Original Research Article

Accuracy of BIRADS mammography reporting system in diagnosis of benign and malignant breast lesions

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Abstract

Background: To evaluate the sensitivity, specificity, positive and negative predictive values and overall accuracy of BI-RADS (Breast Imaging Reporting And Data System) categories II,III,IV and V for detection of malignant breast lesions correlating mammographic and histopathological reports of patients. **Materials and Methods:** This is descriptive analytical study of mammographic reports of 477women who has been reported according to BI-RADS mammography lexicon and has undergone histopathology in the period of 2008 to 2018. Correlation of each Mammographic BI-RADS category done with histopathology report for analyzing sensitivity, specificity, positive and negative predictive value considering histopathological diagnosis as gold standard. **Results:** Overall sensitivity and specificity of BIRADS categories found to be 98.18% and 82.37% respectively. Positive and negative predictive values found to be 74.65% and 98.84% respectively. Overall accuracy found to be 87.84%. BIRADS category II and III lesions which are s/o benign nature of disease has negative predictive values as 98% and 100% respectively for malignant lesions. Category IV and V has positive predictive values as 56.92% and 95.09% respectively for diagnosis of malignancy. **Conclusion:** The present study has demonstrated that BI-RADS allows safe prediction of malignancy in category IV lesions and high suspicion of malignancy in lesions of category V lesions. The category II lesions demonstrated accurate prediction of benign nature of lesions. Thus BIRADS reporting of mammography has high sensitivity and specificity allowing management by surveillance instead of biopsy.

Key Words: BI-RADS(Breast Imaging Reporting And Data System)

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INTRODUCTION

Breast cancer has ranked number one cancer among Indian females with age adjusted rate as high as 25.8 per100,000 women and mortality 12.7 per 100,000 women[1].The survey carried out by Indian Council of Medical Research(ICMR) in the metropolitan cities during 1982 to 2005 has shown that incidence of breast cancer has almost doubled.[2] Indian women having breast cancer are found a decade younger in comparison to western women suggesting that breast cancer occurs at a younger premenopausal age in India.[3-7] Accumulative evidence also suggests that breast cancer in this age group is more aggressive and associated with poorer outcome than in their older counterpart[6]. There is significant increase in incidence and cancer associated morbidity and mortality in Indian subcontinent as described in global and Indian studies[1]. In this scenario extensive screening of female breasts has to be undertaken. Not all lesions in breast are malignant. Benign lesions of the breast are far more frequent than malignant ones[8].Efficient evaluation and prompt diagnosis are necessary to rule out malignancy. Solid palpable masses have traditionally undergone biopsy

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in large part because of palpability[9]. More recently in literature the long standing practice of performing biopsy for any solid palpable breast appearing normal on imaging is challenged. Because many breast masses may not exhibit distinctive physical findings, imaging evaluation is necessary in almost all cases to characterize the palpable lesion[10]. Mammography is a widely used method in breast disease diagnosis and screening which has simple operation, little trauma, low cost and wide application, especially for the display of breast lumps shape and boundary, and diagnosis of sand-like calcification in lesions[11]. Mammography is the most specific and sensitive method for diagnosis of breast cancer at its earliest presentation[12]. However, it was found that the mammographic reports were not standardized, lacked uniformity and there was inconsistent use of imaging terminology. Also there was no mandate to provide further patient management,recommendations based on imaging findings. Keeping this in mind, in 1993 the American College of Radiology (ACR) first developed the Breast Imaging-Reporting and Data System (BI-RADS), in an effort to provide a quality assurance tool that would standardize mammographic reporting, facilitate outcome monitoring and reduce the ambiguity surrounding breast imaging reports[13].The BI-RADS classification has represented the first attempt to standardize mammographic findings in descriptive terms, constituting an important ancillary tool in both in cases of suspected malignancy and definition of conduct to be adopted[12]. The BI-RADS lexicon offers a number of strengths, including the application of a standardized common language to facilitate communication between radiologists, referring physicians, and patients.The system also clarifies the reporting of mammography results and will support the completion of quality improvement activities and clinical research. Each mammographic study should be assigned a single assessment category based on the most concerning findings[14]. There have been multiple studies done else where demonstrating that the ACR-BIRADS assessment categories and lexicon have good correlation with the risk of breast malignancy. In June 1999,Orel *et al.* found that placing mammographic lesions into BI-RADScategories is useful for predicting the presence of malignancy[15]. In 2002,Berg *et al.* found that BI-RADS training resulted in improved agreement with the consensus of experienced breast imagers for future analysis and final assessment [16]. The BI-RADS approach to reporting mammography examination categorizes the overall composition of the breast and then describes noncalcified lesion by their basic shape, border, charactaristics and density. Calcifications are described according to size, morphology and distribution. The findings are then evaluated and an assessment is rendered that includes degree of suspicion for malignancy. Finally the report indicates the pertinent management recommendations.

BI-RADS assessment categories are numbered from 0 to VI. Details of the BIRADS for mammography are as follows:

Category 0: Incomplete assessment, additional imaging evaluation and/or prior mammograms for comparison are needed.

Category I: Negative, annual screening mammogram is recommended.

Category II: Benign finding(s), annual screening mammogram is recommended.

Category III: Probable benign finding, initial short-interval follow up is suggested.

Category IV: Suspicious abnormality, biopsy should be considered.

Category V: Highly suggestive of malignancy, appropriate action should be taken.

Category VI: Known biopsy-proven malignancy, appropriate action should be taken[17].

BI-RADS in general and the lexicon specifically were not intended to be static. After the initial creation of BI-RADS in 1993, 3 more editions were created in 1995, 1998, and 2003[18]. Now the Recent edition is of 2013. The positive predictive value of a biopsy positive for malignancy increases from less than 2% for BI-RADS category III mammograms to 23–30% for category IV mammograms and to 94% for category V mammograms(19,20). Thus, needle core biopsy is recommended for BI-RADS category IV and V lesions[17]. This report system has been used in Dr. Hedgewar Hospital which caters rural population of Marathwada region since 2007 and is accepted to be a very useful and practical way of communication between radiologists and clinicians. The lesions are classified according to BI-RADS descriptors for mammographic features including mass margins, mass shape, calcification morphology and calcification distribution using the single most worrisome descriptor for each feature and were categorized according to the BI-RADS final assessment categories on the basis of the radiologist's individual assessment[21].However, the accuracy and the predictive values of the mammographic reports according to the BI-RADS categories in Dr. Hedgewar Hospital have not yet been studied. The purpose of this study was to determine the sensitivity,specificity and positive and negative predictive values for BI-RADS(Breast Imaging Reporting And Data System) and overall accuracy thereby prove utility of mammography reporting with BI-RADS imaging lexicon. Hence benighn and malignant nature of breast lump determined allowing management by surveillance instead of biopsy in benighn lesions and thereby to reduce the morbidity associated with the procedure.

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MATERIAL AND METHODS

Mammograhic findings according to BIRADS lexicon Of 2000 women in the age group between 20-80 years who came to Dr Hedgewar Hospital for either screening or diagnostic mammography from June 2008 to September 2018 were studied .Those women having not undergone histopathological examination were excluded from study. BIRADS category VI patients and category I and 0 patients excluded from study. Thus 477 women whose histopathological records exist either done by FNAC, needle biopsy or after excision of the lesion are included in the study. The mammograms included At least two standard views of each breast (one craniocaudal view and one mediolateral oblique view) by a dedicated mammography machine (GE MAMMOMAT). Clinical data, Mammographic findings of each patient was reviewed and the category of the lesion and type of parenchyma noted. The information stored in electronic database and compared with allocated mammogram BIRADS category. Continuous variables were summarized as mean, standard deviation or median range as appropriate. Categorical variables were summarized as counts and percentages. Association between histologic findings of malignancy and mammography findings were determined using logistic regression analysis. These associations were reported as odds ratios. Statistical significance was defined as p-value of 0.05 or less. Statistical analyses were performed using stata v.7(sata Corp,College Drive, Texas,USA). The positive predictive value, negative predictive value, sensitivity, specificity and accuracy were calculated considering histopathological examination as gold standard.

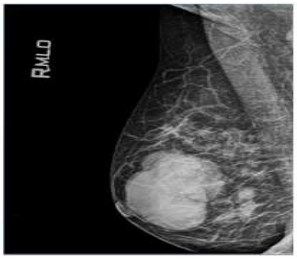

Figure 1: BI-RADS category II lesion

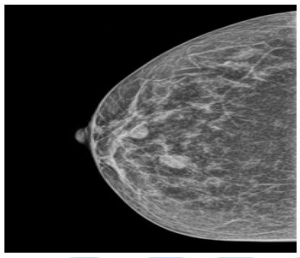

Figure 2: BI=RADS category III lesion

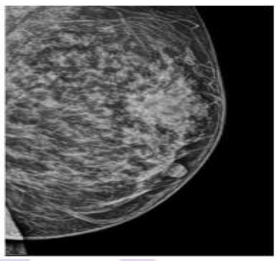

Figure 3: BI-RADS category IV lesion

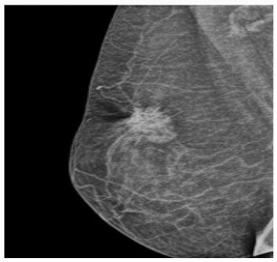

Figure 4: BI-RADS category V lesion

RESULTS

There were 477 patients of screening and diagnostic mammography, who fulfilled the inclusion criteria.

TABLE 1: Age wise distribution of patients

Age group	No of Patients	percentage
20-29	30	6.28%
30-39	140	29.35%
40-49	153	32.07%
50-59	69	14.4%
60-69	54	11.32%
70-79	31	6.49%
TOTAL	**477**	**100%**

The patient's age ranged from 20-79 years, with an average age of 46 years. Maximum number of patients were between 30 to 49 years age group.

TABLE 2: Distribution of various categories in sampled population was as follows

Birads Category	No of patients	Percentage
Category II	245	51.36%
Category III	15	3.14%
Category IV	115	24.10%
Category V	102	21. 38%

The lesions categorised as BIRADS II found in maximum (51%) number of patients and BIRADS category III found in lowest number of patients.

TABLE 3: Agewise distribution of various BIRADS category lesions

Age group	Category			
	II	III	IV	V
20-29	28	2	1	0
30-39	98	2	24	11
40-49	81	4	42	26
50-59	23	7	19	22
60-69	12	0	20	26

70-80	3	0	9	17
Total	**245**	**15**	**115**	**102**

Maximum number of patients in BIRADS category II lesions were found in 30-39 and 40 -49 years age group. Maximum number of patients categorised as BIRADS III are found in 50-59 years age group. BIRADS category IV lesions seen commonly in 40-49 years age group. BIRADS category V lesions found in 40 -49,50-59 and 60-69 years age group.

TABLE 4: Association of age group with BIRADS

Age group	II (n=245)	III (n=15)	IV (n=115)	V (n=102)	Total	P value	Test performed
20-29	28 (11.43%)	2 (13.33%)	1 (0.87%)	0 (0%)	31 (6.50%)	<.0001	Chi square test,24.038
30-39	98 (40%)	2 (13.33%)	24 (20.87%)	11 (10.78%)	135 (28.30%)	<.0001	Chi square test,36.734
40-49	81 (33.06%)	4 (26.67%)	42 (36.52%)	26 (25.49%)	153 (32.08%)	0.336	Chi square test,3.384
50-59	23 (9.39%)	7 (46.67%)	19 (16.52%)	22 (21.57%)	71 (14.88%)	<.0001	Chi square test,21.643
60-69	12 (4.90%)	0 (0%)	20 (17.39%)	26 (25.49%)	58 (12.16%)	<.0001	Chi square test,34.09
70-80	3 (1.22%)	0 (0%)	9 (7.83%)	17 (16.67%)	29 (6.08%)	<.0001	Chi square test,31.722
Total	**245 (100%)**	**15 (100%)**	**115 (100%)**	**102 (100%)**	**477 (100%)**	-	-

Statisticaly significant association is found between the age group and BIRADS categories.

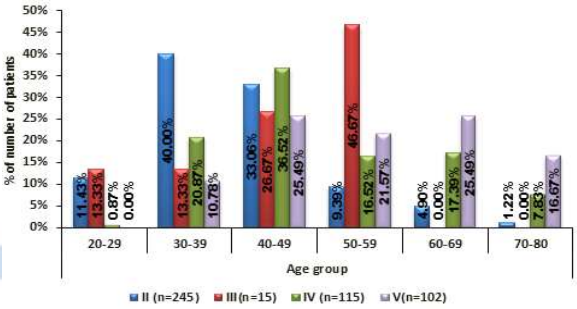

Figure 5: Association of age group with BIRADS

TABLE 5: Histopathologic findings in 244 of 477 patients (51.15%)who were categorized as BIRADS II

Sr. No	Histopath Diagnosis	No of Patient
1	Fibroadenoma	65
2	Fibrocystic Disease	59
3	Chronic Inflammatory lesion/ granulomatous mastitis	27
4	Simple/ Infected cyst/ epidermoid Cyst	22
5	Microglandular / adenomyoepithelialadenosis	14
6	Papilloma	9
7	Benighn Phyloids Tumor	1
8	Negative for malignant cells/intra epithelial lesion	32
9	Lipoma	5
10	Antibioma	2
11	Invasive duct Carcinoma	1
12	Florid ductal Hyperplasia	3
13	Non Hodgkin Lymphoma	2
14	Fibroepithelial polyp	2
15	Ductesia	2
16	Medullary Carcinoma	2
	Total	**245**

Fibroadenoma and fibrocystic disease is the most common histopathological diagnosis seen in BIRADS CATEGORY II lesions.

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TABLE 6: Histopathological findings in 15 patients who were categorized as BIRADS III

Sr. No	Histopath Diagnosis	No of Patient
1	Fibroadenoma	1
2	Fibrocystic disease	6
3	Chronic Mastitis/Granulomatous mastitis/Chronic Inflammatory lesion	3
4	No e/o malignancy	3
5	Borderline Soft tissue tumor	2
	Total	**15**

Fibroadenoma is the commonest finding in category IIII lesion on histopathology.

TABLE 7: Histopathologic findings in 115 patients who were categorized as BIRADS IV

Sr. No	Histopath Diagnosis	No of Patient
1	Invasive duct Carcinoma	53
2	Fibroadenoma	5
3	Medullary Carcinoma	3
4	Chronic mastitis/ Granulomatous Mastitis	13
5	Malignant lesion	8
6	Benighn lesion	11
7	Suspicious Lesion	1
8	Fibrocystic disease	13
9	Leiomyomatous polyp	2
10	Microglandular/ tubular adenosis	2
11	BenighnPhylloidsTumour	1
12	Florid ductal Hyperplasia	3
	Total	**115**

Invasive duct carcinoma was the most common diagnosis in BIRADS category IV lesions followed by fibrocystic disease and chronic mastitis.

TABLE 8: Histopathologic findings in 102 patients categorised as BIRADS V

Sr. No	Histopath Diagnosis	No of Patient
1	Invasive duct Carcinoma	70
2	Colloid Carcinoma	1
3	Malignant lesion	12
4	Invasive Lobular Carcinoma	3
5	Medullary Carcinoma	5
6	Malignant Phylloid tumor	1
7	Negative for malignant cells	3
8	Mucinous Carcinoma	1
9	Tubular Carcinoma	2
10	Ductal Carcinoma in situ	1
11	Fibrocystic disease	1
12	Granulomatous Mastitis	1
13	Adenoma	1
	Total	**102**

Invasive duct carcinoma is the most common histopathology diagnosis in category IV and V lesions.

TABLE 9: Benign and Malignant lesions found in each category

BIRADS	Histopathological diagnosis				
	Benign		Malignant		Total 477 (n)
	%	(n)	%	(n)	
II	98.77 %	242	1.23 %	3	245
III	100 %	15	0	0	15
IV	56.52 %	65	43.47	50	115
V	4.90 %	5	95.08 %	97	102

Maximum number of malignant lesions are found in category V.

Table 10: Association of BIRADS with histopathological diagnosis

BIRADS	Benign (n=327)	Malignant (n=150)	Total	P value	Test performed
II	242 (74.01%)	3 (2%)	245 (51.36%)	<.0001	Fisher Exact test
III	15 (4.59%)	0 (0%)	15 (3.14%)	0.004	Fisher Exact test
IV	65 (19.88%)	50 (33.33%)	115 (24.11%)	0.001	Chi square test,10.176
V	5 (1.53%)	97 (64.67%)	102 (21.38%)	<.0001	Chi square test,243.839
Total	327 (100%)	150 (100%)	477 (100%)	-	-

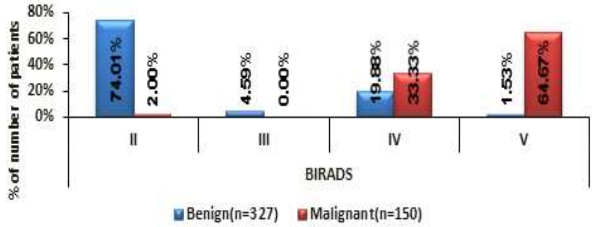

Figure 6: Association of BIRADS with histopathological diagnosis.

Table 11: Rate (%) of malignant findings of BI – RADS categories according to various other studies

Reference	BI – RADS Category				
	I	II	III	IV	V
Lourenzen *et al.*. (12)	NA	NA	3.5	71	97
Libreman *et al.*. (13)	NA	NA	NA	34	81
Mendez *et al.*. (9)	NA	NA	4	15	79
Orel *et al.*. (15)	NA	0	2	30	97
Berube *et al.*. (4)	NA	NA	0	4	54
Mayi – Tsonga *et al.*. (14)	NA	3	11	67	92
Siegmann *et al.*. (18)	NA	NA	6.3	16.7	85
Median	NA	1.50	4	30	85

BIRADS II and III were regarded as negative studies and BIRADS IV and V were regarded as positive studies for malignancy. Therefore, there were 260 negative studies and 217 positive studies .True negative (TN) in BIRADS categories II and III regarded as no known diagnosis of cancer or benign biopsy findings . So for BIRADS categories II and III TN was 242 + 15 = 257 True positive (TP) was regarded as cancer in categories IV and V. TP was 162 .False negative (FN) was regarded as diagnosis of cancer with benighn and probably benign findings (BIRADS categories II and III). FN was 3 = 3 cases . False positive (FP) was no proven cancer diagnosis in (BIRADS categories 4 and 5) or benign biopsy findings with BIRADS categories IV and V . FP was 50 + 5 = 55cases Negative predictive value = TN/number of negative mammographic examinations= 257/260= 98.84%

Positive predictive value = TP/number of positivemammographic examinations= 162/217= 74.65%

Sensitivity = The probability of detecting a cancer when a cancer existed .

Sensitivity = TP/TP + FN= 162/162 + 3= 98.18%

Specificity = The number of mammographically negative cases in a population divided by all negative cases in the population.Specificity = TN/TN + FP = 257/257 + 55= 82.37%

Accuracy = TN+TP/All patients = (257 + 162)/ 477= 87.84%.

TABLE 12: Negative and Positive predicitive values of each category

Sr. No	BIRADS CATEGORY	PPV	NPV
1	II	-	98.77
2	III	-	100
3	IV	56.52	-
4	V	95.09	-

DISCUSSION

The BI-RADS classification has represented the first attempt to standardize mammographic findings in descriptive terms,constituting an important ancillary tool in both in cases of suspected malignancy and definition of conduct to be adopted.(22) In this study a total of 477 patients were examined by both mammography and histo-pathology. These patients were aged between 22 and 80 years with mean age being 46 years . The majority of the participants (51.36%) had breast lesions classified into BI-RADS category II that corresponds to benign lesions .Category IV was next most common (24.10%) corresponding to suspicious abnormalities. 21% cases were of category V lesions which are s/o malignancy. On histopathology 98.77% cases categorised as BIRADS II found to have benign lesions while malignant lesions were found in 43% cases categorised as BIRADS category IV and in 98% cases as BIRADS category V. The study resulted in yielding a high sensitivity (98.18%). Study conducted by Farhat arsalan et, al positive predictive value was hundred percent with negative predictive value of 33.3%. Overall diagnostic accuracy of mammogram was 88% when compared with histopathological diagnosis.(23) Study conducted by José Hermes Ribas do Nascimentoet.al demonstrated that the mammographic accuracy ranged from 75% to 62% in the differentiation between benign and malignant lesions with the utilization of the BI-RADS classification.(24). Our study found accuracy of detecting malignancy as 87 % which is well correlated with study done by Farhat arsalan et,al. The study done by Siriporn Hirunpat, MD et .al reveals total accuracy was 97.8%, sensitivity 62.5% and specificity 98.1%..(25). Sensitivity and specificity found in our study is 98.18% and 82.37%. The positive predictive value of BI-RADS IV and V lesions for cancer according to Yah-Yuen Tan et.al was 27 and 84,respectively.(26) We found positive predictive value for category IV lesion as 56 and that of category V lesions is 95. From this study, the positive predictive value (PPV) of the BI-RADS category V for diagnosing breast cancer was 95 . It is compatible with at least 95 of PPV, suggested by the American Cancer Research (ACR), and also supported by others studies, which suggested PPV ranges from 80-97% (20) Statisticaly significant p values are observed in age and BIRADS categories except in 40-49 age group.Statisticaly significant association also found between BIRADS category of lesions and histopathological diagnosis of the lesion. 43 % malignant lesions were found in category IV lesions and 95 % malignant cases are found in category V lesions.These findings are comparable to findings in studies done by Oreal *et al.*,Libermann *et al.* and Median. According to Study conducted by Vaneska de Carvalho Melhado *et al.* The most frequent malignant breast neoplasm was ductal carcinoma in situ in 59.5% (25/42), followed by invasive ductal carcinoma in 33.3% (14/42), lobular carcinoma in situ in 4.8% (2/42) and invasive lobular carcinoma in one case. In our study we found invasive duct carcinoma to be most frequent neoplasm 82%(123/150) followed by medullary carcinoma and invasive lobular carcinoma each in 2%(3/150) cases. Ductal carcinoma in situ was found in 1 case.

CONCLUSION

Mammography is one of the most important diagnostic tools in the diagnosis of palpable breast diseases and can successfully clarify the nature of breast lumps especially in all age groups. It is highly sensitive and specific test with high diagnostic accuracy but it has its limitation especially in dense breasts which some times can obscure the lesion. In such cases clinical examination, mammography and histopathology must be added to reach definite diagnosis. The accuracy of the mammography can be increased further by improving the image quality, additional views and highly trained staff.

The BI-RADS lexicon allows quantification of the frequency of carcinoma using standardized terminology. By providing a common Ianguage, BI-RADS facilitates communication between radiologists, referring clinicians, and women undergoing mammography .Birads category II and III are highly suggestive of benighn lesions while category IV and V are highly suggestive of malignant lesions. The present study has demonstrated that the BI-RADS classification allows a safe prediction of high suspicion for malignancy in lesions classified as category V,and minimal suspicion in lesions classified as category II and III.

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