Original Research Article

New Indian Journal of Surgery
Volume 9 Number 3, May - June 2018
DOI: https://dx.doi.org/10.21088/nijs.0976.4747.9318.15

Study of Clinical Examination, Ultrasonography, Cytology Parameters in the Diagnosis of Palpable Breast Lump

Nandkishor Shinde[1], Mohammed Abdul Baseer[2], Kiran Desai[3]

[1,2]Assistant Professor, Department of Surgery, [3]Assistant Professor, Department of Radiology, KBN institute of Medical Sciences, Kalaburgi, Karnataka 585104, India.

How to cite this article:

Nandkishor Shinde, Mohammed Abdul Baseer, Kiran Desai. Study of Clinical Examination, Ultrasonography, Cytology Parameters in the Diagnosis of Palpable Breast Lump. New Indian J Surg. 2018;9(3):328-33.

Abstract

Aim: To study the accuracy of Clinical Examination, Ultrasonography, Cytology Parameters in the diagnosis of palpable breast lump. *Material and Methods:* 81 female patients who presented with palpable breast lump who had undergone clinical breast examination , FNAC and HR-USG of breast lump and subsequent excision biopsy were included in the study. Excision biopsy was considered as a mandatory part of the workup for patients with palpable breast lump. Initially patient was subjected for clinical breast examination which included detailed history, Inspection, Palpation of breast and systemic examination. Then patient was subjected to Ultrasonography. Interpretation of sonography was performed prospectively as benign, suspicious or malignant. FNAC was done after imaging studies, the result of the palpation-guided FNAC was analysed by pathologist and reported as benign, suspicious or malignant. Following this workup, all patients underwent an excisional biopsy. The final histopathological diagnosis was compared with the result obtained by Clinical Breast Examination, Ultrasonography, and Fine Needle Aspiration Cytology examination. *Resulits:* Clinical breast examination had sensitivity of 87.09%; specificity of 90.20%; positive predictive value of 84.37%; negative predictive value of 92% and accuracy of 89.02%. Ultrasonography had sensitivity of 80.65%; specificity of 94.23%; positive predictive value of 89.3%; negative predictive value of 89.1% and accuracy of 89.16%. Fine needle aspiration cytology had sensitivity of 86.21%; specificity of 100%; positive predictive value of 100%; negative predictive value of 92.9% and accuracy of 95.06%. The triad of Clinical breast examination, Ultrasonography and fine needle aspiration cytology (modified triple test) had sensitivity of 95.65%; specificity of 100%; positive predictive value of 100%; negative predictive value of 97.87% and accuracy of 98.55%. *Conclusions:* We conclude that the combined triad of clinical breast examination, Ultrasonography and fine-needle aspiration cytology was highly accurate in the diagnosis of breast lumps.

Keywords: PPV-Positive Predictive Value; NPV-Negative Predictive Value; CBE-Clinical Breast Examination; FNAC - Fine-needle Aspiration Cytology; USG- Ultrasonography; Breast Lump.

Introduction

The public has become increasingly aware of breast cancer and its prevalence and as a result, women presenting with breast complaints are anxious about the possibility of being diagnosed with breast cancer. Clinicians evaluating women with breast complaints should provide a comprehensive, efficient, and timely consultation so that anxiety can be relieved by a benign diagnosis or a treatment plan can be instituted promptly if a cancer diagnosed [1].

Historically, a significant number of breast cancers were detected by Clinical Breast Examination alone. Clinical Breast Examination was recommended as a method for detecting palpable breast cancer earlier [2].

Ultrasonography (USG) of the breast has traditionally been performed to evaluate specific areas of abnormality discovered either at clinical examination or at mammography. The utility of breast USG was believed

Corresponding Author: Nandkishor Shinde, Assistant Professor, Department of Surgery, KBN institute of Medical Sciences, Kalaburgi, Karnataka 585104, India.
E-mail: drnandkishorshinde@gmail.com

Received on 02.03.2018, **Accepted on** 02.04.2018

to be dependent solely on its use as a problem-solving modality and as an adjunct diagnostic tool to mammography [3-5]. With the advent of high-frequency (≥ 7 MHz) transducers, the ability to detect clinically important findings in the breast has improved dramatically and characterization of solid masses as benign or suggestive of malignancy can be established with confidence [6].

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. FNAC of breast is simple, cost effective and less traumatic method for diagnosis of breast lump [7].

A variety of diagnostic tools are available but till date no single tool has 100% sensitivity and specificity. The present study aims to study the individual and combined accuracy of clinical breast examination, ultrasonography and fine needle aspiration cytology in preoperative diagnosis of breast lump in correlation with excisional biopsy.

Materials and Methods

This prospective study was conducted in the Department of Surgery, Khaja Banda Nawaz Institute Of Medical Sciences, Kalaburagi, Karnataka during February 2016 to January 2018; All female patients who presented with palpable breast lump who had undergone clinical breast examination, FNAC and HR-USG of breast lump and subsequent excision biopsy were included in the study. Excision biopsy was considered a mandatory part of the workup for patients with palpable breast lump.

Exclusion criteria were

1. Recurrent breast lumps
2. Fungating mass
3. Lumps for which all 3 elements were not performed or for which the results were not clearly recorded
4. Those not willing for study
5. Those patients who refused for or didn't turn up for excisional biopsy.

Verbal consent was taken for Fine-Needle Aspiration Cytology, Ultrasonography (IMAGING) & Clinical Breast examination. Informed written consent was taken before excisional biopsy.

Initially patient was subjected for clinical breast examination which included detailed history, Inspection, Palpation of breast and systemic examination. All findings on clinical breast examination were recorded in the predesigned case proforma. Then patient was subjected to Ultrasonography. The scan was performed with an Esaote MyLab60 Gold Platform, Linear probe of 7.5 to 10MHz. Each lesion was classified according to the BI-RADS sonographic protocol. Interpretation of sonography was performed prospectively as benign, suspicious or malignant (Figure 1,2). FNAC was done after imaging studies, the result of the palpation-guided FNAC was analysed by pathologist and reported as benign, suspicious or malignant (Figure 3,4). Following this workup, all patients underwent an excisional biopsy. The final histopathological diagnosis (Figure 5,6) was compared with the result obtained by Clinical Breast Examination, Ultrasonography, and Fine Needle Aspiration Cytology examination.

Statistical Analysis

Sensitivity was defined as the percentage of cases in which biopsy-proven cancer was correctly diagnosed by diagnostic modality. Specificity was defined as the percentage of cases in which biopsy

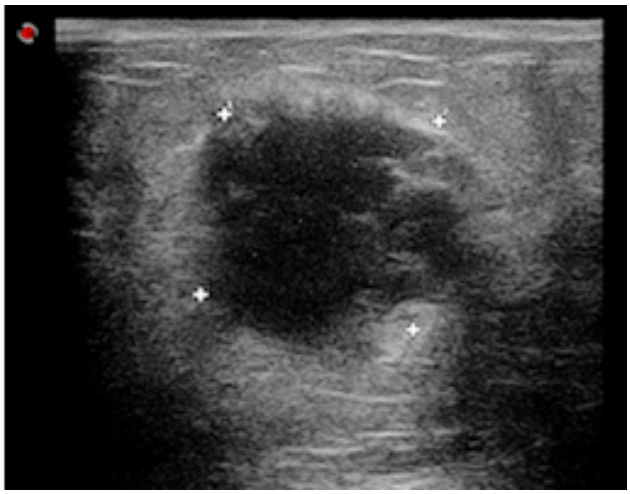

Fig. 1: HRUSG Breast-Benign Lump

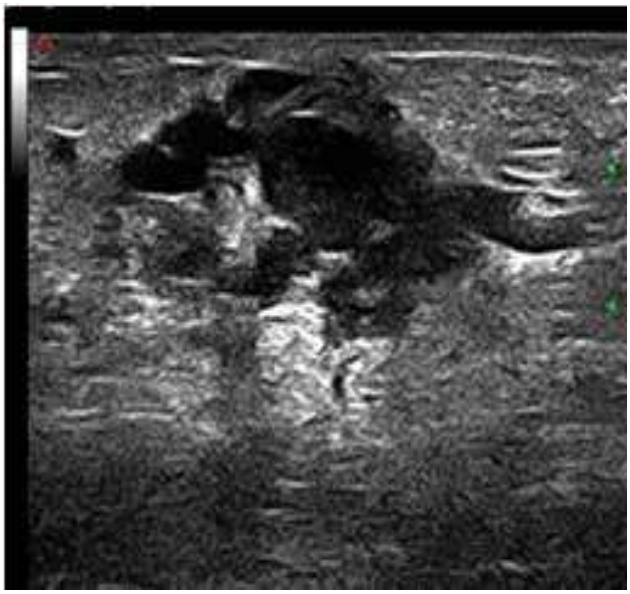

Fig. 2: HRUSG Breast-Malignant Lump

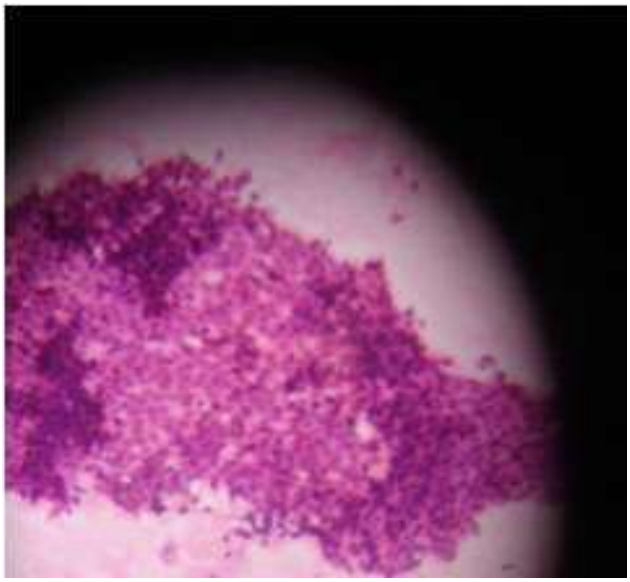

Fig. 3: FNAC –Benign (10X)

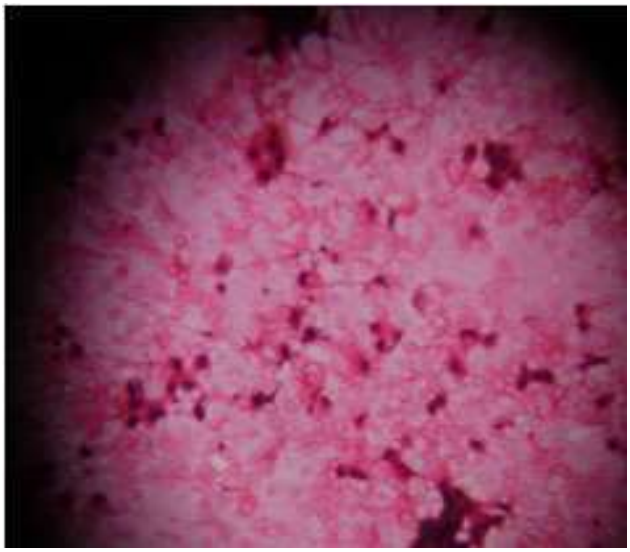

Fig. 4: FNAC-Malignant (10X)

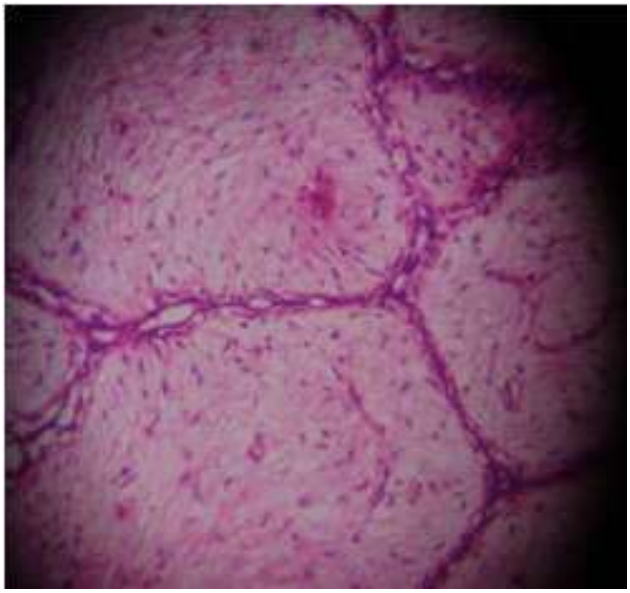

Fig. 5: HPE Fibroadenoma

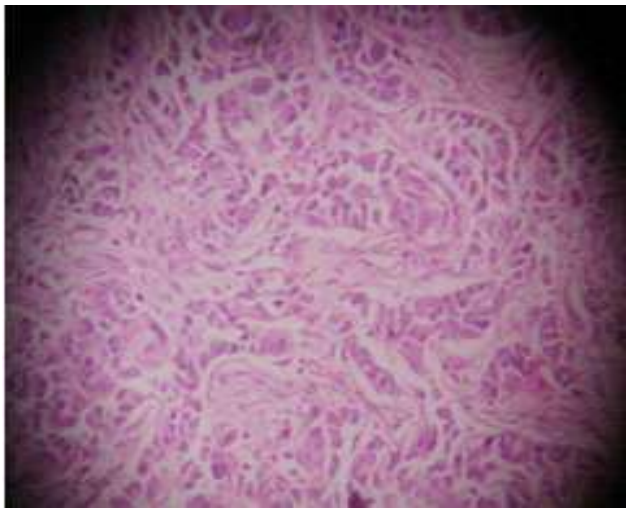

Fig. 6: HPE Ductal Carcinoma

proven benign lesions were correctly diagnosed as benign by diagnostic modality [8].

TP indicates true positive; TN, true negative; FP, false positive; and FN, false negative:

Positive Predictive Value=TP/ (TP + FP)

Negative Predictive Value=TN/ (TN+FN)

Accuracy= (TP + TN)/ (TP+TN + FP+FN)

Sensitivity=TP/ (TP+FN)

Specificity=TN/ (TN + FP)

Statistical analysis was performed using SPSS, version 18.0 software.

Results

There were 81 patients with 84 palpable breast lumps who had fulfilled the inclusion criteria and entered the study. Out of 81 patients 03 patients had bilateral breast lumps. According to the final histopathological diagnosis of excisional biopsy; 53 lumps in 50 patients were benign and 31 lumps in 31 patients were malignant.

According to the final histopathological diagnosis of excisional biopsy; 53 lumps in 50 patients were benign and 31 lumps in 31 patients were malignant. Mean age at presentation of all breast lumps was 37.06±16.42 years and mean age of presentation of malignant lump was 53.52±9.37 years. Mean duration of presentation of malignant lump was 17.52±15.57 weeks. 9.68% (03) patient with malignant lumps had history of contraceptive use. Mean age at menarche in patients with malignant lump was 12.32±0.8years. Mean age at menopause in patients with malignant lumps was 44.8years. 22.58% (07) patients with malignant lumps had family history of breast cancer. 70.96% (22) patients with malignant lumps had Stage-II disease.

Clinical breast examination had sensitivity of 87.09%; specificity of 90.20%; positive predictive value of 84.37%;

negative predictive value of 92% and accuracy of 89.02%. Ultrasonography had sensitivity of 80.65%; specificity of 94.23%; positive predictive value of 89.3%; negative predictive value of 89.1% and accuracy of 89.16%. Fine needle aspiration cytology had sensitivity of 86.21%; specificity of 100%; positive predictive value of 100%; negative predictive value of 92.9% and accuracy of 95.06% (Table 1).

The triad of Clinical breast examination, Ultrasonography and fine needle aspiration cytology (modified triple test) had sensitivity of 95.65%; specificity of 100%; positive predictive value of 100%; negative predictive value of 97.87% and accuracy of 98.55% (Table 2).

Discussion

Breast lumps in women are a common clinical problem that requires rapid and accurate evaluation with an important aim of excluding any malignancy. The classical triple test includes Clinical breast examination, mammogram and fine needle aspiration cytology. We have modified this approach by substituting mammogram with high resolution ultrasound for the assessment of breast lesions.

Many reports supported the usefulness of "triple test" (physical examination, mammography, and fine needle aspiration cytology) for evaluation of palpable breast lesions. With improvement of imaging equipment and techniques over time, sonography is emerging as an important diagnostic tool of breast imaging. In our study we replaced mammography with high frequency ultra sonography for breast imaging as ultrasound is easily available, cost effective, noninvasive and safe. In 1996 modified triple test in which mammography was replaced with sonography for palpable breast masses was studied first time by Vetto JT et al. [8].

In our study, concordant lumps were 69 on combined triad of clinical breast examination, ultrasonography and fine needle aspiration cytology (modified triple test). Out of these 47 were benign and 22 were malignant on modified triple test, but 46 were benign and 23 were malignant on final histopathological diagnosis of excisional biopsy .Thus in our study combined triad of clinical breast examination, ultrasonography and fine needle aspiration cytology (modified triple test) had sensitivity of 95.65%; specificity of 100%; positive predictive value of 100%; negative predictive value of 97.87% and accuracy of 98.55%.

In our study, benign neoplasms were more common than malignant and their distribution was similar to other studies [9-12].

The specificity of modified triple test in our study is comparable with triple test studies in which mammography was used instead of USG by Morris KT et al. [10], Jensen A et al. [11] and Ahmed I et al .[12], but higher than the studies conducted by Ghimire B et al.[13] and Kaufman Z et al. [9] (Table 3).

Table 1: Analysis of Results of Individual Diagnostic Modality

Parameter	CBE	USG	FNAC	Excisional Biopsy
Total Lumps	84	84	84	84
Benign Lumps	50	55	56	53
Suspicious Lumps	02	01	03	00
Malignant Lumps	32	28	25	31
Sensitivity	87.09%	80.65%	86.21%	-
Specificity	90.20%	94.23%	100%	-
PPV	84.37%	89.29%	100%	-
NPV	92.00%	89.09%	92.86%	-
Accuracy	89.02%	89.16%	95.06%	-

Table 2: Analysis of Results of Clinical Breast Examination + FNAC + USG

Concordant Lumps	69
Benign Lumps Oncbe+Usg+Fnac	47
Malignant Lumps On Cbe+Usg+Fnac	22
Sensitivity	95.65%
Specificity	100%
Positive Predictive Value	100%
Negative Predictive Value	97.87%
Accuracy	98.55%

Table 3: Various other studies showed sensitivity, specificity, positive predictive value, negative predictive value and accuracy for triple test as below

Studies	Sensitivity	Specificity	PPV	NPV	Accuracy
Vetto JT et al[8]	100%	91%	29%	100%	91%
Kaufman Z et al[9]	100%	57%		100%	-
Morris KT et al[10]	100%	100%		100%	-
Jensen A et al[11]	99%	100%	99.6%	100%	-
Ahmed I et al[12]	100%	100%	100%	100%	-
Ghimire B et al[13]	100%	95.2%	96.7%		98%
Our series	95.65%	100%	100%	97.87%	98.55%

Some studies found FNAC to be the most sensitive and specific [9-14], while mammography was found highly effective by others [15,16]. These varied results probably reflect the availability of expertise in an institute as cytological and radiological interpretations are dependent on training and experience.

When all three diagnostic modalities were in agreement for a diagnosis of benign disease, the combination of clinical breast examination, Ultrasonography and fine-needle aspiration cytological examinations had excellent concordance with the results of excision biopsy, and in this situation a period of close observation with repetition of FNAC may be safely entertained. If all three modalities were in agreement for a diagnosis of malignant disease, in this situation definitive treatment may be carried out. Lack of concordance of three diagnostic modalities mandates biopsy. Modified triple-test positivity does not predict a worse outcome. As our study was restricted to tertiary care centre in northern Karnataka and the sample size was small as compared to other studies. further studies with a larger data set would be required to validate the results.

Recommendations

We recommend the routine use of combined triad of clinical breast examination, ultrasonography and fine-needle aspiration cytology (modified triple test) in preoperative diagnosis of breast lump.

We recommend replacement of mammography by high resolution ultrasonography in triple test and reconsideration of modified triple test in definitive diagnosis of breast lump as ultrasonography is easily available, noninvasive, cost effective and safe.

Conclusions

We conclude that the combined triad of clinical breast examination, ultrasonography and fine-needle aspiration cytology was highly accurate in the diagnosis of breast lumps.

Conflict of Interest: None

Source of Support: Nil

References

1. Fischer Josef E. Mastery of Surgery, 5th Edition, Philadelphia PA 19106 USA. Lippincott Williams & Wilkins; 2007.
2. McDonald S, Saslow D, Alciati MH. Performance and reporting of clinical breast examination: A review of the literature. CA Cancer J Clin 2004;54:345–61.
3. Frazier TG, Murphy JT, Furlong A. The selected use of ultrasound mammography to improve diagnostic accuracy in carcinoma of the breast. J Surg Oncol 1985; 29:231-32.
4. Kopans DB. What is a useful adjunct to mammography?. Radiology 1986;161:560-61.
5. Bassett LW, Kimme-Smith C. Breast sonography. AJR Am J Roentgenol 1991;156:449-55.
6. Stavros AT, Thickman D, Rapp CL, Dennis MA, Parker SH, Sisney GA. Solid breast nodules: use of sonography to distinguish between benign and malignant lesions. Radiology 1995;196:123–34.
7. Tiwari M, Role of fine needle aspiration cytology in diagnosis of breast lumps; Kathmandu University Medical Journal (KUMS) 2007;5(2):215-17.
8. Vetto JT, Pommier RF, Schmidt WA, Eppich H,Alexander PW. Diagnosis of palpable breast lesions in younger women by the modified triple test is accurate and cost-effective. Arch Surg 1996;131:967–74.
9. Kaufman Z, Shpitz B et al. Triple approach in the diagnosis of dominant breast masses: combined physical examination, mammography, and fine-needle aspiration. J Surg Oncol. 1994 Aug;56(4):254-7.
10. Morris KT, Pommier RF, Morris A et al. Usefulness of the triple test score for palpable breast masses. Arch Surg 2001;136:1008–1012.
11. Jensen A, Rank F et al., Performance of combined clinical mammography and needle biopsy: a nationwide study from Denmark.APMIS; 2006 Dec;114(12):884-92.
12. Ahmed I, Nazir R et al. Triple assessment of breast lump.J Coll Physicians Surg Pak. 2007 Sep;17(9):535-8.
13. Ghimire B. Khan MI et al. Accuracy of triple test score in the diagnosis of palpable breast lump. JNMA J Nepal Med Assoc. 2008 Oct-Dec;47(172):189-92.
14. Abdulrahman Saleh Al-Mulhim, Mohammed Sultan, Faisal Mohammed Al- Mulhim, Adel Al-Wehedy, Adel Mohammed Ali, et al. Accuracy of the "triple test" in

the diagnosis of palpable breast masses in Saudi females. Annals of Saudi Medicine 2003;23(3-4):158-61.

15. Paul Ian Tartter, Judith Samuels, Joan Bratton. Clinical examination, Mammography and Fine-Needle Aspiration Cytology in the Management of palpable breast masses. The Breast Journal 2007 Jan;3(3):127-30.
16. Philip J Drew, Lindsay W Turnbull, Sumohan Chatterjee, John Read, Peter J Carleton, et al. Prospective comparison of Standard Triple Assessment and Dynamic Magnetic Resonance Imaging of the Breast for the Evaluation of Symptomatic Breast Lesions. Annals of Surgery 1999 Nov;230(5):680-5.