Original Article

Comparison of Diagnostic Accuracy of BIRADS Score With Pathologic Findings in Breast Lumps

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ABSTRACT

Background: Breast lump is one of the commonest complaints with which patients present in breast clinics. As approximately 10% of breast masses ultimately lead to a diagnosis of breast cancer, it is important for women with a breast lump to receive appropriate evaluation. A confident diagnosis can be made in 95% of the cases through a combination of clinical examination, imaging and fine needle aspiration cytology. Histopathology is the gold standard for diagnosis.

Methods: This is a prospective study conducted in the Department of Pathology, K.V.G Medical College, Sullia on 50 patients who presented with clinically palpable breast lump. Patients were subjected to sonomammography and Breast Imaging Reporting and Data System (BIRADS) scoring followed by FNAC and histopathological examination. Sensitivity, specificity, accuracy, positive and negative predictive values of sonomammogram in relation to the BIRADS score and FNAC taking histopathology as the gold standard was calculated.

Result: FNAC had significantly higher sensitivity, specificity, positive and negative predictive values and accuracy compared to sonographical diagnosis using BIRADS score.

Conclusion: FNAC could be considered as the first method to evaluate breast lesions, recognized by means of imaging techniques.

Keywords: BIRADS, Fine-needle Aspiration Cytology, Histopathology

Introduction

Breast masses are localized swellings that feel different from the surrounding breast tissue. It is a symptom/sign for a variety of conditions.[1] Breast lump is one of the commonest complaints with which patients present in breast clinics.[2] As approximately 10% of breast masses ultimately lead to a diagnosis of breast cancer, it is important for women with a breast lump to receive appropriate evaluation.[1] Breast cancer is increasingly common in women worldwide. It is one of the leading causes of death among female malignancies. The incidence varies from region to region, more in developed countries (>80 per 100,000 populations) than in developing countries (<40 per 100,000 populations).[3] It commonly affects women older than 40 years of age. However, younger women can also be affected. 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. Early detection and treatment is a key to preventing breast cancer from spreading.[4]

A confident diagnosis can be made in 95% of the cases through a combination of clinical examination, imaging (including mammogram and/or sonomammogram) and fine needle aspiration cytology (FNAC).[1] Mammography is cost efficient and widely accepted technique to evaluate clinically suspected breast lesions and used for screening of breast cancer. High resolution sonography is a useful adjunct modality and helps characterizing a mammographically non-detected palpable abnormality, especially in dense breast.[5,6] Sonomammography is non-invasive, easily available, cheaper and accurate tool in diagnosing breast masses. It is very helpful in pre surgical assessment of tumor size of even 2mm. It is the method of choice for differentiating solid from the cystic lesions, for further characterizing mammographic findings and better appreciating palpable breast lesions.[1]

The American College of Radiology (ACR) created the breast imaging reporting and data system (BIRADS), to achieve trick verbal uniformity so as to get clear, unambiguous and standard language, not only among radiologist but also the treating physicians and surgeons. BI-RADS had 0-6 assessment categories.[6]

✔ 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

FNAC has a high diagnostic accuracy rate (98.9%) in the hands of experienced cytopathologists. FNAC is a reliable method to differentiate whether a suspicious breast mass is benign or malignant.[1] In addition to its high diagnostic accuracy FNAC offers advantages such as minimal invasiveness, minimal discomfort, cost effectiveness and rapidity of results. FNAC is therefore an extremely vital tool in the evaluation of palpable breast lumps especially in resource limited settings.[7]

However, the aspiration cytology is not a substitute for conventional surgical histopathology as a definitive diagnosis is not always possible by cytology, but categorization of disease and differential diagnosis can be provided in the majority of cases.[8]

In the present study we aim to compare the diagnostic accuracy of BIRADS score in detecting benign and malignant lesions with pathological findings (FNAC and Histopathology) which is used for the final diagnosis in patients presenting with breast lumps, thus helping in avoiding unnecessary surgical procedures.

Materials and Methods

This was a prospective study conducted in the Department of Pathology, K.V.G Medical College, Sullia on 50 patients who presented with clinically palpable breast lump. The term "palpable breast lump" meant an area of denser breast tissue felt different from the surrounding tissue. Samples for the study were selected according to the inclusion and exclusion criteria.

Inclusion Criteria
• Female patients of all ages with complaints of breast lump.
• Patients who have underwent breast imaging (including BIRADS scoring) and pathologic examination (i.e., both FNAC and histopathology).

Exclusion criteria
• Patients with recurrent lumps, history of prior irradiation to the chest or breast and cystic breast lesions
• Pregnant and lactating ladies
• Male patients

The clinicians obtained a full history, performed breast examination, and then the patients were sent for sonommamography to the radiology department.

Sonommamography was performed on all cases presenting with breast lump. The images obtained were analyzed and categorized using the BIRADS score as benign and malignant. For the next part of the study, all the patients were subjected to FNAC and later on followed up with histopathology (Excision biopsy/Mastectomy specimens) findings which was used as the gold standard to confirm the diagnosis on sonomammography according to BIRADS classification and FNAC.

FNAC was performed using a 23 G needle attached to 10 mL disposable plastic syringes, smeared on standard microscope glass slides and stained with haematoxylin and eosin (H&E) and Leishman stain. The slides were reviewed under light microscopy. For histopathological examination the tissue was fixed in 10% formalin and sections were taken from representative areas. The samples were labeled and processed, which involves a series of steps lasting 12 -16 hours. The slides were then stained with routine haematoxylin and eosin and examined under the microscope for histopathological diagnosis.

Statistical analysis were performed to compute the sensitivity, specificity, accuracy, positive and negative predictive values of sonomammogram in relation to the BIRADS score and FNAC taking histopathology as the gold standard.

Results

The study included 50 patients presenting with breast lump. The youngest patient was 16 years of age and the eldest was 70 years of age [Table -1]. Maximum number of cases were seen in 15-25 years age group followed by 26-35 years age group.

Results of sonomammogram according to BIRADS score is given in Table -2.There were no patients in categories 0,1 and 6.There were 14 patients(28%) in category 2 revealing benign findings ,16 patients (32%) in category 3 revealing probably benign finding , 10 in category 4 (20%) revealing suspicious abnormality and 10 patients in category 5 (20%) indicating a high suspicion of malignancy. Findings were considered benign if score was 2 or 3 and malignant if score was 4 or 5. Sonomammography diagnosed 60% cases as benign and 40% cases as malignant.

Distribution of cases on FNAC and Histopathological examination are given in Tables- 3 and 4. On FNAC, 32 cases were diagnosed as benign with majority being Fibroadenomatoid hyperplasia and Fibroadenoma (12 cases each) and 18 cases were diagnosed as malignant. On histopathological follow up, 32 cases were diagnosed as benign with majority being Fibroadenoma (15 cases)

and 18 cases as malignant with majority being Infiltrating ductal carcinoma (10 cases) followed by Infiltrating Lobular carcinoma (3 cases).

Four cases were given a score of 4 on BIRADS i.e., suspicious of malignancy of which 3 was diagnosed as Acute suppurative mastitis on FNAC and later on confirmed on histopathological examination as Fibrocystic disease with mastitis. The remaining case was diagnosed as Fibroadenoma / Intraductal papilloma on FNAC and as Intraductal Papilloma on Excision. These cases thus constituted the false positives in our study. Two cases were given a score of 3 i.e., probably benign on imaging, of which one was diagnosed as Atypical ductal

hyperplasia and the other as Ductal carcinoma in situ. Both were later confirmed as Infiltrating ductal carcinoma on histopathological examination. These cases constituted the false negatives in our study.

Tables -5 and 6 (Figure 1- a, b, c and Figure 2- a, b, c) show the comparison of BIRADS scoring and FNAC with histopathologic findings respectively. The sensitivity, specificity, positive predictive value, negative predictive value and accuracy was 88%, 87.5%, 80%, 93% and 88% respectively for BIRADS score and 100% for all the parameters on FNAC. Table- 7 shows the overall accuracy of sonomammography using BIRADS scoring and FNAC in the diagnosis of breast lesions.

Table 1: Age Distribution of Cases

Age Group	Number of Cases	Percentage
15-25	17	34%
26-35	13	26%
36-45	9	18%
46-55	3	6%
56-65	5	10%
66-75	3	6%
Total	**50**	**100%**

Table 2: Distribution of benign and malignant lesions on Sonomammogram

SONOMAMMOGRAPHIC DIAGNOSIS (BIRADS)	NUMBER OF CASES	PERCENTAGE
BENIGN (BIRADS SCORE -2 and 3)	30	60%
MALIGNANT (BIRADS SCORE -4 and 5)	20	40%
TOTAL	50	100%

Table 3: Distribution of lesions on FNAC

LESIONS	NUMBER OF CASES
BENIGN • Fibroadenoma • Fibroadenoma /Intraductal papilloma • Fibroadenomatoid hyperplasia • Fibroadenomatoid hyperplasia with mastitis • Breast abscess • Intraductal papilloma • Acute suppurative mastitis	12 1 12 2 1 1 3
TOTAL	32 (64%)
MALIGNANT • Carcinoma breast • Carcinoma probably medullary type • Carcinoma –Infiltrating ductal /Invasive Papillary Carcinoma • DCIS • Malignant phyllodes • Apocrine carcinoma • Infiltrating ductal • Atypical ductal hyperplasia	7 2 1 4 1 1 1 1
TOTAL	18 (36%)

Table 4: Distribution of lesions on Histopathology (Excision/Mastectomy)

LESIONS	NUMBER OF CASES	PERCENTAGE
BENIGN		
• Fibroadenoma	15	
• Fibroadenomatoid hyperplasia	7	
• Fibroadenoma with cystic change	3	
• Fibroadenomatoid hyperplasia with cystic change	1	
• Fibrocystic disease with mastitis	4	
• Intraductal papilloma	2	
TOTAL	**32**	**64%**
MALIGNANT		
• Infiltrating ductal carcinoma	10	
• Infiltrating lobular carcinoma	3	
• Medullary carcinoma	2	
• Colloid carcinoma	2	
• Malignant phyllodes	1	
TOTAL	**18**	**36%**
TOTAL	**50**	**100%**

Table 5: Comparison of BIRADS score with Histopathology

SONOMAMMOGRAM (BIRADS score)	HISTOPATHOLOGY BENIGN MALIGNANT		TOTAL
BENIGN	28 (TN)	2 (FN)	30
MALIGNANT	4 (FP)	16 (TP)	20
TOTAL	**32**	**18**	**50**

Table 6: Comparison of FNAC with histopathology

FNAC	HISTOPATHOLOGY BENIGN MALIGNANT		TOTAL
BENIGN	32 (TN)	0 (FN)	32
MALIGNANT	0 (FP)	18 (TP)	18
TOTAL	**32**	**18**	**50**

Table 7: Overall accuracy of FNAC and Sonomammography in breast lesions

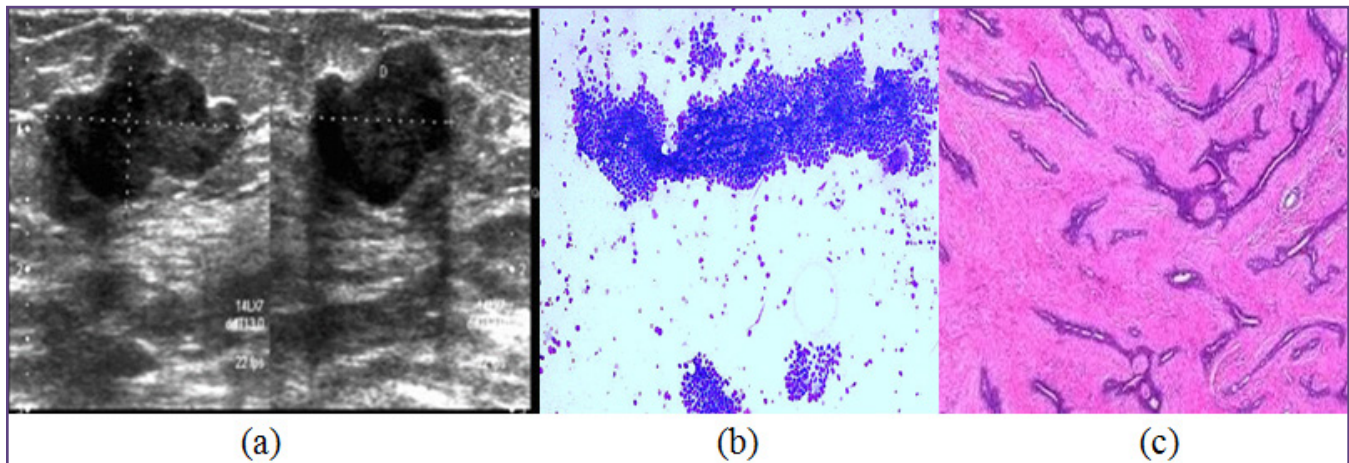|	FNAC	SONOMAMMOGRAM (BIRADS score)
Sensitivity	100%	88%
Specificity	100%	87.5%
Positive predictive value	100%	80%
Negative predictive value	100%	93%
Accuracy	100%	88%

Fig. 1: (a) Breast ultrasound image of a solid lesion-BIRADS Category 3, (b) FNAC of the same case showing cell rich smear of elongated, branching fragments of ductal epithelial cells (H&E,10x) (c) Excision biopsy showing compressed ducts having a linear branching pattern with slit-like lumens- Fibroadenoma(H&E, 10x).
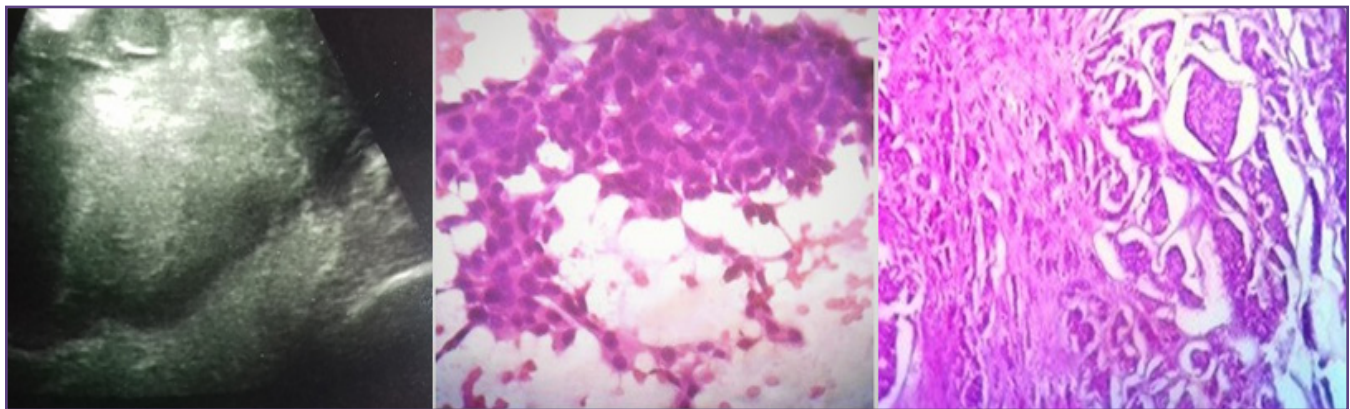

Fig. 2: (a) BIRADS category 5 lesion-well defined horizontally ovoid lobulated predominantly hypoechoic mass. (b) FNAC showing large neoplastic cells having pleomorphic hyperchromatic nuclei (H&E,100x) (c) Histopathology showing neoplastic Invasive Ductal carcinoma in glandular pattern, sheets and clusters (H&E, 100x).

Discussion

Breast diseases are common in females. In developing countries like India, females are unaware of breast pathologies and are hesitant to reveal, hence they are detected usually in advanced stages. Various benign breast lesions like fibroadenomas, breast abscess, galactocele, duct ectasia, enlarged lymph nodes and different malignancies are common pathologies of female breast .[9]

Patients with palpable breast lesions commonly present for radiology evaluation. Mammography is a primary method of detection and diagnosis of breast disease with sensitivity of 85% - 95%. But the false negative findings in mammography in evaluation of palpable breast mass is high, estimated between 4% & 12%.[9] The BIRADS 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. Although mammography is recognized as the best method of screening for breast cancer, breast sonography is now well-established as a valuable imaging technique, and, while there has been some controversy regarding its utility in evaluating solid breast masses for the likelihood of malignancy, several studies have suggested that sonographic appearance can be useful in differentiating malignant from benign solid breast masses.[10]

A wide variation in the sensitivity of sonomammogram in the diagnosis of breast lesions ranging from 67% to 97% have been reported .[11] In a study conducted by Shrestha M K et al the sensitivity and specificity of sonomammography in differentiating benign from malignant lesions using the BIRADS score was 78.9 and 95% respectively .[1] Shumaila S M et al in their study have reported mammography to be positive in 66(90%) and sonomammography to be positive in 68 (93%) out of

73 cases .[12] Ultrasonography can be used to differentiate benign from malignant lesions with negative predictive value of 99.5%, specificity of 67.8% and over all accuracy of 72.9% in a study according to Stavros et al.[13] Emine D et al did a study on 546 breast lesions with histopathology analysis, they reported sensitivity and specificity for sonomammogram to be 72.6 and 88.5% .[14] In the present study we got comparable results with a sensitivity of 88%, specificity 87.5%,positive predictive value of 80%, negative predictive value of 93% and an accuracy of 88% in differentiating benign from malignant masses in sonomammography using the BIRADS lexicon system.

FNAC of breast lumps is an accepted and established method for determining the nature of breast lumps with a high degree of accuracy. Application of Fine Needle Aspiration for the diagnosis of palpable breast masses was first introduced by Martin and Ellis in 1930 and since then, it has been established as an important tool in the evaluation of breast lesions. Most of the patients with breast lumps are in a state of anxiety. So, in reducing anxiety and unnecessary surgical procedures as well as in minimization of delay in the diagnosis, FNAC proves very fruitful. FNA procedure is a safe method with only a few reported complications.[15]

In the present study, 18 and 32 cytologically diagnosed malignant and benign cases were confirmed as malignant and benign respectively on subsequent histopathological examinations. So, in our study, a 100% cyto-histopathological correlation was observed for breast lesions. Zhang Qin et al in their study similarly reported a 97.1 and 97.3% sensitivity and specificity respectively for FNAC in diagnosing breast lesions .[16] Tiwari M has also observed the similar results in their studies with a sensitivity of 83.3% and specificity of 100%.[17] The sensitivity, specificity, accuracy, negative predictive value, and the positive predictive value of FNAC was 98%, 100%, 98%, 100%, and 97%, respectively in the study conducted by Bukhari et al.[18] Our study showed higher values than the range reported with 100% sensitivity, specificity, positive and negative predictive values and accuracy.

FNAC is not only useful in diagnosis and further planning of treatment without need for biopsy, but also helpful in prognostication of the tumor factors such as nuclear grading, mitotic index, hormone receptor status and DNA contents.[19] Histopathological examination should be performed for uncertain diagnostic cases and when the evaluation of the invasiveness or histological type of breast lesion is mandatory.[20] The gold standard test used in our study was the histopathological report which is valid, reproducible and has been accepted as the gold standard

internationally. For a good study, the reference test against which the diagnostic test in evaluation is compared should be gold standard.[11]

Conclusion

Ultrasonography with BIRADS score is an imaging technique and FNAC a tissue diagnostic technique. Both these diagnostic tools should be considered complimentary. The results of our study showed FNAC of breast lumps to be a reliable method to diagnose breast lump with high accuracy compared to sonographic categorization using BIRADS score. Considering patient's comfort, lack of requirement of anesthesia, rapid analysis and reporting and an absence of false positive results, FNAC could be considered an ideal initial diagnostic modality in breast lumps recognized by means of imaging techniques. Further advancement in the technique of both these procedures like FNAC under imaging guidance, addition of immunohistochemistry in cytology and addition of Doppler in USG may increase their accuracy. However all clinically malignant or suspicious masses should be subjected to histopathological examination which is the gold standard for tissue diagnosis.

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