



ADVANCING BREAST LESION DISCRIMINATION: THE EFFICACY OF ELASTOGRAPHY IN DISTINGUISHING FOCAL BENIGN AND MALIGNANT TISSUE LESIONS

Radio-Diagnosis

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ABSTRACT

Breast cancer is a leading cause of death in women, emphasizing the need for early and accurate diagnosis. Elastography, an addition to traditional ultrasound, assesses tissue elasticity, with the strain ratio (SR) emerging as a potential biomarker. This prospective study on 40 patients aimed to determine an optimal SR cut-off value for differentiating benign and malignant breast lesions. Results showed average SR values of 3.57 for malignant and 1.66 for benign lesions, with a threshold of 2.0 yielding 91.6% sensitivity and 62.2% specificity. These findings suggest SR's potential, but also highlight the need for further research to establish a universally recommended cut-off value, solidifying its role in breast cancer diagnosis.

KEYWORDS

Breast Cancer, Strain Ratio, Breast Elastography, Breast Malignancy, Breast Ultrasound, Cancer screening, Women Imaging

INTRODUCTION

Breast cancer stands as the foremost cause of both new cases and fatalities among women on a global scale. The incidence of breast cancer is rising each year and patients tend to be affected at a younger age.¹ The significance of early and precise diagnosis cannot be overstated, both for effective management and the overall well-being of affected individuals. Previous studies have demonstrated that the 10-year survival rate was up to 80% in patients with breast cancer when early and suitable treatment was administered.²

Elastography is a non-invasive imaging technique which is done in the same session of ultrasound in an attempt to increase and improve the accuracy of diagnostic efficiency of ultrasound.³ This emerging technique endeavors to assess tissue elasticity by observing its response to mechanical stress. A pivotal facet of elastography is the integration of the strain ratio (SR) as a semi-quantitative metric within the strain elastography paradigm, thereby conferring its potential as an invaluable imaging biomarker.

Aims Of Study

The central aim of this comprehensive review is to move towards determining an appropriate SR cut-off value. This value, when precisely identified, has the potential to significantly improve the accuracy of diagnosing whether a breast lump is benign or malignant. This pursuit reflects the evolving landscape of breast cancer diagnosis and the continual efforts to enhance the precision of imaging techniques like elastography.

Limitations Of Study

This study's limitations include a relatively small percentage of compliant patients, potentially leading to an underestimation of the true incidence of malignant lesions within the evaluated group.

MATERIALS AND METHODS

This was a prospective study conducted on 40 patients, with benign and malignant breast lesions, from January 2024 to January 2025.

Each patient was subjected to complete history taking, and thorough clinical examination and then the following investigations-

Mammography

Mammogram was done in 34 out of 40 patients while the other 6 patients did not do mammogram as they were young (less than 30 years).

Ultrasound

All patients were subjected to breast US using SAMSUNG Rs80evo.

Ultrasound Elastography

All patients were examined in supine position with the B-mode USG image displayed alongside the elastography strain image. The elastography strain images were then scored according to the Tsukuba elasticity score.

We used semi-quantitative elastography. Color map was generated to the corresponding ultrasound image. (Adequate pressure was identified on the basis of regular waves on the scale). Strain ratio values which were calculated after analysis of strain imaging.

The results were confirmed by histopathological examination core needle biopsy in 14 cases and FNAC in 14 cases, discharge cytology in 2 cases, follow up in 06 cases and MRI mammography in 4 cases.

Breast lesions were evaluated based on BI-RADS and quantitative characteristics which describe the intensity along with stiffness of contrast of the 1–3 mm shell region.

REVIEW OF LITERATURE

Breast cancer stands as the most prevalent cancer among females worldwide.⁴ Even with the recommended frequency of screening via mammography, its applicability is hindered by dense breast tissue, which is prevalent in almost all premenopausal breasts and women below 50 years old. The lack of accessible early detection methods contributes to a significant number of patients being diagnosed at more advanced stages.⁵ Breast ultrasound offer a painless and non-irradiating evaluation. This method has substantial acceptance among the female population; however, the moderate sensitivity and specificity (both around 70%), introduce the potential for false outcomes (both positive and negative). Real Time Elastography, a newer technique, elevates diagnostic quality compared to conventional ultrasonography alone. It offers two potential avenues: a qualitative method employing color scales (such as the Tsukuba scale), which may introduce investigator subjectivity bias, and a quantitative, objective approach involving the Fat to Lesion Ratio (FLR) assessment. Existing literature notes marked increases in sensitivity, ranging from 78% to 91.5%,⁶ and from 71.2% to 89.7%.⁷ Our findings align with these increases.⁸

Malignant tumors have reduced elasticity and also display larger dimensions on elastography due to the accompanying desmoplastic reaction. Benign lesions appear similar to the adjacent tissues and have

a smaller diameter than on B-mode USG images.¹⁰

Certain authors emphasize RTE's advantages in cases showing benign ultrasound characteristics categorized as BI-RADS-US 3 but exhibiting heightened hardness on elastography. This could prompt their reclassification into the BI-RADS-US 4 category.¹¹ Other research highlights superior results for the FLR (qualitative technique) calculation over color map evaluation.⁶ The choice of threshold value remains unsettled.^{12,13} No universally recommended value exists, be it for elastography type or specific manufacturer. Most authors propose values in the range of 4 to 5: 4.8¹⁴, 4.7¹⁵, 4.0¹⁶, 4 to 5¹⁷, and 4.18¹⁸, respectively. Conversely, other authors advocate for values of 3 or below as suitable thresholds: 2.90¹⁹, 3.8²⁰, 3.64²¹, 3.5²⁰, 3¹⁸, and 2.61²². Some researchers even advocate for higher cut-off values, reaching up to 5.6²³. Moreover, specific thresholds for malignant lesions (3.04±0.9) and suggestive values for benign lesions (1.91±0.75) have been proposed²³.

Ana Filipa Gomes et al Our results show that UE when compared to MRI has adequate performance in differentiating benign and malignant breast lesions.²⁴

Xia Gong, Qiuhua Xu et al. The overall mean sensitivity and specificity for the diagnosis of malignant breast lesions by RTE were 0.834 [95% confidence interval (CI) 0.814–0.853] and 0.842 (95% CI, 0.829–0.854) for ES, and 0.883 (95% CI, 0.844–0.916) and 0.814 (95% CI, 0.786–0.839) for SR, respectively.²⁵

Richard G. Barr MD et al. Elasticity imaging has high sensitivity in characterizing malignant lesions of the breast. Variability in specificity between sites and sonographers is possibly due to individual technique differences in performing elastography and measuring lesions.²⁶

Ako Itoh et al For elasticity score, the mean ± standard deviation was 4.2 ± 0.9 for malignant lesions and 2.1 ± 1.0 for benign lesions ($P < .001$).²⁷

RESULTS–

This study included 40 patients with palpable breast lumps. Their ages ranged from 21 years to 77 years with a mean age of 48 years.

Considering the diagnosis in 40 cases, the lesions subdivided into 26 benign and 14 malignant lesions according to histopathological findings, MRI and follow up.

According to the BIRADS classification, 20 breast lesions (50%) were BIRADS 2, 09 lesions (22.5%) were BIRADS 3, 2 lesions (5%) were BIRADS 4, 07 lesions (17.5%) were BIRADS 5 and 2 lesions (5%) were BIRADS 6.

Benign lesions had elastography score 1, 2, 3 and 4 as follow: 6 lesions had elastography score 1, 13 lesions had elastography score 2, 2 lesions had elastography score 3 and 5 lesions had elastography score 4.

However malignant breast lesions had elastography score 3, 4 and 5 as follow: 3 lesions (17.9%) had elastography score 3, 9 lesions (64.2%) had elastography score 4 and 2 lesions (17.9%) had elastography score 5.

No malignant lesions had scores 1 or 2, and none of the benign lesions had a score of 5.

The relationship between BIRADS and elastography score was as follows

BIRADS 2 had score 1, 2, 3 and 4.

BIRADS 3 had score 1, 2, 3 and 4.

BIRADS 4 had score 4.

BIRADS 5 had score 4 and 5.

BIRADS 6 had score 3.

Relation between strain ratio and the diagnosis of breast lesions: all benign lesions had strain ratio with Min.–Max (0.20–8), Mean±SD (1.64±1.62), and Median (1.30) while all malignant lesions had strain ratio with Min.–Max (2–81), Mean±SD (22.56±26.2) and Median (15) (Table).

Pathological diagnosis	Number of lesions 40
Fibro adenoma	13
Simple cyst	3
Fibrocystic disease	3

Duct dilatation	6
Invasive ductal carcinoma	8
Ductal carcinoma in situ	2
Anaplastic carcinoma	3
Fibrocystic disease with atypia	2

DISCUSSION

In our study, FLR demonstrated heightened sensitivity and specificity for diagnosing malignant lesions compared to ultrasonography and qualitative RTE. Our findings suggest the optimal threshold value for malignancy is an FLR >4.88.

The research findings indicated that the average strain ratio values were 3.57 ± 0.8 for malignant breast lesions and 1.66 ± 0.45 for benign lesions ($p < 0.001$). The calculated areas under the ROC curve were as follows: 0.78 (95% CI 0.677; 0.797) for the strain ratio, 0.799 (95% CI 0.792; 0.942) for the Tsukuba score and 0.869 (95% CI 0.828; 0.841) for B-mode ultrasound, and 0.888 (95% CI 0.802; 0.964) for mammography.

Upon utilizing a threshold of 2.0, the sensitivity, specificity, positive predictive value, and negative predictive value of the strain ratio were found to be 91.6%, 62.2%, 73.3%, and 87.4%, respectively. The multivariate analysis, which examined factors influencing accuracy, revealed that only lesions with a depth of ≤ 5 mm were linked with diagnostic limitations.

Collectively, these results suggest that the strain ratio, alongside other imaging methodologies such as the Tsukuba score and B-mode ultrasound, exhibits promise in distinguishing between malignant and benign breast lesions. Nonetheless, it's important to acknowledge that the strain ratio displayed relatively elevated sensitivity but comparatively lower specificity. This implies that it is effective in identifying true positive instances, with a heightened likelihood of false positives.

CONCLUSION–

The synergy of elastography and strain ratio enhances B-mode ultrasound's ability to differentiate benign from malignant breast lesions.

Typically, benign lesions exhibit greater elasticity, while malignant counterparts tend to be stiffer. Among elastography techniques, strain elastography is more widely accessible compared to shear wave elastography. Furthermore, strain ratio (SR) has been incorporated as a semi-quantitative measure, offering potential as an imaging biomarker. The steady increase in the number of annual research publications on breast ultrasound elastography underscores the evolving nature of this field. The World Federation for Ultrasound in Medicine and Biology (WFUMB) issued guidelines in 2015 for breast elastography. These guidelines acknowledge the diversity in SR cut-off values used to distinguish benign from malignant lesions. However, since their publication, a substantial body of research has emerged.

For SR to solidify its potential as a reliable imaging biomarker for distinguishing benign from malignant breast lesions, it is imperative to establish a more optimal cut-off value. This review intends to address this need by incorporating the latest evidence and aiming to ascertain the current status in determining an optimal SR cut-off value.

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