 0.5057$  cm.

The BIRADS scores range from a minimum of 2 to a maximum of 4, with a mean score of  $2.97 \pm 0.577$ . The BIRADS classification shows that 38% of the masses are benign, 37% are indeterminate, and 25% are malignant.

Elastography scores range from a minimum of 3 to a maximum of 5, with a mean score of  $3.38 \pm 0.565$ . Elastography interpretations reveal that 67% of the masses are classified as benign, while 33% are classified as malignant.

The strain ratios range from a minimum of 2.4 to a maximum of 4.8, with a mean ratio of  $3.225 \pm 0.6873$ . Strain interpretation results indicate that 67% of the masses are benign, and 33% are malignant.

FNAC/Histopathology results show that 65% of the masses are benign and 35% are malignant. Among the conditions identified, fibroadenoma is the most common, occurring in 48% of cases. Fibrocystic changes are found in 15%, galactocele in 2%, invasive ductal carcinoma in 10%, invasive lobular carcinoma in 6%, ductal carcinoma in situ (DCIS) in 8%, medullary carcinoma in 5%, and papillary carcinoma in 6% of the patients.

In elastography, 65 of the 67 benign masses identified by FNAC/Histopathology are also classified as benign, and 33 of the 33 malignant masses are similarly classified. This gives a p-value of 0.001, indicating a significant correlation between elastography and FNAC/Histopathology.

- Sensitivity: 95.5%
- Specificity: 96.6%
- Positive Predictive Value (PPV): 96.9%
- Negative Predictive Value (NPV): 93.9%
- Diagnostic Accuracy: 95.9%

Strain analysis shows that 63 benign masses identified by FNAC/Histopathology are also classified as benign, and all 33 malignant masses are similarly classified. This results in a p-value of 0.001, indicating a significant correlation between strain analysis and FNAC/Histopathology.

- Sensitivity: 97%
- Specificity: 100%
- Positive Predictive Value (PPV): 97%
- Negative Predictive Value (NPV): 94.3%
- Diagnostic Accuracy: 96.9%

## Discussion

Breast lumps are a common clinical finding and a significant concern for women due to the potential risk of breast cancer. Early and accurate diagnosis is crucial for effective management and treatment. Traditionally, the evaluation of breast lumps involves a combination of physical examination, mammography, ultrasound, and biopsy. Fine needle aspiration cytology (FNAC) and histopathological examination are commonly used invasive techniques for definitive diagnosis. However, these methods can be uncomfortable for patients and carry certain risks associated with invasive procedures.

In recent years, ultrasound elastography has emerged as a promising non-invasive imaging modality for the assessment of breast lesions. Elastography provides information about the stiffness or elasticity of tissues, which can help differentiate between benign and malignant lesions. Hence, we conducted this study to explore the role of ultrasound elastography in the evaluation of breast lumps and its correlation with FNAC and histopathological findings.

## Demographic particulars

In our study, the mean age of the patients was  $40.63 \pm 6.872$  years. 39% of the masses are found in the left breast, and 61% are in the right breast. The mean size of the mass was  $2.167 \pm 0.5057$  cm and the range was 1.2 cm to 3 cm. Fibroadenoma was the most common condition, occurring in 48% of cases. Fibrocystic changes were found in 15%, galactocele in 2%, invasive ductal carcinoma in 10%,

invasive lobular carcinoma in 6%, ductal carcinoma in situ (DCIS) in 8%, medullary carcinoma in 5%, and papillary carcinoma in 6% of our patients.

In a similar study by Vikrant *et al.*, the mean age was  $48.96 \pm 7.52$  years and the range was 40 to 72 years<sup>[7]</sup>. The mean age of the patients with benign and malignant lesions was  $45.4 \pm 5.47$  and  $51.5 \pm 7.84$  years. The most frequent malignant and benign lesions were infiltrative ductal carcinoma and fibroadenoma, respectively. Out of the 29 malignant lesions, 1 (3%) was mucinous carcinoma, 11 (38%) was invasive lobular carcinoma, and 17 (59%) were infiltrative ductal carcinoma. Three (15%) had breast abscesses, four (19%) had atypical ductal hyperplasia, two (9%) had sclerosing adenosis, and two (9%) had nonspecific mastitis among the twenty-one benign lesions. Three conditions accounted for one (5%) each: benign phyllodes tumour, complicated cyst, and granulomatous mastitis.

In another study by Ramona *et al.*<sup>[8]</sup>, 100 breast lesions were analysed and 75 of them were diagnosed as benign, and 25 were diagnosed as malignant on pathological analysis. The most common benign lesions were Fibroadenoma followed by Fibrocystic change. The most common malignant tumour was Infiltrating ductal carcinoma in their study.

In another study by Andreea *et al.*, the average age of all patients was 46.6 (20–85 years) and there were 74 malignant lesions (34.4%) and 141 (65.5%) benign lesions<sup>[9]</sup>. It was seen that in urban regions, the incidence of malignant lesions was greater. Compared to the right breast, the left breast had a greater involvement in malignant lesions, with a higher distribution in the upper outer quadrant. The diameter of malignant lesions was between 10–43 mm, with an average of 27.3 mm, which was higher than the benign lesions diameter (mean 19.9 mm, range between 1–39 mm).

## BIRADS

The BIRADS scores range from 2 to 4, with a mean score of  $2.97 \pm 0.577$ . The BIRADS classification shows that 38% of the masses were benign, 37% were indeterminate, and 25% were malignant in our study.

In the Vikrant *et al.*<sup>[7]</sup> study, three were allocated BIRADS category 3, eighteen were assigned category 4, and twenty nine were assigned category 5 based on the results of the BIRADS examination.

In the Ramona *et al.* study, out of the 100 lesions studied, 54 belonged to BIRADS category 3, 16 were category 4A, 6 each in category 4B & 4C and 18 lesions were BIRADS category 5<sup>[8]</sup>.

## Elastography, strain & FNAC

Elastography scores in our study ranged from a minimum of 3 to a maximum of 5, with a mean score of  $3.38 \pm 0.565$ . Elastography interpretations revealed that 67% of the masses were classified as benign, while 33% were classified as malignant.

The strain ratios ranged from a minimum of 2.4 to a maximum of 4.8, with a mean ratio of  $3.225 \pm 0.6873$ . Strain interpretation results indicated that 67% of the masses were benign, and 33% were malignant.

FNAC/Histopathology results showed that 65% of the masses were benign and 35% were malignant.

In the Ramona *et al.* study, the mean elastography score was significantly higher for malignant lesions ( $4.97 \pm 0.27$ ) than

for benign lesions ( $2.93 \pm 1.04$ ) ( $p < 0.001$ )<sup>8</sup>. Of the 25 malignant lesions, all had a score of 4 or 5. None of these lesions had a score of 1-3. Of the 75 benign lesions, 29 had a score of 1 or 2 and 33 had a score of 3. The mean strain ratio  $\pm$  SD for the 75 benign masses was  $3.87 \pm 3.52$ . The mean strain ratio for the 25 malignant tumours was  $8.99 \pm 5.34$ . Compared to the benign masses, the malignant masses had strain ratios that were noticeably higher. With a sensitivity of 100% and a specificity of 82.66%, a cut-off point between elasticity scores of 3 and 4 produced the best discrimination between benign and malignant tumours. The best possible discrimination between benign and malignant tumours, with a strain ratio cut off point of 4.72. In this study, the strain ratio was found to perform second best, behind the elastography score.

In the Andreea *et al*<sup>[9]</sup>. study, among malignant lesions, 28 (37.8%) had an elasticity score of 4 and 35 (47.2%) had an elasticity score of 5. The elasticity score for benign lesions was on average  $1.95 \pm 1.1$ , which was significantly lower than for malignant lesions ( $4.21 \pm 0.9$ ).

**Associations**

65 of the 67 masses identified by as benign by FNAC/Histopathology were also classified as benign in elastography. All 33 malignant masses by FNAC/Histopathology were rightly classified as malignant by elastography. In our study we found elastography to have a Sensitivity of 95.5%, Specificity of 96.6%, Positive Predictive Value (PPV) of 96.9%, Negative Predictive Value (NPV) of 93.9% and a Diagnostic Accuracy of 95.9%.

Similarly, 63 benign masses identified by FNAC/Histopathology were also classified as benign, and all 33 malignant masses were rightly classified as malignant in strain ratio. In our study we found strain ratio to have a Sensitivity of 97%, Specificity of 100%, Positive Predictive Value (PPV) of 97%, Negative Predictive Value (NPV) of 94.3% and a Diagnostic Accuracy of 96.9%. Thus, Strain ratio showed higher sensitivity & specificity than Elastography.

In the Vikrant *et al*. study, the elasticity score-based qualitative SE exhibited a 100% sensitivity and 76.1% specificity in identifying cancer<sup>7</sup>. 90% of the cases were diagnosed with a positive predictive value (PPV) of 85.2% and NPV of 100%. Malignant histopathology was substantially correlated with higher elasticity scores.

In the Andreea *et al*. study, Elastography was seen to have a sensitivity of 85.3% and a specificity of 90%<sup>[9]</sup>. They concluded in their study that Breast elastography was a very simple and rapid method that can improve the sensitivity and specificity of ultrasound, especially when dealing with elastography score 3 or 4.

In a study by Xue-Jing *et al*<sup>[10]</sup>. it was concluded that conventional ultrasound combined elastography showed high sensitivity, specificity, and accuracy for group II lesions (10mm < lesion diameter  $\leq$  20mm). Elastography combined with conventional ultrasound show high specificity and accuracy for differentiation of benign and malignant breast lesions. Elastography is particularly important for the diagnosis of BI-RADS 4 and small breast lesions.

In the Ako *et al*<sup>[11]</sup>. study, the mean elasticity score for malignant lesions was  $4.2 \pm 0.9$ , while for benign lesions it was  $2.1 \pm 1.0$  ( $P < .001$ ). Elastography demonstrated 86.5%

sensitivity, 89.8% specificity, and 88.3% accuracy when a cutoff point between 3 and 4 was employed in this study. The sensitivity of elastography was higher than that of conventional US ( $P < .05$ ). Elastography's accuracy was on par with conventional US, and its specificity was not less accurate than that of conventional US. It was concluded in this study that, when evaluating breast lesions, US elastography performed nearly as well as conventional US when compared to the Breast Imaging Recording and Data System classification and was simpler.

In a related study, Mohamed *et al*<sup>[12]</sup>. found that real-time ultrasound elastography (RTE) demonstrated sensitivity of 98.41%, specificity of 96.34%, PPV of 95.38%, NPV of 98.75%, and accuracy of 97.24%, while B-mode US showed sensitivity of 92.06%, specificity of 90.24%, PPV of 87.88%, NPV of 93.67%, and accuracy of 91.03%. They came to the conclusion that the combined use of RTE and traditional B-mode US can enhance the former's diagnostic performance in discriminating breast lesions, hence lowering the rate of needless biopsies in benign lesions.

Similarly, in the Raza *et al*<sup>[13]</sup>. study, upon pathologic inspection it was seen that 67.6% were benign lesions and 32.4% were malignant. Elasticity ratings (ES) of 1 and 2 were present in 76% of benign lesions, while ES of 5 and 4 were present in 84% of malignant lesions. RTE (real-time tissue elastography) had a 92.7% sensitivity, an 85.8% specificity, 16 false-positive findings, and 4 false-negative results. 63 of 76 (82.9%) benign BI-RADS 4A lesions that were confirmed by biopsy had ES values of 1 or 2, which is consistent with normal tissue. They concluded that Real-time tissue elastography may provide additional characterization of breast lesions, improving specificity, particularly for low-suspicion lesions.

**Table 1:** Variables related to various scores related to breast lumps

Variables	Minimum	Maximum	Mean	SD
Mass Size (cm)	1.2	3	2.167	0.5057
BIRADS Score	2	4	2.97	0.577
Elastography Score	3	5	3.38	0.565
Strain Ratio	2.4	4.8	3.225	0.6873

**Table 2:** Interpretation of various scores related to breast lumps

Scores	Frequency	Percentage
BIRADS		
Benign	38	38
Indeterminate	37	37
Malignant	25	25
Total	100	100
Elastography interpretation		
Benign	67	67
Malignant	33	33
Total	100	100
Strain interpretation		
Benign	67	67
Malignant	33	33
Total	100	100

**Table 3:** FNAC/Histopathology

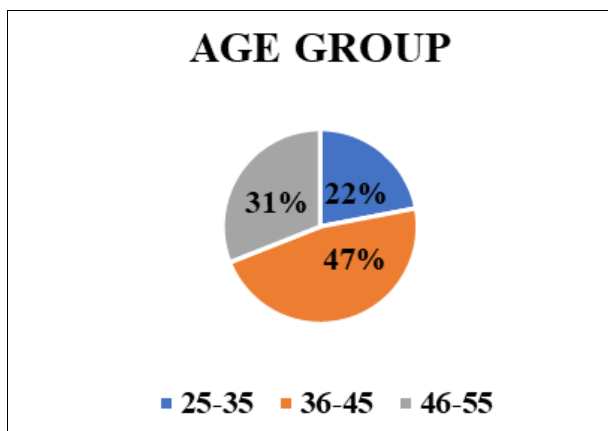
FNAC/Histopathology		
Benign	65	65
Malignant	35	35
Total	100	100

**Table 4:** Association of elastography with FNAC/Histopathology

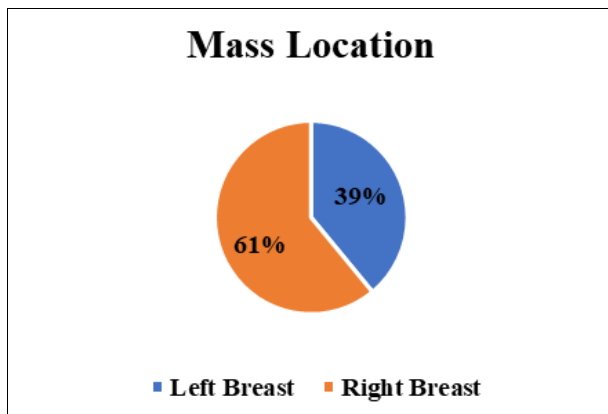
Elastography		FNAC/Histopathology		P Value
		Benign	Malignant	
Benign	Count	64	3	0.001
	%	95.5%	4.5%	
Malignant	Count	1	32	
	%	3.4%	96.6%	
Total	Count	65	35	
	%	65%	35%	

**Table 5:** Association of strain ratio with FNAC/Histopathology

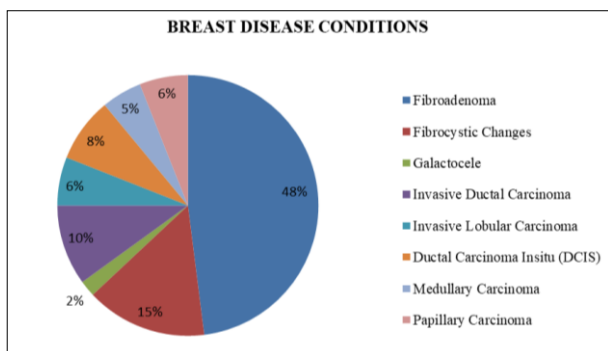
Strain ratio		FNAC/Histopathology		P Value
		Benign	Malignant	
Benign	Count	65	2	0.001
	%	97%	3%	
Malignant	Count	-	33	
	%	-	100%	
Total	Count	65	35	
	%	65%	35%	



**Fig 1:** Age group of the study participants



**Fig 2:** Mass location



**Fig 3:** FNAC/HISTOPATHOLOGY conditions

**Conclusion**

Ultrasound elastography offers several benefits in the evaluation of breast lumps:

- **Non-invasive Nature:** As a non-invasive technique, elastography reduces the need for invasive procedures, minimizing patient discomfort and associated risks.
- **Improved Differentiation:** Elastography enhances the differentiation of benign and malignant lesions, aiding in more accurate diagnosis and treatment planning.
- **Reduction in Unnecessary Biopsies:** By providing additional information about tissue stiffness, elastography can help avoid unnecessary biopsies, reducing healthcare costs and patient anxiety.
- **Operator Dependency:** Strain elastography is operator-dependent, requiring skilled technicians to obtain reliable results.
- **Technical Limitations:** Factors such as lesion depth, size, and surrounding tissue composition can affect elastographic measurements.
- **Complementary Role:** Elastography should be used as an adjunct to, rather than a replacement for, traditional diagnostic methods like FNAC and histopathology.

Despite its advantages, ultrasound elastography has certain limitations:

Advancements in ultrasound elastography technology hold promise for improving its diagnostic accuracy and clinical utility. Continued research and larger studies are needed to validate its efficacy and explore its potential applications in other breast conditions.

Thus, Ultrasound elastography is a valuable tool in the evaluation of breast lumps, providing additional information on tissue stiffness that complements traditional imaging and diagnostic methods. Its non-invasive nature, real-time imaging capabilities, and potential to reduce unnecessary biopsies make it an attractive option for clinicians. When used in conjunction with FNAC and histopathological examination, elastography can enhance the accuracy and efficiency of breast lump diagnosis, ultimately improving patient care and outcomes.

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