Efficacy of Mammography in Detecting Breast Masses Using Histopathology as Gold Standard

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Abstract
Background: Early detection is an essential step in decreasing the morbidity and mortality of breast cancer. Mammography is a proven effective tool for early breast cancer detection. The aim and objective of this study is to assess the efficacy of mammography in the evaluation of breast masses based on the Breast Imaging Reporting and Data System (BI-RADS) for differentiating between benign and malignant breast lesions keeping histopathology as gold standard.

Materials and Methods: The present study is an analytical study of patients presenting with breast masses, with age group ranging between 31 to 89 years referred to the department of radio-diagnosis. Findings of mammogram along with BI-RADS category were correlated with histopathological findings, keeping it as gold standard.

Results: Based on the BI-RADS 50 study cases were categorized and confirmed with histopathology, keeping it as gold standard. The diagnostic accuracy of BI-RADS IV & V was 96% and 88% respectively for BIRADS V and BIRADS IV and V.

Conclusion: This study proves the diagnostic accuracy of mammography as a method of choice to evaluate breast masses keeping histopathology as gold standard.

Keywords: Breast masses, Mammography, histopathology.

Introduction
Correct diagnosis is a prerequisite for successful cancer treatment. The diagnosis of breast cancer relies on a combination of clinical examinations, histopathology, and imaging studies that provide the clinician with relevant prognostic and predictive information to counsel patients and initiate cancer treatment. The earlier it is diagnosed the better the survival rates. Breast tissue is subjected to a great magnitude of hormones with cyclical changes and this renders it susceptible to diseases in females of all ages. Palpable breast lump are the second most common presentation of breast disease in various studies, commonest being breast pain. Breast screening by mammography has increased awareness of breast cancer, which is the second...
most common cause of death in females which necessitates an urgent need to differentiate benign from malignant tumours \[^{5}\]. The National Comprehensive Cancer Network (NCCN), in the most recent Clinical Practice Guidelines, has recommended percutaneous breast biopsy for lesions categorised as Breast Imaging Reporting and Data System (BI-RADS) \[^{6-10}\]. Studies investigating the positive predictive value (PPV) of mammographic features described in the mammography BI-RADS lexicon have found it to be useful in differentiating between benign and malignant breast lesions \[^{11,12}\]. Despite several positive reports on the mammographic distinction between benign and malignant breast lesion \[^{13-15}\], laboratory confirmation of the breast lesion by histopathology is widely held as the gold standard. Histopathology involves an invasive technique of biopsy for both benign and malignant cases. The aim and objective of this study is to assess the efficacy of mammography in the evaluation of breast masses based on the Breast Imaging Reporting and Data System (BI-RADS) for differentiating between benign and malignant breast lesions keeping histopathology as gold standard. The resultant diagnosis finally leads to early and appropriate patient care and subsequent neo adjuvant and surgical treatment in case of malignancy.

Materials and Methods
Ethical Approval: Institutional Ethical Committee clearance was obtained. In addition, informed consent was obtained from all the patients prior to mammography.
Inclusion Criteria: All female patients suspected or clinically diagnosed breast masses based on mammographic findings above 30 years (age group ranging from 31-89 years)
Exclusion Criteria: All female patients with cystic breast lesions based on mammographic findings and below 30 years of age.

This comprised of 50 patients presented with lumps of the breast patients referred for mammography and concurrent histology assessment within the period of the study, who met the inclusion criteria. The equipment used was dedicated mammography unit “METALTRONICA. According to BI-RADS lexicon mammograms fall into six categories

| BI-RADS scale | Interpretation                  |
|---------------|--------------------------------|
| 0             | Inconclusive                    |
| I             | Negative                        |
| II            | Benign finding                  |
| III           | Probably benign                 |
| IV            | Suspicious finding              |
| V             | Highly suggestive of malignancy finding |
| VI            | Proven malignancy               |

No one with BI-RADS score of 0, I, and II was there in the study. For those with BI-RADS-IV and BI-RADS-V lesions biopsies were undertaken, whereas for those with BI-RADS-III lesions, the clinician recommended those patients with a family history for biopsy. A cut off of BIRAD IV or above was considered as positive case of breast cancer, which was confirmed by histopathology. Statistical software namely SPSS version 18 was used for the analysis of data. The study outcome was measured in terms of diagnostic accuracy of mammography using BI-RADS in detecting breast cancer keeping histopathology as gold standard. The sensitivity, specificity, PPV (Positive predictive value) and NPV (Negative predictive value) were measured according to the standard formulae for calculating diagnostic accuracy parameters.

Results
In this study the age of the patients were between 31 to 89 years, the mean age being 50 years. The maximum number of lesions was seen in the age group < 50 years and 23 patients were > 50 years (46 % as in Table I
Table I, Graph I- Percentage distribution of the sample according to age

| Age  | Count | %    |
|------|-------|------|
| <50  | 27    | 54.0 |
| >=50 | 23    | 46.0 |
| Mean ±SD | 50 ± 11.2 |
From table I it can be seen that out of 29 malignant cases, 14 (51.9%) were aged less than 50 years and 15 (65.2%) were > 50 years. Altogether, there were 21 benign cases out of which 13 (48.1%) of them were aged less than 50 years and 8 (34.8%) were >50 years. The Chi-square test gives a value of 0.91 and p value of 0.340 which is not significant. So the present study shows no significant association between age and pathological finding.

Out of the 50 mammograms there was no one with BI-RADS score of 0, I, and II. 17 (34%) were categorized under BI-RADS-III, 6 (12%) were BI-RADS-IV, 27 (54%) were BI-RADS-V and none of the patients in BI-RADS-VI. There were 27 malignant cases and 23 benign cases (Table II). Table II, Graph II- Comparison of BI-RADS category keeping histopathology as gold standard

| BI-RADS category | Malignant | Benign |
|------------------|-----------|--------|
|                  | Count | %      | Count | %      |
| BI-RADS III      | 1     | 5.9    | 16    | 94.1   |
| BI-RADS IV       | 1     | 16.7   | 5     | 83.3   |
| BI-RADS V        | 27    | 100    | 0     | 0.0    |

The table II indicates that 1 (5.9%) out of 17 BI-RADS III masses was malignant and 16 (94.1%) were benign and 1 (16.7%) out of 6 BI-RADS IV masses were malignant and 5 (83.3%) were benign. All 27 (100%) BI-RADS V masses were malignant. In the study, the individual sensitivity (Table III, Graph III) and specificity of BI-RADS V (99.1% and 100%) BI-RADS IV&V (96.6% & 76.2%). Similarly the positive predictive value was 100 % & 84.8% and negative predictive value was 91.3% & 94.1% respectively. The diagnostic accuracy was 96% and 88 % and was found to be very high. The above table (table III) shows that BI-RAD category in predicting malignancy if pathology finding is gold standard is significant from kappa value which were 0.92 and 0.75 respectively for BI-RADS V and BI-RADS IV and V which is consistent with other studies [7,8].

Table III, Graph III-BI-RADS category in predicting malignancy if histopathology as gold standard

| BI-RADS category | BI-RADS V | BI-RADS IV& V |
|------------------|-----------|---------------|
| Sensitivity      | 93.1      | 96.6          |
| Specificity      | 100.0     | 76.2          |
| False Negative   | 6.9       | 3.4           |
| False Positive   | 0.0       | 23.8          |
| Predictive value of positive test | 100.0 | 84.8 |
| Predictive value of negative test | 91.3 | 94.1 |
| Positive likelihood ratio | - | 4.1 |
| Negative likelihood ratio | 0.1 | 0.0 |
| Accuracy         | 96.0      | 88.0          |
| Kappa            | 0.92***   | 0.75**        |

**- Significant at 0.01 level
Discussion
The goal of screening mammogram is to discover breast lesions at its pre-cancerous stage. Mammography is an easy to perform, low cost technique by which breast cancer can be detected. For early detection of breast cancer, it is the modality of choice as it is the only evidence based early detection method [16]. The BI-RADS lexicon was first developed in 1993 for reporting mammography. Since its establishment, several studies have found that it can be helpful to physicians in predicting the likelihood of cancer [11,12,17]. The current study found out a very high sensitivity of BI-RADS V & BI-RADS IV & V (93 % & 96.6%) and specificity (100 % & 76.2%) of BIRADS respectively, in the diagnosis of breast cancer. Many previous investigators also highlighted the importance of BIRADS with high accuracy in terms of sensitivity and specificity of the test [18]. The comparison of BI-RADS categories with histological results was well in line with the results of some studies using mammography [19]. This comparable evidence by previous investigators highlights the importance of BIRADS mammography in the detection of breast cancer. Whilst the incidence of breast cancer is higher in high income countries, mortality due to breast cancer is higher in low and middle income countries due to lack of timely detection and treatment. The American College of Radiology has recently released an updated edition of BI-RADS which includes mammographic illustrations of breast findings [20]. This teaching devise may improve understanding of radiologists to improve their skills about BI-RADS terms and also warrants testing so that the variability in mammographic interpretation can be decreased.

Conclusion
The results of our study show a very high agreement with the likelihood of malignancy after BI-RADS categorization for mammogram. So based on the study results it is concluded that that the diagnostic accuracy of mammography is a method of choice to evaluate breast masses is very good keeping histopathology as gold standard.

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