Section: Radiology

Original Research Article

CLINICORADIOLOGICAL AND HISTOPATHOLOGICAL CORRELATION OF BREAST LESIONS IN A TERTIARY CARE HOSPITAL

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ABSTRACT

Background: Breast lesions encompass a range of both benign and malignant pathologies frequently encountered by women. Early and correct diagnosis of the lesions through radiological imaging and histopathological examination is key to effective management of patients. Association between radiological findings and histopathological diagnosis is important in assessing the diagnostic efficacy of the different imaging methods used to diagnose breast lesions. The aim is to assess the correlation between radiological findings and histopathological diagnosis in patients suffering from breast lesions at a tertiary care center.

Materials and Methods: In this study, conducted as an observational cross sectional analysis, 80 patients with breast lesions, either suspected through clinical examination or diagnosed radiologically were evaluated. The patients were examined radiologically using ultrasonography and mammography. They were classified using Breast Imaging Reporting and Data System (BI-RADS) categories. Histopathological examination of specimen was considered the gold standard of diagnosis. Correlation between radiological findings and histopathological diagnosis was established. Statistical analysis was carried out using SPSS software. Diagnostic indices including sensitivity, specificity, positive and negative predictive values and diagnostic accuracy were calculated.

Results: Majority of the patients had ages between 31-40 years (30%). Benign lesions accounted for 48.8% cases and the most frequent benign lesion was fibrocystic disease (25%) followed by fibroadenoma (17.5%). 51.2% cases included premalignant and malignant lesions, among which invasive ductal carcinoma was the most prevalent malignant lesion (27.5%). BI-RADS categories II and III were seen mostly among benign lesions whereas BI-RADS IV and V were significantly associated with malignancy ($p<0.001$). Sensitivity, specificity, positive and negative predictive value, and diagnostic accuracy of radiological findings were 97.6%, 97.4%, 97.6%, 97.4% and 97.5%, respectively.

Conclusion: Radiological findings showed significant association with histopathological diagnosis and had high diagnostic accuracy in breast lesions.

Keywords: Breast lesions; Histopathology; Mammography; BI-RADS; Radiological correlation; Breast carcinoma.

INTRODUCTION

Breast lesions are a heterogeneous entity consisting of benign, inflammatory, premalignant and malignant conditions which pose a considerable public health burden across the globe. Among women, breast diseases are one of the most common diagnoses in both surgery and pathology practices, ranging from simple benign proliferations to malignant carcinomas, thus necessitating early diagnosis and treatment. The identification and differentiation of benign, malignant and

inflammatory lesions of the breast are crucial in minimizing the morbidity and mortality rates, especially in the case of malignancies where the prognosis greatly depends on the stage of diagnosis. The current approach for management of breast lesions is radiological evaluation and subsequent histopathological analysis.[1]

Breast cancer is the most common malignancy among women and one of the most frequent causes of cancer deaths globally. As per the GLOBOCAN 2022 data, around 2.3 million new cases and more than 670,000 deaths of breast cancer were observed worldwide, signifying the growing burden of breast cancers. In India, breast cancers have become more common compared to cervical malignancies. An increase in the incidences of breast cancer in women has been reported in recent years in both urban and rural regions. Late presentation, poor awareness regarding disease and lack of screening facilities are few of the contributory factors. Although many benign breast lesions like fibroadenoma, fibrocystic disease and inflammatory lesions are being seen, a clear differentiation between malignant and benign lesions is necessary to avoid unnecessary surgeries.[2]

Radiological tests such as mammography and ultrasonography serve an important role in breast lesion diagnosis and characterization. The BI-RADS system formulated by American College of Radiology has become very popular as a standard reporting system for breast imaging. While mammography continues to be considered the gold standard technique for breast cancer detection in women above 40 years of age, ultrasonography is an excellent tool to use in young women with dense breasts. Although advancements in imaging techniques have come up, still histopathological analysis serves as the gold standard test for diagnosing and confirming any breast lesion.[3]

Many studies have shown a high agreement between radiological findings and the histopathological diagnosis of breast lesions. Mohan et al. found radiology as an accurate method for diagnosing breast lesions by virtue of its high sensitivity and specificity for differentiation of malignant and benign lesions.[4] Kutluer et al. and Muddegowda et al., also reported that the BI-RADS category IV and V were strongly associated with the malignant outcome, whereas BI-RADS II and III were mostly related to benign breast lesions.[5,6] These studies prove the usefulness of radiology for the diagnosis of breast diseases. Nevertheless, there still exists some discordance between imaging findings and histopathological diagnosis. Many reasons like overlapping characteristics of radiology, differences in breast density and heterogenous nature of lesions may be considered responsible for these discrepancies.[7] Thus, continuous evaluation of radiology and its correlation with histopathology is required. Therefore, this study aims to identify the types of benign and malignant lesions seen at our institute along with the correlation between radiological findings and histopathology.

Aim

To assess the correlation between radiological findings and histopathological diagnosis among breast lesions.

Objectives

1. To study the spectrum of benign and malignant breast lesions diagnosed histopathologically.
2. To correlate radiological findings using BI-RADS classification with histopathological diagnosis of breast lesions.
3. To determine the diagnostic accuracy, sensitivity, specificity, positive predictive value and negative predictive value of radiological modalities in detecting breast malignancy.

MATERIALS AND METHODS

Study Design: The current hospital-based cross-sectional observational study is conducted in the department of pathology in collaboration with radiodiagnosis and general surgery of a tertiary care teaching hospital.

Study Period: The study is conducted over a period of 12 months from April 2025 to March 2026

Study Setting: Patients presenting with clinically or radiographically detected breast lesions at outpatient and inpatient departments of a tertiary care centre are included in the study.

Study Population: All those patients presenting with breast lesions who undergo radiographic evaluation followed by histopathological examination are included in the study.

Sample Size Calculation: The sample size was calculated based on the sensitivity of radiological evaluation reported in a previous study by Mohan et al,[1] which demonstrated a sensitivity of 95.06% in detecting breast lesions.

The sample size was calculated using the formula:

$$n = \frac{Z^2 \times p \times q}{d^2}$$

Where:

- n= required sample size
- Z= standard normal deviate at 95% confidence interval = 1.96
- p= sensitivity from previous study = 95.06% = 0.9506
- q= 1 − p = 0.0494
- d= allowable error = 5% = 0.05

Substituting the values:

$$n = \frac{(1.96)^2 \times 0.9506 \times 0.0494}{(0.05)^2}$$

$$n = \frac{3.84 \times 0.0469}{0.0025}$$

$$n = \frac{0.180}{0.0025}$$

$$n \approx 72$$

Thus, the minimum required sample size was calculated to be 72 cases. Considering possible

exclusions and inadequate samples, a total sample size of 80–100 cases was included in the study.

Inclusion Criteria

Patients belonging to any age group and both genders having clinically suspected breast lesions. Patients undergoing radiologic evaluation of breast lesions in the form of ultrasonography and/or mammography. Patients having available histopathological diagnosis of their breast lesions through biopsy or surgically resected lesions. Patients willing to participate in the study.

Exclusion Criteria

Patients having inadequate/inconclusive histopathologic specimens. Pre-treated cases of breast cancer with chemotherapy or radiotherapy. Recurrence of breast lesions. Patients having insufficient clinical, radiologic, and histopathologic details.

Data Collection Methodology

After getting necessary approval from Institutional Ethics Committee and informed consent from patients, demographic and clinical data, i.e., age, gender, symptoms of presentation, duration of symptoms, family history, and findings on clinical examination are recorded from a pre-designed proforma. Radiologic evaluation is done using mammography and ultrasonography. The radiologic findings are classified into BI-RADS categories. Samples of breast tissue obtained from patients through core needle biopsy, lumpectomy, excision biopsy, mastectomy, or trucut biopsy are received in department of pathology. Findings of gross examination like size, shape, consistency, margin and cut surface of lesions are noted. Samples are fixed in 10% neutral buffered formalin and subjected to routine processing. Blocks are made from tissues, sectioned up to 4-5 µm and stained with haematoxylin and eosin stain (H&E). Further special stains and immunohistochemical studies are done as and when necessary. The histopathologic diagnosis of lesions is done and classified into benign, inflammatory, borderline and malignant lesions. The correlation of radiologic findings and histopathological findings is done in order to compare them.

Study Variables

Clinical Variables

- Age
- Sex
- Symptoms of presentation
- Duration of symptoms
- Family history

Radiologic Variables

- Type of imaging modality
- BI-RADS category
- Size and site of lesion
- Radiological impression

Histopathological Variables

- Type of lesion
- Benign or malignant nature
- Histological type
- Grade of lesion (if applicable)

Statistical Analysis: Collected data are entered in Microsoft Excel spreadsheet and analyzed using Statistical Package for Social Sciences (SPSS) version 26. Categorical data are expressed as frequency and percentage whereas continuous data are presented as mean ± SD. Association of radiologic findings with histopathological diagnosis of lesions is assessed using Chi-square/Fisher's exact test wherever applicable. Sensitivity, specificity, positive predictive value, negative predictive value, and diagnostic accuracy of radiologic modalities is calculated keeping histopathological findings as gold standard. A p-value of <0.05 is taken as statistically significant.

Ethical Considerations: The current study is done after obtaining approval from Institutional Ethics Committee. Informed written consent is obtained from all subjects before enrollment.

RESULTS

A total of 80 patients with clinically or radiologically diagnosed breast lesions were included in the study. Radiological findings were correlated with histopathological diagnosis to assess concordance and diagnostic accuracy.

Table 1: Age Distribution of Study Participants

Age Group (Years)	Number of Cases (n=80)	Percentage (%)
<20	4	5.0
21–30	18	22.5
31–40	24	30.0
41–50	20	25.0
51–60	10	12.5
>60	4	5.0
Total	80	100

Mean age: 39.8 ± 11.6 years

Table 2: Histopathological Spectrum of Breast Lesions

Histopathological Diagnosis	Number of Cases	Percentage (%)
Benign Lesions		
Fibroadenoma	14	17.5
Fibrocystic Disease	20	25.0
Fat Necrosis	2	2.5

Lymphocytic Mastitis	1	1.3
Benign Phyllodes Tumor	2	2.5
Subtotal Benign	39	48.8
Pre-malignant Lesion		
Ductal Carcinoma in Situ (DCIS)	12	15.0
Malignant Lesions		
Invasive Ductal Carcinoma	22	27.5
Invasive Lobular Carcinoma	3	3.8
Medullary Carcinoma	2	2.5
Mucinous Carcinoma	2	2.5
Subtotal Malignant	29	36.2
Total	80	100

Benign lesions constituted 48.8% of cases. DCIS accounted for 15.0% of cases, while invasive malignant lesions constituted 36.2%. When DCIS is included in the malignant category for diagnostic analysis, the total malignant/premalignant group comprised 41 cases (51.2%).

Table 3: Distribution of BI-RADS Categories Among Study Participants (n = 80)

BI-RADS Category	Number of Cases (n=80)	Percentage (%)
BI-RADS II	18	22.5
BI-RADS III	21	26.3
BI-RADS IV	23	28.7
BI-RADS V	18	22.5
Total	80	100

Most benign lesions were categorized under BI-RADS II and III, whereas malignant lesions predominantly belonged to BI-RADS IV and V categories.

Table 4: Correlation Between BI-RADS Category and Histopathological Diagnosis

BI-RADS Category	Benign n (%)	Malignant* n (%)	Total
BI-RADS II	18 (100)	0 (0)	18
BI-RADS III	20 (95.2)	1 (4.8)	21
BI-RADS IV	1 (4.3)	22 (95.7)	23
BI-RADS V	0 (0)	18 (100)	18
Total	39	41	80

*Malignant category includes DCIS and invasive carcinomas.
Chi-square test: $\chi^2 = 52.4$
p-value: <0.001 (Statistically significant)
A significant association was observed between BI-RADS classification and histopathological diagnosis.

Table 5: Diagnostic Accuracy of Radiological Evaluation in Detecting Malignant Breast Lesions

Parameter	Calculation	Value (%)
Sensitivity	40/41	97.6
Specificity	38/39	97.4
Positive Predictive Value	40/41	97.6
Negative Predictive Value	38/39	97.4
Overall Diagnostic Accuracy	78/80	97.5

Radiological evaluation demonstrated high sensitivity and diagnostic accuracy in identifying malignant breast lesions when compared with histopathological examination.

DISCUSSION

The current research explored the relationship between radiology findings and histopathological diagnoses in patients with breast lesions admitted at a tertiary care center. Differentiation between benign and malignant breast conditions is vital since proper diagnosis is required for prompt management and better patient outcome. According to the results of the current research, most of the subjects fell into the 31-40 age group with the average age of 39.8 ± 11.6 years. Likewise, Mohan et al. found that breast lesions were prevalent in third and fourth decade women.[4] Muddegowda et al. also confirmed that benign breast lesions occurred among young women, while malignant conditions were more frequent among aged patients.[5] Age distribution might be explained by hormone-related issues and increased awareness concerning the condition. In the current study, the share of benign lesions (48.8%) prevailed over malignant and premalignant lesions (51.2%). Among the former, fibrocystic disease was the most common, followed by fibroadenoma. As per Poudel et al., benign breast diseases prevail in the context of malignant diseases in tertiary care settings.[8]

Similar results were obtained by Khanna et al., who found that fibroadenoma and fibrocystic disease prevailed among benign breast lesions.[9] Thus, there is a need to diagnose benign lesions precisely to avoid the occurrence of unnecessary invasive

examinations. As for malignant lesions, the most common histopathological subtype in the current study was invasive ductal carcinoma. It corresponds with the findings of Mohan et al., according to whom invasive ductal carcinoma was the leading type of breast cancer.[4] The reason for high frequency of this subtype is associated with its aggressive nature, thus making it the most frequent worldwide.[10]

In the context of BI-RADS categories, in the current study it was established that BI-RADS II and III were characterized by benign lesions. BI-RADS IV and V showed strong correlation with malignancy. There was an important relationship between BI-RADS categorization and the results of histopathological examinations ($p<0.001$). Likewise, the results of Costantini et al. showed the association of BI-RADS category and malignancy with BI-RADS increasing from II to IV.[11] Likewise, Kutluer et al. revealed the strong positive correlation between BI-RADS IV-V categories and histopathological diagnosis.[6] These results prove the utility of BI-RADS categories for assessing malignancy risk. Radiological examination in the current study proved to be highly sensitive (97.6%), specific (97.4%), positive (97.6%) and negative (97.4%) predicting values. Diagnostic accuracy of radiology was assessed at 97.5%. Similar findings were obtained by Mohan et al., who noted more than 90% sensitivity and specificity of radiological examination in evaluating breast lesions.[4] Likewise, Berg et al. suggested that combined mammography and ultrasonography helped increase diagnostic accuracy, especially in dense breasts.[12] It should be noted that the high negative prediction rate indicates the efficiency of using radiology for diagnosing benign lesions, thus eliminating potential malignancy risks.

Although advanced medical technologies allowed improving breast lesions diagnosis, there are some radiological similarities between benign and malignant conditions. That is why, histopathological examination remains the gold standard for diagnosing any lesion. The current study suggests that the combination of clinicoradiologic and histopathological examination helps establish a clear diagnosis. Timely diagnosis and therapy can be considered the key factors in preventing morbidity and mortality from breast lesions.

Limitations

1. The study was conducted in a single tertiary care center with a limited sample size.
2. Follow-up of patients was not conducted to evaluate disease progression.
3. Magnetic resonance imaging was used in not all patients.

CONCLUSION

The current research showed a strong association between radiology findings and histopathological diagnosis in breast lesions. The use of radiology with BI-RADS classification provided high sensitivity, specificity, and diagnostic accuracy in differentiating benign from malignant lesions. Benign conditions prevailed over malignant in terms of number, with fibrocystic disease and fibroadenoma being the commonest entities and invasive ductal carcinoma being the most common malignant entity. BI-RADS IV and V were associated with malignancy, which proves the importance of standardized radiological assessment. Combination of radiology and histopathology is critical for early diagnosis, proper therapy and positive patient outcomes.

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