

Cytological/ Histological Evaluation of Palpable and Nonpalpable Breast Lesions and Its Correlation with Ultrasonography

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Breast cancer is the most common form of cancer among women and the second most common cancer in the world (an estimated 1, 152, 161 new cases per year), trailing only lung cancer (1).

Breast carcinoma is a common malignancy in urban women, the second leading cause of cancer related death and the third most common cancer throughout the world.

Women have a lifetime breast cancer risk of approximately 1 in 8 (12%). It is one of the leading causes of cancer mortality among woman (2). The age related incidence has also gradually increased by 3-4% per annum since the 1950s.

The incidence of breast cancer varies greatly around the world, being lower in less developed countries and greatest in the more developed countries (3).

Triple assessment of clinical examination, breast imaging and needle aspiration remains the mainstay of breast cancer diagnosis which includes clinical assessment, radiological imaging and pathological diagnosis. Infact, the incidence is rising in the world due to widespread awareness, and better diagnostic aids to detect the lesion at an early stage.

Although ultrasonography is not considered a screening test, it is more sensitive than mammography in detecting lesions in women with dense breast tissue. It is useful in discriminating between benign and malignant solid masses, and it is superior to mammography in diagnosing clinically benign palpable masses (i.e., upto 97 percent accuracy versus 87 percent for mammography) (4, 5).

Fine-needle aspiration cytology (FNAC) was first described and performed in 1930. Thirty years later, it gained acceptance first in Europe and about a decade later in North America. The method is generally considered as a rapid, reliable, safe diagnostic tool to distinguish non-neoplastic from neoplastic breast lesions.

The FNAC report is extremely important because it gives the necessary information for the management of patients, in order to proceed with more invasive diagnostic methods or surgical treatment, and to decide the nature of surgery. In the preoperative phase, FNAC has taken a fundamental role of both palpable and nonpalpable lesions, using ultrasound or stereotactic guidance (6).

FNAC of breast lump is an accepted and established method to determine the nature of the lump and it may play an important role when it is difficult to determine the nature of breast lump by clinical examination. It has been shown that, FNAC can reduce the number of open breast biopsies. FNAC has been found to have sensitivity ranging from 82% to 97.5% and specificity of more than 99% (7,8 and 9).

AIM

To evaluate and correlate FNAC/ Histopathology of palpable and non breast lesions with ultrasound.

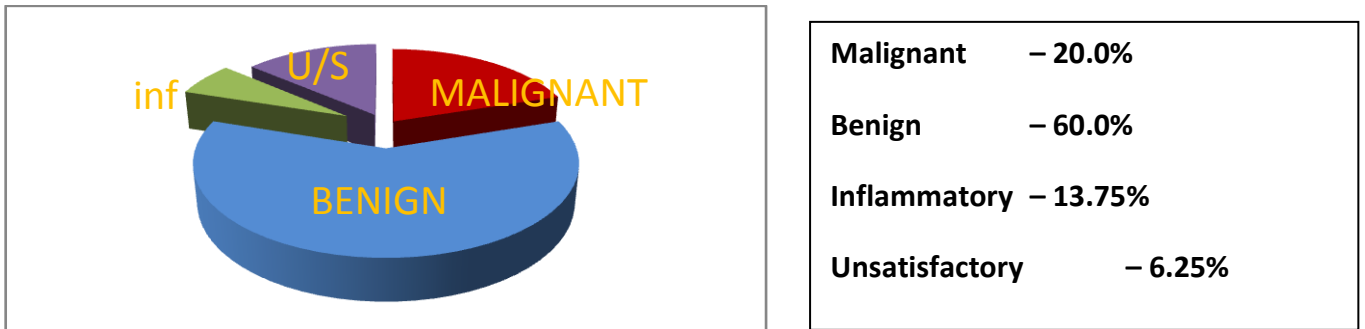
OBJECTIVES

- To evaluate the cases presenting with palpable and non palpable breast lesions from 01 Jul 20013 to 01 Jul 2016.
- Cases to be studied were to undergo sonography as a part of routine screening/ diagnostic modality.
- To correlate FNAC/ Histopathology with sonography in interpretation of breast lesion.

- To validate the use of FNAC in diagnosis of breast lesions and correlate with histopathological findings (wherever available).
- To find the sensitivity, specificity and predictive value of sonography and FNAC used in diagnosis of breast lesions and compare them statistically

RESULTS AND OBSERVATIONS

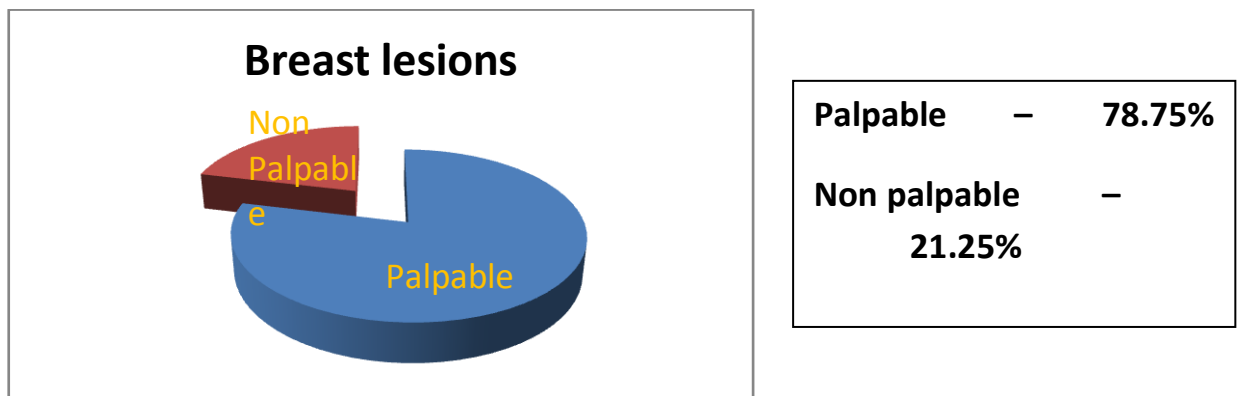
Table – 1: Distribution of total cases



In our study breast lesions were divided into three main groups inflammatory, benign and malignant. Inflammatory - 11/80 cases (13.75%), benign - 48/80 cases (60%), malignant - 16/80 cases (20%) and unsatisfactory – 05/80 (6.25%).

Table - 2 Total no. of cases in palpable and non palpable group

Type of lesions	No. of cases
Palpable	63
Non palpable	17
Total	80



In our study we divided cases into two groups – patients with palpable lumps and patient who did not come with complaints of lump. This group was included in non palpable breast lesions.

Total no. of cases in palpable group were 63/80 (78.75%) and non palpable group was 17/ 80 (21.25%).

Table – 3: Distribution of cases in palpable and non palpable lesions

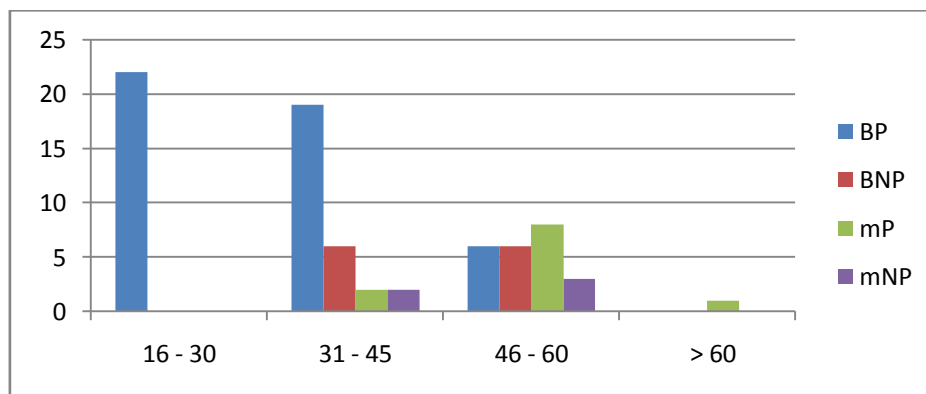
	Palpable	Non palpable	Total
Inflammatory	10 (12.5%)	01 (1.25%)	11 (13.75%)
Benign	37 (46.25%)	11 (13.75%)	48 (60%)
Malignant	11 (13.75%)	05 (6.25%)	16 (20%)
Unsatisfactory	05 (6.25%)	00	05 (6.25%)

Total	63 (78.75%)	17 (21.25%)	80
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In the inflammatory group we had 11/80 cases (palpable – 10, non palpable - 1), in benign group there were 48/80 cases (palpable – 37, non palpable - 11) and in malignant group there were 16/ 80 cases (palpable – 11, non palpable - 5). 05/80 cases (all palpable) were unsatisfactory (inadequate smears on FNAC and no histopathology was available).

Table – 4: Age distribution in breast lesions

	BP	BNP	MP	MNP	Total
16-30	22	0	0	0	22 (29.33%)
31-45	19	6	2	2	29 (38.66%)
46-60	6	6	8	3	23 (30.66%)
>60	0	0	1	0	1 (1.33%)
total	47 (62.66%)	12 (16.0%)	11 (14.66%)	5 (6.66%)	75



BP- benign palpable; BNP- benign nonpalpable; MP - malignant palpable; MNP – malignant non palpable 75/80 cases were divided into type of the lesions as shown in above table (as 05/80 cases were unsatisfactory and final diagnosis was not obtained in these patients). Maximum patients were in age group 31- 60yrs (69.32%). Maximum patients were diagnosed to have benign palpable lumps (62.66%). 11/75 (14.66%) cases were diagnosed to have malignant palpable lumps. All 80 cases were subjected to radiological investigation which included ultrasonography.

Table – 6: Correlation of ultrasonography score with final diagnosis

	0/1 (normal/unequivocal)	2 (benign)	3 (indeterminate)	4/5 (malignant)	Total
Inflammatory					
Duct ectasia		02			02
Abscess		04			04
Granulomatous mastitis		01			01
Lactational mastitis		04			04
Benign breast disease					
Fibrocystic change		15			15
Fibroadenoma		24	01		25
Duct papilloma		04	01		05
Sclerosis			01	01*	02*

adenosis					
Malignant					
Duct carcinoma		01*		13	14*
Lobular carcinoma		01*			01*
Stromal tumor					
Phyllodes benign		01			01
Phyllodes malignant		01*			01*
Total		58 (77.34%)	03 (4.0%)	14 (18.66%)	75

On ultrasonographic evaluation malignancy was diagnosed in 14 cases (18.66%). 13 cases were confirmed on histopathology as duct carcinoma and 01 case was of sclerosing adenosis which was over diagnosed as malignant. 03 cases were put in the category of suspicious which were diagnosed as benign on histopathology (01 case – duct papilloma ; 01 case – sclerosing adenosis ; 01 case fibroadenoma with ADH). There were total 58 cases (77.34%) in benign category of which 03 cases were false negative. 01 turned out to be malignant phyllodes on histopathology and 01 case of duct carcinoma and 01 case of lobular carcinoma.

Table – 7: Correlation of FNAC with Histopathology (where available)

	normal/unequivocal	Benign	suspicious	malignant	Total
Inflammatory					
Duct ectasia		02			02
Abcess		01*			01
Granulomatous mastitis		01			01
Benign breast disease					
Fibrocystic disease		13	02*		15
Fibroadenoma		23	02*		25
Duct papilloma		05			05
Sclerosing adenosis	02*				02*
Malignant					
Duct carcinoma				14	14
Lobular carcinoma		01*			01*
Stromal tumor					
Phyllodes benign		01			01
Phyllodes malignant			01*		01
Total	02 (2.94%)	47 (69.11%)	05 (7.35%)	14 (20.58%)	68

Histopathology was available only in 68 cases (04 cases of lactational change and 03 cases of abscess were offered final diagnosis on FNAC). On FNAC malignancy was diagnosed in 14 cases (20.58%) all of which turned out to be duct carcinoma on histopathology. There were 05 cases (7.35%) in which suspicious of malignancy was given. Of these 05 cases, 02 cases were of fibrocystic disease with atypical ductal hyperplasia, 02 cases were of duct papilloma and 01 case was of malignant phyllodes.

There were 47 cases (69.11%) which were included in benign category. 01 case was false negative which turned out to be lobular carcinoma on histopathology. (01 case which was diagnosed as abscess).

There was scanty aspirate in 2 cases (2.94%) which were diagnosed as sclerosing adenosis on histopathology.

Table -8: Correlation of mammography BIRADS score, USG score & FNAC

	Ultrasonography n = 75	FNAC n = 68*
Normal (0/1)	00 (00%)	02 (2.94%)
Benign (2)	58 (77.34%)	47 (69.11%)
Suspicious (3)	03 (4.0%)	05 (7.35%)
Malignant (4/5)	14 (18.66%)	14 (20.58%)

*68 cases were taken in FNAC (as histopathology of 04 cases of lactational changes and 03 cases of abscess was not indicated).

STATISTICAL ANALYSIS

The statistical tests used in the interpretation of the results obtained in our study were the determination of: Sensitivity of FNAC/ USG as a diagnostic procedure for the entire study Specificity of FNAC/ USG in relation to the malignant lesions Positive predictive value of FNAC/ USG as a diagnostic procedure for the entire study. Negative predictive value in relation to the malignant lesions.

Table –10: Diagnostic failure on Ultrasonography

Diagnostic failure	No. of cases
False positive	01
False negative	03

There was 01 case which was false positive. 3 cases were false negative.

Table – 11: Diagnostic failure on FNAC

Diagnostic failure	No. of cases
False positive	00
False negative	01

There were no false positive on FNAC.

The sensitivity, specificity, diagnostic accuracy, positive predictive value and negative predictive value were calculated with formulas as mentioned above.

Table -12: Comparison by statistical analysis

	Ultrasonography n = 75	FNAC n = 68
Sensitivity	81.2%	93.33%
Specificity	98.20%	100%
Diagnostic Accuracy	94.4%	98.3%
PPV	92.85%	100%
NPV	94.8%	97.8%

DISCUSSION

Modern diagnosis of breast disease is a multidisciplinary activity requiring trained and experienced professionals using specialised equipment with up to date sampling and other diagnostic techniques. Triple assessment, i.e. clinical examination, imaging, and cytological / histological sampling is still regarded as the gold standard (10).

FNAC is the established tool in investigation and management of palpable breast lesions. But it has a limited role in diagnosis of non palpable lesions.

Ultrasound has an established role in assessing breast abnormalities as an adjunct to mammography in older women and as a first line investigation in young women with mammographically dense breasts. Some malignant breast lesions are not visible on mammography but are detected by ultrasound. The use of ultrasound in addition to clinical examination and mammography may result in an increased rate of breast cancer detection (11,12).

Present study was conducted on 80 female patients in Department of Pathology from year jul 2013 jul - 2016. The total inflammatory lesions were 13.75%, benign cases were 60.0% and malignant cases were 20.0%. The prevalence of the disease is in concordance with other studies (13) Patients were divided into palpable and non palpable breast lesions. Non palpable lesions were diagnosed on screening mammogram done in patients with > 40yrs age. Also patient who presented with complaints of nipple discharge/ mastalgia were included in this group. In our study palpable lesions (presenting complaint was lump breast) were 78.75% and non palpable lesions were 21.25%.

In the non palpable group detected by screening/ diagnostic mammogram and then ultrasonography, 1.25% cases were inflammatory, 13.75% were benign and 6.25% were malignant. Maximum patients even in this group had benign breast disease which is supported by literature. Which says that the mammographic and/ or sonographic detection of a non palpable lesions is not always a sign of malignancy; one out of four lesions is commonly reported to be a cancer (14). In the palpable group inflammatory lesions were 12.5%, benign lesions were 46.25% and malignant were 13.75%.

In the 80 patients selected for our study, the age ranged from 15yrs to more than 60 yrs. The maximum patients were from 31 – 45 yrs. In the non palpable group there was no patient < 40yrs or > 60yrs of age. We found that there were no patients before the age of thirty who were detected with malignancy, with the maximum number of patients seen in the 46 – 60 yrs of age. Whereas benign lesions were not seen in patients of age groups more than 60yrs and they were more commonly seen in younger age groups with the maximum number between 31- 45yrs of age.

This age pattern was in concordance with other studies done by Hussain (15) on 50 patients, where the age distribution was between fifteen and sixty-five years and the maximum patients were seen in the thirty one to forty year group (30%). Similar studies done by Homesh et al (16), Tiwari (50) and Ariga et al (17) showed similar age patterns.

In our study unsatisfactory cases were 6.25%. This inadequacy was due to insufficient material aspirated. This is comparable with other studies done by Frable W. J. (1976) where unsatisfactory yield was 8.6% and Anderson et al (1986) where inadequate samples were 10.4% (18, 19).

Our study fulfilled the criterias laid down by European guidelines for quality assurance where acceptable Inadequate rate (INAD) is min < 25%; preferred < 15% (10). Various reasons described for inadequacy in FNAC breast were due to missing the target by the needle as in small fibroadenomas, entering into necrotic region of the tumor or desmoplastic region. Benign conditions like duct ectasia where only acellular material is aspirated. These patients were lost on follow up and no histopathology was available for the same.

Ultrasonography score - 2 i.e benign, was given in 58/75 cases (77.34%) cases. There were 03 cases (5.17%) which were false negative (01- duct carcinoma; 01 – malignant phyllodes; 01 – lobular carcinoma). 02 cases reported as benign in mammography were upgraded to malignant on ultrasonography.

Literature mentions that in Lobular carcinoma because of vague mass and no microcalcification it can be easily missed on radiological investigation (4, 20).

Ultrasonography score – 4/5 ie – were given in 14/75 (18.66%) cases. 13 of which were duct carcinoma on FNAC/ Histopathology and 01 case (false positive) was of sclerosing adenosis

Fine needle aspiration cytology of breast masses has been shown to be a simple and safe diagnostic procedure (21). In our study FNAC was done in 80 cases of which aspirates in 05 cases were inadequate and were lost on follow up for further evaluation. Histopathology was available in 68 cases. FNAC report was also subdivided into four category normal, benign, suspicious and malignant. Subtyping of FNAC was done using the criterias as published by Orell (2005) (22).

There were 2/68 cases (2.94%) which were reported as normal however, on histopathology they were diagnosed as sclerosing adenosis. This is in concordance with the literature that mentions that cytology may not be diagnostic in these cases (10, 22).

47/ 68 cases (69.11%) were reported as benign which were accurately subtyped into various lesions except 01 case (4.25%) (01 case – lobular carcinoma) also 01 case – which was reported as abscess. This 01 case of lobular carcinoma contributed to false negative on FNAC in our study. Literature mentions that lesions like lobular carcinoma, low grade ductal carcinoma and tubular carcinoma carry a risk of false negative diagnosis (10, 22).

There were 05/68 cases (7.35%) which were reported as suspicious and were advised excision biopsy. Of these 02 cases had fibrocystic disease with ADH and 02 cases had fibroadenoma with ADH, 01 case was of malignant phyllodes. The commonest pathology in benign group was that of fibroadenoma (10/23) 36.76%. In their study on 91 patients, Tiwari et al. (21) also reported fibroadenoma as the commonest pathology (39.6%). Other important conditions such as subareolar abscess, invasive ductal cancer, breast abscess, fibrocystic disease, duct ectasia, and galactocoele ranged from 5.5% to 7.7% each.

Size of the needle used for FNAC has often been a point for discussion since patient comfort and patient friendliness is an important aspect of FNAC as a superior diagnostic procedure. Disadvantages of a finer needle were an inadequate aspirate while disadvantages of a thicker needle included pain and hematoma formation. All our patients underwent FNAC using a no. 23 needle with no patient discomfort and none of the patients complained of any untoward side effects. In a study done by Walker et al. (24) showed no statistical difference in the results whichever needle was used in their study.

Image guidance during FNAC is another important aspect of various studies. Increased accuracy is the obvious advantage especially in the smaller, deeper or impalpable lesions. Sonographic and stereotactic guidance have been the most commonly used modalities (25). However in our study only sonographic guidance was used in non palpable breast lesions due to unavailability of the stereotactic machine.

Total malignant cases were 14/68 (20.58%) which were accurately confirmed on histopathology as IDC. Statistical analysis of various diagnostic modalities was performed and is shown as follows.

	Ultrasonography n = 75	FNAC n = 68
Sensitivity	81.2%	93.33%
Specificity	98.20%	100%
Diagnostic Accuracy	94.4%	98.3%
PPV	92.85%	100%
NPV	94.8%	97.8%

Literature (26, 27 and 28) shows that breast sonography can detect an occult malignancy in women with mammographically dense breast parenchyma and normal mammograms. Early detection of breast cancer is associated with good prognosis, thus reducing mortality and morbidity associated.

The sensitivity of ultrasonography has been supported by other studies as shown: (29, 30)

	Sensitivity	Specificity
Yang et al (1996)	97%	97%
Pande AR et al (2003)	95%	94.11%

Ultrasound used liberally as an adjunct to mammography, increases the cancer detection rate by almost 15%. Ultrasound is not only useful in detecting malignancy not visible or not suspected on the mammogram but can also reduce the suspicion of malignancy in some patients although a pathological diagnosis should be obtained in all cases of lumps with suspicious clinical features (26, 27 and 28)

Fine needle aspiration cytology (FNAC) of breast lump is an accepted and established method to determine the nature of the lump and it may play an important role when it is difficult to determine the nature of breast lump by clinical examination. It has been shown that, FNAC can reduce the number of open breast biopsies (21, 31).

FNAC has been found to have sensitivity ranging from 82% to 97.5% and specificity of more than 99% (7, 8 and 9).

Comparison of sensitivity, specificity, positive predictive value and negative predictive value by various authors is as follows: (15, 17 and 32)

Author	Sensitivity	Specificity	PPV	NPV
Hussain et al (2005)	90.9%	100%	-	-
Ariga et al (2002)	99%	99%	99%	99%
Yeoh et al (1998)	79%	98%	92%	94%
Our study (2010)	93.33%	100%	100%	97.8%

Overall sensitivity of FNAC in our study was 93.33% & specificity was 100% which is similar to the various studies done earlier and also, well within the thresholds suggested by European Guidelines for Quality Assurance (2005) where sensitivity - min > 80%, preferred > 90%; Specificity - min > 55%; preferred > 65% and Positive predictive value min > 98%; preferred > 99% (10).

There were no false positive cases and only 01 case was false negative. This data is in keeping up with the literature where false positive varies from 0 - 3.2% and false negative varies from 1- 23% (10, 15, 17 and 31).

False negative cases are attributable to size and location of the tumor, necrosis ,inflammation and scanty aspirates (10).

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 a high negative predictive value for malignancy illustrated the high accuracy of FNAC in the diagnosis of malignancy in the breast. Very importantly, a report negative for malignancy was fairly accurate (>92%) in predicting an absence of malignancy.

SUMMARY AND CONCLUSIONS

- A total number of 80 female patients with palpable/ non palpable breast lesions were taken in this descriptive analytical study.
- The age group ranged from 16 to > 60yrs with mean age of 36.4 yrs in benign lesions and 49.0 yrs in malignant lesions.
- The most common presenting complaint was breast lump followed by nipple discharge and mastalgia.
- Maximum number of patients were diagnosed to have benign breast disease.
- Fibroadenoma is the most common benign breast lesion diagnosed in patients in the 31- 45yrs of age group.
- The sensitivity, specificity and diagnostic accuracy of mammography in our study was 75 %, 94.8% and 89.09 % respectively..
- Ultrasonography imaging of breast lesions enjoyed 81.2 % sensitivity, 98.20 % specificity and 94.4 % diagnostic accuracy in our study.
- However, FNAC is the simple, rapid and cost effective procedure. There are no false positive reports.
- FNAC enjoys high specificity, positive predictive value and negative predictive value of 100 %, 100 % and 97.8% respectively in our study.
- The high specificity and a high negative predictive value for malignancy illustrated the high accuracy of FNAC in the diagnosis of malignancy in the breast.
- Very importantly, a report negative for malignancy was fairly accurate (>92%) in predicting an absence of malignancy.
- In developing countries like ours, economical restrictions, low budget for health care and screening program put the patients at a disadvantage because of the high cost of sophisticated diagnostic methods, thus we recommend that FNAC be used as a routine diagnostic method because of its low cost compared with the others and this policy maximizes the availability of health care to women with breast cancer.
- In centers with facility of sonography and mammography, the diagnostic accuracy stands much improved when used prior to FNAC/ biopsy.
- We conclude that FNAC still plays an important and essential role in the management of patients with breast lesions and also offers a great potential for prediction of patient outcome and assessment of risk of developing breast cancer

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**ANNEXURE - B
MASTER CHART**

S. No.	Age/ Sex	Duration	Symptoms	Clinical diagnosis	Mammography	USG	FNAC	Histopath
Inflammatory Duct ectasia (palpable)								
1.	45/F	2 mths	L/Nd	F	2	2	(B)DE	DE
Duct ectasia (non palpable)								
2	49/F	15 d	Nd	M	2	2	(B)DE	DE
Granulomatous mas								
1.	31/F	2mths	L	F	2	2	(B)GM	GM
Abscess								
1.	34/F	07 d	p/L	Mas	2	2	(B)Mas	NA
2.	24/F	10 d	p/L	Mas	1	2	(B)Mas	NA
3.	25/F	10 d	p/L	Mas	1	2	(B)Mas	NA
4.	30/F	25 d	p/L	Mas	2	2	(B)Mas	Filarial worm*
Lactational change								
1	22/F	20d	L/p	G	1	2	(B)G	NA
2	23/F	25d	L/p	F	1	2	(B)G	NA
3	28/F	25d	L/p	F	1	2	(B)G	NA
4	30/F	27d	L/p	G	1	2	(B)G	NA

Benign proliferative breast disease Fibroadenoma (palpable)								
1.	31/F	4mths	L	F	2	2	(B)F	F
2.	32/F	5mths	L	F	2	2	(B)F	F
3.	35/F	5mths	L	F	2	2	(B)F	F
4.	28/F	2mths	L	F	2	2	(B)F	F
5.	38/F	12mths	L	F	2	2	(B)F	F
6.	42/F	13mths	L	F	2	2	(B)F	F
7.	25/F	6mths	L	F	1	2	(B)F	F
8.	26/F	6mths	L	F	2	2	(B)F	F
9.	25/F	12mths	L	F	1	2	(B)F	F

10.	18/F	1mth	L	F	0	2	(B)F	F
11	40/F	16mths	L	F	2	2	((B))F	F
12	32/F	3mths	L	F	2	2	(B)F	F
13	34/F	4mths	L	F	2	2	(B)F	F
14	22/F	1mth	L	F	1	2	(B)F	F
15	24/F	1mth	L	F	2	2	(B)F	F

ABBREVIATIONS

- D – Days
- L – Lump
- Nd – Nipple discharge
- p – Pain
- mas - Mastitis
- B – Benign
- S – Suspicious
- M – Malignant
- DE – Duct ectasia
- GM – Granulomatous mastitis
- G – Galactocoele
- BBD – Benign Breast Disease
- F – Fibroadenoma
- FC – Fibrocystic disease
- DP – Duct papilloma
- S ad – Sclerosing adenosis
- ADH – Atypical ductal hyperplasia
- Dca – Duct carcinoma
- IDC – Infiltrating Duct Carcinoma
- ILC - Infiltrating Lobular Carcinoma
- St. Tum – Stromal tumor
- Phy - Phyllodes
- NA – Not Available
- Ac – Acellular