

Intra- and Interobserver Reproducibility of Shear Wave Elastography for Evaluation of the Breast Lesions

유방 병변에서 Shear Wave Elastography의 검사자 내, 검사자 간 재현성 평가

Min Ji Hong, MD¹, Hak Hee Kim, MD^{2*}

¹Department of Radiology, Gil Hospital, Gachon University of Medicine and Science, Incheon, Korea

²Department of Radiology and Research Institute of Radiology, University of Ulsan College of Medicine, Asan Medical Center, Seoul, Korea

Purpose: To evaluate reproducibility of shear wave elastography (SWE) for breast lesions within and between observers and compare the reproducibility of SWE features.

Materials and Methods: For intraobserver reproducibility, 225 masses with 208 patients were included; and two consecutive SWE images were acquired by each observer. For interobserver reproducibility, SWE images of the same mass were obtained by another observer before surgery in 40 patients. Intraclass correlation coefficients (ICC) were used to determine intra- and interobserver reproducibility.

Results: Intraobserver reliability for mean elasticity (E_{mean}) and maximum elasticity (E_{max}) were excellent (ICC = 0.803, 0.799). ICC for SWE ratio and minimum elasticity (E_{min}) were fair to good (ICC = 0.703, 0.539). E_{mean} showed excellent ICC regardless of histopathologic type and tumor size. E_{max}, SWE ratio and E_{min} represented excellent or fair to good reproducibility based on histopathologic type and tumor size. In interobserver study, ICC for E_{mean}, E_{max} and SWE ratio were excellent. E_{mean}, E_{max} and SWE ratio represented excellent ICC irrespective of histopathologic type. ICC for E_{mean} was excellent regardless of tumor size. SWE ratio and E_{max} showed fair to good interobserver reproducibility based on tumor size. E_{min} represented poor interobserver reliability.

Conclusion: E_{mean} in SWE was highly reproducible within and between observers.

Index terms

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*Corresponding author: Hak Hee Kim, MD
Department of Radiology and Research Institute of
Radiology, University of Ulsan College of Medicine,
Asan Medical Center, 88 Olympic-ro 43-gil,
Songpa-gu, Seoul 05505, Korea.
Tel. 82-2-3010-4390 Fax. 82-2-476-0090
E-mail: hkhkim@amc.seoul.kr

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INTRODUCTION

Breast ultrasonography (US) is a widely used diagnostic modality for breast lesions. US, however, has some limitations. It is heavily operator dependent (1) and represents hard and soft lesion by similar echogenicity in B-mode US (2). In general, benign masses have tendency to be softer than cancers but harder than normal breast tissue (2, 3). Elastography is a promising technique for enhancing lesion differentiation by measuring tissue stiffness (2). Static elastography (1, 4-6) acquires relative stiffness of images in soft tissues by using US. Elastography calculates local tissue strain by comparison of the US signal gains before

and after operator's light compression of the tissue (1, 5, 6), with hard zones demonstrating as dark and soft zones as bright (1, 5, 6). Static elastography supplies not a quantitative estimation of the local stiffness but a map of the local tissues strain. Moreover, static elastography is easily affected by the operator's compression power, resulting in observer variability (7, 8). To be a reliable diagnostic method, elastography must not be easily affected by operators or interpreters.

To overcome this limitation, the quantitative elastography technique of shear wave elastography (SWE) has emerged (2, 8). In SWE, estimation of the velocity of shear wave is involved in tissue elasticity imaging (1, 9-12). The mechanical vibration is remote-

ly produced by using acoustic radiation force produced by a focused US beam (1, 7, 8). The radiation force rearranges tissue, and the rearrangement causes a transient shear wave (2, 8, 13). The shear wave carries information associated with the local viscoelastic properties of the tissue, facilitating a quantitative approach to the tissue (2, 7, 8). Shear waves move faster in stiffer area and slowly in softer area (9). The velocity information produces a color image of the stiffness and measures SWE features such as the minimum elasticity (Emin), mean elasticity (Emean), and maximum elasticity (Emax) and ratio of lesion-to-fat (SWE ratio) elasticity in a region of interest (1, 2, 9-13). Using quantitative elasticity data, SWE thus provides more objective information than static elastography and enhanced lesion differentiation than conventional grayscale US (14-17). Based on these characteristics, quantitative US elastography using SWE is expected to have higher reproducibility.

The purpose of our study was to estimate the intra- and interobserver reproducibility of SWE for breast masses and to determine which SWE features among Emin, Emax, Emean and SWE ratio was highly reproducible.

MATERIALS AND METHODS

Patients and Breast Masses

The Institutional Review Board approved this retrospective study, and informed consent was waived. Between January 2012 and February 2012, 295 patients underwent conventional US with SWE imaging in Asan Medical Center. Among them, 225 breast lesions of 208 patients (mean age, 47.20 years; range 18–82 years) were included for measurement of intraobserver reproducibility in our study. Inclusion criteria for intraobserver reproducibility included the following: 1) undergoing elastography more than twice on same lesion by one observer 2) having histopathologic results obtained with US-guided biopsy or surgical excision. 3) Not receiving chemotherapy or radiation therapy for any cancer. Among the 208 patients, 40 patients who underwent another US with SWE imaging by other operators during same period were included for interobserver reproducibility.

US Examination

Conventional US and elastographic imaging were obtained using the Aixplorer® ultrasound system (SuperSonic Imagine, Aix-

en-Provence, France) with a 4–15 MHz linear transducer by one of five board certified radiologists who specialize in breast imaging with 1 to 10 years of experience interpreting images from a minimum of 1000 breast US examinations in the prior year. Each reader had experience with more than 100 cases of US breast elastography. At least two orthogonal grayscale images and elastography images were obtained of each solid lesion. For elastography, we used the same depth, focus position, and gain setting as for conventional images. Elastographic images were obtained by applying repetitive light compression at the skin above the targeted breast lesion. SWE imaging was performed by setting the region-of-interest quantification tool (ROI) called the Q-Box™, so that it included the lesion and the surrounding normal tissue. Within the ROI, elastography values were gained by placement of a 3 mm round electronic cursor over the stiffest part of the lesion and an area of fat. The maximum, mean stiffness and standard deviation were obtained within these areas. The SWE ratio was determined by comparing the mean elasticity within the stiffest part of the lesion and fatty tissue (Fig. 1). For the assessment of intraobserver reproducibility, we compared SWE measurements performed on the same subject on the same day by the same operator. SWE measurement includes mean (Emean), minimum (Emin), maximum (Emax) SWE and SWE ratio. For analyzing interobserver reproducibility, we recorded SWE scores individually by different two operators on different days. Performers were blinded to the results of others.

Statistical Analysis

The data were analysed using the statistical software (SAS version 9.1, MAGREE SAS Macro program, SAS Institute, Cary, NC, USA). Intra- and interobserver reproducibility was assessed through the calculation of the intraclass correlation coefficient (ICC). The ICC ranges between 0 and 1.00, with values closer to 1.00 representing better reproducibility. Measurement reliability was classified according to common criteria (Fleiss 1986) as excellent (ICC > 0.75), fair to good (ICC = 0.40–0.75) and poor (ICC ≤ 0.40) (18).

RESULTS

In intraobserver reproducibility, among the 225 breast lesions, 174 (83.7%) were diagnosed as malignant and 51 were diagnosed

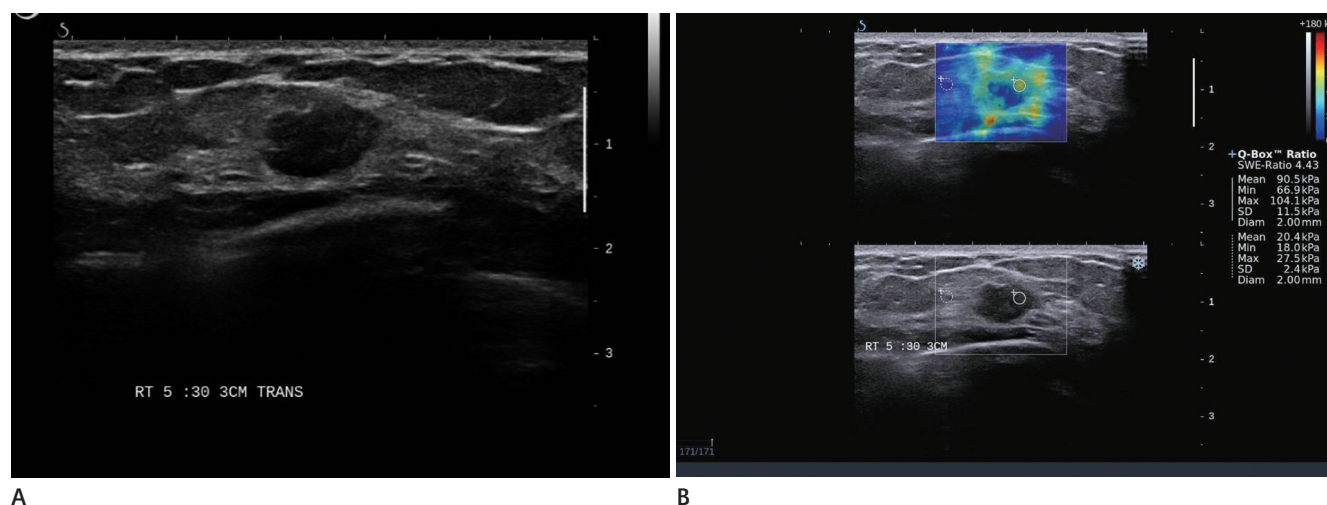


Fig. 1. Conventional US and elastographic images of invasive ductal carcinoma in a 49-year-old woman.

A. Conventional US image shows an irregular hypoechoic lesion without circumscribed margin.

B. Shear wave elastography images of quantification box (Q-Box™) applies on the stiffest part of mass. An additional Q-Box™ is placed in the adjacent surrounding tissue.

US = ultrasonography

as benign on US-guided core needle biopsy or surgical excision. The 174 malignant lesions were 133 cases of invasive ductal carcinoma, 22 of ductal carcinoma *in situ*, 6 of mucinous carcinoma, 5 of tubular carcinoma, 3 of invasive lobular carcinoma, 2 of microinvasive ductal carcinoma, 2 of invasive mammary carcinoma, 1 of secretory carcinoma, respectively. Of the 51 benign lesions, there were 29 cases of fibroadenoma, 5 cases of intraductal papilloma, 4 cases of adenosis, 5 cases of other proliferative breast lesion without atypia, 5 cases of nonproliferative breast change, and other benign disease. Histopathologic results of the 225 lesions are summarized in Table 1. The mean mass size was 18.20 ± 11.55 mm in maximum diameter (range, 4–68 mm). Emean was the most reliable measurement of elasticity, with ICC = 0.803 (Table 2). About benignancy or malignancy, reliability of Emean made by same operator was excellent in malignant and benign lesion, (ICC = 0.762, 0.754 respectively). Emax of intraobserver reproducibility also showed excellent ICC values of 0.799 and was excellent (ICC = 0.769) for malignant lesions and fair to good (ICC = 0.744) for benign lesions, respectively. Overall SWE ratio represented fair to good reliability (ICC = 0.703). ICC for SWE ratio was 0.636 (fair to good) in benign lesion and 0.668 (fair to good) for malignancy. Intraobserver reproducibility of Emin was the least reliable in overall (ICC = 0.539), in benign lesion (ICC = 0.491) and in malignancy (ICC = 0.498). Intraobserver reliability was consistently higher for all measured SWE

Table 1. Pathologic Diagnosis of 228 Breast Lesions in 208 Patients

Pathologic Diagnosis	No. of Lesions
Malignant lesions (<i>n</i> = 174)	
Invasive ductal carcinoma	133
Ductal carcinoma <i>in situ</i>	22
Mucinous carcinoma	6
Tubular carcinoma	5
Invasive lobular carcinoma	3
Microinvasive ductal carcinoma	2
Invasive mammary carcinoma	2
Secretory carcinoma	1
Benign lesions (<i>n</i> = 51)	
Fibroadenoma	29
Intraductal papilloma	5
Adenosis	4
Other proliferative breast lesion without atypia	5
Nonproliferative breast change	5
Columnar cell change	1
Fibroadenomatoid change	1
Pseudoangiomatous stromal hyperplasia	1

features of malignant masses than that of benign masses (Table 2). Ductal carcinoma *in situ* showed higher intraobserver reproducibility than invasive carcinoma in all SWE measurements (Table 3).

Intraobserver reliability based on maximum diameter of the mass is shown in Table 4. Emean showed excellent intraobserver reproducibility regardless of lesion diameter (size ≤ 10 mm; ICC = 0.869, $10 \text{ mm} < \text{size} \leq 15$ mm; ICC = 0.758, $15 \text{ mm} < \text{size} \leq 22$

mm; ICC = 0.760, size ≥ 22 mm; ICC = 0.804). On the other hand, Emin was the least reliable in overall size. Emean represented excellent intraobserver reproducibility regardless of histopathologic results and tumor diameter.

Of 40 lesions, 32 were malignant and 8 were benign in interobserver study. Overall SWE ratio was the most reliable measurement of elasticity, with ICC = 0.909, and Emin was the least reliable (ICC = 0.394) (Table 5). Interobserver reproducibility was generally higher for most SWE measurements of benign masses than of malignancies, except for Emean. Emean, Emax

and SWE ratio showed excellent interobserver reproducibility irrespective of benignancy or malignancy. The interobserver reproducibility for all SWE measurements were better in larger lesion than in smaller lesion (Table 6). ICCs for Emean was nearly perfect regardless of lesion diameter and benignancy or malignancy.

DISCUSSION

Emergence of SWE has facilitated quantitative and non-inva-

Table 2. Intraobserver Reproducibility of Quantitative SWE Measurements

	Overall		Benign		Malignancy	
	ICC	95% CI	ICC	95% CI	ICC	95% CI
SWE ratio*	0.703	0.606 to 0.801	0.636	0.452 to 0.821	0.668	0.555 to 0.780
Emean [†]	0.803	0.760 to 0.845	0.754	0.571 to 0.876	0.762	0.692 to 0.833
Emax [‡]	0.799	0.744 to 0.855	0.744	0.648 to 0.889	0.769	0.667 to 0.822
Emin [§]	0.539	0.419 to 0.660	0.491	0.115 to 0.868	0.498	0.360 to 0.637

*SWE ratio was the ratio between the mean elasticity value in the mass divided by the mean elasticity value in the fat.

[†]E mean was the mean value in the Q-Box™ of the mass as calculated by the system.

[‡]E maximum mass was the maximum value in the Q-Box™ of the mass as calculated by the system.

[§]E minimum mass was the minimum value in the Q-Box™ of the mass as calculated by the system.

CI = confidence interval, ICC = intraclass correlation coefficients, SWE = shear wave elastography

Table 3. Intraobserver Reproducibility of Quantitative Shear Wave Elastography Measurements in Patients with Invasive Cancer Versus with Ductal Carcinoma *in situ*

	Ductal Carcinoma <i>in situ</i>		Invasive Cancer	
	ICC	95% CI	ICC	95% CI
SWE ratio*	0.832	0.688 to 0.976	0.650	0.531 to 0.770
Emean [†]	0.879	0.788 to 0.970	0.744	0.681 to 0.806
Emax [‡]	0.897	0.821 to 0.973	0.718	0.637 to 0.799
Emin [§]	0.677	0.394 to 0.959	0.475	0.319 to 0.631

*SWE ratio was the ratio between the mean elasticity value in the mass divided by the mean elasticity value in the fat.

[†]E mean was the mean value in the Q-Box™ of the mass as calculated by the system.

[‡]E maximum mass was the maximum value in the Q-Box™ of the mass as calculated by the system.

[§]E minimum mass was the minimum value in the Q-Box™ of the mass as calculated by the system.

CI = confidence interval, ICC = intraclass correlation coefficients, SWE = shear wave elastography

Table 4. Intraobserver Reproducibility of Quantitative SWE Measurements according to the Mass Diameter

	Diameter ≤ 10 mm		10 mm < Diameter ≤ 15 mm		15 mm < Diameter ≤ 22 mm		Diameter > 22 mm	
	ICC	95% CI	ICC	95% CI	ICC	95% CI	ICC	95% CI
SWE ratio*	0.718	0.585 to 0.852	0.634	0.412 to 0.856	0.746	0.622 to 0.870	0.644	0.446 to 0.842
Emean [†]	0.869	0.811 to 0.927	0.758	0.626 to 0.831	0.760	0.680 to 0.839	0.804	0.732 to 0.875
Emax [‡]	0.891	0.848 to 0.934	0.752	0.665 to 0.839	0.740	0.656 to 0.825	0.770	0.646 to 0.893
Emin [§]	0.592	0.412 to 0.772	0.603	0.443 to 0.762	0.504	0.301 to 0.707	0.435	0.157 to 0.712

Diameter was the largest measurement of the mass.

*SWE ratio was the ratio between the mean elasticity values in the mass divided by the mean elasticity value in the fat.

[†]E mean was the mean value in the Q-Box™ of the mass as calculated by the system.

[‡]E maximum mass was the maximum value in the Q-Box™ of the mass as calculated by the system.

[§]E minimum mass was the minimum value in the Q-Box™ of the mass as calculated by the system.

CI = confidence interval, ICC = intraclass correlation coefficients, SWE = shear wave elastography

sive measurement of tissue elasticity (19). A previous study showed that elastography had nearly the same diagnostic performance as conventional US, with 86.5% (45 of 52) sensitivity, 89.8% (53 of 59) specificity, and 88.3% (98 of 111) accuracy in the differentiation of benign from malignant solid breast masses (15). Because elastography is performed by free hand technique, variability is avoidable according to the performer's compression motion and probe movement (20). Moreover, the breast is very redundant curved organ, and an application of homogenous continuous compression on breast lesion is difficult (21). To overcome the major limitation of elastography, subjective imaging method, quantitative elastography technique, SWE has been developed (14).

SWE is differentiated from conventional static elastography in automatically induced mechanical vibration via the radiation force of US beams (1, 2, 7, 8, 22). So, it less affected by the individual compression skills than static elastography (1, 2, 7, 8, 22). To be used in daily practice as a reliable diagnostic tool, elastography must be objective. Some studies have reported intra- and interobserver reproducibility of SWE (7, 9, 22). Cosgrove et al. (9) reported that intraobserver reliability for maximum and mean

elasticity was almost perfect (ICC = 0.84 and 0.87) and was substantial for the ratio of mass-to-fat elasticity (ICC = 0.77). Park et al. (7), interobserver variabilities for the elasticity score showed moderate agreement with the highest k value ($k = 0.59$). In phantom study of SWE (22), intraobserver ICCs were 0.65, 0.77, 0.92, and 0.91 for maximum elasticity; 0.70, 0.83, 0.94, and 0.94 for mean elasticity; and 0.67, 0.83, 0.92, and 0.92 for elasticity ratio for operators 1, 2, 3, and 4, respectively. Interobserver reproducibility showed good agreement with ICC values of 0.77 for maximum elasticity, 0.82 for mean elasticity, and 0.79 for elasticity ratio.

In this study, intra- and interobserver reproducibility of SWE was highly reproducible, except for Emin. Compared with previous reports, outcome in our study was similar in intra- and interobserver reproducibility. Especially Emean showed excellent reliability in most cases except in case of invasive cancer. Emean, however, showed nearly excellent reliability even in case of invasive cancer (ICC = 0.744). Emean represented excellent intra- and interobserver reproducibility irrespective of lesion diameter, benignancy or malignancy.

Emin was the least reliable based on intra- and interobserver

Table 5. Interobserver Reproducibility of Quantitative SWE Measurements

	Overall		Benign		Malignancy	
	ICC	95% CI	ICC	95% CI	ICC	95% CI
SWE ratio*	0.787	0.714 to 1.000	0.902	0.535 to 1.000	0.752	0.687 to 1.000
Emean [†]	0.909	0.558 to 1.000	0.879	0.486 to 1.000	0.906	0.481 to 1.000
E _{max} [‡]	0.868	0.661 to 1.000	0.951	0.596 to 1.000	0.831	0.588 to 1.000
E _{min} [§]	0.394	0.000 to 0.828	0.745	0.183 to 1.000	0.341	0.000 to 0.797

*SWE ratio was the ratio between the mean elasticity values in the mass divided by the mean elasticity value in the fat.

[†]E mean was the mean value in the Q-BoxTM of the mass as calculated by the system.

[‡]E maximum mass was the maximum value in the Q-BoxTM of the mass as calculated by the system.

[§]E minimum mass was the minimum value in the Q-BoxTM of the mass as calculated by the system.

CI = confidence interval, ICC = intraclass correlation coefficients, SWE = shear wave elastography

Table 6. Interobserver Reproducibility of Quantitative SWE Measurements according to the Mass Diameter

	Diameter ≤ 15 mm		Diameter > 15 mm	
	ICC	95% CI	ICC	95% CI
SWE ratio*	0.423	0.565 to 1.000	0.760	0.587 to 1.000
Emean [†]	0.878	0.000 to 0.856	0.903	0.343 to 1.000
E _{max} [‡]	0.653	0.169 to 1.000	0.888	0.560 to 1.000
E _{min} [§]	0.217	0.000 to 0.743	0.278	0.000 to 0.766

Diameter was the largest measurement of the mass.

*SWE ratio was the ratio between the mean elasticity values in the mass divided by the mean elasticity value in the fat.

[†]E mean was the mean value in the Q-BoxTM of the mass as calculated by the system.

[‡]E maximum mass was the maximum value in the Q-BoxTM of the mass as calculated by the system.

[§]E minimum mass was the minimum value in the Q-BoxTM of the mass as calculated by the system.

CI = confidence interval, ICC = intraclass correlation coefficients, SWE = shear wave elastography

study. In intraobserver reproducibility, ICC values of Emin were 0.539 in overall, 0.491 in benign lesions and 0.498 in malignant lesions. Emin was also the least reliable based on the mass diameter. ICC values of Emin were 0.592 in the mass smaller than 1 cm, 0.603 in the mass between 1 cm and 1.5 cm and 0.504 in the mass between 1.5 cm and 2.2 cm and 0.435 in the mass larger than 2.2 cm. Emin was also the least reliable (ICC = 0.394) in interobserver reproducibility. These results of our study were concordant with the previous report (9) with the least reproducibility of Emin in breast masses (ICC = 0.71). The previous study explained that a zero value came to the minimum on images where any pixel within the Q-Box™ lacked SWE information, probably leading to lower reproducibility of Emin (9).

Intraobserver reproducibility of malignant lesions was consistently higher than that of benign lesions in all measured SWE features. Benign lesions tend to show a uniform homogeneity on the color map, as compared with malignant lesions (23). The distinct color contrast in malignant lesions on color map might enhance the intraobserver reproducibility. However, this hypothesis could not explain the higher intraobserver reproducibility in ductal carcinoma than invasive carcinoma. The number of invasive cancer was more than five times that of ductal carcinoma *in situ* in intraobserver study. Higher numbers of lesions could cause the heterogeneity in intraobserver reproducibility and the big differences in numbers between invasive cancer and ductal carcinoma *in situ* may influence the results of study. The study including similar numbers of each histopathologic type will be helpful in investigation of reproducibility by histopathologic type.

Contrary to results of previous studies (7, 9, 22), the ICC of interobserver reproducibility was superior to that of intraobserver reproducibility in our study. One previous study (22) showed the results of intraobserver variability of an operator with shorter experience showed lower ICC values than those of the others. In spite of its low intrinsic changeability, SWE imaging may be influenced by operators and operators' experiences (22). The operators had 1–3 years of experience in breast imaging in this study. The operators' relatively short experiences might affect the intraobserver reproducibility for SWE. However, intra- and interobserver reproducibility of SWE for breast lesions was excellent irrespective of operators' experiences in this study.

Our study has several limitations. First, variable sized lesions were included in our study (ranging from 4 to 68 mm). Regarding

the nodule size, a previous study (24) suggested that the careful decision should be made before recommending follow-up or biopsy for a small breast lesion on the basis of SWE features, to minimize false-negative results. However, several studies on SWE including subcentimeter-sized lesions also have showed good performance enough to differentiate benign lesions from malignant lesions (8, 23). Chang et al. (8) reported that significantly higher mean elasticity values was shown in malignant lesions than in benign lesions and even in the 4–5-mm-sized nodules, the elasticity values significantly differed between benign and malignant nodules (8). However, the SWE of small lesions measuring less than 5 mm might induce suboptimal results in this study. On the other hand, a previous study excluded the large breast masses (> 4 cm) that were not fully included in the maximum range of SWE color overlay (25). In case of large lesions, the ROI might not fully cover the breast mass or surrounding breast parenchyma, this also may affect the results of this study. Further studies with larger numbers of patients may provide more confirmative size cutoff that may not affect the results of SWE. Second, elastography images were obtained more than twice by same performers in one day for intraobserver reproducibility, and elastography images for interobserver reproducibility were performed on different days by different operators. This may influence the results, but our study design was not for comparison of intra- and interobserver reproducibility.

In conclusion, intra- and interobserver reproducibility of quantitative SWE for breast lesions was excellent in general. Especially, Mean elasticity is the most reproducible within and across observers in SWE.

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유방 병변에서 Shear Wave Elastography의 검사자 내, 검사자 간 재현성 평가

홍민지¹ · 김학희^{2*}

목적: 유방 병변에서 shear wave elastography (이하 SWE)의 검사자 내, 검사자 간 재현성을 평가하고 어떤 지표가 재현성이 높은지 알아보고자 한다.

대상과 방법: 검사자 내 재현성 평가를 위해서 208명의 225개의 유방 병변에서 얻은 두 번의 SWE 영상을 얻었다. 검사자 간의 재현성 평가를 위해서 40명의 환자에서 같은 병변에 대해 다른 검사자에 의한 SWE 영상을 얻었다. 재현성 평가는 급내상관계수(intraclass correlation coefficients)로 분석하였다.

결과: 검사자 내 재현성은 평균 탄력성과 최대 탄력성에서는 높은(excellent) 재현성을 보였으며, SWE 비율과 최소 탄력성에서는 괜찮은(fair to good) 재현성을 보였다. 평균 탄력성은 병변의 병리나 크기에 상관없이 높은 재현성을 보였다. 최대 탄력성, SWE 비율과 최소 탄력성은 병변의 병리와 크기에 따라 높은 혹은 괜찮은 재현성을 보였다. 검사자 간 재현성 연구에서는 평균, 최대 탄력성과 SWE 비율에서 높은 재현성을 보였다. 평균, 최대 탄력성과 SWE 비율은 병변의 병리에 상관없이 높은 재현성을 보였다. 평균 탄력성은 병변의 크기에도 상관없이 높은 재현성을 보였으나 최소 탄력성은 병변의 병리결과에 따라거나 병변의 크기에 따라서 낮은(poor) 재현성을 보였다.

결론: 평균 탄력성이 SWE 지표 중 검사자 내, 검사자 간 재현성 평가에서 가장 높은 재현성을 보여주었다.

¹가천대학교 의과대학 길병원 영상의학과, ²울산대학교 의과대학 서울아산병원 영상의학과