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RESEARCH ARTICLE

A PROSPECTIVE STUDY OF TRIPLE ASSESSMENT IN EVALUATION OF BREAST LUMP

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Abstract

Breast masses have a variety of etiologies, benign and malignant. Most masses are benign, but breast cancer is the most common cancer and the second leading cause of cancer deaths in women. The Study is done with an aim of assessing the added and singular dependability of modified triple testing in making a pre-procedural diagnosis of a breast lump. A random sample of 150 patients attending the surgery outpatient department was taken. Of the 150 patients presenting with breast lumps most of the lumps were painless 81.3%(n=122), 10% (n=16) of the lumps were associated with pain and 8%(n=12) were associated with nipple discharge. A fine collaboration between experienced radiologists, cytologist and the Clinician is required. Ultrasound when replacing mammography serves as effective an imaging modality in palpable breast lumps and is more comprehensive. Ultrasound breast aids biopsy techniques by guidance to the representative area than increasing yield. CNB is a suitable alternative when FNA is inconclusive and may offer additional information. Thus the use of Modified Triple Test(MTT) to complement findings in differential diagnosis of a lesion in a symptomatic women seeking medical care deserves acceptance and further evolution. This may lead to less delay in treatment when malignancy is suspected and to avoidance of surgical exploration when a benign nature of lesion is suspected.

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Introduction:-

Breast cancer is the 2nd most common malignancy in women worldwide; however, benign lesions of the breast are far more frequent than malignant ones [1]. With the use breast imaging and the extensive use of needle biopsies, the diagnosis of a benign breast disease can be accomplished without surgery. It is to distinguish between in situ and invasive breast cancer so most appropriate treatment modality can be established. The triple test for breast diseases involve; Clinical assessment, imaging modality– Mammography, Fine needle aspiration biopsy/cytology [2-4]. In modified triple test ultra-sonogram is used instead of mammography. 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. Mammography is preferred method for breast cancer screening. But when mammography reveals a non-palpable breast lesion further imaging studies are often required to more precisely identifying the characteristics and location of the mass [5].

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Breast masses have a variety of etiologies, benign and malignant. Most masses are benign, but breast cancer is the most common cancer and the second leading cause of cancer deaths in women. Fibroadenoma is the most common benign breast mass; invasive ductal carcinoma is the most common malignancy. The incidence of the disease has shown a steep rise in women younger than 40 years of age[6,7]. Not more than 50% of the women with breast cancer are alive and free of disease 10 years after the diagnosis[8]. An efficient and accurate evaluation can maximize cancer detection and minimize unnecessary testing and procedures [9]. For effective management, multidisciplinary approach is essential. The study role of the triple assessment test in making a pre-procedural diagnosis of palpable breast lumps. The Study is done with an aim of assessing the added and singular dependability of modified triple testing in making a pre-procedural diagnosis of a breast lump. The components were Clinical Examination, Ultrasound, FNAC/CNB.

Materials and methods:-

Study design:

Cross sectional study.

Sample Size:

A random sample of 150 patients attending the Surgery outpatient department of IMS AND SUM HOSPITAL.

Study Instrument:

Clinical Examination.

Ultrasound

FNAC/ CNB.

Data Collection:

All patients presenting to the OPD with a palpable breast lump.

Inclusion Criteria:

Female patients, Complaining of breast lump- palpable as a discrete lesion with some discrepancy from surrounding breast tissue.

All the patients are subjected to the Triple test. On the basis of examination the lumps are divided into malignant and benign.

Exclusion criteria:

Women with advanced Breast cancer making an obvious diagnosis, Patients with Open biopsy and HPE performed prior to presentation to our hospital.

Results:-

The study was conducted on all the patients who have presented with breast lumps after taking consent. Out of the 150 patients, more than one third of the patients presenting with breast lumps are between the age group of 21-30 i.e. 53 patients in total (Fig 1).

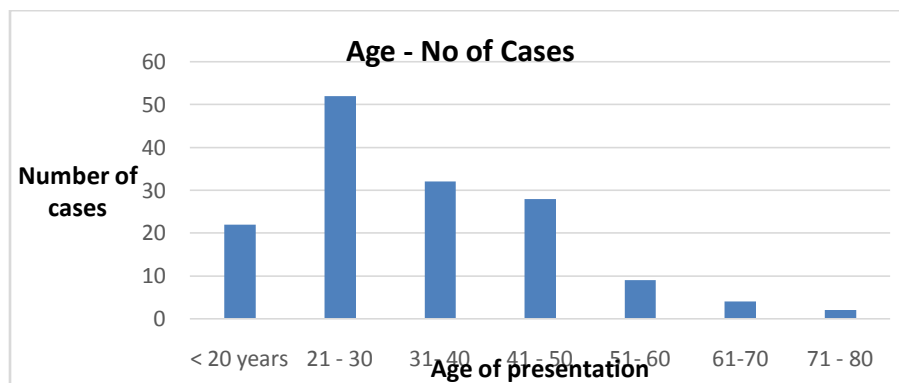


Fig 1:- Age distribution of our enrolled patients.

Of the 150 patients presenting with breast lumps most of the lumps were painless 81.3%(n=122),10% (n=16)of the lumps were associated with pain and 8%(n=12) were associated with nipple discharge (Table 1).

Table 1:- Showing varied clinical presentation.

Clinical Presentation	No of cases(150)
Exclusive Lump	122(81.3%)
Lump with Pain	16(10.6%)
Lump with nipple discharge	12(8%)

Out of the 150 patients a total of 128 patients (85.3%) had breast lumps that were freely mobile,10.6% of the lumps(n=16) had restricted mobility { the lump is mobile in only a few directions or the mobility is reduced on contracting the underlying muscle} and 4% of the lumps(n=6) were fixed(Table 2).

Table 2:- Showing mobility of the lumps.

Mobility	No Of Cases
Mobile	128(85.3%)
Restricted	16(10.6%)
Fixed	6(4%)

78.6%(n=118) had a smooth surface,17.3% were irregular and 4 % were nodular.81.3 % (n=122) of the lumps were firm in consistency,8.6%(13) were cystic to soft in consistency and 10 %(n=15) were hard in consistency (Fig 2).

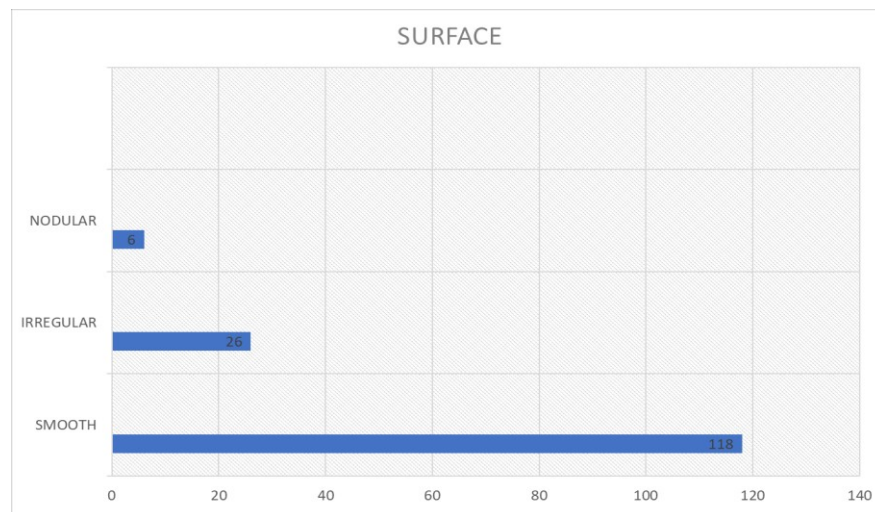


Fig 2:- Graph showing the surface of the lesion.

Upon ultrasonography 70 %(n=105) of the lumps were found to be hypoechoic,9.3%(n=14) were heteroechoic,14%(n=21) were fibrocystic and 6.6%(n=10) were only cystic (Table 3).

Table 3:- The consistency of the lump.

Consistency	No of Cases
Firm	122(81.3%)
Cystic to Soft	13(8.6%)
Hard	15(10%)

Using the BIRADS grading of the lumps it was found that BIRADS II breast lumps were the most common 53.3% (n=80) out of all the breast lumps.23.3 % (n=35) of the breast lumps were BIRADS III,6% (n=10)of the breast lumps were BIRADS IV,10 % (n=15) of the lumps were BIRADS V with BIRADS I &II contributing 3.3% each(n=5) (Fig 3).

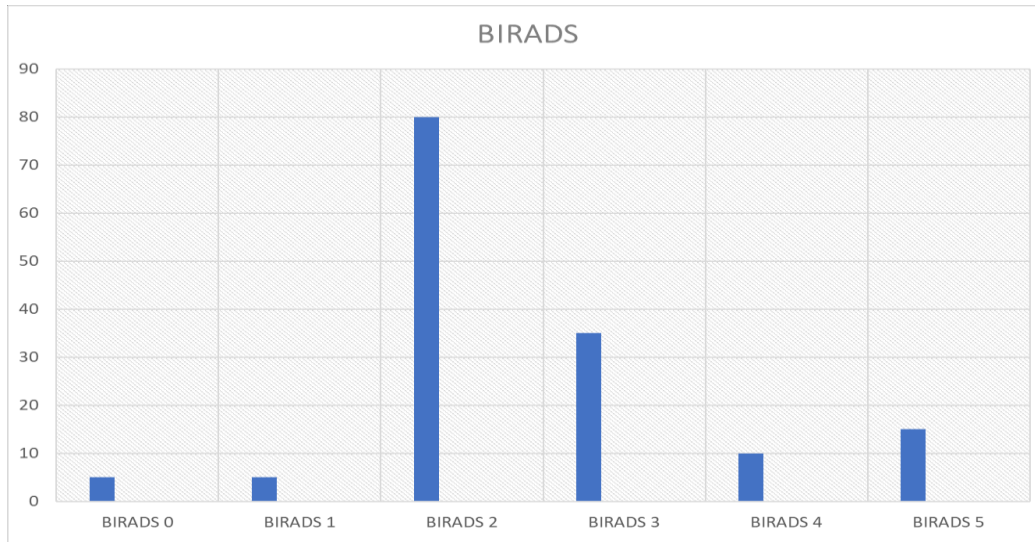


Fig 3:- BIRADS grading of the lumps.

Form the FNAC report it can be inferred that 55.3%(n=83) are fibroadenoma,14.6%(n=22) are fibrocystic disorders,6.6%(n=10) are breast abscesses,galactocele and phylloides contributing 2.6% each(n=4).TB mastitis was 3.3% and malignancies were 14.6%(n=22) (Table 4).

Table 4:- Pathology report.

FNAC/CNB	No of Cases
Fibroadenoma	83(55.3%)
Fibrocystic	22(14.6%)
Breast abscess	10(6.6%)
Galactocele	4(2.6%)
Phylloides	4(2.6%)
Tb	5(3.3%)
Malignancy	22(14.6%)

After taking all the three components of triple assessment the final diagnosis were as follows fibroadenoma 83,fibroadenosis 12,fibrocystic lesions 6,breast abscess 10,antibioma 4,phylloides 4,galactocele 4,TB mastitis 5,carcinoma 22 (Table 5).

Table 5:- Details of the final diagnosis.

Fibroadenoma	83(55.3%)
Fibroadenosis	12(8%)
Fibrocystic lesions	6(4%)
Breast abscess	10(6.6%)
Antibioma	4(2.6%)
Phylloides	4(2.6%)
Galactocele	4(2.6%)
Tb mastitis	5(3.3%)
Ca breast	22(14.6%)

Comparing the clinical diagnosis with the final diagnosis that is achieved after the triple assessment test the sensitivity of CEis found to be at 81.8%,specificity is at 96.88%.The positive predictive value of the CEis 81% and the negative predictive value of the CE is 96%.The accuracy of CE is 94% (Table 6).

Table 6:- Result- CLI DIG VRS FINAL MTT DIG.

Statistic	Value	95% CI
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Sensitivity	81.82%	59.72% to 94.81%
Specificity	96.88%	92.19% to 99.14%
Positive Likelihood Ratio	26.18	9.78 to 70.07
Negative Likelihood Ratio	0.19	0.08 to 0.46
Disease prevalence (*)	14.67%	9.43% to 21.36%
Positive Predictive Value (*)	81.82%	62.71% to 92.33%
Negative Predictive Value (*)	96.88%	92.74% to 98.69%
Accuracy (*)	94.67%	89.76% to 97.67%

This results correlate with the many other studies that were done. Equating the USG diagnosis and the final diagnosis was achieved through the MTT the results were as follows.

The sensitivity of the USG is found to be at 90% and specificity is at 98%. The positive predictive value of the USG is 90% and the negative predictive value is 98%. The accuracy of the ultra sound is 97% (Table 7)

Table 7:- Results- USG DIG VRS FINAL MTT DIG.

Statistic	Value	95% CI
Sensitivity	90.91%	70.84% to 98.88%
Specificity	98.44%	94.47% to 99.81%
Positive Likelihood Ratio	58.18	14.62 to 231.59
Negative Likelihood Ratio	0.09	0.02 to 0.35
Disease prevalence (*)	14.67%	9.43% to 21.36%
Positive Predictive Value (*)	90.91%	71.53% to 97.55%
Negative Predictive Value (*)	98.44%	94.38% to 99.58%
Accuracy (*)	97.33%	93.31% to 99.27%

The FNAC/CNB results almost always correlated with the triple assessment results but this doesn't mean that the other two steps should be bypassed because without the other two tests the size extent, consistency of the lump/swelling could not be assessed. So by combining all the three CE, USG and FNAC the sensitivity of the test could be raised from 81% in CE, 90% in USG to 100% in MTT. Specificity could be elevated from 96% in CE, 98% in USG to 99% in MTT. Hence proving the sensitivity and specificity of the MTT is much higher than that of the individual values of the independent tests (Table 8,9).

Table 8:- Anova: Two-Factor Without Replication details

Anova: Two-Factor Without Replication				
<i>SUMMARY</i>	<i>Count</i>	<i>Sum</i>	<i>Average</i>	<i>Variance</i>
Row 1	2	150	75	6498
Row 2	2	150	75	6050
Row 3	2	150	75	5618
Column 1	3	60	20	4
Column 2	3	390	130	4

Table 9:- Anova: Two-Factor Without Replication details

ANOVA						
<i>Source of Variation</i>	<i>SS</i>	<i>df</i>	<i>MS</i>	<i>F</i>	<i>P-value</i>	<i>F crit</i>
Rows	0	2	0	0	1	19
Columns	18150	1	18150	2268.75	0.00044048	18.51282051
Error	16	2	8			
Total	18166	5				

Discussion:-

Education of the public about the fundamental facts of cancer and self-examination of the breast represents an important factor in the early detection of breast disease. The clinical signs of primary breast neoplasm are few. In the overwhelming majority of cases, there is a painless breast mass and less frequently nipple discharge of erosion, skin retraction, or an axillary mass.

Physical examination, mammography, ultrasonography, core needle biopsy, open excision biopsy, thermography, fine needle aspiration cytology are all used to a greater or lesser extent in the diagnostic work up of a palpable breast mass. Various combinations of these approaches have been studied and have been found to increase the sensitivity and specificity over that of any one test alone. Many diagnostic tools are used in cases of suspected breast cancer as the famous triple assessment which was described in 1975 and it reduces dramatically the use of open biopsy. It was used principally for evaluating palpable breast lumps. Triple test includes clinical assessment, mammography or ultrasonography and fine needle aspiration (FNA).

The highest levels of diagnostic accuracy in the non-operative diagnosis of breast disease are achieved by using a triple approach which combines the results of imaging and clinical examination with fine needle aspiration cytology (FNAC) and/or core biopsy. When the results of all three modalities agree, the level of diagnostic accuracy exceeds 99%. It is of interest to note that similar levels of accuracy have been obtained in the case of impalpable lesions, in which clinical examination is non-contributory. The role of cytopathology in the diagnosis of breast disease is concerned with the examination of cells seen in the nipple discharges and those aspirated from solid and cystic lesions using a fine needle. The former is a well-established diagnostic test for carcinoma of the larger ducts, with or without Paget's disease of the nipple, presenting with a blood stained discharge, but aspiration cytology is a newer technique, which is now finding its place in the breast surgeon's diagnostic armamentarium.

In recent years the place of the rapid frozen section in the diagnosis of breast cancer has become diminished in importance and has been replaced by increasing emphasis on preoperative diagnosis using a combination of clinical examination, mammography and either biopsy, using a wide bore cutting needle or aspiration cytology using a narrow hypodermic needle with rather than attempt to combine tissue diagnosis and mastectomy at one operation. With realization that perhaps less radical surgery will give equal or improved survival as well as less postoperative morbidity, development of more reliable tests for metastatic disease there by making extensive surgery unnecessary, and finally the increasing tendency to involve the patient herself in the decision about the best method of treatment thus making accurate preoperative diagnosis very important. Medical literature abounds with studies of evaluation of breast lumps that emphasizes that the statement — "every palpable mass must be assessed and clarified". Hermansen C. et al in 1987 prospectively studied 650 breast tumors and applied the term Triple test' to the triad of physical examination; mammography and FNAC used to diagnose them. He concluded that the diagnostic accuracy of the triple test is comparable to that of histological examination. Hardy JR. et al. assessed 143 patients with palpable breast modules with clinical examination; FNAC mammography; ultrasonography and magnetic resonance imaging (MRI) and concluded that the combination of cytology and ultrasound was best at correctly diagnosing malignancy. Lawrence N Bassett et al³ assessed the usefulness of mammography and sonography in women less than 35 years of age (1016 women) during a 8 year period. This study found that mammography was not useful in women less than 35 years. However sonography was useful in avoiding unnecessary biopsies and for this reason was the initial examination in younger women. But it was not useful in detecting nonpalpable carcinomas or in differentiating benign from malignant solid masses. Vetto JJ et al⁴ in 1996 studied 55 women below the recommended age of screening mammography with the 3 elements of Modified Triple Test' (C/E, Usg; FNAC/CNB). The test had a specificity and negative predictive value of 100% for malignancy. They concluded that use of MTT for diagnosis of palpable breast lesions in younger women yields high diagnostic accuracy without the need for routine open biopsy, resulting in overall reduction patient charges.

Purasri P et al. retrospectively assessed 603 patients with breast lumps using the Quadruple test' – C/E/USG/Mammography/FNAC. A stepwise logistic discriminant analysis was used to derive a novel diagnostic index. This predicted the diagnosis in 98% of women <35 years correctly. Hatada T et al⁵. retrospectively studied 114 lesions and compared diagnoses obtained by standard FNAC and that of ultrasound guided FNAC with surgical findings and found the accuracy to be 65% and 86% respectively. They concluded that Usg-guided FNAC improves the preoperative diagnosis especially in patients with tumor less than 2 cm. Heiken TT et al conducted a prospective analysis of office-bases breast ultrasound, on 660 breast lesions and found that suspicious lesions determined by USG had a 75% chance of being malignant; however 5% of lesions characteristic of fibroadenoma turned out to be malignancies. Jill S Montrey attempted to determine the usefulness of ultrasound as a screening tool for breast cancer in women <35 years, with indeterminate mammography, persistent symptoms and high risk history.

Conclusion:-

Detection and management of a breast mass requires an optimal environment for interpretation, relevant use of clinical information, technically excellent imaging procedures, and proper interpretation of finding and patient

recommendations. Our results show that the diagnostic accuracy of combined physical examination breast USG and FNA/CNB is comparable to that of histological examination. A fine collaboration between experienced radiologists, cytologist and the Clinician is required. Ultrasound when replacing mammography serves as effective an imaging modality in palpable breast lumps and is more comprehensive. Ultrasound breast aids biopsy techniques by guidance to the representative area than increasing yield. CNB is a suitable alternative when FNA is inconclusive and may offer additional information. Thus the use of MTT to complement findings in differential diagnosis of a lesion in a symptomatic women seeking medical care deserves acceptance and further evolution. This may lead to less delay in treatment when malignancy is suspected and to avoidance of surgical exploration when a benign nature of lesion is suspected.

Conflict of interest:

No potential conflict of interest relevant to this article was reported

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