

## CORRELATION OF DIAGNOSTIC ACCURACY OF BI-RADS SCORING WITH CYTO-HISTOLOGICAL FEATURES OF BREAST LESIONS – A RETROSPECTIVE STUDY FROM A TERTIARY CARE HOSPITAL

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### Abstract

**Background:** Breast lesions are commonly encountered in surgical pathology with an increased incidence of carcinoma. The highest level of preoperative diagnostic accuracy of breast lesions can be achieved using the triple approach of clinical examination, Breast Imaging Reporting and Data System (BI-RADS) grading by sonomammography and fine needle aspiration cytology (FNAC). However, in view of known limitations, a multidisciplinary approach with clinical and pathological correlation aids in the effective detection of the condition thereby helping in planning appropriate management. This study aims to determine the sensitivity, specificity, positive and negative predictive value and diagnostic accuracy of BI-RADS grading with FNAC scoring system considering histopathology as gold standard. **Materials and Methods:** This was a retrospective, cross-sectional observational study conducted on 103 cases with clinically palpable breast lump who underwent sonomammography, FNAC and surgical excision with histopathological examination. Data were collected and statistical analysis was performed to determine the sensitivity, specificity, positive and negative predictive value and diagnostic accuracy of BI-RADS grading with FNAC scoring system, considering histopathology as gold standard. **Result:** On comparison with the final histopathological diagnoses, BI-RADS scoring system showed a high false-positive rate and FNAC showed high true positive rate. The sensitivity, specificity, positive predictive value, negative predictive value and diagnostic accuracy for BI-RADS and FNAC were respectively, 83%,75%,58%,91%,78% and 86%,98%,96%,95%,96%. **Conclusion:** Both imaging studies and FNAC are safe, simple, reliable and have their own advantages and disadvantages. Simultaneous application of both modalities can be complementary to each other. A multidisciplinary approach with both imaging studies and FNAC in all pre-operative patients with breast lump is recommended prior to histopathological diagnosis.

## INTRODUCTION

Breast lesions comprise a diverse and heterogeneous group of disorders ranging from inflammatory lesions to malignancy.<sup>[1]</sup> Breast cancer is the most common malignancy causing death in females. It accounts for nearly 30% of malignancies affecting women in India. It has quickly surpassed cervical cancer to become the most common malignancy among women in India.<sup>[2]</sup> Incidence of breast cancer

related morbidity and mortality is showing an increasing trend in both developed and developing countries.<sup>[3]</sup> Nevertheless, diagnostic imaging modalities combined with pathological study of breast lesions have improved, aiding in the diagnosis of focal and suspicious lesions. In order to ensure an accurate and precise diagnosis, the combination of clinical findings, imaging methods and pathological evaluation is necessary.

The American College of Radiology has developed the Breast Imaging Reporting and Data System (BI-RADS) to standardise the reporting terminologies. BI-RADS assessment has 0-6 categorization.<sup>[4]</sup>

- Category 0: Need additional imaging evaluation
- Category 1: Negative
- Category 2: Benign finding
- Category 3: Probably benign finding; short-interval follow-up suggested
- Category 4: Suggestive abnormality; biopsy should be considered
- Category 5: Highly suggestive of malignancy; appropriate action should be taken
- Category 6: Known biopsy-proved malignancy

Fine Needle Aspiration Cytology (FNAC) is a minimally invasive and cost-effective procedure with minimal discomfort to the patient and rapid generation of results. FNAC has high diagnostic accuracy rate of 98.9% in the diagnosis of breast lesions. FNAC is therefore an extremely important tool in the evaluation of palpable breast lumps especially in resource limited settings.<sup>[5]</sup>

FNAC reports are categorized into five diagnostic assessment categories based on the National Health Services Breast Screening Programme (NHSBSP) of Britain.<sup>[6]</sup>

- C1: Inadequate/ Insufficient
- C2: Benign
- C3: Atypical / Indeterminate
- C4: Suspicious of malignancy
- C5: Malignant

In the present study we aim to evaluate sensitivity, specificity, positive and negative predictive value, Diagnostic accuracy of BI-RADS grading and FNAC scoring system, considering histopathology as gold standard.

## MATERIALS AND METHODS

This was a retrospective, cross-sectional observational study conducted in the Department of Pathology of Mahatma Gandhi Medical College and Research Institute, Puducherry over a period of two years, from January 2021 to December 2022 on a total of 103 patients. Female patients of all age group presenting with clinically palpable breast lump to the Department of General Surgery and who subsequently underwent sonomammography and FNAC, followed by surgical excision and histopathological examination were included for the study. Those who did not undergo any of these three modalities, namely, sonomammography, FNAC or surgical excision and post-chemotherapy patients were excluded from the study.

Detailed clinical history and breast examination findings were noted by the surgeons. The radiological image findings were analysed by radiologists according to BI-RADS scoring system.

FNAC was performed in the Department of Pathology. After breast examination, FNAC was done under aseptic precautions, and the material was obtained using 23-gauge needle and 10 ml disposable

plastic syringe, and smeared on glass slides. Smears were stained with May Grunwald Giemsa (MGG), Papanicolaou (Pap) and Hematoxylin and Eosin (H & E) stains. MGG was performed on air-dried smears while smears were fixed in 95% ethyl alcohol for Pap and H & E staining.

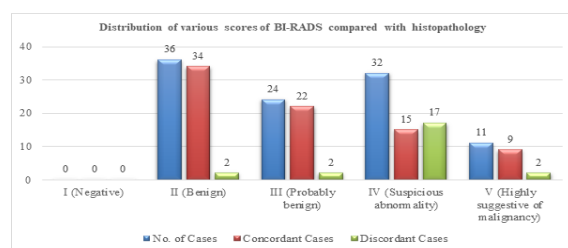
FNAC slides were screened under light microscopy and categorized according to NHSBSP of Britain into five assessment categories.

For histopathological examination, the tissues were fixed in 10% formalin overnight and sections were taken from representative areas. The samples were processed by automated tissue processor. The slides were then stained with H & E stain and examined under the microscope for histopathological diagnosis. BI-RADS scoring and cytological findings were correlated with histopathology for each case. The concordance of BI-RADS and FNAC with histopathology was assessed by sensitivity, specificity, accuracy, positive and negative predictive values BI-RADS score and FNAC taking into account histopathology as the gold standard.

## RESULTS

The study included 103 patients with palpable breast lumps. The youngest patient was 16 years and the oldest was 73 years of age.

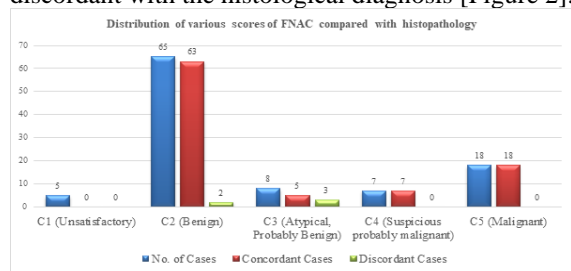
With regard to BI-RADS score of sonomammogram, there were no patients in categories 0 and 6. There were 36 (34.9%) patients in category 2 (benign), 24 (23.3%) patients in category 3 (probably benign), 32 (31.1%) in category 4 (suspicious of malignancy) and 11(10.7%) patients in category 5 (highly suspicious of malignancy). In the present study, the most common was BI-RADS Category 2. Imaging findings with score of 2 or 3 were considered benign and score of 4 or 5 were considered malignant. Of the total 103 cases with BIRADS score, 80 (77.7%) cases were concordant with histological diagnosis and 23 (22.3%) cases were discordant with histological diagnosis [Figure 1].



**Figure 1: Distribution of various scores of BI-RADS compared with histopathology**

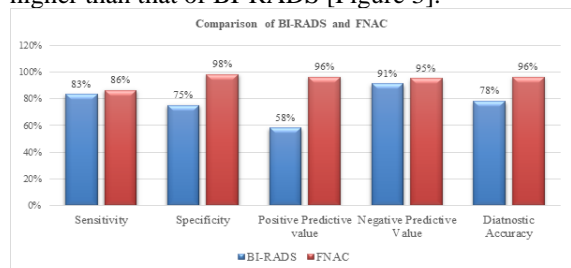
The results of FNAC according to NHSBSP are depicted in Figure 2. Of the total 103 cases, 5 (4.9%) were non diagnostic, 65 (63.1%) were diagnosed as benign, 8 (7.8%) were diagnosed as atypical and probably benign, 7 (6.8%) were diagnosed as suspicious, probably malignant and 18 cases (17.5%) were diagnosed as malignant based upon cytological parameters. Of the remaining 98 cases, excluding the

non-diagnostic cases, 93 (90.3%) were concordant with the histological diagnosis and 5 (4.9%) were discordant with the histological diagnosis [Figure 2].



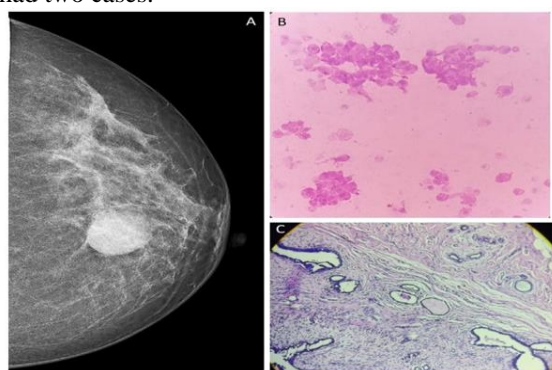
**Figure 2: Distribution of various grades in FNAC compared with histopathology**

The correlation of BIRADS with histopathology is tabulated in [Table 1]. The sensitivity, specificity, positive predictive value, negative predictive value, diagnostic accuracy of BIRADS score were 83%,75%,58%,91%,78% respectively. The correlation of FNAC with histopathology is tabulated in [Table 2]. The sensitivity, specificity, positive predictive value, negative predictive value and diagnostic accuracy of FNAC were 86%,98%,96%,95%,96% respectively, which are higher than that of BI-RADS [Figure 3].



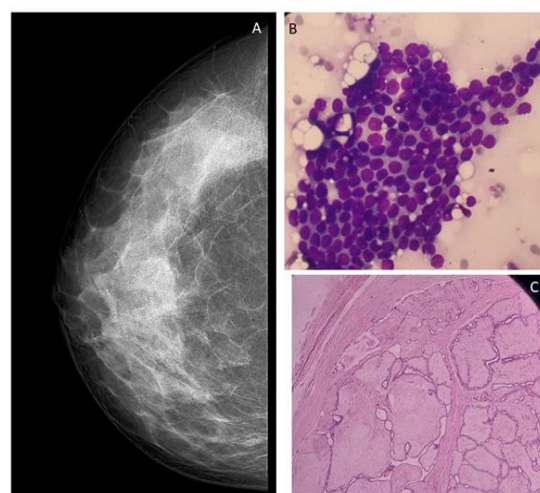
**Figure 3: Comparison of BI-RADS and FNAC**

The distribution of discordant cases by BI-RADS and cytology in correlation with histopathology is tabulated in Table 3. Among the total 23 discordant cases by BIRADS, highest number of discordant cases were observed in BI-RADS category IV with 16 cases (69.5%) followed by BI-RADS category III with 3 cases (13%). BIRADS category II and V each had two cases.

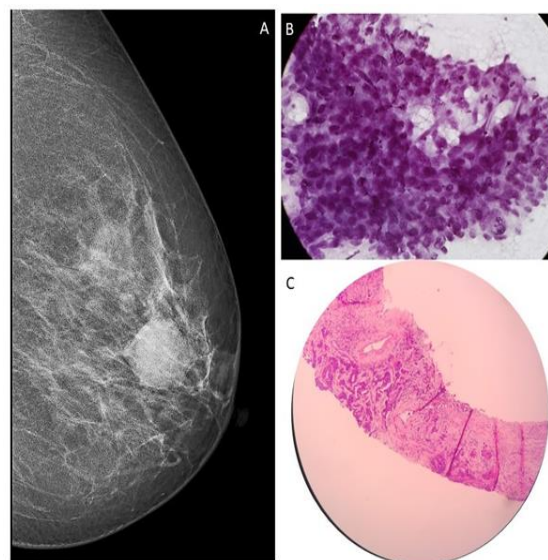


**Figure 4: A. Mammography showing well-defined high-density lesion with circumscribed margins in central breast B. Photomicrograph of breast aspirate showing cyst macrophages, May Grunwald Giemsa stain; 10X C. Photomicrograph showing fibrocystic change with fibrosis, cystically dilated glands and apocrine change, Hematoxylin & Eosin (H&E); 4X**

Totally five discordant cases were present in cytology in correlation with histopathology. The highest number of discordant cases were observed in category C2 and C3 with two cases each. One case of grade I infiltrating ductal carcinoma and one case of medullary carcinoma were reported as benign proliferative breast disease category 2 on FNAC. There was one discordant case in C4 category with cytological diagnosis of suspicious of malignancy, where histological diagnosis proved to be benign fibrocystic disease.



**Figure 5: A. Mammography showing well-defined high-density lesion with circumscribed margins in central breast B. Photomicrograph of breast aspirate showing cyst macrophages, May Grunwald Giemsa stain; 10X C. Photomicrograph showing fibrocystic change with fibrosis, cystically dilated glands and apocrine change, Hematoxylin & Eosin (H&E); 4X**



**Figure 6: A. Mammography showing a fairly circumscribed mass with spiculated borders. B. Photomicrograph of breast aspirate showing pleomorphic tumor cells with high mitotic activity, Pap stain; 40X C. Photomicrograph of core needle biopsy of the case showing features of infiltrating ductal carcinoma, H&E; 4X**

**Table 1: Correlation of BI-RADS with histopathology.**

BI-RADS	Histopathology	
	Malignant	Benign
Malignant (IV + V)	25 (True Positive)	18 (False Positive)
Benign (II + III)	5 (False Negative)	55 (True Negative)

**Table 2: Correlation of FNAC with histopathology**

FNAC	Histopathology	
	Malignant	Benign
Malignant (C4 + C5)	24 (True Positive)	1 (False Positive)
Benign (C2 + C3)	4 (False Negative)	69 (True Negative)

**Table 3: Distribution of discordant cases by BI-RADS and FNAC in correlation with histopathology**

Discordant cases by BIRADS (n=23)	Discordant cases by FNAC (n=5)	Histopathological diagnosis
BIRADS V (n=2)	-	Granulomatous mastitis (n=2)
BIRADS IV (n=16)	C4 – Suspicious of malignancy (n=1)	Fibrocystic disease (n=7)
		Fibroadenoma (n=4)
		Inflammatory (n=1)
		Phyllodes tumor (n=2)
BIRADS III (n=3)	C2 – BPBD <sup>a</sup>	IDCb grade I (n=1)
		IDC grade II (n=1)
		Metaplastic carcinoma (n=1)
BIRADS II (n=2)	C2 – BPBD	Medullary carcinoma (n=1)
		Clear cell carcinoma (n=1)

a Benign Proliferative Breast Disease

b Infiltrating Ductal Carcinoma

**Table 4: Sensitivity, specificity, positive predictive value, negative predictive value and accuracy of BI-RADS reported in various studies and their comparison with the present study**

BI-RADS Correlation with Various Studies				
BI-RADS	Present Study	Mohson et al	Stavros et al	Navya et al
Sensitivity	83.0%	93.0%	80.0%	88.0%
Specificity	75.0%	81.0%	67.8%	87.5%
Positive Predictive Value	58.0%	53.7%	50.0%	55.0%
Negative Predictive Value	91.0%	96.4%	90.5%	93.0%
Diagnostic Accuracy	78.0%	78.7%	72.9%	88.0%

**Table 5: Sensitivity, specificity, positive predictive value, negative predictive value and accuracy of FNAC reported in various studies and their comparison with the present study**

FNAC Correlation with Various Studies				
FNAC	Present Study	Mohson et al	Stavros et al	Navya et al
Sensitivity	86.0%	87.0%	83.3%	98.0%
Specificity	98.0%	98.7%	100.0%	100.0%
Positive Predictive Value	96.0%	98.0%	100.0%	97.0%
Negative Predictive Value	95.0%	94.3%	95.0%	100.0%
Diagnostic Accuracy	96.0%	91.7%	96.5%	98.0%

## DISCUSSION

Breast lump is one of the common presenting complaints encountered by females. Most palpable breast lesions are benign and less than 30% of women with palpable breast lumps are diagnosed with cancer.<sup>[7]</sup> In developing countries like India, breast cancer is becoming more common in younger age (<50 years). Most of the women in developing countries do not have sufficient knowledge about breast diseases and presented to healthcare professionals at a later stage of disease. This is one of the main reasons for advanced breast cancer and high mortality rate in Indian women due to delay in diagnosis and treatment.<sup>[8]</sup>

Patients with palpable breast lesions commonly undergo radiological evaluation for initial diagnosis. Diagnosis of breast disease with mammography has

a sensitivity of 85% - 95%. The percentage of false negative cases reporting in mammography in palpable breast mass evaluation is estimated to be around 15%. American College of Radiology developed BI-RADS to provide a standardised classification for mammographic studies. BI-RADS was established in 1993 to provide uniform reporting and reduce confusion among radiologists and treating physicians.<sup>[9]</sup> Several studies have found that BI-RADS is helpful in predicting the likelihood of cancer. Breast sonography is a valuable non-invasive imaging technique and several studies have suggested that ultrasound is useful for differentiating from malignant from benign solid breast masses. Both Ultrasonography and mammography are important diagnostic modalities in early detection, prompt treatment leading to improved survival rates in younger women.<sup>[10]</sup>

Sensitivity of sonomammography in the diagnosis of breast lesions has a wide variation ranging from 67% to 97% as reported in the literature.<sup>[11,12]</sup> Sensitivity of sonomammography varied significantly with age of the patient and breast density. In a study conducted by Devolli-Disha et al, ultrasonography had a higher sensitivity than mammography in females lesser than 45 years, whereas mammography had a higher sensitivity than ultrasound in females older than 60 years. The sensitivity reported was 52.1% for mammography and 72.6% for ultrasound. The specificity reported was 88.5% for ultrasound and 73.9% for mammography respectively.<sup>[13]</sup> In the present study, we got comparable results with a sensitivity of 83%, specificity of 75%, positive predictive value of 58% and a negative predictive value of 91% and a diagnostic accuracy of 78% in differentiating benign from malignant lesions in sonomammography using the BI-RADS system. In a study conducted by Bharamaramba et al, out of total 120 cases in BI-RADS category IV, 75 cases (62.5%) were diagnosed to be benign on histopathology.<sup>[14]</sup> In the present study, we got comparable results where there were total 23 discordant cases with highest number of discordant cases in BIRADS category IV with 16 cases (69.5%). The histopathological diagnosis was reported to be benign in these 16 discordant cases.

FNAC of breast lesions is an established and accepted procedure for diagnosing the nature of breast lumps with a high degree of accuracy. The utility of FNAC for the diagnosis of breast lumps was initially introduced in 1930 by Martin and Ellis and since then it has widely accepted as a reliable technique in the diagnosis of breast lesions. In developed countries, FNAC has been largely replaced by core needle biopsy owing to the high degree of accuracy in the latter. Nevertheless, FNAC is still practised worldwide, and used as a reliable technique in the preoperative diagnosis of breast lesions.<sup>[15]</sup>

In the present study, 73 cases and 25 cases were diagnosed cytologically as benign and malignant respectively. Among the 73 benign cases, 69 cases were benign on subsequent histological examination, whereas four cases were diagnosed as malignant on biopsy. Among the 25 malignant cases, 24 were confirmed to be malignant on biopsy, whereas one case was benign on histopathology. So, in our study, 95.7% concordance of cyto-histopathological correlation was observed for breast lesions. This is in concordance with similar study conducted by Panwar et al.<sup>[16]</sup>

The sensitivity, specificity, accuracy, negative predictive value and the positive predictive value of FNAC was 66.66%, 81.8%, 75.7%, 100% and 90% respectively in the study conducted by Homesh et al.<sup>[17]</sup> Our study showed sensitivity, specificity, positive predictive value, negative predictive value and diagnostic accuracy of 86%, 98%, 96%, 95% and 96% respectively. Ibikunle et al in their study similarly reported a 99.4% and 100% sensitivity and

specificity of FNAC in diagnosing breast lesions.<sup>[18]</sup> Similar findings were reported in other studies as in [Table 4 and 5].<sup>[19-21]</sup>

Among the total five discordant cases in FNAC, the percentage of discordant cases was highest in C2 and C3 with each having 2 cases (40%). This is in concordance with the study conducted by Goyal et al, where 37.5% cases in C3 category revealed malignant findings on histopathological examination.<sup>[22]</sup> Hence it is imperative to do a biopsy in C3 lesions reported on cytology.

FNAC is a simple and cost-effective procedure for the initial diagnosis of palpable breast lesions. FNAC is a rapid procedure which does not require anaesthesia and can be done on an outpatient basis. Results can be obtained faster compared to core needle biopsy thereby reducing patient anxiety. However histopathological examination should be performed for cases with uncertain diagnosis or when evaluation of the histological type or invasiveness is mandatory. However, in resource limited settings and as a part of triple assessment, FNAC is still preferable to biopsy owing to its cost effectiveness. The gold standard investigation in our study is the histopathological report which is valid, reproducible and accepted as the gold standard reference method internationally.<sup>[23]</sup> Bukhari et al. in his study has advocated the use of combination approach of mammography, FNAC and core needle biopsy which is more accurate, reliable and has good acceptability.<sup>[24]</sup>

## CONCLUSION

Sonomammography with BIRADS score is an imaging technique whereas FNAC and biopsy are tissue diagnostic techniques. All these diagnostic tools should be considered complimentary and used as combination approach in all breast lesions irrespective of the patients' age and symptoms. Clinicians, radiologists and pathologists form part of a multi-disciplinary team in the diagnosis and management of breast lesions. The clinicians should know the advantages and disadvantages of each diagnostic method and formulate the treatment plan accordingly. The results of our study showed that FNAC is still a reliable method in diagnosis of breast lumps with high diagnostic accuracy compared to sonomammographic categorisation using BIRADS score. FNAC is considered as an initial diagnostic modality in breast lumps detected by imaging techniques owing to the simplicity of the procedure and rapid analysis and reporting of results. Use of ancillary techniques like immunocytochemistry, image guided FNAC can improve the accuracy of FNAC results. However, all malignant and clinically suspicious breast lesions should undergo histopathological examination which is the gold standard method for final diagnosis and management. **Acknowledgements:** We would like to acknowledge the support rendered by Department of Surgery and

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