Original Research Article

Diagnosis of breast lumps based on breast imaging reporting and data system score and histopathological examination: a comparative study

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ABSTRACT

Background: Breast cancer incidence in India is increasing and has now become the most common cancer among women. Preoperative pathology diagnosis and mammography (using breast imaging reporting and data system (BI-RADS) scoring system) constitute an essential part of the workup of breast lesions. The present study was aimed to compare the diagnostic accuracy of BI-RADS score with histopathological finding in diagnosis of benign and malignant lesions of breast.

Methods: This is a cross-sectional study. The present study was conducted on 100 randomly selected newly diagnosed cases of breast lump attending the General Surgery Department (OPD).

Results: Considering histopathological examination as gold standard, the sensitivity and specificity of BI-RADS score is 93.9% and 82.3% respectively. The positive predictive value, negative predictive value and diagnostic accuracy of BI-RADS score is 91.1%, 87.5% and 90.0% respectively.

Conclusions: Author conclude from the present study that BI-RADS score being non-invasive, it may become a very useful test for evaluating Breast lump lesions. However, BI-RADS score cannot be considered as gold standard and thus cannot be used as an alternative to histopathology in diagnosis of breast lumps.

Keywords: Breast imaging reporting and data system, Breast lump, Histopathology, Triple assessment

INTRODUCTION

Breast cancer is the most common cancer diagnosed in women worldwide accounting for 21% of all cancers diagnosed in women. Breast cancer incidence in India is increasing and has now become the most common cancer among women, surpassing cervical cancer in all the urban cancer registries. Preoperative pathology diagnosis constitutes an essential part of the workup of breast lesions. Breasts.

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 tumour or other abnormalities. 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. Improvement has occurred over the last decade in the quality of X-rays and the reporting of mammographic studies. 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.

In India, fine needle aspiration cytology (FNAC) is still widely practiced in the assessment of breast masses in both palpable and non-palpable lesions because it provides a rapid, accurate and cost-effective diagnosis. However, there are many pitfalls with FNAC in the...
assessment of breast lesions, leading to too many excision biopsies for diagnosis of breast masses.  

Core biopsy has replaced fine needle aspiration for symptomatic and screen detected breast lesions in most of the western countries. The frequency of nondiagnostic or inadequate sample report is lower than that of FNAC and it is much less invasive and less expensive when compared with excision or incision biopsy for diagnosis.

The Breast Imaging Reporting and Data System (BI-RADS) lexicon was developed by the American College of Radiology to standardize the description and management of findings identified on mammograms, thereby facilitating communication between radiologists and referring physicians. The standardized evaluation of mammographic findings with predictive terms enables stratification of patient risk to optimize treatment planning. The authors of the BI-RADS lexicon have divided morphologic descriptors of microcalcifications into three categories that predict benignity or malignancy: typically benign, intermediate concern, and higher probability of malignancy.

In a study of interobserver variability of BI-RADS usage, microcalcification descriptors were the most difficult to apply consistently among readers. Another study of a large retrospective review of biopsies indicated that two thirds of all microcalcifications sampled for biopsy were described as pleomorphic. In response, the fourth edition of BI-RADS provided refined microcalcification descriptors by dividing the former pleomorphic descriptor into coarse heterogeneous and fine pleomorphic. Results of a study of microcalcifications and categories in the BI-RADS fourth edition indicated that these refinements help predict the risk of malignancy for suspicious microcalcifications.

Stereotactic biopsy and needle-localized open breast biopsy have usually been used for the diagnosis of mammographically detected microcalcifications. Several studies regarding needle-localized open breast biopsy have addressed its diagnostic accuracy, reporting lesion miss rates of 0-18% (mean, 2.6%) and a mean false-negative rate (i.e., cancer miss rate) of 2%.

With this background, the present study was aimed to compare the diagnostic accuracy of BI-RADS score with histopathological finding in diagnosis of benign and malignant lesions of breast.

METHODS

“Comparison of diagnostic accuracy of BI-RADS score with histopathological finding in breast lumps” is a cross-sectional study.

Study Setting of the present study was conducted on randomly selected newly diagnosed breast lump cases coming to the Dept. of Surgery, Dr. D. Y. Patil Medical College, Hospital and Research Centre, Pimpri, Pune.

Study Period of the present study of data collection was spread over one and half year from October 2017 to March 2019.

Sampling method and sample size includes 100 randomly selected newly diagnosed breast lump who attend the General Surgery Department (OPD) were included in the study. Patients were included in the study after taking their voluntary informed consent.

Inclusion criteria

Female patients above 35 years with complaints of breast lump.

Exclusion criteria

- Patients less than 35 years.
- Pregnant and lactating females.
- Patients with recurrent lumps.
- Male patients.

A predesigned semi-structured questionnaire was prepared based on the review of literature on breast lump including epidemiological data, duration of symptom, menstrual and obstetric history and history specific to breast lump. Women underwent mammography, the report of which was evaluated using BI-RADS score. After relevant investigations, trucut biopsy was taken from the lumps and sample sent for histopathological examination. Author have assessed the concordance between both the methods.

Statistical analysis

The categorical variables were assessed using Pearson chi-square. The quantitative variables were assessed using t -test. The test was considered significant only if the p value comes out to be less than 0.05. The concordance between BI-RADS score and histopathology test was assessed using sensitivity, specificity, positive predictive value, negative predictive value and diagnostic accuracy considering histopathology test as Gold standard.

RESULTS

The mean age of the study participants is 55.7±8.3 years. The mean age of benign cases was 52.1±9.4 years and malignant cases was 57.2±8.9 years.

It was observed that among benign cases, 10 (15.2%) cases were between 36-45 years, 16 (24.2%) cases were between 46-55 years, 28 (42.4%) cases were between 56-65 years, 9 (13.6%) cases were between 66-75 years, 3 (4.5%) cases were above 75 years while among malignant cases, 5 (14.7%) cases were between 36-45 years.
years, 7 (20.6%) cases were between 46-55 years, 11 (32.4%) cases were between 56-65 years, 7 (20.6%) cases were between 66-75 years and 4 (11.8%) cases were above 75 years (Figure 1).

On examination using mammography evaluated by BI-RADS score, it was observed that 68 (68.0%) cases were having benign lump while 32 (32.0%) cases were having malignant lump (Figure 3).

It was observed that 12 (12.0%) cases had BIRADS score 1, 32 (32.0%) cases had BI-RADS score 2, 24 (24.0%) cases had BI-RADS score 3, 13 (13.0%) cases had BI-RADS score 4, 10 (10.0%) cases had BI-RADS score 5 and 9 (9.0%) cases had BI-RADS score 6 (Figure 4).

**Table 1: Distribution of findings on BIRADS mammogram and histopathology.**

<table>
<thead>
<tr>
<th>BI-RADS Score</th>
<th>N (%)</th>
<th>HPE positive</th>
<th>HPE negative</th>
</tr>
</thead>
<tbody>
<tr>
<td>BI-RADS score 1</td>
<td>12</td>
<td>0</td>
<td>12</td>
</tr>
<tr>
<td>BI-RADS score 2</td>
<td>32</td>
<td>0</td>
<td>32</td>
</tr>
<tr>
<td>BI-RADS score 3</td>
<td>24</td>
<td>6</td>
<td>18</td>
</tr>
<tr>
<td>BI-RADS score 4</td>
<td>13</td>
<td>9</td>
<td>4</td>
</tr>
<tr>
<td>BI-RADS score 5</td>
<td>10</td>
<td>10</td>
<td>0</td>
</tr>
<tr>
<td>BI-RADS score 6</td>
<td>9</td>
<td>9</td>
<td>0</td>
</tr>
<tr>
<td>Total</td>
<td>100</td>
<td>34</td>
<td>66</td>
</tr>
</tbody>
</table>
Table 2: Correlation between HPE diagnosis and BIRADS score.

<table>
<thead>
<tr>
<th>HPE diagnosis</th>
<th>Benign</th>
<th>Malignant</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td>Benign</td>
<td>62</td>
<td>6</td>
<td>68</td>
</tr>
<tr>
<td>Malignant</td>
<td>4</td>
<td>28</td>
<td>32</td>
</tr>
<tr>
<td>Total</td>
<td>66</td>
<td>34</td>
<td>100</td>
</tr>
</tbody>
</table>

Table 3: Summary of accuracy data for BIRADS score.

<table>
<thead>
<tr>
<th>Parameter</th>
<th>Estimate (%)</th>
<th>Lower-upper 95% CI</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sensitivity</td>
<td>93.9</td>
<td>(85.4-97.6)</td>
</tr>
<tr>
<td>Specificity</td>
<td>82.3</td>
<td>(66.5-91.6)</td>
</tr>
<tr>
<td>Positive predictive value</td>
<td>91.1</td>
<td>(82.0-95.9)</td>
</tr>
<tr>
<td>Negative predictive value</td>
<td>87.5</td>
<td>(72.0-95.0)</td>
</tr>
<tr>
<td>Diagnostic accuracy</td>
<td>90.0</td>
<td>(82.5-94.5)</td>
</tr>
</tbody>
</table>

The Table 2 shows correlation between histopathological examination (HPE) diagnosis and BIRADS score in cases assessed.

Considering BIRADS score 1, 2 and 3 to be benign and score of 4, 5 and 6 to be malignant, it was seen that 62 cases were benign on both HPE and BIRADS score, 4 case was benign on HPE and malignant on BIRADS score, while 6 cases were malignant on HPE and benign on BIRADS score and 28 cases were malignant on both HPE and BIRADS score (Table 2).

Considering HPE as gold standard, the sensitivity and specificity of BIRADS score is 93.9% and 82.3% respectively. The positive predictive value, negative predictive value and diagnostic accuracy of BIRADS score is 91.1%, 87.5% and 90.0% respectively.

**DISCUSSION**

**Age distribution of cases**

In the present study, it was observed that among benign cases, 10 (15.2) cases were between 36-45 years, 16 (24.2) cases were between 46-55 years, 28 (42.4) cases were between 56-65 years, 9 (13.6) cases were between 66-75 years, 3 (4.5) cases were above 75 years while among malignant cases, 5 (14.7) cases were between 36-45 years, 7 (20.6) cases were between 46-55 years, 11 (32.4) cases were between 56-65 years, 7 (20.6) cases were between 66-75 years and 4 (11.8) cases were above 75 years.

This was in contrast to the study conducted by Navya et al, in which 17 (34.0) cases were younger women between 15-25 years, 13 (26.0) cases were between 26-35 years, 9 (18.0) cases were between 36-45 years, 3(6.0) cases were between 46-55 years, and only 5(10.0) cases were above 56-65 years and 5 (10.0) cases were above 66-75 years.

In the study conducted by Mohan et al, 9 (36.0) cases were between 41-50 years, 10 (40.0) cases were between 51-60 years, 5 (20.0) cases were between 61-70 years and only 1 (4.0) case was between 71-80 years.

In the present study, mean age of the study participants is 55.7±8.3 years. The mean age of benign cases was 52.1±9.4 years and malignant cases was 57.2±8.9 years.

In the study conducted by Takalkar et al, a similar mean age of the cases was found, 52.6±10.5 years.

In the study conducted by Arsalan et al, the mean age of the cases was found to be much younger 42.6±7.21 (30-60) years.

In the study conducted by Soyder et al., the mean age of the cases was similar at 50±11 years.

**Distribution of benign and malignant lump on histopathology**

In the present study, it was observed that 66 (66.0%) cases were having benign lump while 34 (34.0%) cases were having malignant lump on histopathology.

In the study conducted by Navya et al, similar findings were observed that 32 (64.0%) cases were having benign lump while 18 (36.0%) cases were having malignant lump on histopathology.

In the study conducted by Soyder et al, it was observed that majority of cases 42 (75.0%) were having benign lump while only 16 (25.0%) cases were having malignant lump.

In the study conducted by Patankar et al, in keeping with this study 44 (69.8%) cases were observed to have benign lump while 19 (20.2%) cases were having malignant lump.

In the study conducted by Kaira et al, it was observed that 47 (40.9%) cases were having benign lump while more 68 (59.1%) cases were found to have malignant lump.

**Distribution of findings on BI-RADS mammogram**

In the present study, it was observed that 68 (68.0%) cases were having benign lump while 32 (32.0%) cases were having malignant lump on BI-RADS score.

In the study conducted by Navya et al, it was observed that 30 (60.0%) cases were having benign lump while 20 (40.0%) cases were having malignant lump on BI-RADS score.
In the present study, it was observed that 12 (12.0%) cases had BI-RADS score 1, 32 (32.0%) cases had BI-RADS score 2, 24 (24.0%) cases had BI-RADS score 3, 13 (13.0%) cases had BI-RADS score 4, 10 (10.0%) cases had BI-RADS score 5 and 9 (9.0%) cases had BI-RADS score 6.

In the study conducted by Arsalan et al, it was observed that in the left breast 2 (4.0%) cases had BI-RADS score 0, 19 (38.0%) cases had BI-RADS score 1, 8 (16.0%) cases had BI-RADS score 2, 1 (2.0%) cases had BI-RADS score 3, 5 (10.0%) cases had BI-RADS score 4 and 15 (30.0%) cases had BI-RADS score 5.15

In the study conducted by Farhat Arsalan et al, it was observed that in the right breast 3 (6.0%) cases had BI-RADS score 0, 28 (56.0%) cases had BI-RADS score 1, 6 (12.0%) cases had BI-RADS score 2, 1 (2.0%) cases had BI-RADS score 3, 1 (2.0%) cases had BI-RADS score 4 and 11 (22.0%) cases had BI-RADS score 5.15

**Correlation between HPE diagnosis and BI-RADS score**

In the present study, it was seen that 62 cases were benign on both HPE and BI-RADS score, 4 cases was benign on HPE and malignant on BI-RADS score while 6 cases were malignant on HPE and benign on BI-RADS score and 28 cases were benign on both HPE and BI-RADS score. Considering HPE as gold standard, the sensitivity and specificity of BI-RADS score is 93.9% and 82.3% respectively. The positive predictive value, negative predictive value and diagnostic accuracy of BI-RADS score is 91.1%, 87.5% and 90.0% respectively.

In the study conducted by Navya et al, it was seen that 28 cases were benign on both HPE and BI-RADS score, 4 case was benign on HPE and malignant on BI-RADS score while 2 cases were malignant on HPE and benign on BI-RADS score and 16 cases were malignant on both HPE and BI-RADS score.12 Considering HPE as gold standard, the sensitivity and specificity of BI-RADS score is 88.0% and 87.5% respectively. The positive predictive value, negative predictive value and diagnostic accuracy of BI-RADS score so far conducted with these findings and were found to be 80.0%, 93% and 88% respectively.

In the study conducted by Arsalan et al, it was seen that 41 cases were positive on both Biopsy (FNAC/ trucut/ excision) and BI-RADS score, 6 case was positive Biopsy (FNAC/ trucut/ excision) and negative on BI-RADS score while 3 cases were negative on both biopsy (FNAC/ trucut/ excision) and BI-RADS score. Considering biopsy (FNAC/ trucut/ excision) as gold standard, the sensitivity and specificity of BI-RADS score is 87.2% and 100.0% respectively. Positive predictive value, negative predictive value and diagnostic accuracy of BI-RADS score, in contrast to this study, were 100.0%, 33.3% and 88% respectively.15

In a study conducted by Shrestha et al, he observed the sensitivity of 78.9 percent and specificity of 95% on sonomammography for differentiating benign from malignant lesions using the BI-RADS score.19

In the study conducted by Shumaila et al, out of 73 cases they observed mammography to be positive in 66(90) and sonomammography to be positive in 68(93).20

In the study conducted by Emine et al, on 546 breast lesions with histopathology analysis, they observed sensitivity and specificity for sonomammogram to be 72.6 and 88.5%.21

In the present study author got similar results with a sensitivity of 93.9% and specificity of 82.3% which is comparable to the above studies.

**CONCLUSION**

Author conclude from the present study that BI-RADS score being non-invasive, it may become a very useful test for evaluating breast lump lesions. However, BI-RADS score cannot be considered as gold standard and thus cannot be used as an alternative to histopathology in diagnosis of breast lumps.

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**Conflict of interest:** None declared

**Ethical approval:** The study was approved by the Institutional Ethics Committee

**REFERENCES**


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