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Ultrasound elastography improves differentiation between benign and malignant breast lumps using B-mode ultrasound and color Doppler

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KEYWORDS
Breast cancer; Ultrasound elastography; Mammography; Color Doppler

Abstract Objectives: To evaluate diagnostic yield of mammography, B-mode ultrasound (US), ultrasound elastography (UE) and color Doppler used alone or in combination for differentiating breast lesions.

Patients and methods: Sixty women presented by breast lump underwent mammographic examination, B-mode US, color Doppler assessment and UE. The result of histopathological examination of excisional biopsy was used as gold standard for comparison of results.

Results: Mammography defined 36 patients had dense glandular breast and 24 patients had fatty parenchyma. Eleven patients had dense glandular parenchyma and 7 of those had fatty parenchyma had malignant lesions. Mean resistive index for malignant lesions was significantly higher than benign lesions. The mean strain ratio was significantly higher for malignant. Combined use of US and UE provided better diagnostic yield than US and Doppler, while combined use of US, UE and Doppler improved the diagnostic yield with high sensitivity and specificity and NPV of 95%. ROC curve analysis assured the high diagnostic yield of combination of US, UE and Doppler.

Conclusion: Combined use of B-mode US, UE and color Doppler achieved NPV of 95% thus allowed sparing of unnecessary invasive diagnostic procedures. UE as a sole diagnostic test has high sensitivity and specificity. Mammography could be used as screening test for its high sensitivity.

1. Introduction

Breast cancer remains a worldwide public health problem. It is considered to be the primary women’s cancer and causes high morbidity and mortality that aroused attention for disease preventive programs. Multiple cross-sectional studies indicated the effectiveness of chemo-preventive measures for breast cancer in high risk women. The relative risk reduction seems similar across all breast cancer risk groups; however, the absolute
risk reduction varies by risk factors for breast cancer and must be balanced against the potential harms to judge the appropriateness of treatment for individual women (1–4).

The debit about the adequacy of chemo-preventive programs deviated attention toward early detection programs starting with breast self-examination for early detection of changes occurring in the breast and ending with mass-screen surveys. Knowledge of women about the risks and benefits of early detection of breast cancer positively affects their health beliefs, attitudes, and behaviors. Health care professionals can develop effective breast health programs and can help women to gain good health behavior and to maintain health (5–7).

Breast ultrasonography (US) plays a critical role in the diagnostic evaluation of screening-detected or palpable breast masses. US with a high-frequency transducer is essential for accurate noninvasive diagnosis of breast cysts and is the method of choice for differentiating solid from cystic lesions. In addition, US has been advocated and shown to be potentially useful in the examination of young or pregnant symptomatic patients. Ultrasound has shown promise in the differentiation of benign from malignant solid masses. Breast ultrasound is the preferable screening method as it provides high sensitivity for detecting breast cancer in women with dense breast tissue and can detect cancers not identified on mammography in asymptomatic women with dense breast tissue. Incremental US cancer detection is reported in 0.27–0.46% of women with mammography-negative dense breasts (8,9).

Degree of lack of the strain of a focal lesion in breast elastography is an important finding which improves the diagnostic reliability of sonography, increases specificity and allows better differentiation between benign and malignant focal findings, particularly between Breast Imaging-Recording and Data System (BI-RADS) US 3 and BI-RADS-US 4. Therefore, the number of false-positive findings in breast diagnostics was able to be reduced by using elastography (10–13).

The current prospective study aimed to evaluate the diagnostic yield of mammography, B-mode ultrasound, ultrasound elastography and color Doppler used alone or in combination for differentiating breast lesions as benign or malignant in comparison with histopathological examination of excisional biopsy.

2. Patients and methods

The current study was conducted at Departments of Radiodiagnosis and General Surgery, Benha University Hospital since June 2011 till Feb 2013. The study included 60 female patients who attended the General Surgery outpatient clinic with breast mass that on clinical examination was suspicious to be malignant and who were admitted for open excisional biopsy.

After consent taken from all, patients underwent radiological workup included mammographic examination, B-mode ultrasonography, Doppler assessment and ultrasound elastography. Mammographic examinations were performed based on the standard crono-caudal and medio-lateral oblique projections of each breast and according to the American College of Radiology (ACR) classification breast density was classified into 4 groups: 1. predominantly fat; 2. fat with some fibroglandular tissue; 3. heterogeneously dense; and 4. extremely dense. Specific lesion descriptions included mass description as regards size, location, shape and margin; calcifications description concerned morphology, distribution and location; architectural distortion, associated findings and lymph nodes assessment regarding number, size and morphology. Then, an overall assessment with BI-RADS category was assigned for each patient (14).

Using B-mode imaging, lesion size was determined as the maximal diameter of the lesion. The detected lesions were described concerning shape, orientation, margin, lesion boundary, echotexture, and acoustic transmission and the presence of calcifications was also documented. Lesions with ovoid, round or macro-lobulated shape, parallel orientation to the skin, circumscribed margin, abrupt interface to the normal parenchyma were categorized as probably benign (BI-RADS category 3). Lesions with irregular shape, not parallel to skin, lacking circumscribed margin, showing thick echogenic halo, complex echotexture, posterior acoustic shadowing or combined pattern with the presence of micro-calcifications were considered as malignant criteria. In the presence of one malignant criterion, lesion was considered as suspicious for malignancy (BI-RADS category 4) and if more than one criterion was present, lesion was considered as highly suspicious for malignancy (BI-RADS category 5).

Lesions were evaluated qualitatively according to their power Doppler ultrasound (PDUS) properties and quantitatively with spectral evaluation depending on the resistive index (RI). Qualitative categorization was based on the number and shape of the vessels (15): no vascularity in the mass (score = 0), one circumferential or central vessel was found in the mass (score = 1) and two or more circumferential or central vessels or a penetrating vessel was found in the mass (score = 2). Quantitative analysis included hypervascularization, penetration of the vessels into the mass, branching-disordered course and RI values >0.85 which were considered as probable malignant criteria (16).

All elasticity images were obtained with a system that consisted of a digital US scanner (EUB-6500; Hitachi Medical, Tokyo, Japan). The US probe was a 7.5-MHz Liner electronic probe (EUP-L53; Hitachi Medical). The top of the region of interest (ROI) included subcutaneous fat and the bottom included the pectoral muscles and lateral borders were set >5 mm from the lesion’s boundary. Depending on the magnitude of the strain, the scale ranged from red for components with greatest strain indicating softest components to blue for those with no strain indicating hardest components and green indicated average strain in the ROI. The color pattern in the detected lesions was evaluated on the basis of five-point elasticity score proposed by Itoh et al. (17): the entire lesion was evenly shaded in green (score = 1) indicated even strain for the entire hypoechoic lesion. The lesion had a mosaic pattern of green and blue (score = 2) indicated strain in most of the lesion with some areas of no strain. The peripheral part of the lesion was green and the central part was blue (score = 3) indicated strain at the periphery of the hypoechoic lesion, with sparing of the center of the lesion. The entire lesion was blue, but its surrounding area was not included (score = 4) indicated no strain in the entire hypoechoic lesion. Both the entire hypoechoic lesion and its surrounding area were blue (score = 5) indicated no strain in the entire hypoechoic lesion or in the surrounding area. The strain index, defined as the fat
to mass strain ratio (B/A ratio) that indicated mass stiffness, was automatically calculated.

The likelihood of malignancy was established based on combined B-mode US, Doppler and Ultrasound Elastography. The likelihood of malignancy category was changed from BI-RADS 4 or 5 (biopsy recommendation) to BI-RADS 3 (follow-up recommendation) when the elasticity score was 0, 1 or 2 or Doppler score was achieved. The likelihood of malignancy category from BI-RADS 3 (follow-up recommendation) to BI-RADS 4 or 5 (biopsy recommendation) when the elasticity score was 4 or 5 or Doppler score was 2 or more was achieved (18).

All patients underwent excisional biopsy and the results of pathologic examination of the obtained specimen were used as gold standard for comparison of the results of imaging studies. The results were statistically analyzed using SPSS software statistical computer package version 17 for quantitative data. Statistical presentation and analysis of the present study were conducted, using, relative operating characteristics (ROC) curve and area under the curve (AUC) to know the clinical significance.

3. Results

The study included 60 women with mean age of 43.6 ± 8.2; range: 32–55 years. Clinically, all patients presented by lump, but 5 patients had additional symptoms: two patients had nipple discharge, another two patients had pain (3.3%) and one patient presented with nodulations (3.3%). No patient had bilateral lesions. Histopathological examination of excised biopsy detected 42 benign lesions, while 18 lesions were malignant.

Mammographic examination defined 36 patients had dense glandular breast (ACR pattern III/IV), while the remaining 24 patients had fatty breast parenchyma (ACR pattern I/II). Comparison versus histopathological results defined 11 malignant lesions among those had dense glandular parenchyma and 7 malignant lesions among patients those had fatty breast parenchyma. BI-RADS categorization of mammographic findings showed that 41 lesions were categorized as BI-RADS category 3; 12 lesions were categorized as BI-RADS category 4; and 7 lesions were categorized as BI-RADS category 5. Only 4 BI-RADS category 3 lesions were malignant and 32 were benign, 7 BI-RADS category 4 lesions were malignant and 5 were benign and the 7 BI-RADS category 5 lesions were malignant with significantly (X² = 21.336, p = 0.001) high frequency of malignancy among BI-RADS categories 4 and 5 lesions compared to the frequency of benign lesions (Table 1).

Mean maximal diameter of studied lesions as estimated by US examination was 21.9 ± 8.8; range: 8–40 mm. Mean diameter of benign lesions was 22.9 ± 9.2; range: 8–40 mm, while mean maximal diameter of malignant lesions was 19.8 ± 7.7; range: 9–34 mm, with non-significantly (p > 0.05) wider diameter of benign lesions compared to malignant lesions. BI-RADS categorization of ultrasonographic findings showed that 37 lesions were categorized as BI-RADS category 3; 17 lesions were categorized as BI-RADS category 4; 6 lesions were categorized as BI-RADS category 5. Only 5 BI-RADS category 3 lesions were malignant and 32 were benign, eight BI-RADS category 4 lesions were malignant and 9 were benign and 5 of the 6 BI-RADS category 5 lesions were malignant, while only one of the 6 BI-RADS category 5 lesions was benign with significantly (X² = 9.635, p = 0.003) high frequency of malignancy among BI-RADS categories 4 and 5 lesions compared to the frequency of benign lesions (Table 1).

Doppler color score 0 was noted in 8 cases (13.3%), score 1 in 30 cases (50%), and score 2 in 22 cases (36.7%). Mean resistive index (RI) value for benign lesions was 0.56 ± 0.12; range: 0.1–0.9.

**Table 1** Mammographic and ultrasonographic findings of 60 breasts compared to histopathological diagnosis.

<table>
<thead>
<tr>
<th></th>
<th>Benign</th>
<th>Malignant</th>
<th>Total</th>
<th>Statistical significance</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Histopathology</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Dense glandular breast</td>
<td>42 (70%)</td>
<td>18 (30%)</td>
<td>60 (100%)</td>
<td></td>
</tr>
<tr>
<td>Fatty parenchyma</td>
<td>25 (69.4%)</td>
<td>11 (30.6%)</td>
<td>36 (100%)</td>
<td></td>
</tr>
<tr>
<td>BI-RADS category 3</td>
<td>17 (70.8%)</td>
<td>7 (29.2%)</td>
<td>24 (100%)</td>
<td></td>
</tr>
<tr>
<td>BI-RADS category 4</td>
<td>37 (90.2%)</td>
<td>4 (9.8%)</td>
<td>41 (100%)</td>
<td></td>
</tr>
<tr>
<td>BI-RADS category 5</td>
<td>5 (41.7%)</td>
<td>7 (58.3%)</td>
<td>12 (100%)</td>
<td>X² = 21.336, p = 0.001</td>
</tr>
<tr>
<td><strong>Ultrasonography</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Lesion diameter (mm)</td>
<td>22.9 ± 9.2 (8–40)</td>
<td>19.8 ± 7.7 (9–34)</td>
<td>21.9 ± 8.8 (8–40)</td>
<td>Z = 0.881, p &gt; 0.05</td>
</tr>
<tr>
<td>BI-RADS category 3</td>
<td>32 (86.5%)</td>
<td>5 (13.5%)</td>
<td>37 (100%)</td>
<td></td>
</tr>
<tr>
<td>BI-RADS category 4</td>
<td>9 (52.9%)</td>
<td>8 (47.1%)</td>
<td>17 (100%)</td>
<td>X² = 9.635, p = 0.003</td>
</tr>
<tr>
<td>BI-RADS category 5</td>
<td>5 (16.7%)</td>
<td>5 (83.3%)</td>
<td>6 (100%)</td>
<td></td>
</tr>
</tbody>
</table>

Data are presented as numbers and mean ± SD; ranges & percentages of corresponding total are in parenthesis.
0.44–0.97, while mean RI value for malignant lesions was 0.86 ± 0.18; range: 0.5–1.2. Mean RI value was significantly (\(Z = 3.421, p = 0.001\)) higher with malignant lesions compared to benign lesions, (Fig. 1). Considering RI at 0.85 as cut-off point for differentiation between benign and malignant lesions, RI missed 4 malignant lesions (False negative) with RI < 0.85 and over-diagnosed 9 benign lesions with RI > 0.85 (False positive) so could differentiate between benign and malignant lesions with sensitivity rate of 77.8% and specificity rate of 78.6% (Table 2).

<table>
<thead>
<tr>
<th>Data</th>
<th>Findings</th>
</tr>
</thead>
<tbody>
<tr>
<td>Color score</td>
<td>Zero 8 (13.3%)</td>
</tr>
<tr>
<td></td>
<td>One 30 (50%)</td>
</tr>
<tr>
<td></td>
<td>Two 22 (36.7%)</td>
</tr>
<tr>
<td>Resistive index (RI)</td>
<td>Benign 0.56 ± 0.12 (0.44–0.97)</td>
</tr>
<tr>
<td></td>
<td>Malignant 0.86 ± 0.18 (0.5–1.2)</td>
</tr>
<tr>
<td>Diagnostic yield at cutoff point of 0.85</td>
<td>False negative cases 4</td>
</tr>
<tr>
<td></td>
<td>False positive cases 9</td>
</tr>
<tr>
<td></td>
<td>Sensitivity 77.8%</td>
</tr>
<tr>
<td></td>
<td>Specificity 78.6%</td>
</tr>
</tbody>
</table>

Data are presented as numbers, mean ± SD and percentages; ranges and percentages are in parenthesis.

Ultrasound elastography scoring showed that 13 lesions were scored 1, 21 lesions were scored 2, 21 lesions were scored 3, 12 lesions were scored 4 and 8 lesions were scored 5. The mean strain ratio of the benign lesions was 3.21 ± 1.65; range: 1–7, while that for malignant lesions was 8.31 ± 4.14; range: 3–15. Strain ratio was significantly (\(Z = 3.012, p = 0.003\)) higher for malignant lesions compared to benign lesions (Table 3, Fig. 2).

Ultrasound examination (b-mode US) showed the higher percentage of fallacies where it showed 15 misdiagnoses for a rate of 25%; 5 were false negative and 10 false positive. Similarly, US Doppler showed 13 misdiagnoses for a rate of 21.7%; 4 were false negative and 9 were false positive. Mammography showed 9 fallacies for a rate of 15%; 4 were false negative and 5 were false positive. Ultrasound elastography showed 8 fallacies for a rate of 13.3%; 3 were false negative and 5 were false positive. Combined ultrasound elastography and Doppler showed the least fallacy rate of 11.7%; 2 were false negative and 5 were false positive (Fig. 3).

Evaluation of test validity characters of applied diagnostic modality alone or in combination for diagnosis of breast cancer showed the combined use of US and UE provided better diagnostic yield than US and Doppler with higher percentage of all characters that superseded the use of any modality alone. However, the combined use of US, UE and Doppler improved the diagnostic yield with high sensitivity and specificity rates and high NPV of 95% (Table 4, Fig. 4).
Analysis of the obtained results using ROC curve analysis assured the high diagnostic yield of combination of diagnostic modality with high AUC for the combined use of US, UE and Doppler, followed by the combined use of US and UE, then mammography, the combined use of US and Doppler and lastly US, (Table 5, Fig. 5).

4. Discussion

The current study showed high diagnostic yield of using combined diagnostic modalities including B-mode US, US elastography and color Doppler; such combination could exclude the presence of cancer by NPV of 95% and accuracy and specificity rates of about 90%. These data indicated the possibility of using such combination for mass screening especially for those at high-risk for developing cancer.

Moreover, ROC curve analysis of the obtained data defined such combination as the most specific predictors (AUC = 0.886) for the presence of cancer. The US elastography showed sensitivity and specificity rates of 83.3% and 88.1%, respectively and NPV of 92.5% and accuracy rate for diagnosis of malignancy of 86.7%. ROC curve analysis defined UE as the highly specific single test for diagnosis of breast malignancy with AUC = 0.859.

The reported high diagnostic yield of the combined methodology could be attributed to the high diagnostic yield of UE which improved the diagnostic yield of both conventional B-mode US and color Doppler when used in combination.

In support of the obtained results Mansour and Omar (19) found UE, using both qualitative and quantitative methods can improve the performance of conventional B-mode ultrasound and enhance its specificity and accuracy in the diagnosis

### Table 4 Test validity characters of applied diagnostic modalities for diagnosis of breast cancer.

<table>
<thead>
<tr>
<th>Test</th>
<th>Sensitivity (%)</th>
<th>Specificity (%)</th>
<th>PPV (%)</th>
<th>NPV (%)</th>
<th>Accuracy (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mammography</td>
<td>77.8</td>
<td>88.1</td>
<td>73.7</td>
<td>90.2</td>
<td>85</td>
</tr>
<tr>
<td>US</td>
<td>72.2</td>
<td>76.2</td>
<td>56.5</td>
<td>86.5</td>
<td>75</td>
</tr>
<tr>
<td>US + Doppler</td>
<td>77.8</td>
<td>78.6</td>
<td>60.9</td>
<td>89.2</td>
<td>78.3</td>
</tr>
<tr>
<td>US + UE</td>
<td>83.3</td>
<td>88.1</td>
<td>75</td>
<td>92.5</td>
<td>86.7</td>
</tr>
<tr>
<td>US + UE + Doppler</td>
<td>88.9</td>
<td>88.4</td>
<td>76.2</td>
<td>95</td>
<td>88.5</td>
</tr>
</tbody>
</table>

Data are presented as percentages; US: Ultrasound; UE: Ultrasound elastography; PPV: positive predictive value; NPV: negative predictive value.

### Table 5 ROC curve analysis of the obtained results of the applied diagnostic modalities for diagnosis of breast cancer.

<table>
<thead>
<tr>
<th>Test</th>
<th>AUC</th>
<th>Std Error</th>
<th>Sig.</th>
<th>95% CI Lower</th>
<th>95% CI Upper</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mammography</td>
<td>0.831</td>
<td>0.064</td>
<td>0.0009</td>
<td>0.705</td>
<td>0.957</td>
</tr>
<tr>
<td>US</td>
<td>0.745</td>
<td>0.072</td>
<td>0.003</td>
<td>0.604</td>
<td>0.886</td>
</tr>
<tr>
<td>US + Doppler</td>
<td>0.784</td>
<td>0.068</td>
<td>=0.001</td>
<td>0.652</td>
<td>0.917</td>
</tr>
<tr>
<td>US + UE</td>
<td>0.859</td>
<td>0.059</td>
<td>0.0005</td>
<td>0.744</td>
<td>0.973</td>
</tr>
<tr>
<td>US + UE + Doppler</td>
<td>0.886</td>
<td>0.052</td>
<td>0.0001</td>
<td>0.785</td>
<td>0.988</td>
</tr>
</tbody>
</table>

AUR: Area under curve; Std Error: standard error; Sig.: significance; CI: confidence interval.
of questionable (BI-RADS categories 3 and 4) breast lesions. Fischer et al. (20) documented that strain ratio calculation contributes to the standardization of sonoelastography with high sensitivity and allows significant differentiation between benign and malignant breast lesions with a higher specificity compared to B-mode, subjective evaluation of elastography and mammography.

Zhi et al. (21) reported a highly significant correlation between the elastogram color distribution and the percentage of malignant lesions with specificity, sensitivity, and accuracy rates of 86.4%, 80.8%, and 83.5%, respectively which were higher than US with AUC = 0.86. Alhabshi et al. (22) found the sensitivity and specificity of combined UE and conventional US were significantly higher than those of conventional

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**Fig. 6** A 34 years old woman presented with clinically right breast mass. Mammography shows: ACR pattern 4; descriptive criteria include macro-lobulated rounded well defined dense right breast mass; BI-RADS 3. B-mode U/S showed lobulated antiparallel oval shaped, rather well circumscribed, hypo-echoic mass with marginal shadowing. Lesion Size: 13 × 8 mm. BIRADS: 3. Doppler Color score: 0. U/S elastography: UE score 1 and SR: 1.5. Final combined (B-mode US, Doppler US & UE) diagnosis: typical fibroadenoma (Follow-up recommended). Pathological diagnosis: typical fibroadenoma.

**Fig. 7** A 38 years old woman presented with clinically right breast mass. Mammography shows: ACR pattern 2; descriptive criteria: macro-lobulated dense well defined right breast mass; BI-RADS 3. B-mode U/S showed lobulated antiparallel hypoechoic mass with well-defined border. Lesion Size: 20 × 12 mm. BIRADS: 4-a. Doppler Color score: 1 & RI: 0.69. U/S elastography: UE score 1 and SR: 2.4. Final combined (B-mode US, Doppler US & UE) diagnosis: Probably benign (Follow-up recommended). Pathological diagnosis: Papilloma.
US alone and the assessment with strain ratio and width ratio in UE were the most useful parameters in differentiating between benign and malignant breast lesions and concluded that this combined technique had the best results in detecting carcinoma and could reduce the need of unnecessary biopsy for benign lesions with indeterminate or equivocal features.

Zhang et al. (23) evaluated and compared diffuse optical tomography (DOT), ultrasound elastography (UE) and
mammography in differentiating breast tumors, found UE was the most specific and DOT and UE were more accurate than mammography and concluded that UE and DOT were superior to conventional mammography in terms of both specificity and accuracy and improve the specificity and accuracy of breast cancer diagnosis, and combining the two modalities improves the diagnostic value (Figs. 6 and 7).

The current study reported a significantly higher mean strain ratio for malignant lesions compared to benign lesions. In line with this finding, Zhao et al. (24) found the mean strain ratios were significantly higher of malignant than benign lesions and that in the 5-point scoring, sonoelastography had 84.2% sensitivity, 84.6% specificity, 84.5% accuracy, 70.6% positive predictive value and 92.4% negative predictive value and concluded that the 5-point scoring system and strain ratio have similar diagnostic performance, and the strain ratio could be more objective to differentiate the masses when those masses were difficult to be judged by using 5-point scoring system in sonoelastographic images. Sayed et al. (25) reported that the strain ratio values for the malignant breast masses were significantly higher compared to benign masses and concluded that the proposed elastographic techniques can be used as a noninvasive quantitative characterization tool for breast cancer, with the capability of visualizing and separating the masses in a three dimensional space and thus may reduce the number of unnecessary painful breast biopsies (Figs. 8 and 9).

Mammography showed high sensitivity rate for detecting breast cancer in comparison with US alone or color Doppler alone; a finding indicating its applicability as a single screening test and so could be used as a sole screening test wherever, the facilities are deficient. However, the main disadvantage of dependence on mammography as the sole test is its high false positive rate inducing high rate of malignant over-diagnosis. These data are in accordance with Kalager et al. (26) who documented that mammography screening entails a substantial amount of over-diagnosis ranged between 18% and 25% of screened women. Coldman and Phillips (27) documented that the use of mammography screening in older women has an increased risk of over-diagnosis and the estimation of over-diagnosis from observational data is complex and subject to many influences so it should be considered in screening decisions (Fig. 10).

It could be concluded that combined use of B-mode US, UE and color Doppler achieved high NPV of 95% thus allowing sparing of unnecessary invasive diagnostic procedures. UE could be used as a sole diagnostic test with high sensitivity and specificity and improved the diagnostic yield of other tests when used in combination. Wherever, other diagnostic procedures are lacking mammography could be used as a screening test for its high sensitivity despite the malignant over-diagnosis.

Conflict of interest

The authors declare that there is no conflict of interest.

References


