

A Study of Fine Needle Aspiration Cytology of Breast Lesions in Females with Special Reference to IAC Standardized Reporting at a Tertiary Care Centre

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Abstract

Background: Carcinoma of the breast is one of commonest carcinomas found in Indian women and also around the world. Fine Needle Aspiration Cytology (FNAC), a quick, cost effective and patient compliant procedure, can give an adequate diagnosis to rule out at best the difference between a benign and malignant breast lump. The International Academy of Cytology (IAC) has developed a process for Fine-Needle Aspiration Cytology (FNAC) reporting that is thorough and standardized. C1 to C5 are the categories for breast lesions. **Methods:** A total of 166 breast FNACs were performed over a period of 2.5 years after fulfilling the inclusion and exclusion criteria and the aspirates were stained by Hematoxylin and Eosin stains and the stained slides were studied and diagnosis was made accordingly. The patients were classified using the IAC classification system that relies on their cytomorphological characteristics. **Results:** Out of 166 cases, 136 were neoplastic, 6 non-neoplastic and 24 cases were inadequate to opine. Of the 136 neoplastic cases, 89 cases (53.61%) were diagnosed as fibroadenoma and 19 cases (11.44%) were diagnosed as duct carcinoma. **Conclusion:** The fine needle aspiration cytology is a critical diagnostic tool in the management of patients with breast lump. It is an easy, reliable, patient friendly, repeatable and simple diagnostic test. FNAC can have a very high diagnostic accuracy when performed by experts.

Keywords: Breast Lesion, Duct Carcinoma, Fibroadenoma, IAC Classification, FNAC

1. Introduction

The lesions of the breast constitute a significant proportion of cases in both developed and developing countries. According to ICMR data, 1.5 lakh new cases (10 percent of all malignancies) were reported in 2016, making it the most common malignancy.¹ There is an urgent need to evaluate benign lesions from malignant lesions before definitive treatment can be started. Due to patient awareness, education and screening programs there has been rise in a number of tumors diagnosed. The breast lesions present as palpable lump, inflammatory lesion, nipple secretion or imaging abnormalities.²

A state of heightened anxiety exists in most of these patients until they have been assessed by a specialist doctor, and the necessary investigations are done and an

eventual reassurance is given. A new minimally invasive technique of diagnosis known as Fine-Needle Aspiration Cytology (FNAC)³ has been popularized by the help of the pioneering work by Torsten Lowhagen and his colleagues, at the Karolinska institute in Stockholm in the 60s and 70s.

The technique is minimally invasive, can produce speedy results, has fewer complications and is also inexpensive. In many situations, when applied by experienced and well trained practitioners, the accuracy of FNAC can approach that of histopathology in providing an unequivocal diagnosis. FNAC should be regarded as an essential component of preoperative investigation of pathological processes, especially in combination with clinical, radiological and other laboratory data.⁴

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FNAC has an average sensitivity of approximately 87%, specificity close to 100%, and the predictive value of a negative diagnosis between 60% to 90%.⁵

Cytology can now be used to identify the subtypes of benign and malignant breast lesions. It can also be used in the detection of minimal residual disease for planning a therapeutic protocol and eventual follow-up.

Thus, it has a major role as an important preoperative assessment procedure, along with clinical correlation and radiological imaging which are often referred to as the “Triple test.”⁶

Fine needle aspiration cytology of the breast lesions can be a substitute to excision biopsy in majority of instances and can differentiate and delineate the nature of the disease in most of the instances.

The use of fine-needle aspiration cytology (FNAC) for preoperative diagnosis of breast cancer is becoming more frequent. A conference on a uniform approach to breast cancer was sponsored by Bethesda. Tumor grading on FNAC material should be included in FNA reports for prognostication.⁷

IAC has developed a thorough and systematic method for classifying FNAC of breast tumors into C1-C5 categories.⁸ Structured reporting can increase the quality, clarity, and reproducibility of reports across departments, cities, and countries, which will help with patient management, breast healthcare, and research.⁸⁻¹⁰ A commonly accepted tumour grading system is the modified Scarff–Bloom–Richardson (SBR) grading system for histological grading of breast cancer. As a result, grading of breast cancer should be included in FNAC reports for prognostication in the era of neo-adjuvant treatment.¹¹

2. Aims and Objectives

1. To study fine needle aspiration cytology in the lesions of the breast in females in age group of 15–65 years.
2. To categorise the breast lesions into non-neoplastic and neoplastic.
3. To categorize the lesions into the IAC system based on their cytomorphological features.

3. Material and Methodology

Study Design: Descriptive study

Study Setting: Department of Pathology, Medical College, Tertiary Health care centre.

Duration of the Study: August 2013 to December 2015.

Study Participants: Sample Size - 166

Eligibility Criteria

Inclusion Criteria – All females of age group 15-65years, clinically and/or radiologically diagnosed as breast lesions.

Exclusion Criteria – Patients who were not willing to give written informed consent were excluded from the study.

The present study was carried out in department of pathology of a Medical College and tertiary health care centre. A total of 166 patients who fulfilled the eligibility criteria were included in our study.

The patients were well informed and counseled about the procedure of FNAC and the informed consents were obtained from the patient before performing fine needle aspiration cytology of the breast lesions. In case of minor patients, written informed consent was obtained from parents/guardians/relatives. A detailed clinical history was taken. Also the radiological findings and other investigation reports were noted in predesigned proforma.

General examinations of patient and local examinations of sites of breast lumps were done. Location of the swelling, the relation of swelling to other structures, shape, size, consistency, and tenderness, redness of the overlying skin, local temperature and appearance of skin over site of puncture were observed and entered in the proforma.

All the study participants underwent FNAC of the breast lesions. When the lesions were easy to palpate, clinical guidance was used. For the lesions which were difficult to palpate, imaging guidance like ultrasound was used to ensure the accuracy of sampling.

FNAC was done by using 10 cc syringes with 22–23 needles under all aseptic precautions. Staining of obtained samples was done. FNAC findings were noted and the cases were classified according to the IAC classification.

IAC has devised a procedure for producing a comprehensive and standardized FNAC reporting method. They divided the breast lesions into C1 through C5 categories (C-Code).

- Code 1 – Insufficient material
- Code 2 – Benign
- Code 3 – Atypical, probably benign
- Code 4 – Suspicious, probably in situ or invasive carcinoma
- Code 5 – Malignant

Data obtained from FNAC findings was analyzed.

4. Results

In this descriptive study of 2 years, 166 breast aspirations were done. The following observations were made in the study.

Age Distribution of Breast Lesions

Age group of patients referred for fine needle aspiration cytology of the lesions of the breast ranged from 15 years to 65 years. Out of the 166 patients, 56 (33.73%) patients were of the age group of 24–34 years, followed by age group 35–44 years with 37 (22.28%) patients. Breast lesions were less frequent above 55 years of age (Table - 1).

Table 1. Age Distribution of Breast Lesions

Age Group in Years	No.	%
15-24	27	16.26
25-34	56	33.73
35-44	37	22.28
45-55	26	15.66
55-64	20	12.04
Total	166	100

Clinical Diagnosis of Breast Lesions

In our study, most of the cases were clinically diagnosed as fibroadenoma 119 cases (71.68%), followed by breast carcinoma 33 cases (19.88%) (Table - 2).

Table 2. Clinical Diagnosis of Breast Lesions

Clinical Diagnosis	No.	%
Fibroadenoma	119	71.68
Breast carcinoma	33	19.88
Mastitis	5	3.02
Galactocele	3	1.80
Tuberculous Abscess	1	0.60
Cyst	5	3.02
Total	166	100

Cytological Diagnosis of Breast Lesions

Among 166 cases studied, cytological diagnosis of fibroadenoma was given in 89 cases, followed in frequency by 19 cases of duct carcinoma and in 24 cases which was inadequate (Table - 3).

Table 3. Cytological Diagnosis of Breast Lesions

Sr. No.	FNAC Diagnosis	No.	%
1.	Fibroadenoma	89	53.61
2.	Duct Carcinoma	19	11.44
3.	Fibrocystic Disease	8	4.81
4.	Acute mastitis	3	1.80
5.	Galactocele	2	1.20
6.	Atypical ductal hyperplasia	11	6.62
7.	Lipoma	1	0.60
8.	Granulomatous mastitis	3	1.80
9.	Fibrolipoma	1	0.60
10.	Simple benign cyst	2	1.20
11.	Phyllodes tumor	2	1.20
12.	Malignant Mesenchymal lesion	1	0.60
13.	Inadequate	24	14.45
14.	Total	166	100.0

Table 4. Classification of the Cytological Diagnosis of Breast Lesions

Sr. No.	Cytological Code	Cytological Diagnosis	No of cases	Percentage
1	C1	Inadequate to opine	24	14.46%
2	C2	Fibroadenoma	109	65.66%
		Fibrocystic Disease		
		Acute mastitis		
		Galactocele		
		Lipoma		
		Granulomatous mastitis		
		Fibrolipoma		
		Simple benign cyst		
3	C3	Phyllodes tumor	2	1.21%
4	C4	Atypical ductal hyperplasia	11	6.62%
5	C5	Duct Carcinoma	20	12.05%
		Malignant Mesenchymal lesion		

Fibroadenoma

FNAC was helpful in making the diagnosis of fibroadenoma in 89 cases.

The ages of the patients ranged from 15 years to 65 years.

Duration of lesion ranged from 1 month to 2 years.

17 patients presented with pain in the lump.

1 patient had hyperemia of skin over the breast.

27 patients had lump on the left side, 32 on the right side and 15 cases had bilateral breast lumps.

Clinical diagnosis of fibroadenoma was given in 69 cases and one case was suspected to be that of breast abscess.

Duct Carcinoma

FNAC was helpful in making the diagnosis of duct carcinoma in 19 cases.

Age of the patients ranged from 27 years to 35 years.

Duration of lesion ranged from 12 months to 5 years.

11 cases had a mass on left side and 06 cases on right side, 1 case had complaints of bilateral masses.

Nipple retraction was seen in 14 cases. Peau d' orange appearance of the skin was seen in 5 cases.

Ulceration of skin was seen in 3 cases. Erythematous bulla was noted in one case and 2 cases showed fungating masses.

14 cases had axillary lymph node enlargement on same side of breast lesion.

2 patients' had family histories of carcinoma of the breast in a first degree relative.

1 patient had history of recurrence after surgery on the same side.

1 case had a history of three cycles of neo-adjuvant chemotherapy.

Fibrocystic Change (FCC)

FNAC was helpful in diagnosing 8 cases of FCC with the ages of the patients ranging from 36 years to 65 years and duration of lesion ranged from 20 days to 7 months.

4 cases had lump on the right side, 3 on the left side and 1 case had bilateral breast lumps.

Clinical diagnosis of fibroadenoma was given in 3 cases.

Galactocele

FNAC was helpful in making the diagnosis of galactocele in 2 cases.

Both the cases were those of lactating mothers.

One was clinically diagnosed as breast abscess and the other as galactocele.

The aspirates in both the cases were grey-white.

Acute Mastitis

FNAC was helpful in making the diagnosis of suppurative mastitis in 3 cases with age of the patients ranging from 21 years to 30 years.

1 case had a right sided mass and 2 cases had masses on the left side.

The aspirate was purulent in all the 3 cases, consisting of RBCs, lymphocytes, neutrophils and macrophages in a background of cellular debris and regenerative epithelial cells.

Granulomatous Mastitis

3 cases of granulomatous mastitis were seen in the present study.

FNAC yielded grey-white aspirate consisting of epithelioid cells, histiocytes, plasma cells and multinucleated giant cells.

Atypical Ductal Hyperplasia (ADH)

FNAC was helpful in diagnosing 11 cases of ADH.

The age of the patients ranged from 30 years to 62 years.

Duration of lesion ranged from 4 months to 3 years.

5 cases had lump on right side and 5 cases on the left and one in bilateral.

1 case had a huge mass, with Peau d' orange appearance of the skin, and a familial history of carcinoma breast in a first degree relative.

Clinical diagnosis of fibroadenoma was given in 6 cases and as carcinoma breast in 4 cases.

Aspirate was hemorrhagic in 7 cases, grey-white in 3 and showed altered blood in 1 case.

On microscopy, all 11 cases had clusters of atypical epithelial cells.

Background had hemorrhage, foamy cells and bare nuclei in all the cases.

Nipple discharge was examined in 1 case which had features consistent with ADH.

5. Discussion

Diseases of the breast are the most common diseases in females. The breast is subjected to various physical and physiological alterations, from puberty till death that may be related to menstruation, pregnancy or menopause.

Almost all of the breast disorders present with pain (most common presentation) or palpable breast lump (second most common presentation).

Numerous and exhaustive studies of many aspects of the breast diseases and conditions are seen due to the high frequency and the diverse variety in breast lesions. In addition, breast carcinoma ranks first amongst malignant tumors affecting females throughout the world. It is a worldwide problem and is seen in all the races or countries. The lesion of the breast can range from as simple as an abscess of the breast to something as ominous as cancer. The presence of a breast lump creates anxiety as it may signify cancer, can cause unbearable pain and may result in a deformity. Benign Breast Disease (BBD) is a very common problem and at least over half of the female populations at some time in life seek medical advice for breast problem.²

Increasing awareness of carcinoma of breast, the commonest female malignancy worldwide has stimulated profound interest in benign breast lesions since certain epithelial benign breast lesions have been associated with malignant transformation.³

Fine needle aspiration cytology (FNAC) forms an important pre-operative and screening test for breast masses. When accompanied with clinical examination and radiological imaging, the sensitivity and specificity of this procedure are extremely high.

The principle objective of FNAC of breast lesions is to distinguish between benign and malignant lesions as malignant lesions require prompt surgical excision.⁴

The true incidence of breast disease is almost impossible to determine because so many lesions go undetected clinically especially in younger women.

Incidence of Breast Lesions

Study	Duration of study	Non-malignant	Malignant
Oluwole, <i>et al.</i> ¹² (1979)	3Years	72%	28%
Khanna R, <i>et al.</i> ¹³ (1998)	20 years	61.3%	38.7%
Ochicha, <i>et al.</i> ¹⁴ (2002)	5 years	73%	27%
Malik R, <i>et al.</i> ¹⁵ (2003)	20 years	89%	11%
Present study	2 years 5 months	74 %	26 %

The frequency in which various lesions are encountered can be stated only in general terms, because it depends greatly upon clinical presentation. The prevalence of lesions also varies among age groups and among different ethnic population. Breast carcinoma is the most common malignancy in adult women. Increasing awareness in the minds of the patients regarding breast carcinoma overshadows the attention to other breast lesions.

However non-cancerous conditions of the breast are far more common than cancer, also there are many benign lesions of breast that would be of concern to the patient and the clinician alike.

Probably cancerous tissue grows faster and produces more systemic and local manifestations. Hence patient with cancer are brought to hospital earlier, whereas, benign lesions are asymptomatic and slow growing and so are frequently neglected.¹⁶

Age Incidence

In the present study, the youngest patient was 15 years and oldest patient was 65 years. In non-neoplastic lesions the ages ranged was 15 to 60 years. Cases of fibroadenoma were the commonest in 2nd to 3rd decade. Age range for carcinoma was from 27 to 65 years. There was steady rise in incidence of carcinoma in 5th decade, the age of menopause.

Accurate diagnosis of breast cancer is made in 99% of cases by the combination of clinical examination, mammography, and simple, non-invasive, cost-effective outpatient department procedure—Fine-Needle Aspiration Cytology (FNAC). Technique of FNAC has wide applicability and utility for the tumors which are easily palpable on external examination.^{13,14}

When compared to the standard breast FNA, core needle biopsy is the preferable method in the developed world. On the other hand, in underdeveloped nations such as India, core needle biopsy is still not routinely performed in most medical institutes. The treatment of breast cancer cases begins with a FNAC-based first-hand diagnosis. FNA is favored over core needle biopsy in a resource-constrained country like India. The former is less expensive, less invasive, and allows for sampling of multiple parts of the lesion at the same sitting at no additional cost, with good findings usually obtained the same day.^{17,18} By decreasing the need for repeat treatments and triaging cases for ancillary tests, rapid onsite evaluation will minimise insufficient rates and costs to the system.¹⁹ The utilization of FNAB cytology

and, where applicable, core biopsy will be improved by linking cytology data to management algorithms. Improved patient care will result from standardized use of cell blocks, immunohistochemistry, in situ hybridization, and other molecular assays of prognostic and diagnostic markers.²⁰

Members of the IAC Breast Group who attended the Yokohama International Congress of Cytology debated whether a 3- or 5-stage coding system should be used. The five categories of IAC standardized reporting are C1, C2, C3, and C5. C1 refers to epithelial cells with an insufficient degree of cellularity. This can occur as a result of incorrect aspiration, smearing, or staining. C2 or benign refers to lesions that have the same pattern as other benign lesions, which are usually cellular, with myoepithelial cells, and a ductal pattern. There could also be an inflammatory background present. C3 or atypical smears have characteristics such as cellular crowding, pleomorphism, and dis-cohesion that are not present in benign lesions. The C4 or suspected malignant category is reserved for aspirates with characteristics such as poor preservation, hypocellularity, or components of a benign smear that preclude the diagnosis of malignancy. C5 is the classification for aspirates with strong malignant features.⁸⁻¹⁰ There have been two primary points of contention, namely, the definitions of “atypia” and “suspicious for malignancy.”^{8,21-23}

Our study had 24 cases (14.46%) in the C1 category, 109 cases (65.66%) in the C2 category, 2 cases (1.21%) in the C3 category, C4 category had 11 cases (6.62%) and the remaining 20 cases (12.05%) in the C5 category.

Comparison between the various studies done for IAC grading system

Studies	C1	C2	C3	C4	C5
Modi, <i>et al.</i> ¹⁶	1.36%	72%	3.4%	6.5%	16.7%
Georgieva, <i>et al.</i> ²¹	25.6%	44.3%	2.2%	5.3%	22.5%
Bajwa and Tariq ¹⁹	13.6%	60.6%	6.2%	9.3%	10.3%
Sunita, <i>et al.</i> ¹⁷	2.9%	50%	3.5%	6.5%	37.1%
Present study	1.3%	82.6%	5.7%	1.7%	8.4%

6. Summary

A prospective study of breast lesions was carried out in the Pathology department at a tertiary care center.

The features noted in the study were as follows:

1. FNAC of palpable breast lesions was performed in 166 patients. There were no complications following this procedure.
2. Majority of the patients were in age group of 25-34 years with 56 cases (33.73%) followed by 35-44 years with 37 cases (22.28%). The ages of the patients included in the study ranged from 15 years to 65 years. Acute mastitis and fibrocystic disease were commonest in 21-40 years age group. Proliferative breast diseases were common in 2nd to 3rd decade of life, whereas carcinomas were common in 5th to 6th decade of life.
3. Among the 166 cases studied, majority of the patients presented with lesion in upper outer quadrant (76 cases) and in the left breast (75 cases).
4. The clinical diagnosis included fibroadenoma, carcinoma breast, breast abscess, galactocele, cystic disease and tubercular abscess.
5. Nipple discharge was obtained in 4 cases. 2 cases were diagnosed as benign epithelial hyperplasia, 1 case as atypical ductal hyperplasia and 1 case as infiltrating duct carcinoma each.
6. Fibrocystic change was diagnosed in 8 cases.
7. Galactocele was diagnosed in 2 cases.
8. Granulomatous mastitis was seen in 3 cases.
9. Fibroadenoma was cytologically diagnosed in 89 cases, with the age group ranging from 15 years to 60 years.
10. Atypical ductal hyperplasia was diagnosed in 11 cases.
11. Duct carcinoma was diagnosed in 19 cases in age group of 27-65 years.
12. FNAC was helpful in diagnosing phyllodes tumour in 2 cases which were clinically diagnosed as carcinoma breast.
13. Among the 166 cases, 1 case was diagnosed as lipoma and 1 as fibrolipoma, both of which were rare diagnosis for breast lesions.
14. FNAC is accepted as specific, safe, sensitive, accurate, and cost effective technique. It can be used for pre-operative diagnosis in the lesions of the breast and can

therefore avoid unnecessary surgical interventions like incisional biopsy or diagnostic excision.

15. As cytological scoring is easy to assess, accurate and reproducible, it should be included in FNAC reports of all proliferative breast lesions.
16. Our study had 24 cases (14.46%) in the C1 category, 109 cases (65.66%) in the C2 category, 2 cases (1.21%) in the C3 category, C4 category had 11 cases (6.62%) and the remaining 20 cases (12.05%) in the C5 category.

7. Conclusion

The fine needle aspiration cytology is an important diagnostic tool for management of patient with breast lumps. It is an easy, reliable, patient friendly, repeatable and simple diagnostic test.

FNAC can have a very high diagnostic accuracy when performed by experts. It is proven by the high sensitivity and a high positive predictive value that a positive FNAC in the breast is a definite diagnosis of the concerned pathology when compared with the final histopathology report.

The high accuracy of FNAC in the diagnosis of malignancy in the breast can be illustrated by the high specificity and a high negative predictive value.

Mastectomy or any other definitive therapy can be used for management of patients in which FNAC is unequivocally diagnostic for cancer.

A repeat FNAC may be advised before advising for open biopsies in cases which were previously being reported as inadequate or unsatisfactory samples, since the accuracy of the needle-tip in localizing the lump is very high.

Thus, it can be concluded without hesitation that FNAC is a very important preliminary diagnostic test in palpable breast lumps, and if performed expertly, the results have a high degree of specificity and sensitivity.

The cytological examination of breast lesions prior to surgical treatment serves as a rapid, economical, and valuable diagnostic tool. Adhering to the principle of "Triple test and acquisition of technical, observational, and interpretative skills will further enhance the diagnostic accuracy of proliferative conditions with atypia or suspicious lesions of breast.

There are numerous cytological grading systems for breast cancer in the literature, all of which have a high

correlate with the Elston–Ellis grading system. Robinson's approach is favored above other methods because of its sensitivity, simplicity, objective set of criteria, and ease of repeatability.^{24–26} The IAC (international academy of cytology) standardized approach to cytological categorization is used. This organized reporting will improve report reproducibility and uniformity in assessment, particularly among practitioners. We conclude that a standardized reporting system for the classification and diagnosis of breast lesions is beneficial because the risk of cancer in each category is directly associated.

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