

Statistical Evaluation of Accuracy of Mammography in Early Breast Cancer Detection

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ABSTRACT

Aim: To assess the clinical significance of mammography in early stage breast lump detection which could assist health practitioners in taking appropriate prognostic measures for lowering breast cancer burden in Faisalabad region.

Methods: Cross sectional comparative study was designed to collect the data of symptoms associated to breast cancer from 250 women enrolled in breast cancer section of Punjab Institute of Nuclear Medicine (PINUM). Afterwards mammography screening of 60 highly suspicious cases was done. Diagnostic reports based on mammograms were analyzed to study the compliance of mammography reports and symptoms reported by patients. True positive (TP), false positive (FP), true negative (TN) and false negative (FN) outcomes were elucidated to evaluate the predictive accuracy of mammography in early breast lump detection by calculation specificity, sensitivity, positive likelihood ratio and negative likelihood ratio. Specificity and sensitivity results were further used to calculate the predictive probability through Pearson chi square test at < 0.05 significance level through SPSS v10.0.

Results: Sensitivity, specificity, positive likelihood ratio and negative likelihood ratio of early breast cancer detection through mammography screening in our study sample of mammography was 83.33% [95%CI= 67.19% to 93.63%], 91.67% [95%CI= 73.00% to 98.97%], 10.00 at [95%CI= 2.63 to 38.00] and 0.18 [95%CI= 0.09 to 0.38] respectively which clearly demonstrate that system is well versed to identify true positive and true negative cases and give least prediction of false negative results. Moreover, Predictive probability (p -value <0.00001) calculated by Pearson Chi-square (χ^2) test at 0.05 significance level indicate a highly significant correlation between mammography performance and clinical symptoms of breast cancer.

Conclusion: Our findings suggest that mammography is highly efficient and promising imaging technique. Looking at its high accuracy in early breast cancer detection, breast cancer screening through mammography should be encouraged and worth being practiced.

Keywords: Mammography, Sensitivity, Specificity, Predictive probability

INTRODUCTION

Breast cancer is characterized by uncontrolled growth of epithelial cells with an acquired ability of local invasion and distant metastatic dissemination. Morphology and distinctive clinical presentation of breast cancer among patients is highly diversified because of heterogeneity acquired due to distinct mutations, diverse sub population of stem cell and heterotypic signalling between parenchymal and

stromal cells within tumor microenvironment. It is second deadliest cancer in women worldwide, as it accounts for 25% of all reported cancers in females. According to International Agency for Research on Cancer (IARC), approximately 1.7 million women across the globe were diagnosed of breast cancer in 2012-2014 while 8.2 million females were died of breast cancer^{1,2}. Among Asian countries, Pakistan is ranked at top with highest burden of breast cancer while in world it is ranked at 58 in terms of breast cancer statistics³. One out of nine women in rural areas of Pakistan is at risk of breast cancer⁴. Majority of the young women at advanced stages of breast cancer were reported in Pakistan. Being a developing country lack of proper medical facilities for early detection and screening of breast cancer made the situation more worst. In addition to this, lack of awareness in women and socio-economic barriers added a lot to the disease burden of breast cancer in Pakistan⁵. One of the main reason of high mortality rate of breast cancer in Pakistan is intentional delay

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made by women in seeking medical counselling despite of the presence of potential clinical symptoms of breast cancer⁶.

During last two decades, high incidence of breast cancer at young age has largely been reported not in Pakistan as well as worldwide. In contrast to Pakistan, over all disease survival rate in developed countries has improved due to early detection and proper disease management⁷.

Early clinical diagnosis of breast cancer involves breast self-examination (BSE), clinical breast examination (CBE) and mammography. A breast self-examination (BSE) being the most in expensive, easy and simple early detection techniques involves check up of the breasts by woman herself. It helps to detect mass in breast tissue and /or any other unusual observable change in the breasts. Once one feels any difference in her breasts normally look or size, any new lump or change in appearance, consultation of health professional must be reached⁸. Breast self-examination can improve the status of early detection and can also ultimately contribute to high survival rate of breast cancer patients⁹.

Mammography is an expensive screening mechanism practiced for detection of breast cancer. World Health Organization (WHO) recommends use of mammography testing as vital part early diagnostic procedures to reduce the mortality rate. Three fold decrease in mortality rate of breast cancer has been reported in developed countries by practicing mammography in early detection of cancerous lumps in breast¹⁰. High mortality rate of breast cancer in Pakistan is due to the poverty, lack of awareness about cancer and its detection methods and high cost as well as fear of mammography testing and other diagnostic procedures^{11,12}.

To detect cancerous breast lump, its shape, nature and boundary at very initial stage, clinical significance of mammography is considered high¹³. Despite of high detection accuracy mammography is still not a reliable and perfect imaging technique. Breast cancer mortality is not actually reduced by imaging technique, it requires proper awareness about disease, follow-up and disease management plan which ensure high survival rate in breast cancer among population¹⁴. Like all other screening techniques, there is 10%-30% error chance in mammographic screening which shows its tendency to report false negative cases. It means that out of the 350 per 100,000 women with symptoms of breast cancer, only 35-105 can be detected by mammography. Inability of mammography to properly identify breast lump is not only due to observer error, but more frequently it is because the cancer is hidden by other dense tissues of the breast and even retrospective review of the mammogram cannot

detect them. Normally cases of lobular cancer have an intricate growth pattern that produces shadows on the mammogram which are indistinguishable from normal breast tissue¹⁵.

Objective of current study was to provide an insight in better diagnosis of breast cancer through statistical evaluation of sensitivity, specificity, predictive accuracy and probability of mammography based breast tumor detection. For this purpose, current study was designed to evaluate the clinical significance of mammography screening in PINUM. All those women were enrolled for the study who presented obvious breast cancer symptoms and had mammography screening for the first time in PINUM to assess the performance of mammography in early stage breast cancer detection.

We summarized the mammography results and evaluated the accuracy of mammography, specificity, sensitivity, positive likelihood ratio, negative likelihood ratios were initially calculated. In addition to all these performance evaluation measures, predictive probability of mammography screening was also evaluated through Pearson chi square analysis.

MATERIALS AND METHODS

Currently reported study covers the one year period of data collection of breast cancer patients at Pakistan Institute of Nuclear Medicine (PINUM) Faisalabad. PINUM Hospital Faisalabad was selected as it is in densely populated region of Punjab with 48 adjoining cities where a high number of breast cancer patients are attended. Study was designed to statistically evaluate the efficiency of breast cancer diagnostic system by measuring its sensitivity and specificity. For that matter, data of patients who had their mammography and follow-ups was recorded. For this cross-sectional comparative study, we prospectively identified patients of age group 40-70 years.

Patients Consent: Patients were properly briefed about the aim of the study. Written consent was taken from the patients who were willing to participate in the study. Afterwards questionnaires were filled through scheduled interviews.

Data Collection: Medical history of all patients presented at PINUM within one year with complain of breast cancer was recorded. Questionnaire based study was designed and data related to clinical presentation and diagnosis details was recorded through patient's interviews and their case history files. Questionnaire includes queries related to patient's age, family history of breast cancer, detail related to previous mammography screenings, presence of self-reported lump, location of lump on left breast, right breast or both sides, any discharge

or leakage from breast tissues, if lump detected than nature of lump whether benign or malignant was recorded.

Inclusion exclusion criteria: The criteria of our study population was restricted to only those patients who underwent mammography screening for the first time in PINUM. From the evaluation of all positively answered questionnaires, we took 60 highly suspicious patients which were subjected to mammography. Suspicious cases were those that have significant breast cancer associated symptoms i.e. lump, pain, inflammation and/or watery discharge from breast tissues.

Mammography protocol: Diagnostic mammography was carried out to take geometrically magnified and spot-compressed views of the area of concern (location of lump). After taking mammograms experienced physician diagnosis report. were prepared by expert physician and image analysts of radiology department. The American College of Radiology (ACR) has established a uniform way for radiologists to describe mammogram findings. The system, called Breast Imaging reporting and database system (BI-RADS), includes seven standardized categories, or levels. Each BI-RADS category has an associated follow-up plan which assists radiologists and physicians in appropriate management of a patient's care¹⁶.

BI-RADS tumor grading criteria: For diagnosis reports BIRADS tumor grading criteria were practiced. It has clearly defined seven grades starting from grade 0 which requires further evaluation through imaging examination; grade 1 encodes for absence of disease or any abnormality; grade 2 defines sign of presence of benign tumor; following this is grade 3 which means lesion is benign but has a possibility of <2% to invade in other tissues. For grade 3 physicians are suggested to plan a short-term follow up of patients. Grade 4 is divided into three categories, A, B & C. In grade 4A category low malignancy is normally reported while 4B reports medium risk of malignancy and last one is 4C which reports high malignancy risk with probability between 3% to approximately 94%. Patients who are diagnosed of grade 4 malignancies are required to undergo biopsy treatment. In stage 5 probability of presence of malignant lesion is $\geq 95\%$ while in grade 6 known biopsy-proven malignancy is reported by physicians as per ACR guidelines¹⁷.

Quantitative Analysis of Mammograms: For 60 highly suspicious cases mammography was done and mammograms were obtained in which area of lump was highlighted and specificity and sensitivity parameters were calculated. Calculations include total number of true positive (TP), true negative (TN), false negative (FN) and false positive (FP) cases

were calculated. among these four classified categories True negative patients were those women in which no lump was identified and symptoms were due to normal breast cycle or clotting of fatty tissues were present. False positive (FP) were those with benign cancer while TP were cases in which malignant or invasive breast cancer was detected. False negatives cases where those who developed malignant breast cancer during the period of screening (12 months). Age of presentation of disease symptoms and mammography screening was also recorded. Predictive probability of breast cancer detection based on mammography screening is examined using chi square χ^2 test at ≤ 0.05 significance level. Along with this percentage distribution of 60 selected cases based on obvious breast cancer clinical symptoms was also calculated shown in table 1 to know the most prevalent and obvious symptoms of breast cancer in women of Faisalabad regions.

Sensitivity: The sensitivity is expressed as the ratio of number of true positive, to the sum of ratio of false negative and true positive. Purpose of calculating sensitivity is to measure the reliability of a diagnostic system at making positive and negative identification. Hence to calculate sensitivity for our system understudy, we applied following formula.

$$\text{Sensitivity} = \left(\frac{TP}{TP+FN} \right) * 100$$

Specificity: Specificity is expressed as the ratio of the number of true negatives, to the sum of false positive and true negative. This value defines the probability of a screening test to identify true negative cases.

$$\text{Specificity} = \left(\frac{TN}{TN+FP} \right) * 100$$

Positive and Negative Likelihood Ratio

Calculation: In the next step, sensitivity and specificity values are used to calculate positive likelihood ratio and negative likelihood ratio. These calculations will further measure the accuracy of mammography based breast cancer detection. Statistical formula used for calculating positive and negative likelihood ratios based on our study sample is given below.

$$\text{Positive Likelihood Ratio} = \frac{\text{Sensitivity}}{1 - \text{Specificity}}$$

$$\text{Negative Likelihood Ratio} = \frac{(1 - \text{Sensitivity})}{\text{Specificity}}$$

Predictive probability: Predictive probability of first screen mammography in accurate detection of breast lumps is calculated through chi square (χ^2) at < 0.05 level of significance. Chi square (χ^2) formula (18) given below was applied through SPSS 10.0 (19) where o denotes observed values of TP, TN, FP

and FN cases given in table 1 and e denotes expected values calculated in table 4.

$$Chi\ square = \Sigma(o - e)^2 / e$$

RESULTS

Percentage distribution of our study sample in terms of reported breast cancer associated symptoms and patient's age group reveals that 10% of the patients had dense calcification, 10% had watery discharge from breast, 40% were complaining of lump, 30% had pain in breast tissues, 5% cases were having both lump and pain. While 5% were suffering from pain as well as discharge from breast tissues given in table 1. Patient's data is categorized into two age groups; 25% cases belongs to age group of 40-50 years while majority (75%) belong to age group of 51-60 years. Mammography details revealed 33% were having benign tumor while malignancies were reported in 50% cases and 17% cases were diagnosed as normal shown in table 1.

Statistical Evaluation of Diagnostic Performance of Mammography for Breast Cancer: To evaluate the performance of diagnostic procedure for primary screening of breast cancer, initially specificity and sensitivity was calculated. Out of 60 patients subjected to mammography for detection of lump in mammary tissues, diagnosis reports analysis revealed 30 cases as TP, as disease was present in them while 06 false negative cases were observed in which diseases was present but symptoms or clinical presentation could not be evaluated through mammography. Likewise, 2 false positive cases were reported through mammography and 22 true negative cases were also identified in which no indication of disease was observed. All the cases in terms of true positive (TP), true negative (TN), false positive (FP) and false negative (FN) are properly summarized in Table 2.

Sensitivity: True positive rate that defines the sensitivity of mammography in accurate detection of breast cancer in currently reported data was 83.33% (95%CI= 67.19% to 93.63%) shown in table 3. Of 60 cases, only six diseased cases were identified as false negative in mammogram evaluation. while it exactly reports majority of diseased cases as true positive. High sensitivity percentage corresponds to accurate detection of breast cancer patients of Faisalabad regions at PINUM.

Specificity: True negative rate that defines the specificity of mammography in identification of non-diseases cases in our study sample was 91.67%

(95%CI= 73.00% to 98.97%) given in table 3. In our study sample of 60 patients, 22 non-diseased cases were identified accurately as true negative through mammography. High specificity percentage corresponds to accurate identification of actual negative cases. this value also state that mammography diagnosis is particularly dedicated to detection of breast lumps in patients.

Positive Likelihood ratio and Negative Likelihood ratio of Diagnostic Mammography: Positive likelihood ratio tell the outcome of a true positive result if lump is present and the probability of a true negative result if lump is absent. For our study sample, value of positive likelihood ratio is 10.00 at [95%CI= 2.63 to 38.00] shown in table 3. Its value corresponds to how well our diagnostic system can differentiate between true positive and false positive results. While negative likelihood ratio of probability of false negative test result in diseased case and the probability of a negative test result given that the lump in breast is absent. Negative likelihood ratio calculated for our study sample is 0.18 at [95%CI= 0.09 to 0.38] (Table 3) which clearly demonstrate that system is well versed to identify true negative cases and give least prediction of false negative results.

Pearson Chi-square (χ^2) test results: To evaluate the diagnostic accuracy of mammographic detection of breast cancer, Pearson Chi-square (χ^2) test was performed to calculate predictive probability. Highly significant *p*-value (<0.00001) indicates that for mammography based initial screening is a reliably diagnosed breast cancer in our study sample (Table 4). A highly significant correlation between mammography performance and clinical symptoms of breast cancer was observed in our study sample.

Table 1: Percentage distribution of study sample (n=60) based on age of disease presentation (years), breast cancer associated symptoms and nature of tumor.

Patient's Factors	%age
Age at diseases presentation (years)	
40-50	25% (15)
51-60	75% (45)
Breast Cancer Associated Symptoms	
Watery Discharge	10% (6)
Calcification	10% (6)
Lump	40% (24)
Pain	30% (18)
Lump & Pain	5% (3)
Pain and watery Discharge	5% (3)
Nature of Tumor	
Benign	33% (20)
Malignant	50% (30)
Normal	17% (10)

Table 2: Summary of total no of cases diagnosed through mammography as true positive (TP), false positive (FP), false negative (FN) and true negative (TN) in selected study sample.

Test	Breast Lump Present (n)		Breast Lump Absent (no)		Total
Positive	True Positive (TP)	30	False Positive (FP)	2	TP +FP=32
Negative	False Negative (FN)	06	True Negative (TN)	22	FN + TN=22
Total	TP +FN = 42		FP+TN 24		60

Table 3: Statistical analysis of Sensitivity, Specificity, Positive and Negative Likelihood ratio at 95% CI to evaluate diagnostic accuracy of mammography for breast cancer detection.

No.	Statistic Evaluation	Formula	Value	95% CI
1	Sensitivity	$\left(\frac{TP}{TP + FN}\right) * 100$	83.33%%	67.19% to 93.63%
2	Specificity	$\left(\frac{TN}{TN + FP}\right) * 100$	91.67 %	73.00% to 98.97%
3	Positive Likelihood Ratio	$\frac{\text{Sensitivity}}{(1 - \text{Specificity})}$	10.00	2.63 to 38.00
4	Negative Likelihood Ratio	$\frac{(1 - \text{Sensitivity})}{\text{Specificity}}$	0.18	0.09 to 0.38

Table 4: Chi square test analysis for evaluation of diagnostic accuracy of mammography for breast cancer detection

Test	Observed value (o)				Row Total
	Breast Lump Present (n)		Breast Lump absent (n)		
Positive	True Positive (TP)	30	False Positive (FP)	2	Sum of row=32
Negative	False Negative (FN)	6	True Negative (TN)	22	Sum of row = 28
Column Total		36	24	N=60	
Chi square(χ^2) Test					
Observed cases (o)	Expected value (e)	o-e	(o-e)2	(o-e) ² / e	p-value
True Positive	$[(32*36)/60] = 19.20$	10.8	116.64	6.07	<0.00001**
False Negative	$[(28*36)/60] = 16.80$	-10.8	116.64	6.94	
False Positive	$[(32*24)/60] = 12.80$	-9.11	82.99	6.48	
True Negative	$[(28*24)/60] = 11.20$	10.80	116.64	10.41	
chi square = $\sum(o - e)^2 / e$				32.54	

Formula of Expected value (e) [sum of row * sum of column / (n)]

** highly significant as p-value is <0.05

DISCUSSION

In Pakistan more than 30% cases of the breast cancer are diagnosed at malignant stages (stage III or stage IV)²⁰. Worst situation of breast cancer detection is mainly due to delay from female patients due to shyness, lack of awareness and cultural barriers. Another reason of high incidence of malignant breast carcinoma is delayed diagnosis or misdiagnosis^{7,9}. To deal with the misdiagnosis of breast cancer, American College of Radiology aimed to fully describe BI-RADS guidelines in 1992 which were updated in 2003. Standardized description of breast imaging not only removed ambiguities but also clearly distinguished solid lesion²¹. Both misdiagnosis and delayed diagnosis increase breast cancer burden and complications in disease management program. Misdiagnosis of breast cancer questions the reliability of detection procedure or technique. Reliability of any screening test is evaluated by its sensitivity and specificity to identify true positive and true negative cases. An efficient breast screening techniques is the one which has low rate of detecting false positive and false negative cases. Number of studies has been reported in which accuracy of mammography in early detection of breast cancer has been reported^{7,22,23}.

To answer the questions about the accuracy of mammography in early breast lump detection, current study was designed on purposive sample collected from PINUM hospital region. Sensitivity, specificity and predictive probability of mammography for accurate diagnosis of breast lesions was statistically evaluated to promote its practice. High values of sensitivity and specificity of mammography screening for breast cancer on sample size of 110 patients has been reported by Li et al and his co-workers⁷. Similarly, our study also reveals 83.33% sensitivity and 91.67% specificity of mammography in early breast cancer diagnosis. These results suggest that mammography screening test practiced in Pakistan is accurate enough to better plan follow-up and disease management programs. It will in turn help us in increasing survival rate in patients like developed countries²⁴. In our study sample 40% of the cases had lumps in breast. Diagnostic accuracy of mammography in detection of breast lumps for our study sample was considered statistically significant as p value was less than 0.05 level of significance. Highly significant p-value (<0.00001) reveals that all cases presented with clinical symptoms of breast cancer are accurately diagnosed as diseased cases during initial screening of breast cancer through

mammography. Our findings suggest good early diagnosis of breast cancer through mammography.

CONCLUSION

In short, mammography used for detection of breast malignancies is reliable enough to circumvent disease mortality as well help us to increase survival rate of breast cancer patients. Therefore, study provides insight into early and accurate diagnosis of breast lumps through mammography and recommends practice of this image based diagnostic test in earlier detection programs. It would be helpful to health professionals for making timely decisions for disease management in breast cancer patients.

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