VALUE OF BREAST ELASTOGRAPHY IN EVALUATION OF BREAST MASSES DETECTED ON SCREENING ULTRASOUND

By

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ABSTRACT

Background: Breast cancer remains one of the leading causes of death in women over the age of 40 years. Breast cancer screening is used to identify women with asymptomatic cancer with the goal of enabling women to undergo less invasive treatments that lead to better outcomes, ideally at earlier stages, and before the cancer progresses.

Objective: To evaluate the additional value of Elastography as complementary to conventional US in breast masses found on screening US.

Patients and methods: The study was performed prospectively between April 2020 and October 2020 at Elsayed Galal University Hospital in 35 consecutive female patients with 39 breast lesions who met all inclusion criteria and no exclusion criteria.

Results: This study included 35 female patients (with 39 breast lesions). Their ages ranged from 16 to 68 years old with mean age 46 ± 12.7 (mean \pm SD). In this study, 8/39 (20.5%) cases were almost fatty (ACR "a") in which 6/6 cases were malignant & 24/39 (61.5%) with scattered area of fibro-glandular tissue (ACR "b") in which 8/24 cases were malignant and 7/39 (17.9%) cases were heterogeneously dense breasts (ACR "c") in which 3/7 cases were malignant. Lesions that scored 1, 2, and 3 were considered benign 24/39(61.5%) cases, whereas lesions that scored 4 and 5 15/39 (38.5%) cases, were considered malignant. When considering lesions with strain ratio less than 3.0 as benign and lesions with strain ratio more than or equal 3.0 as malignant, 15/39 (38.5) lesions were benign, 24/39 (61.5%) were malignant by strain ratio.

Conclusion: US Elastography provides useful information about distinguishing benign and malignant lesions. Thus, consideration of lesion stiffness could increase positive predictive values and reduce unnecessary benign biopsies.

Keyowrds: Breast elastography, breast masses, screening ultrasound.

INTRODUCTION

Whole-breast ultrasound (US) has been suggested to supplement mammography screening of women with dense breasts because of its improved ability to detect cancer in dense breast tissue, lack of associated ionizing radiation exposure, and its wide availability. Breast US is used primarily in the diagnostic setting to evaluate specific findings identified by physical examination or mammography. It is less widely used as a screening test in women who are at high risk for developing breast cancer and cannot tolerate a magnetic resonance imaging (MRI) and to date is infrequently used to screen women at on average risk (*Scheel et al.*, 2015).

Although mammography remains the reference standard for breast cancer detection in women with dense breasts. sensitivity of mammography mav decrease to as low as 30%-48% because non calcified breast cancers are often obscured by the surrounding and overlying dense parenchyma (Drukteinis et al., 2013).

Breast US Elastography has been used as a method for imaging tissue stiffness to improve diagnostic confidence and increase the specificity of US interpretation (*Comstock, 2011*).

Strain elastography (SE) produces an image based on displacement of the tissue from an external manual compression of the transducer. Because it is difficult to measure the amount of the force or stress during compression, the absolute elasticity cannot be calculated (*Berg et al., 2012*), and the amount of lesion deformation can be depicted only as a ratio to that of normal tissues and displayed in relative terms by gray scale or color (*Comstock, 2011*).

The SE features that were studied thus for include both quantitative, i.e., mean and maximum elasticity, lesion-to -fat elasticity ratio, size ratio to B-mode imaging and qualitative assessment, i.e., color assessment of maximum elasticity and homogeneity of elasticity in the mass or surrounding tissue, and several studies have shown that these elastography features can improve the specificity of Bmode US without loss of sensitivity (*Berg et al.*, 2012). Category 4a masses to category 3, and a red color or stiffness greater than 160 kPa were sufficient criteria to upgrade BI-RADS category 3 masses to category 4a. However, those criteria were set for breast masses detected at diagnostic US. Different guidelines may be needed for screening US-detected breast masses because most breast masses detected at screening US are small in size and relatively soft (*Mahoney et al., 2012*).

Multiple studies evaluating the possible role of SE in improving the accuracy of breast US have reported that breast Elastography is useful for differentiating benign from malignant breast lesions and could potentially reduce unnecessary biopsies (*Athanasiou et al., 2010*).

The aim of this study was to evaluate the additional value of Elastography as complementary to conventional US in breast masses found on screening US.

PATIENTS AND METHODS

The study was performed prospectively between April 2020 and October 2020 at El-Sayed Galal University Hospital in 35 consecutive female patients with 39 breast lesions who met all inclusion criteria and no exclusion criteria.

The inclusion criteria were as follows: (1) Positive ultrasound and/or mammography findings of breast masses, (2) Available histopathologic diagnosis (tru-cut needle biopsy or surgery). The local ethics committee approved the prospective design of the study and written informed consent was collected from all patients who were included in the study. On the other hand, exclusion criteria were as follows: (1) Lack of consent to enter the study, (2) Presence of lesions smaller than 4 mm or greater than 5 cm, (3) Presence of mastalgia or breast edema, (4) Purely cystic lesions on conventional ultrasound examination or (5) Superficial (<5 mm deep to the skin surface), and cutaneous lesions.

Ultrasound Elastography was performed following breast ultrasound (+/- mammography) to differentiate benign from malignant masses. Data such as age, number of masses, BI-RADS category, and the longest dimension (cm) were also noted.

Conventional ultrasound examination:

All patients were examined with Bmode ultrasound using a high-end ultrasound system (Toshiba APLIO 500) included a multi-frequency linear probe operating at 6 to 13 MHz. The scanning protocol included transverse and longitudinal real-time imaging of masses of concern. A split-screen imaging mode was used for conventional US and US elastography so as to obtain identical images optimal for accurate application for region of interest (ROI) and strain ratio (SR) measurement later on.

On B-mode ultrasonography, lesions regarding, were evaluated shape, orientation, boundary, margin, echopattern, and posterior acoustic features, presence of calcifications and surrounding tissue as well as the other features of the masses. Lesions were classified according to the American College of Radiology Breast Imaging Reporting and Data System (BI-RADS) classification as follows: category 2 lesions were classified as benign; category 3 as probably benign; category 4 as suspicious for malignancy; category 5 as highly suggestive of malignancy and category 6 lesions were pathologically proven to be malignant. BI-RADS category 4 lesions were further grouped into BI-RADS category 4a, 4b, and 4c (*D'Orsi et al., 2013*).

Ovoid, well-circumscribed, hypoechoic masses that had a parallel orientation to the skin were categorized as BI-RADS category 3. The patients who had at least one suspicious finding for malignancy, such as irregular contour, microlobulation, angulation, vertical orientation to the skin, posterior acoustic shadowing, echogenic halo, or abnormal findings in the surrounding tissue were categorized as BI-RADS category 4 (moderately suspicious malignancy) and 5 (strongly for suspicious for malignancy). The masses that demonstrated at least three suspicious findings for malignancy were classified as BI-RADS category 5. Lesions that could not be categorized as BI-RADS category 3 or 5 were included in BI-RADS category 4 (Costantini et al., 2010). BI-RADS category 3 and 4a lesions were considered as benign, and BI-RADS category 4b, 4c, and 5 lesions were considered as malignant. These data were compared histopathological with findings to calculate sensitivity, specificity, positive and negative predictive values, and accuracy.

Ultrasound elastography:

All patients were examined with ultrasound elastography. Sonoelastographic images were obtained by placing the transducer with coupling gel on the skin and then the considered mass is focused upon.

After activating the sonoelastographic function, images were obtained by repeated compression applying and decompression in a sustained frequency. Color coding is superimposed on the translucent B-mode images. To get a sonoelastographic correct map, the process was repeated until a stable image The sonoelastographic was obtained. images were obtained in a 256-color scale ranging from red to blue. The softest component of the lesion was depicted in red, showing the greatest strain, whereas the hardest component with no strain was depicted in blue; green indicated intermediate elasticity. We selected an image obtained in the early phase of compression because these images provide the best contrast according to *Itoh* et al., (2010).

In the qualitative (color coded) evaluation of the sonoelastographic images, lesion classification was performed on the basis of a 5-point scoring method (Tsukuba scoring system) proposed by *Itoh et al.*, (2010).

In the semiquantitative evaluation of the sonoelastographic images, the strain indices of the lesions were calculated. For each case, normal-appearing breast region approximately at the same level of the concerned lesion was elicited as an internal reference (channel 1) and the region of interest including the lesion was selected as (channel 2), to correctly determine the difference in hardness of the lesion compared with the surrounding normal area. The strain ratio was automatically obtained as the strain measured via channel 1/ the strain measured via channel 2 ratio.

Diagnostic criteria:

All breast lesions included in the study were classified as benign or malignant according to histopathologic findings. Histopathologic diagnoses of surgical specimens or biopsy specimens were obtained. A US-guided core-needle biopsy was performed with a Tru-Cut biopsy needle (Bard Biopsy Systems, Tempe, AZ) in patients with BI-RADS category 4 and 5 lesions within a week of the radiologic assessment by an interventional radiologist blinded to the US and RTE findings. Core biopsies were performed in patients with BI-RADS category due to the clinician's or patients' request. The patient was informed of possible risks associated with the lesion, and follow-up Histopathologic recommended. was diagnoses of BIRADS II lesions were served as reference standards. Diagnoses from elasticity scoring and the strain ratios were compared with the reference standards.

Statistical analysis:

Breast lesions were classified as malignant or benign, and RTE findings were compared. The variables were expressed with standard as means deviations. minimum and maximum values. A receiver operating characteristic curve was performed to obtain an optimal cut-off value of the strain ratio. Diagnostic test values (sensitivity, specificity, positive predictive value, negative predictive value. with accuracy) respective 95% confidential intervals were calculated. A p value < 0.05 was considered significant, and analysis was bidirectional.

RESULTS

Thirty-five female patients (with 39 breast lesions) were included in this study. Their age ranged from 16 to 68 years old with mean age 46 \pm 12.7 (mean \pm SD) (**Table 1**).

Table (1): Age distribution of the patient participating in the study

Age	Years
Minimum	16
Maximum	68
Mean <u>+</u> SD	46 <u>+</u> 12.7

Pathological Diagnoses: Breast lesions were diagnosed histologically by means of radical surgery, excisional or true cut biopsy for 20 cases (17 malignant lesions and 3 benign), In 19 benign looking lesions follow up was done after 6 months to ensure their stationary course and benignity. The final pathologic diagnoses including the total number of benign and malignant lesions (**Table 2**).

Table (2): Final pathological diagnoses

Pathology	Number	Percentage
Benign	22	56.4%
Malignant	17	43.6%

Benign lesions: according to sonographer picture ± mammography and follow up except 3 cases (intraductal papillomatosis and fibroadenoma). Malignant lesions: according to histo-pathological results (**Table 3**).

Table (3):	Final diagnoses of benign breast lesions and malignant breast lesions
	according to sonogram appearance, follow up and 3 cases proved by
	histopathology

	Number & percentage	
Final nathelesis	Fibro adenoma	16 (72.7%)
Final pathologic diagnosis of benign	Hamartoma	2 (9.1%)
breast lesion	Intraductal papillomatosis	3 (13.6%)
bieast lesion	Lipoma	1 (4.5%)
	Invasive intraductal carcinoma	8 (47%)
Final pathologic	Invasive lobular carcinoma	5 (29.4%)
diagnosis of malignant breast lesion	Invasive breast carcinoma (non otherwise specified)	2 (11.8 %)
lesion	Follicle center cell lymphoma	1 (5.9%)
	Chondrosarcoma	1 (5.9%)

Four cases (10 %) were diagnosed by Qualitative Elastography as benign which were diagnosed malignant by ultrasonography. After follow up and revising the pathological result, two cases were malignant (invasive lobular carcinoma and invasive intraductal carcinoma). Two cases were benign

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US BIRADS *Qualitative cross tabulation		Qualitative		T-4-1	
		В	М	Total	
	В	Count	20	0	20
		% within US BIRADS	100.0%	0.0%	100.0%
		% within qualitative	91.6%	8.3 0%	100 %
US BIRADS		% of Total	90.9%	0.0 %	90.9 %
	М	Count	4	15	19
		% within US BIRADS	10.5 %	89.5 %	100.0%
		% within qualitative	21%	79.0%	100 %
		% of Total	21 %	79 %	100 %
Total		Count	24	15	39
		% within US BIRADS	61.5%	38.6 %	100.0%
		% within qualitative	61.5%	38.4%	100.0%
		% of Total	56.4%	43.5%	100.0%

(intraductal	papilloma	and f	fiboadenoma) (Table 4) .
Table (4):	Correlation	ı of U	JS BIRADS	with Qualitative Elastography

The calculated P-value was <0.001.

Four cases (10%) diagnosed by qualitative elastography as benign which are diagnosed malignant by ultrasonography. After follow up and revising the pathological result. Two cases were malignant (invasive lobular carcinoma and invasive intraductal carcinoma) (**Table 5**).

Table (5):	Correlation of US BIRADS with Quantitative Elastography
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US BIRADS Qualitative cross tabulation		Qualitative		Total	
		В	М	Total	
		Count	20	0	20
	р	% within US BIRADS	100.0%	0.0%	100.0%
	В	% within quantitative	91.6%	8.3 0%	100 %
US BIRADS		% of Total 90. 9 % 0.0 %		0.0 %	90.9 %
US DIRADS	М	Count	4	15	19
		% within US BIRADS	10.5 %	89.5 %	100.0%
		% within quantitative	21%	79.0%	100 %
		% of Total	21 %	79 %	100 %
Total		Count	24	15	39
		% within US BIRADS	61.5%	38.6 %	100.0%
		% within quantitative	61.5%	38.4%	100.0%
		% of Total	56.4%	43.5%	100.0%

The calculated P-value was 0.596.

After revising pathology results of the 24 cases diagnosed as benign by Ultrasound elastography, 22 /24(91.7%) were benign (true negative) by pathology and 2/24 (8.3 %) were malignant by pathology (false negative). After revising pathology results of the 15 cases diagnosed as malignant by Ultrasound

elastography, 15/15 (100 %) lesions confirmed to be malignant by pathology (true positive) and 0/15 (0 %) lesion were proved to be benign by pathology (false positive). The calculated sensitivity of combined elastography was 91.7%, specify was 100%, PPV and NPV were

Elastography. number * Pathology Cross			Path	T ()	
	tabulation		B M		Total
	В	Count	22	2	24
		% within Elastography.n	91.6%	8.4%	100.0%
		% within Pathology1	91.6 %	8.4%	100 %
Elastography.		% of Total	56.4 %	5 %	61.5 %
number	М	Count	0	15	15
		% within Elastography.n	0 %	100 %	100.0%
		% within Pathology1	0 %	100 %	100 %
		% of Total	0 %	38.4%	38.4%
Total		Count	22	17	39
		% within Elastography.n	91.6 %	8.4 %	100.0%
		% within Pathology	100.0%	100.0%	100.0%
		% of Total	56.5 %	43.5%	100.0%

100% and 91.7% respectively, and the total accuracy was 94.5% (**Table 6**). **Table (6): Correlation of combined Elastography and pathology**

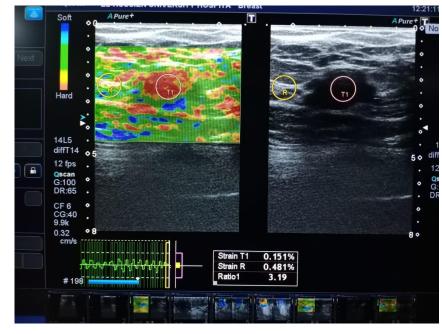


Fig. (1): Female patient 55y old , on US it was BIRADs IVc ,on Qulitative elasotography it was E2 while on quangiative elasotography it was 4. On revising histopathology it was malignant lesion (invasive intraductal carcinoma).

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Fig. (2): Female patient 56year old , on US it was BIRADS IV , on qualitative elastography it was E4 while on quantiative elasography it was 4.58.after revising the histopathology it was invasive duct carcinoma.

The Histopathological part of the study was done at El-Sayed Galal University Hospital by Pro. Dr. Ibrahim Hassan

DISCUSSION

This study included 35 female patients (with 39 breast lesions), their ages ranged from 16 to 68 years old with mean age 46 \pm 12.7 (mean \pm SD).

All patients underwent diagnostic Ultrasound and Elastography (Quantitative & Qualitative)

In this study, 20.5% cases were almost fatty (ACR "a") in which 6/6 cases were malignant and 61.5% with scattered area of fibro-glandular tissue (ACR "b") in which 8/24 cases were malignant and (17.9 % cases) were heterogeneously dense breasts(ACR "c") in which 3/7 cases were malignant.

Ultrasound findings considered (51.2% cases) listed as BIRADS II, III (benign

lesions) and (48.7% listed) as BIRADS IV, V (malignant lesions).

Qualitative Elastography, lesions that scored 1, 2, and 3 were considered benign (61.5% cases), whereas lesions that scored 4 and 5 (38.5% cases), were considered malignant.

Quantitative Elastography findings in this study, When considering lesions with strain ratio less than 3.0 as benign and lesions with strain ratio more than or equal 3.0 as malignant, (38.5% lesions) were benign, (61.5%) were malignant by strain ratio.

Ultrasound considered (51.3%) cases as benign lesions while (48.7%) case as malignant lesion, while Qualitative Elastography considered (61.5%) cases as benign lesions, (38.5%) cases were considered malignant. Qualitative/ qualitative Elastography confirmed (78.9%) of the US diagnosed malignant lesions, while (10.5% cases) were falsely diagnosed malignant with US which are proved benign by qualitative/ qualitative Elastography and histopathology. It falsely characterized 2 of the detected masses as benign, which proved malignant by the US and histopathology.

Elkharbotly and Farouk (2015) stated that the 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 in BI-RADS- 3 and 4 lesions. Therefore, the number of false-positive findings in breast diagnostics was reduced by using Elastography.

In this study, ultrasound falsely characterized 2 of the detected masses as malignant lesions, while proved to have benign characters by Elastography and was proved to be benign by pathology (intraductal papillomatosis and fibroadenoma). Thus, Elastography helps increase specificity and limits unnecessary biopsies.

Ko et al. (2013) stated that. by using Elastography, unnecessary biopsies could eliminated. They retrospectively be reviewed that 65% were benign and 35 % were malignant. When applying Elastography, 16.7% were determined to be falsely negative by Elastography. One of these lesions, which were initially classified as BI-RADS category 4b, was identified as ductal carcinoma in situ (DCIS), and the other which was

classified as BIRADS category 5 was found to be IDC. By applying Elastography for downgrading BI-RADS category 4a lesions to category 3, 15 unnecessary biopsies could have been eliminated from the 19 BI-RADS category 4a lesions (79 %). For these patients, follow-up after 6 months would have been appropriate management. No cancerous lesions were missed.

Ultrasound classified 41% cases as BIRADS II, 10.3% cases as BIRADS III, 33.3% cases as BIRADS IV and 15.4% cases as BIRADS V. Elastography changed the identified BIRADS category in 10% lesions. It upgraded 5% lesions and downgraded 5% lesions. Elastography decreased the number of BIRADS IV lesions from 33% to be 28% lesions and increased the number of BIRADS II lesions from 41% to be 46% lesions.

Yang et al. (2013) had done screening with Ultrasound and Elastography females coming for screening with ages ranging from 21 to 79 years old cases. 13.2% were malignant and 86.8% were benign. Of BIRADS category 4a masses, 65.5% were downgraded to category 3.

Combined ultrasound and Elastography 89.4% lesions confirmed to be malignant by pathology (true positive) and 11.6 % lesions were proved to be benign by pathology (false positive). The calculated sensitivity of ultrasound was 100%, specify was 89.4%, PPV and NPV were 89% and 100% respectively, the total accuracy was 94.5 %. On elastograph, 61.5 % lesions were benign by strain ratio and 38.5% were malignant. After revising the pathology and follow up 15 lesions were true positives, 0 lesions were false positives, 2 lesions was false negative and 22 lesions were true negatives. Elastography strain ratio (Quanlitative) had a sensitivity of 88.2 %, specificity of 100 %, PPV and NPV were 100 % and 88 % respectively. The total accuracy was 93.9%.

Ricci et al. (2017) in a study comparing the different Elastographic and conventional ultrasound in diagnostic work up of breast lesions showed that combined US and Elastography had a sensitivity of 95% and specify 70%. Elkharbotly and Farouk (2015) in a study the diagnostic yield evaluating of mammography, B-mode ultrasound (US), ultrasound elastography (UE) and color Doppler used alone or in combination for differentiating breast lesions. It showed that the combined use of US and UE provided better diagnostic yield. It showed sensitivity and specificity rates 83.3% and 88.1%, respectively and NPV of 92.5% and accuracy rate for diagnosis of malignancy of 86.7%.

Lee et al. (2015), in a study to compare the role of elastography and conventional ultrasound in diagnostic work up of complex cystic and solid breast lesions, showed that combined US and Elastography had a sensitivity of 86.7% and specify 97.3%.

Ko et al. (2013), in a study evaluating the potential role of ultrasound elastography for the differential diagnosis of breast non-mass lesions, showed that combined US and Elastography had sensitivity 83.3% and specificity of 68.2%.

In our study, it was found that a combined use of conventional US and elastography can provide a correct diagnosis as US can prevent the false negative impression when elastography was used alone; more sensitive (sensitivity 100%). The elastography can prevent false positives impressions when US was used alone; more specific (specificity 100 %).

CONCLUSION

US Elastography provides useful information about distinguishing benign and malignant lesions. Thus, consideration of lesion stiffness could increase positive predictive values and reduce unnecessary benign biopsies.

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قيمة قياس مرونة أنسجة الثدي بالموجات الفوق صوتية في تقييم أورام الثدي المكتشفه أثناء الفحص بالموجات الفوق صوتية وليدربيعي محمد، عمرو محمود زايد، حسين منتصر رشدي قسم الأشعة التشخيصية والتداخلية، كلية الطب، جامعة الأزهر

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خلفية البحث: تعتبر الموجات فوق الصوتية وسيلة تشخيصية بسيطة وغير غازية، وعادة ما تكون غير مؤلمة تستخدم مع التصوير الأشعاعي للثدي لتصوير طبيعة الأفات الثديية. وهي سهلة الاستخدام وأقل تكلفة من طرق التصوير الأخرى. هذا إلى جانب عدم وجود خطر التعرض للإشعاع، فإنه يوفر أيضا التصوير أثناء رؤية الفحص، ويمكن بسهولة إكتشاف الأفات في السيدات اللاتى تكون أنسجة الثدي فيهن كثيفة.

الهدف من البحث: معرفة القيمة المضافة لقياس المرونة بالموجات فوق الصوتية في تقييم أورام الثدى المكتشفة أثناء الكشف المبكر للأورام الثديية.

المريضات وطرق البحث: في دراسة مقطعية مستعرضة لـ 35 حالة (39 كتلة ثديية) قدمت لوحدة الكشف المبكر للأورام الثدي في مستشفي السيد جلال جامعة الاز هر، تم مقارنة النتائج بنتائج فحص الأنسجة (الفحص الباثولوجي)، وتم عمل دراسة إحصائية لتحديد دقة النتائج بالنسبة لقياس المرونة بالموجات فوق الصوتية.

نتسائج البحث: شملت هذه الدراسة 35 مريضة (مع 39 آف قبالشدي)، تراوحت أعمار هن بين 16 و 68 سنة بمتوسط عمر 46 ± 12.7 وفي هذه الدراسة، كانت 39/8 (20.5)) حالة دهنية تقريبًا ("a" ACR (ACR (20.5)) حيث كانت 6/6 حالات خبيشة و (ACR (30.5)) مع منطقة متناثرة من الأنسجة الغدية الليفية ("b" ACR) حيث كانت 24/8 حالة خبيثة و 7/92 (17.9)) حالة شدي كثيف بشكل غير متجانس ("c" ACR) حيث كانت 7/3 حالات خبيشة. فيما يتعلق بنتائج متجانس ("c" و 26 من الاراسة، إعتبرت الأفات التي سجلت 1 و 2 و 3

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حالات حميدة 29/24 (61.5%)، في حين أن الأفات التي سجلت 4 و 5 21/35 (38.5%) إعتبرت خبيثة. فيما يتعلق بنتائج التصوير المرن الكمي في هذه الدراسة، عند النظر في الأفات ذات نسبة الإجهاد أقال من 3.0 كأفات حميدة والأفات ذات نسبة الإجهاد أكثر من أو تساوي 3.0 كخبيثة، كانت الأفات 23/15 (38.5) حميدة ، 24/36 (61.5%) كانت الخبيثة بنسبة الإجهاد.

الاستنتاج: قياس المرونة بالموجات فوق الموتية يوفر معلومات مفيدة حول التمييز بين الأفات الحميدة والخبيثة. ويمكن النظر في تصلب الأفة زيادة القيم التنبؤية الإيجابية والحد من الخزعات الحميدة غير الضرورية، والأفضل أن يتم قياس المرونة بالموجات فوق المسوتية بنوعيه الكيفي والكمي حيث أن الكيفي أكثر دقة من الكمى.

الكلمات الدالة: تصوير الثدى، تكتلات الثدى، فحص الموجات فوق الصوتية.