

Original Research Article

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Fine needle aspiration cytology of breast lumps: how reliable is it? A correlative study with histopathology

Sakshi Agrawal^{1*}, Sumedh Agrawal², A. S. Gadre¹, N. V. Dravid¹

¹Department of Pathology, ACPM Medical College, Dhule, Maharashtra, India

²Department of Medicine, SBHGMC, Dhule, Maharashtra, India

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***Correspondence:**

Dr. Sakshi Agrawal,

E-mail: drsakshiagrwal20@gmail.com

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ABSTRACT

Background: Breast carcinoma is one of the most common malignancies in women. Palpable breast lesions are one of the commonest presentations in general and surgical practice. To study the spectrum of benign and malignant breast lesions and the efficacy of FNAC as a diagnostic tool by correlating with histopathological findings.

Methods: The present study was carried out among 250 patients who presented to ACPM medical college and hospital during a 5-year period from January 2018 to January 2023. All cases that presented with a palpable breast lump were evaluated with FNAC and the lesions were categorised as C1-C5 as per National Health Service Breast screening programme (NHSBSP) reporting criteria. Every patient subjected to FNAC with an adequate result, underwent a definitive surgical procedure. All specimens so obtained were subjected to histopathology. The results thus obtained were matched with those of FNAC and a correlation was sought based on statistical tests. In 243 cases cytohistopathological correlation was obtained.

Results: A total of 250 cases was studied which included 170 benign cases (68%), 52 malignant cases (20.8%), 21 proliferative lesions with atypia (8.4%) and 7 inadequate aspirates (2.8%). The diagnostic accuracy of FNAC in this study was 98.77%.

Conclusions: Aspiration cytology can be done as a first line procedure but cannot be considered as a substitute for histopathology.

Keywords: Fine needle aspiration cytology, Breast lumps, Histopathology, FNAC

INTRODUCTION

Breast lump is one of the commonest surgical problems encountered in female patients.¹ WHO reported that around 1 lakh new cases of carcinoma breast are diagnosed every year in India and about 70,218 deaths due to breast cancer was estimated in Indian women every year.² The incidence of breast carcinoma worldwide is 10.4%, developed countries having higher incidence. It is the second most common type of non-skin malignancy (after carcinoma of lung) and fifth most common cause of cancer death.³

Physical examination, mammography and/or ultrasound, FNAC and open surgical biopsy are firmly established in the diagnosis of patients with palpable breast masses. The reliability of these tests has been documented in multiple reports, and they are routinely employed in the preoperative assessment of any woman who presents with a palpable breast mass. This combination has been shown to be highly accurate in making the correct diagnosis.^{4,5} This quadruple assessment is the new “gold standard” in the investigation of breast disease.⁶ The diagnostic accuracy exceeds 99% when all these modalities are concordant.⁷

However, clinical and mammographic evidence either alone or in combination do not identify all the malignant conditions.⁸ Although open surgical biopsy is the gold standard for diagnosis of palpable breast lesions, in recent years, surgery or open biopsies are not playing vital role as a diagnostic tool, due to availability of various methods of screening and diagnostic modalities including FNAC, biopsy, mammography, ultrasound, MRI imaging, gene studies etc. However, two types of minimally invasive breast biopsy techniques, core needle biopsy (CNB) and FNAC, have become established for the diagnostic evaluation of palpable breast lesions.^{9,10}

Fine needle aspiration cytology is defined as the study of cells obtained by a fine needle under vacuum. The specimen consists of a minute quantity of tissue or fluid. The lesion is surrounded by normal tissue zone. It may be a palpable superficial mass or a deep mass only visible by radiological tools. Any accessible area of the body is a suitable target for aspiration cytology.¹² Application of FNAC 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.¹¹

Later, Franzen and Zajicek in around 1960s first introduced FNAC for breast aspirations at the Karolinska Hospital in Stockholm. They did May-Grunwald Giemsa stains on air-dried smears for rapid interpretation and diagnosis. Despite their success, due to lack of confidence in the new procedure, surgeons' unwillingness and for the fear of tumor implantation in the needle track FNAC was not popularly used until 1980s.²

FNAC procedure is safe, reliable and time saving outpatient procedure with little discomfort to the patient. It is not only useful in diagnosis and further planning of treatment without need for biopsy, but is also helpful in prognostication of the tumors such as nuclear grading, mitotic index, hormone receptor status and DNA contents.⁸

Aim and objectives

To evaluate the role of FNAC/diagnostic performance of FNAC in the evaluation of breast lesions. To find out the common causes of breast lumps and to know their cytomorphological patterns. To correlate the incidence of breast lesions with age of the patient and other clinical features. To see how well a preliminary FNAC in a breast lump correlated with the final histopathology report to which every excised specimen would invariably be subjected. To determine the extent to which the FNAC report could be relied upon to proceed towards definitive excisional surgery without resorting to any other diagnostic procedure. To calculate statistical data like sensitivity, specificity, positive predictive value, negative predictive value, and efficiency of FNAC procedure comparing with the histopathology. To draw a conclusion

regarding the reliability of FNAC is the essence of this study.

METHODS

This was a retrospective study done in Pathology department of ACPM medical college and hospital of north Maharashtra. Data on breast FNAC done between January 2018 to January 2023 were retrieved from records of FNAC. Demographic data including age, sex, clinical presentation and relevant examination findings like tumour laterality and topographical assessment of tumour were obtained from request form. Findings of FNAC were correlated with data from histopathology records. Sensitivity, specificity, PPV, NPV and test accuracy were calculated using standard statistical methods.

FNAC and excision biopsy

The patients with palpable breast lump referred from general surgery department in the institution for FNAC were involved in the study after obtaining informed consent along with detailed history. The breast was examined and palpated. The suspicious area was cleaned with antiseptic solution and spirit. The procedure was performed without any anaesthesia by a trained pathologist. The skin over the lump was stretched and few needle passes at different angles were taken with a 10 cc syringe fitted with a 22 G needle. As needle entered in the mass, a change in consistency was felt. The air was drawn out in the syringe and after attaching the needle, the aspirated material was spread on the labelled glass slide and the smear was made. Few of them were air dried and stained by MGG stain while wet fixed smears were stained with papanicoloau (Pap) stains. These smears were graded according to NHSBSP criteria.

According to the criteria C1 is inadequate FNAC, C2 denotes a benign lesion, C3 indicates atypical lesion, probably benign, C4 implies a suspicious lesion favouring malignancy and C5 indicates a malignant lesion.

Biopsy specimens were received in 243 cases. The tissue was fixed in 10% buffered formalin for 24 hours and then processed. Sections were cut at 4-5 microns thickness and stained with haematoxylin and eosin. The histopathological examination was carried out by pathologists without prior knowledge of cytodiagnosis. Correlation between cytological and histological diagnosis were done and accuracy of diagnosis was assessed by using standard statistical methods.

Inclusion criteria

All patients presenting to the cytopathology laboratory in the department of Pathology, during the study period with palpable breast lump of variable duration, irrespective of age and sex, with an unknown primary diagnosis and had undergone FNAC were included in the study.

Exclusion criteria

Patients with diagnosed breast malignancy on treatment, patients with recurrent breast malignancy, patients undergoing chemotherapy, frank malignant mass with skin infiltration, uncooperative patients, repeat FNAC patients, patients not willing for surgery or for FNAC procedure were excluded from the study.

Statistical analysis

All the statistical analysis was performed using SPSS version 20. For statistical analysis, FNAC results of cases which had biopsy confirmation were further subdivided into two categories, first category being benign/ atypical proliferative lesions and second suspicious of carcinoma/carcinoma category. Similarly, the biopsy results were also subcategorised as benign/atypical and malignant categories. The sensitivity, specificity, positive predictive

value (PPV), and negative predictive value (NPV) along with 95% confidence interval (95% CI) and accuracy of FNAC for diagnosing breast lesions were calculated. Qualitative data are summarized using frequency and percentage.

RESULTS

In the present study, the age of patients ranged from 16 to 63 years, with a mean age of 35.5 years. The maximum number of lesions were seen in the age group of 21-30 years (33.2%), followed by 31-40 years (20.4%) and 10-20 years (17.2%). The least number of cases were seen in patients above 60 years age (6%).

Majority of the patients were females (97.6%) while males comprised only 2.4%, of which all of them were in the age group of 21-40 years (just like the female counterpart).

Table 1: Age and sex wise distribution of patients.

S. no.	Age group (in years)	Total cases (N)	Cases (N) %	Females	Males
1	10-20	43	17.2	43	0
2	21-30	83	33.2	81	2
3	31-40	51	20.4	49	2
4	41-50	31	12.4	30	1
5	51-60	27	10.8	26	1
6	>60	15	6.0	15	0
Total		250	100	244 (97.6%)	6 (2.4%)

Table 2: Laterality (tumor side) distribution of breast lump.

Side (laterality)	No. of cases (N)	Cases (N) %
Right	110	44.0
Left	134	53.6
Bilateral	06	2.4
Total	250	100

Table 3: Topographical (quadrant wise) distribution of breast lump.

Quadrant location	No. of cases (N)	Cases (N) %
Upper outer	126	50.4
Upper inner	38	15.2
Lower outer	29	11.6
Lower inner	29	11.6
Subareolar	16	6.4
Diffuse	12	4.8
Total	250	100

Left breast was seen to be more commonly involved (134 cases, 53.6%) than right (110 cases, 44%). Bilateral involvement was seen in 6 (2.4%) cases.

Upper outer quadrant was seen to be the most common quadrant of involvement with 126 cases (50.4%). The next common quadrant to be involved was upper inner (15.2%), while both the lower quadrants (outer and inner) had equal involvement (11.6%). 6.4% cases had lump in the

subareolar region (central quadrant), while the remaining 4.8% (12) cases had diffused involvement (of more than one quadrant) by breast lumps.

The patients had a wide variability in the duration of breast lumps ranging from less than a month to more than 5 years, of which majority of patients had a duration of symptoms ranging from 1-6 months. Cases presented with chief complaints of lump in breast, pain, skin redness, nipple

retraction, nipple erosion, and nipple discharge. In this study, majority of the benign breast lesions clinically presented with painless, firm, mobile, slow growing, small size (<3cm) breast lump while malignant breast lesions

clinically presented as grossly evident, irregular shaped, poorly circumscribed, firm to hard mass, with few fixed to chest wall causing nipple retraction and skin dimpling.

Table 4: Clinical presentation (according to duration of symptoms) in the enrolled patients.

Duration of symptoms	No. of cases (N)	Cases (N) %
<1 month	91	36.4
1-6 months	130	52.0
6 months- 1 year	07	2.8
1-2 years	05	2.0
2-5 years	11	4.4
>5 years	06	2.4
Total	250	100

Table 5: Cytological spectrum of breast lumps on FNAC in the enrolled patients.

Category	No. of cases (N)	Cases (N) %
C1 (Inadequate)	07	2.8
C2 (Benign)	170	68.0
C3 (Atypia probably benign)	21	8.4
C4 (Suspicious probably malignant)	12	4.8
C5 (Malignant)	40	16.0
Total	250	100

Table 6: Age wise distribution of cases presenting with breast masses with respect to cytological spectrum.

Age group (in years)	C1	C2	C3	C4	C5	Total
10-20	02	41	-	-	-	43
21-30	02	79	02	-	-	83
31-40	01	37	09	02	02	51
41-50	01	11	06	04	09	31
51-60	00	02	04	04	17	27
>60	01	-	-	02	12	15
Total	07	170	21	12	40	250

All the lesions were categorized into 5 categories C1 to C5; C1 (inadequate), C2 (benign), C3 (atypia probably benign), C4 (suspicious of malignancy) and C5 (malignant). For calculation of statistical indices, the cases having unsatisfactory aspirates were excluded and suspicious cases were considered positive for malignancy.

We found 7 (2.8%) inadequate cases, 170 (68%) benign cases, 21 (8.4%) proliferative lesions with atypia, 12 (4.8%) cases as suspicious of malignancy and 40 (16%) malignant cases.

Majority of benign breast lesions were seen within the age bracket of 21 to 30 years and malignant lesions were seen within the age bracket of 51 to 60 years. This distribution shows that as the age advances, the likelihood of a breast lesion to be malignant increases. However, the earliest malignant lesion was detected at the age of 38 years. This suggests that breast malignancy can occur in young women also.

We excluded the inadequate category (C1) from our study. The inadequacy may be because of various reasons like deep seated small lesion, presence of only cystic fluid, hypocellularity, excessive blood, insufficient epithelial cells for confident assessment and sclerosing component of the lesion etc.

The cytological spectrum of various benign breast lesions (C2 category) encountered in the present study shows that out of the total 170 cases (68%) that could be satisfactorily labelled as benign, fibroadenoma accounted for 97 cases (38.8%) (which was also the most commonly diagnosed disease in our study), followed by benign epithelial proliferative lesion comprising 19 cases, fibrocystic disease for 13 cases, inflammatory lesions consisting of 22 cases (8.8%) (with 12 cases of breast abscess, 6 cases of chronic mastitis and 4 cases of granulomatous mastitis). Other rare diagnosis on cytopathology were fibro adenosis, galactocele, gynecomastia, lactating adenoma (comprising 3 cases each), fat necrosis, simple cyst, benign phyllodes tumour (comprising 2 cases each) and a single case of duct ectasia.

Table 7: Category wise cytohistological correlation.

Cytological category	FNAC result	N	%	HP examination
C1	Inadequate	7	2.8	-
	Fibroadenoma	97	38.8	FAd- 92 Benign phyllodes- 4 Fibroadenomatoid changes- 1
	Benign epithelial proliferative lesion	19	7.6	FAd- 12 Benign phyllodes- 4 Fibrocystic disease- 1 ADH- 1 UDH- 1
	Fibrocystic disease	13	5.2	Fibrocystic disease- 10 FAd with fibrocystic change- 2 UDH- 1
C2	Breast abscess	12	4.8	Breast abscess- 10 Granulomatous mastitis- 1 Fat necrosis- 1
	Chronic mastitis	6	2.4	Chronic mastitis- 6
	Granulomatous mastitis	4	1.6	Granulomatous mastitis- 4
	Fibroadenosis	3	1.2	Fibroadenosis- 2 IDC – 1
	Galactocele	3	1.2	Galactocele- 3
	Gynecomastia	3	1.2	Gynecomastia- 3
	Lactating adenoma	3	1.2	Lactating adenoma- 3
	Fat necrosis	2	0.8	Fat necrosis- 2
	Simple cyst	2	0.8	Simple cyst- 2
	Benign phyllodes	2	0.8	Benign phyllodes- 2
	Duct ectasia	1	0.4	Duct ectasia- 1
		170	68	
C3	Proliferative lesion with atypia	21	8.4	FAd- 16 DCIS- 3 Fibroadenosis with focal atypia- 1 IDC- 1
C4	Suspicious of malignancy	12	4.8	IDC- 11 ADH- 1
C5	Malignant	40	16	IDC- 34 IDC with HG DCIS- 2 Lobular carcinoma- 2 Mucinous carcinoma- 2

Cytosmears of 97 cases of fibroadenoma were all cellular showing biphasic population of cells composed of spindle stromal cells with naked nuclei, and the epithelium arranged in antler horn clusters or fenestrated honeycomb sheets. 4 cases which were reported as fibroadenoma in FNAC turned out to be benign phyllodes tumour by biopsy and a single case showed features of fibroadenomatoid changes on histology. A case reported as fibrocystic disease on cytology turned out to be usual ductal hyperplasia on biopsy, other cases being concordant. Out of 19 cases of benign epithelial proliferative lesion, we found 12 cases of fibroadenoma, 4 cases of benign phyllodes and a single case each of fibrocystic disease, usual ductal hyperplasia and atypical ductal hyperplasia respectively. We had a case of fibroadenosis which turned out to be invasive carcinoma on biopsy, the other two cases

being concordant. In rest all benign cases (granulomatous mastitis, gynecomastia, benign phyllodes, galactocele, chronic mastitis, duct ectasia, fat necrosis, simple cyst and lactating adenoma) the biopsy matched with the FNA diagnosis, concordance being cent percent. This group had the maximum number of patients; majority of them in 21-30 years, followed by 31-40 years.

There were 21 cases in C3 category (proliferative lesion with atypia), out of which 16 cases were fibroadenoma, 3 were ductal carcinoma in situ and a single case each of infiltrating ductal carcinoma and fibroadenosis with focal atypia respectively in the excision biopsy. To avoid over diagnosing these lesions as suspicious of malignancy or malignancy, we reported these lesions as benign/ negative for malignancy in cytosmears, and the definite diagnosis

was established only on histopathology. These patients showed the incidence in above 3rd decade of their life.

There were 12 cases where suspicion of malignancy was there on cytology (C4 category). The cytomorphological features did not fulfil the criteria of malignancy. The smears were hypercellular with monotonous ductal epithelial cells having mild to moderately high nuclear cytoplasmic ratio, nuclear hyperchromasia and nuclear crowding. In histopathology, 11 turned out to be malignant (invasive ductal carcinoma), while one case was discordant (atypical ductal hyperplasia). These patients presented between 41-60 years of age.

There were 40 malignant cases in our study (C5 category). These smears were hypercellular, cells arranged in a 3-dimensional pattern, with a high N:C ratio, hyperchromatic nuclei, prominent nucleoli, irregular nuclear margins, high mitotic index with no myoepithelial cells and most of them in a haemorrhagic or necrosed background. On histopathology, infiltrating ductal carcinoma (no specific type) was the most common tumor accounting for 34 cases. However, in addition, 2 cases of IDC also had a DCIS component in it. Lobular carcinoma and mucinous carcinoma accounted for 2 cases each. Thus, all these cases showed concordance with histopathology. These patients were predominantly in above 5th decade of their life.

On comparing the different categories of FNAC with histopathological findings, we found that out of 170 cases of C2 category, 1 case turned out to be malignant and other 169 cases were benign; out of 21 cases of C3 category, 20 were benign and 1 turned out to be malignant; out of 12 cases of C4 category, 1 case was benign and 11 cases were malignant; all the cases of C5 category (40 cases) turned out to be malignant histologically. Thus, the diagnostic accuracy of FNAC for breast lesions was 98.77%

False positives noted mainly in the interpretation of suspicious smears or with atypical features were due to uniformly enlarged nuclei with prominent nucleoli, occasional marked nuclear enlargement, and moderate pleomorphism.

Histopathological correlation was available in 243 cases.

Statistical analysis

True positive cases (TP) = 189, False positive cases (FP) = 02, True negative cases (TN) = 51, False negative cases (FN) = 01

Table 8: Comparative evaluation of cytological classification of breast lesions of various studies.

Study name	Year of study	C1 (%)	C2 (%)	C3 (%)	C4 (%)	C5 (%)	Total (%)
Fimate et al ³²	2012	-	76.2	5.8	1	17	100
Shaila et al ³³	2015	-	32.4	10.3	8.8	48.5	100
Chethan et al ¹⁹	2016	4	76	10	2	8	100

Sensitivity = TP X100/TP+FN = 99.47%

Specificity = TN X100/ TN+FP = 96.23%

Positive predictive value= TP X 100/TP+FP= 98.95%

Negative predictive value = TN X100/ TN+ FN =98.08%

Thus, the observations of histopathology were helpful in differentiating the malignant and benign cases.

DISCUSSION

FNAC helps to diagnose the lesions preoperatively and so helps in taking appropriate decision in management of patient with breast lesion. There are several reports in literature on FNAC, and a good correlation between FNAC and histology has been recorded in many series.

Our study included 250 cases with palpable breast lumps in which cytomorphological features of breast lesions were studied in detail and the cytological results were subsequently compared with that of histopathology in available cases. Though the incidence of breast cancer is rising steadily in North Maharashtra, the published data on breast cancer in this region is sparse.

FNAC can reduce the number of operations performed by: (a) confirming the malignant nature of a breast lesion and therefore allowing the planning of definitive surgery and (b) identifying benign lesions that do not require open biopsy.¹³

In our study, commonest age group to present with a palpable breast lump was 21-30 years which was comparable to majority of the studies, for example, the studies done by Vishnu et al, Sreedevi et al, Dayal et al, Pratibha et al and Panjvani et al.^{1,11,14-16}

The male: female ratio in our study was 0.024: 1. The same ratio in the study conducted by Bhavya et al was 0.015:1, by Manas et al was 0.011: 1, Panjvani et al was 0.023:1 and by Lakshmi et al was 0.056: 1.^{2,11,17,22} So, our study is comparable with the other studies. This shows that breast lesions are way more common in females than in males. All the males in our study had benign lesions (gynecomastia in 3, simple cyst in 1) while 2 males had unsatisfactory smears. Gynecomastia accounted for 1.2% cases in our study which was 12.5% in the study done by Rani et al.¹⁰

Continued.

Study name	Year of study	C1 (%)	C2 (%)	C3 (%)	C4 (%)	C5 (%)	Total (%)
Pandey et al ²⁴	2016	2	71.67	4	1.33	21	100
Amitha et al ²⁵	2017	2.6	81.1	1.42	2.3	12.6	100
Bhavya et al ¹⁷	2018	1.5	43.5	2.5	3	49.5	100
Chirag et al ²⁰	2018	10.69	68.83	2.32	3.72	14.41	100
Lakshmi et al ²	2021	7.14	76.7	5.35	1.78	8.92	100
Present study	2023	2.8	68	8.4	4.8	16	100

Table 9: Comparative evaluation of analysis of benign and malignant lesions in various studies

Study name	Chethan et al ¹⁹	Bhavya et al ¹⁷	Amirtha et al ²⁵	Aisha et al ³	Lakshmi et al ²	Chirag et al ²⁰	Dastayya et al ¹²	Hebbar et al ²⁶	Present study
Benign (%)	89.58	43.5	78.4	80.8	82.05	71.15	76	38	76.4
Malignant (%)	10.42	52.5	21.6	19.2	10.7	18.13	24	62	20.8

Table 10: Comparative evaluation of analysis of statistical parameters in various studies.

Study name	Year of study	Sn (%)	Sp (%)	PPV (%)	NPV (%)	Accuracy (%)
Waghmare et al ²³	2003	88.24	100	100	93.2	95.52
Hebbar et al ²⁶	2012	93.10	100	100	90.47	98
Panjvani et al ¹¹	2013	97.82	100	100	97.85	98.90
Pandey et al ²⁴	2016	98.3	98.9	98.3	98.9	98.7
Kishan et al ⁸	2017	97.56	97.82	97.56	97.82	97.77
Punam et al ²¹	2017	98.11	100	100	98.81	99.26
Pratibha et al ¹⁶	2017	75.5	100	100	85.89	90.17
Chirag et al ²⁰	2018	90.90	98.68	96.77	96.15	96.33
Rani et al ¹⁰	2018	97.82	100	100	97.85	98.90
Aisha et al ³	2020	91.66	100	100	98	98.4
Singh ¹	2021	50	100	100	95.9	96.1
Dastayya et al ¹²	2021	94	100	100	93	94
Present study	2023	99.47	96.23	98.95	98.08	98.77

Left sided (53.6%) breast lump was slightly more common in our study than right sided (44%). For this laterality, we got mixed results from various studies. While Aisha et al, Chetan et al and Chirag et al got predominantly left sided breast lumps in their studies, Punam et al, Sridevi et al and Lakshmi et al found predominantly right sided breast lumps.^{2,3,15,19,20,21} This shows that breast lesions can occur equally in both sides. Bilateral breast lumps were seen in just 2.4% cases in this study. The proportion of bilateral breast lumps varied from 5% to 10% in the above stated studies. This finding shows that we got a slightly less proportion of bilaterally involved breasts in our study. However, no surgical importance can be attached to this observation since patient selection was in no way dictated by involvement of any particular breast.

We found that the most common quadrant which was involved was upper outer (50%) followed by upper inner (15.2%). Chetan et al, Chirag et al, Jasmine et al and Punam et al also found upper outer as the most common quadrant involved.¹⁹⁻²² This observation shows that upper and outer quadrant is the dominant quadrant to have a palpable lump. Diffuse involvement of breast was seen in 4.8% cases in our study. Waghmare et al²³ found 7.4% cases with diffuse breast involvement while Pandey et al

found just 0.006% cases with diffuse breast involvement. So, it is now obvious that age-wise distribution, site and topographical location of various breast lesions (both benign and malignant) remain more or less similar everywhere.

Majority of the patients presented within 6 months duration of the lump. This was similar to the findings of Amirtha et al.²⁵ The short duration of symptoms is due to the awareness among general population regarding the importance of early detection of breast lesions in this area.

On cytological classification of all breast lesions according to NHSBSP criteria, we found the most commonly involved criteria was C2 and the least common was C1. This was compared to various studies; whose results are as follows:

Table 10 shows that the values obtained in our study is lying in between the minimum and maximum values of different studies. Thus, our study is comparable with all these studies.

We found just 2.8% cases which were inadequate. This value ranged from 2% to 10.7% in different studies. This

may be because of extensive fibrosis, cystic lesion, lack of technical experience in performing FNA, FNA of ill-defined masses like lesion or lesions with hyalinization and deeply situated lumps or geographic miss by needle. The reason for such less rates of inadequacy in our study is unstained smears are immediately examined microscopically to assess the adequacy and the FNAC procedure is repeated instantly if adequate material was not seen if the patient consents for it. The rate of inadequate aspirates can be reduced by proper training of the person who performs the FNAC and by the use of ultrasound guided FNAC in the case of impalpable or small size swelling.

Category C2 and C3 together accounted for the benign lesions while C4 and C5 accounted for malignant lesions. In the present study, total percentage of benign cases were 76.4% while malignant ones were 20.8%. This was comparable with various other studies who also found benign lesions more common than the malignant ones; the results are as follows. However, studies done by Bhavya et al and Hebbar et al showed a reversed proportion, in which malignant lesions were more common than the benign ones.^{17,26}

21-30 years was the most common age group for benign lesions (C2) in this study; while the most common age group for malignant lesions was above 50 years (51-60 years followed by >60 years). Hebbar et al and Dastayya et al also found the most common age group for benign lesions as 21-30 years.^{12,26} However, in their studies the most common age bracket for malignant lesions was 41-50 years which was a decade earlier than our findings. Pratibha et al found the most common age group for malignant lesion as 51-60 years which was comparable to our study.¹⁶ The earliest case of malignancy in our study was of 38 years age. Aisha et al in their study detected carcinoma breast earliest at the age of 30 years.³ This finding shows that malignancy rates increase with increasing age of patients. However, carcinoma breast can occur at a younger age also.

The most common benign lesion in our study was fibroadenoma (38%) which was also the most common diagnosis of breast lesion overall. Amrittha et al, Khemka et al, Aisha et al, Chirag et al and Manas et al also found fibroadenoma as the most common benign lesion and the most common overall lesion of breast lumps.^{3,18,20,25-27} The second most common benign lesion in our study was epithelial proliferative lesion which was comparable with the study of Bhavya et al.¹⁷ However, Amrittha et al and Khemka et al found fibrocystic disease as the second most common benign lesion in their studies.^{25,27} Fibrocystic disease was the third most common benign lesion in our study. Out of 97 cases of fibroadenoma in our study on cytology, 4 cases turned out to be benign phyllodes and one case of fibroadenomatoid change on histology. Also, from 19 cases of benign epithelial proliferative lesion, 12 turned out to be fibroadenoma. Fibroadenomas are the commonest cause of false-positive diagnosis in FNAC. This is because of the frequent presence of occasional

isolated intact cells with dissociation, epithelial nuclear atypia, and high cellularity. Apocrine metaplasia, multinucleation, and pauci cellularity in hyalinized fibroadenomas are additional pitfalls.

We had 4 (1.6%) cases of tuberculous mastitis on cytology and all these cases were concordant histologically as confirmatory of tuberculosis. They were confirmed by identification of typical histological features under microscopy and detection of tubercle bacilli on Ziehl Neelsen stain. In addition, out of 12 cases of breast abscess, one case turned out to be of granulomatous mastitis. Bukhari et al found 2.3% cases of tuberculous mastitis in their study.²⁸ A single case of breast abscess turned out to be of fat necrosis histologically; the microscopy was characterized by anucleate fat cells surrounded by histiocytic giant cells and foamy macrophages.

The most common malignant lesion in our study was infiltrating ductal carcinoma which was comparable with all the aforementioned studies. A case reported as fibrocystic disease on cytology was discordant on histology as it came out to be usual ductal hyperplasia which was similar to the findings of Jyoti et al.²⁹

Diagnosis of IDC was followed equally by lobular carcinoma and mucinous carcinoma on histopathology. Rani S et al found medullary carcinoma as the second most common malignant lesion after IDC in HPE.¹⁰ We found that all cases of malignancy in FNAC proved to be malignant lesion by biopsy. This was comparable with the study done by Tiwari et al who also found all malignant cases to be concordant histologically.³⁴

In our study, a single case of fibroadenosis on cytology (C2) and a single case of proliferative lesion with atypia (C3) on cytology, turned out to be IDC on histopathology. Similar findings are reported in the literature. Singh D et al in his study found a case of FNAC showing only inflammatory and necrotic material and two cases in FNAC showing fibrocystic disease of breast which turned out to be malignant in the biopsy.¹ Similarly, Vishnu et al 14 found 4 % of benign lesions in FNAC turning out to be malignant on histopathology. Also, one case diagnosed as atypical on cytology was confirmed as carcinoma on histopathology. In the study done by Evith et al out of 4 cases of C3 category, on histopathological examination 2 cases were benign (fibroadenoma and fibrocystic disease), whereas 2 cases were malignant (infiltrating ductal carcinoma).³⁰ We also found fibroadenoma, fibroadenosis as the benign lesions in C3 category apart from three cases of DCIS and a single case of IDC.

Sreedevi et al in their study found reverse of this finding.¹⁵ They found 2 malignant cases of FNAC which turned out to be 1 case of each of fibroadenoma and fibroadenosis on HPE. In the study done by Ramkrishna et al, out of 40 cytologically malignant cases, 39 were found to be concordant on HPE while one case turned out to be fibroadenoma (false positive).⁸

According to a study done by Michael et al it was concluded that FNA of palpable breast lesions is a more sensitive method for the detection of carcinoma regardless of tumor size, type or differentiation.³¹ Also, the addition of core needle biopsy to an already negative FNA failed to increase the sensitivity in the detection of carcinoma.

The overall sensitivity, specificity, PPV, NPV and the diagnostic accuracy in our study was 99.47%, 96.23%, 98.95%, 98.08% and 98.77% respectively. This was compared with various studies. The results are as follows:

This shows that our values are comparable with all other studies.

We had 2 false positive cases. False positive diagnosis is always due to interpretation errors. They are highly undesirable. They occur in the process of evaluation of a rare lesion, diagnostic pitfalls and look alike lesions. False positive diagnosis should be avoided because sometimes surgery or other treatments are performed based entirely on FNA cytologic findings. Factors contributing to false negative results may include the small size of the lesion, hypocellularity, and inadequate sampling during aspiration. Majority of the cases from C4 and all cases of C5 was diagnosed as malignant on HPE. These results were considered as true positive. Both false negative and false positive diagnoses can be reduced by good sampling technique, proper tumour localization, triple assessment, and more importantly availing expert second opinions for doubtful cases.

The reported sensitivities, specificities and positive and negative predictive values vary depending on how insufficient samples are considered (as positive, negative or excluded) and how atypical samples are categorized (positive or negative). The variability in reported sensitivities and specificities depend on the expertise and skill of the aspirator and of the interpreter

Limitation

The main limitation of FNAC is that if sampling is scanty, it may not represent the specimen accurately, which makes the process of diagnosis difficult and necessitates the need of an expert cytologist.

In this study, out of 250 cases of FNAC of breast lump, biopsy was done in 243 cases, 7 were excluded from the study as the cytology sample was inadequate. So, sensitivity and specificity are based on these 243 cases.

CONCLUSION

Fine needle aspiration cytology is an efficient, rapid, patient friendly, easy, repeatable, simple, inexpensive, safe and reliable method which does not require any special instrument or anaesthesia. It causes minimum morbidity with very less complications and has excellent patient acceptance. It is an effective method for the primary categorization of palpable breast lumps into benign,

malignant, atypical, suspicious, and unsatisfactory categories.

Patient comfort is an important consideration when they present to a hospital for treatment. FNAC provides an early pre-operative diagnosis, thus allaying the patient's anxiety. Also, it could help avoid the diagnostic excision/incisional biopsy in most patients.

Inspite of its few limitations, FNAC has high levels of diagnostic accuracy when it is performed by an experienced cytologist. A high sensitivity and a high positive predictive value proved that a positive FNAC in the breast means a definite diagnosis of the concerned pathology if compared with the final histology report. The high specificity and high negative predictive value for malignancy illustrated the high accuracy of FNAC in the diagnosis of breast malignancy. The high accuracy of FNAC bridges the gap between clinical evaluation and final surgical pathological diagnosis in majority of cases. It enables the clinician to obtain a diagnosis in high percentage of cases with minimal expenditure of time and money and often to avoid unnecessary surgery. When the results are obviously benign, patients should be reassured and can be prevented from undergoing unnecessary surgery while in clearly malignant smears, surgery and other treatment should be started without any delay.

The FNAC of breast lump should be used with "triple test" (including clinical, cytology and mammography) for preliminary investigation in outpatient department, which will further enhance the diagnostic accuracy of breast lumps.

Some false negative results are inevitable. Sampling errors and interpretation errors are responsible for false negative results. So, a tru-cut biopsy is recommended whenever a malignancy is suspected clinically or in cases of inadequate material during FNAC. Histopathological study acts as an internal quality measure for cytological diagnosis. Therefore, correlation between clinical examination and histopathology holds high significance in diagnosis of breast cancer

Thus, to conclude, FNAC is a very important preliminary diagnostic test in palpable breast lumps, and if done by expert hands, the results show a high degree of correlation with the final histopathology report. The diagnosis of breast lesions based on FNAC should be practiced as a routine procedure. FNAC is an effective and valid tool as the first line diagnostic modality in the preoperative diagnosis and management of both benign and malignant breast lesions.

Recommendations

Apart from a trained cytologist who will do the procedure, the technical staff should also be well trained regarding the procedure, fixation, transportation and staining of slides, as it increases the test accuracy.

Every case should be clinically and radiologically correlated, if possible.

In cases where the diagnosis is not very clear or the smears are inadequate, there should be no hesitation in advising a repeat procedure or cell block preparation or an excisional biopsy. Cell blocks prepared from residual tissue fluid have been shown to assist in further establishing a more definitive cytopathologic diagnosis. Other limitations of breast FNAC that can readily be overcome by cell blocks are the difficulty in demonstrating invasion and classifying proliferative lesions.

On-site evaluation of the fine-needle aspiration specimens by pathologists using a rapid staining technique (modified Giemsa) should also be used. On-site evaluation of aspirates has been shown to be accurate and cost-effective. It also reduces the likelihood of being recalled for a repeat FNAC and therefore reduces delay in obtaining results.

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