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Triple Assessment of Breast Lump (Physical Examination, Mammography, Fine Needle Aspiration Cytology): A Prospective Study.

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ABSTRACT

The breast lump is clinical presentation of numerous breast disorders ranging from innocent benign cysts to malignant neoplastic lesions. Distinction of benign from malignant is of paramount importance for patient care and proper management. One fourth of the women suffer from breast diseases in their lifetime. Carcinoma of the breast is the second most common cancer in the world. Lump in the breast is the commonest presentation of breast carcinoma. An early and accurate diagnosis is of paramount importance because the treatment can be initiated much earlier and may be life saving in most cases. The conventional open biopsy is considered as gold standard for confirming the diagnosis but it can be time consuming and economically unviable in most cases. A definite preoperative diagnosis of breast lump provides ample opportunity for patients to be counseled and single stage surgical treatment be made possible. Thus the combination of physical examination, mammography and FNAC came in the picture which is known as Triple Assessment. (Triple Test). A triple test has been formed which is quick, least invasive and cost effective in terms of money and time.

Keywords: Triple Test, Fine needle aspiration cytology (FNAC), mammography, breast lump

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INTRODUCTION

The breast lump is clinical presentation of numerous breast disorders ranging from innocent benign cysts to malignant neoplastic lesions. Distinction of benign from malignant is of paramount importance for patient care and proper management.

One fourth of women suffer from breast diseases in their lifetime [1,2].

Carcinoma of breast is second most common cancer in the world [3]. Life time risk of developing breast cancer is one in eight [4]. Lump in the breast is the commonest presentation of breast carcinoma. Timely and accurate diagnosis of breast lump with early intervention can be life saving.

There are various modalities for diagnosis of breast lump such as mammography, ultrasonography, MRI and fine needle aspiration cytology etc..but all of them have their own limitations.

Conventional open biopsy which is considered as gold standard for confirming diagnosis, has significant morbidity, is costly and time consuming.

A definite preoperative diagnosis of breast lump provides ample opportunity for patients counselling and planning of possible single stage surgical treatment, so there is dire need for evolving a method for establishing diagnosis preoperatively, which is cost effective and least invasive to patient with accuracy comparable to open biopsy.

Thus the combination of physical examination, mammography and FNAC came in picture, which is known as TRIPLE ASSESSMENT (or Triple Test) of breast lump. There are numerous reports that if the results of clinical assessment mammography and FNAC are all combined, the accuracy of diagnosis reaches up to 90% [7,8].

Based upon this concept triple test has been formed which is quick, least invasive and cost effective in terms of money and time.

Aims and Objectives

This study was done to compare triple assessment of breast with regards to

- To determine sensitivity, specificity, positive and negative predictive value of triple test {TT} consisting of physical examination, mammography, fine needle aspiration cytology {FNAC} in evaluation of palpable breast lump.
- Evaluate and compare overall accuracy of triple test and its components.
- To check if triple assessment can be employed as an alternative for excisional biopsy.

MATERIAL AND METHODS

This was a prospective study carried out in department of surgery.

Total 50 patients were included in this study. All female patients above or 35 years of age having palpable breast lump were included in this study.

Exclusion criterias were

- Patients with fungating masses.
- Patients with acute inflammatory signs.
- Patients with cystic lesions (confirmed by USG)
- Pregnant women.
- Male patients.

The study was approved by Institutional Ethical Committee.

All patients were explained about the procedure and informed consent was obtained from them.

All patients underwent three types of assessments namely

Physical examination, mammography and fine needle aspiration cytology.

Physical Assessment Included

- a) Detailed patient history regarding the symptoms which commonly included lump in the breast, nipple discharge, axillary lump and weight loss.
- b) Clinical examination :
 - 1) Inspection : Inspection was done in good light with patients arm by her side, above her head, then pressing on her hips. Involved breast was inspected with respect to nipple, areola, details of lump including : size, site, overlying skin.
 - 2) Palpation : breast palpation was performed with patient lying flat with her arms above her head and all the breast tissue was examined using finger tips. If an abnormality was identified it was then assessed for contour, texture and any deep fixation by tensing the pectoralis major muscle, which was accomplished by asking the patient to press her hands on her hips. Clear details of any breast abnormalities, including dimension and exact position were recorded. The other breast was also palpated. Bilateral axillary lymph node examination was done.

Fine Needle Aspiration Cytology

Procedure was carried out by pathologist using 26 gauge needle. The material aspirated was stained and studied under microscope.

Mammography

Mammography was carried out in the radiology department and reports were obtained to differentiate between benign and malignant lumps. Reporting was done in accordance to BIRADS (Breast imaging Reporting And Data System) [5,6].

BIRADS and Its Recommendations

CATEGORY	DEFINITION
0	Incomplete assessment; need additional imaging evaluation
1	Negative; routine mammogram in 1 year recommended
2	Benign findings; routine mammogram in 1 year recommended
3	Probably benign findings; short term follow up suggested
4	Suspicious abnormality; biopsy should be considered
5	Highly suggestive of malignancy; appropriate action should be taken

All the cases had undergone surgery and histopathological examination subsequently. Triple assessment was modified by assigning a score of 1,2 or 3 points per benign, suspicious or malignant result

respectively. Individual element scores were added together to yield a total triple test score for each lesion. This system results in a minimum score of 3 for concordant benign test result and maximum score of 9 for concordant malignant test result.

RESULTS

Of the 50 patients admitted with breast lumps 32 patients were in age group of 35-44 years, 12 were in 45-54 years and 6 were above 55 years. Mean age was 45.36 years. Out of 50 cases 41 were having benign disease and 9 were having malignancy. 31 patients out of 50 had benign disease in age group of 35-44 and only 1 had malignancy in above said age group. 6 patients were found malignant in age group above 55 years.

Table 1 : Agewise patient distribution

Age	Number of patients
35-44	32
45-54	12
>55	6

Table 2 : Distribution according to disease status

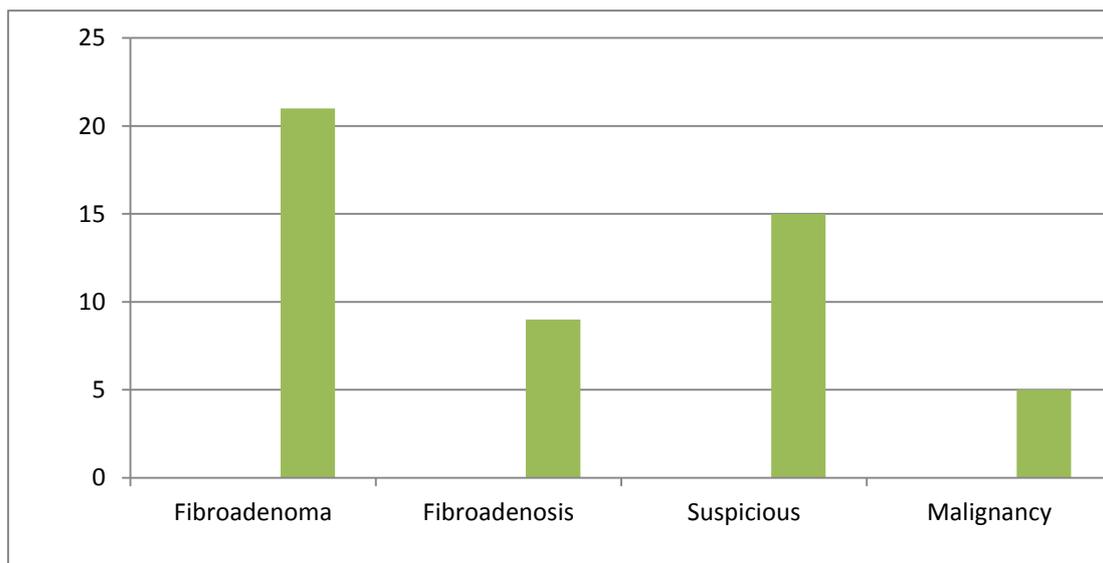
Benign	Malignant
41	9

Table 3 : Distribution of malignancy according to age

Age	Benign	Malignant
35-44	31	1
45-54	10	2
>54	0	6

On clinical examination only 5 were diagnosed as malignancy, 15 were suspicious for malignancy and other were diagnosed as benign lesions.

Clinical Diagnosis Of Breast Lump



**Diagram depicting number of cases and their clinical diagnosis
FNAC diagnosis of breast lumps**

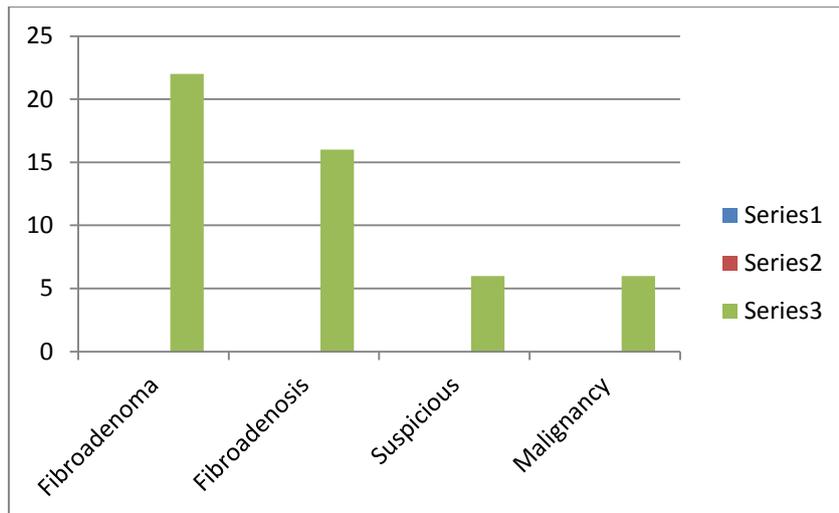


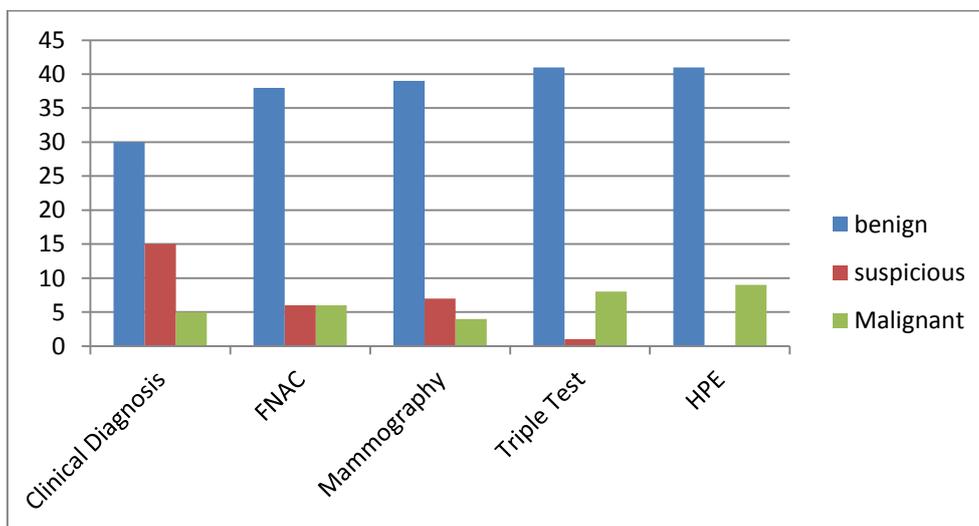
Diagram depicting case wise distribution : FNAC 6 lumps were diagnosed as malignant, 6 were suspicious of malignancy and 38 were benign lumps.

Mammography diagnosis of breast lumps



Mammography had shown 39 benign lumps, 3 suspicious of benign lumps, 4 suspicious of malignant and 4 as malignant lumps.

Comparison of components of triple assessment with histopathological report

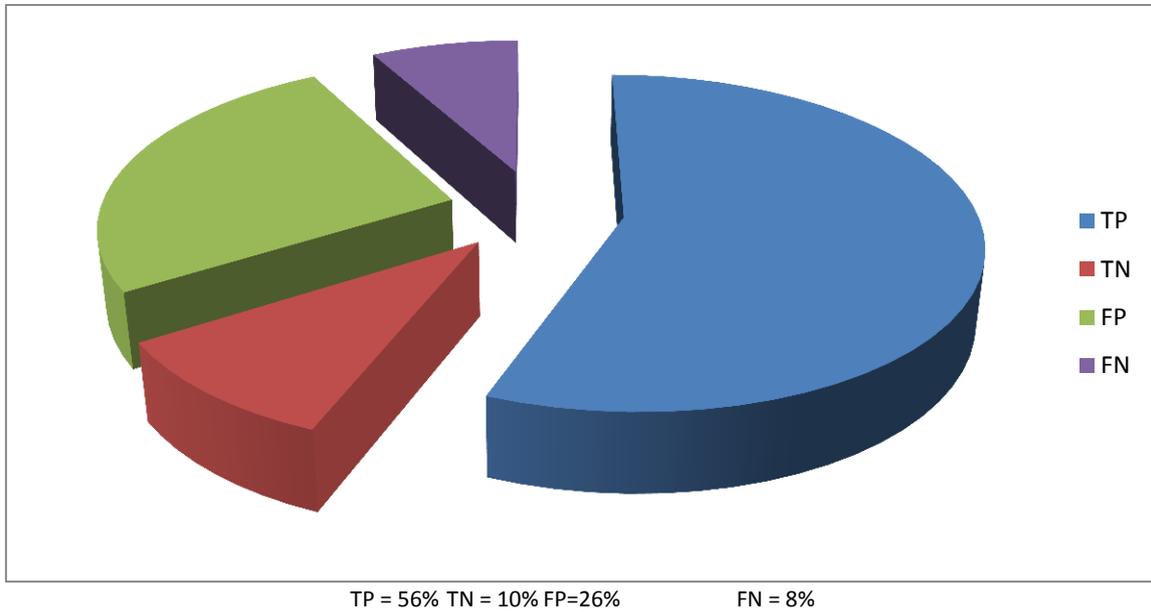


In our study 15 cases were suspicious for malignancy on clinical examination, 6 on FNAC and 7 on mammography. But after applying triple test score only one patient scored 5 who was subjected to open biopsy which turned out to be malignant.

Accuracy of physical examination in diagnosing breast lump

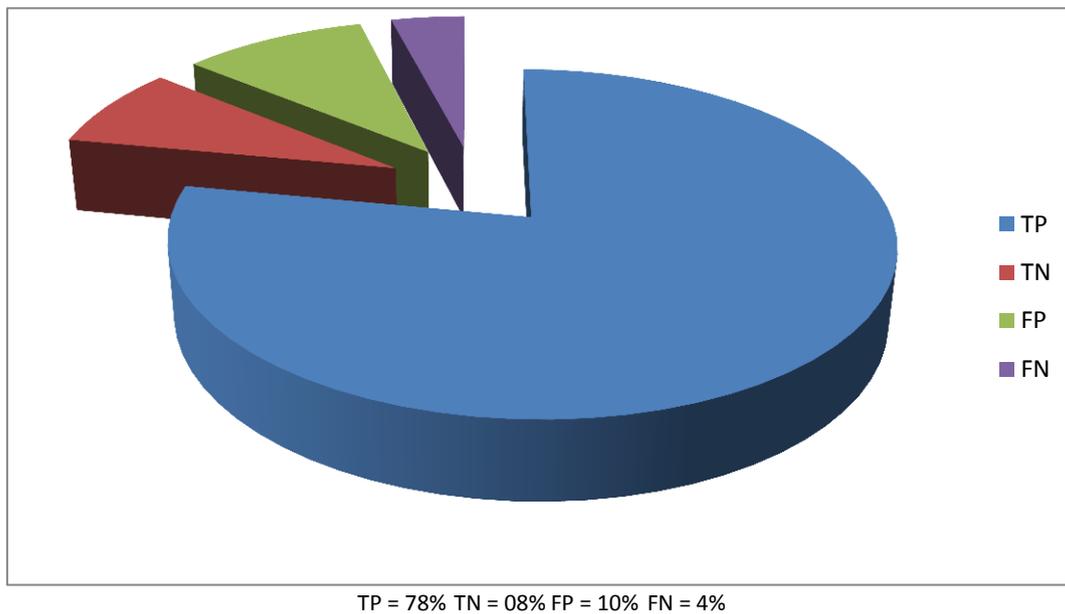
On physical examination, sensitivity is 68.2% specificity is 55.5%, positive predictive value for malignancy is 87% and negative predictive value for malignancy is 27.7%.

Physical Examination



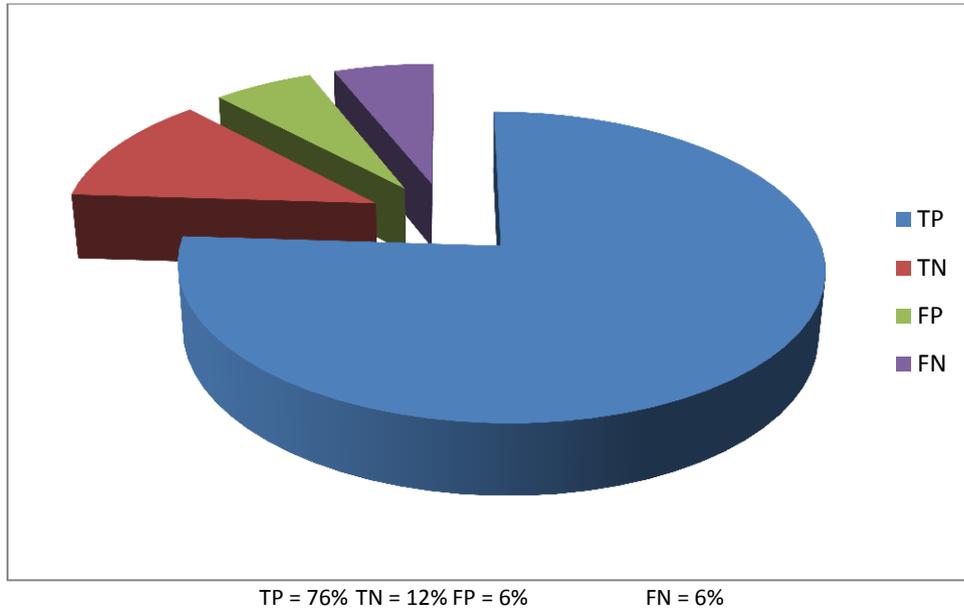
Accuracy of Mammography in diagnosing breast lump

On mammography sensitivity is 95.1% specificity is 44.4% positive predictive value (PPV) for malignancy is 88.6% and negative predictive value for malignancy is 66.6%



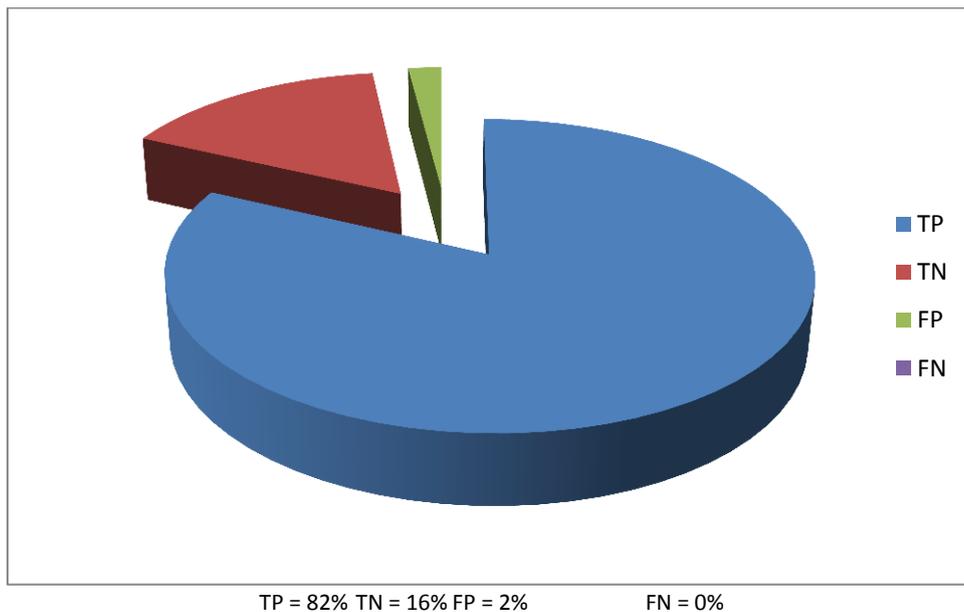
Accuracy of FNAC in diagnosing breast lump

On FNAC sensitivity is 92.6%, Specificity is 66.6%, Positive predictive Value (PPV) for malignancy is 92.6% and negative predictive value for malignancy is 66.6%.



Accuracy of Triple assessment in diagnosing breast lump

Triple assessment of breast lump has sensitivity of 100% Specificity of 88.8% PPV for malignancy is 97.6% and NPV for malignancy is 100%.



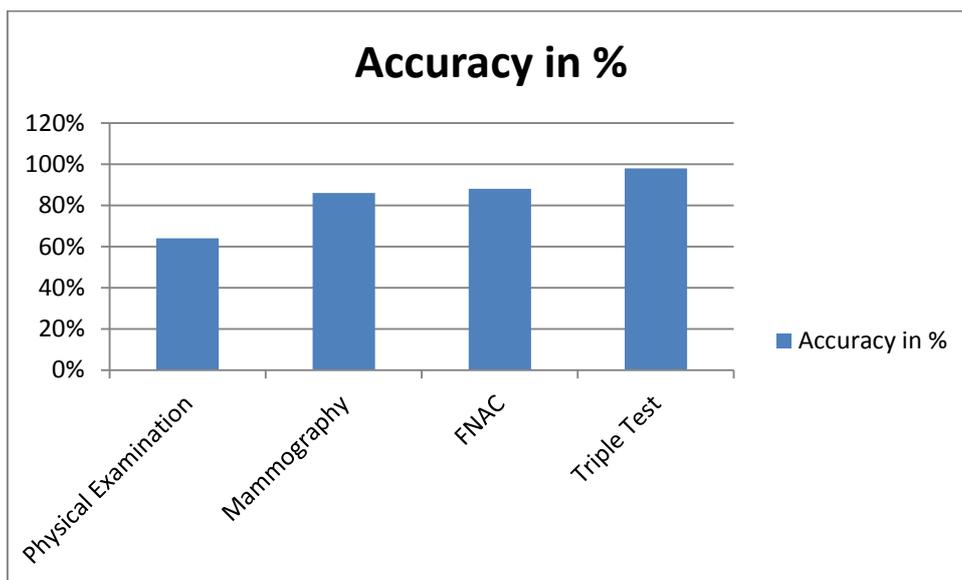
Comparison of accuracy in components of triple test

As shown below physical examination alone has very low sensitivity and specificity. FNAC and mammography have more than 90% sensitivity but lack in specificity. But Triple Assessment has 100% sensitivity and 88.8% of specificity.

Comparison of accuracy in components of triple test

	Sensitivity	Specificity	PPV	NPV
Physical Examination	68.8%	55.5%	87.5%	27.7%
Mammography	95.1%	44.4%	88.6%	66.6%
FNAC	92.6%	66.6%	92.6%	66.6%
Triple Test	100%	88.8%	97.6%	100%

The overall accuracy of Physical examination was the least (64%) and Triple assessment was the highest (98%).



DISCUSSION

Benign lesions of breast are fairly common occurrence. Fibroadenoma is having most frequent occurrence in our study followed by fibroadenosis.

In our study the incidence of fibroadenosis was relatively high that may be because most of the patients fall in perimenopausal group (35- 50 years) [41].

Benign diseases were more common in patients with age less than 55 years whereas malignancy is more common in ≥ 55 years age group.

Malignancy was more evident ≥ 55 years in our study which is also similar to a study done in Ottawa Civic Hospital, Canada. [42]

We only had three unmarried and nulliparous women in our study. None of them had malignancy but these women were falling in 35 to 45 years age group and were premenopausal, so again chance of having malignancy was relatively less.[42]

The occurrence of malignancy was more in post menopausal group, which is also similar to previously done studies.[42,43]

Only 6 patients had history of taking O.C. pills but none of them were harboring malignancy. This result is against literature but it may be due to small sample size.

Large majority of breast disease were found to be localized to upper outer quadrant. This is due to large amount of glandular tissue in this sector.

On clinical examination only 5 were diagnosed as malignancy, 15 were suspicious for malignancy and other were diagnosed as benign lesions. So clinical suspicion for malignancy comprised of 30% of patients. Out of these most were having benign lesions. Also to be noted that on physical examination 2 cases were thought to be benign, turned out to be malignant on investigations.

Multiple studies have shown various rates of accuracy in FNAC.

In our study FNAC was found to have sensitivity of 92.6% and specificity is 66.6% for differentiation of benign from malignancy. Overall accuracy of FNAC was 96% in our study.

These rates were comparable to various studies.

In award winning study done in University of Zambia, Kasonade B et al. had reported FNAC to be 72% sensitive and 94% specific in detecting cancer. [26]

Tiwari M. had shown FNAC sensitivity of 87% overall accuracy of 90% which is comparable to our study.

In the study done at Frontier medical college Abbottabad; the author has mentioned FNAC sensitivity of 87.5% and specificity of 82.4% and overall accuracy of 84%[28]

This is also comparable to our study. On mammography sensitivity is 95.1% specificity is 44.4%, positive predictive value (PPV) for malignancy is 88.6% and negative predictive value (NPV) for malignancy is 66.6%.

In 7 years meta analysis from data of various countries the conclusion was derived as there is high rate of over diagnosis (about 52%) on diagnosing malignancy only based on mammography [44]

This also explains low specificity for detecting benign disease in our study.

In retrospective study of 62,219 mammography reports, Jagpreet C et al found sensitivity of mammography to be 90%. [15]

This data has similar results to our study.

In our study triple assessment of breast lump has sensitivity of 100%, specificity of 88.8%, PPV for malignancy is 97.6% and NPV for malignancy is 100%. Overall accuracy of 98% was noted in triple assessment.

In a study done in 2008 author concluded overall accuracy of triple test to be 98% with sensitivity of 100% and specificity of 95.2% and PPV value of 96.7% [7].

This study has results similar to our study.

In a recently reported study done at Kashmir, Masooda J et.al studied 200 patients. They found triple assessment very accurate (99.3%).

They reported triple assessment 100% sensitive and 99.3% specific. [34]

These reports are supporting our study. In a study of 479 patients, Catherine et al reported that after triple assessment only 8% of patients required excisional biopsy. [33]

In our study this rate was only 2%. The difference between two groups was not statistically significant. So triple assessment can be safely applied to reduced number of excision biopsies for diagnosis.

CONCLUSION

50 cases of breast lump were studied during period of two years and following conclusions were drawn:

- Fibroadenoma is most frequently encountered breast lump.
- Higher incidence of fibroadenosis is seen in perimenopausal group.
- There was almost equal distribution of pre and post menopausal women given lower limit of 35%.
- Lump in the breast was most common presenting symptom that brings women to breast clinic.
- Majority of patients present with shorter duration of symptoms ranging from less than two months to six months.
- Upper outer quadrant is the most commonly affected site.
- Physical examination of breast lump alone has very low accuracy.

- FNAC and mammography have good sensitivity but if used independently they lack in specificity.
- Combination of physical examination FNAC and mammography has given very high accuracy.
- Implementation of triple assessment for diagnosing the breast lumps, reduces need of excisional biopsy for diagnosis.

SUMMARY

- 50 females with complaint of breast lump were admitted to Padmashri D.Y.Patil Medical college & Hospital were studied in perspective of clinical presentation and its relation to pathological and radiological diagnosis.
- Lower limit of age group was kept at 35 years. Among the studied cases the oldest case was 80 years old. Most of the patients were between 35 to 44 years of age.
- There was almost equal number in premenopausal (n=22) and post menopausal (n=28) age group.
- Three of them were unmarried and nulliparous.all of our cases presented to us with a lump in breast of size more than 2 cm. with shorter duration of symptoms ranging from 2 months to 6 months.
- Family history could not be found significant in our study. 25 cases had lump only of right side and 20 had lump on left side. Only 5 had bilateral lumps.
- Most commonly affected site was upper outer quadrant.
- On physical examination only five had palpable lymph nodes, 3 had fixity to pectoralis major muscle and only 2 had skin changes.
- Mammography and FNAC were carried out in all patients and later triple assessment score was calculated for every case.
- All patients had undergone surgery and specimen was sent for histopathology.
- Histopathology report was considered as final diagnosis for patient.
- Accuracy of triple assessment and its components were measured by comparing them with histopathology report.
- If applied alone all three components of triple assessment were having less accuracy but combining them made them more accurate.
- Triple assessment was also found to lower the need for excision biopsy for diagnosis.

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