

## DIAGNOSTIC UTILITY OF STRAIN RATIO ULTRASOUND ELASTOGRAPHY IN BREAST LESIONS

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Received : 05/05/2024  
 Received in revised form : 02/07/2024  
 Accepted : 18/07/2024

**Keywords:**  
 Ultrasound, Breast lesions,  
 elastography, Strain ratio, B mode  
 ultrasound.

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DOI: 10.47009/jamp.2024.6.4.31

Source of Support: Nil,  
 Conflict of Interest: None declared

*Int J Acad Med Pharm*  
 2024; 6 (4); 147-151



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### Abstract

**Background:** The aim and objective is to determine and evaluate the diagnostic accuracy of the role of strain ratio elastography in the characterization of breast masses compared to conventional B-mode ultrasound and to create a strain ratio cut off in distinguishing between benign and malignant breast lesions. **Materials and Methods:** The study was conducted in our institute for 6 months and included 101 female patients using inclusion and exclusion criteria. Protocol: Patients with breast masses underwent conventional B-mode breast ultrasound with a radial scan pattern using a Hitachi Aloka Arietta 70 ultra-high frequency transducer (7.5-12 MHz) and classified according to BIRADS categories, followed by elastography mode. Strain ratio (SR) was calculated. Histopathological evaluations were performed. **Result:** Based on the ROC curve, the strain ratio cut-off value of 2.69 was obtained for the differentiation between benign and malignant breast lesions. The area under the curve for B-mode USG based on BIRADS was 0.891, with a p-value of 0.0005 (statistically significant) with a 95% confidence interval. The area under the curve was 0.925 for strain ratio. p-value 0.005 (of great statistical significance) under 95% confidence interval. BIRADS-based characterization showed a sensitivity of 78.1%, specificity of 100%, PPV of 100%, NPV of 90.8%, and accuracy of 93.1%. Characterization by strain ratio showed sensitivity of 93.8%, specificity of 91.3%, PPV of 83.3%, NPV of 96.9%, and accuracy of 92.1%. **Conclusion:** Strain elastography can be used as a non-invasive tool to characterize benign and malignant breast lesions. Strain ratio elastography plays an important role as an adjunct to conventional B-mode ultrasound in distinguishing between benign and malignant lesions, thus avoiding unnecessary interventional procedures.

## INTRODUCTION

Breast cancer is the leading cause of deaths among cancer patients in female population globally. Based on statistics from world health organisation, in 2020, about 2.3 million females were diagnosed with cancer breast and of which 6,85,000 females died worldwide. There were 7.8 million females alive who were diagnosed with breast cancer, making it the most prevalent cancer worldwide by the end of 2020, in the past 5 years. Breast ultrasound elastography is a unique innovative sonographic imaging technique that, in addition to standard ultrasonography (US) and mammography, gives information on breast lesions. Ultrasound elastography is a non-invasive method of determining a lesion's "stiffness".<sup>[1]</sup> Recent research studies indicate that ultrasound elastography offers

greater diagnostic accuracy during detection of breast cancer than standard conventional B-mode ultrasonography, thus crucial in preventing unnecessary breast biopsy because it lowers false positive results.

### Aim and Objectives

- To determine and evaluate the diagnostic accuracy of the role of strain ratio elastography in characterization of breast masses compared to conventional B mode ultrasonography.
- To create strain ratio cut off in distinguishing between benign and malignant breast lesions.

## MATERIALS AND METHODS

The study was conducted in our institute for a period of 6 months and included 101 female patients.

### Inclusion Criteria

- Outpatients attending to ultrasound clinic with breast mass.
- Inpatients admitted in hospital with breast mass.

### Exclusion Criteria

- Superficial lesions (<5 mm deep to skin surface)
- Breast implants.
- Unwilling patients.

### Protocol

Using a Hitachi Aloka Arietta 70 very high frequency transducer (7.5–12 MHz), patients with breast masses were scanned in a conventional B-mode breast ultrasonography in a radial scanning approach. The patients were then classified based on BIRADS categories and the strain ratio (SR) was calculated using the elastography mode. Histopathological evaluations were carried out.

### Representative Cases

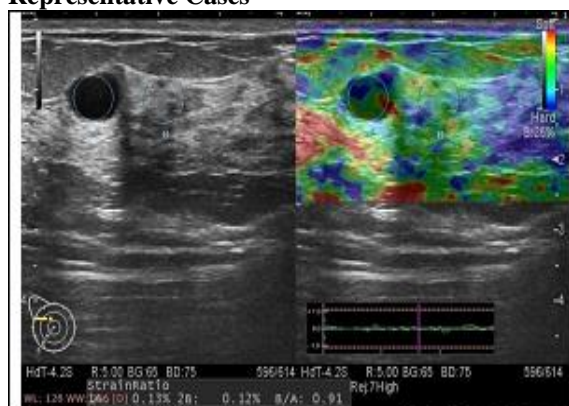


Figure 1: Breast cyst

B MODE USG- A smoothly margined well circumscribed oval anechoic lesion in the right breast with characteristic posterior acoustic enhancement -

Breast cyst- BIRADS-2

ASPIRATE CYTOLOGY- negative for malignant cells

STRAIN RATIO-0.91

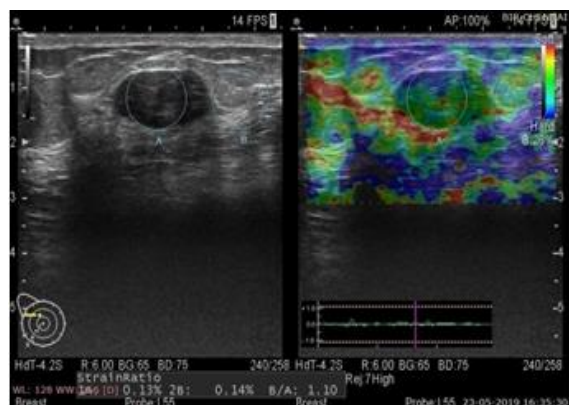


Figure 2: Fibroadenoma

B MODE USG-A smoothly margined well circumscribed oval hypoechoic lesion noted in 6 o'clock position of left breast.

No calcifications or architectural distortion

Breast fibroadenoma - BIRADS-2.

STRAIN RATIO 1.10

HPE -Fibroadenoma

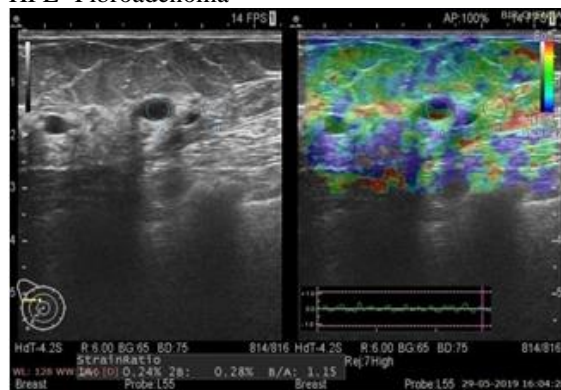


Figure 3: Fibrocystic Disease

B MODE USG showed, Prominent fibro glandular tissue with multiple diffuse anechoic small cysts, - Fibrocystic disease - BIRADS-2.

STRAIN RATIO: 1.15

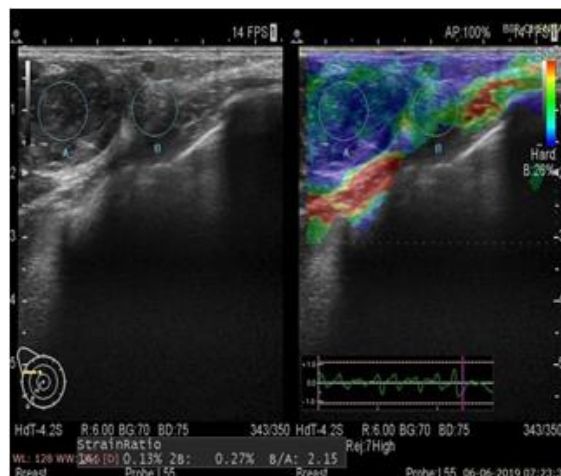


Figure 4: Phyllodes Tumour

B MODE USG shows heteroechoic solid appearing mass containing multiple clefts like spaces in zone 1-2 at 9 o'clock to 12 o'clock position of left breast - BIRADS-3

STRAIN RATIO: 2.15

HPE – Phylloides tumour

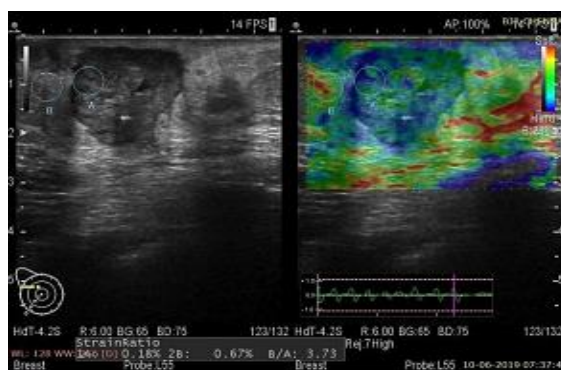


Figure 5 -Ductal Carcinoma

B MODE USG shows ill-defined heteroechoic lesion with predominant solid component, few cystic areas and few specks of calcification in Zone 2 at 7 o'clock position of right breast, BIRADS-4  
 STRAIN RATIO – 3.73  
 HPE – Ductal carcinoma

## RESULTS

As seen in figure 6, of the 101 patients in our study, 69 (68%) had benign lesions and 32 (32%), malignant lesions. According to the literature, the most frequent benign lesion (2) (35%) was fibroadenoma, while the most common malignant lesion (3) (19%) was ductal carcinoma. Figure 7 displays the percentage distribution of the patients in our study's histopathological data.

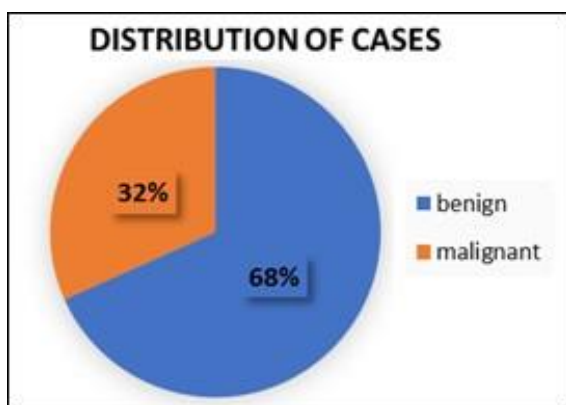


Figure 6: Distribution of cases

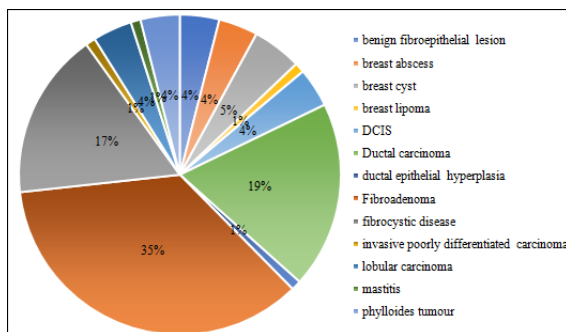


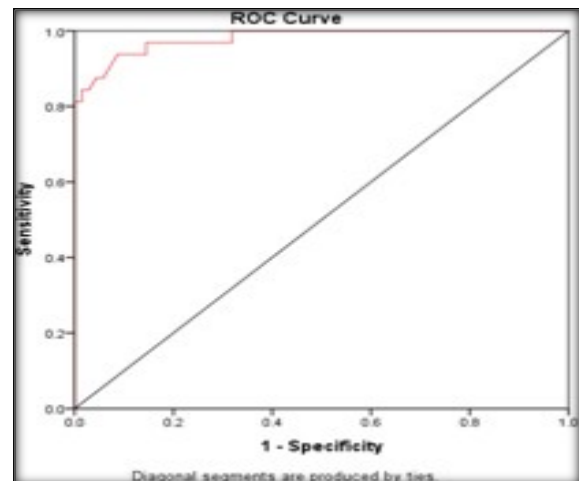
Figure 7: The percentage distribution of histopathology results

### 5. Statistical Analysis

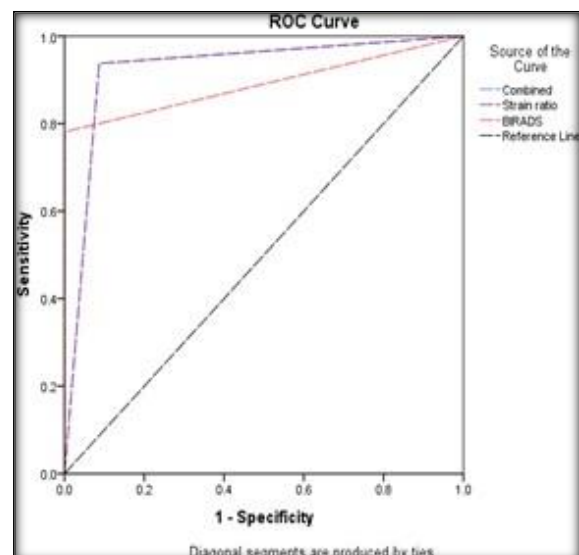
IBM SPSS Statistics for Windows, Version 23.0, was utilised for the analysis of the gathered data. (IBM Corp, Armonk, NY). To describe about the data descriptive statistics frequency analysis, percentage analysis was used for categorical variables and the mean & S.D were used for continuous variables. A receiver operating characteristic (ROC) curve using sensitivity, specificity, NPV, and accuracy was used to examine the effectiveness of malignancy prediction tools. In

the above statistical tool, a probability value of 0.05 is considered a significant level.

Receiver operator curve analysis was performed with the strain ratio as a variable. The area under the curve was 0.979 with a p-value of 0.0005, which is statistically significant with a 95% confidence interval of 0.956-1.000. Based on the ROC curve, Strain ratio cut-off value of 2.69 was set to distinguish between benign and malignant breast lesions.



Based on the ROC curve, the area under the curve for BIRADS-based B-mode USG was 0.891, with a p-value of 0.0005 (statistically significant) with a 95% CI of 0.803–0.978. The area under the strain ratio curve was 0.925. p-value 0.005 (statistically significant) with 95% confidence interval 0.863-0.987. Area under the curve of combined BIRADS and strain ratio was similar to strain ratio with a statistically significant p-value of 0.0005.



Area under the curve

Table 1: Statistical analysis of Strain ratio and BIRADS.

Test/Result/Variable(s)	Area	p-value	95% C.I	
			LB	UB

Strainratio	.925	.0005	.863	.987
BIRADS	.891	.0005	.803	.978

\*\* p value-Highly Significant at p < 0.01

BIRADS-based characterization showed a sensitivity of 78.1%, specificity of 100%, PPV of 100%, NPV of 90.8% and accuracy of 93.1%. The strain ratio elastography based characterization showed sensitivity of 93.8%, specificity of 91.3%, PPV 83.3%, NPV 96.9% and accuracy of 92.1%.

## DISCUSSION

In 1991, J Ophir et al first described the novel imaging technique of Strain Elastography.<sup>[4]</sup> The non-invasive technique of elastography is used to evaluate tissue elasticity. This imaging technique is applicable to variety of organs (Breast, Liver, Thyroid, Prostate, Gynaecology, ...).

The new imaging technique of strain ratio elastography aims to describe the stiffness of tissues, giving more information to clinicians. Although diagnostic tissue biopsy is the gold standard for characterizing breast masses, it cannot be performed in all patients because it is expensive and invasive. Therefore, strain elastography is a complementary paradigm for the characterization of benign and malignant breast lesions.

Generally, malignant breast lesions have a higher strain ratio than benign breast lesions. This may indicate that the stiffness of benign and malignant lesions is different.<sup>[5]</sup>

On review of literature, the results of our study on sensitivity and specificity of strain elastography are better than some of other studies such as Bojanic et al,<sup>[6]</sup>Kumm et al,<sup>[7]</sup>Yilmaz et al,<sup>[8]</sup> and our results are almost similar to studies by Gheonea et al,<sup>[9]</sup> Ahmed et al,<sup>[10]</sup> and zhi et al,<sup>[11]</sup> However, our study showed higher specificity results for conventional B mode ultrasound imaging than strain elastography for unexplained reasons, which is contrary to most of the studies in literature. Kumm et al,<sup>[7]</sup> and Yilmaz et al,<sup>[8]</sup> also reported lower sensitivity and specificity for ultrasound elastography on comparison to the conventional B mode ultrasound.

Kumm et al,<sup>[7]</sup> suggested that the NPV of a diagnostic test should approach 0.98 for a lesion to be characterized as benign. In our study, The NPV of strain elastography was 96.9 %.

The results of accuracy of our study based on strain elastography was 92.1% which is almost similar to Dimpisinha,<sup>[12]</sup> (92%) and better than results of Bojanic et al,<sup>[6]</sup> (86.9%), however, when compared to these studies, the size of the sample was less.

The cutoff of Strain ratio established in our study for distinguishing between benign and malignant lesions was 2.69. Denizozel et al,<sup>[13]</sup> established 3.1 as cut off, 3.0 was the strain ratio cut off in Dimpisinha et al study,<sup>[12]</sup> 3.5 in Bojanic et al,<sup>[6]</sup> 4.25 in Yilmaz et al,<sup>[8]</sup> 3.67 in Gheonea et al,<sup>[9]</sup> 2.57 in Ahmed et al,<sup>[10]</sup> 3.01 in Zhi et al,<sup>[11]</sup> and 2.45 in Thomas et al.<sup>[14]</sup> The variation in values of strain

ratio cut off in different studies could be attributed to interoperator variability and inconsistent placement of Region of interest (ROI) box. The ROI box should be equally sized and should be placed at its cm depth at the lesion as well as at adjacent fat for optimal study. The variability between operators happens due to differences in the magnitude of external compression.

In our study, among 69 benign lesions, 4 benign lesions exhibited strain ratio values above the established cut off. Likewise, out of 32 malignant lesions, 2 had strain ratio values below the established cut off. This suggests that any lesion could potentially be malignant. Therefore, it is necessary to utilize both grey scale and elastography to reduce the need for unnecessary biopsies.

The general limitations of strain elastography in our study encompass external probe pressure variability and dependency on the operator.<sup>[15]</sup> This study was conducted at a single center, and to minimize operator dependency, we did not utilize the shear wave elastography technique, which could be seen as a limitation. Analysis of Intraobserver variations were not done in our study.

## CONCLUSION

A non-invasive method for characterizing benign and malignant breast lesions is strain ratio elastography. When it comes to distinguishing between benign and malignant lesions, strain ratio elastography is a valuable addition to traditional B mode ultrasonography, helping to avoid needless intervention. Notwithstanding the discrepancies between B mode ultrasound and strain ratio elastography results, all solid breast lesions retain the potential to be malignant. The shortcomings of strain elastography can be addressed by future research employing shear wave ultrasound elastography.

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