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Original Research Article

A STUDY ON DIAGNOSTIC ACCURACY OF FRESH FROZEN BIOPSY IN THE DIAGNOSIS OF FNAC INCONCLUSIVE BREAST LUMP

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ABSTRACT

Background: The breast lump comprises wide spectrum of diseases ranging from benign to malignant diseases. So far as treatment is concerned, benign breast diseases are managed with simple assurance or excision and those which are malignant need much extensive procedures. Early diagnosis of the diseases limits the extensive procedures and also cuts down the waiting period and hence the study. **Material and Method:** It is prospective study conducted at department of general surgery of Govt. RDBP Jaipuria Hospital attached to RUHS CMS including 50 patients taken over a period of 1 year who came with clinically palpable breast lump and whose reports to be FNAC inconclusive. **Results:** In this study, the most common age group is 40-60. Upper outer quadrant of right breast being the most common site involved (34%). **Conclusion**: fresh frozen biopsy is simple and safe without significant morbidity and thus can be used a tool in the management of breast lump where FNAC reports are inconclusive.

Keywords: Breast lump, FNAC, fresh frozen biopsy, mammography, BIRADS.

INTRODUCTION

Postpartum Breast neoplasms encompass a heterogeneous group of lesions that may be presenting as a palpable mass, nonpalpable abnormality detected on imaging analysis or an incidental microscopic finding. They constitute a wide spectrum of histological lesions ranging from a benign tumor at one end approximating to carcinoma at the other end. Breast cancer is the most common cancer in women in India and accounts for 14% of all cancers in women**(1,2)** and having recently overtaken cervical cancer in this respect**(3)**.

So far as treatment is concerned, benign breast diseases are managed with simple assurance or excision and those which are malignant need much extensive procedures.

Traditionally, if the clinical diagnosis of breast lump is suspected as carcinoma and fine needle aspiration cytology or core needle biopsies are inconclusive prior to major radical surgery; fresh tissue is submitted for frozen section examination before immediate mastectomy.

Although other methods have been developed to reach a preoperative diagnosis such as imprint and smear cytology, fine needle aspiration and intraoperative cytology, frozen section still plays an important role in aiding the surgeon to choose the definitive treatment without any further delay. Traditionally fresh frozen biopsies are used for assessing sentinel lymph node biopsy which used to guide axillary dissection **(4)**.

MATERIALS AND METHOD

Study Site: The study was conducted in department of general surgery, among indoor and out-door patients of GOVT RDBP Jaipuria Hospital attached to RUHS College of Medical Sciences. All female patients of age 18 years and above presented at surgery OPD during study at RDBP Jaipuria Hospital with breast lump that are clinically suspected to be malignant. This is Hospital based observational diagnostic study. Sample Size and Sampling Technique: In our study, we intend to include 50 patients. The total duration of study was one year.

Inclusion criteria: Female patients 18 yrs and above with lump in the breast who are willing for surgery with following features on investigation: Mammography: BIRADS category 3 or 4 FNAC: Inconclusive

Exclusion criteria:i. Proven case of carcinoma breast on FNAC or core needle biopsy.ii.Breast diseases with signs of metastasis.iii.Breast lump in pregnancy and lactation

Methods: The study was conducted in Dept. of surgery in govt. RDBP Jaipuria hospital. All female patients of age 18 years or more with clinically palpable suspected malignant breast lump was included in this study.

Patient was informed about the disease and treatment plan and written consent was taken from the patients to include them into the study

Detailed history and clinical examination including general physical, systemic and local examination of breast and axilla was done Palpable masses are characterized according to their size, shape, consistency, location and fixation to skin.

They were further subjected to USG breast and mammography. Patients whose breast lumps belong to BIRADS category 3 or 4 was further subjected to FNAC. When FNAC is inconclusive, patient were counselled for Fresh Frozen biopsy after taking consent patient is take in to the OT for fresh Frozen Biopsy, the result of which decides the further treatment. The results of frozen section were compared with final diagnosis reached by histopathological examination.

RESULTS

Among 50 study patients, 16% of the patients were in the age group of 30-40 years, 30% in the age group of 41 50 years, 30% in the age group of 51-60 years, 24% in the age group of 61 to 70 years, and 2% in the age group of above 70 years. The mean age of patients was 52.00 ±10.94 years. Maximum numbers of patients were in the age group of 41-60 years.

In our study right breast was more involved (66%) compared to left (34%). In the right breast cases were presented as Lump in upper outer quadrant in 34% followed by Lump in lower inner quadrant in 14% (n = 7) of the patients, The commonly observed size of the lump on examination was > 5 cm in 21 (42%) of the patients followed by <5cm in 29 (58%)cases and surface was Irregular in 43(86%) with firm consistency was 47(94%) and rest 3(6%) were hard in consistency. Among 50 study patients, 6% of the patients were having family history of Ca breast in maternal side

Table 1.Distribution of the cases according to fresh frozen biopsy:

Fresh Frozen Biopsy	Number	Percentage (%)
Benign		
Chronic granulomatous pathology	5	10
Fibrocystic disease of breast	16	32
Fibroadenosis	3	6
Duct ectasia	2	4
Malignant		0
Ductal carcinoma	11	22
Ductal carcinoma in situ	5	10
Malignant epithelial neoplasm	4	8
Infiltrating duct carcinoma	3	6
Malignant neoplasm with signet ring cells	1	2
Total	**50**	**100**

According to fresh frozen biopsy report , among 50 study patients, commonly observed findings was Benign pathology, Fibrocystic disease of breast was

in 26% followed by Chronic granulomatous pathology in 10% and in malignant conditions, Ductal carcinoma (22%,) Ductal carcinoma in situ (10%).

Table 2.Distribution of the cases according to HPE:

HPE	No	Percentage (%)
Benign		0
Fibrocystic disease of breast	15	30
Chronic granulomatous pathology	5	10
Fibroadenosis	3	6
Duct ectasia	2	4
Malignant		0
Ductal carcinoma in situ	8	16
Invassive duct carcinoma	8	16
Ductal carcinoma breast	7	14
lobular carcinoma in situ	1	2
Oncocytic neoplasm	1	2
	50	**100**

According to histopathological examination, among 50 study patients, in Benign pathology Fibrocystic disease of breast was 30%, followed by Chronic granulomatous pathology in 10% and in malignant pathology, Ductal carcinoma in situ and Invasive duct carcinoma both were 16%.

Table.3 Diagnostic efficacy of the Fresh Frozen Biopsy against Histo pathological Diagnosis (Gold Standard):

	Histopathological Diagnosis (Gold Standard)				
Fresh Frozen Biopsy	Malignant		Benign		Total
	No	%	No	%	
Malignant	24	96	0	0	24
Benign	1	4	25	100	26
Total	**25**	**100**	**25**	**100**	**50**

The diagnostic efficacy of the Fresh Frozen Biopsy against Histo pathological Diagnosis (Gold Standard). The sensitivity 96% specificity 100% PPV 100% NPV 96.15% and accuracy was 98%.

DISCUSSION:

Globally breast cancer is the most common cancer in females. Significant variations are noted in geographic, socio-demographic, and histo-morphological profiles. International variations in incidence and mortality rates are a striking feature of breast cancer. Numerous studies have shown that majority of breast lesions are benign and requires only reassurance **(5)** Early screening and diagnosis of breast lesions can aid in prevention as well as accurate management of the patients thus alleviating discomfort and anxiety in the process **(6,7)**.

In this study, among 50 study patients, 16% of the patients were in the age group of 30-40 years, 30% in the age group of 41 50 years, 30% in the age group of 51-60 years, 24% in the age group of 61 to 70 years, and 2% in the age group of above 70 years. The mean age of patients was 52.00 ±10.94 years. Maximum numbers of patients were in the age group of 41-60 years. According to Fletcher's textbook8, breast cancer can occur at any age, but rare in patients younger than 25 years and over 80 years; the peak incidence is between 45 and 60 years. Christiana SJ9 also studied on age range of patients was 20-70 with a median of 45 years this shows that this difference could be due to reproductive, environmental, and dietary factors. Shah Alam Sheikh. et al**(10)** also observed that the most common age group of malignancy of the breast was (41-50) years. This implies that most common age group of malignancy of the breast was middle age groups. Premenopausal and perimenopausal incidence are reported in Indian **(11,12)** other Asian **(13,14)** and African countries.**(15,16)**

In our study, among 50 study patients, commonly observed site was right (66%). Most of the patients were presented with lump in upper outer quadrant of R breast in upper outer quadrant (34%) followed by lump in lower inner quadrant (14%) Preponderance of right side is noted in some studies reflecting the ethnic variation in population**(11,17)**. The possible explanations are that upper outer quadrant has a relatively large volume of breast tissue**(15)**.

In our study, it is observed that only 6% of the patients were having family history of Ca breast in maternal side and our finding was similar with the study conducted by Raina et al **(18)** who noticed only 7% patients with history of breast cancer in their first degree relative. Rosen etal.**(19)** observed

31% of the patients reported with one or more relatives who were known to have had breast cancer in a study on 1024 patients. Family history is an important breast cancer risk factor, and can cause considerable anxiety to women **(20)**.

In our study, the commonly observed size on examination was < 5 cm in 42% of the patients followed by <5cm in (58%) cases.

In this study, commonly observed surface of the lumps were Irregular 43(86%) and rest were regular. Consistency was firm in 47 (94%) and rest 3 (6%) were Hard in consistency. Nipple and areola complex among 50 study patients, 94% cases were normal. Bloody discharge from nipple was seen in 3 cases (6%). Frequencies of symptoms in breast carcinoma reported by WHO are 60-70% for breast lump, 14-18% for pain, 7-9% for nipple problems, 1% for deformity, 1% for inflammation21. In a study by Raina, et al **(18)**, most of the patients i.e., 96.5% presented with breast lump. 15.8% patients had pain, and 4.9% had nipple discharge in addition. Mode of presentation of the patients in the present study shows almost similar picture of the other studies.

According to Fresh frozen biopsy among 50 study patients, commonly observed findings was in favour of Benign conditions, Fibrocystic disease of breast was in 26% followed by Chronic granulomatous pathology in 10% and in malignant conditions, Ductal carcinoma (22%,) Ductal carcinoma in situ (10%). In the study of Parikshit Patil**(22)** breast comprised sixteen cases; Infiltrating ductal carcinoma (13 cases), benign phyllodes (02 cases) and fibroadenoma (01 case). Shah Alam Sheikh. et al. (2016) **(9)** observed that following Frozen Section, out of the total 70 cases, 47.14% were benign lesions and 52.86% were malignant. Out of the 33 benign lesions, fibroadenoma (18 cases) was the commonest followed by fibrocystic disease (9 cases), epithelial hyperplasia (4 cases), 1 case each of benign phyllodes and granulomatous mastitis. Infiltrating duct carcinoma was the commonest malignant breast lesions (34 cases) followed by 1 case each of DCIS, Infiltrating lobular carcinoma and malignant phyllodes (1.43%) respectively.

Considering among 50 study patients, Benign pathology, commonly observed was Fibrocystic disease of breast was30%, followed by Chronic granulomatous pathology 10%, and in malignant pathology, Ductal carcinoma in situ and Invassive duct carcinoma 16%.

Rakhshindah Bajwa et al**(23)** found that among benign breast lesions (232 cases), fibroadenoma was the commonest benign breast lesion, 161 cases (69.39%), followed by fibrocystic disease, 60 cases (25.85%), Intraductal carcinoma, 2 cases (0.86%), atypical ductal hyperplasia, 2 cases (0.86%)**(27)**. Rosen studied 857 cases of invasive breast carcinoma, and found ductal carcinoma 75%, lobular carcinoma 10% and medullary carcinoma 9%. In the Shah Alam Sheikh. et al**(10)** observed that 32 benign lesions (45.71%), fibroadenoma18 cases (56.25%) being the commonest benign lesion followed by fibrocystic disease 9 cases (28.12%), epithelial hyperplasia, 3 cases (9.37%),1 case (3.13%) of benign phyllodes and 1 case (3.13%) of granulomatous mastitis. Out of the 38 cases (54.29%) of malignant breast lesions, infiltrating duct carcinoma being the most common malignant breast lesion,36 cases (94.74%) followed by 1 case (2.63%) and 1 case (2.63%) of infiltrating lobular carcinoma and malignant phyllodes respectively.

Diagnostic accuracy of Fresh Frozen biopsy:

Frozen Section, analysis of the present study revealed sensitivity of 96%, specificity 100%, PPV 100%, NPV 96.15% and accuracy was 98% well within the range reported in literature. The overall accuracy of frozen section diagnosis reported in the literature varies from 92% to 97.98% **(24,25)**.

Author	Year	Sensitivity (%)	Specificity %	Ppv (%)	Npv (%)
Chandramouleeswari K et al (26)	2013	…	…	…	…
Parikshit Patil(22)	2015	97.22	96.3	98.59	92.86
Shah Alam Sheikh. et al(10)	2016	97.37	100	100	100
Present study	2019	96	100	100	96.15

CONCLUSION

Breast cancer is the most common cancer with varied presentations in females posing a major health problem. There is a need for expedient evaluation of breast masses with an improved clinical and pathological characterization. The burden of breast cancer has to be brought down toward a declining trend.

Hence, there is an urgent need to increase population screening program for early detection, training of

women (breast self-examination), health worker, and medical practitioners. At present mammography serves as a screening tool but is less likely to be effective due to its insensitivity in high-density breast tissue at younger age. Moreover, most patients in our set up are unable to afford mammography due to their poor socio-economic background.

Multimodality treatment approach is required for malignant breast lump which has shown improvement in both loco regional control and survival.

FNAC is thus considered to be a rapid, cost-effective highly sensitive and highly specific first minimal invasive method in diagnosing breast lumps.

According to fresh frozen biopsy most common suggest fibrocystic disease which is a benign condition (32%) and among malignant conditions ductal carcinoma is most common comprising 22% of total. Sensitivity of fresh frozen biopsy is 96%, specificity 100%, positive predictive value is 100%, negative predictive value 96.15 and diagnostic accuracy is 98%. This procedure is simple and safe without significant morbidity and thus can be used a tool in the management of breast lump where FNAC reports are inconclusive.

This procedure is simple and safe without significant morbidity; Definitive treatment can be discussed and scheduled based on fresh frozen biopsy report.

Thus fresh frozen biopsy is a good alternative when reports of FNAC are inconclusive in diagnosis and management of breast lump.

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