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Original Article

Comparison of the Diagnostic Performance of Shear Wave Elastography and Strain Elastography in Differentiating Benign and Malignant Breast Masses: A Retrospective Study in Iran

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Abstract

Background: Elastography is a non-invasive diagnostic imaging technique that assesses the elasticity or stiffness of tissues. This study aimed to compare the diagnostic performance of Shear Wave Elastography (SWE) and Strain Elastography (SE) in distinguishing benign from malignant breast masses.

Methods: In a retrospective study, 447 women with breast masses were evaluated divided into two groups: 223 underwent SE, and 224 underwent SWE. Histopathological findings served as the gold standard. Sensitivity, specificity, Positive Predictive Value (PPV), Negative Predictive Value (NPV), and Receiver Operating Characteristic (ROC) curves were calculated for both techniques. Data analysis was performed using R software (version 4.3), with t-tests and chi-square tests for group comparisons.

Results: The mean age of participants was 46.1±9.8 years. Significant differences were observed between the benign and malignant groups in terms of age, mass size, and family history of breast cancer ($p<0.05$). For SWE, sensitivity, specificity, PPV, and NPV were 92, 93, 89, and 95%, respectively, compared to 85, 87, 82, and 89%, respectively for SE. The diagnostic accuracy of SWE was higher than SE (93 *vs.* 86%). The area under the ROC curve was 0.94 for SWE and 0.88 for SE.

Conclusion: SWE demonstrated superior diagnostic performance compared to SE in differentiating benign and malignant breast masses. This non-invasive technique can serve as a valuable clinical tool to improve diagnostic accuracy for malignancies and reduce unnecessary biopsies. However, multicenter studies with larger, more diverse samples are needed to validate these findings.

Keywords: Biopsy, Breast neoplasms, Elasticity, Elasticity imaging techniques, Female

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Introduction

Breast cancer is the most common malignancy among women worldwide, and timely, accurate diagnosis is critical for improving patient outcomes. Traditional imaging modalities, such as mammography and ultrasonography, are cornerstone tools for evaluating breast masses (1,2).

However, these methods often face challenges in distinguishing benign from malignant lesions, particularly when morphological features overlap (3). This diagnostic ambiguity can lead to increased patient anxiety, healthcare costs, and unnecessary interventions (4). Conventional ultrasound, widely accessible and free of ionizing radiation, has been a mainstay in breast imaging; yet, its specificity in characterizing lesions remains limited (4). The Breast Imaging Reporting and Data System (BI-RADS) classifies masses based on ultrasound features, but complementary techniques are needed to improve diagnostic precision (5). Elastography is not yet fully integrated into BI-RADS, but is under consideration as an adjunct in some protocols (6). Elastography, an emerging imaging technique, assesses tissue stiffness, a key factor in distinguishing benign from malignant masses, and serves as a promising adjunct to conventional ultrasound (7). Shear Wave Elastography (SWE) and Strain Elastography (SE) were chosen for comparison due to their widespread clinical use and differing technical approaches, with SWE offering quantitative measurements and SE providing qualitative assessments (8). Malignant masses tend to be stiffer due to increased cellularity and desmoplastic reactions, unlike their benign counterparts (9).

Numerous studies have assessed the diagnostic performance of ultrasound elastography in distinguishing benign from malignant breast masses, consistently demonstrating improved accuracy and sensitivity when combined with conventional ultrasound (10-13). Elastography operates on the principle that tissue stiffness correlates with pathology. Two primary techniques are employed: SE, which provides a qualitative assessment *via* strain ratios comparing lesion stiffness to surrounding tissue and SWE which quantitatively measures stiffness in kilopascals (*kPa*) using shear wave velocity generated by acoustic radiation force (9). SE, though straightforward, is operator-dependent and qualitative, while SWE offers greater objectivity and reproducibility due to its quantitative nature and reduced reliance on user skill (14,15). Studies report varying diagnostic accuracies for these methods, with SWE often showing higher specificity due to its quantitative capabilities, though comparative data remain inconsistent (11,12). Optimal cutoff values for differentiating lesion types and the influence of factors such as mass size, histopathological subtype, and BI-RADS category require further investigation (16,17). Given elastography's potential to enhance breast cancer diagnosis, reduce unnecessary interventions, and facilitate early detection, this study aimed to compare the diagnostic performance of SWE and SE in distinguishing benign from malignant breast masses, with histopathology serving as the reference standard.

Materials and Methods

Study design

This retrospective observational study evaluated the diagnostic performance of SWE and SE in differentiating benign and malignant breast masses. Outcomes included sensitivity, specificity, PPV, NPV, diagnostic accuracy, and Receiver Operating Characteristic (ROC) curves, benchmarked against histopathological results.

Study population and inclusion/exclusion criteria

The study population comprised women aged 18 years and older with breast masses identified *via* ultrasonography and mammography (BI-RADS 4-5), referred to Dr. Giti Imaging Clinic in Tehran, Iran, between April 2022 and September 2023. Inclusion criteria included the presence of a mass detectable by ultrasound and mammography. Exclusion criteria were BI-RADS 0-3 masses, history of breast surgery or biopsy within six months prior to elastography, or contraindications to ultrasound (*e.g.*, severe skin damage).

A total of 447 participants were enrolled, including 274 with benign and 173 with malignant lesions. Participants were randomly allocated to SE or SWE groups using a simple randomization method to minimize bias.

Data collection

In SE and SWE, Vinno and Supersonic devices were used, respectively. Mass characteristics (size, shape, margins, and echogenicity) were recorded and classified per BI-RADS. Half of the participants (223) underwent SE, and the other half (224) underwent SWE. For SE, strain ratios were calculated by comparing lesion stiffness to surrounding tissue. For SWE, stiffness was quantified in *kPa* using shear wave velocity. Data were collected via a questionnaire capturing demographic details (age, sex, date of birth) and clinical information (reason for examination, breast health history, family history of breast cancer). Elastography type, stiffness measurements, and biopsy results were also recorded. All masses underwent biopsy to confirm histopathological diagnosis.

Ethical considerations

The study protocol was reviewed and approved by the Ethics Committee of Tehran University of Medical Sciences (Approval Number: IR.TUMS.IKHC.REC.1403.300). An IRCTID was not required, as the study is an observational retrospective study, not a clinical trial.

Statistical analysis

Diagnostic accuracy was assessed by calculating sensitivity, specificity, PPV, NPV, and overall accuracy. ROC curves were generated to evaluate overall diagnostic performance, with 95% Confidence Intervals (CI) computed for all metrics. Data were analyzed using R software (version 4.3), with a statistical significance threshold of $p<0.05$. Depending on data distribution, independent t-tests or chi-square tests were used to compare parameters between groups. Sample size was calculated to detect a 10% difference in diagnostic accuracy between SWE and SE, assuming 80% power and a 5% significance level, resulting in a minimum of 200 participants per group.

Results

Of the 447 patients, 50.3% of benign cases and 50% of malignant cases were assessed with SWE, while 49.7% of benign and 50% of malignant cases were assessed with SE, ensuring balanced comparison. The mean age was 43.5±7.5 years for benign cases with SWE, 44±8 years with SE, 54±9 years for malignant cases with SWE, and 56±10 years with SE. Age differences between benign and malignant groups were statistically significant (p=0.030), with older patients in the malignant group. Mean mass size was 15.5±4.5 *mm* for benign cases with SWE, 16.2±5 mm with SE, 20.5±7.5 *mm* for malignant cases with SWE, and 21.1±7 *mm* with SE, with significant differences between groups (p=0.001). Family history of breast cancer was reported in 8% (SWE) and 7% (SE) of benign cases, versus 20% (SWE) and 22% (SE) of malignant cases, with significant differences (p=0.002). Mass location (right/left) was balanced (45/42 for benign SWE, 40/46 for benign SE, 76/61 for malignant SWE, 64/73 for malignant SE; p=0.075). Multiple masses were observed in 13% (SWE) and 14% (SE) of benign cases, versus 20% (SWE) and 21% (SE) of malignant cases (p= 0.043). Table 1 summarizes demographic and clinical characteristics.

Table 1. Demographic and clinical characteristics of study participants

Method	SWE (benign)	SWE (malignant)	SE (benign)	SE (malignant)	p-value
Number of Participants	87	137	86	137	-
Mean Age (years)	43.5±7.5	54±9	44±8	56±10	0.032
Mass Size (*mm*)	15.5±4.5	20.5±7.5	16.2±5	21.1±7	0.001
Family History (n)	7	28	6	31	0.002
Location (Right/Left)	45/42	76/61	40/46	64/73	0.075
Multiple Masses (N)	11	27	12	29	0.043

Diagnostic performance

SWE demonstrated superior performance compared to SE, with a sensitivity of 92 and specificity of 93%, *vs.* 85 and 87% for SE, respectively. This difference may be attributed to SWE's ability to provide quantitative measurements of stiffness (expressed in kilopascals), whereas SE relies on a more qualitative strain ratio. The PPV for SWE was 89%, compared to 82% for SE, indicating SWE's greater ability to correctly identify malignant masses among positive results. The NPV for SWE (95%) exceeded that of SE (89%), suggesting a superior capacity to rule out malignancy. Overall accuracy was higher for SWE (93%) than for SE (86%), a disparity that underscores the significant advantage of SWE in delivering more precise diagnostic outcomes for distinguishing benign from malignant breast masses. The ROC curve, as the primary outcome, reflected overall diagnostic strength, with an Area Under the Curve (AUC) of 0.94 for SWE compared to 0.88 for SE, confirming a statistically significant superiority. The higher AUC for SWE was particularly pronounced for small masses (<10 *mm*), with an AUC of 0.92 *vs.* 0.85 for SE, highlighting its advantage in challenging cases (Figure 1).

Table 2 presents the diagnostic accuracy metrics of elastography for differentiating benign and malignant breast masses.

Table 2. Sensitivity, specificity, PPV, NPV, and accuracy of SWE and SE

Metric	SE (95%CI)	SWE (95%CI)
Sensitivity	85(80-89)	92(88-95)
Specificity	87(82-91)	93(89-96)
PPV	82(76-87)	89(84-93)
NPV	89(84-93)	95(91-98)
Accuracy	86(82-90)	93(90-96)
AUC (ROC)	0.88(0.84-0.92)	0.94(0.91-0.97)

Diagnostic accuracy by mass size

Table 3 presents the diagnostic accuracy of two elastography methods-SWE and strain SE- in differentiating benign and malignant breast masses based on mass size (small: <10 *mm*, medium: 10-20 *mm*, large: >20 *mm*). For small masses, SWE demonstrated higher diagnostic accuracy compared to SE. The percentage of correctly identified benign masses with SWE was 91% [95% confidence interval [CI]: 85-96], and for malignant masses, it was 90% (95%CI: 83-95), whereas the corresponding values for SE were 87% (95%CI: 80-92) and 84% (95%CI: 76-90), respectively. This difference was statistically significant (p=0.03), highlighting the relative

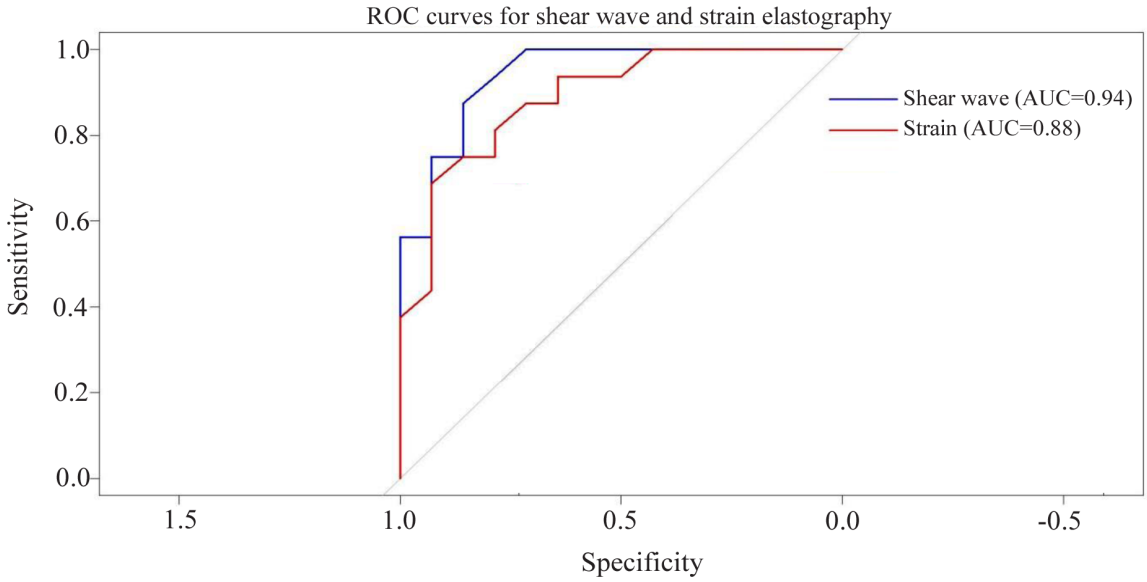

Figure 1. Receiver Operating Characteristic (ROC) curves for shear wave elastography and strain elastography compared to histological findings as the gold standard.

Table 3. Diagnostic accuracy by mass size

Mass Size	SWE Benign (%)	SWE Malignant (%)	SE Benign (%)	SE Malignant (%)	N
Small (<10 *mm*)	91(85-96)	90(83-95)	87(80-92)	84(76-90)	80
Medium (10-20 *mm*)	93(88-97)	92(86-96)	86(81-91)	85(79-90)	250
Large (>20 *mm*)	98(92-100)	94(88-98)	96(87-99)	88(80-94)	117

superiority of SWE in detecting small masses, which may be attributed to its ability to measure tissue stiffness more precisely, even in smaller dimensions. Small masses (<10 *mm*) pose diagnostic challenges due to subtle tissue differences, but SWE showed superior accuracy relative to meta-analysis benchmarks (p=0.03). For medium-sized masses (10–20 *mm*), SWE correctly identified 93% of benign masses (95%CI: 88–97) and 92% of malignant masses (95%CI: 86–96), compared to 86% (95%CI: 81–91) and 85% (95%CI: 79–90) for SE, respectively, demonstrating significantly higher accuracy relative to meta-analysis benchmarks (p=0.03). These findings indicate that in medium-sized masses—the most common size range for breast masses in clinical studies—SWE consistently outperforms SE. The higher AUC for SWE was particularly pronounced for small masses (<10 *mm*), with an AUC of 0.92 *vs.* 0.85 for SE, highlighting its advantage in challenging cases. The statistical significance of SWE's superior performance across mass sizes (p=0.03 for small and medium, p=0.04 for large) further highlight its advantage. This advantage may stem from SWE's capacity to provide quantitative shear wave velocity measurements, which are less influenced by external factors, such as operator pressure, compared to the qualitative strain ratio used in SE. For large masses, both methods exhibited high diagnostic accuracy, but SWE remained superior. The percentage of correctly identified benign masses with SWE was 98% (95% CI: 92-100), and for malignant masses, it was 94% (95%CI: 88-98), while the corresponding values for SE were 96% (95%CI: 87-99) and 88% (95%CI: 80-94), respectively. The difference in malignant mass accuracy (94% *vs.* 88%) was statistically significant (p=0.04).

The higher accuracy in large masses is likely due to more pronounced stiffness differences, which facilitate diagnosis for both techniques. However, SWE, with near-100% accuracy for benign masses and a notable difference in malignant masses, demonstrated a greater ability to reduce false-positive and false-negative results. This is particularly significant in larger masses, which are often associated with a higher likelihood of malignancy, underscoring the clinical importance of SWE in this context.

Discussion

Elastography is an advanced imaging technique that measures the stiffness and elasticity of breast tissue to assist in differentiating benign from malignant masses. Its clinical importance lies in guiding biopsy decisions and reducing diagnostic uncertainty, particularly for small masses where conventional imaging may be inconclusive. Its advantages include reducing unnecessary biopsies, enabling the evaluation of masses smaller than 1 *cm*, and assessing treatment response. The objective of this study was to compare SWE and SE in distinguishing benign and malignant breast masses in a cohort of 447 women.

Based on the findings of the present study, the mean age in the malignant group was significantly higher than in the benign group, which aligns with epidemiological patterns of breast cancer, as the risk of malignancy increases with age (18). The mean size of masses in the malignant group was larger than in the benign group, indicating a greater growth tendency of malignant masses (19). A family history of breast cancer was significantly more than twice as prevalent in the malignant group compared to the benign group; a finding consistent with the well-established role of genetic factors in breast cancer. Additionally, multiple masses were more common in the malignant group than in the benign group, potentially suggesting a more aggressive behavior of malignant masses (20).

The study findings demonstrated that both elastography

methods exhibit acceptable sensitivity and specificity in differentiating benign from malignant breast masses. For instance, a meta-analysis by Sadigh *et al* reported sensitivity endowed specificity of 88% and 83% for elastography in breast masses, which is close to the findings of our study (21). Our results also indicated that SWE outperforms SE, with a sensitivity of 92% and specificity of 93% compared to 85% and 87%, respectively. This superior performance may be attributed to SWE's quantitative measurements, which provide consistent, operator-independent results. This finding aligns with previous studies that emphasize the superior diagnostic performance of SWE due to its quantitative measurement of tissue stiffness. A meta-analysis by Liu *et al*, conducted on 33 studies involving 5,838 breast masses, reported a sensitivity of 88% (95%CI: 85-90) and specificity of 86% (95%CI: 83-89) for SWE (22). Another meta-analysis by Pillai et al. reported sensitivity and specificity values of 86% and 87%, respectively, for SWE (13). The higher AUC for SWE in our study may be due to a higher proportion of medium-sized masses and experienced operators, supported by recent studies, with a call for further research. The observed differences in sensitivity and specificity between our study and the meta-analyses by Liu (20) and Pillai (13) may be attributed to several factors (23,24). One potential reason is the difference in the study population. Demographic characteristics such as age, sex, or disease prevalence in the examined population can influence the diagnostic performance of SWE. For example, studies have shown that the sensitivity and specificity of imaging techniques may vary depending on mass size and breast tissue characteristics (25-27).

Based on our study findings, the area under the ROC curve (AUC) for assessing overall diagnostic performance was calculated as 0.94 for SWE and 0.88 for SE, indicating a relative superiority of SWE over SE. These results suggest that SWE may offer higher diagnostic accuracy in distinguishing benign from malignant breast masses. In a study by Pesce *et al*, the AUC for SWE was reported as 0.89, slightly lower than our findings; however, for more superficial masses, the AUC increased to 0.92 in that study (28). These observations may indicate the influence of lesion depth on the diagnostic performance of SWE. SWE, by utilizing shear waves that directly measure tissue stiffness, may provide greater accuracy in superficial masses with better access to ultrasound waves. In contrast, SE, which relies on manual or automated compression and relative tissue deformation, may face limitations in deeper masses or when uniform pressure is not applied (29). On the other hand, a study by Chang *et al*, which directly compared SWE and SE in breast masses, reported different results (30). In that study, the AUC was 0.92 for SWE and 0.94 for SE, suggesting a slight advantage for SE. This discrepancy compared to our study may be attributed to multiple factors. One such factor is the difference in the study population. For instance, variations in mean age, mass size, or the proportion of malignant masses in the samples could affect the performance of each method (31). Additionally, execution techniques and device settings may play a significant role (15). SE is operator-dependent, and when pressure is applied optimally, it can yield reliable results, whereas SWE, due to its use of quantitative measurements independent of manual pressure, typically offers greater consistency (29). It appears that SWE may perform better under specific conditions, such as in superficial masses or when quantitative stiffness measurement is required (32). This is consistent with findings by Barr *et al*, who demonstrated that SWE, by providing repeatable numerical values (*e.g.*, shear wave velocity), offers greater reliability compared to the more qualitative SE (33).

Positive Predictive Value (PPV) and Negative Predictive Value (NPV) were key metrics in evaluating the diagnostic performance of elastography methods in this study, as these indices directly reflect the ability of the methods to confirm or rule out malignancy in breast masses. Based on the study results, the PPV for SE was 82%, while for SWE it was 89%. Similarly, the NPV for SE was 89%, and for SWE it was 95%. These results indicate a relative superiority of SWE over SE in both PPV and NPV metrics. This advantage may be linked to SWE's ability to provide quantitative measurements of tissue stiffness (*e.g.*, shear wave velocity or *kilopascals*) compared to SE, which relies more on qualitative interpretation of tissue deformation (29). SWE, due to its use of repeatable numerical values, reduces the likelihood of false positives and provides a higher

PPV compared to qualitative methods like SE (34). In contrast, the lower PPV of SE may be related to its dependence on operator skill and the inconsistency of manual pressure application, which can lead to misinterpretation of masses (35). The cost and accessibility of SWE, however, may limit its adoption in low-resource settings, where SE could serve as a more feasible alternative (36).

The study findings also demonstrated that SWE exhibits higher diagnostic accuracy across all mass sizes compared to SE. This superiority in small and medium-sized masses is attributed to SWE's ability to provide quantitative and standardized stiffness measurements, whereas in larger masses, both methods perform well due to more pronounced tissue characteristics, though SWE remains more accurate. These findings indicate that mass size significantly impacts diagnostic accuracy, with accuracy improving as mass size increases; however, SWE consistently outperforms SE across all size groups. These results align with prior studies. For example, Chang's study (30) showed that SWE offers higher accuracy in distinguishing benign from malignant masses, particularly in smaller sizes, compared to SE. Similarly, Seo *et al* (37) demonstrated that SWE surpasses SE in small and medium masses due to its standardized, operator-independent measurements, although both methods exhibit high efficacy in larger masses. Clinically, these results suggest that SWE could be a more effective tool for diagnosing breast masses, especially in smaller sizes where detection is more challenging. With its higher accuracy, SWE can help reduce unnecessary biopsies for benign masses and facilitate the early identification of malignant ones. Although SE has lower accuracy, it still offers acceptable performance across all sizes and can serve as an alternative when access to SWE is limited.

Despite providing valuable insights into the diagnostic accuracy of elastography, this study faced several limitations. First, while the sample size is acceptable for a retrospective observational study, it may not be large enough to fully represent the wide variety of breast masses (*e.g.*, very small or very large masses) or demographic differences. Second, the study was conducted at a single center, which may limit the generalizability of the findings to other populations or clinical settings with different equipment and protocols. Third, the lack of investigation into the impact of variables such as tumor size, lesion depth, breast density, or the experience of different operators on diagnostic performance represents a significant limitation, as these factors can affect measurement accuracy. One limitation was the lack of separate data to assess the impact of multiple masses on diagnostic accuracy, with 13–21% of patients having multifocal masses. SWE's performance may be limited in dense breast tissue or non-palpable lesions due to reduced ultrasound wave penetration. The comparison of SWE and SE is clinically important for guiding biopsy decisions and reducing diagnostic uncertainty, particularly for small masses.

Given the study's findings, which highlight the high diagnostic accuracy of SWE in differentiating benign from malignant breast masses, it is recommended that future studies expand in several directions. First, conducting multicenter studies with larger sample sizes and greater demographic diversity could improve the generalizability of the results and examine the impact of equipment and protocol variations. Second, it is suggested that the influence of confounding factors such as breast density, lesion depth, and operator skill on the performance of SWE and SE be specifically analyzed. Third, exploring combined approaches, such as the simultaneous use of SWE and SE alongside other imaging modalities (*e.g.*, mammography or MRI), could further enhance diagnostic accuracy. Finally, developing standardized algorithms for selecting cutoff points based on clinical objectives (screening or diagnostic confirmation) and disease prevalence in different populations would optimize the clinical utility of these methods.

Conclusion

This study confirms the superior diagnostic performance of SWE over SE in differentiating benign from malignant breast masses, with higher sensitivity, specificity, and overall accuracy. These results underscore the high potential of SWE in improving malignancy detection and reducing unnecessary biopsies. However, limitations such as a relatively small sample size and the single-center design restrict the generalizability of the findings. It is recommended that future multicenter studies validate these results, explore SWE's role in non-palpable lesions, and

evaluate its integration with other imaging modalities like MRI to further enhance diagnostic accuracy. Overall, SWE can serve as a valuable tool in the clinical management of breast masses, and combined approaches with SE may further enhance diagnostic accuracy.

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Conflict of Interest

There is no conflict of interest.

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