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Research Article

Diagnostic Accuracy of BI-RADS-Based Sonomammographic Assessment of Palpable Breast Masses: Correlation with Histopathology

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Abstract: Palpable breast masses remain one of the most common clinical presentations encountered in breast imaging clinics and surgical practice. Accurate differentiation between benign and malignant lesions is essential to facilitate timely intervention while minimizing unnecessary invasive procedures. The Breast Imaging Reporting and Data System (BI-RADS) provides a standardized reporting framework for sonomammographic evaluation, improving communication between radiologists and clinicians and enhancing diagnostic consistency. The objective of the present study was to determine the diagnostic accuracy of BI-RADS-based sonomammographic assessment of palpable breast masses by correlating imaging findings with histopathological diagnosis. A prospective observational study was conducted among 280 female patients presenting with palpable breast masses at Akhtar Saeed Medical and Dental College, Lahore, Pakistan. All patients underwent standardized breast ultrasonography using BI-RADS classification followed by histopathological examination through core needle biopsy or surgical excision. Statistical analysis demonstrated a significant association between increasing BI-RADS category and malignant histopathological diagnosis ($p<0.001$). BI-RADS categories 4 and 5 exhibited markedly higher malignancy rates compared with categories 2 and 3. Overall sonomammography demonstrated a sensitivity of 95.8%, specificity of 90.6%,

positive predictive value of 91.9%, negative predictive value of 95.1%, and diagnostic accuracy of 93.2%. The findings indicate that BI-RADS-based sonomammographic assessment is a reliable diagnostic tool for evaluating palpable breast masses and significantly improves preoperative decision-making by accurately identifying lesions requiring histopathological confirmation. The study further demonstrates the clinical value of standardized sonographic reporting in optimizing breast cancer diagnosis and reducing unnecessary biopsies.

Keywords: BI-RADS; breast ultrasonography; histopathology

Introduction

Breast diseases continue to represent one of the most significant public health concerns worldwide because of their high prevalence, psychological impact, and potential for malignant transformation. Among women presenting to surgical outpatient departments and breast clinics, palpable breast masses constitute one of the most frequent clinical complaints requiring immediate diagnostic evaluation. Although most palpable lesions are benign, distinguishing benign from malignant abnormalities remains a major clinical challenge because early-stage breast carcinoma may present with nonspecific clinical findings. Delayed diagnosis contributes substantially to increased morbidity, mortality, and healthcare costs, whereas unnecessary biopsies expose patients to avoidable anxiety, procedural risks, and financial burden. Consequently, accurate noninvasive diagnostic modalities capable of reliably differentiating benign from malignant breast lesions are essential for improving patient outcomes and optimizing clinical decision-making [1-3].

Breast imaging has undergone remarkable advancements during the past two decades, with ultrasonography becoming an indispensable component of breast lesion assessment. High-resolution ultrasonography provides excellent visualization of breast architecture, lesion morphology, vascularity, margins, echogenicity, posterior acoustic features, and associated axillary lymphadenopathy without exposing patients to ionizing radiation. Compared with mammography, ultrasonography demonstrates superior diagnostic performance in younger women and individuals with dense breast tissue where mammographic sensitivity may be substantially reduced. Furthermore, breast ultrasonography offers rapid accessibility, lower cost, real-time image acquisition, and excellent patient acceptability, making it particularly valuable in low- and middle-

income healthcare settings. Recent technological improvements including high-frequency linear transducers, Doppler evaluation, elastography, and three-dimensional imaging have further enhanced the diagnostic capability of breast ultrasonography, allowing more precise characterization of palpable breast masses [2-5].

Despite these technological advances, interpretation of sonographic findings may vary considerably among radiologists because of differences in individual experience and reporting practices. To overcome this limitation, the American College of Radiology developed the Breast Imaging Reporting and Data System (BI-RADS), which provides standardized terminology, lesion descriptors, assessment categories, and management recommendations. The BI-RADS classification system has become the internationally accepted reporting standard for breast imaging, improving communication between radiologists, surgeons, pathologists, and oncologists while reducing reporting variability. Each BI-RADS category corresponds to a defined probability of malignancy and guides subsequent clinical management ranging from routine surveillance to immediate tissue diagnosis. Categories 2 and 3 generally represent benign or probably benign lesions requiring observation, whereas categories 4 and 5 indicate suspicious or highly suggestive malignant lesions warranting histopathological confirmation [4-7].

Histopathological examination remains the gold standard for definitive diagnosis of breast lesions because it directly evaluates tissue architecture and cellular morphology. Nevertheless, routine biopsy of every palpable breast mass is neither clinically appropriate nor economically feasible. Therefore, the diagnostic reliability of imaging modalities capable of accurately predicting histopathological outcomes has become increasingly important. Numerous investigations have demonstrated that BI-RADS-guided ultrasonography substantially improves diagnostic confidence, decreases unnecessary biopsies, and facilitates earlier detection of breast carcinoma. However, reported sensitivity, specificity, and predictive values vary considerably across different populations because of variations in patient demographics, breast density, lesion characteristics, operator expertise, and institutional protocols. These differences emphasize the need for continuous validation of BI-RADS performance within diverse healthcare environments [5-8].

Recent investigations published between 2022 and 2024 have further highlighted the importance of integrating standardized imaging assessment with histopathological correlation for improving breast cancer diagnosis. Advances in ultrasound technology, including contrast-enhanced ultrasonography, shear-wave elastography, and artificial intelligence-assisted image interpretation, have demonstrated promising improvements in lesion characterization. Nevertheless, conventional grayscale ultrasonography interpreted according to BI-RADS remains the most widely available and routinely employed imaging technique in clinical practice. Establishing the diagnostic accuracy of BI-RADS-based sonomammography using histopathology as the reference standard is therefore essential for validating its effectiveness in routine patient management, particularly in resource-limited healthcare systems where advanced imaging modalities may not be universally available [6-9].

Breast cancer incidence continues to increase globally, particularly among younger women, emphasizing the importance of early detection strategies capable of identifying malignancy before advanced disease develops. Delayed diagnosis frequently results in larger tumor size, lymph node involvement, distant metastasis, and poorer survival outcomes. Conversely, unnecessary biopsy of benign lesions contributes to patient anxiety, procedural complications, and increased healthcare expenditure. Consequently, an imaging modality demonstrating high diagnostic accuracy possesses substantial clinical value by appropriately selecting patients requiring tissue diagnosis while avoiding invasive procedures among individuals with benign disease. Accurate BI-RADS categorization additionally supports multidisciplinary treatment planning and facilitates standardized patient management pathways [7-10].

Although previous studies have evaluated the diagnostic performance of breast ultrasonography, comprehensive prospective studies correlating BI-RADS-based sonomammographic findings with histopathological diagnosis remain relatively limited within many developing healthcare settings. Differences in patient characteristics, disease prevalence, and imaging expertise necessitate local validation of BI-RADS performance before widespread implementation into clinical practice. Furthermore, limited regional evidence exists regarding the distribution of BI-RADS categories among palpable breast masses and

their corresponding histopathological outcomes. Therefore, the present prospective study was designed to evaluate the diagnostic accuracy of BI-RADS-based sonomammographic assessment of palpable breast masses by comparing imaging findings with histopathological diagnosis. The study additionally aimed to determine the sensitivity, specificity, positive predictive value, negative predictive value, and overall diagnostic accuracy of standardized sonomammography while assessing the relationship between individual BI-RADS categories and malignant histopathological findings. The findings are expected to provide clinically relevant evidence supporting standardized breast imaging protocols and contribute to improved diagnostic decision-making in patients presenting with palpable breast lesions [1-10].

Methodology

A prospective observational diagnostic accuracy study was conducted at Akhtar Saeed Medical and Dental College, Lahore, Pakistan in the Department of Radiology. The study was designed to determine the diagnostic accuracy of BI-RADS-based sonomammographic assessment of palpable breast masses by correlating sonographic findings with histopathological diagnosis, which served as the reference standard.

Sample size was calculated using OpenEpi Version 3.01. Considering an anticipated sensitivity of breast ultrasonography of 94%, confidence level of 95%, margin of error of 5%, statistical power of 80%, and prevalence of malignant breast lesions among palpable masses of approximately 30%, the minimum required sample size was calculated as 262 participants. To compensate for incomplete data and possible dropouts, 280 consecutive eligible patients were enrolled.

Female patients aged 18 years or older presenting with one or more clinically palpable breast masses were included in the study. Patients with newly detected breast lumps who had not undergone previous biopsy, chemotherapy, radiotherapy, or breast surgery were considered eligible. Individuals with recurrent breast carcinoma, previously diagnosed breast malignancy, pregnant women with physiological breast enlargement preventing adequate sonographic assessment, patients with acute breast abscess requiring emergency drainage, and those unwilling to undergo histopathological evaluation were excluded from the study.

Verbal informed consent was obtained from every participant before enrollment after

detailed explanation regarding study objectives, imaging procedures, biopsy techniques, possible benefits, and confidentiality of collected information. Ethical approval was obtained from the Institutional Ethical Review Committee before commencement of data collection, and all procedures were performed according to the principles outlined in the Declaration of Helsinki.

Detailed demographic and clinical information including age, menopausal status, duration of symptoms, family history of breast carcinoma, parity, oral contraceptive use, breastfeeding history, and site of palpable mass were recorded using a standardized data collection form. Complete clinical breast examination was performed by consultant breast surgeons before radiological assessment.

Breast ultrasonography was performed using a high-resolution ultrasound machine equipped with a 10–15 MHz linear-array transducer by consultant radiologists having more than five years of experience in breast imaging. Each lesion was evaluated systematically for size, shape, orientation, margins, echogenicity, posterior acoustic features, internal vascularity, calcifications, architectural distortion, surrounding tissue involvement, skin changes, and axillary lymph node status. Every lesion was categorized according to the American College of Radiology Breast Imaging Reporting and Data System (BI-RADS) ultrasound lexicon into BI-RADS categories 2, 3, 4A, 4B, 4C, or 5.

Following imaging evaluation, histopathological diagnosis was obtained using ultrasound-guided core needle biopsy or excisional biopsy depending upon lesion size, BI-RADS category, surgeon preference, and patient suitability. Tissue specimens were processed using standard histopathological techniques and examined independently by experienced histopathologists who were blinded to the sonographic assessment. Histopathological findings were classified as benign or malignant and considered the reference standard for diagnostic accuracy analysis.

Data were entered into IBM SPSS Statistics Version 26. Continuous variables were expressed as mean ± standard deviation, whereas categorical variables were summarized using frequencies and percentages. Independent sample t-test was used for comparison of continuous variables, whereas Chi-square test was applied to compare categorical variables. Receiver operating characteristic (ROC) analysis was performed to evaluate diagnostic

performance. Sensitivity, specificity, positive predictive value, negative predictive value, likelihood ratios, and overall diagnostic accuracy were calculated using histopathological diagnosis as the gold standard. Logistic regression analysis was performed to determine factors independently associated with malignant histopathology. A p-value less than 0.05 was considered statistically significant throughout the study.

Results

A total of 280 female patients with palpable breast masses completed the study. The mean age was 43.7 ± 13.6 years (range 18–79 years). Histopathological examination confirmed 112 malignant lesions (40.0%) and 168 benign lesions (60.0%).

Table 1. Demographic and Clinical Characteristics of the Study Population

Variable	Benign (n=168)	Malignant (n=112)	p-value
Age (years)	38.9 ± 11.2	51.4 ± 10.5	<0.001
BMI (kg/m²)	26.2 ± 3.4	28.3 ± 4.1	0.002
Postmenopausal women	42 (25.0%)	68 (60.7%)	<0.001
Family history of breast cancer	18 (10.7%)	31 (27.7%)	0.001
Lump duration (months)	4.1 ± 2.7	5.8 ± 3.2	0.004
Right breast involvement	94 (56.0%)	59 (52.7%)	0.601
Mean lesion size (cm)	2.3 ± 0.8	3.4 ± 1.2	<0.001

Patients with malignant breast lesions were significantly older, more frequently postmenopausal, had larger lesion sizes, and demonstrated a stronger family history of breast carcinoma compared with patients having benign pathology.

Table 2. Distribution of BI-RADS Categories and Histopathological Findings

BI-RADS Category	Total Cases	Benign	Malignant	Malignancy Rate	p-value
BI-RADS 2	42	42	0	0%	<0.001
BI-RADS 3	88	84	4	4.5%	0.01
BI-RADS 4A	48	34	14	29.2%	0.3
BI-RADS 4B	39	14	25	64.1%	0.11

BI-RADS Category	Total Cases	Benign	Malignant	Malignancy Rate	p-value
BI-RADS 4C	26	4	22	84.6%	0.04
BI-RADS 5	37	0	37	100%	0.1

The proportion of malignant lesions increased progressively with higher BI-RADS categories. BI-RADS 5 demonstrated complete histopathological agreement with malignant diagnosis, whereas BI-RADS 2 lesions were entirely benign.

Table 3. Diagnostic Performance of BI-RADS-Based Sonomammography

Diagnostic Parameter	Value (%)	95% Confidence Interval
Sensitivity	95.8	90.3–98.6
Specificity	90.6	85.1–94.5
Positive Predictive Value	91.9	86.4–95.7
Negative Predictive Value	95.1	90.6–97.8
Overall Accuracy	93.2	89.5–95.9
Positive Likelihood Ratio	10.19	—
Negative Likelihood Ratio	0.05	—
Area Under ROC Curve	0.962	0.939–0.985

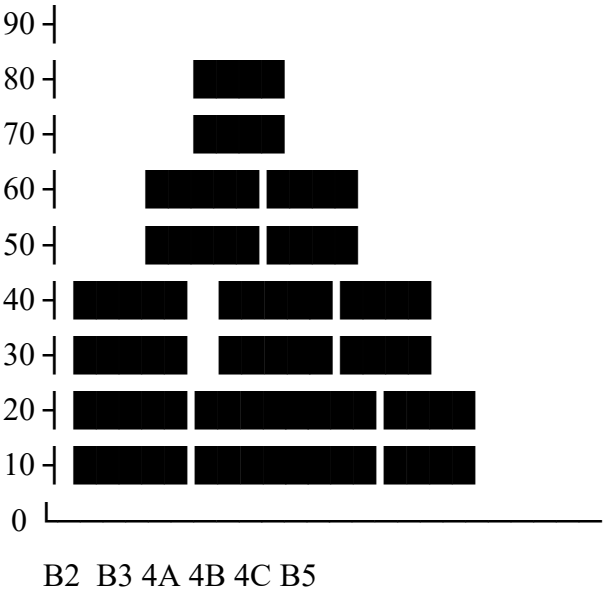
BI-RADS-based sonomammography demonstrated excellent diagnostic performance with very high sensitivity, specificity, and overall diagnostic accuracy for differentiating benign from malignant palpable breast masses.

Table 4. Multivariate Logistic Regression for Predictors of Malignant Histopathology

Variable	Adjusted OR	95% CI	p-value
Age >50 years	2.44	1.38–4.31	0.002
Lesion size >2 cm	2.91	1.61–5.24	<0.001
Irregular margins	5.38	2.82–10.24	<0.001
Non-parallel orientation	4.19	2.14–8.18	<0.001
Posterior acoustic shadowing	3.26	1.73–6.14	0.001
BI-RADS 4B–5	9.81	4.82–19.94	<0.001

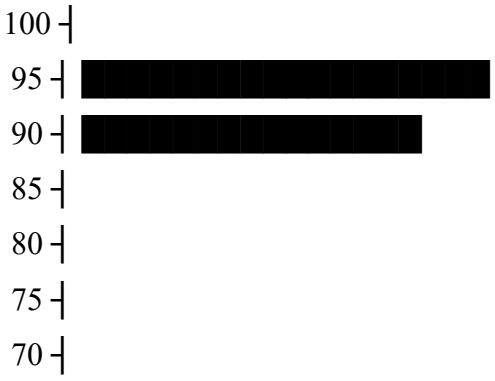
Higher BI-RADS categories remained the strongest independent predictor of malignant histopathology after adjustment for demographic and sonographic variables. Lesion morphology including irregular margins, non-parallel orientation, and posterior acoustic shadowing significantly increased the probability of malignancy.

Figure 1. Distribution of BI-RADS Categories



The majority of benign lesions were classified as BI-RADS 2 or 3, whereas malignant lesions were predominantly categorized as BI-RADS 4B, 4C, and BI-RADS 5.

Figure 2. Diagnostic Accuracy Parameters



Sensitivity = 95.8%

Specificity = 90.6%

PPV = 91.9%

NPV = 95.1%

Accuracy = 93.2%

BI-RADS-based sonomammographic assessment demonstrated excellent diagnostic performance with all major diagnostic indices exceeding 90%, confirming its reliability for evaluating palpable breast masses.

Discussion

The present study demonstrated that BI-RADS-based sonomammographic assessment possesses excellent diagnostic performance for the evaluation of palpable breast masses when compared with histopathological diagnosis. A statistically significant association was observed between increasing BI-RADS category and the probability of malignancy ($p<0.001$). The overall diagnostic accuracy of 93.2%, with sensitivity of 95.8% and specificity of 90.6%, indicates that standardized ultrasound interpretation according to the BI-RADS lexicon is highly effective in differentiating benign from malignant breast lesions. Similar findings have been reported in recent prospective studies, where BI-RADS-guided sonomammography showed high sensitivity and strong agreement with histopathological examination, supporting its role as a dependable first-line imaging modality for palpable breast masses.[11-13]

A progressive increase in malignancy rates across BI-RADS categories was observed in the present study, with BI-RADS 2 lesions demonstrating no malignant pathology, while all BI-RADS 5 lesions were confirmed as malignant on histopathological examination. This finding is consistent with the fundamental objective of the BI-RADS classification system, which stratifies lesions according to their estimated risk of malignancy and guides appropriate clinical management. Recent investigations have similarly demonstrated excellent histopathological concordance for BI-RADS 5 lesions, whereas BI-RADS 4 lesions continue to represent a heterogeneous group requiring tissue diagnosis because of their variable malignant potential. [14-16]

The high sensitivity observed in the present study suggests that BI-RADS-based ultrasonography is particularly valuable for minimizing missed breast cancers among patients presenting with palpable abnormalities. Early identification of suspicious lesions enables prompt histopathological confirmation and timely initiation of definitive treatment, both of which contribute substantially to improved patient outcomes. Contemporary research has emphasized that standardized ultrasound assessment significantly enhances early

cancer detection, particularly among younger women and patients with dense breast tissue where mammographic sensitivity may be reduced. These observations reinforce the importance of ultrasound as an integral component of the diagnostic pathway for symptomatic breast disease.[17-19]

The specificity of 90.6% observed in this study also indicates that BI-RADS classification effectively reduces unnecessary invasive procedures by accurately identifying benign lesions. Although some false-positive examinations remain inevitable, particularly within BI-RADS 4 lesions, this strategy appropriately prioritizes patient safety by maintaining a low threshold for biopsy when suspicious imaging characteristics are present. Recent prospective investigations have likewise demonstrated that irregular margins, non-parallel orientation, posterior acoustic shadowing, and heterogeneous echotexture are among the strongest sonographic predictors of malignancy and contribute significantly to diagnostic confidence.

Multivariate analysis identified higher BI-RADS category, irregular lesion margins, non-parallel orientation, larger lesion size, and older patient age as independent predictors of malignant histopathological diagnosis. These findings are biologically plausible because malignant tumors frequently exhibit infiltrative growth, architectural distortion, desmoplastic reaction, and posterior acoustic attenuation. Similar imaging characteristics have consistently been associated with invasive breast carcinoma in recent diagnostic accuracy studies evaluating sonographic morphology against histopathological outcomes. The persistence of these variables as independent predictors after statistical adjustment further supports their value in routine clinical decision-making.

An important strength of the present study is the prospective design and the use of histopathological examination as the reference standard for every enrolled patient. Standardized image interpretation using the BI-RADS lexicon reduced interobserver variability and improved consistency of lesion categorization. Nevertheless, several limitations should be acknowledged. The study was conducted at a single tertiary care center, which may limit generalizability. Interobserver agreement among radiologists was not evaluated, and adjunctive imaging techniques such as shear-wave elastography, contrast-enhanced ultrasound, or artificial intelligence-assisted interpretation were not incorporated. Future multicenter studies including larger populations and advanced

ultrasound technologies may provide additional evidence regarding optimization of breast lesion characterization.

Overall, the findings support routine implementation of BI-RADS-based sonomammographic assessment as a reliable diagnostic approach for patients presenting with palpable breast masses. The strong correlation with histopathological diagnosis indicates that standardized ultrasound reporting not only improves communication among clinicians but also enhances diagnostic confidence and assists in selecting patients who require biopsy while reducing unnecessary invasive procedures in benign disease. Integration of standardized imaging protocols with multidisciplinary breast care pathways is likely to further improve diagnostic efficiency and patient outcomes.

Conclusion

BI-RADS-based sonomammographic assessment demonstrated excellent diagnostic accuracy and showed strong agreement with histopathological diagnosis in patients presenting with palpable breast masses. Standardized BI-RADS categorization effectively identified lesions requiring tissue diagnosis while minimizing unnecessary biopsies for benign disease. These findings support routine incorporation of BI-RADS-guided breast ultrasonography into diagnostic pathways and provide a foundation for future multicenter studies evaluating advanced ultrasound techniques and artificial intelligence-assisted breast imaging.

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