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Diagnostic performances of shear-wave elastography and B-mode ultrasound to differentiate benign and malignant breast lesions: the emphasis on the cutoff value of qualitative and quantitative parameters

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ABSTRACT

Purpose: To investigate the most effective cutoff values for shear-wave elastography (SWE) for differentiating benign and malignant breast lesions and to evaluate the diagnostic performance of quantitative and qualitative SWE in combination with B-mode ultrasound (US).

Methods: 209 breast lesions from 200 patients were evaluated with B-mode US and SWE. Pathologic results determined by US-guided core needle biopsy or surgical excisions were used as a reference standard. Qualitative (four-color pattern) and quantitative analyses (Emean, Emax, SD, and E ratio) were performed. The cut-off values were defined using Youden's index. The diagnostic performance of B-mode US and combination of B-mode US with four-color pattern or quantitative parameters were compared.

Results: Of the 209 breast lesions, 102 were benign and 107 were malignant. All qualitative and quantitative SWE parameters had significantly higher specificity, positive predictive value (PPV), and accuracy compared to B-mode US ($p < 0.001$). The optimal cutoff values for the Emax, Emean, SD and E ratio were 145.7 kPa, 89.1 kPa, 11.9, and 3.84, respectively. The optimal cutoff for color pattern was between 3 and 4. Combined B-mode US and Emax had the highest improvement, from 17.65% to 98.04% for specificity and from 58.85% to 82.78% for accuracy, with a decrease in sensitivity compared with B-mode.

Conclusion: Quantitative and qualitative SWE combined with B-mode US improved the accuracy to differentiate benign from malignant lesions. Emax (cutoff, 145.7 kPa) appeared to be the most discriminatory parameter.

1. Introduction

Breast ultrasound (US) elastography is a method used to measure the stiffness of a breast lesion. Many studies have shown that US elastography improves the differentiation between benign and malignant lesions in breast tissue [1–3]. There are two main methods for assessment of stiffness; strain elastography and shear-wave elastography [4]. Strain elastography assesses the stiffness from the degree of strain caused by manual compression. The efficacy of strain elastography to assess stiffness is limited by the operator's ability to provide adequate repetitive compression. Therefore, shear-wave elastography (SWE) has been introduced to overcome this limitation as SWE is relatively operator independent and a highly reproducible system [3].The SWE system uses acoustic radiation to induce mechanical vibrations and quantifies the stiffness of the lesion by capturing propagating shear waves [5]. This technique results in quantitative measurement of tissue elasticity in kilopascals (kPa) or meters per second (m/s) [3,5]. Moreover, the color overlay image obtained using B-mode imaging can provide information about stiffness of the breast lesion [2,6].

Recently, several studies on quantitative and qualitative SWE have been published. They reported that the combination of Breast Imaging Reporting and Data System (BI-RADS) and SWE were helpful in the assessment of breast lesions [3,4,7–10]. However, each used different cut-off values with different SWE parameters [3,4,7–9]. Therefore, the purpose of our study is to investigate the most effective and reproducible cutoff value of quantitative and qualitative SWE parameters and to evaluate the diagnostic performance of quantitative and qualitative SWE in addition to B-mode US.

2. Materials and methods

2.1. Patients

An Institutional Review Board (IRB) of our institution approved our

Abbreviations: SWE, shear-wave elastography; US, ultrasound; E_{max}, max elasticity; E_{mean}, mean elasticity; E_{ratio}, elasticity ratio; SD, standard deviation

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retrospective study, and neither patient approval nor informed consent was required for the review of medical records or radiological images. Signed informed consent was obtained from all patients before US-guided biopsy procedures or surgery. We reviewed B-mode US and SWE data from 398 breast lesions in 387 women who were scheduled to undergo US-guided core needle biopsy or surgical excision from August 2013 to September 2015. Exclusion criteria were as follows; (1) SWE was not performed (n = 107) or patients were referred to another hospital (n = 63) and (2) neoadjuvant chemotherapy was performed before surgery (n = 19). Finally, 209 breast lesions in 198 women were included in this study. The mean age of the patients was 47.0 ± 12.5 years (range, 17–78 years).

2.2. US examination

All patients underwent conventional B-mode US and SWE before US-guided core needle biopsy by a single radiologist (Y.M.S.) with 10 years of experience in breast imaging. Conventional B-mode US was performed first, followed by SWE using a 4–15 MHz linear array transducer (Supersonic Imagine, Aix en Provence, France) before biopsy. SWE images were obtained by applying minimal pressure induced by the transducer. For a few seconds of immobilization to let the SWE image to stabilize, the B-mode semitransparent color map revealed stiffness with a range from dark blue to red (0–180 kPa). Quantitative SWE values were acquired by placing a $3mm^2$ round region of interest (ROI) (Q-box; Super-Sonic Imagine) on the stiffest portion including the lesion and surrounding normal breast parenchyma. The system automatically displayed with all the quantitative measurements including maximum elasticity (Emax), mean elasticity (Emean), standard deviation (SD), and the ratio of lesion to surrounding tissue (Eratio) in kilopascals (kPa).

2.3. Image analysis

Final assessments based on conventional B-mode US findings were made and recorded by the American College of Radiology (ACR) BI-RADS before SWE [11]. For statistical analysis, BIRADS category 3 masses were considered as benign, and BI-RADS category 4a and higher masses were considered as malignant on conventional B-mode US. For quantitative SWE analysis, Emax, Emean, SD, and Eratio were retrospectively reviewed by two radiologist (Y.-M.S. and E.J.S.) with 10 years of experience and one year of experience in breast imaging, respectively and reached consensus after each review.

For qualitative analysis from SWE, two radiologists (Y.-M.S. and M.S.) with 10 and 6 years of experience in breast imaging retrospectively reviewed the SWE images in consensus. They also recorded color patterns according to the classifications proposed by Tozaki and Fukuma using a four-color overlay [12]. Images were classified as follows: “pattern 1,” the color around the lesion was not different from the margin of the lesion or its interior, showing a homogeneously blue pattern; “pattern 2,” the color extending beyond the lesion was different from the color around the lesion, showing continuous vertical stripes on the cutaneous or thoracic wall side; “pattern 3,” the localized colored area was at the margin of the lesion; and “pattern 4,” the colored areas were heterogeneously present in the interior of the lesion [12].

Breast lesions with greater than the cutoff values were considered as “positive” and breast lesions with lesser than the cutoff values were considered as “negative” for upgrading category 3 lesions to 4a or downgrading category 4a lesions to category 3. For combination of BI-RADS and SWE parameters, a lesion was assessed as malignant if both BI-RADS and SWE parameters were positive according to our designated cutoff values. The diagnostic performances of B-mode US alone and with a four-color pattern or quantitative parameters were compared based on pathologic results from core needle biopsy or surgical excision.

2.4. Statistical analysis

Statistical analyses were performed with statistical software SAS (version 9.2, SAS Institute Inc., Cary, NC, USA). Continuous variables were described as mean ± standard deviation (SD), and categorical variables were expressed as frequency and percentage. Mann-Whitney *U* test was used to compare Emax, Emean, SD, and Eratio between the benign and malignant groups. Chi-square test was used to compare their qualitative color patterns. Cut-off values were defined using Youden's index (Sensitivity + Specificity − 1). Sensitivity, specificity, and accuracy of B-mode US alone and in combination with qualitative color patterns or quantitative parameters were calculated based on the cutoff.

3. Results

Of the 209 breast lesions, 102 (48.8%) were benign and 107 (51.2%) were malignant (Table 1). The mean diameter of the benign lesions was 12.23 ± 8.74 mm (range, 4.0–50.0 mm), and that of the malignant lesions was 19.43 ± 10.21 mm (range, 5.0–55.5 mm). Therefore, malignant lesions were significantly larger than benign lesions ($p < 0.001$). Table 2 summarizes the US BI-RADS categories of breast lesions.

3.1. Comparison of SWE parameters between benign and malignant lesions

Table 3 shows quantitative and qualitative SWE parameters of benign and malignant lesions. There were significant differences in Emax, Emean, SD, Eratio, and color pattern between benign and malignant lesions. Malignant lesions showed significantly higher values for all quantitative and qualitative elastographic parameters than benign lesions (Fig. 1). For malignant lesions, Emax, Emean, SD, and Eratio were 178.92 ± 70.09, 140.96 ± 56.09, 22.87 ± 16.19, and 9.84 ± 11.11 (mean ± SD), respectively. For benign lesions, the respective values were 67.32 ± 43.29, 55.05 ± 41.20, 7.53 ± 5.36, and 3.26 ± 2.71 (Fig. 2).

Of 107 malignant breast lesions, 97 (90.6%) were assigned to pattern 4, 8 (7.5%) to pattern 3, 2 (1.9%) to pattern 2, and 0 (0%) to

Table 1
Histopathologic diagnoses of malignant and benign lesions.

Histology	N
Malignant (n = 107)	
Invasive ductal carcinoma	78
Ductal carcinoma in situ	16
Invasive lobular carcinoma	4
Invasive papillary carcinoma	3
Metaplastic carcinoma	2
Medullary carcinoma	2
Invasive apocrine carcinoma	1
Mucinous carcinoma	1
Benign (n = 102)	
Fibrocystic change	51
Fibroadenoma	22
Stromal fibrosis	6
Fat necrosis	4
Sclerosing adenosis	3
Intraductal papilloma	2
Duct ectasia	2
Acute or chronic inflammation	2
Granulomatous lobular mastitis	2
Gynecomastia	1
Mucocele-like tumor	1
Radial scar	1
Phyllodes tumor	1
Tubular adenoma	1
Adipose tissue	1
Foreign body reaction	1