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● *Original Contribution*

INTRA-OBSERVER REPRODUCIBILITY AND DIAGNOSTIC PERFORMANCE OF BREAST SHEAR-WAVE ELASTOGRAPHY IN ASIAN WOMEN

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Abstract—Our aim was to evaluate intra-observer reproducibility of shear-wave elastography (SWE) in Asian women. Sixty-four breast masses (24 malignant, 40 benign) were examined with SWE in 53 consecutive Asian women (mean age, 44.9 y old). Two SWE images were obtained for each of the lesions. The intra-observer reproducibility was assessed by intra-class correlation coefficients (ICC). We also evaluated various clinicoradiologic factors that can influence reproducibility in SWE. The ICC of intra-observer reproducibility was 0.789. In clinicoradiologic factor evaluation, masses surrounded by mixed fatty and glandular tissue (ICC: 0.619) showed lower intra-observer reproducibility compared with lesions that were surrounded by glandular tissue alone (ICC: 0.937; $p < 0.05$). Overall, the intra-observer reproducibility of breast SWE was excellent in Asian women. However, it may decrease when breast tissue is in a heterogeneous background. Therefore, SWE should be performed carefully in these cases. (E-mail: MINES@yuhs.ac) © **2014 World Federation for Ultrasound in Medicine & Biology.**

Key Words: **Shear-wave elastography, Elastography, Breast, Ultrasonography, Intra-observer reproducibility.**

INTRODUCTION

Breast elastography has emerged as a promising adjunctive tool to diagnostic ultrasonography (US) for improving lesion differentiation. Strain elastography relies on a freehand technique in which images are obtained by applying rhythmic pressure and release to estimate the stiffness of a lesion. However, this technique is dependent on the organ's deformability and the operator's skill, which can critically affect the images and the subsequent interpretation (Burnside et al. 2007; Fleury Ede et al. 2009; Regner et al. 2006). In addition, the tissue elasticity measured using strain elastography is not a quantitative value, as the image represents the local strain estimated at a given location in tissues, a trait dependent on the surrounding mechanical properties (Tanter et al. 2008).

To overcome these limitations, shear-wave elastography (SWE), a quantitative elastography technique, has been developed. SWE images are obtained by inducing mechanical vibrations with acoustic radiation force created by a focused ultrasound beam provided by a probe and quantifying the stiffness of a lesion by capturing the propagating shear waves (Athanasiou et al. 2010; Bercoff et al. 2004a; Bercoff et al. 2004b; Tanter et al. 2008). Therefore, SWE is not as dependent on the operator's skill as strain elastography is. Recent studies using quantitative SWE on breast masses have shown that adding quantitative information obtained using SWE to Breast Imagining-Reporting and Data System (BI-RADS) feature analysis has improved the specificity and positive predictive values of breast US (Athanasiou et al. 2010; Berg et al. 2012; Burnside et al. 2007; Chang et al. 2011b; Regner et al. 2006; Tanter et al. 2008). However, these studies assessed the diagnostic performances of SWE based only on histologic findings.

Recently, a study of the reproducibility of SWE for breast masses was published (Cosgrove et al. 2012). This study indicated that SWE was highly reproducible for assessing the elastographic features of breast masses within and across observers. However, this study included only Caucasian women from a Western population. While Caucasian women tend to have fattier breast composition, Asian women have more dense breasts (Maskarinec et al. 2001). Dense breast parenchyma has

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been reported to affect image accuracy with strain elastography (Yoon et al. 2013b), but this has not been proven with SWE. Additionally, the reproducibility of SWE, and the factors affecting it, may differ in Asian women compared with Caucasian women. The purpose of this current study was to evaluate intra-observer reproducibility according to various clinicoradiologic factors of SWE in Asian women.

MATERIALS AND METHODS

Patients

This retrospective study was approved by our institutional review board, and informed consent was waived. Signed informed consent for biopsy or surgery was obtained from all patients before the procedures.

Between March 2012 and April 2012, 91 breast masses in 76 consecutive women who were scheduled to undergo US-guided percutaneous needle biopsy or surgical excision at our institution were examined with both B-mode US and SWE. All of the patients included in our study were Asian women. Of the 76 women, seven were excluded for a lack of pathologic diagnosis, because they had breast lesions thought to be benign and did not undergo percutaneous biopsy or surgery. Finally, 64 breast masses in 53 consecutive women (mean age, 44.9 y old; age range, 23–78 y old) were included in our study population. Of these 53 women, 25 (47.2%) women presented with a palpable mass, one (1.9%) woman had nipple discharge, and the remaining 27 (50.9%) women were asymptomatic. Mammograms were available for 47 women with 57 breast masses during US examinations. Lesions were observed as a mass in 18 cases (31.5%), a mass with microcalcifications in seven (12.3%), an architectural distortion in one (1.8%), and a focal asymmetry in one case (1.8%). No mammographic abnormalities were found in 30 (52.6%) lesions.

Conventional US and SWE examinations

Conventional US and SWE images were obtained using the Aixplorer US system (SuperSonic Imagine, Aix en Provence, France) with a 4–15 MHz linear array transducer. Bilateral whole breast examinations including the axillary areas were performed. US images were analyzed according to the American College of Radiology BI-RADS by the radiologists who had performed the B-mode US (American College of Radiology 2003). After assessment of conventional US images, SWE images of the breast lesions were obtained before biopsy or surgery. In 54 of the lesions, two or more consecutive SWE images were obtained for each lesion by the same operator in the same imaging plane, with the probe having been removed and re-applied between each acquisition to obtain the appropriate SWE. The initial two images were chosen if there were more than two SWE images. Quantitative elasticity values were obtained and recorded from each SWE image by applying a 3-mm round region-of-interest at the location of maximum stiffness, and the SWE system automatically calculated and displayed elasticity features such as maximum value, mean value, and standard deviation.

Clinicoradiologic evaluation

Each patient's medical records, radiologic reports, and conventional US with SWE were retrospectively reviewed by one radiologist to obtain information regarding the patient and the breast lesion targeted for SWE. Factors affecting elastography interpretation were divided into those associated with image acquisition: Patient factors consisting of age; palpability; body mass index (body mass index = [mass(kg)/height(m)^2]: Underweight is considered $<$18.5; normal ranges between 18.5 and 24.9; overweight between 25.0 and 29.9; and obese: $\geq$30.0); parenchymal density of the breast on mammography (density 1pp: arenchymal structure consisting of 0%–25%; density 2: 26%–50%; density 3: 51%–75%; density 4: 76%–100%) (American College of Radiology 2003) and on US (homogeneous background echotexture fat, homogeneous background echotexture fibroglandular and heterogeneous background) (American College of Radiology 2003); lesion factors consisting of size (longest diameter measured on conventional US), breast thickness (measured as the vertical distance from the skin to the pectoralis muscle where the lesion was located), length of the lesion (measured as the vertical diameter of the lesion), depth of the lesion within the breast (measured as the vertical distance from the skin to the upper margin of the mass, categorized into superficial, middle, or deep as each one third of the thickness of the breast), and distance from the nipple. US features of the lesion were assessed according to the BI-RADS lexicon (American College of Radiology 2003).

Pathologic diagnosis

The pathologic diagnoses for 37 masses were taken with US-guided core needle biopsy with a 14-gauge dual-action semiautomatic core biopsy needle (Stericut with coaxial; TSK Laboratory, Tochigi, Japan) or US-guided vacuum-assisted biopsy with an 11-gauge or 8-gauge needle (Mammotome, Ethicon Endo Surgery, Cincinnati, OH, USA). Twenty-seven masses were diagnosed with surgical excision using US-guided needle localization.

Statistical analysis

Statistical comparisons of parametric data were performed using the Student's *t*-test. Comparison of nonparametric data was performed using the Chi-square test.