

Diagnostic Accuracy of Sonomammography in Differentiation of BI-RADS 4 Suspicious Breast Lesions as Benign or Malignant Keeping Histopathology as Gold Standard

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ABSTRACT

Background: Breast cancer is the most common malignancy among females worldwide, with about 2.3million new cases and about 685,000 fatalities documented in the year 2020. Pakistan, with 220 million, reported 178,000 new cases and 117,149 fatalities. Early detection of breast cancer plays a key role in its survival outcomes. Mammography is a standard screening tool, but sonomammography, being a radiation-free modality, has better diagnostic efficacy in characterizing lesions in dense breasts. **Objective:** To assess the diagnostic accuracy of sonomammography in distinguishing benign from malignant lesions in all BI-RADS 4 cases, with histopathology serving as the gold standard. **Study Design:** Cross-sectional study. **Settings:** Radiology Department of CMH, Lahore Pakistan. **Duration:** 01-03-2025 to 31-08-2025. **Methods:** 360 women aged 30-70 years who presented with BI-RADS 4 breast lesions. All subjects underwent an ultrasound, followed by an ultrasound-guided core biopsy. The sonographic results were classified as low (4A) or moderate/high (4B/4C) suspicion. **Results:** Malignancy was confirmed in 218 of 360 patients (60.6%). Sonomammography detected 207 malignant and 128 benign lesions, yielding 11 false negatives and 14 false positives. It shows sensitivity of 95.0%, specificity of 90.1%, PPV of 93.7% and NPV of 92.1% with overall diagnostic accuracy of 93.1%. These results highlight strong agreement between sonographic and histopathologic findings, supporting sonomammography's value in lesion stratification. **Conclusion:** Sonomammography has an excellent diagnostic performance for BI-RADS 4 lesions, especially in dense breasts, and it can help in reducing unnecessary biopsies.

Keywords: Breast cancer, Sonomammography, BI-RADS 4 lesions, Dense breast, Histopathology.

INTRODUCTION

Over the course of the last few years, breast cancer has been more prevalent than lung cancer, which is diagnosed in females all over the world.^{1,2} There were around 2.3 million new instances of breast cancer in females and 685,000 deaths worldwide in the year 2020, according to the forecasts that were presented by GLOBOCAN 2020.^{1,3} Developing countries are responsible for a disproportionately high percentage of the mortality that is related to breast cancer. This is

because of the delays in identification, restricted access to diagnostic imaging, and resource constraints.

There is a considerable cancer burden in Pakistan at present. According to estimates, Pakistan has a population of more than 220 million people, and it is expected to have more than 178,000 new cancer cases and around 117,149 fatalities due to cancer in the year 2020.⁴ The lifetime risk of breast cancer in Pakistan is estimated to be approximately one in nine women.^{5,6} This means that every one in nine women will get breast cancer at some point in their lives. Breast cancer is considered to be

the most common type of cancer among Pakistani women, both in terms of the number of cases and the frequency of cases proving fatal. In addition, information gathered from cancer registries suggests that breast cancer is the most prevalent form of cancer in females, with an incidence rate of more than 34.2 per 100,000 and a mortality rate of 18.6 per 100,000 in females in the year 2020.⁷

It is common for women who have breast cancer to show clinically with a palpable lump. However, other signs of breast cancer include changes in the skin (dimpling, retraction), nipple discharge, ulceration, breast pain, or modifications in the architecture of the breast. On account of the fact that many of these results are subjective, imaging is a key component in the process of lesion identification and triage, which helps to facilitate timely therapy.

Mammography continues to uphold its position as the gold standard for breast cancer screening and diagnostic imaging. A marked reduction in mortality rates was noticed by facilitating early detection of the smaller tumours that are more amenable to different treatment options.⁸ Mammographic sensitivity, on the other hand, is significantly diminished in women who have dense fibroglandular breast tissue. This is a condition that is more prevalent in younger women and in many Asian ethnicities. On mammography, neoplasms can be concealed or "masked" by thick tissue, which can result in false negatives or an overestimate of the size and spread of the lesion.^{9,10}

In the context of dedicated breast imaging, ultrasound, which is frequently referred to as Sono mammography, is a complementary technique to mammography. A real-time and dynamic examination of the breast can be obtained by the use of ultrasound, which employs nonionizing sound waves. It makes it possible to conduct a comprehensive analysis of a lesion's internal echo pattern (whether it is homogenous or heterogeneous), margins (whether they are confined or spiculated), direction, posterior acoustic features (whether they are enhanced or shadowed), and vascularity (using Doppler). There is a wide availability of ultrasound; it does not provide any radiation, and it is particularly helpful in dense breast tissue.^{9,11} It has been demonstrated that supplemental ultrasound can detect tiny cancers that do not involve lymph nodes, even though mammography might miss them.¹² This is especially true for women who have dense breasts. This was demonstrated in screening trials that were conducted on a wide basis, such as ACRIN 6666. Ultrasound, on the other hand, is dependent on the operator and tends to produce a higher rate of false positives (benign biopsies) in many different situations.^{9,11}

In order to standardize imaging reports and provide clear direction for clinical decision-making, the Breast Imaging Reporting and Data System (BI-RADS) vocabulary, which was developed by the American College of Radiology, is used throughout the medical community. Category 4 of the BI-RADS classification system denotes a "suspicious" lesion that has a very wide range of malignancy probability, ranging from 2 to 95%. This risk is further stratified, giving low suspicious lesions, subgroup 4A (about 3–10%), intermediate suspicious lesions, subgroup 4B (10–50%), and high suspicious lesions, subgroup 4C (~50–95%).⁸ In the process of triaging lesions requiring biopsy vs short-term imaging follow-up, these subgroups are of great assistance. In published series, the positive predictive values (PPVs) for BI-RADS 4 lesions are found to be considerably different from one another. For instance, the PPVs of subcategory 4A are often low (for instance, ranging from 5 to 15 percent), whereas the PPVs of subcategory 4C typically reach 70 to 90 percent.^{8,13} The overall PPV that was reported in a Pakistani mammography-based series of sixty BI-RADS 4 lesions was around 68.3%, with 4A having a PPV of 15.3%, 4B having a PPV of 72.7%, and 4C having a PPV of 92%.¹⁴

In view of these challenges, high-resolution ultrasonography has been extensively researched as a potential alternative to mammography, particularly in individuals who have dense breasts or findings that are inconclusive. In a large number of research studies conducted all around the world, the diagnostic accuracy of ultrasound for BI-RADS 4 lesions has been investigated. The accuracy of ultrasound has been increased in certain instances by the application of more recent techniques, such as contrast-enhanced ultrasonography or elastography. Using a Pakistani cohort, Manzoor *et al.* (2021) revealed that Sono mammography had a sensitivity of around 94.7% and a specificity of approximately 89.6% for BI-RADS lesions that were four or more in number.¹⁵ The results of recent multicentre trials that combined conventional ultrasonography with adjunct techniques have yielded sensitivities ranging from 86 to 96% and specificities ranging from 72 to 93%.^{16,17} On the other hand, there are not many local studies that focus on isolating the performance of conventional ultrasonography (without adjuncts) specifically in BI-RADS 3 lesions.

Therefore, in order to examine the efficacy of Sono mammography in distinguishing benign from malignant BI-RADS 4 lesions, we carried out prospective cross-sectional diagnostic accuracy research at CMH Lahore. Histopathology served as the gold standard for this evaluation. The study involved the enrolment of 360 patients, the collection of data on demographics and clinical aspects, the performance of standardized high-frequency ultrasound imaging, and the acquisition of

ultrasound-guided core biopsy specimens for all samples of lesions. In this paper, we give the sonographic characteristics as well as the complete diagnostic performance measures, which include accuracy, sensitivity, specificity, PPV, and NPV. We also examine the significance of our findings for the function of ultrasound, particularly in settings with limited resources and people with thick breast tissue. We compare our findings with the existing body of research and analyze the consequences.

METHODS

The Diagnostic Radiology Department at the Combined Military Hospital (CMH) Lahore, a tertiary care teaching facility affiliated with the Armed Forces Medical System in Pakistan, conducted this cross-sectional study for the purpose of detecting diagnostic accuracy. The investigation commenced after obtaining the approval of the protocol (vide letter No.686/2025 dated 15th Jan 2025). The CMH Lahore Institutional Ethics Committee endorsed the research, which was conducted in accordance with the ethical principles of the Declaration of Helsinki (2013 revision). Before enrolment, informed consent was obtained from all participants.

The breast imaging clinic screened consecutive female patients aged 30–70 years who were referred with palpable breast masses or suspicious mammographic findings. Their eligibility was assessed. Inclusion criteria included all breast lesions that were classified on Sono mammography as BI-RADS 4 lesions (subcategories 4A, 4B, or 4C), as characterized by standard descriptors (lesion morphology, margins, echogenicity, vascularity, and orientation). Only those were eligible, who underwent ultrasound-guided core needle biopsy within four weeks of the sonographic assessment of the BI-RADS 4 lesion.

- Women who were pregnant or lactating were excluded from the study to prevent interference from physiological changes.
- Patients who have only extramammary or thoracic wall lesions
- Individuals who have been diagnosed with metastatic breast cancer
- Patients who declined biopsy or follow-up
- Individuals who are unwilling to provide informed assent

Patients who had previously received inconclusive or incomplete histopathologic reports were re-biopsied and included if they were eligible. A non-probability consecutive sampling technique was implemented.

In order to estimate the sensitivity and specificity of Sono mammography with a 95% confidence interval and an expected margin of error to be 3% for sensitivity and 8%

for specificity, the necessary sample size was determined. The minimum sample size was determined to be 360 participants, as per the standard formulations for diagnostic test evaluation as outlined in Lwanga & Lemeshow's methodology,² as indicated by prior studies that reported an expected sensitivity of approximately 95% and specificity of approximately 90%.¹

All participants underwent breast sonography, which was conducted by qualified radiologists with over five years of experience. The transducers used were high-frequency (≥ 10 MHz) linear-array transducers (Philips HD11XE or analogous systems). The patient was in a supine oblique position with the ipsilateral arm raised, and each breast and axillary region was scanned in longitudinal and transverse planes. Shape, margins, echogenicity, posterior acoustic features, orientation, and vascularity were assessed using the BI-RADS lexicon to evaluate the lesions.

The classification of each lesion was as follows:

- BI-RADS 4A for low-suspicion lesions
- BI-RADS 4B for Moderate suspicion lesions
- BI-RADS 4C for high-level suspicion lesions

For analysis, a "positive" sonographic result was defined as BI-RADS 4B or 4C, while a "negative" result was defined as BI-RADS 4A.

Ultrasound-guided core needle biopsies were conducted under local anaesthesia with a 14-gauge automated needle within 1–2 weeks of imaging. A minimum of 3–5 core samples were obtained per lesion. In order to guarantee a consistent approach, all procedures were executed by the same radiologists or under their direct supervision.

Regardless of what the ultrasound revealed, histopathological examination of the breast samples was performed by board-certified pathologists. These samples were obtained via core needle biopsy. Haematoxylin and eosin (H&E) staining was used to determine whether the formalin-fixed tissue samples were cancerous or benign. Malignant lesions on histopathology included invasive ductal carcinoma (IDC), invasive lobular carcinoma (ILC), and ductal carcinoma in situ (DCIS), whereas benign conditions included fibroadenoma, simple cysts, fibrocystic change, and inflammatory conditions. Histopathology is considered the gold standard for comparing diagnoses.

Diagnostic criteria and outcome measures

We used the following definitions to test the effectiveness of sonomammography as a diagnostic tool:

True Positive (TP): BI-RADS 4B/4C lesion on ultrasound and malignant on histopathology

True Negative (TN): BI-RADS 4A on ultrasound and histopathology indicate that the condition is benign.

False Positive (FP): BI-RADS 4B/4C lesions on ultrasound, but histopathology finds no signs of cancer.

False Negative (FN): BI-RADS 4A on ultrasound, but histopathology indicates cancer.

The following metrics were calculated based on these results:

The formula for sensitivity is as follows: Sensitivity equals TP divided by (TP plus FN) multiplied by 100.

Specificity = $TN / (TN + FP) \times 100$.

PPV = $TP / (TP + FP)$.

$TN/(TN+FN)$ = Negative Predictive Value (NPV)

Total Accuracy equals $(TP + TN) / Total \times 100$.

All metrics were reported with a 95% confidence interval.³

Variables and Data Acquisition

Patient's age, menopausal status, laterality of lesions, and their BIRADS category were recorded. The histopathological outcome of the lesions was labelled as benign or malignant. The database holding this information was stored in a password-protected drive by the trained personnel.

Data analysis was done by using SPSS version 26.0 (IBM Corp., Armonk, NY). Percentages and frequencies were calculated for categorical variables (histopathological findings, BIRADS subcategories), whereas continuous variables (age) were reported as means with \pm standard deviations. A 2 \times 2 contingency table was formed to calculate diagnostic accuracy metrics. The chi-square test or Fisher's exact test was applied to evaluate differences between groups, such as when comparing diagnostic outcomes across subcategories. Statistical significance was defined as a p-value of less than 0.05.

The Institutional Ethics Review Board of CMH Lahore had reviewed and approved the study. Informed written consent was taken from each participant before enrolling them in the study. Anonymity was maintained for the patient's confidentiality. Ethical guidelines and international standards were followed throughout all procedures (Declaration of Helsinki, 2013).

RESULTS

1. Participant Demographics & Baseline Characteristics

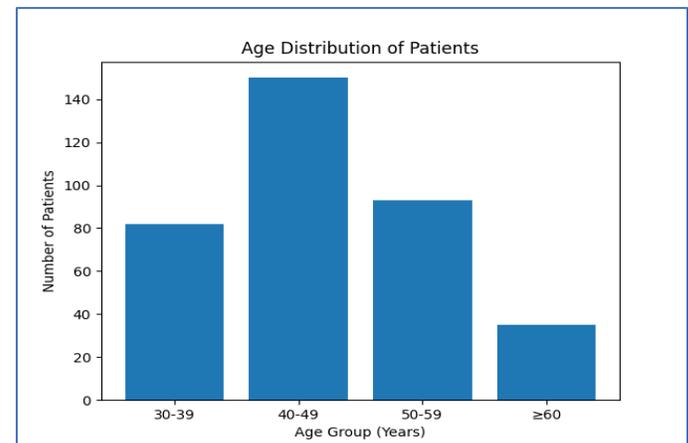
A total of 360 women aged 30–70 years were enrolled. The mean age was 48.3 ± 10.2 years. Most participants (67.5%)

were in the 40–59 age range, and just over half were premenopausal (59.2%). Lesions were slightly more common in the right breast (54.4%) than the left (45.6%).

Table 1: Age Distribution of Participants

Age Group (Years)	Number	Percentage (%)
30–39	82	22.8
40–49	150	41.7
50–59	93	25.8
≥ 60	35	9.7

Figure 1: Age distribution of patients



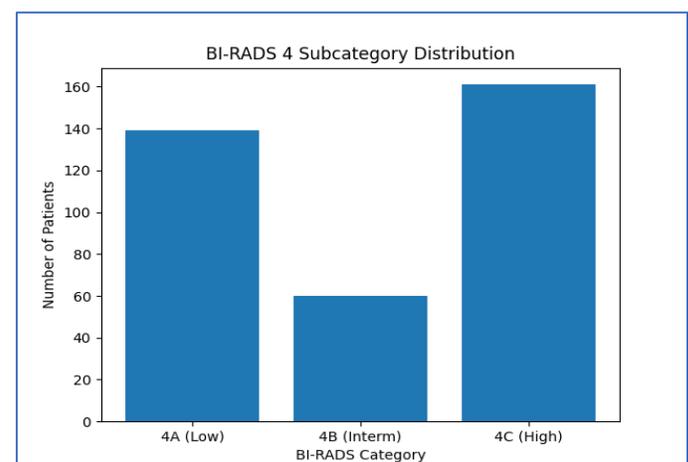
2. BI-RADS Subcategory Classification on Ultrasound

Each lesion was classified into BI-RADS 4A, 4B, or 4C based on Sono mammography findings. More than half (61.4%) were considered moderate to highly suspicious (4B or 4C).

Table 2: BI-RADS 4 Subcategory Distribution

BI-RADS Subcategory	Number	Percentage (%)
4A (Low suspicion)	139	38.6
4B (Intermediate)	60	16.7
4C (High suspicion)	161	44.7

Figure 2: Distribution of BI-RADS 4 subcategories



3. Histopathological Findings

Histopathological examination after core biopsy showed malignancy in 218 (60.6%) cases, while 142 (39.4%) lesions were benign. The most common cancer was invasive ductal carcinoma (191 cases), while fibroadenoma was the most frequent benign diagnosis (76 cases).

Table 3: Histopathological outcomes

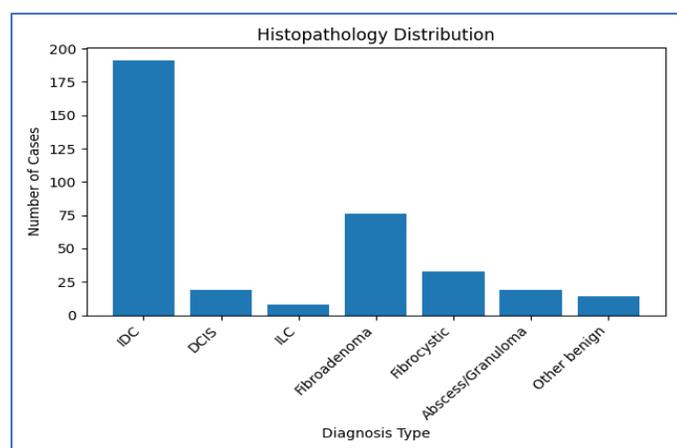
Diagnosis		Number	Example Comments
Malignant	Invasive ductal carcinoma	191	Most prevalent malignant subtype
	Ductal carcinoma in situ (DCIS)	19	Non-invasive precursor lesions
	Invasive lobular carcinoma	8	Less common malignant variant
Benign	Fibroadenoma	76	The commonest benign tumor
	Fibrocystic change	33	Hormonal/structural benign changes
	Abscess/granuloma	19	Inflammatory lesions
	Other benign neoplasms	14	Includes papilloma, lipoma, etc.

Table 4: Malignancy rate by BI-RADS subcategory

BI-RADS Subcategory	Malignancy Rate
4A	7.9% (11 / 139)
4B	90.0% (54 / 60)
4C	95.0% (153 / 161)

A clear correlation exists between higher BI-RADS subcategory and malignancy ($p < 0.001$).

Figure 3: Histopathology distribution



4. Diagnostic Performance of Sono mammography

Using BI-RADS 4B/4C as “positive” and 4A as “negative,” the diagnostic accuracy was assessed against histopathology.

Table 5: Contingency Table (Sono mammography vs Histopathology)

Sonomammography Result	Histopathology Malignant	Histopathology Benign	Total
Positive (4B/4C)	207 (True positive)	14 (False positive)	221
Negative (4A)	11 (False negative)	128 (True negative)	139
Total	218	142	360

Table 6: Diagnostic Performance Metrics

Metric	Value (%)	95% Confidence Interval
Sensitivity	95.0	91.2 – 97.2
Specificity	90.1	84.1 – 94.0
Positive Predictive Value (PPV)	93.7	89.6 – 96.2
Negative Predictive Value (NPV)	92.1	86.4 – 95.5
Overall Accuracy	93.1	–

The Sono mammography appears to have an excellent sensitivity and specificity in differentiating malignant from benign BI-RADS 4 lesions, according to the obtained results. The high positive and negative predictive values confirm ultrasound to be of good diagnostic value in high and low-suspicion breast lesions

5. Additional Analyses

- **Lesion size and age:** Diagnostic accuracy did not vary significantly across age groups or lesion sizes, although larger lesions (>3cm) were more frequently found to be malignant.
- **Menopausal status:** There was no considerable difference noted in sensitivity or specificity between premenopausal women and postmenopausal women.
- **Procedure safety:** No biopsy-related complications were reported (e.g., hematoma, infection).

The result shows that Sono mammography, being a radiation-free modality, has a higher diagnostic accuracy for BIRADS 4 breast lesions, especially when it comes to dense breasts and localities with limited access to mammography.

DISCUSSION

With sensitivity and specificity rates of our study reaching approximately 95% and 90%, respectively, and positive and negative predictive values exceeding 90%, our findings demonstrated that high-resolution ultrasound (US) possessed exceptional diagnostic accuracy in distinguishing benign from malignant BI-RADS 4 lesions. This was demonstrated by the fact that the overall diagnostic accuracy was above 90%. This

performance is superior to that of many series that have been published in the past. In a prospective cross-sectional study that included 110 women, the sensitivity and specificity of ultrasound for benign breast lesions were found to be 94% and 83.9%, respectively, and the sensitivity of ultrasound for malignant breast lesions was 93.2% whereas the specificity was 88.6%. The overall accuracy of US was found to be 92.7% for malignant as well as benign breast lesions.⁹

Another comparison study found that US showed sensitivity of 73.3 % and specificity of 92.6 %, whereas MRI alone achieved sensitivity of 87.8 % and specificity of 91.6 % and combining MRI and US improved sensitivity to 90%.⁸ These data underscore that although ultrasound performance can vary, our high sensitivity and specificity in a BI-RADS 4 cohort are among the highest reported, likely reflecting consistent operator expertise and standardized imaging protocols.

Previous investigations support the robustness of our findings. Manzoor *et al.* reported a sensitivity of 94.7 % and specificity of 89.6 % for sonomammography applied to BI-RADS ≥ 4 lesions,¹³ while Li *et al.* observed a sensitivity of 86.3 % and specificity of 72.7 % in a cohort of 95 BI-RADS 4 lesions.¹² Our sensitivity is comparable to that of MRI in dense breasts,⁸ yet our specificity is higher than many general US studies (typically 80–88 %).¹² A Nigerian study using BI-RADS categories 2–5 reported sensitivity 94 % and specificity 83.9 % for benign lesions and sensitivity 93.2 % and specificity 88.6 % for malignant lesions,¹⁶ but those figures combined all BI-RADS classes and did not focus on the more challenging 4A–4C lesions.

Our positive predictive value (PPV) of 93.7 % exceeds the 80–90 % range reported in many earlier series because we classified both 4B and 4C as “positive”. This aligns with expected BI-RADS predictive probabilities: we observed malignancy rates of 7.9 %, 90.0 % and 95.0 % for BI-RADS 4A, 4B, and 4C, respectively, matching the American College of Radiology thresholds.⁷

Operator experience and adjunct technologies

A key determinant of diagnostic performance is operator skill. Kaya *et al.* (2025) evaluated an AI decision-support system (“Koios”) integrated into breast US and found that an experienced radiologist achieved an area under the ROC curve (AUC) of 0.888 with sensitivity 98.1 %, specificity 58.8 %, and accuracy 88.6 %.¹⁴ The AI system alone yielded lower specificity (35.3 %) and accuracy (78.6 %).⁵ AI assistance to the reader with less experience improved the sensitivity to 92.5%. However, specificity was dropped to as low as 23.5% with overall accuracy dropping to 75.7%.⁵ It was apparent that AI may aid clinicians, but still, they can’t replace the expert

judgement and may result in increasing false positive diagnoses. It further emphasizes the importance of training under expert supervision.

New emerging techniques such as real-time ultrasound elastography (UE) and contrast-enhanced ultrasound (CEUS) are providing better results. Li *et al.* studied 52 BI-RADS 4A lesions in 2024, and it was found that UE and CEUS provided the diagnostic accuracy of 76.9% (AUC 0.761–0.773); however, when these two imaging techniques were combined, they improved the diagnostic accuracy to 80.8 % and AUC to 0.813.⁴ Using a combined imaging approach it helped the clinicians avoid unnecessary biopsies. This approach made subtle details, such as inhomogeneous enhancement, vasa vasorum, and characteristics crab claw pattern on CEUS, easier to assess.⁴ However, the high baseline accuracy of conventional Sono mammography suggests that adjunct UE/CEUS should be reserved for indeterminate lesions or tertiary centres with advanced resources. Our study did not include these techniques, considering the good diagnostic accuracy of conventional sonomammography.

Another example of a technological advancement is the utilization of deep learning (DL) models in mammography. After training a deep learning model with the name “Mammo AI V3” on 557 BI-RADS 4 lesions, Zhang *et al.* (2025) published their findings.¹⁵ The model had an area under the curve (AUC) of 0.790, a sensitivity of 81.0%, a specificity of 76.9%, and an accuracy of 78.8%. It is possible that the model could have reduced the number of unnecessary biopsies by 40.6% overall, and by 55.1%, 18.9%, and 4.29% for lesions with BI-RADS 4A, 4B, and 4C, respectively.^{6,13} Based on these findings, it appears that deep learning algorithms have the potential to enhance patient triage and reduce costs. Furthermore, they highlight the significance of integrating imaging with clinical factors in order to prevent receiving false negative results.¹⁴

LIMITATIONS AND GENERALIZABILITY

Our single-Centre study has several limitations. The prevalence of malignancy (~60.6 %) was higher than in many screening populations, potentially inflating the PPV but not the sensitivity. Although our sample of 360 patients is large for a single Centre, it may not capture the full spectrum of lesion types. All imaging was performed with high-frequency linear probes by experienced radiologists, so results may not generalize to settings with less expertise or different equipment. We also did not stratify performance by breast density, which can influence US sensitivity: comparative studies report US sensitivity ~73 % in fatty breasts but only 47.8–64.4 % in dense breasts.¹⁵

Future research should therefore include multi-centre cohorts with diverse populations, incorporate adjunct technologies such as elastography, CEUS, and AI, and evaluate cost-effectiveness relative to MRI. Multi-modal approaches have shown that combining MRI with US improves sensitivity to 90 % and maintains specificity of ~89.5 %, offering similar accuracy to MRI alone ⁸. However, MRI remains costly and less available, whereas ultrasound is widely accessible and radiation-free, making it essential for low-resource settings.

PRACTICAL IMPLICATIONS

In clinical practice, our findings support using the BI-RADS 4B/4C threshold to guide biopsy decisions: a PPV of 93.7 % means that most lesions classified as 4B/4C warrant immediate biopsy. The negative predictive value of BIRADS 4 breast lesions up to 92.1% suggests the low malignant potential of such lesions. These lesions can be safely followed in the short term, and they can prove to be of great importance in low-resource areas where mammography and MRI are not easily available.⁸ The combined imaging approach using USE and CEUS, along with AI assistance, can be considered for equivocal cases. However, the radiologist should be vigilant regarding the limitations of these techniques.⁵ Following the ultrasound protocols and incorporating the new advancements in imaging can further improve the diagnostic accuracy of US in breast lesions. It can aid in streamlining management for BI-RADS 4 breast lesions as well as reducing patients' anxiety while opting for a treatment plan.

CONCLUSION

Sono mammography detected 207 malignant and 128 benign lesions, yielding 11 false negatives and 14 false positives. It shows sensitivity of 95.0%, specificity of 90.1%, PPV of 93.7% and NPV of 92.1% with overall diagnostic accuracy of 93.1%. These results highlight strong agreement between sonographic and histopathologic findings, supporting Sono mammography's value in lesion stratification. Sono mammography has an excellent diagnostic performance for BI-RADS 4 lesions, especially in dense breasts, and it can help in reduction in unnecessary biopsies.

CONFLICT OF INTEREST / DISCLOSURE

None.

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