Int.j.pathol.2018;16(3)106-111

Original Article

Diagnostic Accuracy of Breast Imaging Reporting and Data System (BI-RADS) in Determination of Breast Malignancy Taking Histopathology as Gold Standard

Ruqaiya Shahid*, Binish Rasheed and Rubina Gulzar***

*Department of Pathology, Dow International Medical College, Dow University of Health Sciences. Dow International Medical College Dow University of Health Sciences, **Department of Radiology, Dow University of Health Sciences

Abstract:

Objective: To determine the yield, reliability and diagnostic accuracy of Breast Imaging Reporting and Data System in evaluation of breast lesions taking histopathology as gold standard.

Design: This cross-sectional, analytical study was conducted at the Pathology and Radiology departments at Dow University of Health Sciences, Karachi from January 2013 to December 2015.

Patients and methods: The data of the core needle biopsies of breast lesions received at the Pathology department was reviewed. The cases which had been categorized on mammogram, according to the Breast Imaging-Reporting and Data System (BI-RADS), were selected for the study. According to BI-RADS, categories II and III were classified as benign and BI-RADs IV and V as malignant. The breast core biopsies were classified as benign and malignant, according to the diagnosis.

Results: A total of 359 patients were included in the study. Females were predominant [n=355 (98.9%)] as compared to males [n=4 (1.1%)] with age 45.80 ±13.39 years [mean±SD]. There were 191 (53.2%) patients with left sidedbreast involvement, while 168 (46.8%) patients had right sided involvement. BI-RADS system for reporting when compared with histopathology had sensitivity of 92.38%, specificity 88.89%, positive predictive value 99.37%, negative predictive value 38.10%and diagnostic accuracy92.20%.

Conclusion:

The findings of this study report a high diagnostic accuracy of BI-RADS in the diagnosis of breast carcinoma; however, based on low negative predictive value we recommend training of radiologists reporting the mammogram, regular reviewing of discordant cases by histopathologist and radiologist, and early follow up in all such patients

Key words:

Breast lesions, mammography, histopathology, Breast Imaging Reporting and Data System (BI-RADS), sensitivity, specificity, accuracy

Introduction

Breast cancer is the commonest of all cancers in females world-wide and an estimated 1.7 million new breast cancer cases were diagnosed in 2012.[1]Sharp rise in breast cancer incidence was noted, with an increase of more than 20% since 2008. Mortality is 14% of total mortality rate; breast cancer is the most frequent cause of cancer death in women and is the highest in less developed countries.[1]Pakistan lacks a national cancer registry, and according to the latest data published, breast cancer is the top most cancer in the females in Pakistan with an age standardized incidence rate of 67.8/ 100,000, which is the highest in Asia.[2]According to another study considerable population of breast cancer patients present in late stages.[3]Regular mammographic screening has shown to effectively reduce the mortality rate by early detection of breast cancer in patients and is recommended after forty years.[4]Few breast screening programs, funded by the

Author for Correspondence:
Author for Correspondence:
Dr. Ruqaiya Shahid.
Department of Pathology, Dow International Medical College Dow University of Health Sciences.
ruqaiyashahid@yahoo.com
Email:ruqaiyashahid@yahoo.com

Government of Pakistan, are existing for the population at risk. [5,6]

Core needle biopsy (CNB) of a suspicious breast lesion is a safe and effective tool for diagnosis, grading of breast cancers and immuno-histochemical studies. Trucut biopsies can be performed percutaneously or under the guidance of U/S or MRI. Neo-adjuvant chemotherapy can be started in patients after trucut biopsy evaluation without the need for an excisional biopsy or mastectomy.[7]Breast Imaging Reporting and Data System (BI-RADS) was recommended by American College of Radiology (ACR) in 1993, to maintain a standardized approach in the reporting of breast cancers, since then it is routinely used in categorization of breast lesions on mammography, ultrasonography (U/S) and Magnetic Resonance Imaging (MRI). According to the ACR BI-RADS Atlas 2013, breast lesions are categorized into seven BI-RAD Assessment categories (0-6).[8]BI-RADS

Category 0: Incomplete examination.

Category 1: Negative, 0% likelihood of malignancy, routine mammographic screening.

Category 2: Benign, 0% likelihood of malignancy, routine mammographic screening.

Category 3: benign lesion, ≤2% likelihood of malignancy, six month follow-up recommended.

Category 4: Suspicious> 2% but less than 95% chances of malignancy; further classified into 4a,4b and 4c with increasing suspicion for malignancy; tissue diagnosis recommended.

Category 5: Highly suggestive of malignancy, tissue diagnosis recommended.

Category 6: Diagnosed case of breast cancer.

As the awareness about breast cancer is increasing, mammogram is routinely performed as screening tool at our tertiary care center, and breast surgeons prefer it due to its low cost and high yield reported in literature.[9] However, we routinely observe discordance in pathology and radiology reports of some cases of breast screening in our practice. Therefore, we conducted this study to know our limitations and strengths. The aim of this study was to determine the yield (sensitivity, specificity), reliability (positive predictive value, negative predictive value) and accuracy of the BI-RADS reporting system in evaluation of breast lesions taking histopathology as gold standard.

Methods

This was a cross-sectional and comparative study, conducted at the Pathology and Radiology departments at Dow University of Health Sciences. Three years' data of trucut biopsies of breast lesions, from January 2013 till December 2015, reported at the Pathology department of our tertiary care hospital, was analyzed.The cases which had been categorized on mammogram, according to the Breast Imaging-Reporting and Data System (BI-RADS), were included in the study. Patients with inadequate samples, biopsies which had not been categorized on mammogram, borderline categories including papillary neoplasms and Phyllodes tumors which could not be classified as benign or malignant on core biopsy were excluded.

According to BI-RADS, categories II and III were classified as benign and BI-RADS IV and V as malignant. The breast core biopsies were classified as benign and malignant, according to the histopathological features observed by consultant with fellowship in histopathology. The variables recorded were the age of the patient, BI-RADS category assigned to the lesions and the histopathological diagnosis of the breast lesions. The diagnosed cases were categorized into benign and malignant. We calculated the frequencies of BI-RADS categories and correlated these with the benign and malignant histopathological diagnosis. Statistical Package for Social Sciences (SPSS) version 16 software was used for data entry and analyses. Mean and standard deviation was calculated for age of the patient. Frequency and percentages were calculated for gender, marital status, site of involvement, BI-RADS categories on mammogram, and benign/ malignant on histopathology. Measures of yield (sensitivity, specificity), reliability (positive predictive value, and negative predictive value) and accuracy were measured by 2x2 tables.

Results

We included 359 patients and mean age of the patients was 45.80 ±13.39 years. Female preponderance was found [n=355 (98.9%)] as compared to males [n=4 (1.1%)]. Majority [n=321 (89.4%)] patients were married. There were 191 (53.2%) patients with left side involvement while 168 (46.8%) patients had right side involvement.

Findings of the BI-RADS showed that radiologically benign cases (BI-RADS II, n=12, 3.3% & BI-RADS III, n=30, 8.4%) were observed in 42 (11.7%) while radiologically malignant cases (BI-RADS IV, n=153,42.6% & BI-RADS V, n=164, 45.7%) were observed in 317 (88.3%) patients.

Findings of histopathology showed that benign cases were observed in 18 (5%) patients while malignant cases were found in 341 (95%) patients.

Diagnostic accuracy of BI-RADS showed that sensitivity of this reporting system for detection of malignancy was92.38%, specificity was 88.89%, positive predictive value was 99.37%, negative predictive value was38.10% and overall diagnostic accuracy was 92.20%. Table 1. Overall, NPV was low in our study i.e. if a radiologist reports a lesion as benign, the chance of it being benign on histopathology is 38.1% and in 62.9% it would turn out to be malignant.

Further stratification was done on the basis of age and marital status and the results are shown in Table 2.

Table 1: Diagnostic accuracy of BI-RADS taking histopathology as gold standard (n=359)

		Histopathology		
		Malignant	Benign	Total
BI-RADS	Malignant	315	2	317
	Benign	**26**	16	42
	Total	341	18	359
Sensitivity: 92.38%				
Specificity: 88.89%				
Positive predictive value: 99.37%				
Negative predictive value: 38.10%				
Diagnostic accuracy: 92.20%				

Table 2: Diagnostic accuracy of BI-RADS with respect to baseline characteristics taking histopathology as gold standard (n=359)

Age ≤45 years (n=196)				**Age >45 years (n=163)**				**Married (n=321)**				**Unmarried (n=38)**			
BI-RADS	**Histopathology**			**BI-RADS**	**Histopathology**			**BI-RADS**	**Histopathology**			**BI-RADS**	**Histopathology**		
	Malignant	Benign	Total		Malignant	Benign	Total		Malignant	Benign	Total		Malignant	Benign	Total
Malignant	163	1	164	Malignant	152	1	153	Malignant	291	2	293	Malignant	24	0	24
Benign	19	13	32	Benign	7	3	10	Benign	22	6	28	Benign	4	10	14
Total	182	14	196	Total	159	4	163	Total	313	8	321	Total	28	10	38
Sensitivity: 89.56%				Sensitivity: 95.6%				Sensitivity: 92.97%				Sensitivity: 85.71%			
Specificity: 92.85%				Specificity: 75%				Specificity: 75%				Specificity: 100%			
Positive predictive value: 99.39%				Positive predictive value: 99.35%				Positive predictive value: 99.32%				Positive predictive value: 100%			
Negative predictive value: 40.62%				Negative predictive value: 30%				Negative predictive value: 21.43%				Negative predictive value: 71.43%			
Note: Gender stratification showed that all 4 males were diagnosed malignant on both BI-RADS and histopathology															

Our results confirm that BI-RADS scoring system for radiological evaluation of breast lesions is a predictable and pragmatic tool for reporting and managing breast lesions; however, the low NPV needs further evaluation and elaboration since this would lead to missed diagnosis of breast cancer and presentation of such patients at advanced stage.

The mean age of our patients was 46 years which is comparable to a study from Shaukat Khanam Hospital reporting an earlier age of breast cancer in Pakistan, compared to 54 years in American and 64 years in European populations.[10]

The sensitivity of BI-RADS in our results was 92.38%, specificity was 88.89%, PPV was 99.37%, NPV 38.10% and accuracy was 92.20 %. According to a meta-analysis performed in 1998 the sensitivity of mammography ranged from 83 to 95% and specificity from 93 to 99%.[9]Most of the latest international studies have shown a chronological increment in the predictive value of BI-RADS. These studies have reported a positive predictive value of BI-RADS category 5 to be in the range of 54-92%.[11-13]One of these studies reported a sensitivity of mammogram to be 90% but specificity to be 19%,PPV of 4% for BI-RADS 3, 15% for category 4 and 75% for category 5 respectively; recommended that BIRADS 3 lesions with microcalcifications should be biopsied, due to association of microcalcifications with malignancy. [11]Another study showed a positive predictive value for categories 3, 4A, 4B, 4C and 5 were, respectively, 3.4%, 10.3%, 11.3%, 36% and 91.7% and an overall PPV of 24.8 % for non-palpable breast lesions.[14]

A study from Singapore showed that as Asian women have dense breasts and a low sensitivity of

mammogram was noted and they recommended Ultrasound to be a better modality for diagnostic purpose in their population. They found PPV of mammogram BI-RADS 4 to be 27% and of BI-RADS 5 to be 84%.[15]

A study showed diagnostic accuracy of mammogram in the range of 62-75% for differentiation of benign and malignant lesions according to BI-RADS classification; and reported inter-observer disparity in the analysis of calcification and mass margins.[16]Another study has correlated morphological features of breast cancers with the mammographic appearance showing that microcalcifications are mostly associated with ductal carcinoma in situ, while mammographic mass and larger size correlated with invasive carcinoma.[17]

A number of studies have been performed in Pakistan to assess the sensitivity and accuracy of BI-RADS reporting system. The sensitivity of BI-RADS mammogram is reported ranging from 36% to 88%,specificity ranges from 73% to 100%, PPV 64 to 100%, NPV 33 to 93% and diagnostic accuracy 88-90%.[18-22]Our findings are comparable to these studies. A study showed sensitivity and specificity of mammogram to be 80% and 73% respectively, and compared it to that of Ultrasound and concluded that mammogram had lower diagnostic accuracy compared to Ultrasound; however, this study used Fine needle aspiration cytology (FNAC) for diagnostic confirmation instead of core needle biopsy, which may have contributed to low accuracy.[20] Another study compared the sensitivity of mammogram (88%) to that of Ultrasound (91%) and found that 85% of times the two reports were concurrent with each other.**Error! Bookmark not defined.** A study from India reports the sensitivity, specificity and accuracy of BI-RADS to be around 88%.[23]

In our study four out of 359 patients were male, concordant with 1% of the reported incidence in males for all breast cancers.[24]This study from Turkey reports sensitivity of mammogram to be 69%, PPV of 53% and accuracy of84% in male breasts, our study showed that all males were accurately reported as malignant on radiology; however, our sample size was much smaller. [24]

Mammogram has been shown to more effective in patients over 40 years who have less dense breasts; **Error! Bookmark not defined.** in our study sensitivity of mammogram increased in patients over 45 years.

A number of factors can affect the reporting of BI-RADS and these include the expertise of the performing radiologist, his understanding of BI-RADS categories, the method, ultrasound or mammography, used for evaluation of the patient and technical aspects of the procedure.**Error! Bookmark not defined.** However, correlation between Pathology and Radiology remains the cornerstone for the treatment of patients in a hospital setting and participation in multi-disciplinary meetings has shown to reduce the false positive and negative reports, thus improving patient care.[25]Latest studies support an integrated reporting system for the two diagnostic disciplines, thus reducing the false positive and false negative cases and improving the diagnostic accuracy of the reporting system as a whole.[26]

Our study did not evaluate the PPV of individual BI-RADS categories, which is a limitation of this study. Another limitation of this study was non availability of mammograms for reevaluation by a single trained radiologist to enhance information validity. Therefore, our reliance on the available reports of mammograms has led to reduction in NPV and specificity. We have compared histopathology of core biopsies rather than FNAC, which has increased the sensitivity and PPV as compared to other studies.

Based on low negative predictive value we recommend; 1) training of specific radiologists reporting the mammogram, 2) regular reviewing of discordant cases by histopathologist in conjunction with radiologists specialized in women imaging, and 3) early mandatory follow up in patients with BI-RADS II and III in order to avoid a delay in diagnosis keeping in view limitations of our circumstances.

Conclusion:

The findings of this study report a high yield, PPV and diagnostic accuracy of BIRADS in the diagnosis of breast carcinoma.

Acknowledgement:

Omair Adil of Radiology Department and Dr. Ghulam Murtaza.

References

1. Ferlay J, Soerjomataram I, Ervik M, Dikshit R, Eser S, Mathers C, Rebelo M, Parkin DM, Forman D, Bray, F. GLOBOCAN 2012 v1.0, Cancer Incidence and Mortality Worldwide: IARC CancerBase No. 11 [Internet]. Lyon, France: International Agency for Research on Cancer; 2013. Available from: http://globocan.iarc.fr, accessed on 07/11/2017.
2. Qureshi MA, Mirza T, Khan S, Sikandar B, Zahid M, Aftab M, Mohsin S, Sharafat S, Avesi L, Hassan S. Cancer patterns in Karachi (all districts), Pakistan: First results (2010-2015) from a Pathology based cancer registry of the largest government-run diagnostic and

reference center of Karachi. Cancer Epidemiol. 2016; 44:114-122.
3. Gilani GM, Kamal S, Akhter AS. A Differential Study of Breast Cancer Patients in Punjab, Pakistan. JPMA 2003; 53:478.
4. Gotzsche PC, Nielsen M. Screening for breast cancer with mammography. Cochrane Database Syst Rev. 2009;4:CD 001877.
5. Free breast cancer screening programme starts. International The NEWS. Tuesday 18th December 2018. Available from: https://www.thenews.com.pk/archive/print/328228-free-breast-cancer-screening-programme-starts. Assessed 18th December 2018.
6. Pink Ribbon: Home. Available from: https://www.pinkribbon.org.pk/national-screening/. Assessed 18th December 2018.
7. Aebi S, Davidson T, Gruber G, Castiglione M; ESMO Guidelines Working Group. Primary breast cancer: ESMO Clinical Practice Guidelines for diagnosis, treatment and follow-up. Ann Oncol. 2010;21 Suppl 5:v9-14.
8. D'Orsi CJ, Sickles EA, Mendelson EB, Morris EA, et al. ACR BI-RADS® Atlas, Breast Imaging Reporting and Data System. Reston, VA: American College of Radiology; 2013.
9. Mushlin AI, Kouides RW, Shapiro DE. Estimating the accuracy of screening mammography: a meta-analysis. Am J Prev Med. 1998;14(2):143-53.
10. Badar F, Mahmood S, Faraz R, Quader AU, Asif H, Yousaf A. Epidemiology of Breast Cancer at the Shaukat Khanum Memorial Cancer Hospital and Research Center, Lahore, Pakistan. J Coll Physicians Surg Pak. 2015; 25(10):738-42.
11. Mendez A, Cabanillas F, Echenique M, Malekshamran K, Perez I, Ramos E. Mammographic features and correlation with biopsy findings using 11-gauge stereotactic vacuum-assisted breast biopsy (SVABB).Ann Oncol. 2004;15(3):450-4.
12. Liberman L[1], Abramson AF, Squires FB, Glassman JR, Morris EA, Dershaw DD. The breast imaging reporting and data system: positive predictive value of mammographic features and final assessment categories. AJR Am J Roentgenol. 1998 Jul;171(1):35-40.
13. Bérubé M, Curpen B, Ugolini P, Lalonde L, Ouimet-Oliva D. Level of suspicion of a mammographic lesion: use of features defined by BI-RADS lexicon and correlation with large-core breast biopsy. Can Assoc Radiol J. 1998; 49(4):223-8.
14. Melhado Vaneska de Carvalho, Alvares Beatriz Regina, Almeida Orlando José de. Radiological and histological correlation of non-palpable breast lesions in patients submitted to preoperative marking according to BI-RADS classification. Radiol bras 2007;40(1):9–11.
15. Tan YY, Wee SB, Tan MP, Chong BK. Positive Predictive Value of BI-RADS Categorization in an Asian Population.Asian J Surg. 2004 Jul;27(3):186-91.
16. Nascimento JHR, Silva VD, Maciel AC. Accuracy of mammographic findings in breast cancer: correlation between BI-RADS classification and histological findings. Radiol Bras. 2010;43:91–96.
17. Jiang L, Ma T, Moran MS, Kong X, Li X, Haffty BG, Yang Q. Mammographic features are associated with clinicopathological characteristics in invasive breast cancer. Anticancer Res. 2011 Jun;31(6):2327-34.
18. Bukhari H, Shaukat A, Ahmad N. Breast cancer screening; mammography
19. versus dynamic MRI breast. Professional Med J 2017;24(1):42-46.
20. DOI: 10.17957/TPMJ/17.3182
21. Sadiq A, Qureshi IA, Tarin BA, Ahmed NS. Mammographic and sonographic features in carcinoma breast. Pak Armed Forces Med J Jun 2006;56(2):97-101.
22. Fatima N, Zaman M, Qadeer uddin, Ahsan Z. Accuracy of mammography and ultrasound for detecting breast cancer at a breast care clinic in Karachi, Pakistan. Journal of Biomedical Graphics and Computing 2011; 1:44-50
23. Zahid Z, Ibrahim Z, Bilal S, Farooq M. Comparison of Diagnostic Accuracy of Film-Screen Mammography and Ultrasound in Breast Masses. P J M H S 2011; 5 (3):433-5
24. Arsalan F, Subhan A, Rasul S, Jalali U, Yousaf M, Mehmood Z, Khan A. Sensitivity and specificity of BI-RADS Scoring system in carcinoma of breast. Journal of Surgery Pakistan (International) 2010; 15:38-43
25. Navya BN, Thomas S, Hiremath R, Alvi SR. Comparison of diagnostic accuracy of BIRADS score with pathologic findings in breast lumps. Annals of Pathology and laboratory medicine 2017; 4(3): A236-242
26. Zehra H. Adibellia Ozgur Oztekina Hakan Postacib Adam Usluc. The Diagnostic Accuracy of Mammography and Ultrasound in the Evaluation of Male Breast Disease: A New Algorithm Breast Care 2009;4:255–259
27. , Littlehale N, Mehta TS. Improving Patient Care by Incorporation of Multidisciplinary Breast Radiology-Pathology Correlation Conference. Can Assoc Radiol J. 2016 May;67(2):122-9
28. Sorace J, Aberle DR, Elimam D, Lawvere S, Tawfik O, Wallace WD. Sorace et al. Integrating pathology and radiology disciplines: an emerging opportunity? BMC Med. 2012; 10: 100. Published online 2012 Sep 5

HISTORY	
Date Received:	26-09-2018
Date sent for Reviewer:	15-11-2018
Date Received Reviewer's Comments:	02-12-2018
Date Received Revised Manuscript:	18-12-2018

CONTRIBUTION OF AUTHORS	
Author	**Contribution**
Ruqaiya Shahid	A,B,C,D
Binish Rasheed	A,B,C,E
Rubina Gulzar	A,B,C

KEY FOR CONTRIBUTION OF AUTHORS:

A. Conception/Study Designing/Planning
B. Experimentation/Study Conduction
C. Analysis/Interpretation/Discussion
D. Manuscript Writing
E. Critical Review
F. Facilitated for Reagents/Material/Analysis