Sonographic Elastography Combined With Conventional Sonography

How Much Is It Helpful for Diagnostic Performance?

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Objective. The purpose of this study was to evaluate the diagnostic performance of conventional sonography combined with sonographic elastography for differentiation between benign and malignant breast lesions and to assess the diagnostic performance with two types of interpretation criteria for sonographic elastography. ***Methods.*** For this study, we included 281 lesions from 267 patients that were diagnosed as benign or malignant by sonographically guided biopsy and prospectively analyzed by conventional sonography and sonographic elastography from October to December 2007. The histopathologic results from sonographically guided biopsy were used as a reference standard. The final assessments were made prospectively on the basis of conventional sonography alone and then by sonographic elastography combined with conventional sonography. The diagnostic performance using area under the receiver operating characteristic (ROC) curve analysis (A_z) was compared on the basis of conventional sonography alone and on elastography combined with conventional sonography. We also calculated the area ratio of lesions detected by elastography and the elasticity score reported by Itoh et al (Radiology 2006; 239:341–350). ***Results.*** The areas under the ROC curve for conventional sonography and the combination of conventional sonography and sonographic elastography were 0.927 and 0.876, respectively. The area ratio of the lesion had better diagnostic performance (A_z, 0.757) than the elasticity score (A_z, 0.54; $P < .05$). ***Conclusions.*** The diagnostic performance of radiologists with respect to the characterization of breast masses as benign or malignant was not significantly improved with sonographic elastography. The area ratio of the lesion had a better diagnostic value in elastography than the elasticity score. ***Key words:*** breast sonography; sonographic elastography; sonographic factors of breast lesions.

Abbreviations

ADH, atypical ductal hyperplasia; A_z, area under the receiver operating characteristic curve; DCIS, ductal carcinoma in situ; NPV, negative predictive value; PPV, positive predictive value; ROC, receiver operating characteristic

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Elastography is a tool that reflects the hardness of a lesion and a technique that produces images that map the strain experienced by tissue elements subjected to compression.[1,2] Malignant lesions are less prone to deformation by pressure than normal breast tissue.[3] Using this characteristic of breast cancer tissue, some investigators have developed an elasticity score grade and a distribution of elasticity by elastography that are helpful for differentiating benign from malignant breast lesions by breast sonography.[4] However, elasticity score grading in daily practice is done by someone performing breast sonography and can be affected by the B-mode sonographic image because this affects the diagnostic performance of elastography. We therefore evaluated the diagnostic accuracy of sonographic elastography and investigated whether measurement of the area ratio (the proportion of the area without strain to the lesion) by elastography can be a complement or an alternative approach to elasticity score grading.

To do this, we evaluated the diagnostic performance of radiologists using conventional sonography alone and a combination of sonographic elastography with conventional sonography for differentiation between benign and malignant breast lesions. We also assessed diagnostic performance using two types of interpretation criteria for sonographic elastography: the proportion of the area without strain to the entire hypoechoic area of a lesion and the elasticity score defined by Itoh et al,[4] with histologic results as the reference standard.

Materials and Methods

Patients

This study was a retrospective study, and the requirement for informed consent was therefore waived. From October to December 2007, 267 patients with 281 breast masses who had been scheduled for sonographically guided core biopsy underwent conventional sonography and sonographic elastography prospectively. The histopathologic results from sonographically guided core biopsy were used as the reference standard. In cases of atypical ductal hyperplasia (ADH) and ductal carcinoma in situ (DCIS) on histopathologic results, for the possibility of underestimation of core biopsy, the final diagnosis was determined by subsequent surgical pathologic confirmation.

Conventional Sonographic Examination

Conventional sonography with elastography was performed by 1 of 5 radiologists, all of whom had different experiences in breast imaging. Conventional sonography was performed with an 8- to 15-MHz linear array transducer and an Antares system (Siemens Medical Solutions, Mountain View, CA).

Images from conventional sonography were displayed in transverse and longitudinal scans. Before the elastography, the breast lesions depicted by conventional sonography were assessed for the probability for malignancy on the basis of a 6-point malignancy scale used to classify the likelihood of cancer, with 1 as definitely not malignant, similar to Breast Imaging Reporting and Data System category 2[5]; 2, probably not malignant, similar to category 3; 3, low-possibly malignant, similar to category 4a; 4, intermediate-probably malignant, similar to category 4b; 5, probably malignant, similar to category 4c; and 6, definitely malignant, similar to category 5. In this study, the Breast Imaging Reporting and Data System categorization for the likelihood of cancer was not used because it is not a continuous scale.[6] Instead, this 6-point malignancy scale was used for categorizing breast lesions. The final assessments were made prospectively on the basis of conventional sonography alone, and the radiologist who performed the examination marked the category of the lesion on a prepared sheet.

Sonographic Elastography

Sonographic elastography was performed after the conventional sonographic examination by the same radiologist who performed the conventional sonography, and the elasticity was measured by a difference in color.[7] To obtain consistent sonographic elastographic images, examiners were trained for 3 months on the appropriate scanning techniques for image acquisition. To obtain images that were appropriate for analysis, we applied the probe with only light pressure.[7] Each pixel of the elasticity image was assigned 1 of 256 specific colors depending on the magnitude of the strain. The scale was set as a default and ranged from blue for components with the greatest strain (softest components) to red for those with no strain (hardest components). Green indicated an average strain in the region of interest.

The elasticity image was evaluated with using the scoring system described by Itoh et al,[4] and the scores were recorded on a prepared sheet. The grade of elastography was classified as 1 to 5 according to the elasticity scoring system reported by Itoh et al.[4] A score of 1 indicated even strain for the entire hypoechoic lesion (the entire lesion was evenly shaded in green). A score of 2 indicated strain in most of the hypoechoic lesion, with some areas of no strain (the hypoechoic lesion had a mosaic pattern of green and red). A score of

3 indicated strain at the periphery of the hypoechoic lesion, sparing the center of the lesion. A score of 4 indicated no strain in the entire hypoechoic lesion (the entire lesion was red). A score of 5 indicated no strain in the entire hypoechoic lesion or in the surrounding area (both the entire hypoechoic lesion and its surrounding area were red; Figure 1).[4,6,7] The area of the breast lesion and the area without strain on elastography were assessed by the continuous tracing method of the area measurement tool included with the ultrasound machine. The examiner manually traced the margin of the hypoechoic area regarded as the lesion and the inner portion of the lesion or abutting the lesion seen as red on sonographic elastography. Then the area ratio, which was defined as the ratio of the area without strain to the area of the lesion on elastography, was automatically calculated by the ultrasound machine. At first, conventional sonography was performed, and the first final impression was determined and recorded, and then with sonographic elastography and calculation of the elasticity score and area ratio, the second final assessment was prospectively assessed, combined with conventional sonography and sonographic elastography by the same examiner for each case according to the probability for malignancy based on a 6-point malignancy scale, conventional sonography, the elasticity scoring system, and the area ratio on conventional sonography. The probability of malignancy, assessed with conventional sonography, was determined by the examiner's own experiences and not directed by the authors. For assessment combined with conventional sonography and sonographic elastography, the examiner was instructed to take the elastographic result into consideration of the probability of malignancy when the conventional sonographic and the sonographic elastographic findings were discordant. For example, if the probability of malignancy was 2 on the 6-point conventional sonography scale and 5 on the sonographic elastography scoring system, the combined probability of malignancy was set as higher than 2, and in the contrary case with a negative elastographic finding and a malignant-looking conventional sonographic finding, the combined probability of malignancy was set as lower than that based on conventional sonography alone. However, the degree of grading modification was based on each examiner's experience and confidence with sonographic elastography at the examination time without other authors' instructions.

Data Analysis

The final pathologic diagnoses by core needle biopsy were reviewed. We performed the evaluation using conventional sonography alone and a combination of conventional sonography and elastography. To summarize the overall performance, the areas under the receiver operating characteristic (ROC) curve (A_z) were calculated and compared for the two techniques with MedCalc for Windows version 9.3.1 (MedCalc Software, Mariakerke, Belgium). The core needle biopsy results were used as the reference standard. Statistically significant differences between A_z values are reported as 95% confidence intervals. Mean differences were regarded as being statistically significant at the 5% level when the corresponding confidence interval did not encompass 0. For descriptive purposes, we esti-

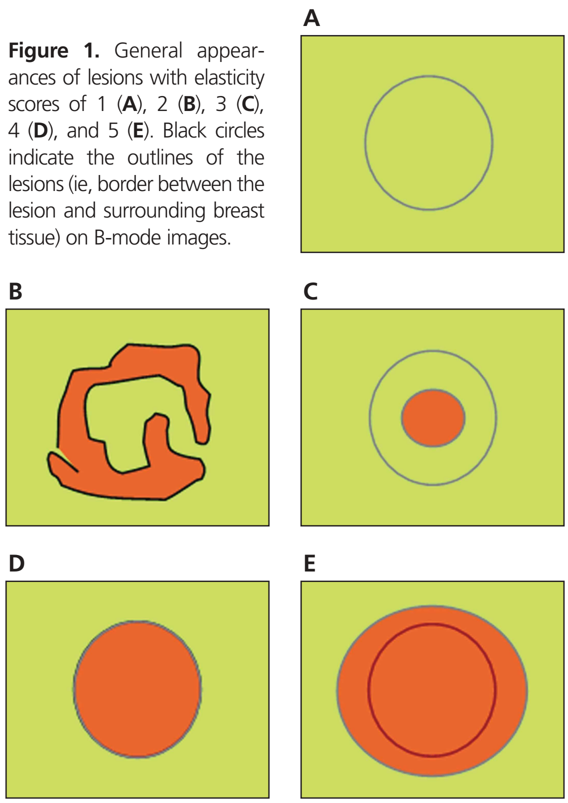


Figure 1. General appearances of lesions with elasticity scores of 1 (**A**), 2 (**B**), 3 (**C**), 4 (**D**), and 5 (**E**). Black circles indicate the outlines of the lesions (ie, border between the lesion and surrounding breast tissue) on B-mode images.

mated the sensitivity, specificity, positive predictive value (PPV), and negative predictive value (NPV) for the two methods of display with histopathologic examination. For this purpose, the scores from the 6-point malignancy scale were dichotomized as negative (score of 1 or 2) and positive (score of 3–6).

We applied 2 different interpretation criteria for diagnosis by elastography. To determine the score for differentiating between malignant and benign lesions, we first compared elasticity scores and the area ratio for real-time sonographic elasticity images between malignant and benign lesions. To identify statistically significant differences, we used the Student *t* test. Two-tailed $P < .05$ was considered statistically significant. We evaluated the ability of the interpretation technique to allow differentiation of malignant and benign lesions by using a ROC analysis to compare the A_z, sensitivity, specificity, PPV, and NPV. Sensitivity values were calculated for malignancies by surgical pathologic findings according to the classification of histologic subgroups and histologic grades of the two sonographic elastographic criteria.

Statistical analyses other than ROC analysis were performed with SAS version 9.1 (SAS Institute Inc, Cary, NC).

Results

Pathologic Diagnosis

All breast lesions were confirmed histologically by means of 14-gauge automated core needle biopsy. Of a total 281 breast lesions, 58 (21%) were malignant and 223 lesions (79%) were benign after core needle biopsy. Of 10 DCIS results on core needle biopsy, 3 additional invasive carcinomas were found on surgical pathologic examination, and of 5 ADH results on core needle biopsy, 1 microinvasive cancer was found. These cases were classified as malignancies; therefore, there were 59 malignant lesions and 222 benign lesions according to the final diagnoses (Table 1).

Conventional Sonography Alone Versus Combined Evaluation With Conventional Sonography and Elastography

With respect to sensitivity, specificity, PPV, NPV, and A_z, there were no statistically significant differences between conventional sonography and a combination of conventional sonography and sonographic elastography (Table 2 and Figure 2). Specificity was increased by 6.4%; sensitivity was decreased by 9.1%; and the A_z decreased to 0.051, without significance for the

Table 1. Final Pathologic Diagnoses in 281 Breast Lesions

Lesion Type	Diagnosis
Malignant (n = 59)	Invasive ductal carcinoma (40), DCIS (7), microinvasive carcinoma (1), invasive lobular carcinoma (1), invasive papillary carcinoma (2), medullary carcinoma (1), mucinous carcinoma (2), intracystic papillary carcinoma (1), metastatic carcinoma from breast (3), leukemia (1)
Benign (n = 222)	Intraductal papilloma (23), fibroadenoma (32), benign phyllodes tumor (1), fibrocystic change (64), stromal fibrosis (26), fat necrosis (5), ADH (4), adenosis (6), granuloma (6), columnar cell hyperplasia (2), sclerosing adenosis (6), cyst,galactocele (4), ductal epithelial hyperplasia (4), radial sclerosing lesion (1), fibroadenomatoid hyperplasia (15), inflammation (3), duct ectasia (4), others (16)

Table 2. Comparison of the Diagnostic Performance of Conventional Sonography Alone and Conventional Sonography Combined With Sonographic Elastography

Parameter	Conventional Sonography	Conventional Sonography and Elastography
Sensitivity, %	98.2	89.1
Specificity, %	44.1	50.5
PPV, %	32.7	34.3
NPV, %	98.9	94.1
A_z	0.927[a]	0.876[a]

[a]*P* = .868.

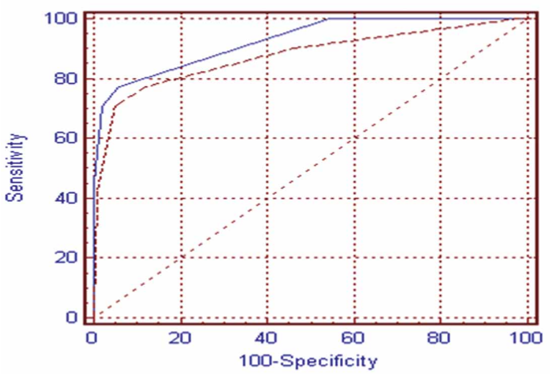


Figure 2. Receiver operating characteristic curves for conventional sonography and sonography combined with elastography. The A_z values were almost the same for conventional sonography (solid line) and combined sonography and sonographic elastography (dashed line; 0.927 and 0.876, respectively; *P* = .868).

combination of conventional sonography and sonographic elastography.

Interpretation Criteria for Elastography

The diagnostic performance of the two interpretation criteria for elastography (area ratio and elasticity scoring) is shown in Table 3. For the area ratio, when the best cutoff point (0.6) was set by the best conventional method for setting a cutoff point with a maximum value of the sum of sensitivity and specificity, sensitivity was 87.7%; specificity, 54.7%; PPV, 35.2%; and NPV, 94.1%.[4] For the elasticity score, the sensitivity (65.5%), specificity (79.0%), PPV (45.8%), and NPV (89.4%) are shown, with the best cutoff point between 3 and 4. When the elasticity scoring system was used as the standard for elastography in differentiating benign from malignant lesions, the median value for benign lesions was 3, and the mean value was 2.7, and the median value for malignant lesions was 4, and the mean value was 3.8 ($P < .0001$; 95% confidence interval of the difference, 0.6531–1.2575). For the area ratio, the median value for benign lesions was 0.56, and the mean value was 0.75, and the median value for malignant lesions was 1.04, and the mean value was 1.19 ($P = .002$; 95% confidence interval of the difference, 0.1562–0.6868). Therefore, the two interpretation criteria together could differentiate benign from malignant breast lesions with statistical significance ($P < .05$). However, the area ratio of the lesion showed better diagnostic performance (A_z, 0.757) than the elasticity score (A_z value, 0.54; $P < .05$; Figure 3).

In histologic subgroups of malignant lesions, there were no pathologic differences in malignant lesions that elastography could show better performances, but in these malignant lesions, the area ratio also revealed better results than that of the elasticity score (Table 4). There was also no difference in the elastographic performance of the area ratio and elasticity score between low, intermediate, and high grades of invasive ductal carcinoma (Table 5).

Discussion

Sonographic elastography is a new screening modality that can be used in addition to sonography to identify breast lesions.[7] Sonographic elastography can be performed in conjunction

Table 3. Sensitivity, Specificity, PPV, and NPV of the Area Ratio Versus Elasticity Score at Various Cutoff Points

Cutoff Point	Sensitivity, %	Specificity, %	PPV, %	NPV, %
Area ratio				
>0.2	98.2	12.8	24	96.3
>0.4	93	34	28.3	94.5
>0.6	87.7	54.7	35.2	94.1
>0.8	66.7	70	38.4	88.2
>1.0	52.6	83.3	46.9	86.2
>1.2	19.3	96.1	57.9	80.9
>1.4	10.5	97	50	79.4
Elasticity score				
1/2	100	5.6	22.3	100
2/3	75.9	48.1	28.4	88
3/4	65.5	79	45.8	89.4
4/5	37.9	93.5	61.1	84.7

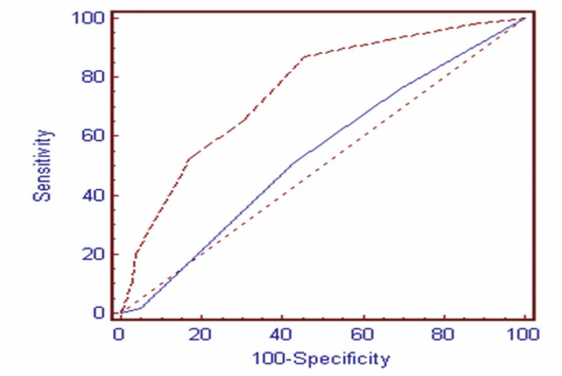


Figure 3. Receiver operating characteristic curves for the elasticity score (solid line) and area ratio (dashed line). The A_z of the area ratio was significantly higher than that of the elasticity score (0.757 and 0.54, respectively; $P < 0.05$).

with conventional sonography without problems and is not more time-consuming. Itoh et al[4] first used sonographic elastography to detect breast lesions and proposed the 5-point elasticity scoring system. Several subsequent studies adopted this scoring system for elastographic assessments to compare the diagnostic performance of conventional sonography and sonographic elastography[3,7–11] (summarized in Table 6). When comparing conventional sonography and elastography, most studies have reported better specificity for elastography and higher sensitivity for conventional sonography with the exception of 2 studies.[4,8] With respect to diagnostic performance, the debate is still ongoing, and some investigators have reported that there was no significant difference between elastography and conventional sonography.[8] However, Zhi et al[7] showed improved diagnostic performance with the combination of conventional sonography and elastography. Our results showed an acceptable value for sensitivity (98.2%) with conventional sonography, which was similar to results from previous studies (87.2%–98.4%). Our study showed better specificity for sonographic elastography than conventional sonography, similar to findings from other studies, with specificity of 79% when the cutoff point was between 3 and 4. However, in our study, the combination of sonography and sonographic elastography did not improve diagnostic performance. This was due to the fact that the diagnostic performance of conventional sonography is already excellent, and the combination of conventional sonography with sonographic elastography, which has high specificity, is not always helpful in all cases.

In several investigations, the cutoff value between positive and negative B-mode findings was set between categories 3 and 4,[8,11] whereas the cutoff value between positive and negative elastographic findings was set between scores 3 and 4.[3,4,9–11] When the two methods are combined, there is no established rule, and some studies have reported that elastography is only useful for limited lesions in conventional B-mode categories 3[9] and 4a.[8,9] Others have suggested that a different cutoff value should be used.[4,8] Itoh et al[4] reported higher sensitivity for sonographic elastography than conventional sonography. In a review of previous reports, their study was the only one showing that sonographic elastography had better sensitivity than conventional sonography. That is why they applied a cutoff point between categories 4 and 5, instead of between categories 3 and 4, which is usually used to recommend biopsy.[4] The cutoff value for

Table 4. Comparisons of the Sensitivity of the Area Ratio and Elasticity Score in Malignant Lesions

	Sensitivity, %	
Malignancy (n = 59)	**Area Ratio[a]**	**Elasticity Score[b]**
Invasive ductal carcinoma (40)	95 (38)	82.5 (33)
DCIS (7)	71 (5)	71 (5)
Microinvasive carcinoma (1)	0 (0)	0 (0)
Invasive lobular carcinoma (1)	100 (1)	100 (0)
Invasive papillary carcinoma (2)	100 (2)	50 (1)
Medullary carcinoma (1)	100 (1)	100 (1)
Mucinous carcinoma (2)	100 (2)	50 (1)
Intracystic papillary carcinoma (1)	100 (1)	0 (0)
Metastatic carcinoma (3)	100 (3)	33 (1)
Leukemia (1)	100 (1)	100 (1)

Values in parentheses are raw data.
[a]At an area ratio cutoff point of 0.6.
[b]At an elasticity score cutoff point of between 3 and 4.

Table 5. Comparisons of the Sensitivity of the Area Ratio and Elasticity Score in Different Grades of Invasive Ductal Carcinoma

	Sensitivity	
Grade	**Area Ratio[a]**	**Elasticity Score[b]**
Low and Intermediate	92	89
High	100	91

[a]At an area ratio cutoff point of 0.6.
[b]At an elasticity score cutoff point of between 3 and 4.

Table 6. Comparisons of the Diagnostic Performance of Conventional Sonography Alone and Conventional Sonography Combined With Sonographic Elastography Based on a Review of the Literature

Study	Lesions (Benign/ Malignant), n	Conventional Sonography						Conventional Sonography With Elastography					
		SN, %	SP, %	AC, %	PPV, %	NPV, %	A_z	SN, %	SP, %	AC, %	PPV, %	NPV, %	A_z
Cho et al[8]	100 (83/17)	82	89	NA	61	96	0.901	82	84	NA	52	96	0.916
Zhu et al[11]	139 (70/69)	94.2	87.1	90.6	NA	NA	NA	85.5	88.6	87.1	NA	NA	NA
Tardivon et al[9]	122 (61/61)	98.4	47.5	NA	65.2	96.9	NA	78.7	86.9	NA	85.7	80.3	NA
Itoh et al[4]	111 (59/52)	71.2	96.6	84.7	NA	NA	0.915	86.5	89.8	88.3	NA	NA	0.918
Zhi et al[7]	293 (209/87)	71.2	73.2	NA	52.5	86	NA	70.1	95.7	NA	87.1	88.5	NA
Thomas et al[3]	300 (168/132)	94	83	NA	81	95	NA	82	87	NA	83	86	NA
Thomas et al[10]	108 (59/49)	91.8	78	NA	NA	NA	NA	77.6	91.5	NA	NA	NA	NA
This study	281 (222/59)	98.2	44.1	NA	32.7	98.9	0.927	89.1	50.5	NA	34.3	94.1	0.876

AC indicates accuracy; NA, not accessible; SN, sensitivity; and SP, specificity.

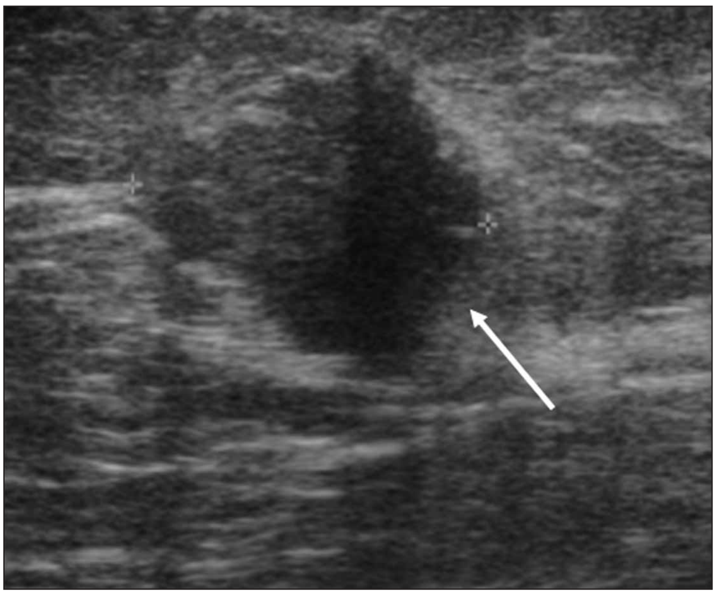
the elasticity score was reported as between 1 and 2 in another study.[8] That report revealed a similar degree of sensitivity and lowered specificity for sonographic elastography compared with conventional sonography by downgrading the cutoff value for elastography.

The elasticity score defined by Itoh et al[4] reflects the ratio of the lesion area without strain, which can help differentiate between benign and malignant tumors. However, in cases of lesions that manifest in a variegated manner due to heterogeneity of the lesion because of cystic changes or necrosis, the elasticity score can be difficult to determine according to the prespecified scores suggested by Itoh et al[4] (Figure 4). Therefore, we suggest that the area ratio itself be used as a supplement in diagnosis. We also found that the A_z value of the area ratio provided better diagnostic value than the elasticity score in the present study.

Although the two interpretation criteria for sonographic elastography failed to show a better A_z value than conventional sonography, the area ratio provided a significantly better score than the elasticity score grading (P < .05). However, the cutoff value for the area ratio that showed a maximum of value for the sum of sensitivity and specificity, 0.6, was less than the value of 1 that corresponds to an elasticity score of 4. That corresponds to a trial by Cho et al[8] that lowered the cutoff value for sonographic elastography. The reason the area ratio has better accuracy than the prespecified elasticity scoring system is that the area ratio reflects the heterogeneity of the lesion and is therefore a more objective measure. In performing elastography, all processes such as

Figure 4. A, Invasive ductal carcinoma with cystic internal content (arrow). **B**, Entire hypoechoic area of a lesion regarded by the examiner as abnormal lesion (arrowheads) and red area of elastography (arrows) on conventional gray scale sonography (left) and sonographic elastography (right). Because of the heterogeneity of the lesion, the elasticity score was difficult to determine on sonographic elastography.

A



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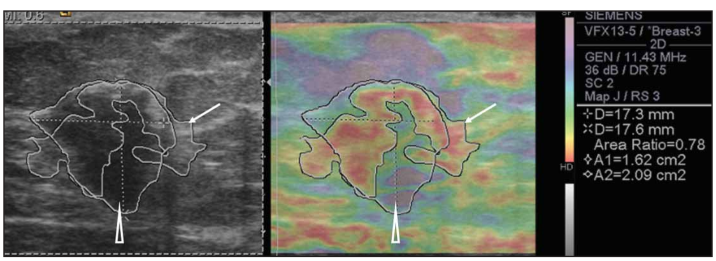

obtaining, classifying, and interpreting the images are affected by the B-mode image. Therefore, the area ratio tracing of the margin between the lesion and surrounding tissue might be more objective. When the cutoff value of the elastic scoring system was lowered in this study, a value between scores 2 and 3 showed increased sensitivity and decreased specificity (75.9% and 48.1%, respectively), in comparison to using a cutoff value between 3 and 4 (65.5% and 79%). However, the sensitivity and specificity for an elastic score between 2 and 3 were still lower than those for an area ratio of 0.6.

Our study had the following limitations. First, we did not assess the interobserver and intraobserver variability or image acquisition reproducibility for the elastic score and area ratio. Because sonographic elastography is influenced by the extent of tissue compression, strong pressure can lead to misdiagnosis, and light pressure should therefore be maintained for accurate diagnosis. Second, we did not evaluate the difference in diagnostic performance according to the content of the lesion. A larger malignant tumor can cause necrosis, hemorrhage, or sarcomatous components, which can affect the elastic score and area ratio. Further studies that take these factors into account are necessary to compensate for these limitations. In addition, there was no differentiation among subgroups of malignant cases in which elastography could show good performance; however, the sample sizes of the histologic subgroups were too small. To resolve this limitation, more malignant lesions should be included.

In conclusion, the diagnostic performance of radiologists characterizing breast masses as benign or malignant is not significantly improved with sonographic elastography. In addition, for elastography, the area ratio of the lesion provides better diagnostic value than the elasticity score.

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