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Radiology Section

# Diagnostic Performance of Shear Wave Elastography in Differentiating Benign and Malignant Breast Masses: A Prospective Observational Study

SHUBHAM YADAV[1], PUNEET MITTAL[2], RANJANA GUPTA[3], CHAINIKA MEHLA[4], ANKITAA THAKRAL[5], NITIKA KATARIA[6]

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## ABSTRACT

**Introduction:** Conventional Breast Imaging Reporting And Data System (BI-RADS) ultrasonography has high sensitivity but limited specificity for breast mass characterisation. Sonoelastography evaluates tissue stiffness and may improve diagnostic accuracy.

**Aim:** To assess the diagnostic utility of Shear Wave Elastography (SWE) in breast masses, determine optimal cut-off values for malignancy.

**Materials and Methods:** This prospective observational study included 40 female patients with breast masses, conducted from March 2024 to February 2025 at the Department of Radio-Diagnosis, Adesh Medical College and Hospital, Shahabad, Kurukshetra, Haryana, India. All patients underwent B-mode ultrasonography with BI-RADS classification and SWE. Qualitative SWE patterns and quantitative elastographic parameters, including maximum elasticity (Emax), mean elasticity (Emean), and elasticity ratio (Eratio), were recorded. Histopathological examination was considered the reference standard. Receiver Operating Characteristic (ROC) curve analysis was performed to determine the optimal cut-off values and diagnostic performance of Emax, Emean, and Eratio for differentiating benign from malignant lesions.

**Results:** Histopathological examination, used as the reference standard, revealed 19 (47.5%) benign and 21 (52.5%) malignant breast lesions among the 40 study participants. Using BI-RADS IV as the threshold for malignancy, conventional USG demonstrated 100.0% sensitivity, 42.1% specificity, 65.6% PPV, 100.0% NPV, and 72.5% diagnostic accuracy. The association between BI-RADS classification and histopathological diagnosis was statistically significant (p-value= 0.003). ROC analysis demonstrated that all three quantitative SWE parameters had good discriminatory ability. The AUC was 0.808 for Emax, 0.817 for Emean, and 0.838 for Eratio, with optimal malignancy cut-offs of 91.0 kPa, 52.95 kPa, and 1.57, respectively. All three parameters showed a statistically significant association with histopathological malignancy (p-value <0.001). Combining quantitative SWE with BI-RADS improved diagnostic performance, achieving 90.5% sensitivity, 89.5% specificity, 90.5% PPV, 89.5% NPV, and 90.0% accuracy.

**Conclusion:** Sonoelastography significantly improves the specificity and overall accuracy of breast ultrasonography and may reduce unnecessary biopsies.

**Keywords:** Breast imaging reporting and data system, Breast ultrasonography, Sonoelastography

## INTRODUCTION

Breast cancer is the most commonly diagnosed malignancy among women worldwide and a leading cause of cancer-related mortality [1]. With a 5-year prevalence of 16.5 per 100,000 people, female breast cancer remains the most prevalent cancer among females, contributing to 13.8% of all new cases [2]. Early and accurate characterisation of breast masses using appropriate imaging modalities, including mammography, ultrasonography, and Magnetic Resonance Imaging (MRI), is essential for differentiating benign from malignant lesions, guiding appropriate management, and reducing unnecessary invasive procedures [3]. Mammography is effective for detecting microcalcifications, while ultrasonography is particularly valuable in younger women and those with dense breast tissue [4,5]. MRI offers high sensitivity but may have limited specificity due to overlapping imaging features [6]. The American College of Radiology BI-RADS provides a standardised lexicon and assessment system for breast ultrasonography. BI-RADS category three represents a probably benign lesion with a >0%-≤2% likelihood of malignancy, whereas category 4A represents a low suspicion for malignancy, with a >2%-≤10% likelihood of malignancy [7]. However, conventional imaging, especially ultrasonography, has limited specificity in indeterminate lesions, leading to unnecessary biopsies and follow-up examinations.

Sonoelastography is an advanced ultrasound technique that evaluates tissue stiffness, providing functional information that complements conventional grayscale imaging. Strain elastography provides qualitative assessment but is operator-dependent, whereas SWE offers quantitative and reproducible measurements of tissue elasticity [8,9]. Previous studies have demonstrated that elastography improves diagnostic accuracy in differentiating benign and malignant breast lesions and may reduce unnecessary biopsies, particularly in BI-RADS 3 and 4a lesions [10-13].

Despite growing evidence, data on elastography in the Indian population remain limited, and optimal quantitative cut-off values for malignancy are not well established. Therefore, this study aimed to evaluate the diagnostic performance of SWE in breast mass characterisation, determine quantitative cut-off values for malignancy, and assess the added value of elastography in combination with BI-RADS ultrasonography in an Indian clinical setting.

## MATERIALS AND METHODS

This prospective observational study was conducted in the Department of Radiodiagnosis, Adesh Medical College and Hospital, Mohri, Kurukshetra, Haryana, India from March 2024 to February 2025 after approval from the Institutional Ethics Committee (Approval No. AMCH/IEC-BHR/2024/04/37).

**Inclusion criteria:** Female patients aged ≥18 years, patients with a palpable breast mass/lesion detected on breast imaging, willingness to undergo B-mode ultrasonography, SWE, and tissue diagnosis, and those providing written informed consent were included in the study.

**Exclusion criteria:** Patients refusing to provide consent, pregnant or lactating women, patients with a history of previous breast surgery, and those with a history of significant breast trauma were excluded from the study.

**Ultrasound and Shear Wave Elastography (SWE):** All patients underwent B-mode breast ultrasonography followed by SWE using a high-frequency linear transducer. Lesions were categorised according to the ACR BI-RADS 5th edition [7].

### Study Procedure

All patients underwent SWE in the supine position with the ipsilateral arm raised above the head. Patients were instructed to remain still and suspend respiration briefly during image acquisition to minimise motion artefacts. The transducer was placed gently over the lesion with minimal probe pressure, avoiding excessive compression.

Both qualitative and quantitative SWE assessments were performed. Quantitative parameters included maximum elasticity (Emax), mean elasticity (Emean), and elasticity ratio (Eratio). For each lesion, ten SWE measurements were obtained using a 3 × 3 mm ROI, placed within the solid and stiffest portion of the lesion, while avoiding cystic or necrotic areas and keeping the ROI away from the lesion margin. For Eratio, the reference ROI was placed in adjacent normal breast tissue at a comparable depth.

A single radiologist with 15 years of experience in radiology and breast ultrasonography performed all examinations and measurements. The operator was not blinded to the BI-RADS assessment, as SWE was performed after B-mode ultrasonography and BI-RADS categorisation. However, the histopathological examination was performed after SWE, so the operator was blinded to the cytopathological findings at the time of elastographic assessment.

**BI-RADS threshold for malignancy**: For diagnostic-performance analysis, BI-RADS III was considered test-negative and BI-RADS IVa-IVc test-positive for malignancy. Thus, BI-RADS ≥IV was used as the positive threshold.

Histopathological examination was used as the reference standard (gold standard) for differentiating benign and malignant breast lesions, and all diagnostic performance analyses of BI-RADS and SWE parameters were performed in comparison with the histopathological diagnosis.

**ROC analysis and SWE cut-offs:** ROC curve analysis was performed to assess the discriminatory ability of Emax, Emean and Eratio for benign versus malignant lesions. The AUC was calculated for each parameter, and the optimal cut-off was determined using the maximum Youden index (sensitivity + specificity- 1).

**The derived cut-offs were:**

- Emax ≥91.0 kPa
- Emean ≥52.95 kPa
- Eratio ≥1.57

The corresponding AUCs were 0.808, 0.817 and 0.838, respectively.

**Combined SWE and BI-RADS assessment:** For combined assessment, a lesion was therefore classified as combined-test positive if it was BI-RADS IV or higher and/or any relevant SWE parameter crossed its malignancy cut-off (Emax ≥91.0 kPa, Emean ≥52.95 kPa or Eratio ≥1.57). A lesion was classified as combined-test negative only when BI-RADS was III (Combined positive= BI-RADS ≥IVb) and all evaluated SWE parameters were below their respective cut-offs. The diagnostic performance was compared with the reference standard.

## STATISTICAL ANALYSIS

Data were entered and analysed using IBM Statistical Package for the Social Sciences (SPSS) Statistics, version 27.0 (IBM Corp., Armonk, NY, USA). Categorical variables were summarised as frequencies and percentages, whereas continuous variables were expressed as mean±Standard Deviation (SD). The associations were assessed between categorical variables, including USG BI-RADS categories and qualitative SWE patterns, and histopathological diagnosis using the Chi-square test. The diagnostic performance was evaluated of conventional ultrasonography, individual quantitative SWE parameters (Emax, Emean, and Eratio), and the combined USG BI-RADS and SWE approach using histopathological diagnosis as the reference standard. Sensitivity, specificity, Positive Predictive Value (PPV), Negative Predictive Value (NPV), and overall diagnostic accuracy were calculated. Receiver Operating Characteristic (ROC) curve analysis was performed to determine the optimal cut-off values for the quantitative SWE parameters. The Area Under the ROC Curve (AUC) was calculated to assess discriminatory performance. A two-tailed p-value <0.05 was considered statistically significant.

## RESULTS

A total of 40 women with breast masses were prospectively evaluated. The majority of participants were aged 41-50 years (30%), followed by 18-30 years (27.5%) [Table/Fig-1]. Most lesions were painless (75%).

| Age group (years) | n (%) |
|---|---|
| 18-30 | 11 (27.5) |
| 31-40 | 7 (17.5) |
| 41-50 | 12 (30.0) |
| 51-60 | 6 (15.0) |
| >60 | 4 (10.0) |

**[Table/Fig-1]:** Age distribution of study participants (n=40).

The upper outer quadrant was the most common location (35%), with a slight right-sided predominance (55%) [Table/Fig-2].

| Parameter | Category | n (%) |
|---|---|---|
| Nipple discharge | No | 39 (97.5) |
| | Yes | 1 (2.5) |
| Laterality | Left | 18 (45.0) |
| | Right | 22 (55.0) |
| Lesion location | Upper outer | 14 (35.0) |
| | Upper inner | 6 (15.0) |
| | Upper central | 4 (10.0) |
| | Outer central | 2 (5.0) |
| | Nipple-areolar | 2 (5.0) |
| | Lower outer | 6 (15.0) |
| | Lower inner | 5 (12.5) |
| | Lower central | 1 (2.5) |

**[Table/Fig-2]:** Distribution of study participants according to clinical and basic lesion characteristics (n=40).

On ultrasonography, most masses were irregular (62.5%) [Table/Fig-3]. BI-RADS IV lesions constituted 80% of cases [Table/Fig-4]. Histopathology confirmed malignancy in 52.5% and benign pathology in 47.5% [Table/Fig-5].

Conventional ultrasound BI-RADS classification showed 100% sensitivity and 42.1% specificity for malignancy (p-value= 0.003), with an overall accuracy of 72.5% [Table/Fig-6,7].

The SWE demonstrated good discriminatory performance. ROC analysis identified optimal cut-offs of 91 kPa for Emax, 52.95 kPa for Emean, and 1.57 for Eratio. All SWE parameters showed a highly significant association with histopathology (p-value <0.001).

| Parameter | Category | n (%) |
|---|---|---|
| Shape | Irregular | 25 (62.5) |
| | Oval | 14 (35.0) |
| | Round | 1 (2.5) |
| Margins | Circumscribed | 15 (37.5) |
| | Lobulated | 15 (37.5) |
| | Indistinct | 5 (12.5) |
| | Spiculated | 4 (10.0) |
| | Angular | 1 (2.5) |
| Echotexture | Hypoechoic | 27 (67.5) |
| | Heterogeneous | 9 (22.5) |
| | Solid-cystic | 2 (5.0) |
| | Hyperechoic | 1 (2.5) |
| | Isoechoic | 1 (2.5) |
| Calcification | Absent | 31 (77.5) |
| | Present | 9 (22.5) |
| Asymmetry | Absent | 32 (80.0) |
| | Present | 8 (20.0) |

**[Table/Fig-3]:** Distribution of study participants according to sonographic characteristics of breast masses (n=40).

| Parameter | Category | n (%) |
|---|---|---|
| USG BI-RADS | III | 8 (20.0) |
| | IVa | 10 (25.0) |
| | IVb | 10 (25.0) |
| | IVc | 12 (30.0) |
| Axillary lymph node status | Normal | 35 (87.5) |
| | Enlarged | 5 (12.5) |
| Lymph node morphology | Oval | 38 (95.0) |
| | Necrotic | 2 (5.0) |

**[Table/Fig-4]:** Distribution of study participants according to BI-RADS and axillary lymph node findings on USG (n=40).

| Histopathological diagnosis | n (%) |
|---|---|
| Benign lesions | 19 (47.5) |
| Fibroadenoma | 12 (30.0) |
| Intraductal papilloma | 6 (15.0) |
| Benign phyllodes tumour | 1 (2.5) |
| Malignant lesions | 21 (52.5) |
| Invasive ductal carcinoma | 10 (25.0) |
| Medullary carcinoma | 5 (12.5) |
| Papillary carcinoma | 3 (7.5) |
| Invasive lobular carcinoma | 3 (7.5) |
| Total | |

**[Table/Fig-5]:** Distribution of study participants according to histopathological diagnosis (n=40).

| USG BI-RADS | Benign | Malignant | Total | p-value* |
|---|---|---|---|---|
| III | 8 (42.1%) | 0 | 8 | 0.003 |
| IV (IVa-c) | 11 (57.9%) | 21 (100.0%) | 32 | |
| Total | 19 (100.0%) | 21 (100.0) | 40 | |

**[Table/Fig-6]:** Comparison of conventional USG (BI-RADS) with histopathology (n=40).

Emax showed the highest sensitivity (90.5%) and accuracy (87.5%), while Emax and Eratio showed equal specificity (84.2%) (84.2%) [Table/Fig-8-12].

The combined SWE and BI-RADS approach significantly improved diagnostic performance, achieving a sensitivity of 90.5%, specificity of 89.5%, and overall accuracy of 90.0% (p-value <0.001) [Table/Fig-13,14]. The representative images are shown in [Table/Fig-15-17].

| Measure | Value |
|---|---|
| Sensitivity | 100.0% |
| Specificity | 42.1% |
| Positive Predictive Value (PPV) | 65.6% |
| Negative Predictive Value (NPV) | 100.0% |
| Accuracy | 72.5% |

**[Table/Fig-7]:** Diagnostic performance of USG BI-RADS (IV as "test positive" for malignancy) (n=40).

| SWE parameter | AUC | Cut-off for malignancy |
|---|---|---|
| Emax | 0.808 | 91.0 kPa |
| Emean | 0.817 | 52.95 kPa |
| Eratio | 0.838 | 1.57 |

**[Table/Fig-8]:** ROC-derived SWE quantitative cut-offs for malignancy (kPa/ratio).

| Emax category | Benign n (%) | Malignant n (%) | Total | p-value* |
|---|---|---|---|---|
| <91 kPa | 16 (84.2) | 2 (9.5) | 18 | |
| ≥91 kPa | 3 (15.8) | 19 (90.5) | 22 | |
| Total | 19 (100.0) | 21 (100.0) | 40 | <0.001 |

**[Table/Fig-9]:** Association of SWE quantitative parameters with histopathology as per Emax (Cut-off 91 kPa).

| Emean category | Benign n (%) | Malignant n (%) | Total | p-value* |
|---|---|---|---|---|
| <52.95 kPa | 15 (78.9) | 3 (14.3) | 18 | |
| ≥52.95 kPa | 4 (21.1) | 18 (85.7) | 22 | |
| Total | 19 (100.0) | 21 (100.0) | 40 | <0.001 |

**[Table/Fig-10]:** Association of SWE quantitative parameters with histopathology as per Emean (Cut-off 52.95 kPa).

| Eratio category | Benign n (%) | Malignant n (%) | Total | p-value* |
|---|---|---|---|---|
| <1.57 | 16 (84.2) | 4 (19.0) | 20 | |
| ≥1.57 | 3 (15.8) | 17 (81.0) | 20 | |
| Total | 19 (100.0) | 21 (100.0) | 40 | <0.001 |

**[Table/Fig-11]:** Association of SWE quantitative parameters with histopathology as per Eratio (Cut-off 1.57).
*Chi-square test; Bold p-values indicate p <0.05

| Parameter (Cut-off) | Sensitivity | Specificity | PPV | NPV | Accuracy |
|---|---|---|---|---|---|
| Emax (≥91 kPa) | 90.5% | 84.2% | 86.4% | 88.9% | 87.5% |
| Emean (≥52.95 kPa) | 85.7% | 78.9% | 81.8% | 83.3% | 82.5% |
| Eratio (≥1.57) | 81.0% | 84.2% | 85.0% | 80.0% | 82.5% |

**[Table/Fig-12]:** Diagnostic performance of SWE quantitative parameters (n=40).

| Combined Result (SWE +USG BI-RADS) | Benign | Malignant | Total | p-value* |
|---|---|---|---|---|
| Classified benign | 17 (89.5%) | 2 (9.5%) | 19 | <0.001 |
| Classified malignant | 2 (10.5%) | 19 (90.5%) | 21 | |
| Total | 19 (100%) | 21 (100%) | 40 | |

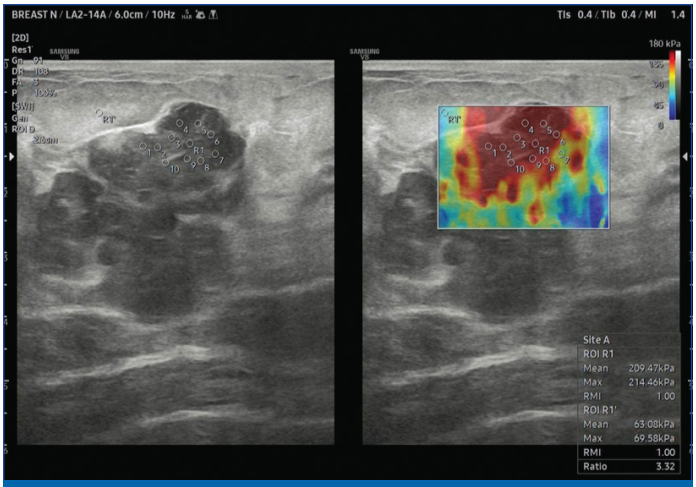
**[Table/Fig-13]:** Combined Classification: SWE quantitative (overall) + USG BI-RADS vs Histopathology (n=40).
*Chi-square test; Bold p-value indicates p <0.05

| Measure | Value |
|---|---|
| Sensitivity | 90.5% |
| Specificity | 89.5% |
| Positive Predictive Value (PPV) | 90.5% |
| Negative Predictive Value (NPV) | 89.5% |
| Accuracy | 90.0% |

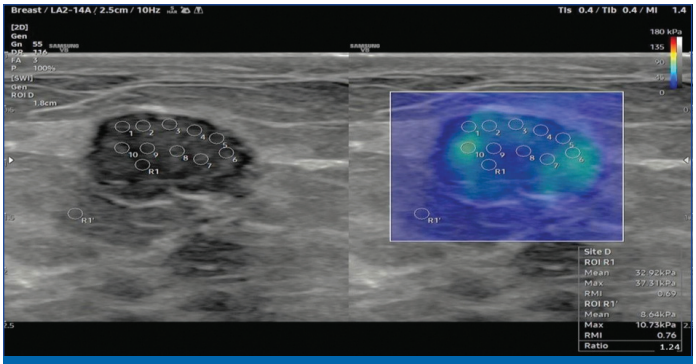
**[Table/Fig-14]:** Diagnostic performance of combined SWE quantitative +USG BIRADS (n=40).

## DISCUSSION

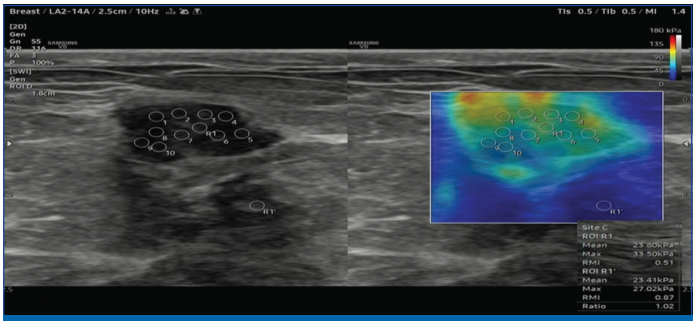
The present study evaluated the diagnostic utility of SWE as an adjunct to conventional ultrasonography in the characterisation of




**[Table/Fig-15]:** Gray-scale Ultrasonography (USG) demonstrates an irregular, hypoechoic lesion with lobulated margins, classified as BI-RADS 4B. Shear Wave Elastography (SWE) reveals a coloured lesion pattern with Emax= 214.46 kPa, Emean= 209.47 kPa, and an E-ratio of 3.32. The grayscale USG findings are suspicious for malignancy, and the elastography parameters also suggest malignant aetiology. Histopathological examination confirms the diagnosis of malignant invasive ductal carcinoma.




**[Table/Fig-16]:** Gray-scale ultrasound shows an oval hypoechoic lesion with focally lobulated margins (BI-RADS 4A). Shear Wave Elastography (SWE) demonstrates no increased stiffness (Emax 37.31 kPa, Emean 32.92 kPa, E-ratio 1.24), favouring benign pathology. Histopathology confirmed fibroadenoma.




**[Table/Fig-17]:** Gray-scale ultrasound shows an irregular hypoechoic lesion with angulated margins and minimal internal vascularity (BI-RADS 4A). Shear Wave Elastography (SWE) demonstrates no increased stiffness (Emax 33.50 kPa, Emean 23.80 kPa, E-ratio 1.02), favouring benign pathology. Histopathology confirmed absence of malignancy.

breast masses. Most patients presented with painless palpable lumps, emphasising the critical role of imaging in early lesion characterisation and risk stratification. These findings were comparable to those reported by Shehata R et al., Dawood MAE et al., and Pesce K et al., who also observed a predominance of symptomatic palpable masses in midlife women [14-16]. In the Shehata R et al., study, 46 of 51 patients had palpable breast masses (90.2%) [14].

Conventional B-mode ultrasonography demonstrated that most lesions were irregular and hypoechoic. Similar sonographic patterns have been reported by Shehata R et al., and Hari S et al., who described irregular morphology and hypoechoic echotexture as frequent features of malignant lesions, while benign lesions were typically oval or round [14,17].

SWE assessment in the present study demonstrated strong correlations with histopathological outcomes. ROC analysis identified optimal cut-off values for Emax, Emean, and Eratio, with Eratio showing the highest AUC, indicating superior discriminatory performance among the evaluated SWE parameters. These findings were in agreement with those reported by Shehata R et al., who evaluated 77 histopathologically proven breast lesions and demonstrated high diagnostic performance of elastographic parameters [14]. They reported an optimal elasticity score cut-off of >3 with sensitivity, specificity, and accuracy of 94.7%, 85.0%, and 90.9%, respectively (AUC=0.926), while the optimal mass strain ratio cut-off of >4.6 showed a sensitivity of 96.5% and specificity of 80.0% (AUC=0.860). The shear wave elasticity ratio cut-off of >4.9 demonstrated a sensitivity of 91.2% and specificity of 80.0% (AUC=0.890). They also found significantly higher mean strain ratio and shear wave elasticity ratio values in malignant lesions compared with benign lesions.

Similarly, Gheonea I et al., reported a sensitivity of 89.7% and specificity of 92.9% for sonoelastography in differentiating benign from malignant breast lesions, with an AUC of 0.924 (p-value =0.0001), supporting the complementary diagnostic value of elastography alongside conventional ultrasonography [18].

Marukatat N et al., similarly demonstrated significantly higher Emean and Eratio values in malignant lesions, with median Emean values of 141.60 kPa in malignant lesions compared with 26.20 kPa in benign lesions, and median Eratio values of 9.24 and 3.11, respectively [19]. Their optimal cut-off values for Emean and Eratio were 90.35 kPa and 5.89, respectively, with sensitivities of 87.1% and 82.8% and specificities of 89.1% and 83.7%, respectively. The meta-analysis by Selim YAY et al., further confirmed the high diagnostic accuracy of SWE across large patient cohorts, supporting its role as a valuable adjunct to conventional breast ultrasonography [20].

Importantly, the combined use of SWE quantitative parameters with BI-RADS classification significantly improved diagnostic performance by increasing specificity and overall accuracy while maintaining high sensitivity [Table/Fig-18] [14,18,19].

| Study | Elastography parameter | Cut-off value | Sensitivity (%) | Specificity (%) | AUC |
|---|---|---|---|---|---|
| Present study | Emax | ≥91.0 kPa | 90.5 | 84.2 | 0.808 |
| Present study | Emean | ≥52.95 kPa | 85.7 | 78.9 | 0.817 |
| Present study | Eratio | ≥1.57 | 81.0 | 84.2 | 0.838 |
| Shehata R et al., (2022) [15] | Shear-wave elasticity ratio (SWER) | >4.9 | 91.2 | 80.0 | 0.890 |
| Marukatat N et al., (2024) [20] | Emean | 90.35 kPa | 87.1 | 89.1 | - |
| Marukatat N et al., (2024) [20] | Eratio | 5.89 | 82.8 | 83.7 | - |
| Gheonea I et al., (2011) [19] | Elastography score | >3 | 89.7 | 92.9 | 0.924* |

**[Table/Fig-18]:** Comparison of diagnostic performance of Shear Wave Elastography (SWE) between the present study and previous studies [14,18,19].

## Limitation(s)

This study had several limitations. First, elastography and Doppler assessments remain operator dependent, and variations in technique and interpretation may influence measurements despite quantitative parameters. Second, differences in ultrasound equipment, transducers, and software algorithms may affect elasticity and vascularity values, limiting reproducibility across platforms. Another limitation of the study was the potential for verification bias arising from the lack of blinding to the BI-RADS category during the ultrasound and sonoelastography assessment. Knowledge of the conventional B-mode/BI-RADS findings may have influenced the interpretation or assessment of elastographic characteristics,

particularly in borderline lesions. Although all lesions underwent tissue diagnosis for final correlation, the absence of blinding could have introduced observer-related bias and may have resulted in an overestimation of the diagnostic performance of sono-elastography. Future prospective studies with blinded, independent assessment of BI-RADS and elastography findings would help minimise this potential bias.

Finally, the moderate sample size may restrict generalisability, and larger multicentre studies are needed to validate cut-off values and confirm clinical applicability.

## CONCLUSION(S)

Sonoelastography is a valuable adjunct to conventional ultrasonography in the evaluation of breast masses. While BI-RADS-based ultrasonography demonstrated excellent sensitivity, its limited specificity resulted in a substantial number of false-positive cases. Quantitative SWE parameters (Emax, Emean, and Eratio) showed strong and statistically significant correlations with histopathological outcomes, with higher stiffness values consistently associated with malignancy. The combined application of SWE quantitative parameters with BI-RADS classification significantly improved diagnostic performance.

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**PARTICULARS OF CONTRIBUTORS:**

1. Postgraduate Resident, Department of Radiodiagnosis, Adesh Medical College and Hospital, Mohri, Shahabad, Kurukshetra, Haryana, India.
2. Professor, Department of Radiodiagnosis, Adesh Medical College and Hospital, Mohri, Shahabad, Kurukshetra, Haryana, India.
3. Professor and Head, Department of Radiodiagnosis, Adesh Medical College and Hospital, Mohri, Shahabad, Kurukshetra, Haryana, India.
4. Senior Resident, Department of Radiodiagnosis, Adesh Medical College and Hospital, Mohri, Shahabad, Kurukshetra, Haryana, India.
5. Senior Resident, Department of Radiodiagnosis, Adesh Medical College and Hospital, Mohri, Shahabad, Kurukshetra, Haryana, India.
6. Postgraduate Resident, Department of Radiodiagnosis, Adesh Medical College and Hospital, Mohri, Shahabad, Kurukshetra, Haryana, India.

**NAME, ADDRESS, E-MAIL ID OF THE CORRESPONDING AUTHOR:**
Dr. Shubham Yadav,
Adesh Medical College and Hospital, Mohri, Shahabad, Kurukshetra-136134, Haryana, India.
E-mail: syadav21995@gmail.com



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