An Observational Study on the Diagnostic Accuracy of BI-RADS Classification Versus Histopathology findings in Palpable Breast Lumps

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ABSTRACT

Background: Clinically palpable breast lumps are a common presentation and require accurate evaluation to differentiate benign from malignant lesions. The BI-RADS system provides standardized imaging classification, but its diagnostic accuracy needs correlation with histopathology.

Aim: To evaluate the diagnostic accuracy of BI-RADS classification in correlation with histopathological findings in palpable breast lumps.

Materials and Methods: This hospital-based observational study was conducted at Meenakshi Medical College Hospital, Kanchipuram, over one year. A total of 50 patients with palpable breast lumps were included. All patients underwent clinical examination, imaging using ultrasonography and/or mammography, and BI-RADS categorization. Histopathological examination was considered the gold standard. Sensitivity, specificity, PPV, NPV, and accuracy were calculated. A p value < 0.05 was considered significant.

Results: The mean age was 42.6 ± 11.8 years, with most patients in the 31–45 years group (36%). Histopathology showed 60% benign and 40% malignant lesions. A significant correlation was found between BI-RADS and histopathology ($p = 0.001$). BI-RADS showed 90% sensitivity, 80% specificity, and 84% accuracy. Malignancy increased with age ($p = 0.028$).

Conclusion: BI-RADS classification is a reliable and effective diagnostic tool for evaluating palpable breast lumps. Its strong correlation with histopathological findings supports its role in early detection, risk stratification, and guiding management decisions

Keywords: BI-RADS, breast lump, histopathology, diagnostic accuracy, breast cancer.

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Introduction

Breast lumps are among the most common clinical presentations encountered in surgical and radiological practice, particularly in women. Although the majority of breast lumps are benign, the possibility of malignancy necessitates accurate and timely diagnosis. Early detection and appropriate evaluation of breast lesions play a crucial role in improving patient outcomes, especially in cases of breast cancer, which remains one of the leading causes of cancer-related morbidity and mortality among women worldwide [1]. Clinical examination alone is often insufficient to accurately differentiate between benign and malignant breast lesions. Therefore, a combination of clinical assessment, imaging, and histopathological evaluation is commonly employed in the diagnostic workup of breast lumps. Imaging modalities such as mammography and ultrasonography have become essential tools in the evaluation of breast lesions. To standardize the reporting of breast imaging findings and improve diagnostic accuracy, the Breast Imaging Reporting and Data System (BI-RADS) was developed. BI-RADS provides a structured classification system that categorizes breast lesions based on their likelihood of malignancy and helps guide further management [2].

The BI-RADS classification system is widely used in clinical practice due to its simplicity, reproducibility, and ability to stratify risk. Lesions are categorized from BI-RADS 0 to BI-RADS 6, with increasing probability of malignancy. Categories such as BI-RADS 4 and 5 are particularly significant as they indicate suspicious and highly suggestive malignancy, respectively, warranting histopathological confirmation. Despite its widespread use, the accuracy of BI-RADS in predicting malignancy varies depending on factors such as imaging modality, observer experience, and patient characteristics [3].

Histopathological examination remains the gold standard for the definitive diagnosis of breast lesions. Techniques such as fine needle aspiration cytology, core needle biopsy, and excisional biopsy provide tissue diagnosis and allow for accurate differentiation between benign and malignant conditions. Correlating imaging findings with histopathological results is essential for validating the effectiveness of diagnostic tools such as BI-RADS and ensuring appropriate patient management [4].

Several studies have evaluated the diagnostic accuracy of BI-RADS classification in predicting malignancy in breast lesions. While many studies have reported high sensitivity and specificity for BI-RADS categories, discrepancies between imaging findings and histopathological results may occur, particularly in intermediate categories such as BI-RADS 3 and 4. Therefore, continuous evaluation of the correlation between BI-RADS scoring and histopathological outcomes is necessary to improve diagnostic precision and reduce unnecessary biopsies [5–7].

In clinical settings where patients present with palpable breast lumps, accurate risk stratification is particularly important for guiding management decisions. An observational approach to studying the diagnostic accuracy of BI-RADS in comparison with histopathology can provide valuable insights into its clinical utility and limitations [8].

Therefore, the present study was undertaken to evaluate the diagnostic accuracy of BI-RADS classification in correlation with histopathological findings in patients presenting with clinically palpable breast lumps.

Materials and Methods

This hospital-based observational study was conducted in the Department of General Surgery, Meenakshi Medical College Hospital and Research Institute, Kanchipuram, Tamil Nadu, over a period of one year. The study was undertaken to evaluate the diagnostic accuracy of BI-RADS classification in comparison with histopathological findings in patients presenting with clinically palpable breast lumps.

A total of 50 patients presenting with palpable breast lumps were included in the study. Patients aged 18 years and above with clinically palpable breast lesions were enrolled. Patients with a prior history of breast malignancy, those who had already received treatment for breast disease, and patients who did not consent to participate were excluded from the study.

All patients underwent a detailed clinical evaluation, including history taking and physical examination. Radiological assessment was performed using ultrasonography and/or mammography, and breast lesions were categorized according to the Breast Imaging Reporting and Data System (BI-RADS) classification.

Following imaging, all patients underwent histopathological examination, which was considered the gold standard for diagnosis. Tissue samples were obtained through appropriate methods such as fine needle aspiration cytology (FNAC), core needle biopsy, or excisional biopsy, depending on the clinical indication.

The BI-RADS categories were correlated with the corresponding histopathological findings. For analytical purposes, BI-RADS categories 2 and 3 were considered benign, while categories 4 and 5 were considered suspicious or malignant.

Data collected during the study were systematically recorded and entered into Microsoft Excel for analysis. Statistical analysis was carried out using SPSS statistical software. Descriptive statistics such as mean, standard deviation, frequency, and percentage were used to summarize the data. Diagnostic performance parameters including sensitivity, specificity, positive predictive value (PPV), negative predictive value (NPV), and overall accuracy were calculated. The association between BI-RADS classification and histopathological findings was assessed using the Chi-square test. A p value less than 0.05 was considered statistically significant.

Results

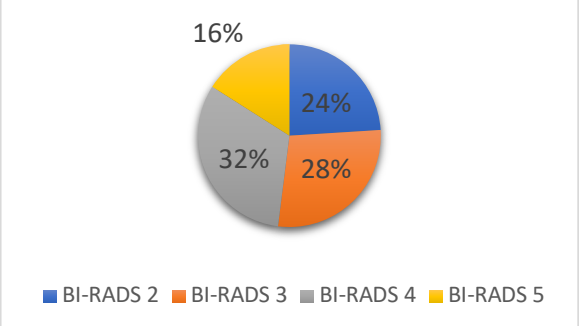
A total of 50 patients presenting with clinically palpable breast lumps were included in the study to evaluate the diagnostic accuracy of BI-RADS classification in comparison with histopathological findings.

Table 1: Demographic Characteristics of Study Participants (n = 50)

Variable	Frequency (%)
Mean age (years)	42.6 ± 11.8
Age 18–30 years	10 (20%)
Age 31–45 years	18 (36%)
Age 46–60 years	14 (28%)
Age >60 years	8 (16%)

The mean age of the study population was 42.6 ± 11.8 years, with the majority of patients in the 31–45 years age group (36%), followed by 46–60 years (28%). This distribution indicates that clinically palpable breast lumps are more commonly observed in middle-aged women. However, a considerable proportion of patients above 45 years were also affected, which is clinically relevant as malignancy risk increases with age.

Chart 1: Distribution of BI-RADS Categories



The distribution of BI-RADS categories showed that 32% of patients were classified as BI-RADS 4 and 16% as BI-RADS 5, indicating that nearly half of the cases (48%) were either suspicious or highly suggestive of malignancy. This highlights the importance of further diagnostic confirmation in a significant proportion of patients presenting with breast lumps.

Table 2: Histopathological Findings

Histopathological Diagnosis	Frequency (%)
Benign lesions	30 (60%)
Malignant lesions	20 (40%)

Histopathological examination revealed that 60% of lesions were benign, while 40% were malignant. Although benign lesions were more common, the relatively high proportion of malignancy underscores the need for accurate diagnostic assessment to avoid missed diagnoses.

Table 3: Correlation Between BI-RADS and Histopathology

BI-RADS Category	Benign	Malignant	Total	p value
BI-RADS 2 & 3	24	2	26	0.001
BI-RADS 4 & 5	6	18	24	

A strong correlation was observed between BI-RADS classification and histopathological findings. Among BI-RADS 2 and 3 lesions, 24 out of 26 were benign, while 18 out of 24 BI-RADS 4 and 5 lesions were malignant. This association was statistically significant ($p = 0.001$), indicating that higher BI-RADS categories are strongly predictive of malignancy.

Table 4: Diagnostic Accuracy of BI-RADS Classification

Parameter	Value (%)
Sensitivity	90%
Specificity	80%
Positive Predictive Value (PPV)	75%
Negative Predictive Value (NPV)	92.3%
Accuracy	84%

BI-RADS classification demonstrated high sensitivity (90%), indicating its strong ability to correctly identify malignant lesions. The specificity was 80%, reflecting good accuracy in identifying benign lesions. The positive predictive value (75%) suggests that a substantial proportion of BI-RADS positive cases were truly malignant, while the negative predictive value (92.3%) indicates a high probability that BI-RADS negative cases were truly benign. The overall diagnostic accuracy was 84%, confirming that BI-RADS is a reliable diagnostic tool in evaluating palpable breast lumps.

Table 5: Association Between Age Group and Malignancy

Age Group	Benign	Malignant	Total	p value
18–30 years	9	1	10	0.028
31–45 years	12	6	18	
46–60 years	6	8	14	
>60 years	3	5	8	

The incidence of malignancy increased with advancing age. In patients aged >60 years, 5 out of 8 cases were malignant, while in the 46–60 years group, 8 out of 14 cases were malignant. In contrast, younger age groups showed predominantly benign lesions. This association between age and malignancy was statistically significant ($p = 0.028$), indicating that increasing age is an important risk factor for malignant breast lesions.

Discussion

The present study evaluated the diagnostic accuracy of BI-RADS classification in correlation with histopathological findings in patients presenting with clinically palpable breast lumps. The findings demonstrated a significant association between BI-RADS categories and histopathological outcomes, highlighting the usefulness of BI-RADS as a diagnostic tool in clinical practice.

In the present study, the majority of patients were in the 31–45 years age group (36%), with a mean age of 42.6 ± 11.8 years. A similar age distribution was reported by Imbelloni LE et al [9], who observed that breast lesions are more commonly detected in middle-aged women. Furthermore, the present study showed that the incidence of malignancy increased with advancing age, with a statistically significant association ($p = 0.028$). This finding is consistent with the observations of Sinha R et al [10], who reported that increasing age is an important risk factor for malignant breast lesions.

The distribution of BI-RADS categories in the present study revealed that 48% of patients were classified as BI-RADS 4 and 5, indicating a high proportion of suspicious lesions. Similar findings were reported by Lee YY et al [11], who demonstrated that higher BI-RADS categories are associated with an increased likelihood of malignancy and require histopathological confirmation.

Histopathological examination in the present study showed that 40% of lesions were malignant, while 60% were benign. These findings are comparable to those reported by Gupta A et al [12], who observed that although benign lesions are more common, a significant proportion of breast lumps may be malignant, necessitating accurate diagnostic evaluation.

The present study demonstrated a strong correlation between BI-RADS classification and histopathological findings, with most BI-RADS 2 and 3 lesions being benign and BI-RADS 4 and 5 lesions showing a higher proportion of malignancy. This association was statistically significant ($p = 0.001$). Similar results were reported by Kaye AD et al [13], who emphasized that BI-RADS classification is a reliable method for risk stratification of breast lesions.

The diagnostic performance of BI-RADS in the present study showed high sensitivity (90%) and specificity

(80%), with an overall accuracy of 84%. These findings are consistent with those reported by Chung F et al [14], who demonstrated that BI-RADS classification has high sensitivity in detecting malignant lesions and is useful in clinical decision-making.

The high negative predictive value (92.3%) observed in the present study indicates that BI-RADS is particularly effective in ruling out malignancy in patients with lower category lesions. Similar findings were reported by Lee JH et al [15], who observed that BI-RADS classification has a high negative predictive value, reducing unnecessary biopsies in benign cases.

Accurate diagnosis and early detection of breast cancer are essential for improving patient outcomes. White PF et al [16] highlighted the importance of combining imaging and histopathological evaluation for accurate diagnosis of breast lesions. Additionally, Walker SM et al [17] emphasized that appropriate diagnostic strategies play a crucial role in improving patient management and reducing morbidity.

The role of structured reporting systems such as BI-RADS in improving diagnostic accuracy has been widely recognized. Hawn MT et al [18] reported that standardized diagnostic approaches contribute to better clinical outcomes and improved patient care. Furthermore, Kehlet H [19] emphasized the importance of evidence-based diagnostic methods in enhancing clinical decision-making.

Overall, the findings of the present study suggest that BI-RADS classification is a reliable and effective tool for the evaluation of clinically palpable breast lumps. Its strong correlation with histopathological findings and high diagnostic accuracy make it an essential component of the diagnostic workup of breast lesions.

Conclusion

The present study demonstrated that BI-RADS classification is a reliable and effective diagnostic tool for evaluating clinically palpable breast lumps. A strong correlation was observed between BI-RADS categories and histopathological findings, with higher BI-RADS categories showing a greater likelihood of malignancy. The association was statistically significant ($p = 0.001$), indicating the usefulness of BI-RADS in predicting malignant lesions. The system also showed high sensitivity (90%) and good specificity (80%), with an overall diagnostic accuracy of 84%. Additionally, increasing age was significantly associated with a higher incidence of malignancy ($p = 0.028$). These findings highlight that BI-RADS classification, when used in conjunction with histopathological evaluation, can aid in early diagnosis, appropriate risk stratification, and effective management of patients with palpable breast lumps.

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