

## DETERMINING THE DIAGNOSTIC ACCURACY OF BI-RADS MAMMOGRAPHY IN DETECTING BREAST CANCER KEEPING HISTOPATHOLOGY AS GOLD STANDARD

### General Surgery

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### ABSTRACT

**Background:** Breast cancer is the most prevalent malignancy among women worldwide, and mammography is the preferred imaging technique for breast cancer, both in screening and evaluation, because of its widespread availability, acceptability, and lucrative nature. Breast Imaging - Reporting and Data System (BI-RADS) yields standardized breast imaging terminology, report formatting, assessment system and a classification for mammography. Previous literature states that mammography can potentially predict breast malignancy with considerable accuracy. **Objectives:** To estimate the diagnostic accuracy, sensitivity and positive predictive value of BI-RADS mammography in detecting breast cancer using histopathological findings as the gold standard **Methods:** Our study with hospital based cross-sectional design was conducted on 150 female patients presented with palpable breast lesions in the Department of General Surgery and Emergency Medicine, at KIMS Hospital and Research Center, Bengaluru. The diagnostic accuracy of BI-RADS score as per mammogram was assessed by comparing with the histopathology reports of the patients. **Results:** The mean age of the subjects was  $43.71 \pm 17.36$  years where majority were still menstruating (70.7%), and family history was present in 19.3% cases. The highest proportion of women had noticed lesions since >6 months (62.0%), where majority measured 5 to 10 cm (51.3%). The most common diagnosis on mammography was BI-RADS 4 (28.67%). Based on HPE, majority lumps were malignant (57.33%), while remaining 42.67% were benign lumps. On comparing the mammographic diagnosis with HPE findings, the sensitivity and specificity were observed to be 78.31% and 79.10% respectively. The PPV and NPV were 82.27% and 74.64% respectively. Overall, the diagnostic accuracy of mammography (BI-RADS) in detecting breast cancer was estimated to be 78.67%. **Conclusion:** Breast cancer screening could be significantly aided by mammography due to its relatively high diagnostic accuracy in detecting breast cancer.

### KEYWORDS

Diagnostic accuracy, BI-RADS mammography, Breast cancer, Histopathology correlation

### INTRODUCTION

At an estimated 2.3 million new cases annually, and representing 11.7% of all cancer cases, breast cancer has become the most common malignancy among women worldwide.<sup>1</sup> More than half a million people every year are killed by it globally.<sup>2</sup> According to epidemiological forecasts, the number of women diagnosed with breast cancer worldwide will approach 2 million by 2030.<sup>3</sup> Even in India, the incidence of breast cancer has been continuously rising over the past decade, with the age-adjusted incidence rate of 258 per million population.<sup>4</sup>

In recent decades, significant advancements have been achieved in medical research regarding the early detection of breast cancer through various imaging techniques, including mammography, ultrasound, and breast magnetic resonance imaging (MRI).<sup>5</sup> Although clinical methods, such as self-breast assessment and routine check-ups, are commonly used for diagnosing breast disease, they may not be adequate for detecting all early-stage breast cancers, which are often hidden or difficult to detect through clinical means.<sup>6</sup>

Mammography is the primary imaging modality for breast cancer, both in screening and diagnosis, due to its wide availability, acceptability, and cost-effectiveness.<sup>7</sup> However, the gold standard for the diagnosis of breast cancer is histopathology, which relies heavily on the use of appropriate biopsy (tissue sampling) techniques, optimal tissue processing, and competent interpretation of gross and microscopic pathology findings.<sup>8</sup>

Breast Imaging - Reporting and Data System (BI-RADS) is a risk assessment and quality assurance tool developed by American College of Radiology that provides a widely accepted lexicon and reporting schema for imaging of the breast.<sup>9,10</sup> It applies to mammography, ultrasound, and MRI, but for the current study we shall correlate between the accuracy of mammography based BI-RADS and histopathological report, with the intent of supporting the advantages of non-invasive diagnosis over invasive ones.

### OBJECTIVES

1. To estimate the diagnostic accuracy of BI-RADS mammography in detecting breast cancer using histopathological findings as the

gold standard

2. To assess the sensitivity and positive predictive value of BI-RADS mammography in detecting breast cancer using histopathological findings as the gold standard

### METHODOLOGY

This hospital based cross-sectional study was conducted for a period of 3 months between January and March 2023, on female patients presented with palpable breast lesions in the Department of General Surgery and Emergency Medicine, at Kempegowda Institute of Medical Sciences Hospital and Research Center, Bengaluru. The sample size was calculated based on the findings from the study by Majeed AI et al<sup>11</sup>, where the positive predictive value of mammography in detecting breast cancer was observed to be 77.0%. Considering the proportion as 77.0%, and keeping the precision at 7.0% with 95.0% confidence level, the sample size was estimated to be 139, which was rounded to 150 subjects.

Our study included female patients above 35 years of age with palpable breast lesions referred from the outpatient clinics in the hospital as well as those aged below 35 years with a clinically suspicious palpable breast lesion and also have a positive family history of breast cancer. Recurrent breast cancer cases or patients whose histopathology results were not available or those who did not undergo biopsy or surgery were excluded from the study. All consecutive cases satisfying inclusion criteria were recruited for the study after taking informed consent. A pre-designed proforma which is internally validated was used to collect the information on all the needed variables.

Basic demographic details and relevant history were collected, physical examination including examination of breast and lymph node status were noted. Routine investigations including CBC, LFT, RFT and coagulation parameters were recorded. Chest X-Ray and ultrasound abdomen findings were noted. BI-RADS score was obtained by the expert opinion of the radiologist from the mammographic evaluation of breast composition, mass, asymmetry, architectural distortion, calcification and other associated features such as skin and nipple changes. Available FNAC, core needle biopsy and post-MRM histopathology reports were collected and noted. Finally, the BI-RADS score as per mammogram was compared with

the histopathology reports of the patients.

The information collected regarding all the selected cases was recorded in MS excel. Continuous data was represented in terms of means and standard deviations, and the categorical data in frequencies and proportions. Statistical Software SPSS version 26 was used to analyze the data. Appropriate tests of significance were used based on the type of data. P-value of <0.05 was considered as statistically significant after assuming all the rules of statistical tests.

RESULTS

Our study analyzed 150 female patients who presented with palpable breast lesions, with the age ranging between 22 years and 64 years. The mean age was 43.71 ± 17.36 years where majority belonged to the age group of 31 to 50 years (64.0%). The next majority were aged above 50 years (21.3%), and the least proportion aged were under 30 years (14.7%). Majority of the women were still menstruating (70.7%), while remaining 29.3% had already attained menopause. Family history of breast cancer was present in about 19.3% of the subjects (Table 1).

Table 1: Characteristics Of The Study Subjects

| Subjects (N=150) |                | Frequency (N) | Percentage (%) |
|------------------|----------------|---------------|----------------|
| Age group        | <30 years      | 22            | 14.7%          |
|                  | 31 to 50 years | 96            | 64.0%          |
|                  | >50 years      | 32            | 21.3%          |
| Menstrual status | Premenopausal  | 106           | 70.7%          |
|                  | Postmenopausal | 44            | 29.3%          |
| Family History   | Present        | 29            | 19.3%          |
|                  | Absent         | 121           | 80.7%          |

All 150 women presented with unilateral breast lesions, with the duration of existence ranging between 2 months and 15 months. Highest proportion of women had noticed the lesions since more than 6 months (62.0%), where upper outer quadrant was commonly affected area (61.3%). The size of the lesions ranged between 3 cm and 14 cm, where majority lesions measured 5 to 10 cm (51.3%), followed by the size less than 5 cm (28.0%), whereas the least proportion of lesions were measuring more than 10 cm (20.7%).

On performing mammography among 150 subjects, majority cases were classified under BI-RADS 4 (28.67%), followed by BI-RADS 2 (27.33%). The next higher proportions were BI-RADS 5 (24.00%) and BI-RADS 3 (12.67%), whereas the diagnosis of remaining 7.33% cases were found to be inconclusive (Figure 1). The histopathological examination was regarded as gold standard investigation in our study, based on which majority lumps were diagnosed to be malignant (57.33%), while remaining 42.67% were benign lumps (Figure 2).

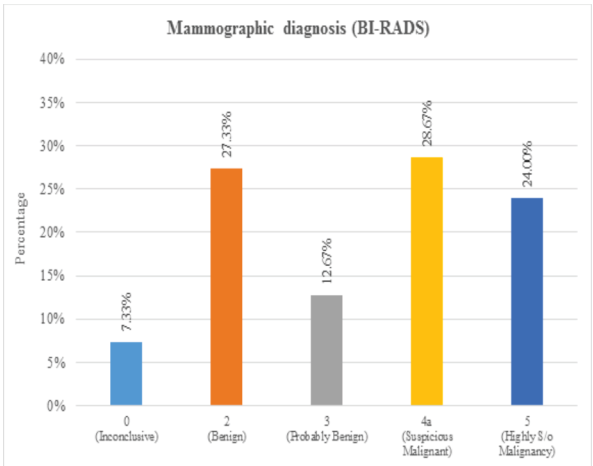


Figure 1: Diagnosis Of The Study Subjects Based On Mammography Findings (BI-RADS)

On further analysis, each mammographic diagnosis (BI-RADS) was confirmed on histopathology to be either malignant or benign. Accordingly higher proportion of true positives were appreciated in BI-RADS 5, whereas majority false positives were observed in BI-RADS 2. Overall, our study found statistically significant relation between mammographic diagnosis and histological diagnosis of the study subjects (Table 2).

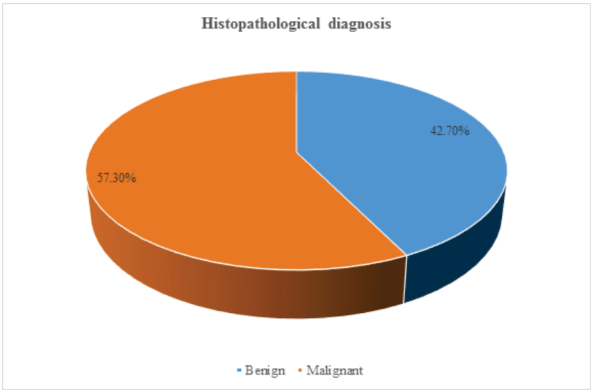


Figure 2: Diagnosis Of The Study Subjects Based On Histopathological Examination

Table 2: Association Between Mammographic Diagnosis And Histological Diagnosis Of The Study Subjects

| Subjects (N=150) | Benign (N=64) |       | Malignant (N=86) |       |
|------------------|---------------|-------|------------------|-------|
|                  | N             | %     | N                | %     |
| BI-RADS 0 (N=11) | 2             | 1.3%  | 9                | 6.0%  |
| BI-RADS 2 (N=41) | 36            | 24.0% | 5                | 3.3%  |
| BI-RADS 3 (N=19) | 15            | 10.0% | 4                | 2.7%  |
| BI-RADS 4 (N=43) | 11            | 7.3%  | 32               | 21.3% |
| BI-RADS 5 (N=36) | 3             | 2.0%  | 33               | 22.0% |

Chi-square value = 68.591, Degrees of freedom = 4, p-value <0.001 (Statistically significant)

BIRADS 1 (Negative) = 0, BIRADS 6 (Malignant) not considered in the study

Finally, the validity of mammography (BI-RADS) in diagnosing the malignant breast lesions was compared with that of HPE. Accordingly, the sensitivity and specificity were observed to be 78.31% and 79.10% respectively. The positive and negative predictive values were 82.27% and 74.64% respectively. Overall, the diagnostic accuracy of mammography (BI-RADS) in detecting breast cancer was estimated to be 78.67%. Also there was moderate agreement (0.570) between the mammography and HPE in diagnosing the malignant breast lesions (Table 3).

Table 3: Validity Of Mammography (Bi-rads) In Diagnosing Malignant Breast Lesions

| Subjects (N=150)      |                 | Histopathological Examination |        |              |        |
|-----------------------|-----------------|-------------------------------|--------|--------------|--------|
|                       |                 | Malignant(N=86)               |        | Benign(N=64) |        |
| Mammography (BI-RADS) | Malignant(N=79) | 65                            | 43.33% | 14           | 9.33%  |
|                       | Benign(N=71)    | 18                            | 12.00% | 53           | 35.33% |

Chi-square value = 49.028, Degrees of freedom = 1, p-value <0.001 (Statistically significant)

Kappa agreement: 0.570

DISCUSSION

In our study, we evaluated the accuracy of mammography based BI-RADS classifications in distinguishing breast masses. Accordingly, the diagnostic accuracy of mammography in detecting breast cancer was 78.6%. This is quite better in comparison with the diagnostic accuracies in the studies by Ghaemian N et al<sup>12</sup> and Nwammuo BC et al<sup>13</sup>, which were observed to be 58.2% and 65.0% respectively. On the contrary, studies such as Mohapatra SK et al<sup>14</sup> and Majeed AI et al<sup>11</sup> found about 87.9% and 92.3% of overall diagnostic accuracies respectively in characterizing breast masses, thereby supporting the use of mammography for early screening.

On further assessment, our study obtained 78.3% of sensitivity for mammography (BI-RADS) in detecting breast cancer which was comparable with the findings observed in most of the previous studies. The sensitivity of mammography was estimated to be 72.6%, 88.0% and 98.7% in the studies by Ghaemian N et al<sup>12</sup>, Majeed AI et al<sup>11</sup> and Mohapatra SK et al<sup>14</sup> respectively, which all substantiated the ability of mammography in the diagnosis of breast malignancy.

In addition, the positive predictive value (PPV) of mammography in

identifying breast cancer was estimated to be 82.3%. From one standpoint, Ghaemian N et al<sup>12</sup> found PPV of just 56.2%, while studies such as Majeed AI et al<sup>11</sup> and Mohapatra SK et al<sup>14</sup> observed PPV of 77.1% and 87.5% respectively, as evident to the diagnostic performance of mammography.

Overall, mammography is an easy to perform, low cost technique by which breast cancer can be detected. By validating the previous reports on the diagnostic accuracy of mammography in detecting breast cancer with our findings, mammography can be regarded as the modality of choice as it is the only evidence based early detection method.

## CONCLUSION

The diagnostic accuracy of mammography in breast cancer diagnosis is generally considered to be quite high. Based on the reported specificity and positive predictive value in this study, the test appears to be particularly effective at accurately characterizing breast lesions. This is especially important in breast cancer screening efforts aimed at identifying and ruling out the presence of the disease in adult females across the population.

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## Declarations

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**Conflict Of Interest:** None declared

**Ethical Approval:** The study was approved by the Institutional Ethics Committee

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