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Shear wave elastography for solid breast masses evaluation: Quantitative measurement of mean elasticity value and elasticity ratio

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ABSTRACT

Purpose: Shear wave elastography (SWE), an ultrasonographic technique to measure the elasticity of mass lesions to evaluate breast mass. This study aimed to find out the cutoff values identifying breast malignancy using the mean elasticity (E-mean) and elasticity ratio (E-ratio) of breast masses.
Methods: This retrospective study included women underwent SWE and US-guided biopsy of breast masses. During conventional US, the SWE mode was also performed, determining elasticity measurements, E-mean and E-ratio. Histopathological reports were obtained to identify mass status. The optimal and alternative cutoff values for E-mean and E-ratio to determine malignancy were assessed by receiver operating characteristic (ROC) curve analysis and Youden's index score.
Results: Among 147 benign and 93 malignant masses, the median of E-means were 26.20 (IQR 15.70–56.60) and 141.60 (IQR 119.80–154.60) kPa and the median E-ratios were 3.11 (IQR 1.83–5.23) and 9.24 (IQR 6.76–12.44), respectively. Using Youden's index, the optimal cutoff values for E-mean and E-ratio were 90.35 and 5.89, with sensitivity of 87.1 % and 82.8 %, specificity of 89.1 % and 83.7 %, positive predictive value (PPV) of 83.5 % and 76.2 %, negative predictive value (NPV) of 91.6 % and 88.5 %, positive likelihood ratio (LR+) of 8.00 and 5.07, and negative likelihood ratio (LR-) of 0.14 and 0.21, respectively.
Conclusion: This study revealed that SWE is useful in predicting malignancy. With the optimal cutoff values of E-mean and E-ratio at 90.35 kPa and 5.89, the sensitivity was nearly 90 % with E-mean and slightly over 80 % with E-ratio, respectively. These findings could be used in conjunction with conventional US.

1. Purpose

Ultrasonography (US) is a common imaging modality in evaluation of breast abnormalities, especially breast masses. The American College of Radiology (ACR) Breast Imaging Report and Data System (BI-RADS) guidelines have categorized breast masses evaluated by the grayscale image features of shape, orientation, margin, echo pattern, and posterior features [1]. The fifth edition of the ACR BI-RADS Atlas in 2013 additionally includes elasticity assessment as associated features in a new section with three descriptors of 'elasticity': soft, intermediate, or hard. The one elastography technique of the US system called shear wave elastography (SWE), has been used in clinical practice in breast mass evaluation. The integration of elastography, assessing a feature of tissue hardness that usually differs between benign and malignant masses, along with imaging findings from the conventional US, shows improving precision in breast mass evaluations [2–4]. The advantages of SWE are being technically simple, highly reproducible, and with a high sensitivity [5].

Many studies had deployed varieties of elasticity parameters for a diagnosis of breast mass i.e. mean elasticity (E-mean), elasticity ratio (E-ratio), E-velocity, etc. The benefit of utilizing qualitative elastographic features and quantitative values was reported resulting in more accurate

Abbreviations: SWE, Shear wave elastography; US, Ultrasound; E-mean, Mean elasticity; E-ratio, Elasticity ratio; ROC, receiver operating characteristic; KPa, pressure/elasticity; IQR, interquartile range; PPV, positive predictive value; NPV, negative predictive value; RL+, positive likelihood ratio; LR-, negative likelihood ratio.

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categorization of breast masses, leading to either an upgrade or a downgrade in the BI-RADS classification [3]. The authors who demonstrated better diagnostic performances of a combined conventional US and SWE over conventional US groups suggested a potential value of SWE into the routine of breast US [6]. In 2015, the World Federation for Ultrasound in Medicines and Biology also had guidelines and recommendations for clinical use of US elastography [7].

Despite an increasing use of SWE to enhance the diagnostic performance of breast mass, various parameters and cutoff values of each parameter had been reported [8–12]. Although the benefit of elasticity features of breast mass over conventional grayscale were reported, there has been no international standard value for each elasticity parameter. Common elasticity parameters which had been reported include the E-mean of the mass as well as the E-ratio which assesses elasticity of mass lesion relative to adjacent normal surrounding tissue as the reference. The higher E-mean or E-ratio indicates a higher degree of suspicion for malignancy [10, 11, 13]. Hence, more data of SWE parameters with superior performance should be collected. Our study aimed to evaluate the optimal cutoff values of E-mean and E-ratio by SWE in predicting malignant breast masses.

2. Methods

This retrospective study was conducted in an urban tertiary care academic center in Thailand. Ethical approval was obtained from the Institutional Review Board before the study was conducted (COA 060/2566). Individuals who had mammograms and US of breast masses between January 1, 2021, and Feb 28, 2023, were identified from the institutional Radiology Information System. Inclusion criteria were women who underwent US-guided core biopsy and had available histopathological diagnosis. Exclusion criteria were those with breast mass larger than 3 cm due to a technical limitation in covering all regions of interest (mass and surrounding tissue). Additionally, any breast masses located near a prior surgical scar were also excluded concerning the effect of postsurgical fibrosis on the E-ratio.

As a general practice in our institution, an imaging study of breast mass usually includes mammography along with grayscale US using a 14 MHz linear transducer (Canon Aplio A550) by the radiologists on service. The features of the masses which are assessed according to the ACR BI-RADS include size, shape, orientation, margin, echogenic pattern, posterior features, calcifications, and vascularity. Cases with suspicious masses for malignancy are referred to the radiologist specializing in breast imaging (N.M.) for reassessment of the mass. The mass morphology from grayscale US and primary BI-RADS categorization were reviewed before SWE mode study and subsequent US-guided biopsy.

After obtaining the mass in a good grayscale, a square region of interest (ROI) box is selected to cover the mass and appropriate surrounding tissue. Two-dimensional SWE is then applied perpendicular to the mass, with awareness of precompression artifacts. Motion artifacts

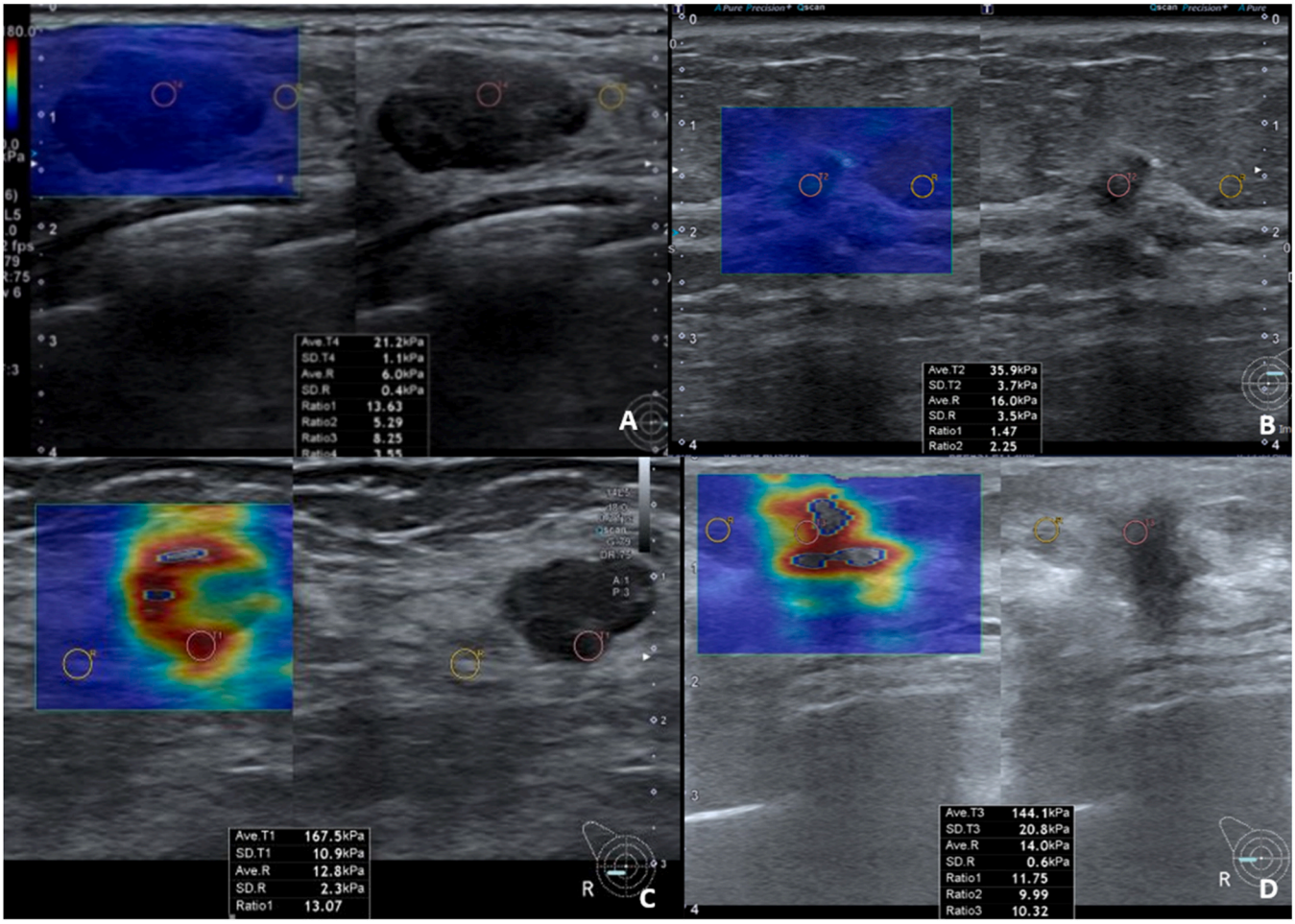

Fig. 1. Fig. 1A. Shear wave elastography and grayscale ultrasound image of a 20 mm fibroadenoma. The shear wave image shows the lesion in homogeneous blue, defined the most stiffness site as inside tumor. The E-mean and E-ratio are 21.2 kPa and 3.55. Fig. 1B. A 7 mm invasive ductal carcinoma with homogeneous blue. The E-mean and E-ratio are 35.9 kPa and 2.25. Fig.1C. A 22 mm invasive ductal carcinoma. The shear wave image shows the mass and surrounding tissue in heterogeneous color and the zone of stiffness is irregular in red, yellow, and green color. The most stiffness site is red and inside tumor. The E-mean and E-ratio are 167.5 kPa and 13.07. Fig. 1D. A 11 mm invasive ductal carcinoma defined the most stiffness site as peritumoral site. The E-mean and E-ratio are 144.1 kPa and 10.32.

during SWE measurement are prevented by instructing participants to hold their breath for a few seconds. Qualitative stiffness is determined by the color of imaging in SWE mode, with tissue elasticity displayed in color ranging from dark blue, yellow, to red color. The values range from 0 to 180 kPa. If any artifacts are observed in the image (such as vertical bands of hard elasticity), SWE mode captures are repeated until a good quality image is obtained. The area with the highest stiffness is selected and encircled for elasticity measurement and recorded as either inside or at peritumoral site. Another small circle is placed over normal surrounding tissue at the same penetration level to obtain the E-ratio. For technical image quality and consistency, two or three SWE evaluations in different transducer orientations are performed. The one with the best qualitative image is selected to determine the elasticity values. Fig. 1. illustrates the US acquisition of SWE. The color map of SWE depends on the stiffness of the mass and surrounding tissue.

The data collected for the study included the age of the women, mass size, BI-RADS category, site of the most stiffness location on SWE, E-mean, E-ratio, and final histopathology obtained from core needle biopsy or subsequent excision of the mass.

2.1. Statistical analysis

The data were analyzed using IBM SPSS Statistics for Windows, Version 28.0 (IBM Corporation, Armonk, NY, USA). Continuous variables were presented as mean ± standard deviation (SD) for normally distributed data or else with median and interquartile range (IQR). Categorical data were presented as frequencies and percentages. Data between clinical (age), sonographic features of benign and malignant masses were compared by univariable analysis using Student's t-test or Mann-Whitney U test for continuous variables and chi-square or Fisher's exact test for categorical variables, as appropriate. Clinical important features or significant by univariate analysis were included for a multivariate analysis by logistic regression analysis. The odds ratio (OR) of each BI-RAD category was also studied. Diagnostic performance including sensitivity, specificity, positive predictive value (PPV), negative predictive value (NPV), positive likelihood ratio (RL+), and negative likelihood ratio (LR-) of E-mean and E-ratio was determined by using the receiver operator characteristics (ROC) curve. Statistically significant was considered at a p-value < 0.05.

Sensitivity and specificity from ROC analysis data were extracted from SPSS and put into a spreadsheet to calculate Youden's index score (sensitivity + specificity -1). The highest score was selected to use for the optimal cutoff values of E-mean and E-ratio. This process used Microsoft Excel for Microsoft 365 (Version 2404 Build 16.0.17531.20140, 64-bit).

3. Results

During the study period, 245 women had suspicious imaging studies of breast masses and were consulted for further study and proceeding. Out of these, 17 women were excluded: 12 had mass larger than 3 cm and the other 5 who had surgical scars. A total of 228 women met all inclusion criteria and were included in the study.

The mean age was 52.18 ± 14.92 years. Out of a total of 240 breast masses, the mean diameter was 14.6 ± 6.3 mm. The most common BI-RADS category was BI-RADS 4A (44.17 %) followed by BI-RADS 4B (20.83 %). By SWE, peritumoral stiffness was identified in 37.9 % of masses, while it was inside the masses in the remaining 62. 1 %. The median E-mean and E-ratio were 59.40 (IQR 9.78, 38.45) kPa and 4.98 (IQR 2.52, 9.10), respectively. US findings and BI-RADS categories of breast masses are shown in Table 1.

Subsequent tissue biopsy of breast masses revealed benign histopathology in 61.3 % and malignancy in 38.7 %. The most common benign histopathology was fibroadenomas (60 %), followed by fibrocystic change with adenosis (15 %), and benign breast tissue with hyalinized stroma (10 %). Among malignant masses, invasive ductal carcinoma was the most common (84 %), followed by ductal carcinoma in situ (DCIS) (15 %). Except for one woman who was lost to follow-up, subsequent operations of the other DCIS cases confirmed the diagnosis without an invasive component.

Table 1
Baseline characteristics.

Features of breast mass			
Mass size (mean ± SD)			14.6 ± 6.3 mm
SWE findings	Stiffness site	Inside tumor	149 (62.1)
		Peritumoral Stiffness site	91 (37.9)
	Elasticity parameters	E-mean (kPa), median (IQR)	59.40 (19.75–138.45)
		E-ratio, median (IQR)	4.98 (2.52–9.10)
BIRADS category		3	5 (2.1)
		4A	106 (44.2)
		4B	50 (20.8)
		4C	36 (15.0)
		5	43 (17.9)

We found a direct correlation between BI-RADS and malignancy (Table 2). We also studied the association of the women's age, tumor diameter, and SWE parameters of breast masses with malignancy status. By univariate analysis, women with malignant breast masses were significantly older. Compared to benign breast masses, the malignant breast masses had significantly larger median diameter (1.70 cm vs 1.20 cm, p= 0.017), more frequent peri-tumoral stiffness (72 % vs 28.0 %, $p < 0.001$), and higher E-mean (141.60 kPa vs 26.20 kPa, $p < 0.001$) and E-ratio (9.24 vs 3.11, $p < 0.001$) (Table 3). By multivariate analysis, all of these features remained statistically significant. Peritumoral stiffness site had the highest risk (adjusted OR 6.059; 95 % CI 2.448–14.998). Of note, the size of breast mass had an inverse association with malignancy by multivariate analysis.

We also assessed the malignancy status according to BI-RADS category and stiffness parameters (E-mean and E-ratio) of the masses (Table 2). The E-mean and E-ratio were consistent with the BI-RADS categories. These findings should help ascertain the malignancy rates of tumors based on BI-RADS categories. One informative finding in our study pertained to SWE findings in BI-RADS 4. We found breast masses of BI-RADS 4A which were revealed as malignant in only 5 (4.7 %), their SWE parameters (both E-mean and E-ratio) did not have high values. Hence, the SWE findings should have a role in helping a clinician to avoid unnecessary surgical biopsy in breast mass with this BI-RADS 4A.

The diagnostic performances of E-mean and E-ratio in detecting malignant masses were determined by ROC curve (Fig. 2). The area under the curves were 0.914 (95 % CI 0.875–0.953) for E-mean and 0.877 (95 % CI 0.832–0.923) for E-ratio. By Youden's index, the optimal cutoff values of E-mean was 90.35 kPa with sensitivity of 87.1 % and was 5.89 for E-ratio with sensitivity of 82.8 % (Table 4).

4. Discussion

During US study of breast mass, an assessment of tissue elasticity can be used as an additional technique for distinguishing between benign and malignancy. US strain elastography (SE) was initially deployed by manually compressing the transducer over the mass to evaluate tissue consistency represented by elasticity. Despite a high accuracy of the SE [14], it yields only semi-quantitiative results without an exact measurement and is subjected to bias by the operators' skill on exerting the transducer compression. Hence, the SWE which can provide quantitative measurement derived from acoustic radiation and requires only steady transducer application, should result in a more objective finding and lower the technique limitation. Despite the increasingly common use of SWE, the cutoff values for its quantitative parameters still vary.

Our study demonstrated that peri-tumoral stiffness, high E-mean, and high E-ratio were all independent risk features associated parameters with malignancy. A significantly higher E-mean value among malignant breast masses compared to benign ones (adjusted OR 1.03) was

Table 2
Difference of E-mean and E-ratio between histopathology of each BI-RADS.

BIRADS (n)	Malignant rate (%)	E-mean, Median (IQR)		P-value	E-ratio, Median (IQR)		P-value
		Benign	Malignant		Benign	Malignant	
3 (5)	0 (0 %)	13.00 (8.00–17.40)	-	-	1.32 (0.97–1.43)	-	-
4A (106)	5 (4.7 %)	23.30 (15.65–42.95)	27.80 (17.65–54.75)	0.619	2.83 (1.78–4.64)	3.09 (1.49–6.70)	0.800
4B (50)	14 (28.0 %)	54.15 (18.55–102.88)	140.40 (88.78–156.13)	< 0.001	4.72 (2.43–6.76)	9.55 (6.08–11.99)	0.001
4C (36)	31 (86.1 %)	143.00 (75.85–162.10)	145.00 (120.00–158.40)	0.625	8.40 (5.23–14.17)	9.24 (6.62–13.40)	0.756
5 (43)	43 (100 %)	-	142.10 (132.20–154.50)	-	-	9.71 (7.64–12.88)	-

Table 3
SWE features to predict malignancy.

	Histopathology		Crude OR (95 % CI)	P value	Adjusted OR (95 % CI)	P value
	Benign (n = 147)	Malignant (n = 93)				
Site of stiffness (%)						
Inside	123 (83.7)	26 (16.3)	13.207 (7.037–24.787)	< 0.001	6.059 (2.448–14.998)	< 0.001
Peritumoral	24 (28.0)	67 (72.0)				
E-mean (kPa), median (IQR)	26.20 (15.70–56.60)	141.60 (119.80–154.60)	1.039 (1.030–1.047)	< 0.001	1.036 (1.023–1.050)	< 0.001
E-ratio, median (IQR)	3.11 (1.83–5.23)	9.24 (6.76–12.44)	1.513 (1.362–1.681)	< 0.001	1.225 (1.062–1.412)	0.005
Mass diameter (cm), median (IQR)	1.20 (0.90–1.80)	1.70 (1.05–2.05)	1.663 (1.095–2.524)	0.017	0.168 (0.064–0.438)	< 0.001

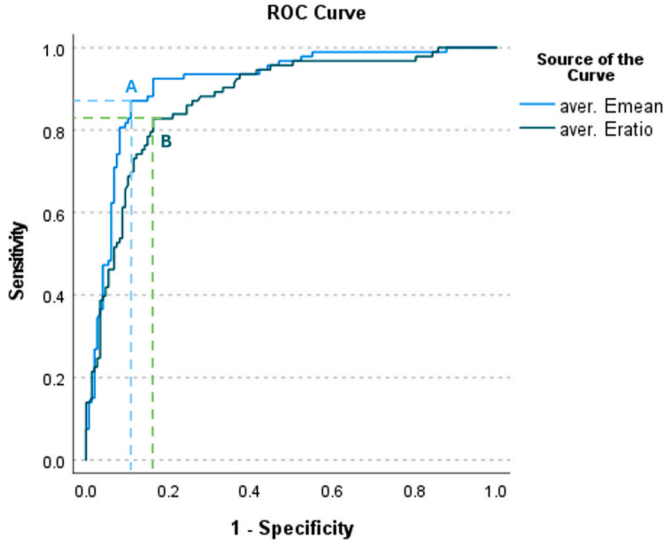

Fig. 2. ROC Curve of E-mean and E-ratio to determine malignancy status of breast masses. Cutoff value for average E-mean at 90.35 kPa (A; sensitivity 0.871 and specificity 0.891), while cutoff value for average E-ratio at 5.89 (B; sensitivity 0.828 and specificity 0.837).

Table 4
Sensitivity and specificity of elasticity parameters at different cut-off points.

Cut-off point	Sensitivity (%)	Specificity (%)	PPV (%)	NPV (%)	LR+	LR-
E-mean						
Optimal						
90.35 kPa	87.1	89.1	83.5	91.6	8.00	0.14
Alternative						
50.60	93.6	70.8	66.9	94.6	3.20	0.09
143.65	47.3	95.2	86.3	74.1	9.94	0.55
E-ratio						
Optimal						
5.89	82.8	83.7	76.2	88.5	5.07	0.21
Alternative						
3.64	94.6	56.5	57.9	94.3	2.17	0.10
10.37	41.9	95.2	84.8	72.2	8.81	0.61

found. An E-mean of 90.35 kPa yielded the most optimal cutoff value with 87.1 % sensitivity and 89.1 % specificity for detecting malignant breast masses. Although the good performance of E-mean found in our study consistent with previous studies, our optimal E-mean of 90.35 kPa to discriminate malignant and benign breast mass was higher than other studies which reported various cutoff values ranging from 50 to 89.1 kPa [11,15–18]. Evan et al. advocated that combining an E-mean of 50 kPa with grayscale BI-RADS yielded superior sensitivity and NPV compared to each individual test [15]. Change et al. found a significantly higher E-mean in malignant masses compared to benign masses (153.3 kPa vs 46.1 kPa), reported 89.0 % sensitivity and 85.0 % specificity using an E-mean of 80.17 kPa [16]. Au et al. proposed the optimal cutoff of 42.5 kPa for E-mean with 88.6 % sensitivity and 89.7 % specificity [18]. Lee et al. reported that the high area under the ROC curve for E-mean of 68.4 kPa, showing 88.9 % sensitivity 76.7 % specificity [17]. Song et al. offered an E-mean of 89.1 kPa in their study along with 81.31 % sensitivity and 82.35 % specificity [11].

We found a higher E-ratio in malignant masses compared to benign masses. The optimal E-ratio of 5.89 could discriminate malignant masses with an adjusted OR of 1.225 which was higher than that found with high E-mean value (adjusted OR 1.036). Youk et al. reported an E-ratio of 5.14 could best predict malignant breast masses (sensitivity, 88.0 %; specificity 90.6 %) [2]. Song et al. found that combining grayscale US with an E-ratio of 3.84 improved diagnostic accuracy from 58.9 % to 77.0 % compared to grayscale US alone [11]. Au et al. have reported an optimal E-ratio of 3.56 in predicting malignancy. They also demonstrated that incorporating E-ratio into the assessment could downgrade BI-RADS 4a masses by 90 % to BI-RADS 3 [18]. Others found an optimal E-ratio of 4.39, but there was no significant difference when using SWE with grayscale US compared to grayscale alone ($p > 0.05$) [17].

Among the 3 parameters, the highest risk of malignancy was found to be associated with peri-tumoral stiffness (adjusted OR 6.06). This pathologic feature arises from the invasion of tumor cells into surrounding tissue, causing a desmoplastic reaction characterized by fibrosis. Other studies have also highlighted the significance of the stiff rim sign or stiffness of the surrounding tissue of malignant breast masses as an important feature. They recommended this feature to be evaluated in conjunction with grayscale US to differentiate between benign and malignant breast lesions [19–21].

The optimal values of E-mean or E-ratio in predicting malignancy may vary across studies and depend on several factors. These factors

include the prevalence of malignancy among breast masses, the resolution of images from different US models, the quality of the images, features of the target area of measurement (mass and surrounding tissue), as well as potential confounding features or technical errors made by the operators [22,23].

One caveat found in our study was the false-negative finding (absence of peri-tumoral stiffness, low E-mean and E-ratio) in five small malignant masses categorized as BI-RADS 4A. Some authors also reported that SWE was more effective in evaluating large symptomatic masses compared to small subclinical lesions [24]. Therefore, we would like to emphasize that the 'stiffness' and SWE features should be carefully employed as the biopsy threshold when dealing with small masses.

We would like to address one issue, aside from the different optimal cutoff values for these parameters obtained by statistical means, was their clinical application. The selection of the cutoff value for any qualitative test in clinical practice should balance between the aim of not missing any possible malignant lesion (high sensitivity and negative predictive value) against the risk of over-treatment (high specificity). For instance, if we chose the E-mean value of 90.35 kPa determined by statistical means using Youden's index to predict malignant lesions (with a sensitivity of 87.1 %), we could potentially miss 12.9 % of malignant cases. On the other hand, if we alternatively selected an E-mean value of 50.60 kPa (with a sensitivity of 93.6 %), only 6.4 % would be missed, but at the cost of an unnecessary surgical procedure in approximately 30 % of cases (with a specificity of 70.8 %). (Table 4).

Similarly, with statistically optimal cutoff of E-ratio at 5.89 which yielded a sensitivity of 82.8 %, this may have led us to miss some malignant cases. However, the number of missed cases would decrease to 5.4 % with an alternative cutoff at 3.64. Nevertheless, this would lead to an unnecessary tissue biopsy in 44% of cases. Therefore, decision-making by clinicians in any institution should be based on their own data, such as the risk of breast cancer in each woman, the prevalence in the country, rates of false positives and false negatives in each institution, access to subsequent surgical treatment or follow-up, and the woman's concern.

We were aware of some limitations in our study. Firstly, the data were obtained from a single center and had a retrospective design. Secondly, only one radiologist reviewed all grayscale US images and conducted the SWE measurements. Although every effort was made throughout the process to prevent any potential technical errors and ensure the best possible views, the results might be operator dependent. Additional interpretation by a greater number of the interpreting radiologists might have rendered the results more reliable. Lastly, only specific SWE parameters of interest were selected for the study. Maximum and minimum elasticity, which could provide additional diagnostic information, were not obtained due to the limitations of the ultrasound machine. Combining SE with SWE could prove to be more valuable in future work.

Nevertheless, this study had some strengths. Throughout the procedure, the optimal image was selected from two or three measurements to minimize intra-personal variation. These measures should have resulted in more reliable data. The significant findings regarding the site of stiffness, E-mean, and E-ratio in discriminating between benign and malignant breast tumors hold clinical value, aiding in the planning of whether to proceed with tissue biopsy or opt for simple observation.

Our study yielded consistent findings with previous research, indicating that the site of tumor stiffness, E-mean, and E-ratio are valuable in discriminating between benign and malignant breast masses. There were a few cases of BI-RADS 4A that resulted in false negatives during SWE assessment. Therefore, special precautions should be taken, particularly with small breast cancer masses (< 1 cm), especially those exhibiting soft elasticity. The selection of an appropriate cutoff value for each parameter is crucial for making decisions about surgical procedures. This is important to avoid missing most malignant lesions while also preventing over-treatment.

In conclusion, this study underscored the clinical value of SWE as an adjunct to grayscale US in evaluating breast masses. The peri-tumoral site of tumor stiffness with high E-mean and E-ratio, can effectively differentiate malignant from benign breast masses. In clinical practice, aside from using the statistical optimal value, the clinician may select an alternative value to fit for the clinical scenario, such as the prevalence of malignancy in their population, degree of suspicion from other clinical findings, availability of surgical teams, and etc. to select the most appropriate alternative cutoff value in their setting. Future prospective studies to validate the proposed cutoff value in a larger population should be conducted to confirm our findings and to potentially integrate them into breast mass evaluation protocols.

CRediT authorship contribution statement

Chavanant Sumanasrethakul: Writing – review & editing, Writing – original draft, Visualization, Validation, Methodology, Formal analysis, Data curation. **Piyarat Parklug:** Writing – review & editing, Resources, Methodology. **Suwara Issaragrisil:** Writing – review & editing, Resources, Methodology. **Naruporn Marukatat:** Writing – review & editing, Writing – original draft, Validation, Resources, Methodology, Investigation, Conceptualization.

Ethics approval

This study was approved by the ethics committees of Faculty of Medicine Vajira Hospital, Navamindradhiraj University, Bangkok, Thailand. (Approval no. COA 060/2566).

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Declaration of Generative AI and AI-assisted technologies in the writing process

During the preparation of this work the author(s) used ChatGPT 3.5 in order to check and correct grammatical errors during manuscript writing process. After using this tool/service, the author(s) reviewed and edited the content as needed and take(s) full responsibility for the content of the publication.

Declaration of Competing Interest

All authors declare that they have no conflicts of interest.

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