

Clinico-Pathological Evaluation Of Palpable Breast Lump : Hospital Based Prospective Study

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ABSTRACT

Breast lump remains a common complaint of females attending a surgical outpatient department. Different types of lesions ranging from inflammation to carcinoma can be presented as a breast lump. A definitive diagnosis of breast lump must be made by histopathological examination. In case of breast cancer, an early and accurate diagnosis can save the patient from metastases and may thus reduce mortality and morbidity. The objective of the present study is to evaluate the clinical profile of patients who has palpable breast lumps and a wide range of breast diseases in palpable breast lumps. Histopathology was performed on these breast lumps. In addition to histopathology, clinico - pathological correlation was also done. A prospective observational study was conducted for one year in the Department of Pathology, Vivekananda Polyclinic & Institute of Medical Sciences (VPIMS), Lucknow. All patients with discrete breast lumps have undergone a triple assessment to make an early diagnosis. Surgical resection specimen includes lumpectomy and mastectomy. They were received, processed, reported and recorded in the Pathology laboratory and the data was collected and analysed. All the cases had a unilateral side of the breast lump and most of the cases had a breast lump on the right side. The majority had lesion size between 2-5 cm, firm consistency, single lump/mass, spread in the outer quadrant. The clinical diagnosis was benign in 19 cases (45.2%) and malignant/suspected of malignancy in 23 cases (54.8%). The histopathological diagnosis was benign in 14 cases (33.3%), borderline in 2 cases (4.8%) and malignant in 26 cases (61.9%). Fibroadenoma was the most common benign tumour and invasive ductal carcinoma was the most common malignant tumour. The final histopathological examination confirmed that the few cases of clinically suspected benign breast lumps were actually borderline and malignant breast lumps. These cases confirm that the histopathological examination of a breast lump is the gold standard to establish a correct diagnosis.



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1. INTRODUCTION

Breast lumps are very common in the reproductive age group of females. Over 25% of women are affected by breast disease in their lifetime. Breast lumps have a wide range of diseases from benign to malignant. The majority of breast lumps are benign [1]. A malignant breast lump is a life-threatening condition for females. Each year thousands of women are diagnosed to have invasive breast cancer, leading to a life expectancy of less than one year in almost one-quarter of the affected women [2]. The majority of the patients with breast cancer are diagnosed in the advanced stage (57.0%) [3]. A definitive diagnosis of a breast lump follows the triple-assessment pathway of clinical examination, radiological examination, and pathological examination [4]. The clinico –radiological examination only provides a clue to whether a lump is benign or malignant. The preoperative diagnosis of a breast lump is a crucial part of the final therapeutic plan. Preoperative tests like Fine Needle Aspiration Cytology and Core needle biopsy are used to evaluate palpable breast lumps [5]. Histopathological examination is the gold standard to diagnose almost all types of breast lumps [6]. Management of breast cancer cases is dependent on the appropriate diagnosis which is based on the stage of the disease. It is mainly dependent on seven factors: extent (size) of the tumour (T), spread to nearby lymph node (N), spread to distant sites – metastasis (M), estrogen receptor status (ER), progesterone receptor status (PR), Her2neu status and grade of cancer (G). All these factors play a role in assessing the biological character of breast cancer which has a major impact on clinical course. Moreover, all these factors are helpful in the prognosis of breast cancer [7].

2. MATERIAL & METHODS

This prospective and descriptive study was approved by the Institutional Ethics Committee. After obtaining informed consent from the patients, the study was conducted in the Department of Pathology, Vivekananda Polyclinic & Institute of Medical Sciences (VPIMS), Lucknow. A total of 42 women who presented with breast lumps with clinical or radiological suspicion (BIRADS III to BIRADS-V) for malignancy were enrolled in the study and admitted to surgery and oncology wards.

The sample size was calculated using the following formula

$$n = (Z_{\alpha/2})^2 \frac{p(1-p)}{d^2} \times \text{Prevalence}$$

where, n is the required sample size, p= Sensitivity, d=Precision, $Z_{(\alpha/2)}$ = Significance level. Taking 80% power, and 5% significance level with 0.08 precision, the calculated sample size was 42.

$$n = (1.96 \times 1.96) \times 0.84 \times 0.16 / (0.08 \times 0.08) \times 0.52 = 42$$

The inclusion criteria included all female patients with breast lumps which carry the likelihood of malignancy either clinically or radiologically. We excluded the patients with breast lumps who decided not to go for surgery, who had bleeding disorders or who were not suspected of malignancy through clinico-radiologically examination.

The data was collected and analyzed. The clinical history and physical examination of all the patients were retrieved from case files. Those patients who had a suspicion of malignancy either clinically or radiologically were planned for surgical excision of breast lump or mastectomy. After that surgical resection specimen was sent for a final histopathological diagnosis.

3. RESULTS

The present study included a total of 42 patients with breast lumps. All of the patients were female. The age of patients enrolled in the study ranged from 30 to 76 years. The majority of the patients were aged 31-50 years (78.6%). Figure 1 shows age histogram.

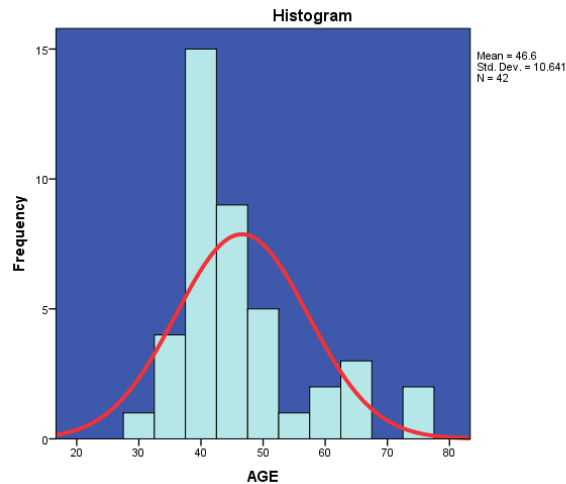


Fig. 1: Age Profile of patients enrolled in the study

The right side of breast was more dominant (57.1%) than the left side (42.9%) of breast. None of the cases had bilateral involvement. As shown below in Table 1.

Table 1: Distribution of cases according to affected side

SN	Affected Side of breast	No. of patients	Percentage
1.	Left	18	42.9
2.	Right	24	57.1

Table 2 shows that more than three-fourths (78.6%) of patients had a duration of complaints <1 year. A total of 8 (19%) had complaints for 1-2 years. There was only 1 (2.4%) patient having complaints for 5 years in the >2 years category. The mean duration of complaints was 1.05±0.84 years.

Table 2: Distribution of cases according to duration of complaints

SN	Duration	No. of patients	Percentage
1.	≤1 Years	33	78.6
2.	1-2 Years	8	19.0
3.	>2 Years	1	2.4
Mean duration±SD (Range) in years		1.05±0.84 (1 month-5 years)	

The size of the lump ranged from 1.5 to 8 cm. The majority of cases (61.9%) had a lump size 2-5 cm, followed by those having lump size <2 cm (28.6%). There were only 4 (9.5%) cases with lump size >5 cm. The mean lump size was 3.45±1.44 cm. The consistency of the lump was firm in 30 (71.4%) cases. A total of 10 (23.8%) had hard lumps while 2 (4.8%) had soft lumps. Except for 3 (7.1%) cases having two lumps all the others had only one lump. Outer quadrant was most commonly involved (35.7%) followed by retroareolar (n=14; 33.3%), inner quadrant (n=8; 19%) and all quadrants (n=4; 9.5%). The lower quadrant was involved in 1 (2.4%) case as shown in Table 3. We have not enrolled cases with a provisional diagnosis of a benign lesion

in both imaging and clinical diagnosis.

Table 3: Clinical/Imaging Evaluation findings

SN	Finding	No. of patients	Percentage
1.	Size		
	≤2 cm	12	28.6
	2-5 cm	26	61.9
	>5 cm	4	9.5
	Mean size±SD (range) in cm	3.45±1.44 (1.5-8.0)	
2.	Laterality		
	Unilateral	42	100.0
3.	Consistency		
	Firm	30	71.4
	Hard	10	23.8
	Soft	2	4.8
4.	Number of lumps/masses		
	One	39	92.9
	Two	3	7.1
5.	Location		
	All quadrants	4	9.5
	Outer quadrant	15	35.7
	Retroareolar	14	33.3
	Lower quadrant	1	2.4
	Inner quadrants	8	19.0

Clinically, a total of 19 (45.2%) cases were diagnosed as benign and 23 (54.8%) were diagnosed as malignant/suspected of malignancy. Among benign cases, maximum (n=7; 16.7%) were identified as fibroadenoma followed by mastitis (n=4; 9.5%), fibrocystic breast disease (n=3; 7.1%), breast abscess (n=2; 4.8%), papilloma, phyllodes tumor and benign breast disease (n=1; 2.4% each). Among 23 cases under the malignant/suspected of malignancy group a total of 15 (35.7%) were diagnosed as carcinoma breast and 8 (19.0%) were suspected of malignancy clinically. As mentioned below in Table 4.

Table 4: Distribution of cases according to Clinical Diagnosis

SN	Clinical Diagnosis	No. of patients	Percentage
1.	Benign	19	45.2
	Fibroadenoma	7	16.7
	Mastitis	4	9.5
	Fibrocystic breast disease	3	7.1
	Breast abscess	2	4.8
	Papilloma	1	2.4
	Phyllodes tumor	1	2.4
	Benign breast disease	1	2.4

2.	Malignant/Suspected of malignancy	23	54.8
	Carcinoma breast	15	35.7
	Suspected of malignancy	8	19.0

The benign, borderline and malignant histopathological diagnosis were made respectively in 14 (33.3%), 2 (4.8%) and 26 (61.9%) cases. Out of 14 benign cases, 5 were fibroadenoma, 3 fibrocystic breast disease, 4 mastitis (granulomatous -2, chronic-1, tubercular – 1), one benign phyllodes tumor and one ductal hyperplasia respectively. There were two borderline cases – one each Fibroadenoma with Atypical ductal hyperplasia and Borderline phyllodes tumor respectively. Of 26 cases diagnosed as malignant – maximum 12 were invasive ductal carcinoma, 5 were ductal carcinoma in situ, 4 were invasive lobular carcinoma, 2 were complex cystic lesion with DCIS and 1 each was invasive papillary carcinoma, invasive mucinous carcinoma and invasive carcinoma with medullary features respectively as shown below in Table 5.

Table 5: Final Histopathological Diagnosis

SN	Histopathological diagnosis	No. of patients	Percentage
1.	Benign	14	33.3
	Fibroadenoma + Fibroadenoma with usual ductal hyperplasia	5	
	Fibrocystic breast disease	3	
	Mastitis	4	
	Phyllodes	1	
	Ductal hyperplasia	1	
2.	Borderline	2	4.8
	Fibroadenoma with Atypical ductal hyperplasia	1	
	Borderline phyllodes tumor	1	
3.	Malignant	26	61.9
	Invasive ductal carcinoma	12	
	Ductal carcinoma in situ	5	
	Invasive lobular carcinoma	4	
	Complex cystic lesion with DCIS	2	
	Invasive papillary carcinoma	1	
	Invasive mucinous carcinoma	1	
	Invasive carcinoma with medullary features	1	

4. DISCUSSION

One of the commonest clinical presentations of breast lesions is a lump [1]. The triple assessment which is used to diagnose all breast lumps includes clinical examination, radiological examination, and pathological examination [4]. Despite the common occurrence of a breast lump and the dominance of benign lesions, breast cancer is considered one of the most dreadful diseases among women that has both physical as well as

emotional impacts [2]. Despite improvement in clinical management during the last few decades, it continues to be a major cause of cancer death among women in less developed countries [3].

In the present study, all the cases had unilateral involvement. The right side was more commonly involved (57.1%) than the left side (42.9%). Bilateral involvement is a relatively less frequent problem, especially in breast cancer suspect cases. The present study also had suspects and not confirmed cases of breast cancer. [8] reported that bilateral involvement has rarely been reported in 1.5% of cases. However, [9] reported a much higher proportion of bilateral involvement (12%). As far as the dominance of the side is concerned, there are controversial reports. Several studies report dominance of the left side over the right side while some studies including this study report the right side to be more commonly involved than the left side [10- 12].

In our study, the majority of patients had lesion size between 2-5 cm (61.9%), firm consistency (71.4%), single lump/mass (92.9%), and spread in the outer quadrant or retroareolar area (69.0%). Compared to the present study, [13] in their study found <3 cm lumps in 48.5% of their patients, however, they did not report other physical characteristics of the lump. [14] reported the mean lump size as 6.38±4.33 cm and the majority with size >5 cm. The differences in lump size in different studies could be dependent on the stage of progression of the breast disease. [14] found the majority of cases with lump size >5 cm also reported a high prevalence of malignancy (84%) which could be possibly linked with the higher proportion of patients with larger lumps. As shown by our study, a low prevalence of lump sizes >5 cm was also reported by [15] who reported them to be present in only 24.29% of cases. A high prevalence of lumps with firm consistency was also documented by [9] in their study (74%). The multiplicity of breast masses despite unilateral presentation is not an uncommon finding. Though they are rare and indicators of more advanced or metastatic disease, their clinical presence cannot be ruled out. We also found in our study that only a nominal (7.1%) proportion of patients had more than one lump, thus endorsing the rarity of multiple masses. With respect to localization, similar to the findings of the present study, [14] too found the outer quadrant and retroareolar area to be the most commonly involved locations. Similar observations were also made by other authors too [8], [11].

A definitive diagnosis of breast lump was made by histopathologic examination which differentiates benign tumours from malignant tumors. The histopathologic assessment of malignant breast tumors has long provided the basis for the prediction of recurrence risk and the prescription of adjuvant therapy. However, histopathological examination tells about both the diagnosis and prognosis of breast cancer [7].

In the present study, the clinical diagnosis was benign in 19 (45.2%) and malignant/suspected of malignancy in 23 (54.8%) cases. As the inclusion criteria of the present study was based on radiological grading, there is a possibility of having some cases with a non-malignant clinical diagnosis. Histopathological diagnosis was benign in 14 cases (33.3%), borderline in 2 cases (4.8%) and malignant in 26 cases (61.9%). On final histopathological examination we found that 5 cases of clinically suspected benign breast lumps were actually borderline (2 cases) and malignant breast lumps (3cases). Hence, it confirms that the histopathological examination of a breast lump is the gold standard to establish a correct diagnosis.

We also found that fibroadenoma was the most common benign diagnosis while invasive ductal carcinoma was the most common malignant diagnosis. The proportion of malignant and benign and their dominant histopathological profile in different studies and its comparison with the present study is as follows in Table 6.

Table 6: Proportion of Benign and Borderline/Malignant Histopathological Diagnosis and dominant histopathological types in different contemporary studies and their comparison with the present study

SN	Author (Year)	Sample size	Malignant/ Borderline (Dominant HPE type)	Benign (Dominant HPE type)
1.	[13]	68	57.3% (Invasive ductal carcinoma)	42.6% (Fibroadenoma)
2.	[14]	50	84%	16%
3.	[16]	62	48.4% (Infiltrating ductal carcinoma)	51.6% (Fibroadenoma)
4.	Present study	42	66.7% (Infiltrating ductal carcinoma)	33.3% (Fibroadenoma)

Histopathologically, most of the studies diagnosed infiltrating/invasive ductal carcinoma as the most common malignant type while fibroadenoma was the most common histopathological type for benign masses [13], [14], [16], [17]. Thus, the findings of the present study are in agreement with the observations of the contemporary evidence in different studies and do not show any discrepancy. Breast cancers are classified according to the histopathological features of the tumor because each of them influences the outcome and response to the treatment [18].

SUMMARY – Diagnosis of breast cancer mainly done by triple assessment – clinical examination, radiological examination and pathological examination. Pathological examination includes Fine needle aspiration cytology (FNAC) and core needle biopsy (CNB) and complete surgical resection specimen histopathological examination. Preoperatively FNAC and CNB are complimentary to each other and are useful in the diagnosis of breast lump. Histopathological examination of complete surgical resection specimen is the gold standard to establish the correct diagnosis and prognostic factor. Types of breast cancers are classified according to the histomorphological features. Each of them influences the outcome and response to the treatment. This study shows that majority of malignant breast lumps are invasive ductal carcinoma. Clinically benign looking breast tumors may actually be malignant or borderline tumors. Hence, a high index of suspicion of malignancy must be practiced in clinically benign breast swellings. We suggest that women presenting with a palpable breast lump should be confirmed by a detailed histopathological examination.

5. REFERENCES

- [1] Daly C, Puckett Y. New Breast Mass. [Updated 2022 Feb 4]. In: StatPearls [Internet]. Treasure Island (FL): StatPearls Publishing; 2022 Jan-. Available from: <https://www.ncbi.nlm.nih.gov/books/NBK560757/>
- [2] Sung H, Ferlay J, Siegel RL, Laversanne M, Soerjomataram I, Jemal A, Bray F. Global Cancer Statistics 2020: GLOBOCAN Estimates of Incidence and Mortality Worldwide for 36 Cancers in 185 Countries. *CA Cancer J Clin.* 2021 May;71(3):209-249. Link
- [3] Mathur P, Sathishkumar K, Chaturvedi M, Das P, Sudarshan KL, Santhappan S, Nallasamy V, John A, Narasimhan S, Roselind FS; ICMR-NCDIR-NCRP Investigator Group. Cancer Statistics, 2020: Report From National Cancer Registry Programme, India. *JCO Glob Oncol.* 2020 Jul;6:1063-1075. doi:

10.1200/GO.20.00122. PMID: 32673076; PMCID: PMC7392737.

[4] Karim MO, Khan KA, Khan AJ, Javed A, Fazid S, Aslam MI. Triple Assessment of Breast Lump: Should We Perform Core Biopsy for Every Patient? *Cureus*. 2020 Mar 30;12(3):e7479. doi: 10.7759/cureus.7479. PMID: 32351857; PMCID: PMC7188022.

[5] Chakrabarti I. FNAC Versus CNB: Who Wins the Match in Breast Lesions? *J Cytol*. 2018 Jul-Sep;35(3):176-178. doi: 10.4103/JOC.JOC_35_18. PMID: 30089949; PMCID: PMC6060573.

[6] Rashmi, R., Prasad, K. & Udupa, C.B.K. Breast histopathological image analysis using image processing techniques for diagnostic purposes: A methodological review. *J Med Syst* 46, 7 (2022). <https://doi.org/10.1007/s10916-021-01786-9>

[7] Webster LR, Bilous AM, Willis L, Byth K, Burgemeister FC, Salisbury EL, Clarke CL, Balleine RL. Histopathologic indicators of breast cancer biology: insights from population mammographic screening. *Br J Cancer*. 2005 Apr 25;92(8):1366-71. doi: 10.1038/sj.bjc.6602501. PMID: 15812557; PMCID: PMC2362010.

[8] Bhatta U., Karki S., Sayami G., & Regmi D. (2019). Comparison of fine needle aspiration cytology and core needle biopsy findings with excisional biopsy in breast malignancy. *Journal of Pathology of Nepal*, 9(2), 1564–1570. <https://doi.org/10.3126/jpn.v9i2.25031>

[9] Mandal A, Jana P, Bakshi S, Mandal KR . A comparative clinicopathological study between ultrasonography, mammography, fine needle aspiration cytology and core needle biopsy of breast lump. *International Surgery Journal*. 2020;vol 7:page2325-31. <https://dx.doi.org/10.18203/2349-2902.isj20202844>.

[10] Satoko Nakano, Masahiko Otsuka, Akemi Mibu, Toshinori Oinuma. Significance of Fine Needle Aspiration Cytology and Vacuum-Assisted Core Needle Biopsy for Small Breast Lesions. *Clinical Breast Cancer*.2015;Volume 15(1):23-26.ISSN 1526-8209.<https://doi.org/10.1016/j.clbc.2014.07.001>.

[11] Kocaay AF, Celik SU, Sevim Y, Ozyazici S, Cetinkaya OA, Alic KB. The role of fine needle aspiration cytology and core biopsy in the diagnosis of palpable breast masses. *Niger Med J*. 2016 Mar-Apr;57(2):77-80. doi: 10.4103/0300-1652.182078. PMID: 27226679; PMCID: PMC4872495.

[12] Sangma MB, Panda K, Dasiah S. A clinico-pathological study on benign breast diseases. *J Clin Diagn Res*. 2013 Mar;7(3):503-6. doi: 10.7860/JCDR/2013/5355.2807. Epub 2013 Jan 10. PMID: 23634406; PMCID: PMC3616566.

[13] Mitra K S., Rajesh R., Misra K R., Rai P., Vahikar S., Singhal P. Comparative evaluation of FNAC, core needle biopsy and excisional biopsy in subtyping of breast lesions. *Tropical Journal of Pathology and Microbiology*.2016 JAN-JUN;2(1):9-15. <https://doi.org/10.17511/jopm.2016.i01.02>

[14] Saha A, Mukhopadhyay M, Das C, Sarkar K, Saha AK, Sarkar DK. FNAC Versus Core Needle Biopsy: A Comparative Study in Evaluation of Palpable Breast Lump. *J Clin Diagn Res*. 2016 Feb;10(2):EC05-8. doi: 10.7860/JCDR/2016/15889.7185. Epub 2016 Feb 1. PMID: 27042469; PMCID: PMC4800534.

- [15] Tikku G, Umap P. Comparative Study of Core Needle Biopsy and Fine Needle Aspiration Cytology in Palpable Breast Lumps: Scenario in Developing Nations. *Turk Patoloji Derg.* 2016;32(1):1-7. doi: 10.5146/tjpath.2015.01335. PMID: 26832175. A.,
- [16] Shashirekha C A., Rahul S R., Ravikiran H R., Sreeramulu P N., Krishna P C. Fine needle aspiration cytology versus trucut biopsy in the diagnosis of breast cancer: a comparative study. *International Surgery Journal.* 2017 Oct;vol.4(11)p.3718-21. <https://dx.doi.org/10.18203/2349-2902.isj20174893>.
- [17] Njeze GE. Breast lumps: a 21-year single-center clinical and histological analysis. *Niger J Surg.* 2014 Jan;20(1):38-41. doi: 10.4103/1117-6806.127111. PMID: 24665202; PMCID: PMC3953633.
- [18] Makki J. Diversity of Breast Carcinoma: Histological Subtypes and Clinical Relevance. *Clin Med Insights Pathol.* 2015 Dec 21;8:23-31. doi: 10.4137/CPath.S31563. PMID: 26740749; PMCID: PMC4689326.