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Reproducibility and diagnostic performance of shear wave elastography in evaluating breast solid mass

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ABSTRACT

Shear wave elastography (SWE) was performed independently by two radiologists in 264 solid breast masses. The images were reviewed for color overlay pattern (COP) classification by the two radiologists, double blinded to any information. The interobserver agreement of the COP was almost perfect ($\kappa = 0.908$) and high in E_{max} (ICC $= 0.89$). The AUC value of the COP (0.954) was significantly higher than that of E_{max} (0.915) ($p = 0.002$) but not significantly different from that of E_{max} combined with COP (0.957) ($p = 0.098$).
The SWE color overlay pattern and E_{max} of breast masses were highly reproducible. The COP had better diagnostic ability than E_{max}, suggesting that COP may be a more reliable parameter for solid breast mass evaluation.

1. Introduction

Breast ultrasound has long been a standard imaging tool in breast pathologies. Conventional ultrasound in conjunction with mammography is not only used to assist in differentiating benign from malignant breast lesions, but also can directly correlate imaging findings with clinical information through ultrasound-guided tissue biopsy [1,2]. However, despite its high sensitivity, conventional ultrasound and ultrasound-guided biopsy are controversial for their false-positive and over-diagnosis rates. Therefore, there have been constant attempts to improve the diagnostic performance of breast ultrasound and to reduce the number of unnecessary biopsies. Recently, a new ultrasonographic technique called shear wave elastography (SWE) is recognized as a useful tool that provides additional information in breast lesion characterization.

SWE is a new method of obtaining elastography images based on the combination of a radiation force induced in tissue by an ultrasonic beam and an ultrafast imaging sequence capable of measuring the propagation of the resulting shear waves in real time [3,4]. Elasticity, or tissue stiffness, varies depending on a lesion's malignancy. Benign lesions tend to be soft, while malignant lesions are firmer and relatively stiff. Using SWE, radiologists can quantitatively measure tissue stiffness (elasticity) as well as its color overlay pattern in a region of interest (ROI).

Several recent studies have reviewed the diagnostic performance of SWE. Some studies showed that the diagnostic performance of SWE was not significantly better than that of conventional ultrasound alone [3,5]. However, other studies have suggested that SWE has potential to aid in the differentiation of benign and malignant breast lesions [6–8] and to improve the diagnostic performance and reduce false positive biopsies [9]. This technology may improve the diagnostic accuracy by providing not only quantitative factors such as the maximum, mean, and ratio of elasticity, but also semi-quantitative factors such as the color overlay pattern. However, only few studies have evaluated the reproducibility of SWE in quantitative factors and color overlay pattern [3,10]. It is important for an imaging technique to have high reproducibility in order to become clinically widely accepted. Therefore, it is critical to evaluate SWE consistency among radiologists in a large number of breast lesions.

In this study, we evaluated the reproducibility of SWE with regard to the color overlay pattern and quantitative elasticity values by recruiting two breast radiologists to perform double-blind SWE on each breast lesion. In addition, we analyzed the diagnostic performance of SWE using the color overlay pattern, maximum elasticity value, and color pattern combined with the maximum elasticity value in determining whether a breast lesion is malignant or benign.

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2. Methods and materials

2.1. Patients and breast lesions

This retrospective study was conducted with institutional review board approval and a waiver of patient informed consent. A total of 218 patients underwent SWE between April 2014 and December 2015, and a total of 264 solid breast masses were analyzed. Each lesion was evaluated histologically using either ultrasound-guided core needle biopsy or surgical excision.

All 218 patients were women between the ages of 18 and 81 years (mean 46.36 years). Of the 264 solid breast masses, 152 (57.6%) were malignant and 112 (42.4%) were benign. The size of the breast masses, defined as the maximal diameter on conventional US, were in the range of 0.27–6.0 cm (mean 1.57 cm). The mean size of the benign breast lesions was 1.07 cm (range, 0.27–4.78 cm), and that of malignant masses was 1.86 cm (range, 0.4–6.0 cm).

2.2. Breast US examination and image evaluation

Each lesion was evaluated with SWE with gray scale ultrasound on two separate occasions, once at time of initial diagnosis and a second time just before biopsy. Two breast radiologists with 5 and 10 years of experience in breast ultrasound, respectively, independently performed conventional breast ultrasound and elastography using a linear array transducer with a bandwidth of 4–15 MHz. Prior to performing elastography supplemental to conventional breast ultrasound, the two breast radiologists were educated how to perform elastography and how to interpret those results via various training courses conducted by the Korean Society of Radiology. In performing SWE, the radiologists were advised to image the lesion without applying additional pressure with the transducer and to allow a few seconds of immobilization before obtaining the elastography image (elastogram).

Each radiologist had access to the clinical and mammography information at the time of ultrasound examination. However, they were blinded to each other's SWE images and ultrasound reports. During US examination, at least one conventional grayscale image and SWE image were obtained for each breast lesion. Each breast lesion's size was measured in centimeters on the conventional gray scale ultrasound image. The SWE images were obtained after evaluating each conventional gray scale ultrasound image. When performing SWE, each radiologist placed a 2-mm round built-in ROI at the stiffest part of the lesion. This ROI represented tissue stiffness by color ranging from dark blue (indicating the lowest stiffness) to red (indicating the highest stiffness). A second ROI was placed in the breast fatty tissue in order to calculate the ratio between the lesion's mean elasticity value and that of fat (E_{ratio}). The other elasticity values, including E_{min}, E_{max}, E_{mean}, and SD, were measured in kPa. Depth was measured in centimeters.

After all examinations and biopsies for 264 breast masses were completed, a third radiologist collected all SWE images and randomly distributed the two pairs of SWE images of each breast mass to the two breast radiologists who previously performed breast grayscale ultrasound and SWE. The SWE images were reviewed independently by the two radiologists for semi-quantitative measurement of the breast lesion and color overlay pattern. During the review session, the radiologists were blinded to the clinical, mammographic, and pathologic findings and to who had performed the elastography. The SWE color overlay patterns were assessed using the four color overlay pattern proposed by Tozaki and Fukuma [11]. The image was classified as having "no findings" (pattern 1) when there was no difference between the color at the lesion's margin and in its interior (coded blue homogeneously). When the color differed from that around the lesion, but extended beyond the lesion and continued vertically in cords on the cutaneous side or thoracic wall side, it was considered to be an artifact unique to SWE and classified as a negative finding (pattern 2). In contrast, when a localized colored area was present at the lesion's margin, it was classified as a positive finding (pattern 3). When heterogeneously colored areas were present in the interior of the lesion, it was classified as a positive finding (pattern 4).

2.3. Data evaluation and statistical analysis

Clinical data, including patient age and histopathological results of the ultrasound-guided core needle biopsy or surgical excision, were collected retrospectively.

Interobserver agreement was used to evaluate the reproducibility of SWE. Kappa statistics were used for semi-quantitative measurement of the color overlay pattern of each solid breast mass. Weighted kappa was used because the color overlay pattern is an ordered categorical variable [12]. The weighted kappa value is interpreted in the same way as kappa, with a maximum value of 1 (perfect agreement). A kappa value of 0–0.2 indicates slight agreement, 0.21–0.4 fair agreement, 0.41–0.6 moderate agreement, 0.61–0.8 substantial agreement, and 0.81–0.99 almost perfect agreement. The intraclass correlation coefficient (ICC) was used for quantitative values, including E_{ratio}, E_{min}, E_{max}, E_{mean}, SD, and depth.

Receiver operating characteristics (ROC) curves were analyzed to evaluate the diagnostic performance of color overlay pattern, E_{max}, and color overlay pattern combined with E_{max}. The 95% confidence interval (CI) was generated using the binomial exact and optimal cut-off value of E_{max}. The optimal cut-off value of color overlay pattern was assessed at the maximal sum of sensitivity and specificity.

Statistical analyses were performed using a statistical analysis program (SAS, version 9.1.3, SAS Institute Inc., Cary, NC, USA). p Values < 0.05 were considered statistically significant.

3. Results

3.1. Lesion diagnosis

Of the 264 solid breast masses, 152 (57.6%) were malignant and 112 (42.4%) were benign. Each lesion's histopathology was confirmed with either ultrasound-guided core needle biopsy or surgical excision.

3.2. Interobserver agreement of quantitative elasticity values

Interobserver agreement of quantitative elasticity values varied from mild to almost perfect (Table 1). E_{max} (kPa) demonstrated almost perfect agreement with an intraclass correlation coefficient of 0.89 (95% CI, 0.86–0.91). E_{min} (kPa) and depth (cm) also had substantial agreement, with ICC values of 0.74 (95% CI, 0.68–0.79) and 0.76 (95% CI, 0.70–0.81), respectively. SD (kPa) had moderate agreement and an intraclass correlation coefficient of 0.66 (95% CI, 0.58–0.72). The ratio (kPa) and E_{mean} (kPa) had fair agreement, with ICC values of 0.31 (95% CI, 0.20–0.42) and 0.31 (95% CI, 0.19–0.41 respectively), respectively.

3.3. Interobserver agreement of color overlay pattern

The interobserver agreement of the four color overlay patterns on the SWE image was almost perfect (weighted kappa value = 0.908;

Table 1
Interobserver agreement of SWE values.

SWE features	Interobserver agreement	p Value
Ratio (kPa)	0.312 (ICC)*	<0.0001
Mean (kPa)	0.308 (ICC)	<0.0001
Min (kPa)	0.742 (ICC)	<0.0001
Max (kPa)	0.886 (ICC)	<0.0001
SD (kPa)	0.657 (ICC)	<0.0001
Depth (cm)	0.759 (ICC)	<0.0001
Pattern (1, 2, 3, 4)	0.908 (weighted kappa)	<0.0001

* ICC (intraclass correlation coefficient).