ORIGINAL ARTICLE

DIAGNOSTIC ACCURACY OF BIRADS SCORE OF ≥IV ON MAMMOGRAPHY FOR THE DETECTION OF MALIGNANT BREAST LESIONS BY TAKING HISTOPATHOLOGY AS GOLD STANDARD IN PATIENTS PRESENTING WITH BREAST LUMP

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ABSTRACT

INTRODUCTION: Breast cancer is the most prevalent cancer type in females worldwide. Currently, radiological imaging plays an important role in early diagnosis of breast cancer including ultrasonography, mammography and magnetic resonance imaging (MRI) examination. **OBJECTIVE:** To determine the diagnostic accuracy of BIRADS score of ≥ IV on mammography for the detection of malignant breast lesions by taking histopathology as gold standard in patients presenting with breast lump at a tertiary care hospital. **MATERIALS AND METHODS:** A cross-sectional prospective study was conducted in the department of Radiology at Dr. Ziauddin University Hospital, Karachi from January 2023 to December 2023. A total of 187 patients presenting with breast lumps were included in this study. Brief history for demographic information was taken. Mammography was performed in all patients and the breast lump was classified according to the BIRADS scoring system. The histopathological correlation of breast lesions was taken as gold standard. All information were entered in performa and statistical analysis was done using SPSS version 25. **RESULTS:** The average age of the patient was 50.04 ± 7.85 years. Sensitivity, specificity, PPV, NPV and accuracy of BIRADS score ≥ IV on mammography for the detection of malignant breast lesions were 94.1%, 89%, 76.2%, 97.6% and 90.3% respectively. **CONCLUSION:** Taking BI-RADS grade 4A or higher as the positive standard, the sensitivity of mammography in diagnosing breast cancer was 90.3%; therefore, it is an effective tool and noninvasive method for early detection of breast cancer.

Key words: Breast cancer, BI-RADS grading, Breast lump, Mammography, Malignant, Benign.

Introduction

Breast cancer is the most prevalent cancer type among women globally, with approximately 2.3 million new cases diagnosed in 2022, making up 11.6% of all cancer cases according to the GLOBOCAN report. It is the fourth leading cause of cancer-related mortality worldwide, with 6.9% of all cancer deaths. It accounts for approximately one in four cancer cases and one in six cancer deaths in women worldwide.[1] It is particularly more prevalent in less developed countries, where it contributes to 15% of total cancer deaths. Notably, past studies have indicated a higher incidence of breast cancer in developed nations. However, recent findings reveal a concerning rise in both incidence and mortality rates in low- and middle-income countries. Time trends in breast cancer incidence mainly reflect changes in hormonal, reproductive and lifestyle determinants as

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well as increased detection through mammographic screening.[2]

The diagnostic journey for breast cancer often takes 2 to 3 years from the onset of symptoms, allowing the disease to advance from localized in-situ to invasive stages during this time. Therefore, early detection, diagnosis, and treatment are crucial, not only for improving recovery rates and extending survival but also for enhancing the quality of life for patients, including maintaining their physical appearance and boosting confidence.[3]

Imaging techniques play a vital role in the early diagnosis of breast cancer, with mammography, ultrasonography and magnetic resonance imaging (MRI) being the primary methods. Each of these methods has its own strengths and limitations. For instance, ultrasonography's sensitivity can vary based on the operator's technique, which affects both its specificity and sensitivity. MRI shows strong sensitivity and specificity but involves complex procedures, takes considerable time, can be uncomfortable for patients and is also an expensive imaging modality. It also has limitations in detecting calcifications. Mammography serves as a standard initial imaging investigation, utilizing standard views to identify masses, architectural distortions, or calcifications, with results scored using the breast imaging reporting and data system (BIRADS) guidelines.[4]

Different researches have highlighted that a BIRADS score of 4 is critical; a study by Li et al. reported the sensitivity, specificity, and accuracy of mammography at 90.80%, 84.60%, and 87.40%, respectively.[5] The use of mammography in cases of clinically significant breast masses can reduce overdiagnosis and unnecessary treatments by minimizing unwarranted biopsies. Early detection of malignant lesions allows for prompt treatment initiation, which is essential for improving patient outcomes. This study aims to evaluate the diagnostic accuracy of BIRADS score of ≥ IV on mammography for detecting malignant breast lesions, using histopathological results as the gold standard. Conducting this study at a tertiary care facility, serving a large patient population, means that the results can set a benchmark for other healthcare facilities, aiding in the development of management guidelines for breast cancer diagnosis and treatment and to address a gap in local data.

Material and Methods

A cross-sectional prospective study was conducted in the department of Radiology at Dr. Ziauddin University Hospital, Karachi from January 2023 to December 2023. This study was approved by ethical review committee of Dr Ziauddin Hospital. Sample size was taken as 187 patients, calculated by taking, sensitivity 90.8%, specificity of 84.6% of mammography, prevalence 23%, the margin of error d=9% for sensitivity and d=9% for specificity and confidence interval 95%. Sampling technique was non-probability consecutive sampling. All women between 35-70 years age presented with breast lump for a period of two or more months or women with any impalpable lump detected on ultrasound were included in the study. Women less than 35 years, pregnant women, with infective / inflammatory pathology, known breast cancer, on chemotherapy were excluded from the study. This study was conducted after approval from the ethical review committee of College of Physicians and Surgeons of Pakistan. Informed consent was obtained from all the patients. Brief history for demographic information (age and residence status) was taken. The quantitative variable (age and duration of breast lump) and qualitative variables (marital status, side of breast lump, family history of breast cancer, true positive BIRADS score of ≥ IV on mammography and malignant breast lesion on histopathology) were entered in performa. Mammography was performed in all patients and was reviewed by a senior consultant radiologist with over five years of experience and specialization in breast imaging. The breast lumps were classified according to the BIRADS scoring. The histopathological findings were taken as a gold standard to label malignant breast lesion. Data was analyzed on SPSS Version 25. Mean and standard deviation was calculated for continuous variables such as age and duration of breast lump. Mean ± SD was reported for the normally distributed while median (IQR) was reported for the non-normality distributed quantitative variables. Frequency and percentages were calculated for marital status, side of breast lump, family history of breast cancer, BIRADS score of ≥ IV on mammography (Positive/Negative) and malignant breast lesion on histopathology (Positive/Negative). Sensitivity, specificity, positive and negative predictive values and diagnostic accuracy were calculated. Stratification was done with regards to age,

marital status, side of breast lump, family history of breast cancer and duration of breast lump. Post stratification sensitivity, specificity, positive and negative predictive values and diagnostic accuracy were also calculated.

Results

In this study, a total of 187 patients presenting with breast lumps were included. The demographic and clinical characteristics of the patients and post stratification diagnostic measures are summarized in (Tab.1).

	Sensitivity	Specificity	PPV	NPV	Accuracy
Age					
< 40	98.50%	93.50%	86.80%	87.60%	95.50%
> 40	83.30%	83.10%	60.00%	94.20%	83.10%
Marital status					
Unmarried	97.20%	97.5%	98.10%	97.30%	96.5%
Married	93.60%	88.10%	94.60%	97.40%	93.60%
Duration of lump					
< 6 weeks	92.90%	90.30%	84.30%	97.70%	90.90%
> 6 weeks	95.70%	86.00%	88.60%	97.40%	89.40%
Site of Lump					
Right Breast	92.30%	90.00%	87.80%	93.80%	91.00%
Left Breast	98.0%	88.40%	94.50%	97.0%	89.80%
Family History					
Positive	90.60%	97.0%	98.30%	85.70%	94%
Negative	98.0%	87.30%	85.90%	94.50%	84%

Table 1: The demographic and clinical characteristics of the patients and post stratification diagnostic measures.

The study assessed the diagnostic performance of the BIRADS score of ≥ IV on mammography for detecting malignant breast lesions and the results are summarized in (Tab.2) and the diagnostic measures as summarized in (Fig.1).

BIRADS score of ≥ IV on mammography	Histopathology		Total
	Positive	Negative	
Positive	48	15	63
Negative	3	121	124
Total	51	136	187

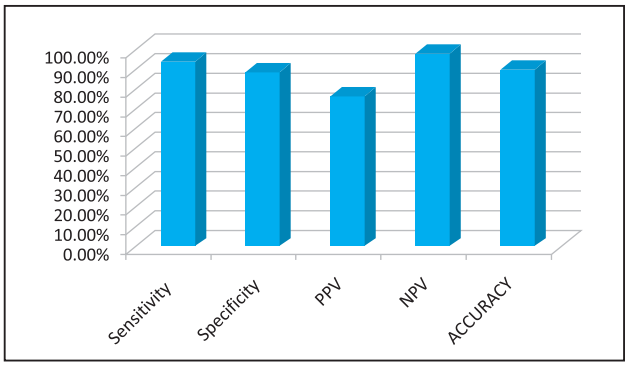

Figure 1: Diagnostic measures of the BIRADS score of ≥ IV on mammography for detecting malignant breast lesions taking histopathology as gold standard.

The diagnostic accuracy of the BIRADS score varied with age, with a reported accuracy of 95.5% for women aged ≤ 50 years and 83.1% for those aged > 50 years. Additionally, the diagnostic accuracy of the BIRADS score of ≥ IV was consistently above 80% across all stratified groups, as illustrated in (Tab.1). A stratification analysis indicated that the diagnostic accuracy ranged from 77% to 93% in various defined groups. This range demonstrates the robustness of the BIRADS scoring system across diverse patient demographics, highlighting its effectiveness in identifying malignant lesions in breast cancer evaluations.

Discussion

The BI-RADS (Breast imaging reporting and data system) classification system plays a crucial role in the evaluation of breast masses, categorizing them based on imaging findings to aid in diagnosis. Categories 3 and 4 are particularly significant, as they help differentiate between likely benign and suspicious lesions. BI-RADS 3 masses, with a malignancy risk of less than 2%, generally require short-term follow-up for two years unless there is clinical suspicion or patient preference for biopsy. On the other hand, BI-RADS 4 lesions, which exhibit varying degrees of suspicion for malignancy (4A with low suspicion (>2% to <10%), 4B with moderate suspicion (>10% to <50%), and 4C with high suspicion (>50% to <95%), typically require biopsy for definitive diagnosis. BI-RADS 5, indicating a greater than 95% likelihood of malignancy, always necessitates biopsy. When used properly, the indeterminate categories reduce the number of benign biopsies while allowing

the radiologist to maintain a high sensitivity for the detection of early-stage breast cancer.[6] In the present study, we evaluated the accuracy of BIRADS classification of breast lesions with histopathological confirmation to detect malignant breast lesions. Our results showed high accuracy of BIRADS score ≥ IV on mammography for the detection of malignant breast lesions with a sensitivity 94.1%, specificity 89%, positive predictive value (PPV) 76.2%, negative predictive value (NPV) 97.6% and overall accuracy of 90.3%.

Lehman et al.[7] the benchmark sensitivity of mammography for non-palpable lesions is 92.2% and for palpable lesion is 93.2%. Li et al.[5] study reported Breast imaging reporting and data system (BI-RADS) grade 4 as the critical point, the true positive, sensitivity, specificity and accuracy of mammography was 14.86%, 90.80%, 84.60% and 87.40%. In our study, the sensitivity for palpable breast lesions was 94.1%. Factors contributing to higher sensitivity in our study included small selective sampling of patients in a tertiary cancer center and categorical exclusion of ill-defined breast lesions in extremely dense breasts requiring additional imaging or investigations (BI-RADS 0).

In this study, the average age of the patient was 50.04 ± 7.85 years. This was in concordance to the study conducted by Mohapatra et al,[8] in which in which the average year was 49 years. In the study conducted by Mohan et al,[9] (36.0) cases were between 41-50 years, 10 (40.0) cases were between 51-60 years, 5 (20.0) 79 cases were between 61-70 years and only 1 (4.0) case was between 71-80 years. In the study conducted by Arsalan et al,[10] the mean age of the cases was found to be much younger 42.6 ± 7.21 (30- 60) years. In the study conducted by Soyder et al.,[11] the mean age of the cases was similar at 50 ± 11 years.

Over recent years, several studies stated that the BI-RADS system could be useful to discriminate malignant and benign breast masses. However, breast density is a major factor that influences the diagnostic accuracy. Reduced sensitivity and failures in diagnosis are observed in patients with dense breasts, as fibro glandular density obscures subtle imaging finding, leading to diagnostic failures and increased interval cancer detection. There are various other factors that can affect the diagnostic accuracy of imaging methods. Some are related to the patients, such as age, lesion characteristics, menstrual/menopausal status, family history, duration of symptoms and collaboration between patients and technicians in the imaging process, and some are related to the health system, including hardware i.e., presence of standardized device of imaging and human resources i.e., presence of an expert radiologist. These factors can explain the differences in the results between the various studies. In the study conducted by Navya et al,[12] considering HPE as gold standard, the sensitivity and specificity of BI-RADS score is 88.0% and 87.5% respectively. The positive predictive value, negative predictive value and diagnostic accuracy of BI-RADS score too concurred with these findings and were found to be 80.0%, 93% and 88% respectively. In the study conducted by Arsalan et al,[10] the sensitivity and specificity of BI-RADS score is 87.2% and 100.0% respectively. Positive predictive value, negative predictive value and diagnostic accuracy of BI-RADS score, in contrast to this study, were 100.0%, 33.3% and 88% respectively. In a study by Brown et al[13] mammography contributed to delineation of disease extent, detection of incidental malignancies, and confirmation of benign diagnoses in women above 30 yr of age. Differentiation between BI-RADS 3 and 4 by US elastography had 84 per cent sensitivity and 84 per cent specificity while dynamic contrast-enhanced MRI had 88 per cent sensitivity but only 80 per cent specificity according to a study conducted by El Said and Mohamed.[14] However, Strobel et al[15] concluded that MRI is useful for the non-invasive workup of lesions classified as BI-RADS category 4 at mammography or US and can help avoid 92 per cent of unnecessary biopsies.

World Health Organization (WHO) has emphasized a tailored approach to breast cancer detection and management, taking into account resource availability. In high-resource settings, organized population-based mammography screening is effective and is recommended every 2 years, but in lower-resource settings, where early detection can be more challenging due to limited access to screening tools, the focus is on ensuring early diagnosis and improving access to treatment.[16]

The Global Breast Cancer Initiative, launched in 2021, aims to reduce breast cancer mortality globally by emphasizing early detection, timely diagnosis, and comprehensive treatment. With its goal of saving 2.5 million lives over the next 20 years, the initiative encourages collaboration across sectors to improve outcomes for women, particularly in areas where the disease is

often diagnosed at more advanced stages.[17,18,19] Taking BI-RADS grade 4A or higher as the positive standard, the sensitivity of mammography in treating breast cancer was 90.3%; therefore, it is applicable for general investigation of breast cancer to lower the misdiagnosis rate of malignant tumor.[20] Patients suffering from grade 4A breast cancer can be regarded as the key monitoring objects; regular ultrasonic review, surgical treatment and frozen pathology are required to timely discover malignant lesion and improve the survival rate of patients.

Conclusion

Our results show that digital mammography is a highly sensitive tool for the evaluation of palpable breast masses. Further advancements in imaging technology and techniques are needed to improve detection, especially in patients with dense breast tissue. In addition, educating the public on self-breast examination and promoting regular mammographic screenings can help detect breast cancer at an early stage, ultimately improving survival rates. To further enhance diagnostic accuracy and ensure consistent clinical outcomes, the establishment of a nationwide digital mammogram database is recommended, enabling peer review and fostering a culture of continuous improvement among radiologists resulting in better clinical outcomes.

CONFLICT OF INTEREST: The authors declared no conflict of interest.

PATIENT CONSENT: Informed consent was taken by all the patients.

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