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Evaluation of Breast Diseases by Clinical, Pathological and Radiological Assessment

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Abstract
Introduction: *Breast masses are common clinical presentation in breast clinics, have variety of etiologies, benign or malignant, their management and prognosis depend on early diagnosis and prompt treatment. The triple assessment has been routinely practiced in the developed world since its earliest evaluation .Triple assessment includes clinical, radiological and pathological assessment of breast lump*
Materials & Methods: *All patients with lump in the breast or any other breast complaint, attending OPD / admitted in a tertiary care Hospital, during the period from Oct 2013 to Sep 2015 about 50 patients were evaluated with clinical examination, ultrasonography and FNAC or biopsy of the lump. Results were made into charts based on different parameters and conclusions regarding sensitivity and specificity of each parameter and predictive values were drawn*
Conclusion: *Triple test is a very useful tool in evaluating the breast diseases. In patients with definite lump, Clinical examination and FNAC alone may be sufficient to rule out malignancy and this may be cost-effective by avoiding a mammogram. Mammogram is needed in patients with no clinically palpable lump and to rule out multi-centric and multi-focal disease. USG may be used instead of mammogram to avoid the radiation due to mammogram.*
Keywords*: Breast Lump, FNAC, Triple assessment, Ultrasonography*

Inroduction

Breast masses are common clinical presentation in breast clinics, have variety of etiologies, benign or malignant, their management and prognosis depend on early diagnosis and prompt treatment[1]

The diagnostic approach of palpable breast lumps should involve the use of rapid, inexpensive, most accurate and least invasive methods to evaluate and distinguish between benign and malignant lumps in outpatient clinics, such methods would benefit both patients and surgeons by promoting proper preoperative diagnosis and management. Further limits unnecessary testing and procedures[2,3,4].

The triple assessment has been routinely practiced in the developed world since its earliest evaluation[5,6] .

Evaluation of Breast Masses

The general approach to evaluation of breast masses or other symptoms suspicious of carcinomas has become formalized as triple assessment, involving a combination of Clinical assessment (history and examination), Imaging studies(usually ultrasound and or mammography) and Tissue sampling taken for either (cytological or histological) analysis[3,4].

The aim of evaluation is to avoid missing malignant lesions, provides reassurance in benign conditions and determines what treatment if any, is indicated.

Clinical diagnosis of breast cancer is of higher sensitivity than specificity and has high diagnostic error. Mammography and FNAC respectively have lower sensitivity than specificity but have high positive predictive values.

When combined in the triple assessment, a definitive diagnosis can be made when the diagnoses concur, suggesting that the triple assessment has a high sensitivity, specificity, positive predictive value and negative predictive value with minimal error and excellent Kappa statistic.

This thesis explores contrast mechanisms in X-ray imaging. Special emphasis is given to the benefits of and problems encountered in application of monochromatic X-rays for imaging, which provides more

detailed information from the specimen examined than is available with standard systems. The results of the original articles are summarised and conclusions and prospects for future development are presented.

Aim And Objectives

- To study the clinical, radiological & pathological assessment in evaluation of breast diseases.
- To compare efficacy of clinical and radiological diagnostic modalities with histopathological examination to create a road map for treatment.

Patients And Methods

Source Of Data

All patients with lump in the breast or any other breast complaint, attending OPD / admitted in tertiary care hospital , during the period from Oct 2013 to Sep 2015.

II. Method Of Collection Of Data

A Performa drafted for the study of all patients with breast complaints, like lump, nipple discharge or retraction. Evaluation will be done by history, clinical examination, mammography, Ultrasonogram, FNAC and HPE

Sample size : 50 patients
Sampling method : Simple random sampling

Inclusion criteria :

- Females presenting with any Breast related complaints

Exclusion criteria:

Patients with

- Lump associated with fungation
- Open biopsy and HPE performed prior to presentation to our hospital
- Patients who did not continue treatment / lost follow up / underwent non- surgical treatment (chemotherapy/radiotherapy).

Investigations

- Mammography of both breasts
- Ultra-sonogram of both breasts
- Fine needle aspiration cytology of breast lesion, direct or image guided
- Histopathological examination

Clinical examination

Can be considered under following heads

Patient position: Patient Examined in sitting position with hands by side and hands above head, supine position, recumbent position and leaning forward position.

Breast boundaries: The rectangular area bordered by the clavicle superiorly, midsternum medially, the mid axillary line laterally and the inframamarry or 'bra line' inferiorly.

Examination pattern: Palpation begins in the axilla in a straight line down the midaxillary line to the bra line. Fingers then move medially and palpation continues up the chest in a straight line to clavicle. Entire breast is covered in this manner going up and down.

Fingers: The three middle fingers with metacarpophalangeal joint slightly flexed are used and the pads of these fingers are the palpating area.

Duration: About 3 minutes are to be spent on each breast.

Other issues: Palpation of supra clavicular and axillary regions to detect adenopathy is a standard part of clinical breast examination.[7]

Mammography and / or Ultra sound was done for patients before FNAC. The results were analyzed and categorized according to BIRADS (Breast Imaging Reporting and Data System) score. Both cranio-caudal and medio-lateral views are taken and the image was assessed and scored using the BIRADS

Breast Imaging Reporting and Database System (BI-RADS®)	
CATEGORY	ASSESSMENT
0	Needs further evaluation
1	Negative
2	Benign Finding
3	Probably Benign
4	Probably Malignant
5	Malignant
6	Proven Malignancy

Fig. Birads scoring system

Fnac

Materials

Needles - 23/22 gauge 30-50 mm needle are recommended for the breast

Syringes - 5-10ml, good quality plastic disposable syringes that provide good negative suction.

Slides thoroughly cleaned dry glass slides free of grease to be used. The aspirate can be smeared between two standard microscope slides.

Fixative - 90% ethanol.

FNAC diagnoses were respectively scored as: Insufficient sample - C1

Benign - C2

Probably Benign - C3

Suspicious of malignancy - C4

Malignant - C5

Patient preparation

Procedure must be explained and patient must be placed in a comfortable position. For breast lumps simple spirit swab provides disinfection and local anesthesia is not usually required except in apprehensive patients.

Technique

The needle connected to a syringe is introduced into the lesion. A vertical approach is less painful and gives better perception of depth. Negative suction is applied and multiple passes are made within the lesion. Negative suction is released before the needle is withdrawn.

Processing the sample

The sample is expelled onto a slide. Aspirate can be 'dry' (numerous cells in small amounts of tissue fluids) or 'wet' (small number of cells suspended in fluid or blood). A dry aspirate is smeared with the flat of a microscopy slide.

A wet aspirate is smeared in two steps, first move the smearing slide from one end of the specimen slide holding it at a blunt angle and second smear cellular component with the flat of the slide. Smear is fixed with alcohol and subjected to Pap/H&E staining.[8]

II. Results

The patients attending surgery OPD with breast related complaints and who expressed consent for the study were involved and investigations were done as outlined in method of study. 50 patients entered the study and all patients were subjected to all investigations. The results of the study are shown in the following tables.

The sensitivity, specificity, positive and negative predictive values of each investigation was calculated individually.

Table : Age Distribution In Breast Neoplasm

Age group (years)	Number of cases	Percentage
<20	4	8
21-30	8	16
31-40	8	16

41-50	18	38
51-60	12	24
> 60	-	-
Total	50	100

Table : Distribution of breast neoplasms according to the side of involved breast

Side	**Number of cases**	**Percentage**
Right breast	28	56
Left breast	22	44
Bilateral	-	-

Table : Presenting Complaints

Complaints	**No.of Cases**	**Percentage**
Lump	43	86%
Pain	6	12%
Discharge	1	2%
Total	50	100

Table : Distribution Of Cases Based On Clinical Diagnosis

Clinical diagnosis	**Number of cases**	**Percentage**
Fibroadenoma	1	3
Fibrocystic disease	6	1
Phyllodes tumour	4	8
Carcinoma	2	4
T	5	1

Table : Distribution Of Benign And Malignant Lesions Diagnosed Clinically

Lesions	**No.of Cases**	**Percentage**
Benign	28	56
Malignant	22	44
Total	50	100

Table : Distribution Of Cases Diagnosed By Mammography

Mammographic diagnoses (BI-RADS)	**Number of cases**	**Percentage**
1	5	10%
2	24	48%
3	5	10%
4	3	6%
5	13	26%
Total	50	100%

Table : Distribution Of Benign And Malignant Cases On Mammography

Lesions	**No.of Cases**	**Percentage**
Benign	29	58%
Malignant	16	32%
Nonconclusive	5	10%
Total	50	100

Table : Distribution Of Cases Based On Fnac

FNAC Diagnosis	**No.of Cases**	**Percentage**
C1	1	2%
C2	30	60%
C3	3	6%
C4	0	0
C5	16	32%
Total	50	100.00%

Table : Distribution Of Benign And Malignant Cases In Fnac

Lesions	**Number of cases**	**Percentage**
Benign	34	68
Malignant	16	32
Total	50	100

Table : Distribution Of Cases Diagnosed By Ultrasonography

USG(BIRADS)	No.of Cases	Percentage
1	0	0
2	15	30%
3	23	46%
4	6	12%
5	6	12%
Total	50	100%

Table : Distribution Of Benign And Malignant Cases In Usg

Lesions	No.of Cases	Percentage
Benign	38	76
Malignant	12	24
Total	50	100%

Table: Distribution of cases based on histopathology

Histopathological diagnosis	Number of cases	Percentage
Fibroadenoma	21	42
Benign phyllodes	4	8
Fibrocystic Disease	6	12
DCIS	1	2
Invasive carcinoma	8	36
Total	50	100

Table : Distribution Of Benign And Malignant Cases On

Histopathology

Lesions	Number of cases	Percentage
Benign	31	62
Malignant	19	38
Total	50	100

Table : Comparison Of Diagnostic Modalities With Histopathology

Diagnostic modalities	Benign	Malignant	Inconclusive	Total
Clinical examination	28	22	-	50
Mammography	29	16	5	50
USG	38	12	-	50
FNAC	34	16		50
Histopathology	31	19	-	50

Table : Comparison of clinical diagnosis with histopathology

Clinical diagnosis	Histopathological diagnosis		Total
	Benign	Malignant	
Benign	28	-	28
Malignant	3	19	22
Total	31	19	50

Sensitivity:100%
Specificity: 92 %
Positive Predictive value: 88.2 % Negative Predictive Value: 100 %

Table : Comparison Of Mammographic Diagnosis With Histopathology

Mammographic diagnosis	Histopathological diagnosis		Total
	Benign	Malignant	
Benign	29	3	32
Malignant	2	16	18
Total	31	19	50

(P = 0.000)

Sensitivity: 86.67 % Specificity:
92 %
Positive Predictive value: 86 % Negative
Predictive Value: 92 %

Table: Comparison Of Usg Diagnosis With Histopathology

USG diagnosis	**Histopathological diagnosis**		**Total**
	Benign	**Malignant**	
Benign	31	7	38
Malignant	-	12	12
Total	31	19	50

(P = 0.005)
Sensitivity:66.67%
Specificity: 100 %
Positive Predictive value: 100 % Negative
Predictive Value: 83 %

Table : Comparison Of Fnac Diagnosis With Histopathology

FNAC diagnosis	**Histopathological diagnosis**		**Total**
	Benign	**Malignant**	
Benign	31	3	34
Malignant	-	16	16
Total	31	19	50

(P = 0.000)
Sensitivity: 86.67 % Specificity:
100 %
Positive Predictive value: 100 % Negative
Predictive Value: 92 %

III. Discussion

A lump in the breast is a common complaint presenting in the surgical out- patient department of all major hospitals, with anxiety regarding a possible malignancy being extremely common. Accurate diagnosis of cancer has been a diagnostic dilemma since long. A differential diagnosis of the benign, traumatic and malignant lesions is very essential in early stages of the disease. It is extremely important that unnecessary surgeries or invasive treatment for benign diseases are minimized, and malignant lesions are managed aggressively in early stages.

Mammography is the preferred screening examination for breast cancer. It is widely available, well-tolerated and inexpensive. Randomized controlled trials have demonstrated a mortality benefit for women from 40 to 74 years old. The earliest sign of breast cancer can be an abnormality depicted on a mammogram, before it can be felt by the woman or her physician. Screening mammography accounts for the greatest contribution to early detection and decrease in breast cancer mortality, although its use has resulted in a minor increase in the number of in situ cancers detected. According to the American Cancer society the death rate from breast cancer was increasing until 1990 when the advent of widespread screening began to have an effect on the population. The death rate from breast cancer has decreased by 34% between 1990 and 2010 in the United States[9].

Mammography is a special type of x-ray imaging used to create detailed images of the breast. It is estimated that 48 million mammograms are performed each year in the US. Mammography plays a major role in the early detection of breast cancers, detecting about 75% of cancers at least a year before they can be felt. Mammography uses low-dose ionizing radiation[10]. Patients receive less radiation from a mammogram than from background environmental sources each year. The significant reduction in breast cancer mortality far outweighs the risks and inconvenience of the test.

Screening mammography is now recommended annually for all women older than 40 years. Of all of the screening mammograms performed annually, approximately 90% show no evidence of cancer (BI-RADS category 1), and 10% show abnormalities that require further diagnostic testing, which typically includes the acquisition of spot compression or magnification mammographic views and/or sonography. On additional imaging, about 85% of all cases are determined to be normal (BI-RADS category 1) or involve benign findings (BI-RADS category 2) that do not require further evaluation. About 15% are shown to be abnormal and require biopsy (BI-RADS category 4 or 5). Among cases referred for biopsy, approximately 60-75% of the abnormalities are shown to be benign, and 25-40% of the abnormalities are shown to be cancerous.

Ultrasonography has been playing an increasingly important role in the evaluation of breast cancer.

Uitrasonography is useful in the evaluation of palpable masses that are mammographically occult, in the evaluation of clinically suspected breast lesions in women younger than 30 years of age, and in the evaluation of many abnormalities seen on mammograms. Ultrasonography was primarily used as a relatively inexpensive and effective method of differentiating cystic breast masses from solid breast masses. However, it is now well established that ultrasound also provides valuable information about the nature and extent of solid masses and other breast lesions. Ultrasonography does not expose a patient to ionizing radiation — a factor that is particularly important for pregnant patients and young patients. It is believed that in these patients, the breast is more sensitive to radiation. Kolb et al and Buchberger et al found that, when performed carefully, ultrasonography may be useful in detecting occult breast cancer in dense breasts.

A large multicenter study supported by the Avon Foundation and the National Institutes of Health was created through the American College of Radiology Imaging Network[11]. In this project, a protocol to assess the efficacy of screening breast ultrasound was implemented in 14 imaging centers to better define the role of US in breast cancer screening. The study reported higher cancer detection in high-risk women that underwent annual ultrasound screening in addition to mammography compared to those that underwent mammography alone.

In September 2012, the U.S. Food and Drug Administration approved the first ultrasound system, the somo-v Automated Breast Ultrasound System, for breast cancer screening in combination with standard mammography specifically for women with dense breast tissue. It is indicated for women with a negative mammogram, no breast cancer symptoms and no previous breast intervention such as surgery or biopsy[12].

Stavros et al[13] proposed a US scheme for prospectively classifying breast nodules into benign, indeterminate and malignant categories.

To be classified as benign, a nodule had to have no malignant characteristics. In addition, 1 of the following 3 combinations of benign characteristics had to be demonstrated:

- Intense uniform hyperechogenicity
- Ellipsoid or wider-than-tall (parallel) orientation, along with a thin, echogenic capsule
- 2 or 3 gentle lobulations and a thin, echogenic capsule.

A nodule was classified as indeterminate by default if it had no malignant characteristics and none of the 3 benign characteristic combinations listed above.

To be classified as malignant, a mass needed to have any of the following characteristics:

- Spiculated contour
- Taller-than-wide (not parallel) orientation
- Angular margins
- Marked hypoechogenicity
- Posterior acoustic shadowing
- Punctate calcifications
- Duct extension
- Branch pattern
- Microlobulation

Breast is an important and popular site for fine needle aspiration cytology. There is an increasing tendency to confirm the diagnosis of the breast cancer at first consultation by some form of needle biopsy technique. This allows better investigation and wiser preoperative discussion than was possible when excision biopsy and frozen section confirmed the clinical diagnosis[14].

The expansion of FNAC in the primary diagnosis of cancer in the last 30 years has been enormous and hugely successful. Its use in detecting the presence of cancer before surgery and as a guide to rational treatment has been well documented. Countries with most developed aspiration biopsy techniques are Sweden, Slovenia, the USA and India. At Karolinska hospital (Stockholm, Sweden), FNACs average 11,000 annually and at the Institute of Oncology Ljubljana, Slovenia 10,000. In the USA, the highest number is encountered at M. D. Anderson at Houston, Texas with 7,000 aspirates every year. At All India Institute of Medical Sciences (AIIMS) the annual volume of cytology specimens is more than 15,000, with FNACs comprising roughly half of the aspirations[15].

Size of the needle used for FNAC has often been a point for discussion since patient comfort and patient friendliness is an important aspect of FNAC as a superior diagnostic procedure. Disadvantages of a finer needle were an inadequate aspirate while disadvantages of a thicker needle included pain and hematoma formation. All our patients underwent FNAC using a no. 23 needle with no patient discomfort and none of the patients complained of any untoward side effects. Walker et al.[16] compared the use of 21G and 23G needles for FNAC in breast lumps; 125 patients were included; 61 and 64 patients

underwent FNAC with a 21G and 23G needle, respectively. A chi squared test had showed no statistical difference in the results whichever needle was used in their study.

Expertise of the person performing and interpreting the fine-needle aspiration often influences results. Yeoh et al.[17] from Hong Kong reported a high proportion of unsatisfactory samples (48%) with doctors who performed FNAC occasionally. Patel et al.[18] showed that FNAC results were influenced by the number of needle manoeuvres performed with less than ten needle manoeuvres being associated with a 54% unsatisfactory aspiration rate, as compared to 25% when more than ten manoeuvres were performed. They concluded that experience and technique are the most important factors in obtaining a satisfactory aspirate from breast lumps. Padel et al.[19] showed that sensitivity of FNAC increased and inadequate samples decreased when pathologists took the samples for cytodiagnosis. Cohen et al.[20] and Ljung et al.[21] also reported on the influence of training and experience in aspiration cytology of the breast with a maximum influence on sensitivity values which dropped sharply from 98.2% to 75% with an untrained person performing the aspiration.

Our present study was conducted on 50 female patients presented with breast related complaints were evaluated using clinical examination, mammography, ultrasound, fine-needle aspiration cytology followed by excisional surgery either in the form of a lumpectomy or a definitive surgical procedure like a mastectomy, depending on the diagnosis at triple assessment. The clinical examination, mammography, ultrasound and FNAC were then matched with the final histology report to see as to how accurate clinical examination, mammography, ultrasound and FNAC were as compared to Histopathology report.

Table : Parameters Of All Investigations

Investigation	Sensitivity	Specificity	Positive predictive value	Negative predictive value
Clinical examination	100	92	88.24	100
USG	66.67	100	100	83
FNAC	86.67	100	100	92
Mammography	86.	92	86	92

In the present study of 50 female patients, median age of presentation was 37.5yrs. Out of 50 patients 38% belonged to age group 41-50yrs, 24% belonged to age group 51-60yrs, 16% belonged to age group 31-40yrs, 16% belonged to age group 21-30yrs and 8% belonged to age group <20yrs.

In our study, majority of the patients presented with complaints of Lump (86%). The lesion involved the right breast (56%) more commonly and in the upper and outer quadrant (50%). Benign diseases (62%) were more common than malignant (38%), of which fibroadenoma constituted 42% of cases.

Out of 50 patients, 43 patients presented with lump (86%), 6 patients presented with pain (12%) and 1 patient presented with discharge (2%).

In our study, the right breast was involved in 28 patients (56%) while the left breast was involved in 22 patients (44%). No surgical importance can be attached to this observation since patient selection was in no way dictated by involvement of any particular breast.

The upper and outer quadrant was the commonest site of the lump in our patients (50%), followed by upper inner quadrant (16%) while the central quadrant was involved in 12% cases, the lower and inner in 4% cases, the axillary tail in 6% cases and the lower and outer quadrant in 2% cases.

The sensitivity, specificity, positive and negative predictive values of each investigation was calculated individually. Clinical examination had highest sensitivity (100%), FNAC had highest specificity and positive predictive value (100%) for all palpable lesions.

Out of 50 patients, Clinical examination revealed benign in 28 patients and malignant in 22 patients. The overall sensitivity of clinical examination in our study was 100%, specificity was 92%, positive predictive of 88.2% and negative predictive value of 100%.

Mammography revealed benign in 29 patients, malignant in 16 patients and suspicious in 5 patients. The overall sensitivity of mammography in our study was 86.67%, specificity was 92%, positive predictive of 86% and negative predictive value of 92%.

Ultrasound revealed benign in 38 patients and malignant in 12 patients. The overall sensitivity of ultrasound in our study was 66.67%, specificity was 100%, positive predictive of 100% and negative predictive value of 83%.

Fine needle aspiration cytology revealed benign in 34 patients, and malignant in 16 patients with false negative results of 3 and false positive zero. The overall sensitivity of fine needle aspiration cytology in diagnosing the palpable breast lump in our study was 86.67%, specificity was 100%, positive predictive of 100% and negative predictive value of 92%.

The commonest pathology found in our patients was fibroadenoma in 21 patients. This was followed by fibrocystic disease in 6 patients, benign phyllodes in 4 patients, ductal carcinoma insitu in 1 patient and malignancy in 19 patients.

Fibroadenoma exhibits a smear patter composed of large sheets and cluster of epithelial cells in honeycomb patter with some degree of nuclear atypia. The key to the diagnosis of fibroadenoma is the detachment of oval naked nuclei from the cell clusters and sheets.

Fibrocystic disease includes chronic cystic mastitis, mammary dysplasia and metaplasia. We had six cases of fibrocystic disease, which was reported as benign on fine needle aspiration cytology .

Phyllodes tumor, macroscopically most small tumors have a uniform white consistency with a lobulated surface, similar to that of a fibroadenoma. Large tumors on cut section often have a red or grey "meaty" consistency with fibrogelatinous, hemorrhagic, and necrotic areas with leaf like protrusions into the cystic spaces. As both phyllodes tumors and fibroadenomas belong to a spectrum of fibroepithelial lesions, accurate cytological diagnosis of phyllodes tumors by fine needle aspiration can be difficult. The presence of cohesive stromal cells, isolated mesenchymal cells, clusters of hyperplastic duct cells, foreign body giant cells, blood vessels crossing the stromal fragments, and bipolar naked nuclei and the absence of apocrine metaplasia are highly suggestive of a phyllodes tumor. We had 4 cases of benign phyllodes tumor.

One case was reported as ductal carcinoma insitu in our study. There are many morphological variants of DCIS including comedo, solid, clinging, cribriform, papillary, solid variant of papillary DCIS, micropapillary, neuroendocrine, apocrine, cystic secretory, and Pagets disease. A significant proportion of DCIS lesions will harbour more than one morphological variant.

In our study we had 19 cases of infiltrating ductal carcinoma. For cytology it appears as much cellular smear, often with necrotic background, monomorphic cell population with variable cell pattern including conspicuous loss of cellular cohesion, numerous isolated single cells and variable degree of anisonucleosis.

This study documented the fact that the benign lesions of breast are the most common lesions. This increased case of benign lesions indicates increase in awareness of patients. In such lesions the reassurance is the main line of treatment though close follow up is mandatory.

When a patient presents with a lump in breast, Clinical examination and FNAC alone can distinguish benign from malignant lesions. Thus the accuracy of clinical examination (by a experienced hand) and FNAC alone reaches up to 100% without need of mammogram.

Incorporation of mammography just adds up to the diagnosis when patient has a lump that is clinically palpable and to rule out multi-centric / multi-focal disease. Yet Mammogram becomes a very important tool when there is no obvious lump on clinical examination but the patient has other breast related complaints like discharge.

But ultrasound becomes a very important tool when a situation arises where mammogram could not differentiate a solid tumor from a cyst. USG can replace mammogram as the improved techniques approaches the specificity and positive predictive value by 100% in the present study.

Similar studies evaluating the components of triple assessment are taken and the results of the present study compared with those studies.

Table : Comparison Of Fnac Results With Other Studies

Study	L Khoda et al[22]	S Kharkwal et al[23]	Rajan V et al[24]	Present study
Sensitivity	91.6%	94.7%	96.6%	86.7%
Specificity	100%	98.3%	100%	100%
Positive predictive value	100%	97.3%	100%	100%

Table : Comparison Of Usg Results With Other Studies

Study	Ghazala et al[25]	L Khoda et al[22]	Rajan V et al[24]	Present study
Sensitivity	67%	91.6%	93.10%	66.7%
Specificity	92.4%	100%	95.9%	100%
Positive predictive value	-	100%	93.1%	100%

Table : Comparison Of Mammogram Results With Other Studies

Study	Philip J et al [26]	Al-Muhim et al[27]	S Kharkwal et al[23]	Present study
Sensitivity	87.6%	87.5%	94.9%	86.7%
Specificity	86.4%	97.3%	90%	92%
Positive predictive value	-	87.5%	86%	86%

Table : Comparison Of Clinical Examination Results With Other Studies

Study	L Khoda et al[22]	S Kharkwal et al[23]	Rajan V et al[24]	Present study
Sensitivity	66.6%	75%	96.67%	100%
Specificity	100%	83.3%	84%	92%
Positive predictive value	100%	75%	78.4%	88.2%

L Khoda. et al[22] (2015) done a study on Evaluation of modified triple test in the diagnosis of palpable breast lumps. In the study of total 50 cases, The age range was 18-56 years. The sensitivity, specificity, positive predictive value, negative predictive value, and accuracy of CBE were 66.6%, 100%, 100%, 90%, and 91.6% respectively; those of USG 91.6%, 100%, 100%, 97.3%, and 97.9% respectively; and those of FNAC 91.6%, 100%, 100%, 97.4%, and 98% respectively. Out of 50 patients, the three tests concurred in 42 (35 benign and 7 malignant) cases. When all the three tests concurred, there were no false positive or false negative cases, and sensitivity, specificity, positive predictive value, negative predictive value, and accuracy were all 100%. And they Concluded that The triple test is valid and reliable, with a high degree of accuracy for the diagnosis of breast lumps. Of all the three components of the triple test, FNAC is the most accurate. A patient with a concordant benign triple test report can be safely followed up without the need for biopsy.

Suman Kharkwal. et al[23] (2014) done a study on Triple Test in Carcinoma Breast. In the study of total 100 cases, 60 cases were benign and 40 cases were of malignant breast disease. The age of patients with carcinoma breast in the series varied from 35 years to 70 years. The highest incidence of malignancy noted was 30% in 41-50 years age group (4^{th} decade) followed by 27.5% in 51-60 years age group (5^{th}decade). The sensitivity of clinical examination was found to be 75%, specificity was 83.3%, positive predictive value (PPV) of 75% and diagnostic accuracy of 80%. The sensitivity, specificity, positive predictive value and diagnostic accuracy of mammography was calculated and was found to be 94.9% , 90% , 86% and 92% respectively. The sensitivity, specificity, positive predictive value and diagnostic accuracy of FNAC was 94.7%, 98.3%, 97.3% and 96.6% respectively. Out of 100 cases triple test was concordant (all three test either benign or malignant) in 80 cases, all the benign cases detected by triple test were benign on final biopsy i.e. 100% specificity and 100% negative predictive value. And they concluded that TT is an accurate and least invasive diagnostic test based on which definitive treatment can be initiated.

Rajan V. et al[47] (2013) done a study on value of modified triple test in the diagnosis of palpable breast lumps. According to this study Physical examination showed 96.67% sensitivity, 84% specificity and 78.4% positive predictive value for diagnosing malignant breast lumps. Ultrasonography showed 93.10% sensitivity, 95.9% specificity and 93.1% positive predictive value. Fine needle aspiration cytology (FNAC) showed 96.6% sensitivity, 100% specificity and 100% positive predictive value and the modified triple test showed 100% sensitivity, 82% specificity and an accuracy rate of 88.7%. And they concluded that the triple test is 100% accurate in the diagnosis of palpable breast lesions when all three elements were concordant (benign or malignant). Among the three components, FNAC had the highest specificity. MTT is reliable in guiding the clinician in the efficient management of patients with breast lumps. MTT is beneficial in reducing the number of unnecessary open biopsies to confirm the diagnosis. The output of MTT is easily reproducible, making it a valid and reliable diagnostic test in the management of palpable breast lumps.

In a study done by Philip J Drew et al[26] to compare the sensitivity and specificity of the traditional triple assessment of symptomatic breast lesions with contrast-enhanced dynamic magnetic resonance imaging, they found the sensitivity of each modality: clinical examination 84%, mammography 87.6%, fine-needle aspiration cytology 79.1%, and specificity : clinical examination 83.1%, ultrasound 88.9%, mammography 86.4%, fine-needle aspiration cytology 97%. The results of this study were similar to the results of the present study.

Al-Muhim et al [27], in a study to assess accuracy of the "triple test" in the diagnosis of palpable breast masses in Saudi females, found that Physical examination showed 82.6% sensitivity, 97.3% specificity and 86.4% positive predictive value. Mammography showed 87.5% sensitivity, 97.3% specificity and 87.5% positive predictive value and fine-needle aspiration cytology (FNAC) showed 91.7% sensitivity, 100% specificity and 100% positive predictive value in concordant cases (elements had either all malignant or all benign results). They concluded that the triple test was 100% accurate in the diagnosis of palpable breast lesions when all three elements were concordan treatment without delay.

A palpable mass in a woman's breast represents a potentially serious lesion and requires evaluation by history taking and physical examination.

A solid lesion requires a firm diagnosis and this usually calls for removing the lesion for Histopathological examination. A positive result on cytology after aspiration is sufficiently accurate to justify one stage diagnosis and treatment.

A negative or suspicious finding on FNAC is inconclusive and a radiological investigation is required. Although in some instances the probability of malignancy may be exceedingly small, it is never zero. If biopsy is not recommended, the probability of malignancy in that patient should be estimated so as to decide whether the level of risk is acceptable for that particular patient.

In such instances methods like "Triple test" an increase the accuracy of diagnosis, at least from an unnecessary surgical procedure.

IV. Conclusion

- Triple test is a very useful tool in evaluating the breast diseases.
- In patients with definite lump, Clinical examination and FNAC alone may be sufficient to rule out malignancy and this may be cost-effective by avoiding a mammogram.
- Mammogram is needed in patients with no clinically palpable lump and to rule out multi-centric and multi-focal disease.

USG may be used instead of mammogram to avoid the radiation due to mammogram.

V. Summary

The vast majority of the lesions that occur in the breast are benign. Much concern is given to malignant lesions of the breast because breast cancer is the most common malignancy in women in Western countries. Because the majority of benign lesions are not associated with an increased risk for subsequent breast cancer, unnecessary surgical procedures should be avoided.

Clinical diagnosis of breast cancer is of higher sensitivity than specificity and has high diagnostic error. Mammography and FNAC respectively have lower sensitivity than specificity but have high positive predictive values. When combined in the triple assessment, a definitive diagnosis can be made when the diagnoses concur, suggesting that the triple assessment has a high sensitivity, specificity, positive predictive value and negative predictive value. The output of the triple assessment in reproducible, making it a valid and reliable diagnostic approach to diagnosis of breast cancer.

In this study the patients with breast related complaints were evaluated with clinical examination, FNAC, Mammogram and Ultrasonogram. The sensitivity, specificity, positive and negative predictive values were calculated for each of the modalities and compared.

50 patients present with breast related complaints were included in the study. Benign diseases (62%) were more common than malignant (38%), of which fibroadenoma constituted 42% of cases.

The sensitivity, specificity, positive and negative predictive values of Clinical Examination is 100%, 92%, 88.2%, 100%; FNAC is 86.67%, 100%, 100%, 92%; Mammogram is 86.67%, 92%, 86%, 92%; and USG is 66.67%, 100%, 100%, 83%, respectively.

Triple test is a very useful tool in evaluating the breast diseases. In patients with definite lump, Clinical examination and FNAC alone may be sufficient to rule out malignancy and this may be cost-effective by avoiding a mammogram.

Mammogram is needed in patients with no clinically palpable lump and to rule out multi-centric and multi-focal disease. USG may be used instead of mammogram to avoid the radiation due to mammogram

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