



## Assessing The Diagnostic Accuracy of BIRADS Score Versus Histopathological Findings in Clinically Palpable Breast Lumps: A Comparative Study

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### KEYWORDS

BI-RADS classification, histopathological results, mammography, radiological examinations, malignancy

**Introduction:** Breast Imaging Reporting and Data System (BIRADS) scores are widely used in clinical practice to assess breast lesions detected through imaging. This study aims to compare the diagnostic accuracy of BIRADS scores with histopathological findings in clinically palpable breast lumps.

**Aims and Objectives:** To compare the diagnostic accuracy of BI-RADS score in detecting Malignant lesions with histopathological findings

**Methods:** A study was conducted on 100 female patients presenting with clinically palpable breast lumps at the Department of General Surgery of MKCG Medical College. The patients were classified according to BI-RADS categories 2, 3, 4a, 4b, 4c, or 5 based on radiological examinations. The correlation between BI-RADS classification and histopathological results was evaluated using descriptive statistics. Sensitivity, specificity, positive predictive value (PPV), negative predictive value (NPV), and accuracy were calculated to assess the diagnostic performance of BI-RADS scores.

**Results:** A total of 100 patients with clinically palpable breast lumps were included in the study. Considering histopathological examination as the gold standard, the sensitivity and specificity of BI-RADS score is 93.9% and 82.3% respectively. The BI-RADS score has a positive predictive value of 91.1%, a negative predictive value of 87.5%, and a diagnostic accuracy of 90.0%, respectively.

**Conclusions:** This comparative study reveals that while BIRADS scores provide valuable information for the assessment of clinically palpable breast lumps, their diagnostic accuracy varies. BI-RADS score being non-invasive, it may become a very useful test for evaluating Breast lump lesions but cannot be considered as gold standard and thus cannot be used as an alternative to histopathology in diagnosis of breast lumps.



## Background

Breast cancer is the most common cancer among women worldwide, with an estimated 2.3 million new cases diagnosed in 2020. Breast cancer is the leading cause of cancer-related deaths among women globally, with approximately 685,000 deaths reported in 2020.<sup>[1]</sup> The incidence of breast cancer varies significantly across regions, with higher rates observed in developed countries compared to developing nations. Early detection through screening programs and advancements in treatment have contributed to improved survival rates for breast cancer patients worldwide <sup>[2]</sup>.

Breast cancer is the most common cancer among Indian women, comprising approximately 27% of all cancer cases in females. The incidence of breast cancer in India has been steadily rising, with an estimated 162,468 new cases reported in 2020. Breast cancer mortality rates in India are also significant, accounting for approximately 14% of all cancer-related deaths among women. Late-stage diagnosis is a major challenge in India, leading to poorer outcomes for breast cancer patients due to limited access to healthcare facilities and awareness about the disease <sup>[3]</sup>.

Breast cancer is a significant public health concern in India, with increasing incidence rates and a substantial burden on affected individuals and healthcare systems <sup>[4]</sup>. Early detection of breast cancer is paramount for improving survival rates and treatment outcomes, highlighting the importance of accurate diagnostic methods. Clinical examination remains a fundamental aspect of breast cancer screening in India, particularly for detecting palpable breast lumps that may signify malignancy.<sup>[5]</sup>

The Breast Imaging Reporting and Data System (BIRADS) is widely utilized in India as a standardized classification system for interpreting findings from breast imaging studies, including mammography, ultrasound, and magnetic resonance imaging (MRI) <sup>[6]</sup>. BI-RADS scores provide valuable guidance to clinicians in assessing the likelihood of malignancy and determining appropriate management strategies for breast lesions.

Histopathological examination of breast tissue obtained through biopsy or surgical excision remains the gold standard for diagnosing breast cancer and determining tumour characteristics in Indian clinical practice <sup>[7]</sup>. However, obtaining histopathological confirmation often entails invasive procedures and may not be feasible or accessible for all patients, particularly in resource-limited settings.

While BI-RADS scores provide valuable information, histopathological examination is often required to definitively confirm malignancy. Given the importance of accurate diagnosis in guiding treatment decisions and improving patient outcomes, there is a growing interest in evaluating the diagnostic accuracy of BI-RADS scoring compared to histopathological findings in India. Understanding the concordance between BIRADS scores and histopathological diagnoses is essential for optimizing diagnostic algorithms and enhancing the quality of breast cancer care in the Indian context.

This study aims to assess the diagnostic accuracy of BI-RADS scores in clinically palpable breast lumps and compare these scores with histopathological results. The research focuses on a population of women presenting with clinically palpable breast lumps, a group with particular clinical relevance <sup>[8]</sup>.

The outcomes of this comparative study will contribute to refining breast cancer diagnostic protocols and enhancing clinical decision-making. Reducing misdiagnoses and unnecessary procedures is vital in the management of breast cancer, aligning with global efforts to improve care and outcomes <sup>[7]</sup>.

## Objective:

The primary objective of this study is to assess the diagnostic accuracy of BI-RADS scores in predicting histopathological findings in clinically palpable breast lumps among Indian women. Specifically, the study aims to:

1. To evaluate the sensitivity, specificity, positive predictive value (PPV), and negative predictive value (NPV) of BI-RADS scoring in detecting breast cancer in the Indian population.



2. To determine the degree of agreement between BI-RADS scores and histopathological diagnoses, including the identification of false-positive and false-negative cases.

### Methodology

The study employed a retrospective comparative design to assess the diagnostic accuracy of Breast Imaging Reporting and Data System (BI-RADS) scoring in the Department of General Surgery at MKCG Medical College and Hospital. Data collection occurred over a specified period, from November 2022 to November 2023. During this time, patients meeting specific inclusion criteria were identified. These criteria encompassed women of all ages who had undergone breast surgery at the institution following preoperative mammogram or sonomammogram with BI-RADS scoring and possessed conclusive histopathology reports, along with well-documented clinical records. Exclusion criteria were applied to patients with a history of previous breast surgery or those who underwent surgery elsewhere. Ethical clearance for the study was obtained from the Institutional Ethical Committee. Written informed consent was taken from all the participants after explaining the purpose of the study in their local language.

The sample size for the present study was determined to be 100 newly diagnosed breast lump cases attending the General Surgery Department's outpatient department. This sample size was chosen consecutively, based on considerations of feasibility, statistical power, and the anticipated prevalence of breast cancer cases in the study population.

Data analysis was conducted with statistical significance set at a p-value less than 0.05. Concordance between BI-RADS score and histopathology was assessed using various parameters, including sensitivity, specificity, positive predictive value (PPV), negative predictive value (NPV), and diagnostic accuracy. Histopathology served as the reference standard for comparison, given its role as the gold standard for diagnosing breast cancer and determining tumour characteristics.

This comprehensive approach aimed to provide a thorough assessment of the utility and reliability of BI-RADS scoring in the diagnostic evaluation of clinically palpable breast lumps.

### Results

	N	Mini mum	Maxi mum	Me an	St d. error	Std. Devia tion
Benign_ age	66	36	78	56.55	1.31	10.61
Maligna nt age	34	36	78	56.85	1.78	10.39

Table 1: Distribution of study population based on age (N=100)

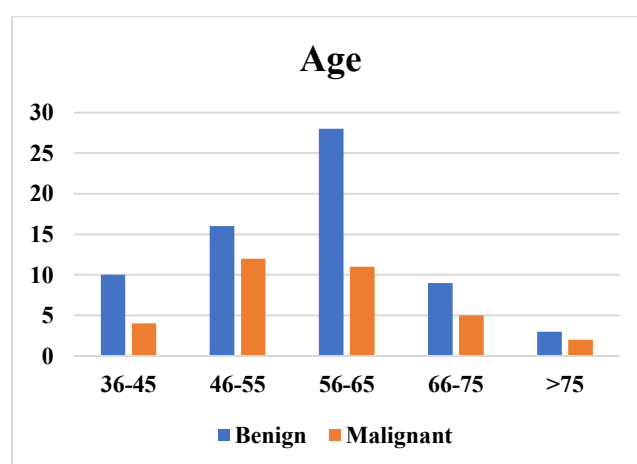


Figure 1: Distribution of study population based on Age group (N=100)

The mean age of the study participants was 56.65 years. The mean age of benign cases was 56.55 years and malignant cases was 56.85 years [Table 1]. The distribution of benign cases by age was as follows: 10 (15.2%) cases were between 36-45 years, 16 (24.2%) cases were between 46-55 years, 28 (42.4%) cases were between 56-65 years, 9 (13.6%) cases were between 66-75 years, and 3 (4.5%) cases were above 75 years. The distribution of malignant cases by age was as follows: 4 (11.8%) cases were between 36-45 years, 12 (35.3%) cases were between 46-55 years, 11 (32.4%) cases were between 56-65 years, 5 (14.7%) cases were between 66-75 years, and 2 (5.9%) cases were above 75 years [Figure 1].



HPE Dx	Frequency (N=100)	Percentage
Benign	66	66
Malignant	34	34
BIRADS Score	Frequency (N=100)	Percentage
Benign	68	68
Malignant	32	32

Table 2: Distribution of study population based on Histopathological examination and BIRADS score (N=100)

The analysis of breast lesions by histopathological examination (HPE) revealed that among the 100 cases studied, 66 (66%) were diagnosed as benign, while 34 (34%) were identified as malignant. The

Breast Imaging Reporting and Data System (BIRADS) scores showed a similar distribution, with 68 cases (68%) categorized as benign and 32 cases (32%) classified as malignant [Table 2].

BI-RADS Score	N (100)	HPE+	HPE-
1	12	0	12
2	29	0	29
3	27	2	25
4	13	11	2
5	9	9	0
6	10	10	0
TOTAL	100	32	68

Table 3: Distribution of study population based on BI-RADS score and Histopathological examination (N=100)



The analysis of breast lesions according to the BI-RADS score revealed varying distributions within the study population. Among the 100 cases examined, 12 (12%) were classified as BI-RADS 1, all of which were histopathologically negative (HPE-). Similarly, BI-RADS 2 comprised 29 cases (29%), all of which were also HPE-negative. In BI-RADS 3, out of 27 cases (27%), 2 (7.4%) were found to be histopathologically positive (HPE+), while 25 (92.6%) were HPE-negative. For BI-RADS 4, 13 cases (13%) were identified, with 11 (84.6%) being HPE-positive and 2 (15.4%) HPE-negative. Moreover, BI-RADS 5 included 9 cases (9%), all of which were HPE-positive, while BI-RADS 6 consisted of 10 cases (10%), all of which were HPE-positive as well. Overall, among the total of 100 cases, 32 (32%) were histopathologically positive, while 68 (68%) were histopathologically negative, indicating the presence or absence of malignancy in the breast lesions across different BI-RADS categories. [Table 3]

Considering HPE as gold standard, the sensitivity of BI-RADS in detecting breast cancer was 94.44%, specificity was 100%, positive predictive value was 100% and negative predictive value was 97.06%. The diagnostic accuracy was 98.04%.

## Discussion

Breast cancer is the most common cancer among women worldwide, and early detection is crucial for better outcomes. Mammography is a widely used screening tool for breast cancer, but its sensitivity and specificity vary depending on various factors such as age, breast density, and lesion characteristics. The Breast Imaging Reporting and Data System (BI-RADS) is a standardized system for reporting mammography findings and helps in the diagnosis and management of breast lesions. The study found that mammography had a high sensitivity (93.9%) and positive predictive value (91.1%) in detecting breast cancer, but its specificity (82.3%) and negative predictive value (87.5%) were relatively lower.

The findings from our study on breast lesions, categorized by the Breast Imaging Reporting and Data System (BI-RADS) score, provide valuable insights into the relationship between radiological

assessment and histopathological diagnosis. Our results reveal that the distribution of lesions varies across different BI-RADS categories, with an increasing likelihood of malignancy associated with higher BI-RADS scores.

Our observation of a higher percentage of histopathologically positive cases (HPE+) in BI-RADS categories 4 and 5 aligns with previous research indicating that these categories are associated with an elevated risk of malignancy (Lazarus et al., 2016).<sup>[7]</sup> Lazarus et al. demonstrated a strong correlation between BI-RADS 4 and 5 lesions and subsequent histopathological confirmation of malignancy, underscoring the importance of these categories in guiding clinical management decisions.

Furthermore, our study found that a substantial proportion of BI-RADS lesions were histopathologically negative (HPE-), consistent with existing literature highlighting the challenge of accurately characterizing lesions in this category (Lourenco et al., 2015).<sup>[11]</sup> Lourenco et al. emphasized the need for additional imaging modalities or close follow-up to further assess BI-RADS 3 lesions due to their intermediate risk of malignancy. In the Chavan, Ganesh et al.<sup>[12]</sup>, it was seen that 62 cases were benign on both HPE and BI-RADS score, 4 case was benign on HPE and malignant on BI-RADS score while 6 cases were malignant on HPE and benign on BI-RADS score and 28 cases were benign on both HPE and BI-RADS score.

The overall concordance between radiological assessment and histopathological diagnosis in our study supports the utility of the BI-RADS system as a standardized tool for breast lesion classification. Our findings corroborate the recommendations of previous studies advocating for the use of BI-RADS categories to stratify the risk of malignancy and guide clinical decision-making in breast imaging (American College of Radiology, 2013).<sup>[13]</sup>

## Conclusion

The study underscores the importance of integrating radiological and histopathological assessments in the evaluation of breast lesions. The BI-RADS system serves as a valuable framework



for risk stratification, facilitating appropriate management strategies and optimizing patient care. The study has some limitations, such as a small sample size and a single-center design, which may affect the generalizability of the findings.

The study suggests the need for further research to evaluate the diagnostic accuracy of BI-RADS score and mammography in larger and more diverse populations and to explore the role of other imaging modalities such as ultrasound and magnetic resonance imaging in the diagnosis of breast lesions.

### Funding

Nil

### Conflict of Interest

The author declares no conflict of interest.

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