

DIAGNOSTIC PERFORMANCE OF ULTRASOUND ELASTOGRAPHY AND DIFFUSION-WEIGHTED MRI IN DIFFERENTIATING BENIGN AND MALIGNANT BREAST LESIONS: A PROSPECTIVE STUDY

Monika Choudhary¹, Nisha Aurora², Bijendar Kumar³, Abhimanyu Singh¹, Bhawana Chauhan¹

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Corresponding Author:

Dr. Monika Choudhary,

Email: drmonachoudhary95@gmail.com

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ABSTRACT

Background: Differentiating benign from malignant breast lesions remains challenging, particularly when conventional imaging findings are indeterminate. Ultrasound shear-wave elastography (SWE) and diffusion-weighted magnetic resonance imaging (DWI-MRI) provide quantitative information on tissue stiffness and water diffusion, respectively. This study evaluated the diagnostic performance of SWE and apparent diffusion coefficient (ADC) measurements in differentiating benign and malignant breast lesions. **Materials and Methods:** A prospective observational study was conducted over 18 months at the Department of Radiodiagnosis, NIMS, Jaipur. Sixty-five female patients with breast lesions underwent conventional breast ultrasound, SWE, and breast MRI with DWI. Quantitative SWE and ADC measurements were recorded before histopathological diagnosis was considered. Histopathology served as the reference standard. Receiver operating characteristic (ROC) curve analysis was performed to determine optimal cut-off values and assess the diagnostic performance of ADC and SWE. **Result:** Histopathology identified 42 (64.6%) malignant and 23 (35.4%) benign lesions. The overall mean ADC was $1.057 \pm 0.282 \times 10^{-3} \text{ mm}^2/\text{s}$, while the mean SWE value was $3.152 \pm 1.001 \text{ kPa}$. At an ADC cut-off of $\leq 0.86 \times 10^{-3} \text{ mm}^2/\text{s}$, sensitivity was 78.6%, specificity 39.1%, positive predictive value (PPV) 70.2%, negative predictive value (NPV) 50.0%, and accuracy 64.6%, with an area under the ROC curve (AUC) of 0.562 (95% CI: 0.407–0.707). At an SWE cut-off of $\leq 3.12 \text{ kPa}$, sensitivity was 66.7%, specificity 78.3%, PPV 84.8%, NPV 56.3%, and accuracy 70.8%, with an AUC of 0.684 (95% CI: 0.548–0.812). **Conclusion:** SWE demonstrated numerically greater discriminatory performance than ADC in this cohort, although both parameters showed limited standalone diagnostic discrimination. ADC and SWE may provide complementary quantitative information when interpreted alongside conventional imaging and BI-RADS assessment. Larger multicentre studies with standardized imaging protocols and validated cut-off values are warranted.

INTRODUCTION

Breast cancer is one of the most common malignancies among women worldwide and remains a major cause of cancer-related morbidity and mortality.^[1-3] Early detection and accurate characterization of breast lesions are essential for appropriate clinical management and for reducing unnecessary invasive procedures.^[4] Mammography and conventional B-mode ultrasonography are widely used for the detection and characterization of breast lesions; however, considerable overlap in imaging features between benign and malignant lesions can result in indeterminate findings and

unnecessary biopsies.^[5-9] Therefore, there is a continuing need for reliable, non-invasive imaging techniques that provide additional quantitative information to improve lesion characterization.

Ultrasonography is particularly valuable in the evaluation of palpable breast masses and in women with dense breasts. B-mode ultrasound assesses morphological features such as lesion shape, margins, echogenicity, and internal characteristics.^[10,11] However, the overlap of sonographic features between benign and malignant lesions may limit its specificity. Ultrasound elastography has emerged as a useful adjunctive technique by providing information about the

mechanical properties and stiffness of breast tissue.^[12] Malignant breast lesions may demonstrate altered tissue stiffness because of increased cellularity, stromal changes, and desmoplastic reaction.^[13,14] Shear-wave elastography (SWE) provides a quantitative assessment of tissue stiffness by measuring the propagation of mechanically induced shear waves through tissue and expressing stiffness in quantitative units such as kilopascals (kPa).^[15–18] Although SWE may improve the characterization of breast lesions, its diagnostic performance can be influenced by lesion depth, tissue composition, acquisition technique, equipment, and operator-related factors.^[19]

Magnetic resonance imaging (MRI) is a highly sensitive modality for breast lesion evaluation, particularly when conventional imaging findings are inconclusive or in selected high-risk patients.^[2] Diffusion-weighted imaging (DWI) is a functional MRI technique that evaluates the movement of water molecules within tissues. The apparent diffusion coefficient (ADC), derived from DWI, provides a quantitative measure of water diffusion and is influenced by tissue cellularity and extracellular space.^[1,3] Malignant breast lesions frequently demonstrate restricted diffusion and lower ADC values than benign lesions because of increased cellular density and reduced extracellular space. However, considerable overlap in ADC values may occur between benign and malignant lesions, limiting its use as an isolated diagnostic parameter.^[5,6] SWE and DWI-MRI provide complementary information about different biological characteristics of breast lesions. While ADC reflects tissue microstructure and water diffusion, SWE provides information regarding tissue mechanical properties and stiffness.^[7] Combining these quantitative parameters with conventional imaging and Breast Imaging Reporting and Data System (BI-RADS) assessment may therefore improve diagnostic confidence and potentially reduce unnecessary biopsies.

Previous studies have demonstrated variable diagnostic performance for both SWE and DWI-MRI, with differences in reported cut-off values, imaging protocols, patient populations, and histopathological characteristics.^[12,13] Further evaluation of these techniques in different clinical settings is therefore warranted. The present study was undertaken to evaluate the diagnostic performance of ultrasound SWE and DWI-MRI-derived ADC measurements in differentiating benign from malignant breast lesions. The study specifically assessed quantitative SWE and ADC values and determined their sensitivity, specificity, predictive values, accuracy, and area under the receiver operating characteristic (ROC) curve using histopathology as the reference standard.

MATERIALS AND METHODS

Study Design and Study Population: A prospective observational study was conducted in the Department of Radiodiagnosis, NIMS, Jaipur, Rajasthan, over a period of 18 months. Female patients aged >15 years presenting with breast lesions detected on ultrasonography or mammography, or with clinically palpable breast lumps, were considered for inclusion. Patients were recruited using a convenience sampling method. The study was designed to evaluate the diagnostic performance of ultrasound shear-wave elastography (SWE) and diffusion-weighted magnetic resonance imaging (DWI-MRI) in differentiating benign from malignant breast lesions.

Inclusion Criteria

Patients were included if they met the following criteria:

- Female patients aged >15 years.
- Presence of a breast lesion detected on ultrasonography or mammography.
- Patients presenting with a clinically palpable breast lump.
- Patients willing to undergo breast ultrasonography, SWE, MRI with DWI, and histopathological evaluation.
- Availability of histopathological diagnosis as the reference standard.

Exclusion Criteria

Patients were excluded if they had:

- Postoperative or post-procedural breast changes that could significantly alter tissue stiffness or diffusion characteristics.
- Breast implants or other conditions precluding reliable imaging assessment.
- Previous chemotherapy or radiotherapy to the breast.
- Contraindications to MRI.
- Male breast lesions.

Sample Size

The minimum sample size was calculated using the formula:

$n = Z^2 \times SD^2 / d^2$, where Z represents the standard normal deviate at the selected confidence level, SD represents the standard deviation of the parameter used for estimation, and d represents the allowable margin of error. Using $Z = 1.96$, $SD = 0.206$, and $d = 0.05$, the calculated sample size was 65 patients.

Ultrasound and Shear-Wave Elastography

All patients underwent breast ultrasonography using conventional B-mode imaging followed by shear-wave elastography. B-mode ultrasound findings were assessed according to the Breast Imaging Reporting and Data System (BI-RADS) classification.

SWE was subsequently performed to quantitatively assess the stiffness of the breast lesion. The region of interest was positioned within the solid component of the lesion while avoiding cystic areas, necrosis, hemorrhage, and surrounding tissue as far as possible. Quantitative stiffness measurements were

recorded in kilopascals (kPa). A representative SWE value was obtained for each lesion and used for subsequent statistical analysis.

Magnetic Resonance Imaging and Diffusion-Weighted Imaging: All patients underwent breast MRI using a standard breast MRI protocol, including diffusion-weighted imaging. DWI was acquired using appropriate diffusion-sensitive sequences, and corresponding apparent diffusion coefficient (ADC) maps were generated.

ADC measurements were obtained by placing a region of interest within the lesion, avoiding areas of necrosis, haemorrhage, cystic degeneration, or other non-representative components wherever identifiable. The ADC value was recorded in $\times 10^{-3}$ mm²/s. MRI lesions were also assessed according to the BI-RADS classification.

Histopathological Assessment: Histopathological examination was considered the reference standard for final diagnosis. Imaging examinations and quantitative measurements were performed before knowledge of the histopathological diagnosis to minimize potential interpretation bias. Lesions were subsequently categorized as benign or malignant based on histopathological findings.

Data Collection and Statistical Analysis: Demographic, clinical, imaging, and histopathological data were recorded in a structured database and subsequently analyzed using IBM SPSS Statistics version 29.0 and Microsoft Excel. Continuous variables were expressed as mean $\pm$ standard deviation, while categorical variables were summarized using frequencies and percentages. Differences in quantitative imaging parameters between benign and malignant lesions were assessed using independent-samples t-test, or Mann–Whitney U test statistical tests based on data distribution. Categorical variables were analyzed using the chi-square test or Fisher's exact test, as appropriate.

Receiver operating characteristic (ROC) curve analysis was performed to assess the diagnostic performance of ADC and SWE in differentiating benign from malignant breast lesions. The area under the ROC curve (AUC) with 95% confidence intervals was calculated. Diagnostic cut-off values were assessed, and sensitivity, specificity, positive predictive value (PPV), negative predictive value (NPV), and overall diagnostic accuracy were calculated.

For the present analysis, an ADC value of $\leq 0.86 \times 10^{-3}$ mm²/s and an SWE value of ≤ 3.12 kPa were considered positive for malignancy. All statistical tests were two-sided, and a p value < 0.05 was considered statistically significant.

Ethical Considerations: The study was conducted after obtaining approval from the Institutional Ethics Committee of NIMS. Ethical approval was granted under reference number NIMSUR/IEC/2024/1021, dated 11/05/2024. The study was conducted in accordance with the principles of the Declaration of Helsinki. Written informed consent was obtained from all participants. For participants younger than

18 years, consent was obtained from a parent or legal guardian along with assent from the participant.

RESULTS

A total of 65 female patients with breast lesions were included in the study. The participant recruitment process is illustrated in Figure 1. The mean age of the study population was 50.5 ± 17.9 years. A family history of breast cancer was present in 13 (20.0%) patients, while lymphadenopathy was observed in 33 (50.8%) patients. The detailed clinical characteristics of the study population are presented in [Table 1].

The age-wise distribution of the participants is shown in [Figure 2]. The largest proportion of participants belonged to the 31–40-year age group (21.5%), followed by the 41–50-year age group (18.5%).

The distribution of lesions according to ultrasound and MRI BI-RADS categories is summarized in [Table 2]. On ultrasonography, BI-RADS category 4 was the most frequent category, accounting for 28 (43.1%) lesions, followed by category 3 in 23 (35.4%) lesions. On MRI, BI-RADS category 5 was the most frequent, comprising 24 (36.9%) lesions, followed by category 4 in 23 (35.4%) and category 3 in 18 (27.7%) lesions.

Histopathological examination, used as the reference standard, identified 42 (64.6%) malignant and 23 (35.4%) benign lesions. The distribution of lesions according to histopathological diagnosis is presented in [Figure 3].

The quantitative imaging parameters according to histopathological diagnosis are presented in Table 3. The overall mean ADC value was $1.057 \pm 0.282 \times 10^{-3}$ mm²/s. The mean ADC was $1.019 \pm 0.285 \times 10^{-3}$ mm²/s in benign lesions and $1.079 \pm 0.278 \times 10^{-3}$ mm²/s in malignant lesions. The overall mean SWE value was 3.152 ± 1.001 kPa, with mean values of 3.573 ± 0.832 kPa in benign lesions and 2.921 ± 1.024 kPa in malignant lesions.

The diagnostic performance of ADC and SWE at the selected optimal cut-offs is summarized in [Table 4]. For ADC, a cut-off of $\leq 0.86 \times 10^{-3}$ mm²/s yielded a sensitivity of 78.6%, specificity of 39.1%, PPV of 70.2%, NPV of 50.0%, and diagnostic accuracy of 64.6%. The corresponding AUC was 0.562 (95% CI: 0.407–0.707). For SWE, a cut-off of ≤ 3.12 kPa demonstrated a sensitivity of 66.7%, specificity of 78.3%, PPV of 84.8%, NPV of 56.3%, and diagnostic accuracy of 70.8%, with an AUC of 0.684 (95% CI: 0.548–0.812).

The corresponding two-by-two diagnostic classifications at the selected cut-offs are presented in [Table 5]. At the ADC threshold, 33 of 42 malignant lesions were correctly classified as positive, while 14 of 23 benign lesions were incorrectly classified as positive. At the SWE threshold, 28 of 42 malignant lesions were correctly classified as positive, while only 5 of 23 benign lesions were classified as positive.

The ROC curves for ADC and SWE are presented in [Figure 4A] and Figure 4B, respectively. SWE demonstrated a numerically higher AUC than ADC (0.684 vs. 0.562), indicating greater discriminatory performance within this dataset. However, a formal statistical comparison between the two correlated ROC curves was not performed; therefore, statistical superiority of SWE over ADC cannot be concluded.

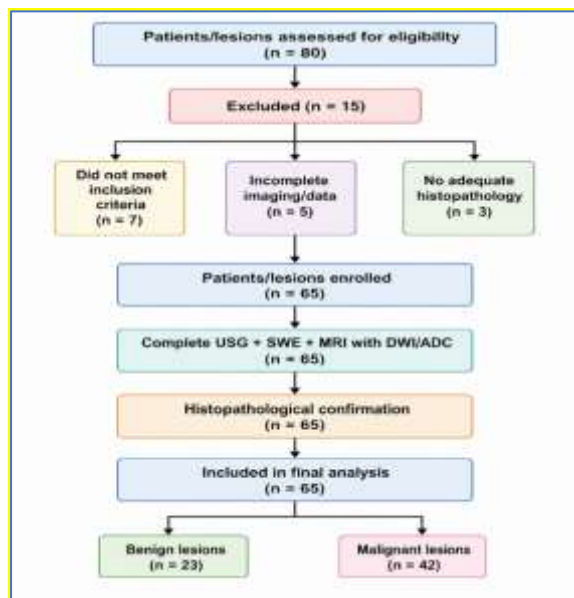


Figure 1: Flow diagram of participant recruitment

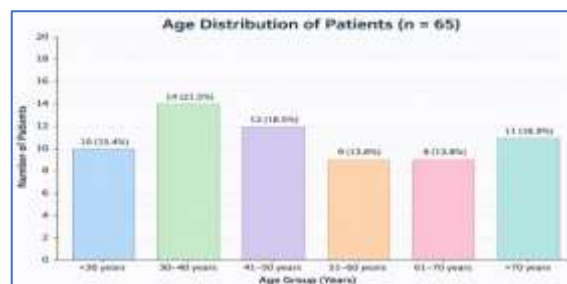


Figure 2: Age-wise distribution of study participants

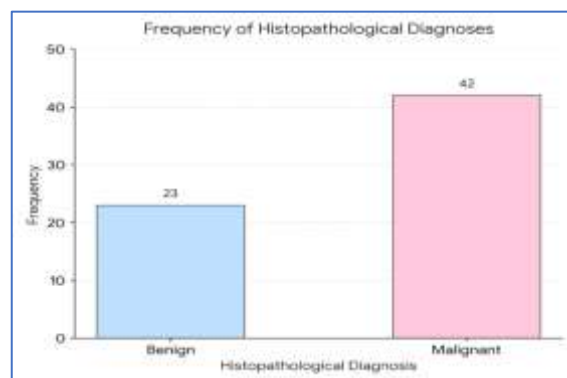


Figure 3: Distribution of lesions according to histopathological diagnosis

Table 1: Clinical characteristics of the study population

Parameter	Category	Frequency (%)
Family history of breast cancer	Present	13 (20.0)
	Absent	52 (80.0)
Lymphadenopathy	Present	33 (50.8)
	Absent	32 (49.2)
Total		65 (100.0)

Table 2: Distribution of breast lesions according to ultrasound and MRI BI-RADS categories

Imaging modality	BI-RADS category	Frequency (%)
Ultrasonography	0	1 (1.5)
	1	2 (3.1)
	2	2 (3.1)
	3	23 (35.4)
	4	28 (43.1)
	5	9 (13.8)
MRI	3	18 (27.7)
	4	23 (35.4)
	5	24 (36.9)

Table 3: Quantitative imaging parameters according to histopathological diagnosis

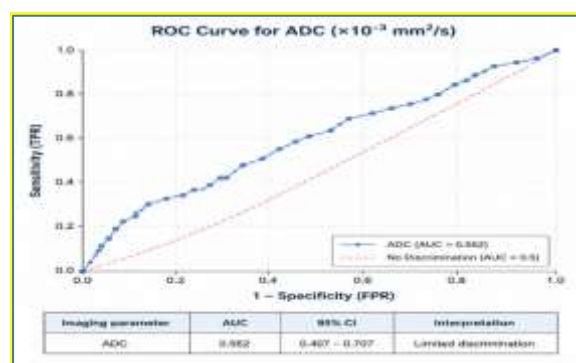
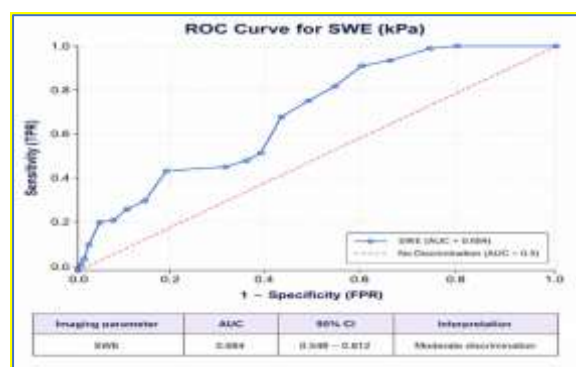
Parameter	Benign (n=23) Mean ± SD	Malignant (n=42) Mean ± SD	Overall Mean ± SD
ADC ($\times 10^{-3}$ mm ² /s)	1.019 ± 0.285	1.079 ± 0.278	1.057 ± 0.282
SWE (kPa)	3.573 ± 0.832	2.921 ± 1.024	3.152 ± 1.001

Table 4: Diagnostic performance of ADC and SWE for differentiation of malignant and benign breast lesions

Parameter	Optimal cut-off	Sensitivity (%)	Specificity (%)	PPV (%)	NPV (%)	Accuracy (%)	AUC (95% CI)
ADC ($\times 10^{-3}$ mm ² /s)	≤0.86	78.6	39.1	70.2	50.0	64.6	0.562 (0.407–0.707)
SWE (kPa)	≤3.12	66.7	78.3	84.8	56.3	70.8	0.684 (0.548–0.812)

Table 5: Two-by-two diagnostic classification at optimal cut-offs

Imaging parameter	Histopathological status	Test positive	Test negative	Total
ADC ≤ 0.86	Malignant	33	9	42
	Benign	14	9	23
SWE ≤ 3.12	Malignant	28	14	42
	Benign	5	18	23

**Figure 4A: ROC curve for ADC****Figure 4B: ROC curve for SWE**

DISCUSSION

Accurate differentiation of benign and malignant breast lesions remains an important objective of breast imaging. BI-RADS provides a standardized framework for morphological assessment and risk stratification,^[1] while DWI-MRI and ultrasound elastography provide complementary functional information regarding tissue diffusion and mechanical properties.^[2,3] In the present study, both ADC and SWE were evaluated against histopathology in 65 breast lesions.

Diffusion-weighted MRI and ADC: In our study, the mean ADC was $1.019 \pm 0.285 \times 10^{-3} \text{ mm}^2/\text{s}$ in benign lesions and $1.079 \pm 0.278 \times 10^{-3} \text{ mm}^2/\text{s}$ in malignant lesions. The slightly higher ADC in malignant lesions was contrary to the commonly reported pattern of lower ADC in malignancy. Partridge et al. described restricted diffusion and lower ADC as characteristic of many malignant breast lesions, although considerable overlap between benign and malignant lesions was recognized.^[2] The unexpected direction observed in our cohort may therefore reflect differences in tumour histology, cellularity, necrosis, stromal composition, lesion heterogeneity, ROI placement, or DWI acquisition parameters.

At a cut-off of $\leq 0.86 \times 10^{-3} \text{ mm}^2/\text{s}$, ADC demonstrated 78.6% sensitivity, 39.1% specificity, 64.6% accuracy, and an AUC of 0.562. These findings indicate limited standalone discrimination. This is consistent with Kul et al., who demonstrated that quantitative ADC does not necessarily provide superior diagnostic information compared with qualitative DWI assessment.^[15] El Ameen et al. also emphasized the complementary role of DWI when interpreted alongside conventional and dynamic contrast-enhanced MRI rather than as an isolated parameter.^[17] Yadav et al. further demonstrated the potential of advanced diffusion techniques as complementary approaches to breast MRI.^[16] More recently, Lahooti et al. highlighted the diagnostic limitations and heterogeneity of advanced diffusion techniques, supporting cautious interpretation of diffusion-derived biomarkers.^[9]

Shear-wave elastography: The mean SWE values in our study were $3.573 \pm 0.832 \text{ kPa}$ for benign lesions and $2.921 \pm 1.024 \text{ kPa}$ for malignant lesions. Although malignant lesions are generally expected to be stiffer, our results showed the opposite direction. Liu et al. reported overall diagnostic utility of quantitative SWE for differentiating benign and malignant breast lesions but also demonstrated substantial variation in diagnostic thresholds across studies.^[3] Shahzad et al. similarly reported diagnostic value for strain and SWE while highlighting the influence of threshold selection and technical factors.^[12] These observations may explain, at least partly, the unexpected SWE pattern in our cohort.

At the cut-off of $\leq 3.12 \text{ kPa}$, SWE showed 66.7% sensitivity, 78.3% specificity, 70.8% accuracy, and an AUC of 0.684. Thus, SWE demonstrated a numerically higher AUC and greater specificity than ADC in our study. Kanagaraju et al. reported useful diagnostic performance of ultrasound elastography for differentiating benign and malignant breast lesions,^[11] while Li et al. demonstrated the potential value of quantitative elastographic parameters particularly in BI-RADS 3–4 lesions.^[13] More recent evidence from Woo et al. has continued to support the diagnostic potential of SWE and shear-wave dispersion imaging, while emphasizing methodological differences between techniques.^[5]

Comparison of ADC and SWE: Our findings are also supported by studies evaluating diffusion and elastographic parameters together. Kapetas et al. demonstrated that DWI and elastography provide different but complementary information regarding breast tissue microstructure and mechanical properties.^[10] Aricò et al. more recently evaluated SWE and ADC together and further supported the concept of combining diffusion and mechanical

biomarkers for breast lesion characterization.^[4] Zhou et al. reported potential diagnostic value when SWE was combined with ultrasound and MRI, while Sabharwal et al. emphasized the role of multiparametric quantitative ultrasound integrating morphology, vascularity, and elasticity.^[6,7] In our study, SWE had a higher AUC than ADC (0.684 vs. 0.562), but this difference should not be interpreted as statistically significant because formal comparison of the two correlated ROC curves was not performed. Rather, the findings suggest that SWE provided greater discriminatory information than ADC within this particular cohort. Chen et al. similarly demonstrated improved diagnostic performance when SWE was combined with other ultrasound information, supporting a multiparametric rather than single-parameter approach.^[14]

Clinical implications: The present findings support the use of ADC and SWE as adjunctive techniques alongside conventional ultrasound, MRI morphology, and BI-RADS rather than as independent diagnostic tests. This approach is consistent with EUSOBI recommendations emphasizing standardized breast ultrasound assessment,^[19] and with recent multiparametric imaging studies.^[6–8] Soliman et al. demonstrated the diagnostic potential of multiparametric MRI for breast lesions, further supporting integration of complementary imaging parameters.^[8] Importantly, our study did not evaluate a combined ADC-SWE diagnostic model or its effect on biopsy decisions. Therefore, improved biopsy avoidance or clinical outcomes cannot be inferred from the present findings.

Limitations: The study was limited by its relatively small sample size and single-centre design. Selection bias is also possible because the included lesions underwent histopathological evaluation. Both ADC and SWE demonstrated substantial overlap between benign and malignant lesions. In addition, SWE measurements may vary with equipment, lesion depth, ROI placement, and operator technique, while ADC measurements are influenced by MRI acquisition parameters and ROI selection. The unexpected direction of the ADC and SWE group differences also requires confirmation in larger cohorts. Finally, although SWE demonstrated a numerically higher AUC than ADC, no formal statistical comparison between the ROC curves was performed.

Overall, the findings indicate that ADC and SWE provide complementary but limited diagnostic information. Their greatest potential may lie in integration with conventional imaging and BI-RADS within a multiparametric diagnostic framework. Larger prospective multicentre studies with standardized acquisition protocols and validated cut-off values are required before these quantitative parameters can be routinely used for independent diagnostic decision-making.

CONCLUSION

Ultrasound shear-wave elastography (SWE) and diffusion-weighted MRI (DWI) provided complementary quantitative information for the characterization of breast lesions. In this study, SWE demonstrated better overall diagnostic performance than ADC, with a higher AUC (0.684 vs. 0.562), although neither technique showed sufficiently strong discrimination to replace conventional imaging or histopathological assessment. The atypical direction of ADC and SWE values between benign and malignant lesions highlights the influence of lesion composition and technical factors. Therefore, SWE and DWI should be considered adjunctive tools within a multiparametric breast imaging approach rather than standalone diagnostic methods. Larger, multicentre prospective studies are warranted to validate optimal thresholds and establish their clinical utility.

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