Comparative analysis of the quantitative parameter method and elasticity color mode method for real-time shear wave elastography in the diagnosis of benign and malignant solid breast lesions

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Abstract

Objective: To examine the performance of real-time shear wave elastography (RT-SWE) in routine clinical practice.

Methods: This was a prospective study of 500 patients. The elasticity color mode method was judged by a four-mode system. The quantitative parameter method was used to measure the modulus of elasticity of the lesions. Pathologic reports were used as a gold standard to comparatively analyze the diagnostic performance of the two methods.

Results: A total of 553 tumors were detected. The average mode value and the modulus of elasticity (E\text{max}) of the benign breast masses was lower than that of malignant masses (p < 0.05). With E\text{max} = 67.4 as the diagnostic threshold value, the sensitivity, specificity, accuracy, negative predictive value, and positive predictive value of the two methods were not statistically significant different (p > 0.05).

Conclusions: The shear wave quantitative parameter method and the elasticity color mode method showed similar performances in the diagnosis of benign and malignant breast masses. The elasticity color mode method is convenient and intuitive, whereas the quantitative parameter method can be used to objectively assess the lesions when it is difficult to score the elasticity of an image, but could not be relied on alone.

Keywords
RT-SWE, breast lesions, quantitative parameter method, elasticity color mode method, comparative analysis

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Introduction

Ultrasound elastography is a new technique that has been developed rapidly in recent years and has attracted much attention. It can reveal the histologic characteristics of a lesion by detecting the elasticity of the tissue. The hardness of tissue detected by real-time shear wave elastography (RT-SWE) is expressed using the modulus of elasticity (Young modulus [E]), which can simultaneously obtain in real time a series of elasticity orientation indicators, such as the maximum (E\text{max}), mean (E\text{mean}), minimum (E\text{min}), and standard deviation (E\text{std}), of the tissue, making RT-SWE a true elasticity quantification technique.¹–⁶ The main methods for evaluating RT-SWE are the quantitative parameter method and the elasticity color mode method, both of which show good diagnostic performance,⁷–¹⁴ but produce slightly different results when different parameters and samples are used.¹⁵–¹⁸ In clinical practice, due to the complexity and variety of internal components of the masses and the subjective factors of different physicians,
the elasticity color modes based on the acquired images of the sum or subtraction of different colors may not be the same. A comparison of the diagnostic efficacy of the two methods has not yet been reported.

We compared breast mass analysis using the elasticity quantitative parameter method and the elasticity color mode method and aimed to provide a basis for improving the accuracy of breast cancer diagnosis.

Materials and methods

Patients

This prospective study was approved by the ethics committee of our hospital and was implemented in accordance with ethical principles with informed consent signed by the participating patients. The demographic information and imaging examination of the patients were managed by specific individuals and the physicians of the ultrasound examination were blinded to them. This study included 500 patients from January 2015 to May 2018. There were a total of 553 cases of solid breast lesions, including 357 benign lesions in 306 patients and 196 malignant lesions in 194 patients. The following inclusion criteria were used: female patients aged 18–80 years; underwent both 2D breast ultrasonography and RT-SWE; and received ultrasound-guided biopsy (16-G disposable biopsy needle; Bard) or surgical treatment and obtained pathologic results. Exclusion criteria were as follows: pregnancy or lactation; neoadjuvant chemotherapy and radiotherapy or chemotherapy or a history of breast augmentation or prosthesis implantation; lesions immediately adjacent to scar tissue; or refusal to participate in the study.

Ultrasonography

An Aix Plore full digital color Doppler ultrasound diagnostic apparatus (Supersonic Imagine) was used and a high-frequency probe with a frequency of 4–15 MHz was selected.

Conventional scanning. The focus was on the location, size, shape, border, and internal and posterior echoes of the mass and then was switched to elastography mode, using a dual-image mode. The elastography examination was conducted: after applying enough coupling agent, the probe was placed and stabilized on the body surface as gently as possible, trying to avoid applying pressure. No abnormal color area due to pressure on the probe should have appeared on the monitor for the tissue below the probe in contact with the skin unless the lesion was very close to the skin. During the image acquisition, the patient was asked to hold the breath, and the images of each lesion were collected three times in succession. After obtaining a stable image, it was frozen, captured, and saved.

Region of interest selection. Region of interest (ROI) was set as a circle and followed four conditions. (1) For the rule for the lesion shape, the ROI was set inside the lesion, covering the entire lesion with the least surrounding tissue and including the area with the greatest hardness on the elasticity color image. (2) If focal or annular plaque-like colored areas appeared at the border or periphery of the lesion, the rule of "larger ROI" was applied to include some or all of the "focal or annular colored areas" but the least possible surrounding normal tissue. (3) When measuring $E_{ratio}$, the reference ROI with a diameter of 2–5 mm was selected in the "normal tissue area" at the same depth of the lesion showing no abnormality on the conventional ultrasound and a uniform dark blue color on the elasticity color image. (4) If the lesion was large or irregular and there was no normal tissue area on the elasticity color image, the normal tissue area at another position can be selected to measure the modulus of elasticity, and then the $E/ \text{B}_{\text{ratio}}$ of the lesion manually calculated.

Repetitive study. Thirty lesions (14 benign, 16 malignant) included in the study were randomly selected, and the examinations of conventional ultrasonography and SWE on these lesions were carried out by two independent sonographers. The consistency of the elasticity scores by the two sonographers was evaluated using the kappa value. The consistency of the Young modulus for the same patient by the two sonographers was evaluated using the intraclass correlation coefficient to determine the repeatability of the measured modulus of elasticity of the SWE. A difference with $p < 0.05$ was considered statistically significant.

Diagnostic criteria

The elasticity color images were analyzed based on the elasticity color model proposed by Tozaki et al. and supplemented by Shi et al. The images were classified as follows: mode 1: showing uniform blue areas inside and around the lesion; mode 2: showing vertical abnormal color stripes inside and at the border of the lesion; mode 3: showing a focal or ring-shaped abnormal color change in areas around the lesion, or if abnormal color stripes in mode 2 appeared in this mode, it was classified as mode 3; mode 4: showing uneven abnormal colored areas inside the lesion. If the color code inside the lesion was not shown in the center of the area, it was classified by the surrounding color and according to the above rules. Modes 1 and 2 were considered benign lesions, and modes 3 and 4 indicated a malignant lesion.

The diagnostic thresholds of breast lesions for a series of quantitative parameters of SWE were determined using the receiver operating characteristic (ROC) curve. To evaluate the repeatability of the elasticity quantitative parameters and elasticity color modes of SWE, two sonographers randomly selected 30 breast lesions from the included patients to
measure the modulus of elasticity and assess the elasticity color mode.

**Image analysis**

All 2D and elasticity images were read by two independent ultrasound diagnosticians with 7–20 years of experience and more than 6 months of SWE diagnostic experience. They did not participate in the ultrasound image acquisition and were blinded to the clinical data and pathologic results of the patients. First, each ultrasound diagnostician analyzed the 2D conventional ultrasound images and used the Breast Imaging Reporting and Data System (BI-RADS) classification criteria for diagnosis. Second, the two diagnosticians independently analyzed and evaluated the elasticity color characteristics according to the elasticity color model by Tozaki.6 Finally, the malignancy of the mass was judged based on the cutoff values of the modulus of elasticity.

**Statistical analysis**

The statistical analysis was performed using SPSS 18.0 statistical software (IBM), and the measurement data were represented as the mean ± standard deviation (\( \bar{x} \pm s \)). The differences in the measurement data between the two groups were compared using an independent sample \( t \) test, while the differences in the measurement data among multiple groups were compared using a one-way analysis of variance. The area under the curve (AUC) was calculated by the ROC curve and the \( z \) test. The diagnostic performance of each method was evaluated, and the optimal diagnostic critical point was determined. The sensitivity, specificity, accuracy, positive predictive value, and negative predictive value of the two methods were compared using the McNemar test. A difference with \( p < 0.05 \) was considered statistically significant.

**Results**

**Pathologic types of breast lesions**

A total of 553 breast lesions in 500 female patients were included in this study, including 357 benign lesions in 306 patients and 196 malignant lesions in 194 patients (Table 1). The patients were 19–76 years old (average 45.15 ± 17.62) and the diameters of the lesions were 5–78 mm, with an average of 19.16 ± 15.24 mm. The diameters of the benign and malignant lesions were approximately 6–78 mm (22.46 ± 16.58 mm) and 7–46 mm (17.88 ± 14.63 mm), respectively. Among the 196 malignant lesions, 29 cases were diagnosed as nonspecific invasive carcinoma (ductal carcinoma \( n = 15 \), lobular carcinoma \( n = 1 \)), carcinoma in situ (\( n = 4 \)), medullary carcinoma (\( n = 3 \)), metaplastic carcinoma (\( n = 1 \)), mucous carcinoma (\( n = 2 \)), diffuse large B-cell lymphoma (\( n = 2 \)), and apocrine carcinoma (\( n = 1 \)). A total of 63 of 357 benign lesions were false-positive, including fibroadenoma (\( n = 29 \), 7 associated with calcification), intraductal papilloma (\( n = 4 \)), adenosis with or without fibroadenoma (\( n = 15 \)), sclerosing adenosis (\( n = 5 \)), lobular neoplasms (\( n = 3 \), borderline tumor \( n = 2 \), benign \( n = 1 \)), fibrocystic hyperplasia (\( n = 4 \)), and others (\( n = 3 \)).

**Table 1. Pathologic results of 553 cases of benign and malignant breast lesions.**

| Pathologic Type                        | N = 196 | N = 357 |
|---------------------------------------|---------|---------|
| Invasive ductal carcinoma (nonspecific) | 167     | Breast fibroadenoma | 186     |
| Ductal carcinoma                      | 15      | Intraductal papilloma | 38      |
| Lobular carcinoma                     | 1       | Mastitis | 35      |
| Carcinoma in situ                     | 4       | Breast hyperplasia | 29      |
| Medullary carcinoma                   | 3       | Adenosis, with fibroadenomas formation | 34      |
| Metaplastic carcinoma                 | 1       | Sclerosing adenosis of breast | 7      |
| Mucous carcinoma                      | 2       | Breast phyllodes tumor (benign and borderline) | 12      |
| Apocrine carcinoma                    | 1       | Fibrocystic hyperplasia | 3      |
| Diffuse large B-cell lymphoma          | 2       | Breast fat necrosis with fatty granuloma formation | 1      |
| Other                                 |         |          |         |

**Analysis of the role of conventional 2D ultrasonography and the elasticity color model in the combined diagnosis of malignant breast lesions**

Among the 196 malignant lesions, 139 (70.9%) were clearly diagnosed by conventional 2D ultrasonography and the elasticity color model. Among the cases clearly diagnosed by conventional 2D ultrasonography, 163 cases (83.1%) were diagnosed correctly, and 33 patients (16.9%) were misdiagnosed. Among the cases clearly diagnosed by the elasticity color model, 167 patients (85.2%) were diagnosed correctly, and 29 patients (14.8%) were misdiagnosed as false negatives (Figure 1).

**Results of elasticity quantitative parameters and elasticity color model**

The correlation coefficients of \( E_{\text{max}} \), \( E_{\text{mean}} \), \( E_{\text{min}} \), and \( E_{\text{SD}} \) were 0.89, 0.78, 0.80, and 0.74, respectively. The consistency of the elasticity color modes was moderate (Kappa...
The modulus of elasticity parameters $E_{\text{max}}$, $E_{\text{mean}}$, $E_{\text{min}}$, $E/B_{\text{ration}}$, and $E_{SD}$ of the benign lesions were $38.12 \pm 25.56$ kPa, $31.22 \pm 16.70$ kPa, $19.92 \pm 13.17$ kPa, $2.39 \pm 1.04$ kPa, and $4.56 \pm 3.81$ kPa, respectively, and those of malignant lesions were $147.93 \pm 96.04$ kPa, $52.13 \pm 22.40$ kPa, $16.70 \pm 9.84$ kPa, $5.67 \pm 1.91$ kPa, and $23.50 \pm 1.91$ kPa, respectively. The differences between the benign and malignant lesions were statistically significant ($p < 0.001$). The distribution of $E_{\text{max}}$ and $E_{\text{mean}}$ in the two groups is shown in Figure 2.

The benign breast lesions were evaluated with the elasticity color model of mode 1 and mode 2 in 328 cases out of 357, and the malignant breast lesions were evaluated with the elasticity color model of mode 3 and mode 4 in 168 cases out of 196. The difference between the two groups was statistically significant ($p < 0.001$) (Figure 3, Table 2).

**Comparison of the diagnostic performance of the SWE elasticity quantitative parameter method and elasticity color mode method**

Because pathologic diagnosis was always used as the gold standard, we compare the results of 2D and 4-mode with the pathologic diagnosis. The AUCs corresponding to $E_{\text{max}}$, $E_{\text{mean}}$, $E_{\text{min}}$, $E/B_{\text{ration}}$, and $E_{SD}$ and the elasticity color modes for evaluation were $0.95$, $0.89$, $0.51$, $0.93$, and $0.93$, respectively (Figure 4). $E_{\text{max}}$ showed an area under the ROC curve of $0.512$ ($p > 0.05$). The evaluation based on $E_{\text{max}}$, $E_{SD}$, and the elasticity color mode showed good diagnostic performance, and the diagnostic performance of $E_{\text{max}}$ was the best (Table 3) in multiple breast lesions.

When the maximum sensitivity and specificity of $E_{\text{max}}$, $E_{\text{mean}}$, $E/B_{\text{ration}}$, and $E_{SD}$ were obtained, the corresponding optimal diagnostic thresholds were $67.4$, $25.75$, $2.75$, and $6.54$, respectively. The corresponding sensitivity, specificity, and Youden index were $0.86$, $0.95$, and $0.82$ for $E_{\text{max}}$; $0.87$, $0.73$, and $0.60$ for $E_{\text{mean}}$; $0.87$, $0.81$, and $0.68$ for $E/B_{\text{ration}}$; and $0.81$, $0.92$, and $0.73$ for $E_{SD}$.

The elasticity quantitative parameter method and elasticity color mode method were applied for the diagnosis of different breast lesions (Table 4). There were no significant differences in the sensitivity, specificity, accuracy, positive predictive value, or negative predictive value between the two methods ($p > 0.05$; $p$ values were $0.586$, $0.394$, $0.296$, $0.417$, and $0.579$, respectively).

**Discussion**

The histologic characteristics of a lesion determine its echogenicity and hardness. Elastography can identify benign and malignant lesions by assessing the hardness information of the tissue. Because benign lesions have no cellular atypia, the interstitial cells and the cells inside the tumor are relatively uniform, with no invasiveness to the surrounding tissues. Thus, the modulus of elasticity parameters are more stable than those of breast cancer, and the modulus of elasticity values should thus be lower than those of breast cancer.20,21 This study showed that the indicators of the modulus of elasticity method and the elasticity color mode method were significantly different in benign and malignant breast lesions ($p < 0.05$), and 54 cases of four degrees of BI-RADS lesions with unclear boundaries and irregular shapes were evaluated by the modulus of elasticity as being benign lesions, including mastitis, sclerosing adenosis, and hyperplasia. Therefore, ultrasound elasticity can help to identify the four degrees of BI-RADS lesions that are difficult to diagnose.

With the increase in the elasticity color mode levels, the modulus of elasticity $E_{\text{max}}$ and $E_{SD}$ also gradually increased, and the differences between the different elasticity color modes were statistically significant ($p < 0.05$). Our study showed that $E_{\text{max}}$ was the most reproducible, which is related
to the maximum coverage of the lesion by ROI and the surrounding abnormal area. The hardest part of the lesion was included, so the size of the ROI has little impact on the $E_{\text{max}}$, a finding similar to those in the related studies.\textsuperscript{6,7} In this study, $E_{\text{max}}$ was highly positively correlated with the elasticity color mode ($r = 0.817$). Of the 196 malignant lesions, 101 cases were classified as mode 3 or showed a stiff rim sign, and the Young modulus $E_{\text{max}}$ was mostly more than 100 kPa. Therefore, the stiff rim sign in the elasticity color mode method is an effective and clear sign of malignant lesions, reflecting the invasiveness of the lesion to the surrounding tissues.\textsuperscript{14,22,23} $E_{\text{SD}}$ is a modulus of elasticity parameter that

Table 2. Evaluation of elasticity color model of benign and malignant breast lesions.

| Elasticity color mode | Benign lesion (n = 357) | Malignant lesion (n = 196) | Total (n = 553) |
|-----------------------|-------------------------|---------------------------|-----------------|
| 1                     | 155                     | 4                         | 159             |
| 2                     | 173                     | 24                        | 197             |
| 3                     | 26                      | 101                       | 127             |
| 4                     | 3                       | 67                        | 70              |

Figure 3. Elasticity color model of malignant and benign lesions. The circles indicate region of interest.

Figure 4. The area under the receiver operating characteristic curve of each elasticity quantitative parameter method and color mode method for the diagnosis of benign and malignant breast lesions.
refers to the degree of internal dispersion and variation in the
lesion and corresponds to the arrangement of different patho-
logic components in the lesion. The larger the ESD value, the
more uneven the modulus of elasticity distribution in different
regions of the lesion and the more significant the heterogene-
ity. Therefore, the ESD value can translate the subjective char-
acteristic of the tissue uniformity into a quantifiable indicator.1
In this study, 55 lesions were classified as mode 4, reflecting
that ESD was highly positively correlated with the elasticity
color mode (r = 0.736), a finding consistent with that of
Gweon.24 Therefore, the elasticity color mode method pro-
vides a good diagnostic index that can reflect the hardness of
the tissue and the distribution of the tissue hardness to a cer-
tain extent. This method has similar diagnostic performance
to that of the shear wave quantitative parameter method in the
diagnosis of benign and malignant breast masses. These two
methods are consistent and complementary.

The elasticity color images of the breast are complex, are
diverse, and overlap quantitative method. When a malignant
lesion is complicated by necrosis, liquefaction, or hemorrh-
age, its hardness can be reduced, resulting in a false-nega-
tive diagnosis25; on the other hand, when calcification
occurs or the fibrosis degree increases in a benign lesion, the
hardness of the lesion may be increased, which may lead to
the diagnosis of false-positive.26 Because RT-SWE is a
quantitative method, the results can be more objective.27
Especially when it is difficult to score the elasticity image,
the quantitative parameter method can be used.

Among the 357 benign lesions, most of the false-posi-
tive results were for sclerosing adenosis, borderline phyl-
lodes tumors, calcified tumors, and atypical hyperplasia,
probably due to the increased hardness of the lesions
caused by the large number of hard stromal cells.28 Among
the 196 malignant lesions, most of the false-negative
results were early breast cancer and special types of breast
cancer, such as medullary carcinoma, mucinous carci-
noma, and lymphoma. This finding is because the essential
components of the medullary carcinoma are mainly com-
posed of cells, most of which are accompanied by necrosis
and hemorrhage, and the tumor cells of mucinous carcino-
ma can secrete mucus, resulting in relatively soft lesions,
especially for pure mucinous carcinoma.

Relying on ultrasound elasticity alone fails to correctly
diagnose the above false-positive or -negative lesions, and
a comprehensive analysis and diagnosis should be carried
out based on 2D ultrasonography, assisted by ultrasound
elasticity. In this study, a combination of 2D ultrasonogra-
phy and ultrasound elasticity was applied. Among the 196
cases of malignant lesions, misdiagnosis in 14 out of the
33 cases of false-negative lesions could be avoided. Among the 357 cases of benign lesions, misdiagnosis in 28
out of 63 cases of false-positives could be avoided. The
combination of these two methods can reduce false-positi-
tives and false-negatives and improve the accuracy of
diagnosis, which is consistent with the results in the previ-
ous studies in the literature.7,29

This study has some limitations. First, RT-SWE is mainly
based on conventional 2D ultrasound imaging. Although a
double-blind method was applied, and the physicians read-
ing the images did not participate in the image acquisition
process, it is difficult to completely avoid the influence of
2D basic information on the elasticity imaging.30 Second,
the ROI was set as a circle by default, but most lesions have
different shapes. Some lesions might not be completely cov-
ered, such as lymphoma, or too much normal tissue in the
immediate vicinity of the lesion might have been included.
Although the effect on Emax is minor, there is a certain degree
of impact on the moduli of the other elasticity parameters
and the diagnostic thresholds. Third, the size and depth of
the lesion as well as the thickness of the breast have a certain
impact on the moduli of elasticity.31 This study is a single-center
prospective study, and the results may be limited by the selected
samples.

### Table 3. The area under the receiver operating characteristic curve (AUC) of each elasticity quantitative parameter method and color mode method.

| Method                      | AUC   | 95% Confidence interval | p Value | Diagnostic threshold |
|-----------------------------|-------|-------------------------|---------|----------------------|
| Emax                        | 0.957 | 0.945–0.969             | 0.000   | 67.4                 |
| Emean                       | 0.892 | 0.870–0.914             | 0.000   | 25.75               |
| Emin                        | 0.512 | 0.470–0.553             | 0.582   | —                   |
| ESD                         | 0.935 | 0.919–0.951             | 0.000   | 2.75                |
| E/B ratio                   | 0.910 | 0.890–0.931             | 0.000   | 6.54                |
| Color mode method           | 0.933 | 0.916–0.950             | 0.000   | 3                   |

### Table 4. Elasticity quantitative parameter Emax and color mode method used for the evaluation of breast lesions.

| Method                      | Se    | Sp    | ACC   | PPV   | NPV   |
|-----------------------------|-------|-------|-------|-------|-------|
| Quantitative parameter Emax | 88.9  | 94.6  | 92.5  | 90.3  | 93.8  |
| Color mode method           | 85.2  | 92.1  | 89.7  | 85.7  | 91.9  |

ACC: accuracy; NPV: negative predictive value; PPV: positive predictive value; Se: sensitivity; Sp: specificity.

Values are percentages.
Conclusion

RT-SWE has good clinical value in the differential diagnosis of benign and malignant breast lesions. The shear wave quantitative parameter method and the elasticity color mode method have similar performance in the diagnosis of benign and malignant breast masses. The two methods are consistent and complementary. In clinical practice, the elasticity color mode method is convenient and intuitive, but the quantitative parameter method can be used to objectively judge the lesion when it is difficult to score the elasticity image. The combination of these two methods can reduce false-positives and false-negatives in the diagnosis of breast lesions and improve diagnostic efficacy.

Declaration of conflicting interest

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