

**A single Centre prospective study of correlation between bi-rads on mammography and pathological diagnosis of breast lesions**

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**Abstract**

**Aim:** The purpose of this study was to assess the correlation between the BI-RADS Classification System and the pathology results. To determine the reliability of the BI-RADS Classification.

**Material and Methods:** This prospective cohort study was conducted between October 2022 – December 2022. The study included a total of 50 female patients, who came to the department of General Surgery and department of Surgical oncology, Alluri Sitaram Raju academy of medical sciences & Hospital with the complaints of breast lump, pain and discharge who were

classified as BIRADS - 3, BIRADS – 4 (4a, 4b, 4c) sub categories and BIRADS – 5 categories, and were evaluate during the epacris is forms, test results (radio logical imaging and tumor markers) and pathology reports.

**Results:** This study includes 50 patients, of which 9 were BI-RADS 3, 21 as BI-RADS 4a, 5as BI-RADS 4b,5 as BI-RADS 4c and 10 as BI-RADS 5. Of all the cases pathologically 36 cases are benign and 14 cases were malignant. Out of 36 benign cases, 9 cases were classified as BI-RADS 3, 19casesasBI-RADS 4a, 4 cases as BI – RADS 4b, 3 cases as BI – RADS 4c and 1 case

as BI – RADS 5. Out of 14 malignant cases, 2 case was classified as BI – RADS 4a, 1 as BI-RADS 4b, 2 cases as BI – RADS 4c and 9 cases as BI-RADS 5.

**Conclusion:** These statistics lead us to the conclusion that the BI-RADS classification is a highly reliable method to differentiate benign and malignant conditions inexperienced hands.

### Introduction

Breast cancer is the most common cancer among women. It is one of the few malignancies which allow screening and subclinical diagnosis. Studies reveal that one in ten women will develop breast cancer over the course of a life time; perhaps even higher, according to the recent assessments. Mammography screening can cut the mortality rate from breast cancer by about 30%, by achieving diagnosis at early stage.

The diagnosis and treatment of breast cancer must be approached from a multidisciplinary perspective, as is the case with many other cancer forms. Since almost 20 years ago, the BI-RADS classification has been applied to the multi-disciplinary standardization of radiological technique interpretation.

In 1997, the system was established for the first time in an attempt to standardize mammography findings by the American College of Radiology (ACR) and the American Cancer Society (ACS). BI-RADS (Breast Imaging Reporting and Data System) is a numerical scale in which the scores range between the codes of 0-6. The first mammography machine was developed by Jean Bens and Emile Gab Bay in 1960s. As with all X-rays, mammograms use doses of ionizing radiation to create images. These images are then analyzed for abnormal findings.

It is usual to employ lower-energy X-rays, typically Mo (K-shell X-ray energies of 17.5 and 19.6 keV) and Rh

(20.2 and 22.7 keV) than those used for radiography of bones.

Digital mammography is a specialized form of mammography that uses digital receptors and computers instead of X-ray film to help examine breast tissue for breast cancer. The electrical signals can be read on computer screens, permitting more manipulation of images to allow radiologists to view the results more clearly.

Digital mammography may be "spot view", for breast biopsy, or "full field" (FFDM) for screening. Digital mammography is also utilized in stereotactic biopsy.

Three - dimensional mammography, also known as digital breast tomosynthesis (DBT), tomosynthesis, and 3D breast imaging, is a mammogram technology that creates a 3D image of the breast using X-rays. When used in addition to usual mammography, it results in more positive tests. Another concern is that it more than doubles the radiation exposure.

Currently, the American Cancer Society, the American Congress of Obstetricians and Gynecologists (ACOG), the American College of Radiology, and the Society of Breast Imaging encourage annual mammograms beginning at age 40. Screening mammography shows greatest benefit—a 39.6 percent mortality reduction—from annual screening of women 40–84 years old. This screening regimen saves 71 percent more lives than (the USPSTF - recommended regimen of) biennial screening of women 50–74 years old, which had a 23.2 percent mortality reduction.

By not getting a yearly mammogram after age 40, women increase their odds of dying from breast cancer and that treatment for any advanced cancers ultimately found will be more extensive and more expensive.

The aim of the system was to establish a common image interpretation by clinicians in order to facilitate follow up of suspicious cases. Thus, it was aimed to evaluate the changes in breast in respect to the probability of malignancy and to decide on follow-up or further treatment options.

The objective of this prospective cohort study was to evaluate the correlation between mammography BI-RADS categories and pathologic diagnoses. Aiming to estimate the performance of mammogram in breast cancer detection.

Classification	Description
BI-RADS 0	Additional imaging methods required
BI-RADS 1	Unremarkable mammogram
BI-RADS 2	Benign findings
BI-RADS 3	Probably benign
BI-RADS 4	
4a	Low suspicion
4b	Moderate suspicion
4c	High suspicion
BI-RADS 5	Highly suggestive of malignancy
BI-RADS 6	Known malignancy (verified by biopsy but not yet treated)

Table 1:

**Material and Methods**

This study was conducted between October 2022 – December 2022. We prospectively analyzed a total of 50 cases who applied to the department of General Surgery and surgical oncology Alluri sitarama Raju academy of medical sciences & Hospital. Patients presenting with the complaints of breast lump, pain, discharge and ulcer who were classified as BIRADS - 3, BIRADS - 4a, BIRADS - 4b, BIRADS - 4c and BIRADS - 5 on mammography are included in the study.

In this study, we examined the epacris is forms and medical records of 50 female patients who underwent biopsy for breast masses.

Age, menopause, symptoms, mammography, ultra sonography and pathology results were valuated.

**Statistical analysis**

The data analysis was performed using SPSS (Statistical package for social sciences) Windows 11. 5 package programs.

The quantitative data were compared using descriptive statistics (mean, standard deviation, median) in addition to the Kruskal-Wallis H and Mann-Whitney Utests.

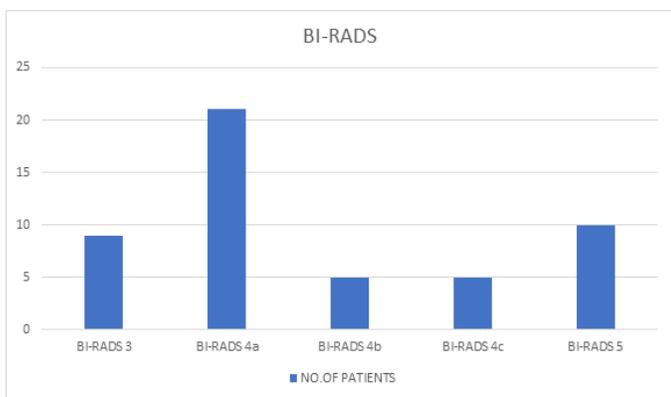
The values between  $p < 0.01$  and  $p < 0.05$  in 95 % and 99 % confidence intervals were considered statistically significant between the groups.

**Results**

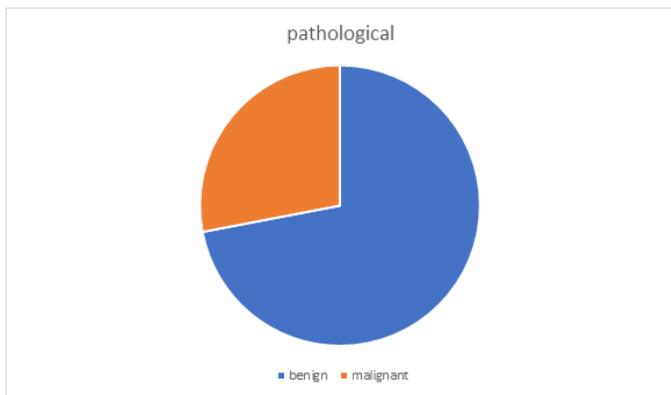
The mean age was 47. 5 (18 -77) years. The most common complaint among the patients was breast lump. Other symptoms included breast pain and nipple discharge. There were also patients who presented for routine mammography screening.

The study included a total of 50 patients; 9 of which were classified as BI-RADS 3, 21 as BI-RADS 4a, 5 as BI-RADS 4b, 5 as BI-RADS 4c and 10 as BI-RADS 5. Of the masses determined to be benign, 9 cases were classified as BI-RADS 3, 19 cases as BI-RADS 4a, 4 cases as BI-RADS 4b, 3 cases as BI-RADS 4c and 1 case as BI -RADS 5.

Of the malignant masses, 2 case was classified as BI – RADS 4a, 1 as BI – RADS 4b, 2 cases as BI-RADS 4c and 9 cases as BI - RADS 5.



Graph 1:



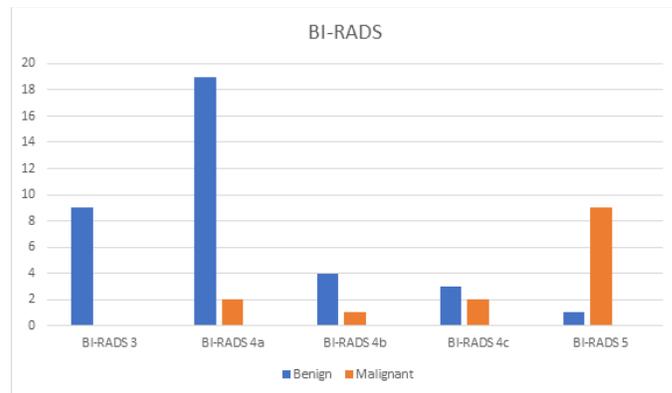
Graph 2:

9 patients in BI-RADS 3 category had a negative family history, in which those over 45 were examined for tumor markers and tested negative. The other patients in BI-RADS 3 category were in the younger group and underwent surgical operations for breast masses sized 2cm or more. Out of the 9 patients with BI-RADS 3 revealed by pathology results, 5 had fibroadenoma, 2 had fibrocystic changes, 1 had a typical columnar cell hyperplasia, 1 had granulomatous mastitis. Out of the 21 patients with benign lesions classified as BI-RADS 4a, the most common pathology was fibrocystic changes in 9 patients, fibroadenoma in 6 patients, intraductal papilloma in 3 patients, ductal epithelial hyperplasia in 3 patients. Out of the 5 patients with benign lesions classified as BI-RADS 4b, the most common pathology was determined as fibrocystic changes in 3 patients and severe ductal epithelial hyper-

plasia in 1 patient, 1 patient had sclerosing adenosis. Among the 5 cases in BI-RADS 4c category reported as benign, the most common lesion was severe ductal epithelial hyperplasia, which was present in 3 patients. 2 patients had tubular adenoma; 1 patient had intraductal papilloma. Among the BI-RADS 5 cases, 1 was benign and histopathologically diagnosed as fat necrosis.

Two patients with malignant lesions classified as BI-RADS 4a had ductal carcinoma in situ and 1 patient classified as BI-RADS 4b had mucinous carcinoma. In BI-RADS 4c category, 2 patients had histopathologically malignant masses. 1 patient had infiltrating ductal carcinoma. It was determined that 1 patient had ductal carcinoma in situ.

In BI-RADS 5 category, 9 cases were malignant. 5 of them were in infiltrating ductal carcinoma, 2 were invasive ductal carcinoma, 2 were infiltrative ductal carcinoma.



Graph 3:

BIRADS * HPE Crosstabulation					
		HPE		Total	
		Benign	Malignant		
BIRADS	3	Count	9	0	9
		% within BIRADS	100.0%	0.0%	100.0%
	4a	Count	19	2	21
		% within BIRADS	90.5%	9.5%	100.0%

4b	Count	4	1	5
	% within BIRADS	80.0%	20.0%	100.0%
4c	Count	3	2	5
	% within BIRADS	60.0%	40.0%	100.0%
5	Count	1	9	10
	% within BIRADS	10.0%	90.0%	100.0%
Total	Count	36	14	50
	% within BIRADS	72.0%	28.0%	100.0%

Table 2:

On Fishers exact test p value is 0.00 which is highly significant

### Discussion

Various studies have been conducted regarding the management of suspicious breast lesions. In 1997, ACS (American Cancer of Society) and ACR (American Committee of Radiology) introduced a standard system for mammography reports with the aim to facilitate the evaluation of breast masses. BI -RADS classification aims to establish a common interpretation and reach consensus regarding the follow -up of suspicious cases. It has become widespread all over the world and become a surgical guide in many health centers since the beginning of the 2000 s. Recently, it has al so been adapted to ultra sonography in order to increase the reliability of examination due to the low specificity of conventional mammography (5). In our study, mammography results were supported by ultra sonography. Recent studies have reported that the BI -RADS classification, which is adapted to ultrasonography, provides high consensus among radiologists and gives hope for the future (6, 7). The

sensitivity, specificity, positive and negative predictive values of BI -RADS categorization were reported as 95.7 %, 21.2 %, 37.8 % and 94.3 %, respectively (8).

Barren ge Retal. Evaluated BI-RADS classification as a significant guide in the study, in which they investigated the surgical approaches for micro calcifications. They reported that wire localization was effective in non -palpable solid masses and micro calcifications revealing correlation between radiological and his to logical findings and stated that the method should be more widely used (8, 10,11).

BIRADS – 3 and BIRADS – 4 are the most controversial categories of the system. A review reported that patients classified as BIRADS – 3 have low risk for cancer and 6 – month mammo graphy follow-up is appropriate (8). The authors stated that BIRADS-3 lesions are to be followed every 3 - 6 months, but bio psy maybe per formed according to the patient’s preference and concern about cancer.

BI-RADS 1 and 2 indicate a negative and benign screening mammogram respectively. BI-RADS 3 assessment is for those diagnostic mammograms classified as probably benign. BI-RADS 4 indicates a mammogram which is suspicious for malignancy and BI-RADS 5 suggests that the mammogram is highly suggestive of malignancy. BI-RADS 6 assessment is for those with biopsy-proven breast cancer. Only BI-RADS 0, 1 or 2 assessment categories can be assigned to screening mammograms. BI-RADS 3, 4, 5 and 6 are for diagnostic mammograms after performing a complete imaging workup

There are four options for management under the BI-RADS system. These recommendation options are (1) additional imaging studies, (2) routine interval mammography, (3) short-term follow-up, and (4) biopsy.

All categories reflect the radiologist's increasing level of suspicion for malignancy and have also been shown to have correlations with an increased risk of malignancy. The overwhelming majority of screening mammograms will end up classified as BI-RADS 1 and 2. A small percentage of mammograms (approximately 5 to 9%) will need additional imaging for further evaluation, short interval follow-up or possibly a biopsy. Approximately 7% of diagnostic mammograms will achieve a BI-RADS 3 assessment. Only 2% of diagnostic mammograms will receive a BI-RADS 4 or 5 assessment and will require biopsy.

Mentes et al. determined the probability of malignancy in BI-RADS 3 as 1.5% and as 32.6% in BI-RADS 4. Positive predictive values were reported as 15.4% in BI-RADS 3 and 32.6% in BI-RADS 4. The authors noted that it is appropriate to follow up BI-RADS 3 lesions every 3 – 6 months, but biopsy may be recommended depending on the patient's preference and concern about cancer. The study, which found 3-fold increased probability of cancer in BI-RADS 4 lesions, reported that biopsy must be performed for patients in this category (12). In our study, the malignancy rate was 0% in BIRADS-3, 2.28% in BIRADS - 4a, 2.86% in BIRADS - 4b, 63.64% in BIRADS - 4c and 96.43% in BIRADS - 5. 11 patients classified as BIRADS -3 underwent biopsy and recommended follow-up after the lesions were determined to be benign. The lesions were found to be histologically benign. The negative predictive value of category 3 was determined as 100% in our study, in which the correlation between radiological and histological results was consistent with the literature. It indicates that the reliability of the BI-RADS Classification will increase when performed by experienced radiologists. These findings demonstrate

that it is appropriate to follow up BIRADS - 3 lesions at 6-month intervals.

Age is also an important factor in management of breast lesions. It should be kept in mind that the risk of breast cancer increases with age. In the literature, it has been emphasized that BIRADS – 4 and 5 non palpable lesions in patients above 50 years of age should necessarily be biopsied using wire localization.

In our study, 85.7% of malignant cases were in post-Meno pausal period, whereas 14.3% of them were in pre – Meno pausal period. Malignancy rate generally increased in patients over the age of 47 years. The evaluation of BIRADS - 4 sub - categories according to the mean age was as follows; 4a < 4b < 4c. These findings indicate that age may be useful for the BI-RADS classification. The removal of non-palpable lesions using a wire marker seems to be an effective method for early Diagnosis in many malignant cases.

### Conclusion

These statistics lead us to the conclusion that the BI-RADS classification is a highly reliable method to differentiate benign and malignant conditions in experienced hands. In addition sub-categorization of BI-RADS category 4 is crucial to the management of breast masses. However, a greater number of patients and multi center studies are needed to obtain more accurate results.

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