



**SAINT PAUL HOSPITAL MILLENNIUM MEDICAL COLLEGE
DEPARTMENT OF PATHOLOGY**

**CORRELATION BETWEEN BREAST CYTOLOGY REPORT
AND BIRADS CATEGORIZATION AT SAINT PAUL'S
HOSPITAL MILLENNIUM MEDICAL COLLEGE, **ADDIS
ABABA, ETHIOPIA****

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St. Paul Hospital Millennium Medical College

**Correlation between Breast Cytology Report and BIRAD
Categorization at Saint Paul Hospital Millennium Medical College,
From January to November 2022**

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Abbreviations and Acronyms

FNAC	Fine Needle Aspiration Cytology
BIRADS	Breast Imaging Reporting And Data System
SPHMMC	Saint Paul Hospital Millennium Medical College
ACR	American College Of Radiology
FNAB	Fine Needle Aspiration Biopsy
USG	Ultrasonography
PPV	Positive Predictive Value
NPV	Negative Predictive Value
CNB	Core Needle Biopsy

Abstract

Background: Breast cancer is the commonest cancer in women worldwide and in Ethiopia. Worldwide accepted protocol for diagnosis of breast lumps is the “Triple Assessment” – encompassing; clinical examination, mammosonography and pathological diagnosis. Although many studies focusing on the diagnostic accuracy of Fine-needle aspiration and Ultrasonography were conducted globally, the correlation between the BIRADS category and Cytology report in Saint Paul’s Hospital Millennium Medical College was not well studied.

Objective: To compare and correlate the Fine-needle aspiration findings of breast lesions with BI-RADS grading on ultrasound and to point out major pathologic conditions that contribute to their discordances in Saint Paul’s Hospital Millennium Medical College, Addis Ababa, Ethiopia.

Methods: Prospective hospital based observational study was conducted from January to November, 2022. Data were collected from pathology and radiology departments using structured tool. Female of any age who presented at Pathology and Radiology departments for breast Ultrasound guided Fine-needle aspiration during the study period was included. Fine Needle Aspiration Cytology smears were stained by wright and Giemsa stain. FNAC results were correlated with BI-RADS categories.

Result: A total of 116 cases were included and majority of the cases were in the 4th and 5th decades of life 68(58.6%). FNAC reported 82(70.68%) as benign and 21(18.1%) as malignant. BIRADs 4 accounts for 55.2% of cases, BIRADs 5 cases 7(6%) and BIRADs 1, 2 and 3 cases 43(38.9%). Sensitivity, specificity NPV, PPV and Accuracy of BIRADs categorization by ultrasound as compared to FNAC was 53.2%, 97%, 97.7%, 46.4% and 66.07%, respectively. BIRADs 5 showed 100% concordant malignant with FNAC results. BIRADs 4 was 14/62 (22.58%) concordant malignant, 40/62 (64.5%) discordant malignant Proliferative lesion without atypia, fibroadenoma, inflammatory lesions, duct ectasia and fat necrosis were the major cases that resulted in discordant malignant findings on FNAC.

Conclusion: Correlation of FNAC and BIRADs categorization by imaging is essential in preoperative evaluation of breast lumps and decrease unnecessary delay of breast carcinoma cases and surgical innervations. BIRADs categorizations by ultrasound had high (97%) specificity and 97.7% of NPV. Additional diagnostic modalities like CNB should be implemented for categories with high variable sensitivity and discordant reports in BIRADs 4.

Key words: Fine Needle Aspiration Cytology, Breast lesions, Mammosonography, BIRADs

1. INTRODUCTION

1.1. Background

Cancer is an increasingly important public health problem in developing countries (1). Breast cancer is a disease in which cells in the breast grow out of control and the kind of breast cancer depends on which cells in the breast turn into cancer (2). Breast cancer is the most common cancer in women worldwide, with nearly 1.7 million new cases diagnosed in 2012 (second most common cancer overall). This represents about 12% of all new cancer cases and 25% of all cancers in women (3).

A significant increase in breast cancer incidence is also reported in most Sub-Saharan Africa countries suggesting an increasing health problem in the continent too (1). In Ethiopia, Breast cancer is the most common malignant neoplasm among women in Addis Ababa. The Addis Ababa Cancer registry report which was published on 2018 states that breast cancer accounts for 34% of all female cancer cases, followed by cervical cancer at 16% (4). Widespread urbanization, changing patterns of reproductive and environmental risks factors, obesity, decreased physical activity, and increasing life expectancy [3, 4] are among the salient factors implicated in the steady rise in breast cancer incidence across low income countries, including Ethiopia (5).

The clinical presentation of breast lesions encompasses a wide range of symptoms, the most common being palpable lumps (6), and various diagnostic methods have been developed to evaluate palpable and non- palpable breast lesions. The worldwide accepted protocol for diagnosis of breast lumps is the “Triple Assessment” which encompasses the triad of clinical examination, mammosonography and pathological diagnosis (7).

The Breast Imaging and Data system (BI-RADS) developed by the American College of Radiology (ACR) has standardized the assessment and reporting of breast lesions. Breast Imaging Reporting and Data System (BI-RADS) is a widely accepted risk assessment procedure for carcinoma breast in clinical practice. BI-RADS is designed to reduce confusion in breast imaging interpretation and to achieve verbal uniformity so as to get clear, unambiguous and standard language, not only among radiologist but also among treating physicians and surgeons (8). The fifth ACR-BIRAD classify the categories as follow (9).

Table -1. Category in Diagnostic Mammography Examinations

Category 0	Incomplete – Need Additional Imaging Evaluation
Category 1	Negative
Category 2	Benign
Category 3	Probably Benign
Category 4	Suspicious
Category 4A	Low suspicion for malignancy
Category 4B	Moderate suspicion for malignancy
Category 4C	High suspicion for malignancy
Category 5	Highly Suggestive of Malignancy
Category 6	Known Biopsy-Proven Malignancy

The BI-RADS categories described the overall structure of the breast imaging report, which included a summary of breast density, a description of significant findings (using appropriate descriptors as well as size and location), and a final assessment and management section. Fine needle aspiration biopsy (FNAB) of breast lesions has been considered to be the primary investigation in detecting breast cancers, especially in low-cost settings, with good sensitivity, specificity and accuracy in the diagnosis of both neoplastic and non-neoplastic breast lumps thereby assisting in early diagnosis and further management (10).

FNA has been used as the first diagnostic step in the investigation of palpable breast lumps in my hospital. Its distinct advantages include accurate diagnosis, low cost, excellent patient acceptance, and minimal or no morbidity (11). Overall, breast FNA is enormously successful, with an overall diagnostic sensitivity ranging from 80% to 100%, with specificity over 99%. FNA alone, however, is subject to inaccuracies and does not definitively diagnose all breast cancers (11). Hence, it is most commonly used in combination with physical examination and mammography to increase accuracy of breast masses evaluation. Therefore, understanding the correlation between FNA and imaging findings could help early diagnosis and treatment for this population.

1.2. Statement of the problem

St. Paul's Hospital millennium medical college (SPHMMC) is one of the biggest Hospitals in Ethiopia which serves patients from different parts of the country and one of the health facilities providing tertiary care for cancer patients. SPHMMC, pathology department performs large number of breast cytology samples from different hospitals in the capital, Addis Ababa, and outside the capital.

Early screening and diagnosis of breast lesions and categorization into different groups of breast pathology can be helpful in accurate management of the breast lesions. Various diagnostic methods have been developed to evaluate palpable and non- palpable breast lesions with the goal of identifying a sensitive, specific, efficient, and economical approach to diagnose and stage breast cancer, so that the most appropriate treatment modality for each case can be established. Physical examination, mammography, ultrasonography, core needle biopsy, open excisional biopsy, and Fine-Needle Aspiration (FNA) are all used to a greater or lesser extent in the diagnostic workup of a palpable breast mass (12). Various combinations of these approaches have been studied and have been found to increase sensitivity and specificity over that of any one test alone (13).

Still combination of clinical examination, mammosonography and pathological diagnosis remains to be the agreed standard of diagnosis. This triple assessment helps to reach on more reliable diagnosis and both cytologic reports and imaging report standardized by BIRADS categorizations play a major role.

Correlation between BI-RADS categories and cytological findings are useful approach to establish an important and accurate preoperative diagnosis as well as for planning therapeutic protocol in carcinoma of breast(14). However, correlation of findings has been questioned because of the variability in results reported and a lot of discordances in the BIRADS categorization and cytologic reports were noted in my hospital. Nevertheless it continues to be used and this problem is not well studied. Discordance of findings leads to delayed diagnosis and increase number of deaths due to breast cancer. **To the best of my knowledge, there is no study conducted to compare cytologic findings with imaging reports.** The present study is intended to contribute to bridging the information gap, and subsequently serve as an evidence to improve local breast cancer diagnosis and standard of care.

1.3. Significance of the study

Early detection and treatment is a key to preventing breast cancer from spreading, which necessitate an accurate evaluation. Identifying the concordance/ discordance in various breast lesions between FNAC findings and BI- RADS category will allow clinicians to recognize the cytology cases which need further follow-up and investigation, like open biopsy. This will also help to avoid unnecessary surgical procedures. I believe that the findings of this study will provide additional clinical guidance to improve early detection and control of breast cancer in Ethiopia as well as other similar set-up countries.

2. LITERATURE REVIEW

Breast cancer is increasingly common in women worldwide. It is one of the leading causes of death among female malignancies and one-fourth of women suffer from breast disease in their life time(15,16). Breast lump is one of the commonest complaints with which patients present in breast clinics and approximately 10% of breast masses ultimately lead to a diagnosis of breast cancer. This shows it is important for women with a breast lump to receive appropriate evaluation (17). Accurate evaluation, early detection and treatment is a key to preventing breast cancer from spreading (8).

Evaluation of breast lumps begins with a detailed history, clinical examination of breasts, various imaging modalities and tissue diagnosis. Only clinical breast examination alone is unreliable and insufficient to differentiate between benign and malignant lesions and hence, imaging is used for evaluation to better delineate the lesions. Also younger women tend to have denser breast parenchyma and this increased density compromises the mammography and so for younger females USG becomes the imaging choice.

All detected breast lesions are not malignant and all the benign masses do not progress to cancer; nevertheless the precision of the final diagnosis can be greatly increased by imaging (mammography, ultrasonography) and pathological diagnosis (18). Ultrasound is a very useful adjunct in the FNAB procedure and is essential if the lesion is impalpable. It can confirm that the needle has actually sampled the target lesion.

However, when ultrasound is used it can be more difficult for inexperienced operators to immobilize the lesion adequately, and there is a potential for the dwell time of the needle in the lesion to be increased resulting in increased blood contamination of the sample and clotting of the material in the needle [14]. Imaging-Pathology correlation is also of critical importance in Imaging- guided breast biopsies to detect possible sampling errors and avoid diagnostic delay. It was shown that a core biopsy is superior to FNAC in terms of sensitivity and specificity. However quick, cheap and basic diagnosis by FNAC cannot be undermined. FNAC is an established diagnostic procedure for breast lesions, in experimental hands can achieve a very high sensitivity, specificity and low false positive or false negative results.

A study conducted in India by Ravi, A total of 55 cases with breast lump confirmed on USG were included in the study where majority of the cases 45 (81.7 %) were in the fourth and fifth decades and 45 (81.7 %) were reported as benign. Most of the benign lesions were noted in the 20 - 50 years age group while all malignant lesions were observed between 41 to 70 years and 35 cases (63.6 %) were located in the upper outer quadrant. In this study based on ultrasonography grade of lesion (BI-RADS) 45 (81.8 %) lumps were reported as benign and 07 (12.7 %) as malignant and 3 (5.4 %) were reported as suspicious for malignancy. In the study, FNAC reported 45 breast lumps as benign and 8 as malignant and 2 cases as Usual Ductal Hyperplasia (UDH) (25).

The sensitivity, specificity, PPV (Positive Predictive Value) and NPV (Negative Predictive Value) of ultrasonography and FNAC in diagnosing breast lesions were 87.5 %, 93.6 %, 70 %, and 97.7 % respectively. BIRADS IV category has a wide range of probability for malignancy ranging from 2 % to 95 % and has a high rate of unnecessary biopsies. They concluded that Ultrasonography is complementary to FNAC and when both modalities are used together they can diagnose majority of the lesions. This can reduce the radiation exposure and the more invasive and expensive breast biopsy procedure (13).

Another study conducted in India by Chaitanya and Prabhala, they observed the positive predictive value for BIRADS 4 lesions for malignancy to be 49 %. They concluded that core biopsy for BIRADS IV lesions is a better method to diagnose malignancy in breast lesions and has high accuracy compared to ultrasound categorization using BIRADS score alone.

Out of the 540 patients who have taken up both FNAC and Radio-imaging, 340 (62.9%) patients reported to be having BI-RADS II and III lesions which revealed 98.9% benign morphology on FNAC. The majority of these benign cases included Fibro adenoma followed by fibrocystic disease. The remaining 200 cases out of 540 cases for which ultrasonography and mammography were done, reported to be BI-RADS IV and V category (26).

In a total number of 120 patients with BI-RADS IV, 75 cases are of benign pathology, 30 are malignant on FNAC. Concordant malignancy found to be 25 % (n=30), discordant benign lesions are 62.5% (n=75) and borderline cases with high risk of malignancy are 12.5%. In a total number of 80 cases with BI-RADS 5, majority i.e., 66 Cases found to be malignant and 4 cases are of benign pathology. A high percentage of cases 82.5% (n=66) have shown concordant malignancy whereas discordant benign cases found to be only 5% (n=4) and remaining 12.5% (n=10) of cases are borderline cases (20).

Their study revealed combination of these two modalities are synergistic resulting in greater specificity and sensitivity in diagnosing breast lesions especially high risk categories of grade 4 and 5 and suggest that a careful imaging and pathological correlation is a useful approach to establish an important and accurate preoperative diagnosis, as well as for planning therapeutic protocol in carcinoma breast cases (20).

In Iraq, Baghdad University, A study conducted by Mustafa, 85.4% (n=158) of patients BI-RADS 4 lesion whilst 14.6% (n=27) had BI-RADS 5 lesion. FNAC results revealed 68.35% (n=108) of BI-RADS 4 patients had benign pathologies, 18.99% (n=30) had malignancy and just 12.66% (n=20) showing borderline or high risk lesions. The majority (85.18%) of women with BI-RADS 5 displayed malignant lesion and benign lesions were 7.41%. 37.9% of patients with BI-RADS 4 finding on ultrasound and benign results on FNAC analysis had no specified pathology (foamy or proteinaceous material) and 13.2% had inflammatory tissue; fibroadenoma (5.6%), fibrocystic changes (4.6%), galactocoele (3.1%), fibroadenosis (2.5%), chronic abscess (1.2%), duct ectasia (1.2%), and intra-ductal papilloma and atypical lipoma (0.6%) (26).

In a study conducted by Mohson et al, Iraq, Baghdad University, total of 50 cases with BIRADS 4 category studied and correlated with FNAC findings. Breast carcinoma (11 cases, 22%) and moderate to severe atypia (20 cases, 40%) totally represented 62% of all BIRADS IV detected lesions seen by ultrasound in this study. With a positive predictive value of ultrasound to detect suspicious BIRADS IV lesions was 75%. This low value was based on inflammatory, fibrocystic changes and mild atypia as false positive results assuming that FNAC could play as a gold standard for diagnosing specific breast lesions. In their study there was high concordance between the ultrasound diagnosis of BIRADS category and the results of FNA and they concluded by stating the collaborative roles of thorough history, proper clinical examination and

competent cytology remain of utmost importance in yielding a high productive and precise diagnosis (21). In contrary to the study conducted by Anipta there was significant difference between FNAC and breast ultrasound in detecting breast lesions, p-value >0.05. Among the lesion that results in false positive by u/s were cellular fibroadenoma and radial scar with proliferative disease. They concluded that breast FNAC is more reliable method to diagnose breast lesions with high diagnostic accuracy compared to breast ultrasound (22).

In a study conducted by Takhellambam , When they compare FNAC and USG in the diagnosis of malignancy in breast mass, both was found to have 100% specificity and 100% positive predictive value suggesting either test can be considered confirmatory and further treatment decision can be made solely on this report without any further additional diagnostic investigation. Sensitivity of USG was found higher than that of FNAC with sensitivity result of FNAC to be 90.48% and a sensitivity of USG 94.74%. These values give an impression that USG is a better tool than FNAC in ruling out the probability of malignancy in breast mass. However, the percentage of indeterminate result was much higher in USG than in FNAC. This study conclude that both diagnostic tools should be considered complementary and the physician should use the basis of his clinical findings and experience in choosing either one of or both the tools (23).

In a study conducted by Anipta, a total number of 92 patients underwent both Mammography with BI-RADS grading and FNAC procedure in diagnosis of breast lumps in the department of Pathology. There were 51 (55.43%) lesions reported to be benign and 35 (38%) were found to be malignant. In this study concordant benign were observed in 47 (51%) cases whereas concordant malignant were observed in 31 (33.6%) cases. Discordant benign to be 4.34% and discordant malignant accounting 10.86%. The sensitivity, specificity, positive predictive value, and negative predictive value was 88.57%, 82.46%, 75.61%,92.16% , respectively for BIRADS score and 100% for all the parameters on FNAC (24).

This study concluded that FNAC could be considered an ideal initial diagnostic modality in breast lumps recognized by means of imaging techniques. In experienced hands it is not only give as safe, cost effective, rapid and presumptive diagnostic method but also limits unnecessary testing and procedures (24).

In the study by Krithika et al 16 the ultrasound features which were more predictive for a benign lesion were oval shape, less than 3 smooth macro lobulations, circumscribed margins, presence of pseudo capsule and presence of edge refraction. 100 % of the lesions with round shape were benign but round shape was reported only in 5 % of cases only. The features predicting malignancy were presence of irregular shape and non-circumscription (speculated, angular, indistinct, micro lobulated) margins.

3. OBJECTIVE

3.1. General objective

- To compare and correlate the FNAC findings of breast lesions with BI-RADS grading on ultrasound

3.2. Specific objectives

- To identify the common breast lesions that contribute for major discrepancies
- To assess the PPV/NPV of BIRAD category in relation to FNAC of breast
- To assess the major ultrasound findings that result in discordance of benign and malignant lesions on FNAC results

4. METHODOLOGY

4.1. Study Area

Geographically, Addis Ababa is located between 9°1'48"N and 38°44'24"E. The city is located at the center of Ethiopia with an area of 540 km² of which 18.174 m² is rural and its altitude ranges from 2000m – 2800m. According to the most recent Census (2007), the size of the population is 3,147,000, of which 1,511,000 is men and, 636,000 is women with eight percent annual growth rate and density of 5936.2/km². The household size varies from 7.6, 6, 5 persons per household in lower, middle, and higher income families respectively. The health service delivering institutions in the city comprise 41 hospitals, 169 higher clinics, 146 private medium clinics, and 31 health centers. St Paul's Hospital millennium medical college is one of the referral hospitals in Addis Ababa town under the administration of Federal ministry of health.

4.2. Study period

This study was conducted from January 2022 to November 2022.

4.3. Study design

Prospective hospital based observational study design was employed.

4.4. Source population

All patients who had presented to SPHMMC for breast evaluation during the study period

4.5. Study population

All patients who undergone FNAC and Ultrasonography workup of breast lesions during the study period

4.6. Sample size and sampling technique

All cases during the study period were included. During, the procedure patients were in supine position. Local part examination was carried out. The overlying skin disinfection was done with spirit swabs. The current technique of FNA uses a 23- to 25-gauge needle, 1–1.5 inches long on a 10- to 20- mL syringe with or without a syringe holder. Obtained material was smeared on slides and air dried for Romanowsky-type stains. Suggested cut points for adequacy have included: a single fragment of epithelial cells; at least 6 epithelial tissue fragments of 5 or more cells; at least 10 bipolar cells in each of 10 medium power (×200) fields; a minimum of 7 tissue fragments each consisting of more than 20 cells; or any number of appropriately smeared and fixed epithelial cells (7). The contraindications to breast FNA are almost nonexistent. The complication rate is generally quite low and the complications themselves minor.

4.7. Selection Criteria

Inclusion criteria

- ✓ Patients in all age groups willing to participate in the study.
- ✓ Patients with breast lumps confirmed by USG.

Exclusion criteria

- ✓ Patients not willing to participate in the study.
- ✓ Patients who had prior breast carcinoma diagnosis and present with recurrence.
- ✓ Patients who came for axillary lymph node evaluation with prior diagnosis of breast carcinoma.
- ✓ Male patients with breast lumps.

4.8. Data collection procedure

Data were collected from pathology and radiology departments using structured, self-prepared and anonymous questionnaire designed to include the following variables.

Table -2. Data extraction tool

Case no.	Age	Clinical presentation	Duration	Breast quadrant	U/S findings	BIRAD category	FNAC result
1.							
2.							

4.9. Study variables

For the purpose of this study:

Independent variables: Age, clinical presentation, duration, breast quadrant, number of cases

Dependent variable: U/S findings, BIRADs category and FNAC results.

4.10. Quality assurance

To keep the reliability of the data, the principal investigator with the data collectors collected the data and filled them in the self-prepared questionnaire.

4.11. Data management and analysis

Using data extraction tool, data collection form was created on Microsoft Excel 2010 according to their code. The coded data then entered to statistical package for social science (SPSS) version 21.0 for analysis. Categorical variables were presented in frequencies and percentages, whereas numerical variables were expressed in means and standard deviations. Sensitivity, specificity, positive and negative predictive values and accuracy of BIRADs category were calculated compared to FNAC results.

4.12. Ethical Considerations

Ethical clearance was obtained from the Ethical review committees of research & publication of the Department of public health, SPHMMC after approval by the research advisor. Confidentiality was kept by avoiding recording of names of clients on data collection format. Permission to collect data was obtained from the department of pathology and radiology, SPHMMC.

4.13. Data Dissemination

At the end of the research analysis, the information will be disseminated by hard copy and in some cases as softcopy to SPHMMC, pathology department. I will also try my best to publish the paper in peer reviewed journals.

4.14. Operational Definitions

- ✓ Concordant Benign - When U/S finding is benign and FNAC reports Benign result
- ✓ Discordant Benign – When U/S finding is benign and FNAC reports malignant result
- ✓ Concordant Malignant – When both U/S and FNAC results report Malignant
- ✓ Discordant Malignant – When U/S reports malignant and FNAC report is Benign

5. Results

A total of 116 cases were included in this study and majority of the cases were in the fourth and fifth decades of life, 68 cases (58.6%). The minimum age being 20 and maximum of 66 years.

Table -3. Distribution of cases based on age

Age groups	Frequency	Percent (%)
20-30	35	30.2
31-40	41	35.3
41-50	27	23.3
>51 years	13	11.2

In the present study most of the cases 55 (64.7 %) were located in the upper outer quadrant followed by central quadrant 21 (21.7 %).

Table - 4. Frequency of cases based on Breast quadrant

Breast quadrant	Frequency	Percent (%)
Upper outer quadrant	55	47.4
Central quadrant	21	18.1
Retro areolar	7	6.0
Lower outer quadrant	1	0.9
Diffuse	1	0.9

Patients usually presented within 1 to 6 month duration of clinical presentation 43 (37.1%). BIRADs 4 category cases accounted for 64 (55.2%) while BIRADs 5 cases were 7 (6%). BIRADs 1, 2 and 3 cases were 45 (38.8%).

Table - 5. Frequency of cases based on BIRADs categorization

BIRADs category	Frequency	Percent (%)
BIRADs 1	1	0.9
BIRADs 2	4	3.4
BIRADs 3	40	34.5
BIRADs 4	27	23.3
BIRADs 4a	22	19
BIRADs 4b	5	4.3
BIRADs 4c	10	8.6
BIRADs 5	7	6

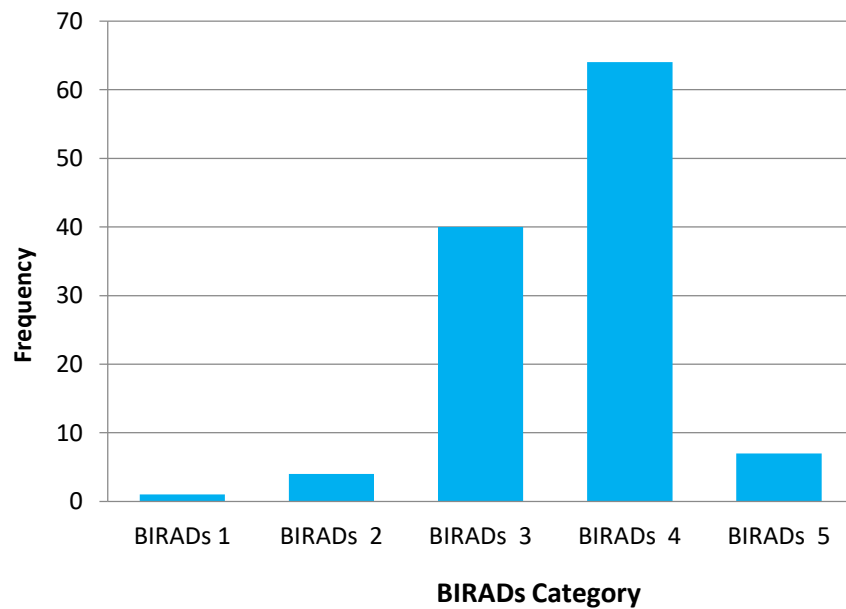


Fig - 3. Frequency of cases based on BIRADs categorization

The commonest clinical presentation was breast lump 79.3% and 9.5% of the participant had breast lump with pain and ulceration. Pain alone and nipple discharge constituted 8.6% and 2.6%, respectively.

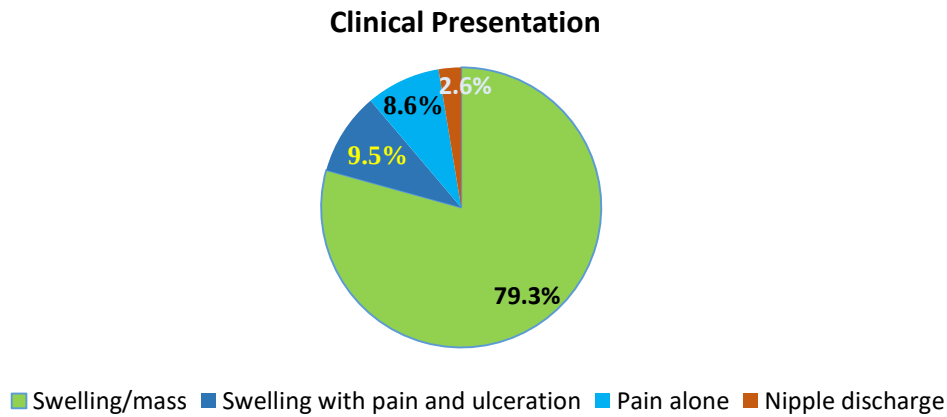


Fig - 4. Frequency of clinical presentation

In the present study, FNAC reported 82 cases (70.68%) as Benign, 9 cases (7.7%) as suspicious for malignancy and 21 cases (18.1%) as Malignant. There were 4 (3.4%) cases reported as non-diagnostic. From the Benign category, Fibrocystic changes/ Benign cystic lesion accounts for 22 (19%), Fibroadenoma and Proliferative lesion without atypia accounts 14.7% and 10.3% respectively. There were 8 (6.9%) inflammatory cases like Acute on chronic mastitis, Granulomatous mastitis and Breast abscess. All the malignant cases were signed out as Ductal carcinoma, NST.

Table - 6. FNAC findings

	Total Number	FNAC findings	Number of cases	Percent (%)
Non-diagnostic	4 (3.4%)	Inconclusive and Non diagnostic	4	3.4
Benign	82 (70.68%)	FCC/Benign cystic lesion	22	19
		Fibroadenoma	17	14.7
		Proliferative lesion without atypia	12	10.3
		Inflammatory	8	6.9
		Duct ectasia	9	7.8
		Galactoceles	2	1.7
		Lipoma	2	1.7
		Fat Necrosis	6	5.2
		Lactating Adenoma	2	1.7
Suspicious	9 (7.7%)	Suspicious for Malignancy	9	7.7
Malignant	21 (18.1%)	Ductal carcinoma, NST	21	18.1

In the present study most of the benign lesions 62 (78.4%) were found in age groups between 20 and 40. The malignant lesions 23 (69.7%) were found between 41 and above 51 years of age.

Table -7. Distribution of cases among age groups

FNAC results		Age groups			
		20 - 30	31- 40	41-50	≥ 51
	Benign	31, (39.2%)	31, (39.2%)	13, (16.5%)	4, (5.2%)
	Malignant	4, (12.1%)	6, (18.2%)	14, (42.2%)	9, (27.3%)

In the study sensitivity, specificity, PPV and NPV of BIRADs category in relation to FNAC result was 53.2%, 97.0%, 97.7% and 46.4%. The accuracy of BIRADs in detecting breast lesions was 66.07%.

The benign categories of BIRADs i.e. 1 and 2 show 5 cases (100%) benign concordant with FNAC results, BIRADs 3 category shows 37/38 (97.4%) concordant benign results and only one case was discordant benign which was signed out on FNAC as Atypical proliferative lesion. All the BIRADs 5 cases, i.e. 7/7 (100%) shows concordant malignant with FNAC results. The majority of the discrepancies occur on category 4 lesions in which only 14/62 (22.58%) of cases show concordant malignant and the rest i.e. 40/62 (64.5%) of cases became discordant malignant. 8/62 (12.9%) of cases were suspicious for malignancy on FNAC report. Majority of the discordant malignant cases of BIRADs 4 category was diagnosed on FNAC as proliferative lesion without atypia 10 (15.62%), Fibroadenoma 7 (10.93%), inflammatory lesion including granulomatous mastitis 6 (9.3%). Duct ectasia and fat necrosis accounts for 4 (6.25%), each.

Table - 8. Sensitivity, Specificity, PPV and NPV of BIRADs categorization and FNAC

BIRADs categorization	FNAC result			Total
		Benign	Malignant	
	Benign	(TP) 42, 53.2%	(TN) 1, 3%	43, 38.4%
	Malignant	(FP) 37, 46.8%	(FN) 32, 97%	69, 61.6%
		79, 70.5%	33, 29.5%	112, 100%

Keys; TP – True Positive, TN – True Negative, FP – False Positive, FN – False Negative

Table- 9. Concordant and discordant cases

BIRADs category	FNAC result		Border line (suspicious)	Total
	Benign	Malignant		
BIRADs 1	1 (100%)	0		1
BIRADs 2	4 (100%)	0		4
BIRADs 3	37 (97.4%)	1 (2.6%)		38
BIRADs 4	40 (64.5%)	14 (22.58%)	8 (12.9%)	62
BIRADs 5	0	7 (100%)		7

BIRADs 1 and 2 categories have a sensitivity and PPV of 100%, while BIRADs 3 has a sensitivity of 97.4%. BIRADs 5 category has 100% specificity and NPV. In this study 69 cases had their ultrasound findings and the commonest ultrasound finding was well circumscribed lesion 26/69 (37.7%) followed by irregular and speculated lesion and intra ductal lesion 31.9% and 11.6%, respectively.

Table -10. Ultrasound findings, others include hypo echoic lesion and calcifications

Ultrasound findings	Frequency	Percent %
Well circumscribed lesion	26	37.7
Irregular/speculated lesion	22	31.9
Complex solid and cystic lesion	5	7.2
Intra ductal lesion	8	11.6
Others	8	11.6

Well circumscription was found to be a good predictor of benign lesion 24/26 (92.3%) and irregular or speculated margin has 15/21 (71.4%) detection of malignant lesions when compared to FNAC results.

6. DISCUSSION

The sample size in the present study was 116 cases of USG confirmed breast lumps. Other authors like Ravi et al (25) and Takhellambam et al (23) had a sample size of 55 cases and 62 cases respectively. A close number of cases, 100 were seen on a study by poojaba et al. (7).

Comparative Studies Based On Age Distribution

In my study, majority of the cases were among the fourth and fifth decades accounting for 68 cases (58.6%) while the minimum and maximum age being 20 and 66. A study by poojaba et al reported the youngest patient was 15 years of age and the oldest was 76 years of age and maximum number of cases were seen in the fourth and fifth decades of life (7). A study by Ravi et al in India reported their majority cases were also in the fourth and fifth decades 45 (81.7 %) (25).

Comparative Study Based On Clinical Presentation and Site of Lesion

The commonest location of breast lesions in my study is Upper outer quadrant 55 (64.7%) followed by central quadrant 21 (21.7%) which is similar to findings with poojaba et al and Ravi et al which is 69% and 63.3% in upper outer quadrant respectively. In my study 88.8 % of patients present with breast lump alone or in association with pain and ulceration while 8.6% of patients present with pain alone and 2.6% with nipple discharge. A similar finding was reported by poojaba et al, 92% of patients presented with breast lump followed by nipple retraction and nipple discharge (7).

Comparative Study Based On BIRADs Categorization and FNAC Results

In the present study, FNAC reported 82 cases (70.68%) as Benign, 9 cases (7.7%) as suspicious for malignancy and 21 cases (18.1%) as Malignant. There were 4 (3.4%) cases which were reported as Non diagnostic. Similarly Arpita et al reported 51 (55.43%) lesions reported to be benign and 35 (38%) were found to be malignant. Among benign diseases, fibroadenoma was the most common 34 (66.6%) whereas in malignant cases invasive duct carcinoma was the maximum numbers 33 (94.28%) (24). The benign cases were more common than the malignant cases and the most common benign lesion in my study was Fibrocystic change (19%), Fibroadenoma and Proliferative lesion without atypia, 14.7% and 10.3%, respectively. Most of the later cases were signed out with a differential diagnosis of Fibroadenoma thus increasing its frequency. This finding is in concordance with Poojaba et al, they stated similar findings (7).

Majority of cases in this study were found to be BIRADs 4 (55.2%) followed by the benign categories i.e. BIRADs 1, 2 and 3 (38.8%). Malignant or BIRADs 5 cases accounts 6%. In the present study most of the benign lesions 62 (78.4%) were found in age groups between 20 and 40. The malignant lesions 23 (69.7%) were found between 41 and above 51 years of age. A study conducted in India by Ravi et al showed the malignant lesions were observed between 50 - 60 years of age; while most of the benign lesions were noted in the 20 - 50 years age group (23). Takhellambam et al also reported 58 % (36 cases) were observed to be benign and 29 % (18 cases) were malignant. Indeterminate cases were 9.6 % (6 cases) (25).

Correlations of BIRADs category and FNAC results

In this study all (100%) BIRADs 1 and 2 cases turnout to be concordant benign on FNAC results and 97.4% of BIRADs 3 cases were concordant benign. Arpita et al stated, patients reported to be having BIRADS I, II and III lesions revealed 47 (92.15%) benign morphology on FNAC (24). 100 % (7/7) BIRADs 5 cases in my study become concordant malignant. This is a higher number when compared to Mustafa et al (26). Findings which were done in Iraq, 85.18% and it's in concordant with supposed malignancy rate in ACR BI-RADS lexicon, which is more than 95% (9). BI-RADS malignancy rates per category especially in category 4 associated with a highly variable rate of cancers but in general, BI-RADS 4 lesions malignancy rates range from 2-95 %. (9). In this study the highest discordance was observed in BIRADs 4 cases in which 22.58% of cases were concordant malignant and 64.5% of cases were discordant malignant, 12.9% of cases were suspicious for malignancy on FNAC reports. My findings of true positivity of BIRADs 4 cases are almost similar to Mustafa et al which was 18.9% and 25 % as compared to K. Bhramaramba et al (20).

Majority of the discordant malignant cases of BIRADs 4 category was diagnosed on FNAC as proliferative lesion without atypia 10 (15.62%), Fibroadenoma 7 (10.93%), inflammatory lesion including granulomatous mastitis 6 (9.3%). Duct ectasia and fat necrosis accounts for 4 (6.25%) each. According to Mohsen et al attention should be directed to the fact that most inflammatory masses are the cause of poorly demarcated lesions, thus reported as suspicious by ultrasound (21).

Table -11. Comparision with other studies

BIRADs category	FNAC result	Current study	Mustafa et al	K. Bhramaramba et al
BIRADs 4	Benign	64.5%	68.35%	62.5%
	Malignant	22.58%	18.9%	25%
	Borderline	12.9%	11.89%	12.5%
BIRADs 5	Benign	0	7.41%	5%
	Malignant	100%	85.18%	82.5%
	Borderline	0	10.11%	12.5%

In the present study sensitivity, specificity, PPV and NPV of BIRADs category in relation to FNAC result was 53.2%, 97.0%, 97.7% and 46.4%. The accuracy of BIRADs in detecting breast lesions was 66.07%, which is comparable with a study conducted in Uganda by M. Gonzaga, The sensitivity and specificity of ultrasound for detecting breast carcinoma was 57.1% and 62.8% respectively with a positive predictive value of 68.1%, a negative predictive value of 99.5%.(27) But it's lower than a report by Ravi et al. Sensitivity, specificity, PPV and NPV ultrasound and FNAC in diagnosing breast lesions were 87.5, 93.6 %, 70 %, and 97.7 % (25).

Comparative Study Based On Ultrasound Findings

In this study well circumscription was found to be a good predictor of benign lesion 24/26 (92.3%) and irregular or speculated margin has 15/21 (71.4%) detection of malignant lesions when compared to FNAC results similarly in the study by Krithika et al (19) the ultrasound features which were more predictive for a benign lesion were oval shape, less than 3 smooth macro lobulations, circumscribed margins, presence of pseudo capsule and presence of edge refraction. All of the lesions with round shape were benign. The features predicting malignancy were presence of irregular shape and non-circumscription (speculated, angular, indistinct, micro lobulated) margins.

7. LIMITATIONS OF THE STUDY

- ✓ One of the limitations of this study was inability of including the histopathologic diagnosis of cases so that we can compare my results with the gold standard.
- ✓ Inconsistent schedule and shortage of working staff of breast unit in radiology department contributed a lot for the low number of cases from the expected during the study period
- ✓ Lack of previous similar studies in the country.

8. CONCLUSION

Based on my findings I conclude that correlation of FNAC and BIRADs categorization by imaging is essential in preoperative evaluation of breast lumps and decrease unnecessary delay of breast carcinoma cases and surgical innervations. BIRADs categorization by ultrasound has high (97%) specificity and 97.7% of NPV. Additional diagnostic modalities like CNB should be implemented for categories with high variable sensitivity and discordant reports in BIRADs 4. Attention should be directed to the fact that most inflammatory masses are the cause of poorly demarcated lesions and thus reported as suspicious by ultrasound.

9. RECOMMENDATIONS

- ✓ I believe my study will be used as a foundation and I recommend the department of Pathology and radiology to conduct a large scale study including the histopathologic findings of cases
- ✓ As the sensitivity of BIRADs 4 category is highly variable we recommend the clinicians to correlate clinical breast examinations, FNAC results and U/S findings. Additional diagnostic modalities like CNB should be used in highly suspicious cases and discordant reports.

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