Role of Ultrasound Elastography in Characterization of Indeterminate Breast lesions (BIRADS 3&4 lesions).

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Abstract

With the expanded role of screening breast ultrasonography and accumulating clinical experience, the American College of Radiology (ACR) has established the Breast Imaging Reporting and Data System (BI-RADS) ultrasonography lexicon to standardize terminology for description and management recommendations according to stratified risks.

It has been established that probably benign (BI-RADS category 3) lesions having a malignancy rate of less than 2% require short-term imaging follow-up rather than immediate biopsy. The BI-RADS 4 category is assigned to suspicious lesions for which biopsy is recommended.

Routine screening methods such as mammography and breast ultrasound are valuable methods for managing breast 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.

In our study we included 46 patients with different breast lesions. All patients had a conventional B-mode ultrasound examination and were evaluated according to the BIRADS categories, then real time free-hand ultrasound elastography was performed in the same session and images were evaluated using both the Tsukuba elasticity score and the strain ratio method. Finally, the results were compared to the histopathologic results of those lesions. It was found that conventional B-mode ultrasound examination had a sensitivity of **72.73% and** specificity of **83%** While, elastography scoring alone turned out to have sensitivity of **65.5%,** specificity of **83.4%** using the Tsukuba score system. The additional of Strain ratio parameter for evaluating the elastography images showed the highest sensitivity **98.4%** and specificity **85.68%** at a best cutoff point of 3.47.

So we have found that elastography is an easy procedure with high diagnostic performance which can be easily integrated with the B-mode ultrasound examination in the same session and improves its specificity. That has proven benefit in minimizing the number of unnecessary biopsies especially in the assessment of BIRADS 3 and 4 lesions

Key words:
Ultrasound, BIRADS, Elastography, Strain ratio, Elastacity score.

Introduction

Elastography was introduced in early 1990, it is an easy procedure with high diagnostic performance which can be easily integrated with the B-mode ultrasound examination in the same session and improves its specificity. It has proven benefit in minimizing the number of unnecessary biopsies especially in the assessment of BIRADS 3 and 4 lesions.(1)

Elastography is an imaging technique that refers to the measurement of elastic properties of tissues, based on the well established principle that malignant tissue is harder than normal and benign tissues. It

measures the relative stiffness of lesions in contrast to the surrounding normal tissue; the information displayed in the images is a surrogate for that obtained with manual palpation. The technique is typically performed with ultrasound, but researches with Magnetic resonance imaging are also ongoing.

In breast imaging, conventional B-mode ultrasound is often used after mammography to investigate suspicious findings, but it tends to result in more biopsies because of its relatively low specificity. Several studies have been performed on elastography aiming to improve ultrasound specificity in differentiating between benign and malignant lesions hence help to reduce the number of unnecessary biopsies. (2)

Elastography is performed in the same clinical setting with conventional B-mode breast ultrasonography. Images are produced prior to and post slight axial compression with the ultrasound probe, then image are displayed either by the lesion size comparison method or the color coding method. (3)

The color code ranges from red for the softest components to blue for the hardest components. Normal breast tissue is displayed in the green range. The images are interpreted using an elasticity scoring system. The lesion usually is displayed in a mixture of colors and according to the overall pattern of the lesion it will be assigned an elasticity score.(3)

The most well-known and applied score is the Tsukuba scoring system; it is a five point scale:

- A score of 1: the entire lesion is evenly shaded in green. This indicates that lesions have almost the same compressibility as the surrounding breast tissue.
- A score of 2: the lesion has a mosaic pattern of green and blue. This indicates lesions that are soft yet somewhat harder than normal breast tissue.
- A score of 3: the peripheral part of lesion is green, and the central part is blue.
- A score of 4: the entire lesion is blue, but its surrounding area is not included.
- A score of 5: both the entire lesion and its surrounding area are blue.

Strain ratio is a semiquantitative method that has been developed recently. It is the ratio obtained by dividing the mean strain of the fat by the mean strain of the lesion. The mean strain ratio in breast cancer was considerably higher than the mean strain ratio in benign lesions. (5)

Aim of the work:

The aim of the study is evaluation of the diagnostic accuracy of Ultrasound Elastography in differentiating benign form malignant findings in indeterminate breast lesions categorized as BIRADS 3 & 4.

Patients and Methods:

The study is a prospective study which included 46 patients referred to the Radiology Department, at Sohag university hospital. From the "Surgical Breast Clinic" and Surgical outpatient's clinics and wards in the period between January 2017 to July 2017. The study was approved by the Editorial Review Board of the Radiology Department of Sohag University Hospitals.

The mean age was (42.1 ± SD) years (age range from 20 to 75 years). With inclusion criteria: Patients who have positive ultrasound findings of breast masses (Indeterminate breast lesions categorized as BIRADS 3 & 4). And exclusion criteria: Cases with Diffuse edema and diffuse pathologic process.

All patients were subjected to

- High resolution Ultrasonography and Elastography on a digital Ultrasound scanner (Aplio 500, Toshiba Medical Systems) with real time tissue Elastography unit.
- Biopsy(histopathologic diagnosis).

-The following data was collected from all patients:

****Demographic data***: Name , Age , sex , Residence and Occupation

****Medical history:***

All patients presented complaining of breast lump with no age specification.(4) ****Investigations:***

High resolution Ultrasonography and Elastography.

Correlation with the histopathologic diagnosis.

Statistical analysis:

The collected data will be statistically analyzed using Statistical Package for the Social Science (SPSS) version 16 program and expressed in tables and charts. Conclusions and recommendations will be suggested based on.

Results

- ❖ The study population included forty-six patients with clinical symptoms and signs of breast masses.
- ❖ 24/46 cases (52%) were finally diagnosed as benign lesions.
- ❖ (22/46) cases (48 %) were finally diagnosed as malignant lesions.

- **Conventional Ultrasound: Ultrasound BIRADS categories.**

When considering US BIRADS categories of 3 as benign and that of 4 as malignant.

There were 26 /46 (56.5%) cases diagnosed as benign by conventional US, 20/26 (77%) of them were benign (true negative) by pathology, and 6/26 (23%) were malignant by pathology (false negative).

On the other hand 20/46 (43.5%) lesions were diagnosed as malignant by US, out of which 16/20 (80%) lesions confirmed to be malignant by pathology (true positive) and 4/20 (20%) lesion were benign by pathology (false positive).

The calculated sensitivity of conventional US was 72.73%, specifity was 83.33%, The PPV,and NPV were 80%, and 76.92 % respectively,

Elasticity Scores

Lesions that scored 1, 2, and 3 were considered benign, whereas lesions that scored 4 and 5 were considered malignant.

- ❖ After revising pathology results, 32/46(69.6%) diagnosed as benign by elastography 20/32 (62.5%) were benign (true negative) by pathology and 12/32 (37.5%) were malignant by pathology (false negative). After revising pathology results of the 14/46 (30.4%) cases diagnosed as malignant by elastography scoring, 10/14 (71.4%) lesions confirmed to be malignant by pathology (true positive) and 4/14 (28.6%) lesion were proved to be benign by pathology (false positive).
- ❖ The calculated sensitivity of elastography scoring was 65.45%, specifity was 83.33%, PPV and NPV were 71.43% and 62.50% respectivly,

Strain ratio

By applying a ROC curve, the true positive rate (sensitivity) was plotted against false positive rate (1- specificity) analysis with the area under the curve =0.924 **,**it was found that:

When the cutoff point was 2.81, sensitivity was 100% while the specificity was 71.4%.

By increasing the cutoff point to 3.47 the sensitivity decreased to 98.4% and increased the specificity to 85.68%. **So it was found that the best cutoff point is 3.47 with a sensitivity of 98.4% and specificity of 85.68%.**

Discussion

In our study, we included 46 patients, all lesions were subjected to 2-D ultrasound studies, which was followed by elastographic evaluation, and scored according to Itoh et al into one of the five elasto-scoring categories, then strain ratio was calculated for each lesion, and compared with the histological results after radical surgery, excisional, true cut biopsy, or fine needle aspiration cytology.

The final pathologic diagnoses In our study revealed 24/46 cases (52%) benign breast lesions.

The remaining 22 (48%) lesions were diagnosed pathologically as malignant lesions.

In our study, conventional ultrasound scanning was performed for the 46 breast lesions. 26 (56.5%) lesions were categorized as BIRADS 3, 20 lesions (43.5 %) as BIRADS 4. for statistical analysis we considered conventional ultrasound BIRADS categories of 3 as

benign and that of 4 as malignant guided in such assumption by the managment of such catogeries whether needing urgent interventional proecdures (i.e. urgent biopsy or surgical excision) or not. On performing this, there were 26 /46 (56.5%) cases diagnosed as benign by conventional US, 20/26 (77%) of them were benign (true negative) by pathology, and 6/26 (23%) were malignant by pathology (false negative).

On the other hand 20/46 (43.5%) lesions were diagnosed as malignant by US, out of which 16/20 (80%) lesions confirmed to be malignant by pathology (true positive) and 4/20 (20%) lesion were benign by pathology (false positive).

According to the previous results the calculated sensitivity of conventional US was 72.73%, specifity was 83.33%, The PPV,and NPV were 80%, and 76.92 % respectively**.**

These results agree with the study done by **Itoh et al., (2006),** which reported the same best cutoff point but showed higher value for sensitivity (96.2%) and lower values for specificity (62.7%) than ours. Also the study done by **Sohn et al., (2009)** showed the same best cutoff point with higher value for sensitivity (98.2%) and much lower value for specificity (44.1%).

According to, Tsucuba scoring, lesions in our study were classified into 5 elasto-scores, as previously described. In our study, we considered elastographic scoring of 1,2,3 as benign and that of 4, 5 as malignant.

After revising pathology results, 32/46(69.6%) diagnosed as benign by elastography 20/32 (62.5%)were benign (true negative) by pathology and 12/32 (37.5%) were malignant by pathology (false negative). After revising pathology results of the 14/46 (30.4%) cases diagnosed as malignant by elastography scoring, 10/14 (71.4%) lesions confirmed to be malignant by pathology (true positive) and 4/14 (28.6%) lesion were proved to be benign by pathology (false positive).

The calculated sensitivity of elastography scoring was 65.45%, specifity was 83.33%, PPV and NPV were 71.43% and 62.50% respectivly

For strain ratio (SR) By applying a ROC curve The true positive rate (sensitivity) was plotted against false positive rate (1- specifity) analysis with the area under the curve =0.924 **(fig.)**, it was found that:

When the cutoff point was 2.81, sensitivity was 100% while the specificity was 71.4%.

By increasing the cutoff point to 3.47 the sensitivity decreased to 98.4% and increased the specificity to 85.68%.

So it was found that the best cutoff point is *3.47* with a sensitivity of 98.4% and specificity of 85.68%.

Our results are comparable to the results reported by **Itoh et al., (2006),** who stated that the best cutoff point is between 3 and 4 elasticity scores, but showed higher sensitivity of (86.5%) and specificity of (89.8%), & to the study done by **(Elsaid. N & Mohamed G, 2012)**, that showed higher sensitivity of (84%), specificity of (84%).

Our results were comparable to the results reported by Schaefer et al, (2011), who stated a cut-off point of elastography scores between 3 and 4, but showed higher value for sensitivity 96.9% and lower values for specificity (76.0%) than ours.

Conclusion:

Elastography is an easy procedure with high diagnostic performance which can be easily integrated with the B-mode ultrasound examination in the same session and improves its specificity. It has proven benefit in minimizing the number of unnecessary biopsies

especially in the assessment of BIRADS 3 and 4 lesions.

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