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A new qualitative pattern classification of shear wave elastograghy for solid breast mass evaluation

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ABSTRACT

Objectives: To examine the efficacy of qualitative shear wave elastography (SWE) in the classification and evaluation of solid breast masses, and to compare this method with conventional ultrasonograghy (US), quantitative SWE parameters and qualitative SWE classification proposed before.
Methods: From April 2015 to March 2016, 314 consecutive females with 325 breast masses who decided to undergo core needle biopsy and/or surgical biopsy were enrolled. Conventional US and SWE were previously performed in all enrolled subjects. Each mass was classified by two different qualitative classifications. One was established in our study, herein named the Qual1. Qual1 could classify the SWE images into five color patterns by the visual evaluations: Color pattern 1 (homogeneous pattern); Color pattern 2 (comparative homogeneous pattern); Color pattern 3 (irregularly heterogeneous pattern); Color pattern 4 (intralesional echo pattern); and Color pattern 5 (the stiff rim sign pattern). The second qualitative classification was named Qual2 here, and included a four-color overlay pattern classification (Tozaki and Fukuma, Acta Radiologica, 2011). The Breast Imaging Reporting and Data System (BI-RADS) assessment and quantitative SWE parameters were recorded. Diagnostic performances of conventional US, SWE parameters, and combinations of US and SWE parameters were compared.
Results: With pathological results as the gold standard, of the 325 examined breast masses, 139 (42.77%) samples were malignant and 186 (57.23%) were benign. The Qual1 showed a higher Az value than the Qual2 and quantitative SWE parameters (all $P < 0.05$). When applying Qual1 = Color pattern 1 for downgrading and Qual1 = Color pattern 5 for upgrading the BI-RADS categories, we obtained the highest Az value (0.951), and achieved a significantly higher specificity (86.56%, $P = 0.002$) than that of the US (81.18%) with the same sensitivity (94.96%).
Conclusions: The qualitative classification proposed in this study may be representative of SWE parameters and has potential to be relevant assistance in breast mass diagnoses.

1. Introduction

In addition to conventional ultrasonograghy (US), US elastography has become a popular complementary imaging technique that makes it possible to visualize the intrinsic features of the targeted breast mass [1,2]. Shear wave elastography (SWE) is a newly developed elastography technique that processes acoustic radiation force which induce vibrations. It employs an ultrafast acquisition sequence capable of capturing the propagation of the resulting shear waves in real time [3,4]. This new technique makes it possible to determine the elasticity of tissues both quantitatively and qualitatively. As the quantitative parameters, such as the mean or maximum elasticity, have been already proven and commonly used, the qualitative SWE parameters were considered inferior to the quantitative parameters [5,6]. Recent studies have demonstrated that the validity of qualitative classifications may be comparable to that of quantitative parameters, with similar diagnostic performances for the evaluation of breast masses [7,8]. Several studies showed that the qualitative classifications had good correlations with the quantitative SWE parameters, including the standard deviation (SD), Emax, and Emean [9,10]. Based on prior studies, the SWE patterns visualized on images were either classified as the three-color overlay pattern of Berg et al. [11] or the

Abbreviations: ACR, American College of Radiology; BI-RADS, breast imaging reporting and data system; NPV, negative predictive value; PPV, positive predictive value; ROC, receiver operating characteristic; ROI, region-of-interest; SWE, shear wave elastography; US, ultrasound; Qual1, qualitative classification 1; Qual2, qualitative classification 2.

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four-color overlay pattern classification proposed by Tozaki and Fukuma [12]. Recently, Klotz et al. [13] proposed a new qualitative classification system. Several studies reported that peritumoral stiffness in the color elastic map was a typical sign of malignancy [14–16]. In the study of Zhou et al. [17], this finding was called the "stiff rim" sign. Our clinical findings are consistent with those of Zhou et al. [17]. Therefore, using our clinical experience and preliminary test results, we described a qualitative classification for the diagnosis of breast masses, to simplify the clinical use of SWE.

The purpose of our study was to evaluate the diagnostic performance of SWE qualitative classifications, by comparisons with the conventional US and the quantitative SWE parameters for solid breast masses. We propose this convenient qualitative method as an effective method to assist in breast mass diagnoses.

2. Materials and methods

2.1. Patients

The Ethics Committee of the University Hospital approved this prospective study. Females 18 years of age or older, with a solid breast mass seen on ultrasound, who were scheduled to undergo core needle biopsy and/or surgical biopsy, and who consented to participate in the study were included. Patients who underwent neoadjuvant chemotherapy before biopsy and/or who were pregnant or lactating were excluded.

From April 2015 to March 2016, 314 consecutive females with 325 breast masses were enrolled. The mean age was 44.56 ± 11.79 years (age range, 18–81 years). The decision to undergo biopsy was made by the patients and the referring physician on the basis of previous clinical, mammogram, and ultrasound findings. All breast masses were imaged by conventional US and SWE before biopsy. Informed consent was obtained from all patients.

2.2. US examinations

All conventional US and SWE images were obtained by one board certified radiologist with approximately 20 years of experience in breast US and at least 2 years of experience performing SWE on breast masses, using the Aixplorer® system (Supersonic Imagine, Aix en Provence, France), equipped with a 4–15 MHz linear array transducer. During the conventional US imaging, we obtained the US characteristics, then the BI-RADS categories were prospectively assessed by the radiologist who had performed the US, according to the American College of Radiology (ACR) Breast Imaging Reporting and Data System (BI-RADS).

To obtain the SWE images, the transducer was applied very lightly to the skin above the mass with a generous amount of transducer jelly. The image acquisitions were carried out after asking the patient to hold her breath, and by waiting at least 5 s for the image to stabilize. Subsequently, six images in two orthogonal planes were recorded for each mass.

2.3. Evaluation of SWE parameters

For each image, quantitative analyses were conducted automatically, using the region of interest (ROI) (Q-box; Supersonic Imagine) with suitable dimensions over the hardest intra- or perilesional area (Q-Box lesion), and a second Q-Box region in adjacent adipose tissue (Q-Box Fat). We obtained six measurements for the following parameters: maximum stiffness (Emax, kPa), mean stiffness (Emean, kPa), ratio of lesion stiffness to that of the surrounding fat (Eratio), and SD. The average of the six measurements from the six images was used for analyses.

The qualitative analyses were performed independently by two trained but inexperienced observers. The observers were trained by an experienced radiologist to analyze SWE images and to recognize SWE artefacts, but were not trained in US image evaluations. Therefore, the image evaluation was independent of the US appearance of the masses. Two different qualitative lesion classifications were applied to the same image and the results were compared. We proposed a qualitative classification (Fig. 1) to evaluate masses, herein named Qual1. The color map pattern identified on the SWE could be classified into five main categories: homogeneous pattern, called Color pattern 1 (Fig. 1a); comparative homogeneous pattern, called Color pattern 2 (Fig. 1b); irregularly heterogeneous pattern, called Color pattern 3 (Fig. 1c); intralesional echo pattern, called Color pattern 4 (Fig. 1d); and the "stiff rim" sign pattern, called Color pattern 5 (Fig. 1e). The classifications were, therefore, according to the presence of intralesional echo or "stiff rim" signs, and the homogeneity and maximum color of the SWE images. The specific standards and methods of these color patterns are shown in Table 1. All masses were then subclassified into four-color overlay patterns based on the classification described by Tozaki and Fukuma [12], herein named Qual2. If the two observers assigned different classifications, then discussions with the experienced radiologist resulted in a joint decision.

In the Supersonic system, the SWE image is a semitransparent map of tissue stiffness overlaying the US image, with a default quantitative scale from 0 to 180 kPa. For evaluating the presence or absence of the "stiff rim" sign classified as Color pattern 5 of Qual1, the display scale was first automatically set at 180 kPa for every mass, and then, for masses that did not display high stiffness color in the peritumoral tissues, the scale was adjusted downward to a level such that at least part of the peritumoral tissues was coded in yellow or red. If the absence of the stiff rim sign was confirmed, we chose not to modify the standard color scale for evaluation of the other patterns (Fig. 2). The method for confirming the "stiff rim" sign has previously been described by Zhou et al. graded. [17].

By using ROC analyses, we obtained the optimal thresholds of every SWE parameter to distinguish benign versus malignant breast masses. When combining conventional US and SWE parameters, we chose to downgrade the BI-RADS category if the value of the SWE parameter was equal to or less than its optimal threshold, and we upgraded the category if the SWE parameter was higher than its optimal threshold. Lesions with BI-RADS category of 3 were not downgraded and BI-RADS 5 lesions were not upgraded.

2.4. Statistical analyses

Statistical analyses were performed using SPSS, version 17.0 (SPSS, Chicago, IL, USA) and MedCalc for Windows, version 15.8 (MedCalc Software, Mariakerke, Belgium). Pathological results from biopsies were used as the reference standards. An independent *t*-test was performed for comparisons of continuous variables and the chi-square test was used for categorical variables. Spearman's correlation coefficient was used to assess the correlation between qualitative and quantitative SWE measurements. The weighted kappa statistics were calculated to assess the proportion of interobserver agreement between two observers.

Area under the ROC curves (Az), using the calculated cutoff for each parameter, were obtained to compare the diagnostic performances of each SWE parameter, conventional US alone, and combinations of US and SWE, and were reported along with a 95% confidence interval (CI). A P value of ≤ 0.05 was considered to indicate a statistically significant difference.