

**Role of Frozen Section Evaluation in Patients with Breast Lumps**Yogesh Dighe<sup>1</sup>, Smita Hilalpure<sup>2</sup>, Shubhangi N Jibhkate Bawankule<sup>3</sup>, Richa Lath<sup>4</sup>,  
Aniruddha Jibhkate<sup>5</sup><sup>1</sup>Senior Resident, Department of Pathology, Vasanttrao Pawar Medical College, Hospital and Research Centre, Nashik<sup>2</sup>Assistant Professor, Department of Pathology, Government Medical College, Parbhani<sup>3</sup>Assistant Professor, Department of Pathology, Government Medical College and Hospital, Nagpur<sup>4</sup>Professor, Department of Biochemistry, DMMC, Nagpur<sup>5</sup>Professor, Department of Physiology, DMMC, Nagpur

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**Abstract:****Background:** Adverse drug reactions (ADRs) are known causes for increased mortality, and morbidity. The aim of this study is to assess the knowledge, attitude, and practice of pharmacovigilance among the second year Medical, Pharmacy, Dental and Nursing students.**Materials and methods:** This is a cross sectional questionnaire based study and 345 Health Care students from various branches of second year students were selected non-randomly as the participants. This study was conducted at CAIMS, Bommakal, Karimnagar. Institutional ethical committee approval was obtained from the Institution prior to the study. Pre-design validated and self-administered Knowledge, attitude, and practices (KAP) questionnaire on Pharmacovigilance was structured in Google form and the link was sent to the students. The response was analyzed by chi – square test and one way ANOVA by using the SPSS software Version -20.**Results:** The distribution of knowledge about the pharmacovigilance in the MBBS students have more adequate knowledge 44 (24.6%) than other professional students and the dental students have poor knowledge 28 (34.1) than other professional students. The awareness of ADRs reporting was higher in MBBS students 168(93.9%) than other professional students. Over all practice of ADR among the professional student showed more negative response.**Conclusion:** This study concluded that the continuous education and training about the PV and ADR reporting system is necessary for all healthcare students.**Keyword:** Adverse Drug Reaction, Pharmacovigilance, KAP questionnaire.This is an Open Access article that uses a funding model which does not charge readers or their institutions for access and distributed under the terms of the Creative Commons Attribution License (<http://creativecommons.org/licenses/by/4.0>) and the Budapest Open Access Initiative (<http://www.budapestopenaccessinitiative.org/read>), which permit unrestricted use, distribution, and reproduction in any medium, provided original work is properly credited.**Introduction**

Breast cancer remains a major public health concern, with incidence rates on the rise globally. Despite ongoing prevention efforts, projections indicate further increases over the next two decades. Contributing to this trend are factors such as earlier menarche, delayed first pregnancy, fewer childbirths, reduced breastfeeding, and later menopause, alongside rising rates of obesity, alcohol consumption, sedentary lifestyles, and hormone replacement therapy (HRT) use. [1]

Breast carcinoma is a heterogenous disease, exhibiting diverse clinical behaviours, representing one of the most prevalent malignancies affecting women worldwide. With over 1,000,000 new cases diagnosed annually and a notable uptick in diagnoses, particularly among younger women, breast cancer poses substantial threats to both physical and mental well-being. [2] Annually,

approximately 1.38 million individuals are impacted by this disease. [3]

Historically, breast tissue has been a subject of intense study. One of the earliest organs to be studied by frozen section in the year 1891 was the breast. Since then, frozen section has been an invaluable and a popular tool for intra-operative evaluation of breast lumps. While Fine Needle Aspiration Cytology (FNAC) has since supplanted frozen section evaluations for breast lumps in many cases, the latter remains relevant, especially when FNAC yields inconclusive results. This study aims to assess the indications for frozen section requests in breast lump evaluations and to evaluate the method's accuracy, false positivity, and false negativity. Results will be compared with existing literature to re-evaluate the role of frozen section diagnosis in the current diagnostic landscape. [4]

### Aim & Objectives

1. To study the role of frozen section evaluation in patients with breast lumps
2. To calculate the overall accuracy, false positivity, false negativity for frozen section of breast lumps.
3. To correlate frozen section of breast lumps with FNAC and mamography
4. To compare the data with that of published literature on frozen section of breast lumps.

### Materials & Methods

This prospective study, conducted at the Department of Pathology, GMC Aurangabad, spanned from November 2018 to October 2020, enrolling 51 cases of females having breast lumps undergoing Frozen section analysis. Comprehensive evaluation of patients with breast lumps, inclusive of clinical details and various investigations (hematological, radiological, cytological, frozen section, and histopathological), was performed.

**Inclusion Criteria:** Female patients with hard, non-tender breast lumps categorized as BIRADS(breast imaging reporting & data system) 4 or 5 on mammography and exhibiting inconclusive/atypical hyperplasia on FNAC.

#### Exclusion Criteria:

- Confirmed carcinoma cases via core needle biopsy.
- Metastatic breast carcinoma.
- Male breast lumps.
- Breast lumps during pregnancy.

Female patients aged 40 years and above, presenting with firm to hard, irregular, non-tender breast lumps clinically suspicious for malignancy,

underwent sonomammography. Patients with BIRADS(Breast Imaging Reporting and Data System) category 4 or 5 lesions proceeded to FNAC. Inconclusive FNAC cases underwent incisional biopsy or lumpectomy, with specimen analysis by both frozen and paraffin sections. Results from frozen sections were compared with final diagnoses from paraffin sections. Cryostat machine Leica CM 3050 S was utilized for frozen section examination.

A frozen section diagnosis of infiltrating neoplasia was reported only with unequivocal evidence, while in situ carcinoma was considered a provisional diagnosis needing confirmation. Doubtful diagnoses were deferred to paraffin sections, categorized by technical imperfection, focal nature of lesion, or morphological misinterpretation. Results and causes of concordant, discordant, and deferred cases were recorded on a pre-designed proforma.

After rendering the frozen section diagnosis, tissues were thawed, fixed in formalin overnight, and processed for paraffin embedding. Remaining unfrozen tissue was also formalin-fixed for paraffin embedding.(5) Evaluation emphasized studying paraffin-processed sections alongside actual frozen section slides. Lesions were classified as fibrocystic disease, fibroadenoma, inflammatory lesions, and malignancies, with further subclassification wherever possible. [5]

### Results

In the present study, 51 cases of breast lump that had undergone Frozen section examination were enrolled.

Following observations were made.

**Table 1: Age distribution of patients studied (n=51)**

Age in years	Number of patients	Percentage (%)
21-30	7	13.7
31-40	17	33.34
41-50	12	23.59
51-60	7	13.7
61-70	7	13.7
71-80	1	1.97
<b>Total</b>	<b>51</b>	<b>100</b>

In the present study, age ranged from 21 to 80 years. Majority 36 cases (70.63%) belong to 31 to 60 years.(Table 1)

**Table 2: Menstrual status of patients studied (n=51)**

Menstrual status (age in years)	Number of patients	Percentage (%)
Reproductive	31	60.8
Postmenopausal	20	39.2
<b>Total</b>	<b>51</b>	<b>100</b>

In our study, 31(60.8%) patients were in reproductive age and 20(39.2%) patients were postmenopausal age .(Table 2)

**Table 3: Side of involvement of breast lump (n=51)**

Side involved	Number of patients	Percentage (%)
Right side	22	43.14
Left side	29	56.86
<b>Total</b>	<b>51</b>	<b>100</b>

Majority of cases 22 (43.14%) presented with right side of involvement and 29 (56.86%) presented with the left side.(Table 3)

**Table 4: Duration of Breast Lump in months (n=51)**

Duration in months	Number of patients	Percentage (%)
0-6 months	35	68.62
7-12 months	5	9.8
13-18 months	2	3.92
19-24 months	6	11.76
>24 months	3	5.9
<b>Total</b>	<b>51</b>	<b>100</b>

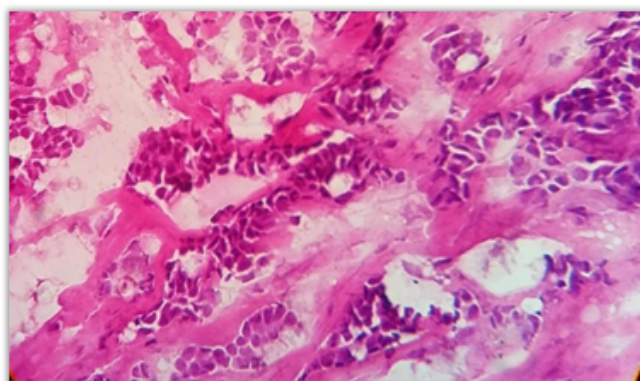
Duration of breast lump in majority of cases 35 (68.62%) was 0 to 6 months, while in 3(5.9%) cases presentation was more than 24 months.

**Table 5: Paraffin section diagnosis of 51 breast frozen requests.**

Paraffin Section Diagnosis	No.	Percentage (%)
Infiltrating duct carcinoma	21	41.17
Fibroadenoma	15	29.41
Fibrocystic disease of breast	4	7.84
Intracystic papillary carcinoma of breast	1	1.96
Phyllodes tumors	2	3.92
Paget's disease	1	1.96
Duct ectasia	1	1.96
Inflammatory lesion(mastitis)	5	9.8
No evidence of malignancy	1	1.96
<b>Total</b>	<b>51</b>	<b>100</b>

Out of the 51 breast lesions received for a primary diagnosis, 22 were malignant and 29 were benign. As expected, the maximum frozen requests (41.17%) were for lumps diagnosed ultimately on paraffin sections as infiltrating duct carcinoma(fig 1, 2) and 29.41% lumps were diagnosed as

fibroadenoma whereas 7.84% lumps subsequently diagnosed as fibrocystic disease of the breast. 9.80% lumps were diagnosed as Inflammatory lesions (mastitis). This represents the general pattern of accession of breast lumps in the pathology laboratory.(Table 5)

**Figure 1: Frozen section slide, Invasive Breast Malignancy (40X)**

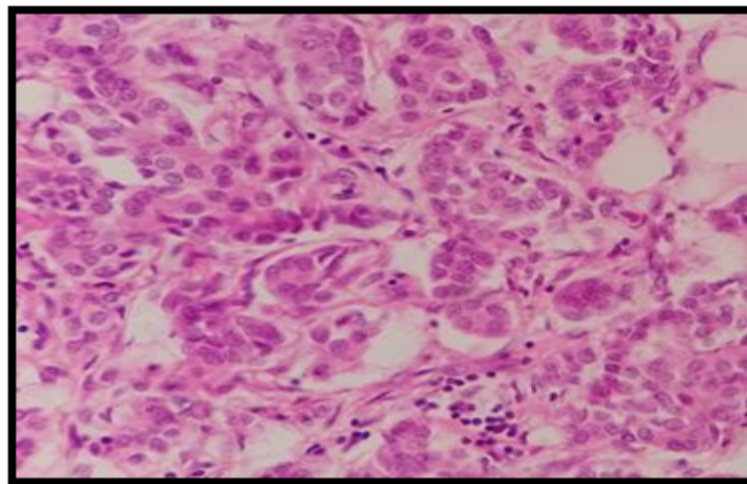


Figure 2: Paraffin section slide, Invasive Breast Malignancy (40X)

Table 6: Frozen section diagnosis versus paraffin section diagnosis (n = 51)

Frozen Diagnosis	Total No.	Paraffin section Diagnosis		False Positive	False Negative	Accuracy%
		Benign	Malignant			
Benign	28	27	1		1	98.73
Malignant	22	-	22		-	100
Deferred	1	1				
Total	51	28	23	0%	0.42%	99.57

On comparing the frozen section diagnoses with paraffin section diagnoses (Table 6) it was found that there were no false positives and 0.42% false negative results. The accuracy for benign lesions was 98.73%, for malignant lesions it was 100%, and the overall accuracy was 99.57%. The term deferred included the category "Await paraffin section". The deferred diagnoses were labelled as no evidence of malignancy.

Table 7: Minor modifications of the frozen diagnosis

Frozen Section Diagnosis	No.	Paraffin Section Diagnosis
Infiltrating duct carcinoma	1	Duct carcinoma in situ
Benign breast lesion? FA with epithelial hyperplasia	1	Benign phyllodes tumor with epitheliosis with apocrine change
s/o Proliferative disease of breast	1	Chronic granulomatous mastitis

There are 3 cases in which minor modification frozen diagnosis was necessary after studying paraffin sections (Table 7)

Table 8: Prior FNAC Diagnosis in 29 breast lumps sent for Frozen Section

FNAC Diagnosis	Total no.	Frozen Diagnosis	
		Malignant	Benign
Malignant disease	4	4	-
Benign breast disease	14	3	11
Suspicious (frozen Section diagnosis suggested)	7	7	-
Inconclusive	4	2	2
Total	29	16	13

In the present study, 56.86% of frozen sections on breast lumps were requested despite earlier FNAC evaluation as shown in [Table 8]. Seven cases of the FNACs were suspicious for malignancy for which tissue diagnosis was suggested and four cases were inconclusive. In both the above situations frozen was essential.

Table 9: Correlation of BI-RADS categories II,III,IV,V with frozen diagnosis

BI-RADS	Frozen diagnosis		
	Benign %(n)	Malignant %(n)	Total n (20)
II	100(8)	-	8
III	75(3)	25(1)	4
IV	42.85(3)	57.15(4)	7
V	-	100(1)	1



Out of 51 cases, 20 underwent mammography screening tests. Among these 20 cases, the distribution of mammographic diagnoses according to BI-RADS categories was as follows: 40% (8) for category II, 20% (4) for category III, 35% (7) for category IV, and 5% (1) for category V. Out of these 20 cases, 6 had a frozen diagnosis of malignant disease. Among these, one was classified as BI-RADS category III, four were in category IV, and one was in category V.(Table 9)

### Discussion

Breast carcinoma ranks as the second most prevalent malignant tumor among rural Indian women, trailing only carcinoma cervix. However, in urban areas, breast carcinoma surpasses carcinoma cervix in incidence. Frozen section

analysis proves valuable for diagnosing breast lumps, assessing axillary nodes, and examining lumpectomy margins. Although fine-needle aspiration cytology (FNAC) is a cost-effective technique commonly used for evaluating breast lumps and axillary nodes, situations necessitating frozen section evaluation include:

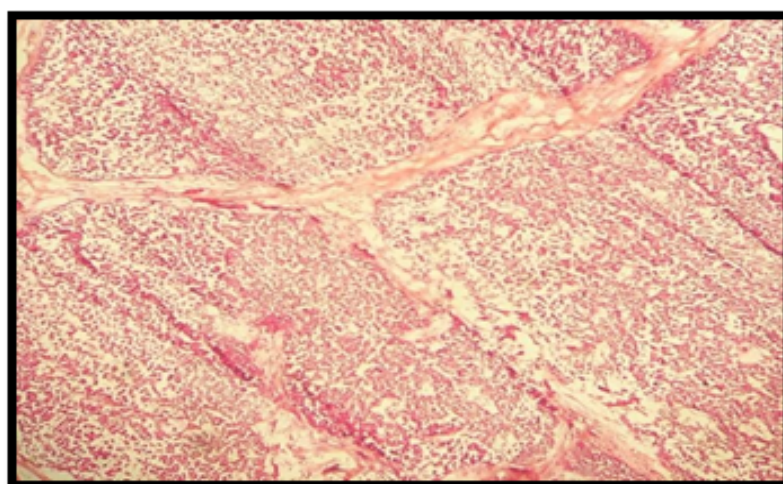
1. Scanty or acellular aspirates due to desmoplastic reactions or extensive necrosis.
2. Low cytologic grade tumours.
3. Lesions presenting as lobular carcinoma or lymphoma, where distinguishing between the two is therapeutically crucial.
4. Assessment of lumpectomy margins.

**Table 10: Comparison with other other studies for accuracy of breast frozen section diagnosis**

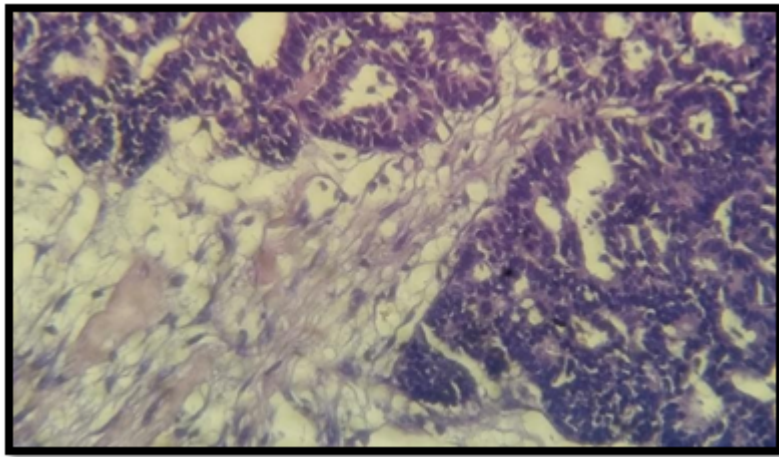
Author(s) (year)	No. of Cases	FALSE Positive%	FALSE Negative%	Diagnosis Deferred %	Accuracy %
Simmonetta [6](1994)	672	0.44	3.57	3.27	95.84
Brunner et al.,2009 [7]	120	0	3.3	0	99.36
Kaira et al., 2018 [8]	115	1.7	0	3.5	98.3
Mahadevappa et al., 2017 [9]	62	1.62	0	1.60%	98.3
Present Study (2018)	51	0	0.96	0.84	99.57

Published data analysis regarding frozen section examination of breast lumps revealed an accuracy rate ranging from 95.84% to 98.3%, false positivity rate between 0% to 1.62%, false negativity rate between 0% to 3.57%, and deferral rate between 0% and 3.27% (Table 10). Our study exhibited an accuracy rate of 99.57%, false positivity rate of

0%, false negativity rate of 0.96%, and deferral rate of 0.84%, falling within established literature ranges. [4] A single false negative diagnosis in our study occurred due to an error of interpretation, wherein an intracystic papillary carcinoma was mistaken for proliferative disease of breast on frozen section.(Fig 3,4)



**Figure 3: Frozen section slide, Proliferative disease of breast(10X)**



**Figure 4: Paraffin section, Intracystic papillary CA of breast P (40X)**

The incidence of false negativity on frozen tissues increases with diminishing size of the lesion, due to artifactual distortion on freezing, and the apprehension about lack of adequate tissue for paraffin section. Hence the Association of Directors of Anatomic Surgical Pathology recommends that lesions less than 1cm should not be frozen. [4]

Literature suggests benign lesions frequently misdiagnosed as malignancy on frozen section include micro glandular adenosis, epithelial proliferations, sclerosingadenosis, radial scar, intracystic papilloma, juvenile papillomatosis, and fat necrosis. [6,10,11,12,13]

Microglandularadenosis, resembling malignancy due to poorly circumscribed glandular proliferation in a collagenous stroma, often presents colloid-like material within lumina without nuclear atypia, indicating its benign nature. Epithelial hyperplasias are commonly misinterpreted as malignancy, with cytologic appearance crucial in distinguishing atypical hyperplasia from ordinary hyperplasias. Sclerosingadenosis is best diagnosed under a scanner lens. lobulocentricity, a regular basement membrane around each glandular space and a two-cell layer favor a diagnosis of sclerosingadenosis. Radial scars, though clinically non-palpable, may mimic malignancy microscopically, particularly when spindle cells and inflammation are notable. Papillomas, whether solitary or multiple, can undergo infarction and sclerosis, leading to over diagnosis of carcinoma; however, recognizing blandness of epithelial proliferation is crucial. Distinguishing papilloma from papillary carcinoma on frozen section is challenging and often deferred until paraffin section is available. A false-positive diagnosis at frozen section may result in an excessively aggressive surgical intervention, such as a modified radical mastectomy with axillary clearance, even for non-cancerous growths. This could result in physical disfigurement and profound psychological distress for the patient. In such

instances, it is wise to defer-re the diagnosis until paraffin section is available. [14]

With the increased popularity of breast conservation therapy and limited axillary node dissection there have been increasing requests for frozen section of margins of lumpectomies and axillary nodes. [4] Confirmation of breast malignancy with frozen section or a needle core biopsy and assessment of ER/ PR status on paraffin is being increasingly sought before starting chemotherapy. [4]

In our study, before frozen section and core biopsy, diagnostic results on mammography were as follows: 08 (40%) benign lesions (BI-RADS II), 4 (20%) probably benign (BI-RADS III), 07 (35%) suspicious lesions (BI-RADS IV), and 01 (5%) lesions highly suggestive of malignancy (BI-RADS V). Most benign lesions were confirmed on core biopsy. However, among probably benign lesions, 75% were diagnosed as benign and 25% as malignant on frozen section diagnosis. Among suspicious lesions (BI-RADS IV), 42.85% were diagnosed as benign and 57.15% as malignant on frozen while all lesions highly suggestive of malignancy (BI-RADS V) were confirmed as malignant on frozen section diagnosis.

Therefore, positive predictive value (PPV) of mammography was: 25% (1/4) for BI-RADS III, 57.15% (4/7) for BI-RADS IV, 100% (1/1) for BI-RADS V.(Table 9) This is in correlation with other studies. [15,16,17]The BI-RADS classification has represented the first attempt to standardize mammographic findings in descriptive terms. Thus the present study has demonstrated that the BI-RADS classification allows a safe prediction of high suspicion for malignancy in lesions classified as category V, and minimal suspicion in lesions classified as category II and III. Notably, our study highlights a good correlation between FS analysis and BIRADS classification, particularly in BIRADS 4 and 5 patients.

**Table 11: Comparison of our series with others from two academic centers and from four community hospitals**

BI-RADS category	Breast cancer: Mendez (community hospital) [18]	Breast cancer: Liberman (academic center) [19]	Breast cancer: Berube (academic center) [17]	Breast cancer: Margolin (community hospital) [20]	Breast cancer: Tate (community hospital) [21]	Breast cancer: Travade (community hospital) [22]	Breast cancer: Present study (our Institute)
3(III)	7/156(4%)	0/2 (0%)	0/16(0%)	1/16 (6%)	2/87 (2%)	0/12 (0%)	1/4(25%)
4(IV)	116/757 (15%)	25/141 (18%)	16/397 (4%)	39/299 (13%)	159/961 (17%)	23/160 (14%)	4/7 (57.15%)
5(v)	27/34 (79%)	46/50 (92%)	43/82 (54%)	5/6 (83%)	36/40 (90%)	30/34 (88%)	1/1 (100%)

In present study, 56.86 % of frozen sections on breast lumps were requested despite earlier FNAC evaluation as shown in [Table 8]. Seven cases of the FNACs were suspicious for malignancy for which tissue diagnosis was suggested and Four cases were inconclusive. In both the above situations frozen was essential.

Also following FNAC out of 29 cases, 4 cases are inconclusive. So for comparative study 4 cases which are inconclusive are omitted. Hence 25 cases studied shows 14 cases (56%) were benign lesions and 11 cases (44%) were malignant including suspicious cases.

PV Karve et al. (2005) (4) reported that 51% of frozen sections on breast lumps were requested despite earlier FNAC evaluation. One-fourth of

FNACs were suspicious for malignancy, requiring tissue diagnosis, while another one-fourth yielded inconclusive results, necessitating frozen section analysis. In present study, 56.86% of frozen sections on breast lumps were requested despite prior FNAC evaluation (Table 8). Seven FNAC cases were suspicious for malignancy, requiring tissue diagnosis, while four cases were inconclusive, warranting frozen section analysis. Additionally, out of 29 FNAC cases, four were inconclusive, thus for the comparative study, these cases were omitted. Therefore, the study of 25 cases reveals 14 cases (56%) with benign lesions and 11 cases (44%) with malignant lesions, including suspicious cases. So the FNAC had Sensitivity=78.57, Specificity=100% and Accuracy=88%

**Table 12: FNAC diagnosis in relation to frozen section diagnosis**

FNAC	Total no.	Frozen diagnosis		FP	FN	Accuracy
		Benign	Malignant			
Benign	14	11	3	0	3	88%
Malignant	11	0	11	0	0	
Total	25	11	14	0	3	

So the of FNAC was Sensitivity=78.57, Specificity=100% and Accuracy=88%

**Table 13: Comparison of sensitivity, specificity and accuracy of FNAC in diagnosis of breast pathology between this study & other studies**

Author	Year	Sensitivity (%)	Specificity (%)	Accuracy (%)
Kamphausen BH et al. [23]	2003	90	100	---
Nggada et al. [24]	2007	95.7	98.7	97.7
Nguansangiam S et al. [25]	2009	92.5	90.2	91.2
Kuo Y L et al. [26]	2010	100	94	---
Prakash HM et al. [27]	2011	94.5	98	97
Shah Alam Sheikh. et al. [28]	2012	92.11	96.88	94.29
Present study	2018	78.57	100	88

This study was conducted to compare the diagnostic accuracy of FNAC and frozen sections in differentiating benign and malignant lesions of the palpable breast lumps using histopathology as gold standard. Our study shows 78.57% Sensitivity which is lower as compared to other studies with 100% Sensitivity in Kuo Y L et al (26) study may be because of low sample size. Our study shows

100% specificity which is similar to the result of Kamphausen BH et al [23] while there is no much significant difference in specificity in rest of the studies. Our accuracy rate is 88% which is slightly lower than rest of the studies which range from 88% to 97.7%.

## Conclusion

Frozen section is an invaluable intra-operative tool for evaluation of breast lumps, despite increasing popularity and undisputed utility of FNAC, there are situations where frozen section still stands out as the method of choice for rapid diagnosis. Only in those few conditions where frozen section fails to provide a conclusive diagnosis, will the final paraffin section be needed to accurately arrive at a definitive diagnosis. A judicious selection of one or more of these modalities is required in every patient presenting with a suspicious breast lump. Frozen section has a role despite the raging popularity of aspiration cytology in the following setting such as difficult cytology, evaluation of lumpectomy margins and intraoperative nodal status. If the surgery is performed on basis of FS analysis and Mammography BIRADS classification, it is useful to know that frozen section has a good correlation in BIRADS 4 and 5 patients.

Gross inspection, sampling by pathologist, frozen complemented with cytological and histological review and intimal cooperation with surgeon can avoid certain limitations and provide rapid, reliable, cost effective information necessary for optimum patient care. Thus frozen section examination of breast lumps can be performed with a high degree of accuracy.

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