Can ultrasound elastography help avoid some benign breast biopsies?

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Authors: S. Raza¹, S. A. Choudhery², M. Sekar¹, C. S. Giess¹, R. Birdwell¹;
¹Boston, MA/US, ²Dallas, TX/US
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Purpose

1. To determine the difference in size and volume ratios for benign versus malignant lesions.
2. To determine fat-to-lesion strain ratios (FLSR) in benign versus malignant lesions.
3. To correlate BI-RADS assessment with ES.
4. To correlate BI-RADS 4A lesions with ES and determine percentage of 4A/ES 1 or 2 lesions that are benign on biopsy.
5. To correlate layered appearance on elastography (blue-green-red or BGR) with cystic lesions.

Methods and Materials

This prospective study was approved by the Institutional Review Board, was compliant with the Health Insurance Portability and Accountability Act, and signed, informed consent was obtained from enrolled patients. The Hitachi company (Hitachi Medical Corporation, Twinsburg, Ohio) provided equipment and partial financial support for this study. The authors had full control of the data and the manuscript.

Subject Selection and Diagnostic US Examination

Patients presented to our breast imaging center for diagnostic work-up for various indications including palpable breast findings, nipple discharge, or abnormalities detected on mammography or MRI. Diagnostic breast ultrasound exams were performed on Philips iu22 machines (Philips/ATL, Bothell, Washington), using linear 5-12 or 5-17 MHz transducers. Sonographic mass interpretation was based on established criteria and included assessment of shape, margins, internal echotexture, long-axis orientation, and acoustic transmission. Management decisions during the diagnostic work-up took into account all available data including clinical examination findings, MRI, mammographic and sonographic features. The decision to biopsy was based on the most suspicious finding, and reflected in final BI-RADS categories. All patients with breast lesions for which biopsy was recommended (BI-RADS 4A, 4B, 4C or 5) or being performed based on patient or referring physician request (BI-RADS 2 or 3), were considered potential study subjects. The study population consisted of consecutive patients who agreed to participate. Patients who had prior percutaneous or surgical intervention in or adjacent to the area of current clinical concern were excluded. RTE was performed following diagnostic work-up or immediately prior to a scheduled US-guided biopsy.

Real-time Tissue Elastography (RTE)
RTE was performed on an FDA-approved Hitachi Hi Vision 900 (Hitachi Medical Corporation, Twinsburg, Ohio), capable of conventional B-mode ultrasound, Doppler, RTE, and software to calculate strain ratios. Each study lesion was first examined with B-mode US, using a 50 mm footprint 12.5 MHz linear array transducer to evaluate shape, margins, orientation, acoustic transmission, size (longest dimension) and distance from the anterior surface of the mass to the skin. B-mode size included the echogenic halo when visible. RTE size included visible mass margins based on color assignment. RTE was performed by study radiologists (either the PI with 18 years of experience in breast US and specifically trained on site by Hitachi applications staff or one of multiple breast imagers with 3 to 20 years of experience) breast imaging, trained by the PI and by Hitachi applications staff). Freehand manual compression technique described by Itoh [9] was used to generate RTE images. This was performed by applying initial light pressure with the transducer, just enough to maintain skin contact. An RTE map was then created by depressing the breast posteriorly approximately 1-2 mm and releasing while maintaining skin contact in a mild vibratory manner, approximately five to seven cycles of depression and release per second or 300 cycles per minute. A compression scale of 1-7 was visible on the screen and images were obtained at an optimal compression in the 2-4 range. It should be noted that manual compression for RTE actually necessitated first a "letting up" of the usual scanning pressure and then applying light compression. An elasticity color map superimposed on the B-mode images, was displayed on the left side of a dual display image while the corresponding gray scale (B-mode) image was on the right. This allowed continuous real-time visualization for proper transducer positioning over the target lesion. In all cases, 3-dimensional lesion size and FLSR were recorded in real-time. ES were assigned upon completion of the study or during retrospective review. During RTE, both static images and video clips were obtained and stored on the hard drive, and transferred to the department PACS. Elasticity Score (ES) were based on a five-point scoring system proposed by Itoh et al [9], and summarized here: (Figure 1).

Score 1: Normally pliable tissue showing even strain throughout the examined area.

Score 2: Even strain over most of the hypoechoic mass with minimal variability.

Blue-Green-Red (BGR): layered RTE image with appearance of blue superficially, and then green and red in the deeper portion of a lesion. For the purpose of this study, these lesions are considered a subcategory of ES 2.

Score 3: Strain at the periphery with sparing of the hypoechoic mass.

Score 4: Minimal strain over the hypoechoic region.

Score 5: Minimal strain over the entire hypoechoic mass or the surrounding area.

**Biopsy method and pathologic correlation**
All percutaneous breast biopsies were performed as large core needle biopsies, using a 14 gauge multi-fire spring-loaded device, or an 11-gauge vacuum-assisted device. Chart review provided final pathologic diagnoses.

**Statistical Analysis**

Hypothesis testing was used to calculate p-values for lesion size, volume, and FLSR. Sensitivity and specificity summary statistics using 2 x 2 contingency tables, and ROC analysis were performed for overall accuracy.

**Images for this section:**

**Fig. 1:** Elastography scores are based on classification proposed by Itoh. This illustration shows normal strain in Score 1 lesions, represented by green color, gradually decreasing to minimal strain in and around the lesion in Score 5, represented by blue. Red represents most even and highest strain. ES 1 and 2 have been shown to be associated with benign lesions while ES 4 and 5 with malignant lesions, and ES 3 is indeterminate.
Results

A total of 287 examined lesions comprise the study data, after exclusion of lesions for which complete data was not available. On biopsy, 79/287 (28%) were malignant (mean age 57.3 years), and 208/287 (72%) were benign (mean age 47.4 years).

Size and Volume Ratios

Size ratios were calculated based on the single longest dimension on gray scale and on RTE. There was a significant difference in the mean SR of malignant lesions (mean SR 1.1) and benign lesions (mean SR 1.0) with p< 0.0001 (Figure 2). Volume ratios were calculated using measurements of all three planes and calculating the volume of an ellipse. The VR of malignant lesions (mean 1.71) and benign lesions (mean 1.09) was significantly different (p<0.0001).

Fat-to-Lesion Strain Ratio (FLSR)

FLSR was determined during real time evaluation, and was significantly higher in malignant (mean 14.27) versus benign (mean 2.24) lesions (p<0.0001). ROC analysis of FLSR data shows the optimal cut off value for predicting malignancy was 3.26, with an area under the curve (AUC) of 0.853, sensitivity of 76.9%, specificity of 88.3%, positive predictive value of 71.4%, and negative predictive value of 91% (Figure 3, 4).

BI-RADS and Elastography Correlation

Of 79 malignant lesions, 75 (95%) were BI-RADS 5, 4C or 4B, and 59/79 (75%) were assigned ES 4 or 5, 6 (8%) were ES 3, and 14 (18%) were ES 1 or 2 (Figure 5).

Of the 208 benign masses, 149 (72%) were BI-RADS 4A, with 137 of these 149 (92%) assigned ES 1, 2 or BGR (Figure 6).

Of all BI-RADS 4A lesions in the total study population (n= 153), 4/153 (2.6%) were malignant, of which 3 were prospectively assessed as ES 2 (Figure 7). These 3 lesions were therefore assessed as low suspicion and probably benign by both BI-RADS categorization and elastography interpretation.

Layered appearance on elastography

There were 49 lesions showing blue-green-red layering (BGR), with 1/49 (2%) malignant. This was a papillary carcinoma. The remaining 48 were benign and 47 of these 48 (98%) lesions were cysts (Figure 8).

Elastography "false negative" cases
Of the 20 malignancies with ES of 1, 2 or 3, there were 3 which were also assessed as BI-RADS 4A, mentioned above. The pathologic diagnoses for these included a 5 mm DCIS lesion, a 12 mm invasive mucinous carcinoma, and a 13 mm IDC. The remaining 17/20 had pathologies as follows: 8 invasive ductal cancers (IDC), 2 invasive mucinous cancers, 1 invasive cancer with ductal and lobular features, 2 invasive papillary cancers (Figure 9), 1 invasive lobular cancer, and 3 ductal carcinomas in situ (DCIS).

Elastography "false positive" cases

Of the 208 benign lesions in the study, 7/208 (3%) were prospectively categorized as elastography score 4 or 5. The pathologic diagnoses included 3/7 (42%) fat necrosis lesions (Figure 10), 2/7 (29%) papillomas (one with sclerosis and 1 with atypia), and 2/7 (29%) fibroadenomas.

Images for this section:

**Fig. 3:** Strain ratio between the target lesion and adjacent normal fatty tissue was determined in real-time during elastography for all malignant and benign study lesions.
Receiver Operator Curve analysis shows the optimal cut-off value for fat-to-lesion strain ratio to be 3.26.

**Fig. 5:** Malignant Lesions: Distribution of elastography scores (ES) for different BI-RADS categories.
**Fig. 6:** Benign Lesions: Distribution of elastography scores (ES) for different BI-RADS categories.
**Fig. 7:** ALL BI-RADS 4 lesions correlated with distribution of ES categories. The majority of BI-RADS 4A lesions were assessed as ES 1 or 2.
Fig. 8: 73 year old woman with a new, small, round left UOQ mass on screening mammogram. US showed a 5 mm hypoechoic circumscribed mass with low level internal echos. Aspiration was recommended with a final assessment of BI-RADS 4A. RTE showed no difference in lesion size on elastography versus gray scale, and a strain ratio of 1.27. Additionally, elastography showed an easily reproducible layered appearance within the lesion (left image, arrows), leading to Elastography Score of 2 with specific description of blue-green-red layering (BGR). This was successfully aspirated to completion.
**Fig. 9:** 77 year old woman with a spiculated mass on routine screening mammogram, persistent on spot compression views. Diagnostic US exam showed a bilobed subtle, hypoechoic mass (right image, arrows). Combined mammographic and US final assessment was BI-RADS 4C. On RTE the mass shows strain throughout the lesion with a hint of red layering at the posterior aspect (left image, arrows). There is no difference in size and the FLSR was near 1 (not shown). The layering was more prominent in real time, and it was felt to represent BGR, therefore assessed as ES 2. Subsequent biopsy showed it to be an invasive papillary carcinoma.
Fig. 10: 49 yr old with history of non-Hodgkin lymphoma 6 years prior. Routine screening mammogram showed a small focal asymmetry, persistent on spot compression views. US showed a heterogeneous mass possibly representing fat necrosis, and a short interval follow-up was recommended. At 8 weeks follow-up the mass appeared slightly more prominent on US (right image, arrows) and biopsy was recommended with an interpretation of BI-RADS 4B. RTE showed a predominantly blue lesion which appeared larger than on B-mode imaging (left image, arrows). Subsequent biopsy revealed focal fat necrosis and inflammation.
**Fig. 4:** Same patient as in Figure 2 above. RTE shows no strain throughout the mass and extending well beyond it showing a size ratio of 2.3. The fat-to-lesion strain ratio is 7.29 (left image: circles in lesion and in adjacent fat at a similar depth). This was interpreted with Elastography Score of 5. Pathology revealed grade I invasive ductal carcinoma (IDC), with ductal carcinoma in situ (DCIS).
Fig. 2: 86 year old woman with new right breast architectural distortion on screening mammogram, confirmed on spot compression views. Conventional US showed a vertically oriented irregular mass interpreted as BI-RADS 4C. RTE shows no strain throughout the mass and extending well beyond it (deep blue on the color map). Lesion size on RTE (left image, arrows) is 12.9 mm and on B-mode (right image, arrows) it is 5.6 mm, for a size ratio of 2.3. This was interpreted with Elastography Score of 5. Pathology revealed grade I invasive ductal carcinoma (IDC), with ductal carcinoma in situ (DCIS).
Conclusion

1. Size, volume, and strain ratios on RTE help predict likelihood of malignancy in breast lesions.
2. BI-RADS 4A lesions with ES of 1, 2, or BGR have a very high likelihood (98%) of benignity and may be watched rather than biopsied.
3. The majority (98%) of lesions showing a layered pattern on RTE were cysts.

References


Personal Information