Journal of Diagnostic Medical Sonography
2022, Vol. 38(3) 226–234

DOI: 10.1177/87564793211073682
journals.sagepub.com/home/jdm
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The Role of Ultrasonography and Elastography in Differentiating Benign From Malignant Breast Masses With Pathologic Correlation

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Abstract

Objective: Elastography has the potential in differentiating benign from malignant masses. The objectives of the study were to evaluate morphology of the breast masses with routine ultrasonography and elastography, to assess the role of elastography and conventional B-mode ultrasonography in differentiating benign from malignant breast masses and to correlate elastography and B-mode ultrasonography results with pathologic findings.

Materials and Methods: This prospective observational study was conducted over a period of 18 months from January 2018 to June 2019 on 86 patients with 101 clinically palpable breast lumps who underwent B-mode ultrasonography and elastography of the breast. Baseline data, sonographic features, a modified color score, and mean strain ratio were recorded and compared with final diagnosis.

Results: Sonography showed a sensitivity of 89.8%; specificity of 96.15%; positive predictive value (PPV) and negative predictive value (NPV) of 95.65% and 90.91%, respectively; and overall diagnostic accuracy of 93.07%. New modified dual color score showed sensitivity of 97.8%, specificity of 87.0%, PPV of 86.79%, and NPV of 87.08% with a diagnostic accuracy of 92.08%. The risk of missing a malignant case with the new modified dual color score was 2.1%. Mean strain ratio showed sensitivity of 100%; specificity of 98.11%; PPV and NPV of 97.96% and 100%, respectively; and diagnostic accuracy of 99.01%.

Conclusion: This study demonstrates the promise of elastography in identifying possible breast malignancies, thus preventing unnecessary invasive procedures.

Keywords

elastography, ultrasonography, modified color score, BIRADS, mean strain ratio, strain elastography

India constitutes one-third of the global breast cancer burden along with China and United States. There is an increase in incidence of breast cancer in India. Most of the patients present in advanced stage, making treatment difficult. The mortality rate due to breast cancer in India is high when compared with developed and some developing countries. Locally aggressive lesions or distant metastases are the causes for death in breast cancer.[1]

Currently, a pathologic examination is the standard investigation to differentiate benign from malignant breast mass. It is, however, an invasive procedure and yields a benign diagnosis in more than 75% of patients, making it challenging to deploy effective cancer screening programs.[1] The basic principle in elastography is similar to clinical palpation. Strain elastography is now used to assess various structures like breast, prostate, liver, blood vessels, thyroid, and musculoskeletal structures. The breast is currently the most widely and successfully imaged organ with elastography. Breast cancers are generally harder in consistency than normal breast tissue. Elastography can provide information about tissue stiffness.[2] In strain elastography, the relative stiffness on

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Received May 20, 2021, and accepted for publication December 14, 2021.

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the tissue in response to manual force applied is calculated.

Elastography has the potential to improve specificity of breast sonography in differentiating benign from malignant masses, thus reducing the number of benign biopsies. Elastography parameters such as modified color score and strain ratio were compared, using the trichromatic blue green red (BGR) artifacts, which is due to the fact that the gradient of the tissue displacement happens following compression. Through this research, it was further recommended that a new modification in the color score, previously in use and a mean strain ratio of 3.2, be used to differentiate benign from malignant breast masses.

Materials and Methods

This was a single-center prospective observational study of 86 patients with 101 clinically palpable breast lumps from January 2018 to June 2019. These patients were recruited after obtaining approval from the Institutional Ethics Committee. All the patients with clinically palpable breast lumps were included in the study. Those with prior biopsy proven and recurrent breast cancers were excluded. Sonographic assessment was performed using PHILIPS EPIQ 5G ultrasound equipment using a 5 to 12 MHz linear-array transducer by qualified radiologists. Patients underwent B-mode ultrasonography followed by elastography subsequently. Ultrasonography was performed in supine position in radial fashion. Morphologic changes in ultrasonography were interpreted based on the American College of Radiology Breast Imaging-Reporting and Data System (ACR BI-RADS 5th edition). In elastography, the transducer was placed perpendicular to the lesion, and gentle compression was applied. A modified color score and strain ratio were used to determine the nature of a lesion. The modified color score uses a color pattern to determine the nature of lesion, with blue indicating malignancy (hard lesions), red indicating benign lesions (soft lesions), and green indicating strain similar to normal adjacent tissue. The blue color was given a score of 2, uniformly green and the BGR artifact were given a score of 0, and mixture of blue and green was given a score of 1. Strain ratio is the ratio of hardness of the target tissue to the adjacent normal breast fat. Lesions with higher score were considered as malignant (hard) and lesions with low strain ratio were considered as benign. Strain ratio was calculated by placing region of interest (ROI) 1 on normal breast fat and similar size ROI 2 was placed in the lesion. The two ROIs should be near horizontally placed. The strain ratio was calculated as ratio of ROI 1 to ROI 2 and values were generated. The cutoff strain ratio used to differentiate benign and malignant lesions was 3.2. The cutoff value was taken based on the initial work completed after 6 months, which showed a good correlation for differentiating benign from malignant lesions. Consent was obtained from the patient after pathology was found on the B-mode sonogram and elastography images to include in the study. Ultrasound-guided fine needle aspiration (FNA) or trucut biopsy was completed in the pathology department of the university hospital by qualified pathologist. The results were compared with the ultrasonographic and elastographic findings.

Statistical Analysis

The data were entered in Microsoft excel sheet. The measurable variables were analyzed and interpreted between them by the student's *t* test, and the ordinal and categorical variables between them were interpreted by chi-square (χ^2) test. The receiver operating characteristic (ROC) curves for mean strain ratio and cutoff values were obtained. The statistical procedures were performed with the help of MedCalc ver 19.1.7 and OpenEpi ver 3.01. *P* value less than .05 ($P < .05$) were considered as statistically significant.

Results

From January 2018 to June 2019, 86 patients with 101 breast lesions were included in the study, in which 85 were women and 1 was a man. A total of 100 lesions were present in female patients and one lesion was seen in the male patient. The mean age of the patients was 42.45 ± 16.2 years with range of 14 to 95 years. When BIRADS category was considered, there was an increase in average age with increasing BIRADS score, which was statistically significant. A similar statistically significant association was also seen with modified color score and mean strain ratio with increasing age (Table 1).

In this study, benign lesions constituted for 52.48% of cases (n = 53), while remaining cases were malignant (n = 48; 47.52%). Among 53 benign lesions, 35 were benign solid lesions and remaining 18 lesions were benign cystic lesions. There were 48 malignant lesions. In the age group between 41 and 60 years, there was an increasing trend in malignancy as evidenced by greater number of lesions in BIRADS categories 4 and 5 (73.6% of lesions), modified color score of 2 and strain ratio of >3.2 (78.9% of lesions in each group) as shown in Figure 1. Pathologic diagnosis showed 30 lesions as malignant. In patients with age group >60 years, there were 13 lesions of which 10 (76.9%) were classified as malignant on ultrasound (BIRADS 4 and 5) and modified color score (score 2) and 9 (69.2%) were classified as malignant on mean strain ratio. On pathologic diagnosis, all the cases classified as malignant on mean strain ratio were malignant and four lesions (31.8%) were benign (see Table 1).

Table 1. Distribution of Lesions Based on Age Group of Patients and BIRADS Score, Modified Color Scoring, Strain Elastography Ratio, and Final Diagnosis.

	Age Group (in Years) (No. of Lesions; %)				
Classification of Lesion	<21	21–40	41–60	>60	Total
Ultrasonography					
BIRADS 2	5 (4.9%)	12 (11.8%)	3 (2.9%)	1 (1%)	21 (20.8%)
BIRADS 3	5 (4.9%)	17 (16.8%)	7 (6.9%)	2 (2%)	31 (30.6%)
BIRADS 4	0 (0%)	10 (9.9%)	19 (18.8%)	5 (4.9%)	34 (33.6%)
BIRADS 5	0 (0%)	1 (1%)	9 (8.9%)	5 (4.9%)	15 (14.8%)
Elastography					
Modified color scoring					
0	1 (1%)	15 (14.8%)	5 (4.9%)	1 (1%)	22 (21.8%)
1	8 (7.9%)	12 (11.9%)	3 (3%)	2 (2%)	25 (24.8%)
2	1 (1%)	13 (12.9%)	30 (29.7%)	10 (9.9%)	54 (53.5%)
Mean strain ratio					
<3.25	10 (9.9%)	30 (29.7%)	8 (7.9%)	4 (4%)	52 (51.5%)
>3.25	0 (0%)	10 (9.9%)	30 (29.7%)	9 (8.9%)	49 (48.5%)
Final diagnosis					
Benign cystic	2 (2%)	11 (10.9%)	4 (4%)	1 (1%)	18 (17.8%)
Benign solid	8 (7.9%)	20 (19.8%)	4 (4%)	3 (3%)	35 (34.7%)
Malignant	0 (0%)	9 (8.9%)	30 (29.7%)	9 (8.9%)	48 (47.5%)
Total	10 (9.9%)	40 (39.6%)	38 (37.6%)	13 (12.9%)	101 (100%)

Abbreviations: BIRADS, Breast imaging reporting and data system.

Cystic masses revealed the classic BGR artifact on the modified color scoring scale in elastography (see Figure 2). Among 18 benign cystic lesions, 10 lesions were diagnosed with fibrocystic disease and 8 lesions were diagnosed as breast abscess. Pathologic investigation included either FNA cytology or histopathologic examination. In 101 breast masses in which either cytology or histopathology was performed, 48 were malignant and 53 were benign breast masses (Table 2).

In 101 breast masses, most of the lesions (n = 54) were categorized as score 2 in modified color score. Out of these 54 lesions, 47 were pathologically proven as malignant breast masses and 7 were benign lesions. A total of 25 breast masses had score of 1 and 22 lesions were categorized with score 0. Of the 25 breast masses with score 1, 24 lesions were benign, and 1 lesion was malignant. All the 22 lesions with score of 0 were benign. The modified color score showed sensitivity of 65.2%, specificity of 75.8%, and positive predictive value (PPV) and negative predictive value (NPV) of 87% and 46.8%, respectively, for differentiating benign from malignant lesions with overall diagnostic accuracy ranging up to 68.32%. The researchers further adjusted the modified color score to include only two categories, benign and malignant. Table 3 shows the results obtained with the new modified dual color scoring system where modified color scores of 0 and 1 (Tsukuba scores of 1 to 3) can be considered as benign and modified color score of 2 (Tsukuba scores of 4 and 5) be considered as malignant. This modification had a sensitivity of 97.8%, specificity of 87.0%, PPV of 86.79%, and NPV of 87.08% with a diagnostic accuracy ranging to 92.08%. This modification has overall improved diagnostic accuracy when compared with three-category classification. In this category, there was one case which was considered as benign (score 0) and was revealed as malignant on pathologic diagnosis. With the new modified dual color scoring system, the chance of missing a malignant lesion was 2.1%.

A cutoff strain ratio of 3.2 was used to differentiate benign from malignant breast masses. In 101 breast masses, 52 breast masses had strain ratio <3.2, suggesting a benign etiology and 49 breast masses had strain ratio >3.2, indicating the mass was malignant as shown in Table 1. Mean strain ratio for benign solid breast lesions was 1.932 ± 1.205 (mean $\pm$ SD), for benign cystic lesion was 1.210 ± 0.792 (mean $\pm$ SD), and for malignant breast masses was 4.551 ± 0.933 (mean $\pm$ SD). The overall mean strain ratio for benign lesions was 1.686 ± 1.135, which was statistically significant when compared with mean strain ratio of malignant lesions ($P < .001$).

A ROC curve was obtained based on the mean strain ratio and the nature of disease (benign vs malignant) with area under curve (AUC) of 0.981 (95% confidence interval [CI], 0.932–0.998). The ROC curves showed the following criterion values for various mean strain ratio (see Figure 3). It can be noted from Figure 3 that mean strain ratio >3.2 has sensitivity of 100% (95% CI, 92.6%–100%) and specificity of 98.11% (95% CI, 89.9%–100%)

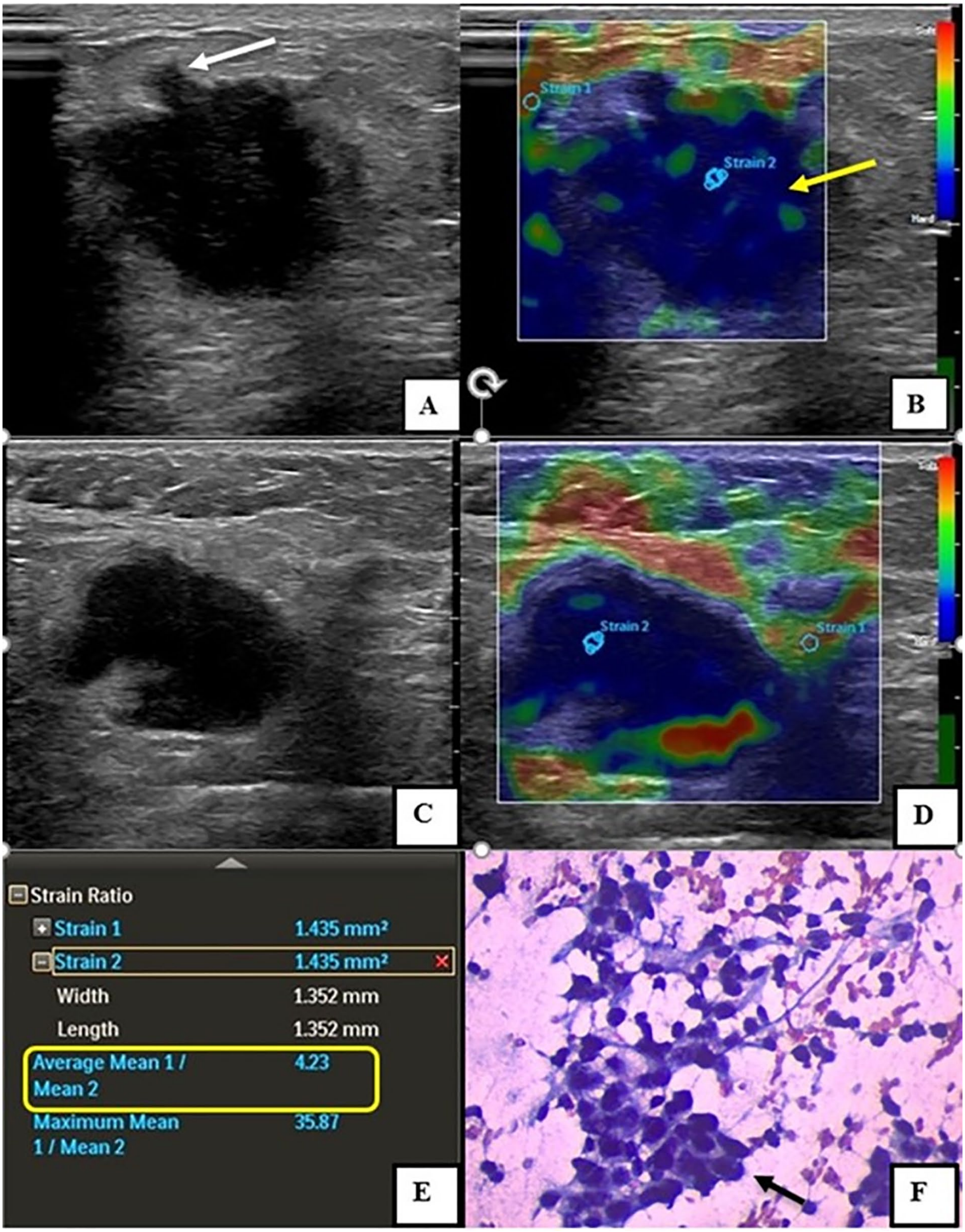


Figure 1. Ultrasonography in a 40-year-old patient showed a spiculated (thick white arrow), hypoechoic solid lesion (A) with multiple right axillary lymph nodes enlargement and loss of fatty hila (C) suggestive of Breast imaging reporting and data system (BIRADS) 5. On elastography, (B & E) the lesion (thick yellow arrow) and lymph nodes (D) showed uniform blue color pattern suggestive of malignancy (score 2). Mean strain ratio was 4.23 (E; yellow box) and 4.03 for mass and axillary lymph node, respectively. Fine Needle Aspiration Cytology (FNAC) showed ductal epithelial cells with high nuclear cytoplasmic ratio suggestive of infiltrating ductal carcinoma (F).

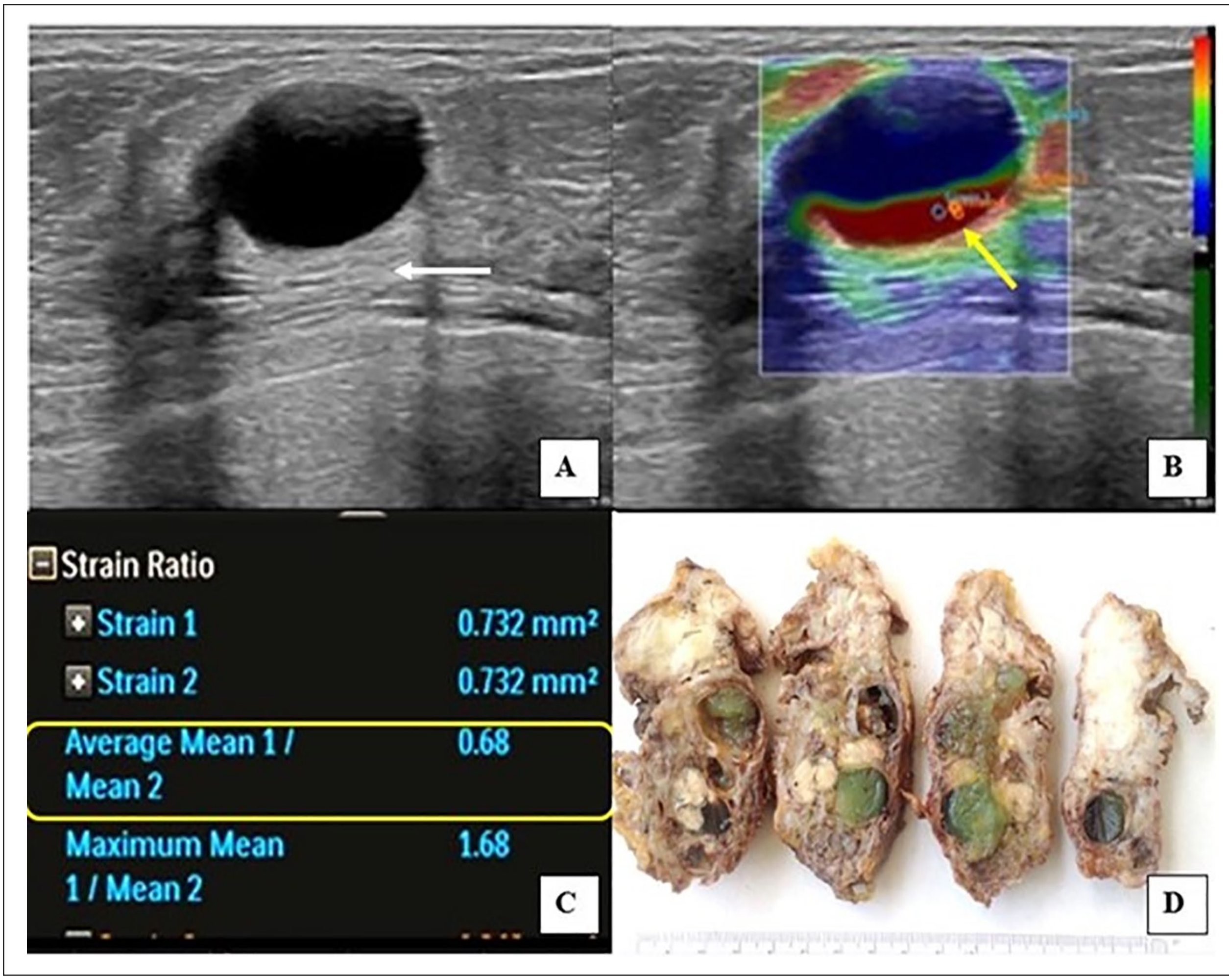


Figure 2. Ultrasonography in a 36-year-old patient with palpable right breast lump showed well-defined, ovoid, anechoic cystic lesion with posterior acoustic enhancement (thick white arrow), suggestive of Breast imaging reporting and data system (BIRADS) 2 lesion (A). On elastography, the lesion demonstrated BGR (thick yellow arrow) trichromatic interface pattern (score 0) in modified color score (B). Mean strain ratio was 0.68 (yellow box, C). On gross image, multiple cysts filled with greenish fluid and gray, white areas representing fibrosis were seen (D). BGR, blue green red.

Table 2. Correlation Between Ultrasonography and Elastography Diagnosis With Final Diagnosis.

Diagnosis Based on Modality	Pathologic Diagnosis		
	Benign	Malignant	Total
USG			
Benign	50	2	52
Malignant	5	44	49
Elastography			
Benign	52	0	52
Malignant	1	48	49
Total	53	48	101

Note. On ultrasound, Breast imaging reporting and data system (BIRADS) score of ≤ 3 are considered as benign and >3 are considered as malignant. On elastography, strain ratio is considered for differentiating benign from malignant lesion. A strain value of <3.2 is considered as benign and ≥3.2 is considered as malignant.

for differentiating benign from malignant lesions. This is important because with mean strain ratio of >3.2, none of the malignant lesions are missed.

Mean strain ratio identified all 48 malignant masses correctly. Mean strain ratio could identify all malignant lesions correctly, and only one benign lesion was classified as malignant. All cases, which were benign on strain ratio were benign on histopathology.

In 101 breast masses, 35 solid and 18 cystic lesions were proven benign by pathologic examination. Ultrasonography was accurate in picking only 33 solid and 17 cystic benign lesions, whereas elastography diagnosed 34 solid and all 18 cystic masses correctly. Table 2 shows comparison of B-mode ultrasonography and elastography with pathologic correlation. For final comparison with sonography, mean strain ratio was used as elastography parameter as it showed high sensitivity and

Table 3. Classification of Breast Lesions Based on Modified Color Scoring and New Modified Dual Color Scoring System and Correlation With Final Diagnosis.

	Number	Benign	Malignant
Modified color scoring system[a]			
0	22	22	0
1	25	24	1
2	54	7	47
Total	101	53	48
New modified dual color scoring system[b]			
0 (benign)	47	46	1
1 (malignant)	54	7	47
Total	101	53	48

Abbreviation: PPV, positive predictive value.
[a]Modified color score showed sensitivity of 65.2%, specificity of 75.8%, positive and negative predictive values of 87 and 46.8%, respectively, for differentiating benign and malignant lesions with overall diagnostic accuracy of 68.32%.
[b]New Indian color scoring system has sensitivity of 97.8%, specificity of 87.0%, PPV of 86.79%, and NPV of 87.08% with a diagnostic accuracy of 92.08%.

specificity and is an objective measurement. Among the 48 pathologically proven malignant breast masses, elastography diagnosed all malignant masses accurately, whereas ultrasonography was able to diagnose only 44 malignant masses. Overall, the sonogram demonstrated a sensitivity of 89.8%, specificity of 96.15%, PPV of 95.65%, NPV of 90.91%, and overall diagnostic accuracy of 93.07%.

Discussion

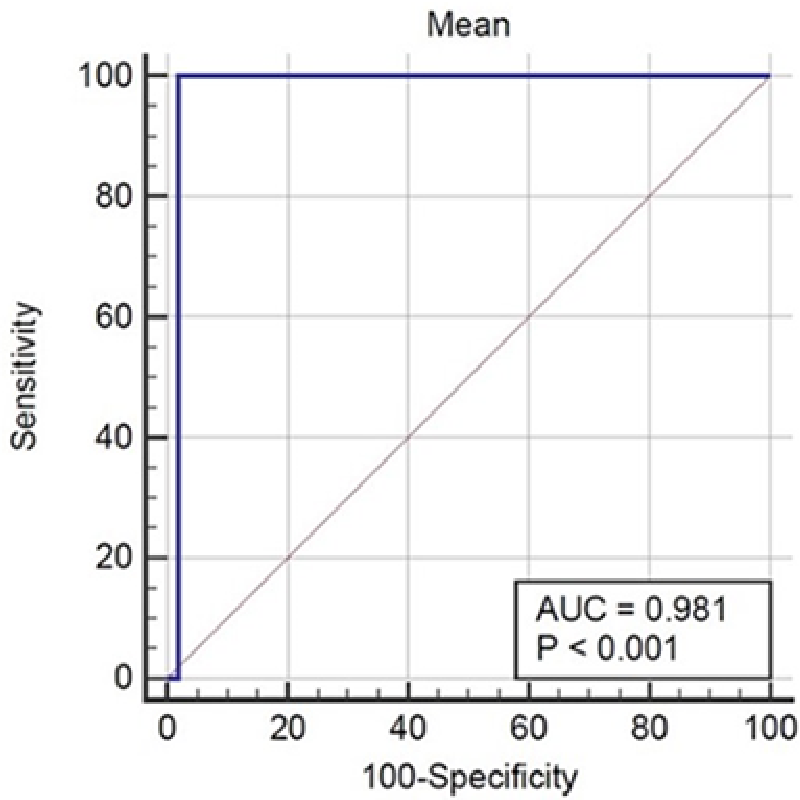
Diagnosing a breast lesion as benign or malignant is clinically important because it can avoid unnecessary biopsies. Addition of elastography technique helps to differentiate benign from malignant breast masses. Especially, it is important in the lesions with BIRADS score 3 and 4. Elastography is having a potential in reducing unwanted biopsies particularly in benign and/or cystic lesions.

The most common age group in our study was 41 to 60 years (37.6%), followed by 21 to 40 years (34.6%) with a mean age of 42.45 ± 16.2 years (mean ± SD) with a range of 14 to 95 years. Our results are similar to study by Menezes et al who reported the most common age of women with breast lesions to be 45 to 60 years of age.[3] A similar observation was also made by Dong et al. They reported a mean age of 45.39 ± 12.97 years (range 21–77 years) in women presenting with breast lesions.[4]

In the present study, most of the breast masses were categorized under BIRADS 4 (n = 36) constituting 35.64% of cases. Yilmaz E et al, also showed that BIRADS 4 lesions constituted majority in his study constituting about 43.09% of total cases.[5] In the present study, 53 masses (52.47%) were benign, and 48 masses (47.53%) were malignant. Özel and Özel, in their study, reported high incidence of benign lesions (71%) of which benign solid lesions constituted 47.8% of overall lesions, and benign cystic lesions formed 23.3% of overall cases. Malignant lesions constituted only 28.9% of overall lesions.[6] The current findings also differ from observations made by Xiao et al, who observed that cystic lesions constituted about 39% of overall cases and solid benign lesions constituted about 25.3% of overall lesions. They also reported more benign lesions (64.2%).[7] These differences could be attributed to the different geographic areas, where the studies were conducted, that is, in Poland[6] and China,[7] respectively.

All cystic lesions in the present study demonstrated BGR artifact. Cho et al, in their study of 13 cystic lesions showed that strain elastography showed BGR artifact. The authors proposed that the presence of trichromatic pattern (BGR artifact) helps in differentiating a cystic lesion from solid mass.[8] This artifact can effectively differentiate between a cyst and a solid lesion. A modified color score was used as one of the parameters in the current study. It is a modification of Tsukuba scoring. Chang et al in their study proposed modification of Tsukuba score into three categories as negative (score 0), borderline (score 1), and malignant (score 2).[9] The Korean Breast Elastography Study Group released the practice guideline for breast elastography, which also recommended a similar modification.[10] This study used the same scoring systems and classified lesions as benign (negative category; score 0), equivocal (score 1), and malignant (positive category; score 2). The current findings demonstrated that the modified color scoring may be further modified to include negative (benign lesion) or positive (malignant lesion) finding, which has been described in the results. This modification has sensitivity of 97.8%, specificity of 87.0%, PPV of 86.79%, and NPV of 87.08% with a diagnostic accuracy of 92.08% for benign lesions. This modification has overall improved diagnostic accuracy when compared with three-category classification, which has diagnostic accuracy of 68.32%. With new modified dual color scoring system, the chance of missing malignant lesion was 2.1%. A similar finding was observed by Shamla et al, who reported a sensitivity of 85.3%, specificity of 87.8%, PPV of 92.7%, NPV of 76.5%, and overall diagnostic accuracy of 86.2%.[11]

In the present study, a mean strain ratio of 3.2 was considered as cutoff to differentiate benign from malignant breast masses. Among 101 breast masses, 52 (51.48%) had strain ratio values less than 3.2, and 49 (48.52%) had strain ratio values more than 3.2. One benign case of granulomatous mastitis showed a higher mean strain ratio (7.8) and was classified under malignant category



Criterion	Sensitivity	95% CI	Specificity	95% CI
≥0.34	100	92.6 - 100	0	0 – 6.7
>3.2	100	92.6 - 100	98.11	89.9 - 100
>6.77	0	0 – 7.46	98.11	89.9 - 100
>7.8	0	0 – 7.4	100	93.3 - 100

Figure 3. The receiver operator characteristic (ROC) curve for mean strain ratio for benign and malignant breast lesions. AUC, area under curve; CI, confidence interval.

(see Figure 4). None of the malignant lesions were classified as benign. This is important as it avoids unnecessary breast biopsy, particularly in patients with strain ratio of <3.2. Moreover, strain elastography ratio can itself be established as an indicator for differentiating benign from malignant lesion without the need to resort to an ultrasound BIRADS category or use of modified color scoring system. Malignant breast lesions show large aggregates of elastin fibers, a process called elastosis. It is believed that the stromal (fibroblasts and myofibroblasts) and malignant cells cause aggregation of elastotic material in breast tissue. Furthermore, other changes like changes in extracellular matrix and high cellularity all cause the malignant area to be stiff resulting in increased stiffness of malignant lesions.[12]

Özel and Özel obtained a strain elastography ratio of 3.1 as cutoff for differentiating benign from malignant lesions, which is comparable with our study.[6] Bojanic et al, obtained a higher strain elastography ratio cutoff of 3.8 for differentiating benign from malignant lesions

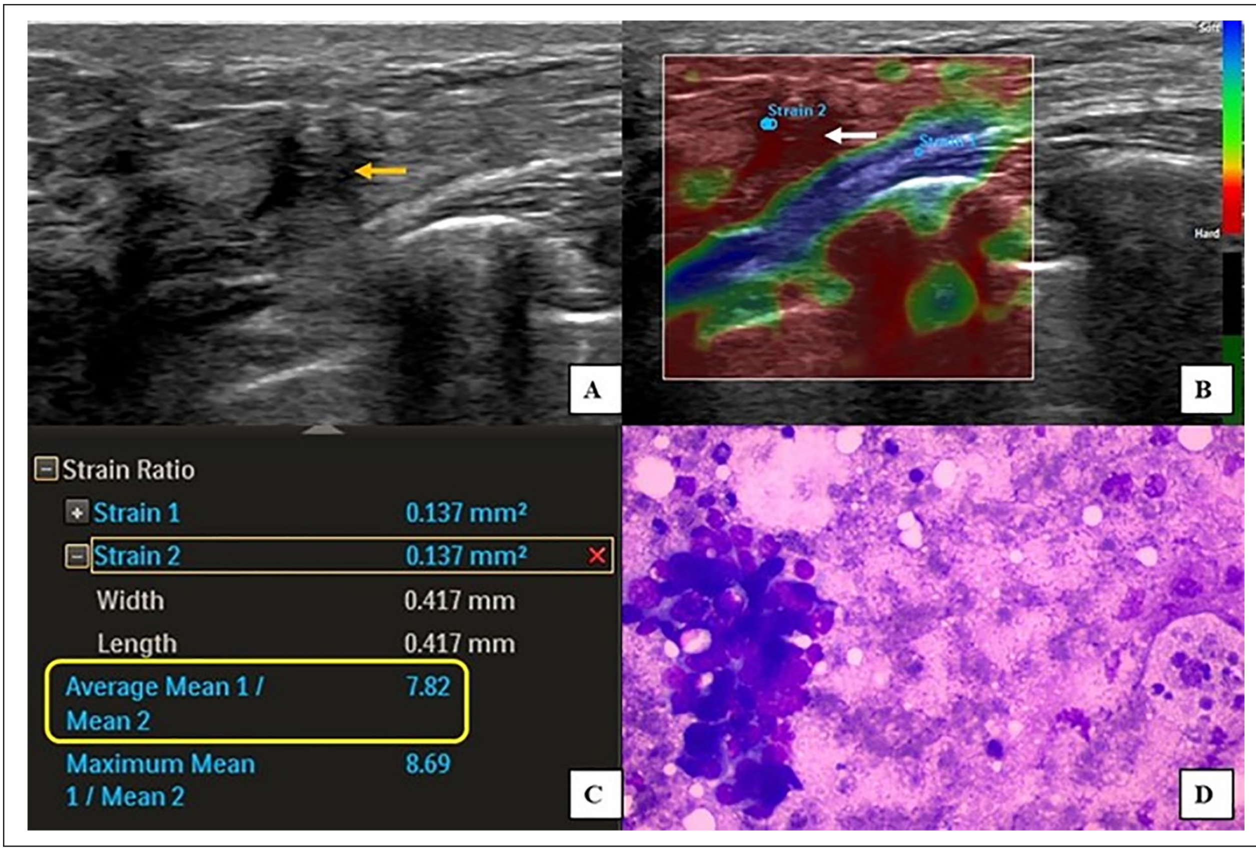


Figure 4. Ultrasonography in a 32-year-old patient with palpable left breast lump showed a spiculated solid lesion with posterior acoustic enhancement, suggestive of Breast imaging reporting and data system (BIRADS) 5 lesion (A). On elastography, the lesion demonstrated uniform patterns of red color (red color was considered as hard) (score 2, thick white arrow) suggestive of malignant lesions (B). Mean strain ratio is 7.82 suggestive of malignant solid lesion (C). FNAC confirmed it as mastitis (D).

with sensitivity and specificity of 90.5% and 93.2%, respectively.[12] Various studies done by Gheonea et al,[13] Mousa A E et al,[14] and Balçık et al[15] showed that strain ratio more than 3.0 will be most probably a malignant breast mass.

In the current study, it was observed that elastography and ultrasonography incorrectly diagnosed granulomatous mastitis. Mutala et al also reported higher mean strain ratio for granulomatous mastitis in their study. The authors hypothesized that presence of granulomatous tissue may result in increased stiffness and can explain the increased mean strain ratio.[16] The current finding is contrary to data reported by Yağcı et al and Durur-Karakaya A et al, who reported lower strain ratio for granulomatous mastitis with strain ratios ranging from 1.5 ± 0.8 (range 0.2–4) and 1.10 ± 0.79 (range 0.29–4), respectively.[17,18] Our study shows that strain ratio cutoff had excellent prediction rate in comparison with modified color in diagnosing both benign and malignant breast masses. With strain ratio cutoff of 3.2, all 48 malignant breast masses were correctly diagnosed and 52 out of 53 benign breast masses (98.11%) were correctly correlated with pathologic diagnosis.

Limitations

This study had certain limitations. The sample size was relatively small to provide more meaningful data on rare conditions such as phyllodes tumor, granulomatous mastitis, and squamous cell carcinoma. Elastography is certainly operator dependent. FNAC was performed initially, and this provided inconclusive results in many cases, which finally had to undergo core biopsy or surgical excision for pathologic diagnosis. In this study, the researchers did not evaluate the inter- or intra-observer variability, because it was not designed initially.

Conclusion

In the future, elastography can act as good adjuvant to conventional B-mode ultrasonography in differentiating benign from malignant breast lesions thereby reducing the frequency of benign biopsies. Ultrasonography along with cutoff strain ratio, and modified and new modified dual color scoring parameters can increase the sensitivity, specificity, PPV and NPV, and diagnostic accuracy compared with ultrasonography alone. Elastography has significant role in characterizing a lesion whenever diagnosis by ultrasonography was equivocal. Further studies on the elastography parameters, regarding real-time elastography and elastography-guided breast biopsies are needed to determine its role in breast malignancy screening programs.

Acknowledgment

Dr C.S.B.R. Prasad, Professor, Department of Pathology, Sri Devaraj Urs Academy of Higher Education and Research.

Declaration of Conflicting Interests

The authors declared no potential conflicts of interest with respect to the research, authorship, and/or publication of this article.

Funding

The authors received no financial support for the research, authorship, and/or publication of this article.

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