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Research Article

Correlation of Breast Imaging Reporting and Data System (BI-RADS) Classification with Histopathological Findings in Patients with Breast Lesions

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ABSTRACT

Background: Breast lesions encompass a wide spectrum of benign and malignant conditions requiring accurate diagnosis for appropriate clinical management. The Breast Imaging Reporting and Data System (BI-RADS) provides standardized radiological classification and malignancy risk assessment. This study aimed to correlate BI-RADS classification with histopathological findings and evaluate its diagnostic performance in patients with breast lesions.

Materials and Methods: This hospital-based, observational, cross-sectional study included 90 patients with breast lesions who underwent mammography, ultrasonography, or both, followed by histopathological examination. Lesions were categorized according to BI-RADS classification and correlated with histopathological diagnoses. Sensitivity, specificity, positive predictive value (PPV), negative predictive value (NPV), and diagnostic accuracy were evaluated.

Results: Among 90 patients, 96.67% were females, and breast lump was the predominant presenting complaint (72.22%). Histopathological examination revealed 58 benign (64.44%) and 32 malignant (35.56%) lesions. Fibroadenoma (31.11%) was the most common benign lesion, while invasive breast carcinoma of no special type (25.56%) was the predominant malignancy. Malignancy rates increased progressively from 4.17% in BI-RADS 3 to 11.11%, 50.00%, 90.00%, and 100% in BI-RADS 4A, 4B, 4C, and 5, respectively. BI-RADS demonstrated sensitivity of 96.88%, specificity of 60.34%, PPV of 57.41%, NPV of 97.22%, and overall diagnostic accuracy of 73.33%.

Conclusion: BI-RADS classification demonstrated high sensitivity and negative predictive value in identifying malignant breast lesions. Radiological–histopathological correlation remains essential for accurate diagnosis, appropriate biopsy selection, and effective clinical management.

Keywords: Bi-Rads, Breast Lesions, Histopathology, Breast Cancer, Diagnostic Accuracy, Radiological–Histopathological Correlation.

INTRODUCTION

Breast cancer is one of the most commonly diagnosed malignancies and a leading cause of cancer-related mortality among women worldwide. According to GLOBOCAN 2022 estimates, approximately

2.3 million new cases and 670,000 breast cancer-related deaths were reported globally[1]. Early detection and accurate diagnosis are essential for improving survival, reducing mortality, and ensuring appropriate treatment [2]. Breast lesions encompass a wide spectrum of pathological conditions, ranging from benign abnormalities such as fibroadenoma, fibrocystic changes, and intraductal papilloma to malignant lesions, including ductal carcinoma in situ and invasive breast carcinoma[3]. Differentiating benign from malignant lesions is therefore crucial for effective clinical management.The diagnostic evaluation of breast lesions commonly involves triple assessment, comprising clinical

examination, radiological imaging, and pathological examination. Mammography and ultrasonography are widely used for detecting and characterizing breast abnormalities, while magnetic resonance imaging is utilized in selected cases. Mammography plays an important role in breast cancer screening, whereas ultrasonography is particularly useful in evaluating palpable masses and lesions in dense breast tissue. However, overlapping radiological features between benign and malignant lesions may create diagnostic uncertainty, necessitating standardized imaging assessment and histopathological confirmation [4,5].The Breast Imaging Reporting and Data System (BI-RADS), developed by the American College of Radiology (ACR), provides a standardized framework for describing breast imaging findings, estimating malignancy risk, and guiding subsequent management [6]. The classification includes categories 0–6, ranging from incomplete assessment to biopsy-proven malignancy. BI-RADS category 3 represents probably benign lesions with a malignancy probability of ≤2%, while category 4 includes suspicious abnormalities requiring tissue diagnosis. Category 4 is further subdivided into 4A, 4B, and 4C according to increasing malignancy risk, whereas category 5 indicates a ≥95% probability of malignancy [7,8].Histopathological examination remains the reference standard for definitive diagnosis of breast lesions, enabling accurate differentiation between benign and malignant conditions[9,10]. Correlation between BI-RADS classification and histopathological findings is essential for assessing diagnostic reliability, identifying radiological–pathological discrepancies, and minimizing unnecessary biopsies or missed malignancies. Previous studies have demonstrated variations in the positive predictive value of BI-RADS categories, particularly category 4, emphasizing the importance of evaluating imaging accuracy across different patient populations [11,12].Therefore, the present study aims to correlate BI-RADS classification with histopathological findings in patients presenting with breast lesions. It seeks to determine the distribution of benign and malignant lesions across BI-RADS categories, assess radiological–histopathological concordance, and evaluate the usefulness of BI-RADS in predicting malignancy.

MATERIALS AND METHODS

The present study was conducted as a hospital-based, observational, cross-sectional study to evaluate the correlation between Breast Imaging Reporting and Data System (BI-RADS) classification and histopathological findings in patients presenting with breast lesions. The study assessed the diagnostic utility of BI-RADS classification in differentiating benign and malignant breast lesions by comparing radiological findings with histopathological diagnoses.The study was carried out in the Department General Surgery at a tertiary care teaching hospital. Patients presenting with breast-related complaints who underwent radiological evaluation followed by histopathological examination were included in the study.The study was conducted over the designated study period 18 months

Study Population

The study population comprised patients presenting to the outpatient and inpatient departments with clinically or radiologically detected breast lesions. Patients who underwent breast imaging using mammography, ultrasonography, or both, followed by histopathological examination, were considered for inclusion. Both benign and malignant breast lesions were included to assess the relationship between BI-RADS categories and histopathological diagnoses.A total of 90 patients with breast lesions were included in the study.

Sampling Technique

A non-probability consecutive sampling technique was employed. Patients who fulfilled the eligibility criteria and underwent both radiological assessment and histopathological examination during the study period were consecutively enrolled until the required sample size of 90 patients was achieved.

Selection Criteria Inclusion Criteria

1. Patients aged 18 years and above who presented with clinically or radiologically detected breast lesions were included.
2. Patients who underwent mammography, breast ultrasonography, or both, with documented BI-RADS classification were included.
3. Patients who underwent histopathological examination of breast lesions through core needle biopsy, excisional biopsy, or surgical specimen examination were included.

4. Patients with complete clinical, radiological, and histopathological records were included.
5. Patients who provided written informed consent for participation in the study were included.

Exclusion Criteria

1. Patients who did not undergo histopathological confirmation of the breast lesion were excluded.
2. Patients with incomplete radiological or histopathological records were excluded.
3. Patients who had received neoadjuvant chemotherapy or radiotherapy before the initial radiological evaluation were excluded.
4. Patients with previously diagnosed and treated breast malignancies presenting for routine follow-up were excluded.
5. Patients who declined to provide informed consent were excluded.

Study Procedure

Following approval from the Institutional Ethics Committee, patients fulfilling the inclusion criteria were enrolled in the study. A detailed clinical history was obtained, including age, presenting complaints, duration of symptoms, family history of breast cancer, previous breast disease, and relevant reproductive and hormonal history.All patients underwent a thorough clinical breast examination to assess the presence of palpable masses, their location, size, consistency, mobility, tenderness, associated skin changes, nipple abnormalities, and axillary lymphadenopathy.Radiological evaluation was performed using mammography, ultrasonography, or both, depending on the patient's age, clinical presentation, breast density, and clinical indication. Imaging findings were documented, and each lesion was assigned an appropriate BI-RADS category according to the American College of Radiology classification.Patients subsequently underwent tissue sampling as clinically indicated. Histopathological findings were recorded and correlated with the corresponding radiological BI-RADS categories. The collected information was entered into a structured data collection sheet for statistical analysis.

Radiological Evaluation Mammographic Examination

Mammography was performed in patients for whom the examination was clinically indicated. Standard craniocaudal and mediolateral oblique views were obtained, and additional views were performed when required.Mammographic findings were evaluated for breast density, lesion location, mass shape, margins, density, calcifications, architectural distortion, and associated abnormalities. Particular attention was given to radiological features suggestive of malignancy, including irregular or spiculated margins, suspicious microcalcifications, and architectural distortion.The findings were interpreted by a radiologist, and the lesions were classified according to the BI-RADS assessment categories.

Ultrasonographic Examination

Breast ultrasonography was performed using a high-frequency linear-array transducer. The examination included systematic evaluation of the affected breast, surrounding breast tissue, retroareolar region, and axilla when indicated.The sonographic characteristics of each lesion were assessed in terms of size, shape, orientation, margins, echogenicity, internal echo pattern, posterior acoustic features, and associated tissue changes. Suspicious features such as irregular shape, non-circumscribed margins, non-parallel orientation, and posterior acoustic shadowing were documented.The ultrasonographic findings were assigned BI-RADS categories according to standardized imaging criteria. In patients who underwent both mammography and ultrasonography, the final BI-RADS assessment was recorded on the basis of the combined imaging findings.

BI-RADS Classification

Breast lesions were categorized according to the American College of Radiology Breast Imaging Reporting and Data System.BI-RADS category 0 indicated an incomplete assessment requiring additional imaging evaluation. BI-RADS category 1 represented negative findings, while category 2 indicated benign findings. BI-RADS category 3 represented probably benign lesions with an expected malignancy probability of not more than 2%.BI-RADS category 4 included suspicious lesions for which tissue diagnosis was recommended. This category was further subdivided into category 4A, indicating low suspicion of malignancy (greater than 2% to 10%); category 4B, indicating moderate suspicion (greater than 10% to 50%); and category 4C, indicating high suspicion (greater

than 50% to less than 95%).BI-RADS category 5 represented lesions highly suggestive of malignancy, with an expected malignancy probability of at least 95%. BI-RADS category 6 indicated known biopsy-proven malignancy.For the purpose of radiological–histopathological correlation, the final BI-RADS category assigned before tissue diagnosis was considered. Categories 3, 4, and 5 were evaluated for their association with benign and malignant histopathological outcomes. Where available, category 4 subcategories were also analyzed separately.

Histopathological Examination

Histopathological examination was considered the reference standard for establishing the definitive diagnosis of breast lesions.Tissue samples were obtained through core needle biopsy, excisional biopsy, or surgical excision, depending on the clinical and radiological characteristics of the lesion. The collected specimens were fixed in 10% neutral-buffered formalin and transported to the Department of Pathology for processing.The specimens were subjected to routine gross examination, tissue processing, paraffin embedding, sectioning, and hematoxylin and eosin staining. The prepared slides were examined microscopically by a pathologist.Histopathological diagnoses were established on the basis of morphological features and were classified into benign and malignant categories. Benign lesions included fibroadenoma, fibrocystic changes, benign proliferative breast disease, intraductal papilloma, and other non-malignant conditions. Malignant lesions included ductal carcinoma in situ, invasive breast carcinoma of no special type, invasive lobular carcinoma, and other malignant breast neoplasms.The final histopathological diagnosis of each lesion was documented and compared with the corresponding BI-RADS category.

Radiological–Histopathological Correlation

Radiological–histopathological correlation was performed by comparing the BI-RADS classification of each breast lesion with its final histopathological diagnosis.The distribution of benign and malignant lesions across different BI-RADS categories was assessed. Particular emphasis was placed on determining the frequency of malignancy in BI-RADS categories 3, 4, and 5.For binary diagnostic accuracy analysis, BI-RADS categories 4 and 5 were considered radiologically positive for suspected malignancy, whereas categories 1–3 were considered radiologically negative, where applicable. BI-RADS category 0 was not considered a definitive assessment, and category 6 was excluded from the primary diagnostic accuracy analysis because malignancy had already been established by biopsy.The imaging findings were classified as true positive, true negative, false positive, or false negative according to their agreement with histopathological findings.Radiological–histopathological concordance was assessed by determining whether the final tissue diagnosis was consistent with the degree of suspicion indicated by the imaging classification. Discordant cases were identified and evaluated to understand possible reasons for discrepancies between radiological and pathological findings.

Study Variables

The following variables were recorded and analyzed:

1. Demographic variables: Age and sex of the patients.
2. Clinical variables: Presenting complaints, duration of symptoms, laterality, lesion location, and relevant clinical history.
3. Radiological variables: Imaging modality, lesion size, shape, margins, echogenicity or density, calcifications, associated imaging findings, and final BI-RADS category.
4. Histopathological variables: Type of breast lesion, final histopathological diagnosis, and benign or malignant status.
5. Diagnostic variables: Radiological–histopathological concordance, malignancy frequency in individual BI-RADS categories, sensitivity, specificity, positive predictive value, negative predictive value, and overall diagnostic accuracy.

Outcome Measures Primary Outcome

The primary outcome of the study was the correlation between BI-RADS classification and histopathological findings in patients with breast lesions. The association between increasing BI-RADS categories and the presence of histopathologically confirmed malignancy was evaluated.

Secondary Outcomes

The secondary outcomes included determination of the frequency and

percentage of benign and malignant lesions in different BI-RADS categories, assessment of radiological–histopathological concordance, and evaluation of the diagnostic performance of BI-RADS classification.Sensitivity, specificity, positive predictive value, negative predictive value, and overall diagnostic accuracy were calculated using histopathological findings as the reference standard. The frequency of false-positive and false-negative radiological assessments was also determined.

Statistical Analysis

The collected data were entered into Microsoft Excel and analyzed using SPSS.29 statistical software. Descriptive statistics were used to summarize demographic, clinical, radiological, and histopathological characteristics. Categorical variables were expressed as frequencies and percentages, while continuous variables were presented as mean and standard deviation or median and interquartile range, depending on the distribution of the data. The association between BI-RADS categories and histopathological diagnoses was assessed using the Chi-square test or Fisher's exact test, as appropriate. The proportion of histopathologically confirmed malignancies within each BI-RADS category was calculated to determine the observed malignancy rate. The diagnostic performance of BI-RADS classification was evaluated by calculating sensitivity, specificity, positive predictive value, negative predictive value, and overall diagnostic accuracy using a 2 × 2 contingency table. Histopathological diagnosis was considered the reference standard. Agreement between radiological assessment and histopathological findings was assessed using Cohen's kappa coefficient where applicable. Receiver operating characteristic (ROC) curve analysis was performed where appropriate to evaluate the discriminatory ability of BI-RADS classification in identifying malignant breast lesions. The area under the ROC curve (AUC) was used to summarize diagnostic performance. A p-value of less than 0.05 was considered statistically significant.

RESULTS

Table 1 presents the distribution of study patients according to demographic and clinical characteristics. Among the 90 patients, the largest proportion belonged to the 31–40 years age group (27.78%), followed by 41–50 years (25.56%). Females constituted the majority (96.67%), while males accounted for 3.33%. Breast lump was the most common presenting complaint (72.22%), followed by breast pain (13.33%) and nipple discharge (8.89%). Right-sided breast lesions were observed in 47.78% of patients, left-sided lesions in 46.67%, and bilateral lesions in 5.56%.Table 2 and Figure 1 illustrate the distribution of breast lesions according to BI-RADS classification. BI-RADS 3 was the most frequently observed category (26.67%), followed by BI-RADS 4A (20.00%), BI-RADS 5 (15.56%), BI-RADS 2 (13.33%), BI-RADS 4B (13.33%), and BI-RADS 4C (11.11%). Overall, 60.00% of lesions were classified as BI-RADS 4 or 5, indicating varying degrees of radiological suspicion for malignancy.Table 3 and Figure 2 demonstrate the histopathological distribution of breast lesions. Benign lesions constituted 64.44% of cases, while malignant lesions accounted for 35.56%. Fibroadenoma was the most common benign diagnosis (31.11%), followed by fibrocystic changes (14.44%) and benign proliferative breast disease (8.89%). Among malignant lesions, invasive breast carcinoma of no special type was the predominant diagnosis (25.56%), followed by invasive lobular carcinoma (4.44%) and ductal carcinoma in situ (3.33%).Table 4 and Figure 3 show the correlation between BI-RADS classification and histopathological findings. All BI-RADS 2 lesions were benign (100.00%), whereas 95.83% of BI-RADS 3 lesions were benign. The proportion of malignant lesions progressively increased across higher BI-RADS categories, from 11.11% in BI-RADS 4A to 50.00% in BI-RADS 4B and 90.00% in BI-RADS 4C. All BI-RADS 5 lesions were confirmed malignant on histopathological examination (100.00%). These findings demonstrated an increasing frequency of malignancy with increasing BI-RADS category.Table

5 presents the diagnostic performance of BI-RADS classification in predicting breast malignancy, considering BI-RADS 4–5 as radiologically positive and BI-RADS 2–3 as radiologically negative. Of the 32 histopathologically confirmed malignant lesions, 31 were correctly identified as positive, while one was classified as negative. Among 58 benign lesions, 35 were correctly classified as negative, whereas 23 were classified as positive. The sensitivity and specificity were 96.88% and 60.34%, respectively. The positive predictive value was 57.41%, while the negative predictive value

was 97.22%. Overall diagnostic accuracy was 73.33%, with a false-positive rate of 39.66% and a false-negative rate of 3.13%.

Table 1. Distribution of Study Patients According to Demographic and Clinical Characteristics (N = 90)

Characteristics	Number (n)	Percentage (%)
Age group (years)		
18–30	16	17.78
31–40	25	27.78
41–50	23	25.56
51–60	16	17.78
>60	10	11.11
Sex		
Female	87	96.67
Male	3	3.33
Presenting complaint		
Breast lump	65	72.22
Breast pain	12	13.33
Nipple discharge	8	8.89
Other complaints	5	5.56
Laterality of lesion		
Right breast	43	47.78
Left breast	42	46.67
Bilateral	5	5.56

Table 2. Distribution of Breast Lesions According to BI-RADS Classification (N = 90)

BI-RADS category	Number (n)	Percentage (%)
BI-RADS 2 – Benign	12	13.33
BI-RADS 3 – Probably benign	24	26.67
BI-RADS 4A – Low suspicion	18	20.00
BI-RADS 4B – Moderate suspicion	12	13.33
BI-RADS 4C – High suspicion	10	11.11
BI-RADS 5 – Highly suggestive of malignancy	14	15.56
Total	90	100.00

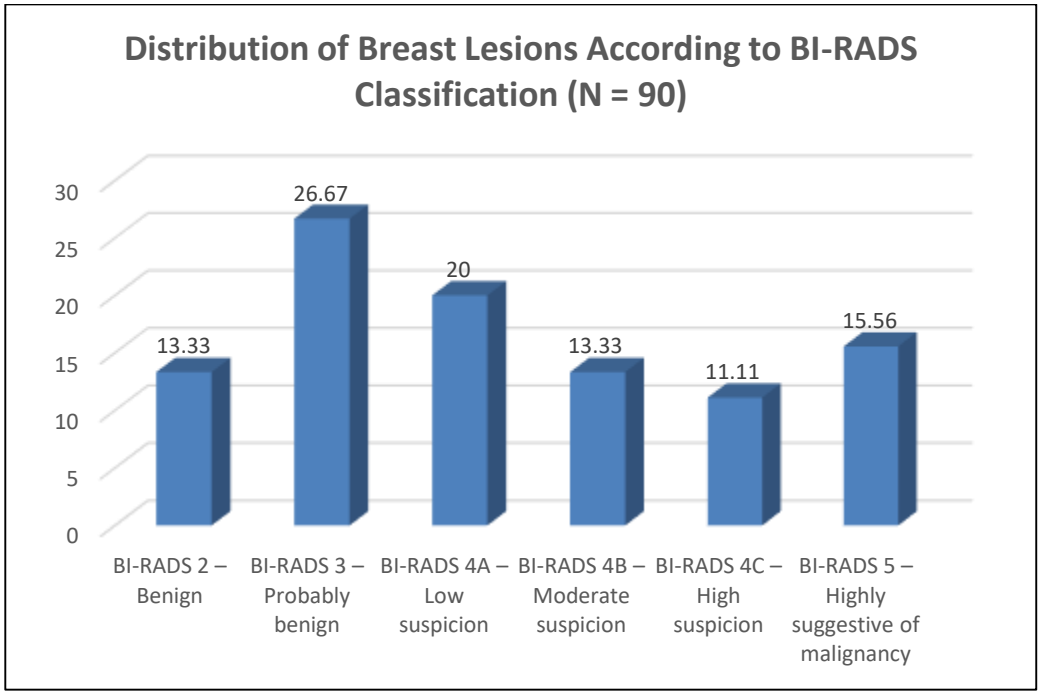


Figure 1 Distribution of Breast Lesions According to BI-RADS Classification (N = 90)

Table 3. Distribution of Breast Lesions According to Histopathological Diagnosis (N = 90)

Histopathological diagnosis	Number (n)	Percentage (%)
Benign lesions		
Fibroadenoma	28	31.11
Fibrocystic changes	13	14.44
Benign proliferative breast disease	8	8.89
Intraductal papilloma	5	5.56
Other benign lesions	4	4.44
Total benign lesions	58	64.44
Malignant lesions		
Invasive breast carcinoma of no special type	23	25.56
Invasive lobular carcinoma	4	4.44
Ductal carcinoma in situ	3	3.33
Other malignant lesions	2	2.22
Total malignant lesions	32	35.56
Grand total	90	100.00

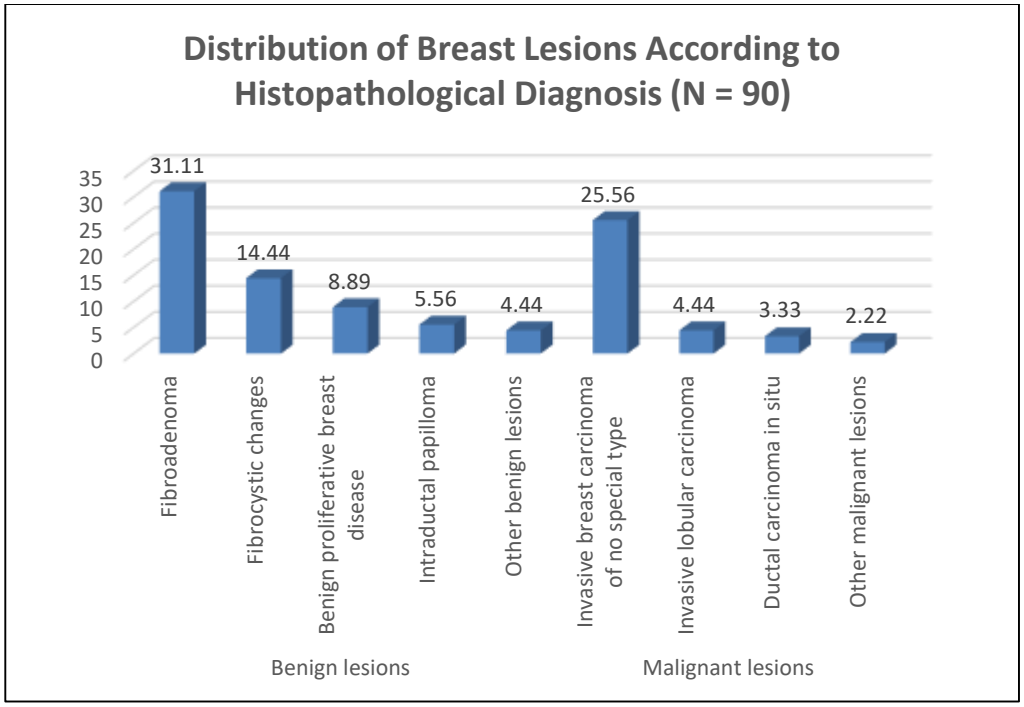


Figure 2 Distribution of Breast Lesions According to Histopathological Diagnosis (N = 90)

Table 4. Correlation Between BI-RADS Classification and Histopathological Findings (N = 90)

BI-RADS category	Benign, n (%)	Malignant, n (%)	Total (n)
BI-RADS 2	12 (100.00)	0 (0.00)	12
BI-RADS 3	23 (95.83)	1 (4.17)	24
BI-RADS 4A	16 (88.89)	2 (11.11)	18
BI-RADS 4B	6 (50.00)	6 (50.00)	12
BI-RADS 4C	1 (10.00)	9 (90.00)	10
BI-RADS 5	0 (0.00)	14 (100.00)	14
Total	58 (64.44)	32 (35.56)	90

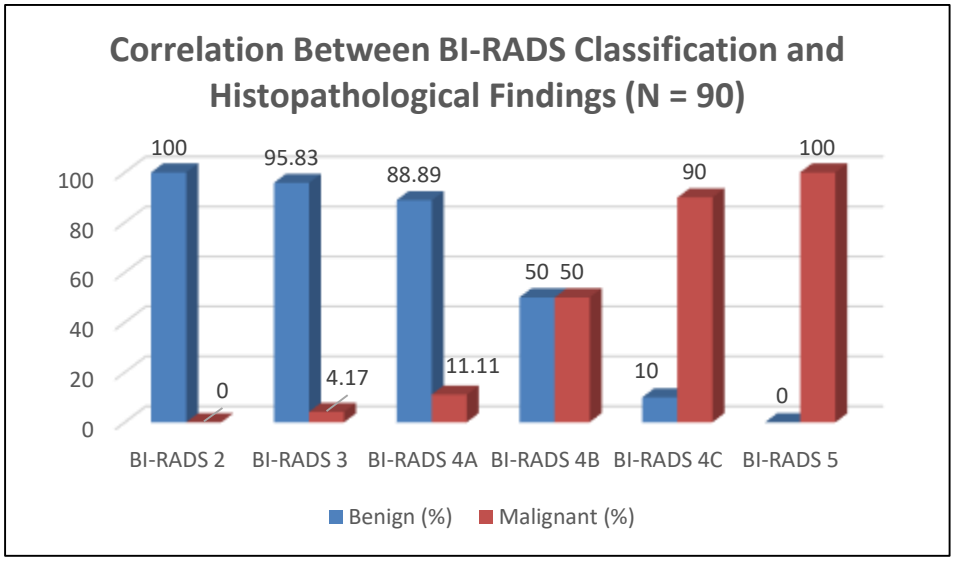


Figure 3 Correlation Between BI-RADS Classification and Histopathological Findings (N = 90)

Table 5. Diagnostic Performance of BI-RADS Classification in Predicting Malignancy (N = 90)

A. Comparison with histopathology

Radiological classification	Malignant on histopathology	Benign on histopathology	Total
BI-RADS 4–5 (Positive)	31	23	54
BI-RADS 2–3 (Negative)	1	35	36
Total	32	58	90

B. Diagnostic accuracy measures

Diagnostic parameter	Value (%)
Sensitivity	96.88
Specificity	60.34
Positive predictive value (PPV)	57.41
Negative predictive value (NPV)	97.22
Overall diagnostic accuracy	73.33
False-positive rate	39.66
False-negative rate	3.13

DISCUSSION

The present study evaluated the correlation between Breast Imaging Reporting and Data System (BI-RADS) classification and histopathological findings in 90 patients with breast lesions. The study demonstrated an increasing proportion of malignant lesions with higher BI-RADS categories, supporting the clinical usefulness of standardized breast imaging assessment. In the present study, the largest proportion of patients belonged to the 31–40-year age group (27.78%), followed by 41–50 years (25.56%). Female patients constituted 96.67%, while males accounted for 3.33%. Breast lump was the predominant presenting complaint (72.22%), followed by breast pain (13.33%) and nipple discharge (8.89%). Right-sided lesions were observed in 47.78% of patients, left-sided lesions in 46.67%, and bilateral lesions in 5.56%.The distribution of BI-RADS categories showed that 26.67% of lesions were classified as BI-RADS 3, followed by BI-RADS 4A (20.00%), BI-RADS 5 (15.56%), BI-RADS 4B (13.33%), BI-RADS 2 (13.33%), and BI-RADS 4C (11.11%). Histopathological examination identified 58 benign lesions (64.44%) and 32 malignant lesions (35.56%). Fibroadenoma was the most frequent benign diagnosis (31.11%), whereas invasive breast carcinoma of no special type was the predominant malignancy (25.56%).

The proportion of malignant lesions increased progressively across BI-RADS categories, from 0% in BI-RADS 2 and 4.17% in BI-RADS 3 to 11.11% in BI-RADS 4A, 50.00% in BI-RADS 4B, 90.00% in BI-
RADS 4C, and 100% in BI-RADS 5. These findings demonstrated a strong descriptive relationship between increasing radiological suspicion and histopathologically confirmed malignancy.Mohapatra et al. (2021)[1]

investigated the predictive value of BI-RADS 4 lesions and emphasized the importance of subdivision into 4A, 4B, and 4C for malignancy risk stratification. Similarly, Aziz et al. (2022)[13], in a study involving 316 breast specimens, reported malignancy in 9 of 75 BI-RADS 3 lesions (12.0%), 84
of 166 BI-RADS 4 lesions (50.6%), and 70 of 75 BI-RADS 5 lesions (93.3%). A retrospective Indian
study involving 215 patients at Kolar reported malignancy rates of 8.9%, 32.7%, 46.3%, 82.1%, and 91.8% in BI-RADS categories 3, 4A, 4B, 4C, and 5, respectively. These findings were broadly consistent with the present pattern, although the observed malignancy rate in BI-RADS 4A was lower in the present dataset (11.11% versus 32.7%). Regarding diagnostic performance, the present dataset demonstrated sensitivity of 96.88%, specificity of 60.34%, positive predictive value of 57.41%, negative predictive value of 97.22%, and overall accuracy of 73.33%. Aziz et al. (2022)[13] reported sensitivity of 94.48%, specificity of 43.14%, PPV of 63.9%, and NPV of 88.0%. Similarly, the Kolar study reported sensitivity of 96.3%, specificity of 38.3%, PPV of 61.2%, NPV of 91.1%, and accuracy of 67.4%. Ciurescu et al. (2025)[14], studying 67 women, reported sensitivity of 93.8%, specificity of 80.0%, and an area under the ROC curve of 0.877. These comparisons suggest that BI-RADS generally provides high sensitivity for identifying suspicious breast lesions, although specificity varies across populations and diagnostic thresholds.

CONCLUSION

The present study of 90 patients demonstrated a progressive increase in malignancy rates with higher BI-RADS categories, indicating a strong correlation between radiological classification and histopathological findings. Benign lesions accounted for 64.44% of cases, while malignant lesions constituted 35.56%. BI-RADS classification showed high sensitivity (96.88%) and negative predictive value (97.22%), with an overall diagnostic accuracy of 73.33%. These findings highlight the usefulness of BI-RADS in identifying suspicious breast lesions and guiding biopsy decisions. However, histopathological examination remains essential for definitive diagnosis and appropriate clinical management.

Limitations

The present study was limited by its relatively small sample size of 90 patients and single-center design, which may restrict the generalizability of the findings. Selection bias may have occurred because only patients who underwent histopathological examination were included. Interobserver variability in BI-RADS interpretation and differences in imaging modalities may have influenced diagnostic accuracy.

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