



DIAGNOSTIC ACCURACY OF FINE NEEDLE ASPIRATION CYTOLOGY (FNAC) IN DIFFERENTIATING THE BENIGN AND MALIGNANT LESIONS OF PALPABLE BREAST LUMP: A COMPARATIVE STUDY BETWEEN FNAC AND HISTOPATHOLOGY

Dr. Ankit Patel

Assistant Professor, Department of Surgery C.U.Shah Medical College, Surendranagar.

Dr. Hetal Koringa*

Associate Professor, Department of community medicine, C.U.Shah Medical College, Surendranagar. *Corresponding Author

ABSTRACT

Background: A method of definitive diagnosis of patients who present with palpable breast lump at the outpatient clinic is needed now a days and it must be accurate, easy to perform, acceptable to the patient and can be carried out in a busy clinic setting.

Methods: It was a one-year prospective observational study in which 50 patients underwent FNAC of the palpable breast lump after physical examination. The cytological report was described as benign, suspicious and malignant. After this reporting all the patients were later subjected to open/excision biopsy and histopathological confirmation. Later diagnostic accuracy of cytology reporting was compared with that of histopathology. Accuracy of the needle tip in localizing the tumour in FNAC was also studied. Data was analysed in Microsoft excel 2013 Appropriate statistical analysis was done.

Results: The most common age group for benign lesions was between 25 to 34 years and for the malignant lesion was 45 to 64 years. The study found accuracy rate of 100 % for benign lesion and 90 % for malignant lesion of FNAC in the diagnosis of palpable breast lump. False negative rate and false positive rate were calculated 10% and zero respectively. The overall sensitivity, specificity, positive predictive value and negative predictive value of fine needle aspiration cytology in diagnosing the palpable breast lump is 90 %, 100 %, 100 % and 93.55 % respectively. The accuracy rate of needle tip in localizing the tumour in FNAC is 96 %.

Conclusions: FNAC is a prime initial diagnostic test in palpable breast lumps. It shows a high degree of correlation with the final histopathology, if done appropriately. The study recommends FNAC as a diagnostic test in palpable breast lumps, and with the result of FNAC, patient can be advised for further treatment.

KEYWORDS : FNAC, breast lump, carcinoma of breast, diagnosis of breast lump

Background

Diseases of the breast constitute a significant proportion of surgical cases seen in both developed and developing countries.¹ Suspicious lump of breast can't be differentiated by clinical examination only. Therefore, a method must be there for definitive diagnosis of patients with breast lumps at outpatient department level and this method must be simple, uncomplicated, painless for the patients, accurate, replicable, less time consuming and can be performed without too much preparation.

Torsten Lowhagen and his colleagues at the Karolinska institute in Stockholm became pioneers in the 60s and 70s by inventing a new minimally invasive technique of diagnosis known as Fine-Needle Aspiration Cytology (FNAC).² Gradually, FNAC of breast has become an accepted and established method to determine the nature of the lump especially when it is difficult by clinical examination.³

It is supportive to identify benign disease at primary stage which can avoid further biopsy and to detect malignancy in non-suspicious masses. The optimum benefit of aspiration cytology, however, rests in its confirmation of malignant disease, when other diagnostic methods are indecisive.⁴ FNAC of breast can be a replacement to excision biopsy in majority of cases and furthermore, it can differentiate and delineate the nature of the disease in most of the instances.⁵

Though experts have rightly pointed to the possibility of false negative reports regarding malignant lesions, FNAC reported by an expert cytologist as "unequivocally malignant" is now considered as a most sufficient evidence to proceed for definitive surgery.²

AIMS AND OBJECTIVES:

1) To compare the diagnostic accuracy of fine needle aspiration cytology (FNAC) with histopathology in differentiating the benign and malignant lesions of palpable breast lump.

2) To find out the accuracy of the needle tip localizing the tumor during FNAC procedure.

METHODS:

It was a one-year prospective observational study done at K.V.G. Medical College and Hospital, Sullia, Karnataka, India during August 2011 to July 2012. Study participants included female patients who were having palpable breast lump of variable duration. Patients with acute and tender breast abscess, with ulcerated breast lump, with Recurrent breast lump of previously operated case of confirmed malignancy, with frank malignant mass with skin infiltration and who were not willing for surgery were excluded from the study. The study protocol was reviewed by The Institutional Ethical Committee of the institution and permitted. Purposive sampling was used for this study. All the patients with breast lump attended surgical OPD between September 2011 to November 2011 were included in the study. Total 53 women with breast lump were there between this time-period and informed consent was taken but 3 women had not given consent to be included in the study. Final sample size came to be 50. Detailed history and thorough physical examination of the patient having palpable breast lump was carried out and entered in pre designed, semi structured proforma. Informed consent was obtained from the patient before subjecting to FNAC of the breast lump.

The standard procedure was followed for FNAC and the interpretation of the slide was made by the cytopathologist. The final cytological report was described as malignant, suspicious, benign or unsatisfactory (inadequate) due to insufficient epithelial cells being present. The patients were informed about the cytological diagnosis. If the lumps on the cytological examination was reported as malignant, then mastectomy or modified radical mastectomy was performed and the specimen sent for the histopathological confirmation of the diagnosis. In those cases, which were reported as suspicious of malignancy, they underwent intraoperative rapid haematoxylin and eosine staining for confirmation of malignancy before underwent modified radical mastectomy

and histopathological confirmation. Accuracy of the needle tip in localizing the tumour in fine needle aspiration cytology was also studied by comparing the normal glandular aspirate with tumour cell aspirate. Since the fine needle aspiration was done for palpable tumour ultrasound guidance was not followed and repeat fine needle aspiration was carried out before open/excision biopsy if the pathologist reports the cytology slide as "inadequate".

STATISTICAL ANALYSIS

Data entry and analysis were done using MS Excel 2013. Mean was calculated for descriptive analysis and the number with percentage was calculated for categorical variables. Sector diagrams were used for graphical presentation of the data to show proportions of various subtypes of benign and malignant breast lumps. Cytological diagnosis was correlated with the histopathological diagnosis. Sensitivity, specificity, positive predictive value, negative predictive value and accuracy were calculated by appropriate formula below. Sensitivity = True positive/(True positive + False negative), Specificity = True negative/(True negative + False positive), Positive predictive value = True positive/(True positive + False positive), Negative predictive value = True negative/(True negative + False negative) and Accuracy = True positive + True negative/(True positive + True negative + False positive + false negative).

RESULTS

Table 1 shows the socio-clinical profile of patients having benign and malignant breast lump. Age incidence for the benign and malignant lesions ranged 15 years to 45 years (mean age 26.55 years) and 30 to 70 years (mean age 52.66 years) respectively. Benign breast lumps and malignancy was found most commonly between 25 to 34 years and above the age of 45 years respectively. Out of total 50 patients, 26 patients had lump in right breast, 23 had lump in left breast and 1 patient had lumps in both sides. Malignant lesions were found more common in the right breast and the incidence of benign breast lesions was found more in left side of breast. The size of the breast lump in case of benign lesions ranged between 2 to 6 cms and majority (96.55 %) of the benign lesions were less than 6 cms. Malignant lesions were ranged in size between 5 to 11 cms and majority of them (85.72 %) measured 6 to 10 cms in its greatest diameter. Out of total benign breast lump, majority (37.93 %) were located in lower inner quadrant of breast and very few (10.35 %) were located in upper inner quadrant. Malignant lump was found more in upper inner quadrant (61.90 %) followed by central quadrant (28.575) of the breast. The duration of symptoms varied from few months to few years. The mean duration of symptoms for benign lesions was 23.51 months (range: 6-60 months) and for the malignant lesions was 5.71 months (range: 4 -8 months). Most common complaint was lump in the breast(100%),and other symptoms were pain in the lump, discharge from the nipple and lump in the axilla. Almost three fifth (61.9%) of malignant lumps had discharge from nipple while in cases of benign lumps the proportion was less (10.34 %). Among 50 patients, 3 patients of breast lump were having family history of breast carcinoma (in mother).

Table 2 shows the result of the fine needle aspiration cytology and histopathology among study participants.

Variables		Breast lump		Total n (%)
		Benign n (%)	Malignant n (%)	
Age	15-24	8(27.59)	0(0%)	8(16.0)
	25-34	13(44.82)	1(4.76)	14(28.0)
	35-44	7(24.14)	2(9.52)	9(18.0)
	45-54	1(3.45)	8(38.10)	9(18.0)
	55-64	0(0%)	8((38.10)	8(16.0)
	≥65	0(0%)	2(9.52)	2(4.0)
Affected	Right	13(44.83)	13(61.90)	26(52 %)

	Left	15(51.72)	8(38.10)	23(46 %)
	Both	1(3.45)	0(0%)	1(2 %)
Size of lump (in cm)	0-5	28(96.55 %)	2(09.52 %)	30(60 %)
	6-10	1(03.45 %)	18(85.72 %)	19(38 %)
	>10	0(0%)	1(04.76 %)	1(2 %)
Quadrant of breast involvement	U.O.Q.	4(13.79 %)	13(61.90 %)	17(34 %)
	U.I.Q.	3(10.35 %)	2(9.53 %)	5(10 %)
	Central	6(20.69 %)	6(28.57 %)	12(24 %)
	L.O.Q.	5(17.24 %)	0(0%)	5(10 %)
	L.I.Q.	11(37.93 %)	0(0%)	11(22 %)
Discharge from nipple	Yes	3(10.34 %)	13(61.90 %)	16(32 %)
	No	26(89.66 %)	8(38.10 %)	34(68 %)
Family history with malignant lesions of breast	Yes	NA	3(14.29)	--
	No	NA	18(85.71)	--
Total		29 (100 %)	21(100 %)	50(100 %)

Table 1. Socio-Clinical Profile of Patients having benign and Malignant Breast Lump (n=50)

Result of the fine needle aspiration cytology				
Diagnosis	Benign	Malignant	Suspicious	Total
Frequency	31	18	1	50
Result of the fine needle histopathology				
Diagnosis	Benign	Malignant	Total	
Frequency	29	21	50	

Table 2. The Result of the Fine Needle Aspiration Cytology and Histopathology (n=50)

Test result (FNAC)	Diseased (malignant)	Not diseased (benign)	Total
Positive	18 (a) (True positive)	0(b) (False positive)	18
Negative	2(c) (False negative)	29(d) (True negative)	31
Total	20	29	49

Table 3: The predictive value of the fine needle aspiration cytology of the palpable breast lump

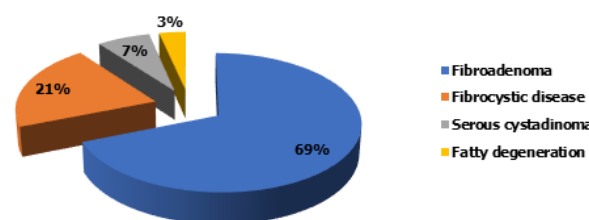


Figure 1. The Histopathological Results of the Benign Breast Lumps (n=29)

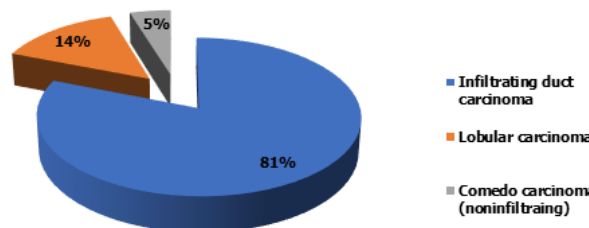


Figure 2. The Histopathological Results of the Malignant Breast Lumps (n=21)

Results of benign lumps

Out of total 31 cases of benign lumps reported by FNAC, 29 was confirmed by histopathology. False negative were 2 cases. False positive was zero. Two cases were reported as unsatisfactory (inadequate) sampling, which on repeat fine needle aspiration cytology revealed benign fibroadenoma,

later confirmed by histopathology after local excision.

The results of the benign lesions were as follows
 Accuracy rate for benign lesions 100 %
 False positive 0 %
 Unsatisfactory specimen rate 6.45 %

Results of malignant lumps

Out of total 21 cases of malignant lesions confirmed by histopathology, FNAC reported 18 as malignant, 2 as benign and one as suspicious lesion. False negative was 2 and false positive was zero. One FNAC was reported as suspicious lesion for malignancy which was confirmed by histopathology later on. There was no unsatisfactory (inadequate) sampling for malignant lesions.

The results of the malignant breast lesions were as follows
 Accuracy rate for malignant lesion 90.00 %
 False negative rate 10.0 %
 Unsatisfactory specimen rate 0 %

Histopathological results of the benign breast lesions shows that majority (69 %) of the lumps were confirmed as fibroadenoma followed by fibrocystic diseases (21 %), serous cystadenoma (7 %) and fatty degeneration (3 %). (figure:1) In this study, majority of the malignant lesions were infiltrating duct carcinoma (81 %) followed by lobular carcinoma (14 %) and comedo carcinoma (5 %) as per histopathological report. (Figure: 2)

The study found Sensitivity of FNAC as 90 %, Specificity was 100 %, Positive predictive value was 100 % and negative predictive value was 93.55 %. (Table 3)

Inadequate sampling (unsatisfactory report)

Two unsatisfactory sampling were reported by FNAC in the present study. On repeat fine needle aspiration both were reported as fibroadenoma and later confirmed with histopathological reports. Inadequate sampling rate and accuracy rate of the needle tip in localizing the tumour in fine needle aspiration cytology were found 4% and 96 % respectively for the present study.

DISCUSSION

The most common age group for benign lesions was between 25 to 34 years and for the malignant lesion it was 45 to 64 years in this study. The study done by A.Khemka et al² in their study found peak incidence for benign and malignant lesions in 2nd and 3rd decade and between 40-44 years respectively. Similar studies done by Homesh et al⁶ Tiwari⁷ Alam et al⁸ and Mane PS et al⁹ showed almost similar age patterns. This study found that benign lesions ranged between 2 to 6 cms (96.55 % of the benign lesions were less than 6 cms) and malignant lesions ranged between 5 to 11 cms (85.72 % measured 6 to 10 cms in its greatest diameter). Similar results were reported by A.Khemka² in their study. The duration of the lump varied from few months to few years in our study. Furthermore, mean duration of symptoms for benign lesions was 23.51 months (range: 6-60 months) and for the malignant lesions it was 5.71 months (range: 4 -8 months) in study participants. A.Khemka² in his study showed the duration of the lumps in a range

between 1 month to 2 years with a majority of patients having a history of between 6 months and a year.

The upper and outer quadrant was the commonest site of the lump in our patients in benign cases while lower and inner quadrants were involved the most in malignant cases. Alema et al¹⁰ noted in his study that out of total 85 cases 49 cases had lump in Upper outer quadrant and out of them 6 cases (12.2 %) were malignant and malignancy was not found in other quadrants of breast.

The commonest benign pathology found in our patients was fibroadenoma followed by fibrocystic diseases. Infiltrating ductal carcinoma was the most common malignant breast lesion in the present study. It forms the 80.95 % of the malignant lesions aspirated for cytology (17 out of total 21 cases). Although its incidence peaks in the postmenopausal women, it is seen as early as in the second decade.

Tiwari et al⁷ also reported in his study that among 91 patients fibroadenoma was the commonest pathology (39.6 %). Other diseases like subareolar abscess, invasive ductal cancer, breast abscess, fibrocystic disease, duct ectasia, and galactocoele ranged between 5.5 % to 7.7 %. Invasive ductal carcinoma (IDC) accounts for only 6.6 % of the total 91 cases. A.Khemka et al.² in their study, the commonest pathology found was fibroadenoma in 29 patients followed by fibrocystic disease in 4 patients and malignancy in 13 patients. Sumaira Zareef et al¹¹ found almost similar findings in their study.

FNAC affirmed 31 benign lesions, 18 malignant lesions, 1 suspicious with 2 false negative and zero false positive results for this study. The diagnostic accuracy of FNAC for benign lesions and malignant lesions were 100% and 90.00 % respectively. Though false negative rate was 10.0 % and false positive rate was 0 % noted in the present study.

The sensitivity of a test can be considered a statistical index of the diagnostic accuracy of that particular test. With regarding FNAC, it hints that if FNAC is positive, it certainly means presence of the disease but if it is negative, it does exclude the disease. The specificity of a particular test means its ability to identify those individuals who do not have the disease. To give extensive interpretation of the results, we intended the specificity of FNAC as a diagnostic test for malignant lesions, i.e., how specific is FNAC as test in the identification of malignancy in a breast lump. The positive predictive value of a test shows the probability of a patient with a positive result to have the disease. Accordingly, it reveals the diagnostic power of the test while the negative predictive value of a test, on the flip side, specify the probability of a patient with negative result not to have the disease.

The overall sensitivity, specificity, positive predictive value and negative predictive value of fine needle aspiration cytology in diagnosing the palpable breast lump is 90 %, 100 %, 100 % and 93.55 % respectively. Diagnostic accuracy for malignant lumps was noted 90% in the present study. Table 4 shows comparison of present study results with the similar studies results.

Name of Study	Sensitivity	Specificity	Positive Predictive Value	Negative Predictive Value	Diagnostic accuracy
A.Khemka et al ²	96 %	100 %	100 %	95.12 %	--
Tiwari et al ⁷	83 %	100 %	-	-	--
Mane P et al ⁹	85%	100%	100%	96.3%	97%
O.N. Alema et al ¹⁰	83.3 %	100 %	100 %	98.6 %	--
Kocccay A F ¹²	95%	100%	--	--	--
Wang A M ¹³	87%	98%	--	--	--
Randa et al. ¹⁴	56.1%	80.9%			63.8%
Mulazim H B et al. ¹⁵	98%	100%	97%	100%	98%
Moschetta M ¹⁶	97%	94%	91%	98%	95%

Panjvani SI et al ¹⁷	97.8%	100%	100%	97.8%	98.9%
Saraf S et al ¹⁸	98.2 %	99.4 %	98.9 %	97.8 %	--
Modi P et al ¹⁹	94%	98.5%	97%	97%	97%
Present study	90%	100%	100%	93.55%	90%

Table 4. Comparison of present study results with other studies results

Two false negative reports were found in this study and it could be due to sampling error. False negative rate in this study was 10.00 %. While Kocay A F¹² mentioned in their study false negative rate was 5%. Great care must be taken to avoid false positive reports. Cellular fibroadenoma and papilloma bear a risk in this respect. We had no false positive cases in our study. It must be reemphasized that proper clinical judgment should prevent an erroneous mastectomy being performed.

CONCLUSIONS

A high sensitivity and a high positive predictive value were noted in the study. This can show that a positive FNAC in the breast can be decisive of the agitated pathology if compared with the final histology report. Similarly, the high specificity and a high negative predictive value for malignancy exemplified the high accuracy of FNAC in the diagnosis of malignancy. Since the accuracy of the needle tip in localizing the lump was found very high, in case of unsatisfactory samples, repetition of FNAC should be done before advising for open biopsy. The study recommends the use of FNAC as a very important preliminary diagnostic test in palpable breast lumps, and with the result of FNAC, patient can be advised for further appropriate treatment.

Limitations

Continuous research in the same topic is desirable as the data are old and the same can be compared with the latest data.

REFERENCES

- [1] Mulford DK, Dawson AE. Atypia in fine needle aspiration cytology of nonpalpable and palpable mammographically detected breast lesions. *Acta Cytol* 1994; 38:9-17.
- [2] A. Khemka, N. Chakrabarti, S. Shah, V. Patel. Palpable Breast Lumps; Fine-Needle Aspiration Cytology versus Histopathology: a Correlation of Diagnostic Accuracy. *The Internet Journal of Surgery*. 2009;18(1).
- [3] Hindle WH, Payne PA, Pan EY. The use of fine needle aspiration in the evaluation of persistent palpable dominant breast masses. *Am J Obstetrics Gynaecol* 1993; 168 (6 Part 1): 1814—8.
- [4] Kothi A, Sulya M, Malik R. Role of Fine-Needle Aspiration Cytology in Evaluation of Breast Lumps, *Annals of Applied Bio-Sciences* 2017; 4(3) :143-149.
- [5] Khajuria R, Goswami KC, Singh K, Dubey VK. Pattern of Lymphadenopathy on Fine Needle Aspiration Cytology in Jammu. *JK Science*, 2006; 8(3).
- [6] Homesh N A, Issa M A, El-Sofiani H A. The diagnostic accuracy of fine needle aspiration cytology versus core needle biopsy for palpable breast lump(s). *Saudi Med J* 2005; 26(1): 42-46.
- [7] Tiwari M. Role of fine needle aspiration cytology in diagnosis of breast lumps. *Kathmandu University Medical Journal* (2007), Vol. 5(18): 215-217.
- [8] Alam A, Faruq TA, Bahar MM, Sultana MT. Age Related Incidence of Carcinoma of Breast in Female. *Dinajpur Med Col J* 2012 Jan; 5 (1):47-51.
- [9] Mane S P, Kulkarni A, Ramteke R. Role of fine needle aspiration cytology in diagnosis of breast lumps. *Int J Res Med Sci*. 2017 Aug;5(8):3506-3510.
- [10] O.N. Alema, A.M Gakwaya, D.Wamala. Comparison of Fine Needle Aspiration Cytology and Fine Needle Sampling without Aspiration in Diagnosis of Palpable Breast Lumps in Mulago Hospital. *East and Central African Journal of Surgery*. 2012 March/April; 17(1), 104-111.
- [11] Zareef S, Younis M, Hayat A. Fine Needle Aspiration Cytology of Breast Lumps. *Journal of Rawalpindi Medical College (JRMCC)*; 2011;15(1):35-37.
- [12] Kocay 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;57(2):77-80. doi:10.4103/0300-1652.182078
- [13] Wang M, He X, Chang Y, Sun G, Thabane L. A sensitivity and specificity comparison of fine needle aspiration cytology and core needle biopsy in evaluation of suspicious breast lesions: A systematic review and meta-analysis. *Breast*. 2017;31:157-166. doi:10.1016/j.breast.2016.11.009
- [14] Randa Z, A Khair, Mohamed T, Musa MI, Yahia Al-Tayeb Al-Arabi, evaluation of cytopathology in diagnosing breast cancer in Khartoum. *Khartoum Medical Journal* 2009; 2(1):169 – 171.
- [15] Mulazim Hussain Bukhari, Madiha Arshad, Shahid Jamal, Shahida Niazi, Shahid Bashir, Irfan M. Bakhshi, Shaharyar, "Use of Fine-Needle Aspiration in the Evaluation of Breast Lumps", *Pathology Research International*, vol. 2011, Article ID 689521, 10 pages, 2011
- [16] Moschetta M, Telegrafo M, Carluccio DA, et al. Comparison between fine needle aspiration cytology (FNAC) and core needle biopsy (CNB) in the diagnosis of breast lesions. *G Chir*. 2014;35(7-8):171-176.
- [17] Panjvani SI, Parikh BJ, Parikh SB, Chaudhari BR, Patel KK, Gupta GS, et al. Utility of fine needle aspiration cytology in the evaluation of breast lesions. *J Clin Diagnostic Res*. 2013;7(12):2777-9. Sudarat Nguansangiam, Somneuk Jesdapatarakul, Siriwan Tangjitgamol. Accuracy of Fine Needle Aspiration

Cytology from Breast Masses in Thailand. *Asian Pacific Journal of Cancer Prevention*, Vol 10, 2009, 623-626.

- [18] Saraf S, Khare M, Kalgutkar A. Fine needle aspiration cytology of breast lumps- a correlation with histopathology diagnosis. *In J Pathol Oncol*. 2016;3(1):103-6.
- [19] Modi P, Oza H, Bhalodia J. FNAC as preoperative diagnostic tool for neoplastic and non-neoplastic breast lesions: a teaching hospital experience. *National J Med Res*. 2014;4(4):274-8.