

Malignancy Rates in BIRADS 4 and 5 Lesions on MammographySamta Budania¹, Rajendra Chaudhary², Aayush Ajmera³¹Assistant Professor, Department of Radiodiagnosis, Dr. SN Medical College, Jodhpur, Rajasthan, India²Associate Professor, Department of Radiodiagnosis, Dr. SN Medical College, Jodhpur, Rajasthan, India³Senior Resident, Department of Radiodiagnosis, Dr. SN Medical College, Jodhpur, Rajasthan, India

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Abstract:

Background: In India, breast cancer has become a major oncological issue for women, making strict screening and diagnostic procedures necessary. The Breast Imaging-Reporting and Data System (BI-RADS) is the worldwide benchmark for mammography evaluation; nevertheless, the Positive Predictive Value (PPV) for high-risk groups, namely BI-RADS 4 and 5, varies significantly between regional and demographic groups.

Objective: This study's main goal was to assess the diagnosis accuracy and malignancy rates of mammographic lesions classified as BI-RADS 4 and 5, as well as to compare these radiological impressions with histological results in a Jodhpur tertiary care context.

Methods: Over the course of a year, the Department of Radiodiagnosis at Mathura Das Mathur (MDM) Hospital in Jodhpur carried out this prospective observational study. Fifty female patients with suspicious breast lesions classified as either BI-RADS 5 or BI-RADS 4 (subcategorized as 4a, 4b, and 4c) were included. Every subject had either a surgical excision or an ultrasound-guided core needle biopsy. The gold standard for determining malignancy rates and predicting values was histopathology.

Results: The population under research had an average age of 47.5 years. According to histopathological investigation, 18 (36%) of the 50 patients had a diagnosis of cancer, while 32 (64%) had benign pathology. According to stratification, the malignancy rates were 10.5% for BI-RADS 4a, 28.6% for 4b, and 75.0% for 4c. A 92.3% malignancy rate was found in BI-RADS 5 lesions. Mammography's total sensitivity for these high-risk groups was 94.4%, and its specificity was 81.2%.

Conclusion: The BI-RADS 4 and 5 categories successfully stratify malignancy risk, according to the study. However, the presence of inflammatory mimics in the area indicates that histological confirmation is still essential even though BI-RADS 5 requires immediate action.

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Introduction

In several urban and semi-urban population-based cancer registries, breast cancer has gradually overtaken cervical cancer as the most often diagnosed carcinoma among Indian women. This change in the epidemiology is concerning and emphasizes how urgently strong early detection systems are needed. Due to the region's size and the wide range of health literacy, Western Rajasthan presents particular healthcare issues. In order to properly prioritize patients for either aggressive surgical intervention or conservative observation, it is crucial to rely on reliable first imaging.

The Role of Mammography: The primary method for detecting and diagnosing breast cancer is still mammography. Its capacity to detect non-palpable lesions, subtle architectural deformities, and clusters of microcalcifications all of which frequently indicate early-stage disease is even more valuable than its ability to detect palpable masses. Mammography is the first line of defense due to its

affordability and accessibility, even with the development of more advanced modalities. However, there is intrinsic complexity and inter-observer variability in the interpretation of mammograms. The Breast Imaging-Reporting and Data System (BI-RADS) was created by the American College of Radiology (ACR) to solve this issue. In order to provide clear, practical management recommendations based on the likelihood of cancer, this standardized vocabulary and reporting format were created [1].

Clinical Significance of BI-RADS 4 and 5: The management of lesions falling into categories 4 and 5 poses a major clinical challenge, whereas the lower BI-RADS categories (1, 2, and 3) typically provide comfort to both the patient and the clinician. BI-RADS 4 is referred to as the "grey zone" in breast imaging and denotes a "suspicious abnormality." In this category, the likelihood of cancer ranges from as low as 2% to as high as 95%. The 5th version of

the ACR BI-RADS vocabulary promotes sub-stratification because a single label covering such a large probability gap is therapeutically wasteful. A mild suspicion of cancer is implied by category 4a, a moderate suspicion by category 4b, and a high suspicion by category 4c. BI-RADS 5, on the other hand, is only used for lesions with a theoretical likelihood of cancer more than 95% that are highly suggestive of malignancy and include classic radiographic features such spiculated high-density masses or fine linear branching calcifications [2, 3].

Rationale for the Study: The Positive Predictive Value (PPV) of these categories is not constant despite the existence of these established worldwide recommendations; it varies depending on the prevalence of the disease in the area, the equipment's technical quality, and the radiologists' interpretative skill. There is a dearth of localized data that measures the precise cancer risks connected to these particular BI-RADS subcategories in the Indian setting, particularly in areas like Jodhpur. It is essential for MDM Hospital's surgeons and oncologists to comprehend these particular rates. It enables evidence-based patient counseling that strikes a balance between the need for reassurance for BI-RADS 4a patients who might be experiencing severe anxiety despite a low chance of cancer and the necessity of aggressive management for BI-RADS 5 patients. In order to verify the lexicon's local applicability, this study intends to audit the malignancy rates in BI-RADS 4 and 5 lesions at a significant tertiary center in Western India.

Methodology

Study Design and Setting: The Department of Radiodiagnosis at Mathura Das Mathur (MDM) Hospital, which is connected to Dr. S.N. Medical College in Jodhpur, was the site of this prospective observational study. The data was gathered over a period of precisely one year. MDM Hospital serves a wide range of patients from Jodhpur and the neighboring districts of the Thar Desert region as a high-volume tertiary care referral center. Before the study started, the institutional review board granted ethical clearance, guaranteeing that all procedures followed the Declaration of Helsinki.

Study Population and Patient Selection: Fifty female patients who either visited the outpatient department or were referred from the surgery department made up the study population. We carefully considered women who had palpable breast tumors, nipple discharge, or abnormalities found after routine screening mammography. The mammography results had to be strictly classified as BI-RADS 4 or 5 in order to be included in the final analysis, and the patients had to have given their informed consent for biopsy or excision histological verification. In order to concentrate only on the high-risk groups, we eliminated individuals with benign-appearing lesions (BI-RADS 1, 2, or 3). In order to prevent confounding variables linked to altered breast density and radiation safety profiles, women with a known prior history of breast cancer, those who had recently undergone breast surgery or irradiation, and pregnant or lactating women were also excluded [4].

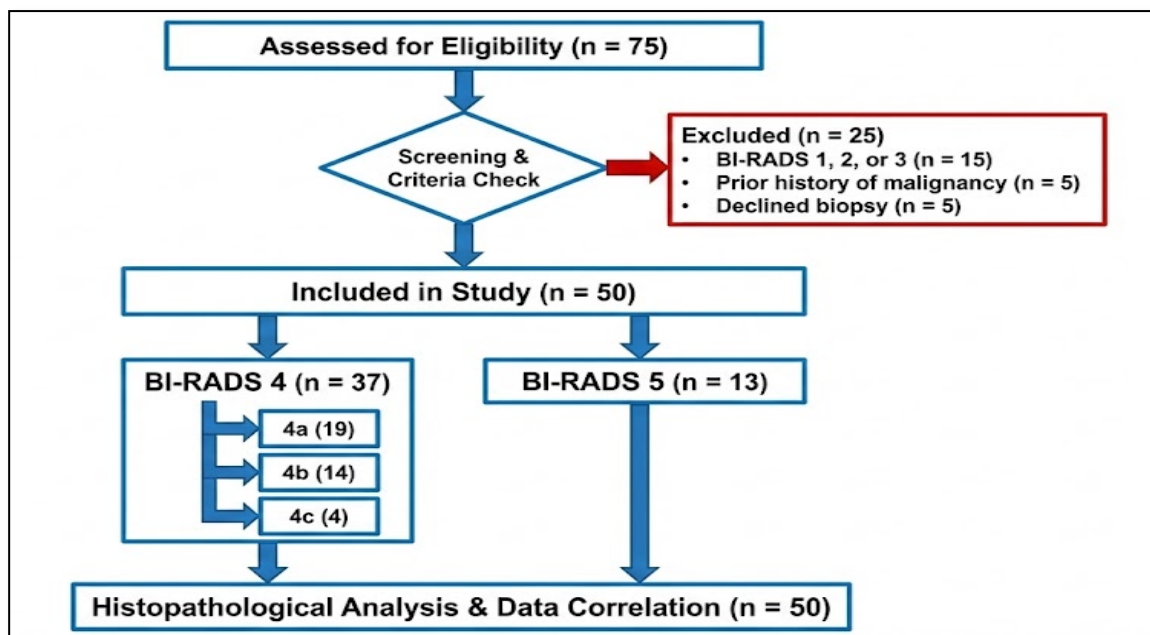


Figure 1: Study participant flow diagram

Imaging Protocol and Interpretation: A special Full-Field Digital Mammography (FFDM) device at the facility was used to perform mammograms on patients upon enrollment. To provide excellent consistency, the imaging protocol was standardized. For both breasts, standard Craniocaudal (CC) and Mediolateral Oblique (MLO) images were acquired so that symmetry could be compared. Additional specialist views, such as spot compression or magnification views, were obtained when the standard views were not adequate to adequately characterize a lesion, such as in situations of subtle microcalcifications or unclear architectural distortion.

Senior radiologists with at least five years of expertise in breast imaging interpreted these images. Using the adjectives found in the ACR BI-RADS 5th Edition lexicon, the lesions were carefully described. The radiologists assessed calcifications based on morphology and distribution and masses based on form, margin, and density. This thorough evaluation was followed by the assignment of a final BI-RADS category. In order to link physical observations with imaging data, this procedure was not just a technological exercise but also a clinical one, frequently necessitating discussion with the referring surgeons.

Histopathological Correlation: Through tissue sample, the final diagnosis was determined for each patient. The main technique for obtaining samples was ultrasound-guided Core Needle Biopsy (CNB), which made use of a 14G automated biopsy gun to guarantee sufficient tissue output. The standard of treatment is this minimally invasive method, which lowers patient morbidity in comparison to open surgery. However, patients received an open excision biopsy when the core biopsy results were unclear, inconsistent with the imaging findings, or technically impractical. The Department of Pathology handled the processing and analysis of the tissue samples. The radiological BI-RADS classification was evaluated using these histology results as a benchmark [5].

Statistical Analysis: The information gathered about pathological outcomes, imaging characteristics, and patient demographics was methodically documented. SPSS software (Version

26.0) was used for statistical analysis. By dividing the total number of cases in each BI-RADS category by the number of histologically confirmed malignant cases, we were able to determine the malignancy rate. Additionally, we calculated typical diagnostic accuracy metrics such as Sensitivity, Specificity, Positive Predictive Value (PPV), and Negative Predictive Value (NPV). We were able to measure the effectiveness of the BI-RADS system in distinguishing between benign and malignant entities in our particular patient cohort thanks to these parameters.

Results

Demographic Distribution: Fifty women, ages ranging considerably from 32 to 78, made up the study cohort. The participants' mean age was determined to be 47.5 ± 11.2 years. The 41–50 age group, which made up 38% of the research population, had the highest incidence of worrisome lesions classified as BI-RADS 4 and 5, according to an analysis of the age distribution. The age group of 51 to 60, which accounted for 30% of the cases, came next. A noteworthy demographic result is this comparatively younger age of presentation as compared to Western averages.

Distribution of BI-RADS Categories: A prevalence of BI-RADS 4 lesions was found when the 50 individuals were categorized. In particular, 13 patients (26%) were in the highest risk category of BI-RADS 5, whereas 37 patients (74%) were in BI-RADS 4. The sub-stratification revealed that 19 patients were 4a, 14 patients were 4b, and 4 patients were 4c within the diverse group of BI-RADS 4.

Histopathological Outcomes and Malignancy Rates: The relationship between the final histology diagnosis and the assigned BI-RADS category is the main discovery of this investigation. 18 (36%) of the 50 biopsied lesions were found to be malignant, whereas the remaining 32 (64%) were benign. Fibrocystic changes and granulomatous mastitis were the next most common benign diseases, after fibroadenoma. The most common subtype among the malignant category was Invasive Ductal Carcinoma (IDC)-No Special Type (NST) [6].

Table 1 below lists the particular malignancy rates (Positive Predictive Values) for each category.

Table 1: Malignancy Rate per BI-RADS Category

BI-RADS Category	Total Patients (n)	Benign (n)	Malignant (n)	Malignancy Rate (PPV)
4a	19	17	2	10.5%
4b	14	10	4	28.6%
4c	4	1	3	75.0%
5	13	1	12	92.3%
Total	50	32	18	36.0%

We examined the relationship between patient age groups and the probability of cancer in order to have

a better knowledge of the patient profile. Age is a crucial independent risk factor since, as Table 2

illustrates, the rate of cancer rose noticeably with age.

Table 2: Age Distribution and Correlation with Malignancy

Age Group (Years)	Total Patients	Benign Cases	Malignant Cases	Percentage Malignancy
30 – 40	12	11	1	8.3%
41 – 50	19	13	6	31.6%
51 – 60	15	7	8	53.3%
> 60	4	1	3	75.0%
Total	50	32	18	36.0%

Additionally, we assessed the correlation between the final result and the morphological features of the lesion on mammography. Compared to lesions that only appeared as calcifications or architectural

distortion, mass lesions especially those with spiculated margins had a stronger correlation with cancer. Table 3 provides a summary of these results.

Table 3: Lesion Morphology and Malignancy Outcomes

Mammographic Feature	Total Cases	Benign	Malignant	Malignancy Rate
Mass alone	28	16	12	42.8%
Calcifications alone	14	11	3	21.4%
Mass with Calcification	5	2	3	60.0%
Asymmetric Density / Arch. Distortion	3	3	0	0.0%

Diagnostic Accuracy: The system showed excellent reliability when assessing the effectiveness of mammography in this group. In these high-risk groups, mammography rarely missed frank malignancies, as indicated by the computed total sensitivity of 94.4%. It was discovered that the specificity was 81.2%. The great sensitivity ensures that very few false negatives occur at this level, confirming the usefulness of BI-RADS 4 and 5 as efficient "red flags" for malignancy [7].

Discussion

Interpretation of Malignancy Rates: To reduce needless surgical biopsies and guarantee that no tumors are overlooked, good preoperative prediction of breast cancer is crucial. This study, which examined 50 patients at MDM Hospital Jodhpur, gave an overview of the BI-RADS lexicon's diagnostic value in Western Rajasthan. According to our research, the combined BI-RADS 4 and 5 lesions had an overall malignancy rate of 36%. This is consistent with global standards, which typically set category 5 at more than 95% and category 4 between 2 and 95% [8].

The data becomes much more informative when we examine the subcategories. Although our observed rate of 10.5% for BI-RADS 4a is rather higher than the ACR standard of 2–10%, it is in line with other research carried out in similar Indian healthcare environments. For instance, a recent study by Augustine et al. in an Indian tertiary center reported a PPV of 18.7% for 4a lesions, reinforcing the low-to-moderate risk profile of this subcategory [9]. Referral bias, where patients frequently appear late with more advanced pathology, even within "lower suspicion" categories, may be the cause of the

somewhat higher prevalence in our context. The large percentage of benign cases (17 out of 19) in this group mostly fibrocystic changes highlights the necessity of a biopsy, but it also implies that patients' worry should be controlled by reassuring them that the risk of cancer is still rather low.

The actual "gray zone" of breast imaging is represented by the BI-RADS 4b category. Our PPV of 28.6% is well within the 10–50% ACR anticipated range [10]. These lesions frequently manifested as coarse, heterogeneous calcifications or veiled masses. A benign result in 4b necessitates a thorough radiologic-pathologic concordance assessment to be sure the target was not overlooked, in contrast to 4a, when a negative biopsy can be accepted with follow-up.

Malignancy rates were 75.0% and 92.3%, respectively, for the highest risk groups, BI-RADS 4c and 5. The radiologist's ability to detect frank cancer is validated by these high rates. But BI-RADS 5's PPV of 92.3% is little less than the theoretical 95%. The prevalence of granulomatous mastitis in India is the main cause of this disparity. Studies from comparable populations have shown that chronic mastitis and tuberculosis can appear as spiculated masses with architectural deformation that resemble cancer [11, 12]. One BI-RADS 5 lesion in our sample turned out to be granulomatous mastitis, emphasizing that although BI-RADS 5 is a surgical alert, histology is still required prior to mastectomy or chemotherapy.

Comparative Analysis with Literature: The PPV for BI-RADS 5 was 94.7% while for BI-RADS 4 it was 32.5% in a similar study by P. Sharma et al. [1]. These findings and our results are statistically

equivalent, indicating that MDM Hospital's diagnostic standards are uniform and on par with those of other national facilities. Additionally, the benchmark for sub-classification has been established by international investigations by Liberman et al. and Orel et al. [13, 14]. Their claim that sub-stratification greatly enhances the clinical

value of the mammography report is corroborated by our findings. Our group was primarily symptomatic, which explains the slightly higher aggregate malignancy rates compared to pure screening cohorts documented by Sickles et al. [15], in contrast to certain Western studies where screening populations are big and asymptomatic.

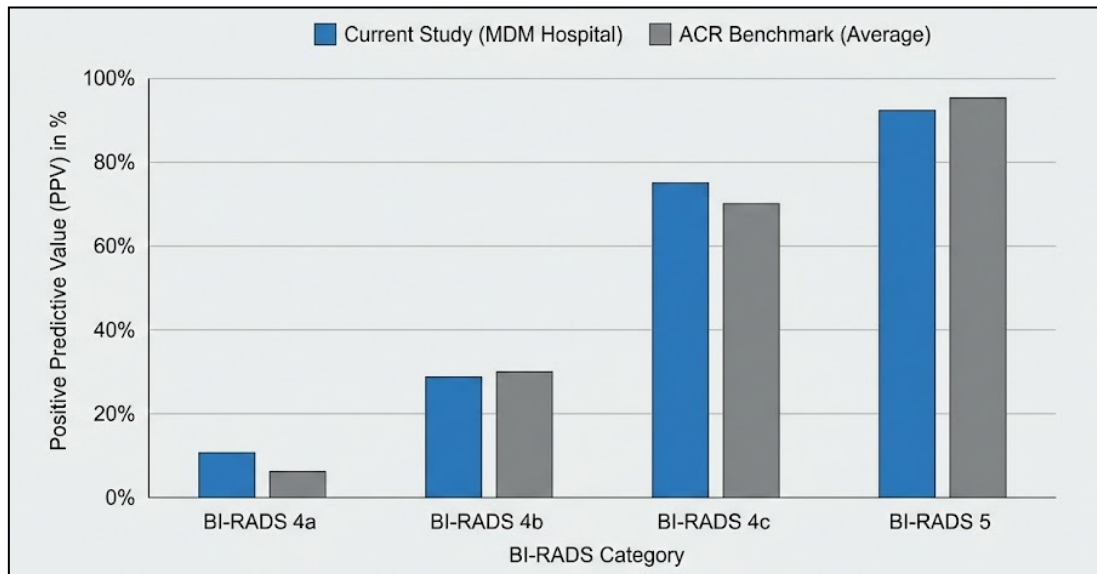


Figure 2: Comparative analysis of Positive Predictive Values (PPV)

False Positives and Negatives: The majority of the false positives in our analysis were inflammatory diseases, which are described as benign lesions classified as 4c or 5. In underdeveloped countries, where infectious breast etiology is more prevalent than in the West, this presents a special issue. On the other hand, the majority of false negatives, or cancers that showed up as 4a, were Ductal Carcinoma In Situ (DCIS). This highlights the fact that evaluating calcification morphology is still the most challenging aspect of mammography and that precise definition necessitates high-resolution digital imaging [16].

Conclusion

This study, which was carried out at MDM Hospital Jodhpur, validates the BI-RADS grading system in the particular demographic setting of Western Rajasthan. The results show that the BI-RADS method is a reliable indicator of cancer, and that the clinically significant split of Category 4 into a, b, and c. The clear stratification of cancer rates seen to increase from about 10% in category 4a to more than 90% in category 5 shows that this classification is more than just academic and has significant effects on patient care.

The great dependability of the BI-RADS 5 category is a crucial finding from this study. A rating of five, which carries a very high risk of cancer, demands

prompt and firm intervention. However, the study also highlights a problem unique to the area: the existence of benign inflammatory mimics such as granulomatous mastitis. Prior to receiving final surgical or oncological treatment, histological confirmation must always be performed because these diseases might radiologically resemble high-grade malignancies.

Additionally, the information about Category 4a lesions is crucial. Even though it has a "low suspicion" label, the malignancy rate is high enough to warrant a biopsy. This disproves the idea that imaging alone can be used to follow up on 4a lesions in our context. Based on these findings, we suggest that all radiological reports at our institution be subject to a thorough sub-categorization of BI-RADS 4. This will make it easier to make nuanced surgical decisions, protecting patients with lower-risk lesions from needless worry while giving those with higher-risk lesions the immediate care they need.

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