SENSITIVITY AND SPECIFICITY OF BI-RADS SCORING SYSTEM IN CARCINOMA OF BREAST

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ABSTRACT

Objective — *To find out the sensitivity and specificity of mammogram according to BI-RADS scoring, in correlation with pathological findings so as to develop protocol for biopsy in patients presenting with clinically palpable breast lump or nipple discharge.*

Study design — *Cross sectional study.*

Place & Duration of study — *Jinnah Postgraduate Medical Centre, Surgical unit 1 (Ward 3) Karachi, from July 2007 to June 2008.*

Methodology — *Female patients who presented with clinically palpable breast lumps or nipple discharge in general surgical OPD were examined and referred for mammography. Ultrasound examination was also done where considered necessary. The final diagnosis regarding the lump or nipple discharge as shown in the mammography was made and patients sent for biopsy (FNAC / Trucut / excision biopsy). The mammographic diagnosis was compared with the histopathological report.*

Results — *Fifty patients were examined of whom 47 clinically suspected patients had confirmation of diagnosis on biopsy while 3 were found negative. Forty one suspected cases on BI-RADS mammogram were true positive that revealed 87.2% sensitivity of BI- RADS mammogram while 6 cases were false negative. All three cases of negative on biopsy were true negative that revealed hundred percent specificity. In this way positive predictive value was also hundred percent with negative predictive value of 33.3%. Overall diagnostic accuracy of mammogram was 88% when compared with histopathological diagnosis.*

Conclusions — *Mammography can be used as an important diagnostic tool for the diagnosis of breast diseases and where there is doubt, diagnosis should be made by means of triple assessment i.e. clinical examination, mammography, and histopathology.*

Key words — *Mammography, Breast carcinoma, BI-RADS*

INTRODUCTION:

Breast cancer is the second most common malignant disease among females. It commonly affects women older than 40 years of age. However, younger women can also be affected especially those with the genetic predisposition.[1,2]

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Its management requires a multi-dimensional approach and a collaboration with different specialists. An accurate evaluation can maximize cancer detection and minimize unnecessary testing and procedures.[3]

Mammography is a primary imaging modality for breast cancer screening and diagnosis. This soft tissue imaging x-ray of the breast is designed to detect tumor or other abnormalities[4]. However on its own, it doesn't exclude breast cancer and must be performed as a part of triple assessment. It has sensitivity of ninety percent, as ten percent of carcinomas are not detected initially by this method.[5] Improvement has occurred over the last decade

in the quality of x rays and the reporting of mammographic studies.[6] It has both screening and diagnostic values. Screening mammography is an x-ray examination that detects unsuspected breast cancer at an early stage in asymptomatic women. This may also be designed as screening if the woman is scheduled for routine examination, if no abnormal findings on physical examination or if she had a previous benign biopsy. Women who have had a mastectomy should undergo screening mammography of the remaining breast.

The diagnostic technique is useful for suspicious breast changes such as breast pain, an unusual skin appearance, nipple thickening or nipple discharge,[7] examination of indeterminate mass presenting as a solitary lesion that may be a neoplasm, examination of indeterminate mass that can not be considered a dominant nodule especially when multiple cysts or other vague masses are present and the indication for biopsy is uncertain, follow-up examination of contralateral breast after segmental to total mastectomy, evaluation of large fatty breast and in symptomatic patients in whom nodules are not palpable are all indications of further workup.[8]

The American College of Radiology (ACR) created the breast imaging reporting and data system, to achieve trick verbal uniformity so as to get clear, unambiguous and standard language, not only among radiologist but also among treating physicians and surgeons. BI-RADS had 0-5 assessment categories and mammography report has to be classified in one of these categories. The objective of study was to find out the sensitivity and specificity of mammogram according to BI- RADS scoring.

METHODOLOGY:

This study was conducted at Jinnah Postgraduate Medical Centre, Surgical unit 1 (Ward 3) Karachi, from July 2007 to June 2008. This was a cross-sectional study. The sampling technique was purposive non probability. All women patients of age more than 35 years with clinical or suspected breast lump or nipple discharge in the surgical OPD, were included in this study. All previously biopsied patients were excluded. All patients were examined after having appropriate history of lump or nipple discharge and subjected to mammography. Later on biopsy (FNAC/Trucut/Excision) of the lesions was done to confirm the findings of mammography according to the newly introduced BI-RADS classification. In this way sensitivity and specificity of mammogram were calculated in percentages or proportions.

Data analysis was preformed through SPSS version-10. Age of the patients was presented as mean ± standard deviation. Frequencies and percentages were computed to present qualitative response variables like marital status, parity status, presenting complaints of breast lump and nipple discharge, BI-RADS mammogram findings and biopsy (FNAC/Trucut/ excision) findings. Analysis was performed to compute sensitivity, specificity, accuracy, positive and negative predictive values of BI-RADS mammogram in the diagnosis of breast cancer on the basis of biopsy (FNAC/ Trucut/ excision) findings as gold standard.

RESULTS:

Among fifty suspected patients for breast cancer on the basis of clinical presentations, forty six (92%) were married and four (8%) unmarried. Mean age was 42.6 ± 7.21 (ranging from 30 to 60) years. Among forty six married females, 7 (15.2%) were nulliparous, 8 (17.4%) uniparous, 18 (39.1%) multiparous and 13 (28.3%) were grand multipara. Family history of breast cancer in their blood relatives was positive in 10 (20%) cases.

Breast lump was present in 41 (82%) patients on clinical examination. Nipple discharge was reported in 10 (20%) cases. BI-RADS mammogram of the left breast showed 2 (4%) patients in category-0 revealing need of additional imaging evaluation, 19 (38%) in category-1 revealing negative finding, 8 (16%) in category-2 revealing benign finding, 1 (2%) in category-3 revealing probably benign finding – short interval follow up suggested, 5 (10%) in category-4 revealing suspicious abnormality and 15 (30%) patients in category-5 revealing highly suggestive of malignancy.

BI-RADS mammogram of right breast showed 3 (6%) patients in category-0 revealing need of additional imaging evaluation, 28 (56%) in category-1 revealing negative finding, 6 (12%) in category-2 revealing benign finding, 1 (2%) in category-3 revealing probably benign finding – short interval follow up suggested, 1 (2%) in category-4 revealing suspicious abnormality and 11 (22%) patients in category-5 revealing highly suggestive of malignancy. BI-RADS mammogram findings of left and right breast imaging according to confirmed diagnosis biopsy (FNAC/ trucut/ excision) is presented in table 1 and 2.

Forty seven (94%) clinically suspected patients were confirmed on biopsy (FNAC/ trucut/ excision) while 3(6%) were found negative. Suspicion of breast cancer on BI-RADS mammogram was considered for categories 1-5 from either side of breast while category-0 was considered negative. Out of 47 confirmed diagnoses on biopsy (FNAC/ trucut/ excision), 41 suspected cases on BI-RADS mammogram were true positive that revealed 87.2% sensitivity of BI-RADS mammogram while 6 cases were false negative. Out

of 3 negative cases on biopsy (FNAC/ trucut/ excision), no false positive case found and all 3 cases were true negative that revealed 100% specificity of BI-RADS mammogram in the diagnosis of breast cancer.

Out of 41 positive cases on BI-RADS mammogram, all 41 cases were true positive that revealed 100% positive predictive value of BI-RADS mammogram. Out of 9 cases that were negative for breast cancer diagnosis on BI-RADS mammogram, 3 were true negative that revealed 33.3% negative predictive value. Overall accuracy of BI-RADS mammogram in the diagnosis of breast diseases was 88% (table-3).

Table I: Findings of BI-RADS Mammogram of Left Breast According to Biopsy (FNAC/Trucut/Excision) Findings (N=50)

BI-RADS Mammogram of left Breast	Confirmed diagnosis		Total
	Positive	Negative	
Category 0	1 (2)	1 (2)	2
Category 1	19 (38)	0 (0)	19
Category 2	8 (16)	0 (0)	8
Category 3	0 (0)	1 (2)	1
Category 4	5 (10)	0 (0)	5
Category 5	14 (28)	1 (2)	15
Total	47	3	50

Table II: Findings of BI-RADS Mammogram of Right Breast According to Biopsy (FNAC/Trucut/Excision) Findings (N=50)

BI-RADS Mammogram of left Breast	Confirmed diagnosis		Total
	Positive	Negative	
Category 0	2 (4)	1 (2)	3
Category 1	26 (52)	2 (4)	28
Category 2	6 (12)	0 (0)	6
Category 3	1 (2)	0 (0)	1
Category 4	1 (2)	0 (0)	1
Category 5	11 (22)	0 (0)	11
Total	47	3	50

Table III: Overall Validity of Mammographic Diagnosis on the Basis of Biopsy (FNAC/Trucut/Excision) Findings (N=50)

BI-RADS Mammogram	Biopsy (FNAC/ trucut/ excision) (Gold standard)		Total
	Positive	Negative	
Positive	41 (TP)	0 (FP)	41
Negative	6 (FN)	3 (TN)	9
Total	47	3	50

Key:
TP = True positive, FP = False positive, FN = False negative,
TN = True Negative
Sensitivity = TP/ (TP+FN)*100 = 87.2%
Specificity = TN/ (FP+TN)*100 = 100%
Positive predictive value = TP/ (TP+FP)*100 = 100%
Negative predictive value = TN/ (TN+FN)*100 = 33.3%
Accuracy = (TP + TN)/ (TP+TN+FP+FN) * 100 = 88.0%

DISCUSSION:

The American College of Radiology breast imaging, reporting and data system was designed to standardize the interpretation of mammography examinations and the reporting. Therefore BIRADS scoring system used to determine the sensitivity and specificity of mammogram. Several studies have reported substantial variability among radiologists in interpretation of mammographic examinations and recommendations for management of breast lesions.[9,10] In this study, BIRADS was used to minimize the variability, to maximize the accuracy of mammography and to minimize the number of false positive evaluation. In this study, all patients above the age of 35 years were included because greater proportion of younger women have dense breast as compared to older women (i.e. eighty percent for ages 40 – 49 years, 54% for ages 50 -59 years and forty two percent for ages 60 – 69 years). Kerlikowske and colleagues reported in their study that mammography had a higher sensitivity among women who were fifty years or above with primarily fatty (that is more radiolucent) breast density. There may be greater variability in interpretation of findings among women of younger age as it enhances more denser breast density. Therefore in this study patients below 35 years of age were excluded which in turn increased the sensitivity of the mammogram.

The family history of breast cancer was negative in majority of the patients. The knowledge of family history and age of the patient resulted in more apparent and easier identification of breast lesion. However in an another study the provision of the knowledge of family history of breast cancer reduced the diagnostic accuracy of mammogram because the radiologist tend to investigate more breast lesion without improving accuracy.[11] One study showed sisters of breast cancer cases are more affected with the disease than their mothers.[12]

In this study out of 50 patients, 46 were married and only 7 were nulliparous. The literature showed the increase incidence of breast cancer in nulliparous women in west which is in contradiction to this study probably because of small sample size. However studies in Pakistan showed that the cancer occurring predominantly in younger age group with high parity and at least six years of lactation.[13] Approximately one in every nine Pakistani women is likely to suffer from breast cancer which is one of the highest incidence rate in Asia.[14]

The incidence of malignant breast lumps after third decade of life is increasing substantially in Pakistan.[15] In this study breast lump and nipple discharge were taken as two major presenting complaints and no screening mammogram was included. Eighty percent of the patients presented with lump and only twenty percent presented with nipple discharge. As a general emphasis of lump on patients psyche is that lump should be a malignant lesion as compared to nipple discharge. So patients with lumps present early and more to tertiary care hospitals as compared to nipple discharge or any other complaint.

On the basis of the result of mammogram more patients were found in assessment category 1 and the second most assessment category was 5, which showed that two types of patients exist in our setup. Firstly, those who are literate and conscious about their health and in turn seek medical advice early. Secondly, those who are illiterate, neglected patients and inhibition in seeking treatment of the female patients by male doctors.[16] At this point, the role of screening mammography and general awareness about breast cancer is very important in our country. Increased awareness should be made through health education and by encouraging breast self-examination, clinical breast examination and mammography practice.[17] The higher the social class, better is the level of education, knowledge, attitude and practice towards the breast cancer screening.[18]

In this study six of the patients mammographic diagnosis did not correlate with histopathological results. Six patients were found to be false negative. Probably as in one case the patient was young i.e. 35 years old and thus the mass was obscured in dense glandular tissue and difficult to characterize. The report of mammography showed it to be (BI-RADS 0), however it was malignant lesion on biopsy. In another patient who presented with thickened skin and nipple retraction with enormously edematous breast, the mammogram was very inconclusive and clinical diagnosis was carcinomatosis (BI-RADS 0) but it turned out tuberculous mastitis on histopathology. The third patient was 58 years old and had an asymmetrical thickening of one breast in upper outer quadrant. No mass lesion, calcification, parenchymal distortion or skin changes were obvious on mammogram and therefore concluded as asymmetrical increased density of breast tissue (BI-RADS-1). However her biopsy showed lobular carcinoma as the final diagnosis. Other three patients were diagnosed as phylloides tumour (BI-RADS 3) on mammography but all three were reported by histopathologist as phylloides tumour with sarcomatous change. So phyllodes tumour must be vigorously treated with wide local excision or mastectomy followed by adjuvant chemoradiotherapy in malignant or border line tumour to minimize recurrence.[19]

Out of 9 cases which were negative for breast cancer diagnosis on BI-RADS mammogram, three cases were true negative. Probably because the inflammation of the breast is common and most common in lactating

women, and lactating women were not excluded, so three cases which were reported negative on mammogram had inflammation of breast including tuberculous mastitis. One study highlighted the importance of tuberculous mastitis. Its frequency being 2.3% in the patients with lump in the breast. Doctors should keep tuberculosis in the differential diagnosis of breast lump.[20] Tuberculous mastitis respond well to anti-tuberculous chemotherapy, and early diagnosis, before sinuses develop is important in preventing disfigurement.[21]

The sensitivity of mammogram was calculated as 87.2%.The specificity of mammogram was hundred percent in this studies due to a smaller sample size. In this way negative predictive value turn was 33.3 percent and the overall diagnostic accuracy of BI-RADS mammogram in the diagnosis of breast diseases was 88%. This indicates that mammography is an important diagnostic tool for diagnosing breast diseases. Finally, to improve the accuracy of mammographic interpretation examination either better education tools to communicate BIRADS terms or development of more effective criteria for reporting mammographic findings and selecting assessment categories must be used. The American College of Radiology recently released an updated edition of BI-RADS that includes mammographic illustrations of breast findings. This teaching devise may improve understanding of radiologists as to how and when to use BI-RADS terms and warrants testing to becoming whether its use decrease variability in mammographic interpretation.

CONCLUSIONS:

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 older age group with less glandular tissue with high incidence of malignant lesions. It is highly sensitive and specific test with high diagnostic accuracy but it has its limitation especially in dense breasts which some time 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.

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