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Evaluation of Palpable Breast Lumps Using Triple Assessment

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ABSTRACT

Triple assessment is a very useful diagnostic tool to evaluate patients with palpable breast lumps and to detect patients with breast cancers with an overall accuracy of 99.3%. A prospective cross-sectional study of 100 female patients with history of breast lump-clinically palpable as a localized lesion differing from the surrounding breast tissue. Triple Test were then analyzed individually and as a combination. The mean age of women in this study was 41.84+9.1 years. On excision biopsy, the 57 lumps were confirmed histopathologically as either Malignant (n=24) and Benign (n=33). When the lumps are palpable clinically and of size more than 2cms FNAC itself has a sensitivity of 100%. Where as when the lumps are <2cms CBE+USG has a sensitivity of 92.8%. It was found that when clinical examination, USG and FNAC were all negative for malignancy in a patient with a breast lump, the patient can be safely observed, obviating the need for histology (surgical biopsies). Triple assessment did not require hospitalization, but was performed on OPD basis, without any complications The modalities used are either non-invasive or minimally invasive. Recent advances in imaging and cytopathology have made the diagnosis of breast cancer easy and accurate. We found that sensitivity of triple assessment when correlated to histopathology was 100, specificity was 85% and concordance was 88.3%. The mortality and morbidity of malignant breast lesions can be brought down by early recognition and evaluation of the palpable lumps using triple assessment it is proved to be most reliable and cheapest mode of evaluation which involves limited resources. On FNAC examination out of 24 diagnosed to be malignant all 24 cases were confirmed to be malignant on histopathological examination. When triple assessment was compared with the histopathological report out of 29 cases found to be malignant by triple assessment 24 found to be malignant on HPE and 24 cases found to be benign on triple assessment all are benign on HPE report. Triple assessment was useful in diagnosing breast cancers at an earlier stage, with most of breast cancers detected at stage I or stage II (T1 or T2: N0 or N1, M0). The sensitivity, specificity, positive and negative predictive value of triple assessment in present study was 100%, 85%, 83%, 100% respectively.

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Key Words

Breast lumps, FNAC, ultrasound, malignancy

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INTRODUCTION

Breast masses in women are common and cause much anxiety. The majority of lesions are benign. A quick reliable non-invasive or minimally invasive means of diagnosis helps to lessen the anxiety and aids in instituting early definitive care[1,2].

- Majority of the breast lumps are benign.
- However breast malignancy is also common in women.
- The presentation of both benign and malignant diseases is not much different.
- Both may present with lump and nipple discharge etc.
- pain usually absent or late feature in malignancy.
- To differentiate the benign breast diseases from malignant diseases of breast is not possible by physical examination alone or imaging alone.

Hence there is need for triple assessment in palpable breast masses[3-5]. Johansson coined term triple test, which is defined as evaluation of palpable breast masses by history/physical examination, USG, FNAC in women aged 40 yrs and older[1]. Triple assessment includes history and physical examination, along with

- Risk stratification.
- Imaging.
- Cytological and histopathological examination.
- The chances of missing a malignant lesion of breast are minimal by triple assessment.

MATERIALS AND METHODS

A prospective cross-sectional study of 100 female patients attending the outpatient department at the Department of General Surgery with the complaint of a palpable lump/lumps in the breast was undertaken.

The Inclusion Criteria Were:

- Female >12 years.
- c/o breast lump-clinically palpable as a localized lesion differing from the surrounding breast tissue.

Exclusion Criteria:

- Those who have already been diagnosed to have carcinoma of breast and treated for same.
- Those patients who are not willing for triple assessment.
- Patient in who breast lump is due to lactational breast abscess.
- Patients with debiliting illness like CRF, CAD, liver failure, CHF.

Each patient was put through the Modified Triple Test. On the basis of a systematic clinical examination, the lumps were grouped as-Malignant, Benign or inconclusive.

Benign Lesions on Clinical Examination: Breast lump with a long duration and slow growth and cyclical breast pain without bloody discharge from nipple and with negative family history. And a clinical examination finding of soft or firm mass with smooth surface, regular margins tend to slip off palpating fingers, fluctuation test positive and not fixed to underlying structures and skin, freely mobile within the breast tissue were taken as benign lesions.

Malignant Lesions on Clinical Examination: A painless breast lump of short duration and fast growth with any one or more of the following features bloody discharge from nipple or any associated body pains and on clinical examination a hard irregular lump with uneven surface, ill-defined margins, fixity to skin or underlying structures with any palpable axillary lymph nodes were taken as malignant lesions.

Inconclusive Results on Clinical Examination: Lumps which do not fit into any of the benign and malignant criteria on clinical examination with any positive family were taken as inconclusive results. Then patients were subjected to ultrasound scan of both breasts and axilla with special focus on the palpable lump. For deeply seated lesions ultrasound was utilized to aspirate cysts and to take biopsies. Findings were scored using criteria set by ACR-BIRADS SYSTEM (2005). The lesions were classified as malignant, benign or inconclusive based on the following feature.

- Malignant-ill defined, heterogeneous mass with sharp angulations., presence of micro calcifications, variable echogenecity.
- Benign lesions were either cystic or solid.

Cysts: Round, oval, anechoic, well defined with through and through transmission in simple cysts. Abscesses show low level internal echoes.

Solid:

Fibro Adenoma:

- Round, oval Bi/Trilobulated.
- Well defined with pseudo capsule Homogenous internal echoes.

Fibroadenosis:

- Generalized increase in the fibro glandular Elements of breast.
- Hyperechoeic shadows with cystic areas No distortion of breast architecture.

Inconclusive: The results of the modified triple assessment are inconclusive if any of all the three components are discordant with the other two components. After this fnac was performed by attending surgeon and sent for cytological/ histopathological examination.

FNAC was Reported as Follows:

- **Insufficient Material:** Cell content in the aspirate too poor for cytological assessment.

- **Benign Cells:** Sufficient material with benign cells indicating Fibroadenoma of Fibrocystic disease.
- **Atypical Cells:** Slight atypia., interpreted as benign lesion.
- **Suspicious:** Malignancy-suspect cells., not interpretable as carcinoma with certainty.
- **Carcinoma:** Cells indicative of malignancy.

Results were Interpreted as Follows:

- C0- no epithelial cells present C1-scanty benign cells.
- C2-benign cells.
- C3-suspicious of malignancy.
- C4-highly suspicious of malignancy C5- definitely malignant.

The results of the modified Triple Test were then analyzed individually and as a combination. Any components indicating a malignant report were taken as malignancy. Inconclusive reports were subject to excision biopsy on an inpatient basis. Patients with malignancy were treated with definitive surgery. The post procedural histopathological reports were compared to the results of the Modified Triple Test. Statistical analysis was done using SPSS16 software. Data is expressed as means and standard deviation for continuous variables and as percentages for categorical variables. P value <0.05 was considered statistically significant. Negative predictive value and positive predictive value calculated.

RESULTS AND DISCUSSIONS

Of the 80 patients randomly referred for the study, 23 patients not fulfilling the inclusion criteria were excluded. Thus 57 patients with breast lumps were included into the study. Thus the final study group (N=57) underwent the MTT followed by excision biopsy, the results of which were available for comparison. Out of 57 cases that underwent triple assessment and histopathological assessment were 5 discordant results. These cases were given as malignant lesions by triple assessment and later they proved to be benign lesions on histopathological report. The mean age of women in this study was 41.84+9.1 years. the mean age was 47 in patients with confirmed diagnosis of malignancy, the youngest patient was 30 years and the oldest was 65 years. This justifies the age for start of screening mammography which is 49 years in many countries. 9 women were nulliparous of whom only 3 had malignant lesions. The rest (n-48) were multiparous. The results do not point to any positive association between parity and malignancy (P>0.05).

Table 1. Association Between Parity and Breast Pathology (N=57)

Parity	malignant	Benign
nullipara	3	6
multipara	21	27

Benign lesions were more common amongst premenopausal women (n=33)., though malignancy could not be excluded in this group (n=24). However, all the lesions detected in perimenopausal (n=5) postmenopausal women were malignant.(N=6).(table no-4).

Table 2. Association Between Menstrual Status and Malignancy

Menstrual status	Malignant	Benign (p<0.001)
Post menopausal	6	0
Peri menopausal	5	0
premenopausal	13	33

On excision biopsy, the 57 lumps were confirmed histopathologically as either Malignant (n=24) and Benign (n=33).

The Pathological Reports were Total of Malignancies =24:

- Intra Ductal Carcinoma=20.
- Lobular Carcinoma=1.
- Medullary Carcinoma=1.
- Carcino Sarcoma = 1.
- Malignant cystosarcoma Phylloides=1.

Total no. of Benign Lesions=33:

- Fibroadenoma=14.
- Fibrocystic Disease=10.
- Breast Abscess=6.
- Benign cystosarcoma Phylloides=3.

The associations between each component of MTT and the combined MTT with the biopsy report were subjected to computer generated analysis.

- Clinical examination finding of a hard, irregular lump was more like to be malignant, while a soft or firm mass with regular surface suggested benign lesions(P>0.001). Benign lesions most often confused with malignancy were Benign cystosarcoma phylloides and Fibrocystic disease.

Table 3: Correlation of Consistency of the Lump with Histopathological Examination

Consistency	Malignancy	Benign (p<0.001)
Hard	18	3
Firm	5	30
Soft	0	1

Table 4: Surface Character of Lesion and Histopathology Diagnosis (N=57)

Surface	Malignant	Benign
Irregular	18(31.5%)	6(10.5%)
Regular	6(10.5%)	27(47.5%)

The initial indications of USG in differentiating a solid from cystic lesions may be non beneficial in coming to a correct diagnosis. Our study shows no association between character of the lesion and diagnosis (P>0.05).

Table 5: Correlation Between the Histopathology and Ultrasound Scan

	Malignant	Benign
Cystic	2(25%)	6(75%)
Solid	22(44%)	28(56%)

A regular, well defined., hyperechoeic lesion was usually benign. An irregular., ill defined mixed echogenic mass indicated malignancy. Hypoechoeic lesions were not characteristic of either (P=0.05). Echogenicity could not thus be used as a singular feature to rule out malignancy except when they were hyperechoeic.

Table 6: Correlation of Echogenicity of the Lump with Histopathological Diagnosis (N=57)

Echogenicity	Malignant	Benign
Mixed	10	6
Hypoechoic	14	23
Hyperechoeic	0	4

Ultrasound detected Axillary nodes in all patients (n=12) found to be clinically node positive., however it could not distinguish whether the node had malignant infiltration or not. Ultrasound guided FNA/CNB was done to axillary nodes in 6 cases., 2 of which were cystic lesions with a residual mass on aspiration of the cysts. Both turned out to malignancies missed on non image guided FNAC. Amongst the individual tests., clinical examination was more likely to miss a malignancy (Sensitivity 75%)., as against ultrasound (Sensitivity 92%) or FNA / CNB (Sensitivity 100%). FNA/CNB correctly identified malignancy in all 24 cases., while ultrasound misinterpreted 1 case as malignant (a case of Benign cystosarcoma phylloides) with specificities of 100% and 85% respectively. The MTT was 85% specific with malignant lesions. But 5 cases were mis diagnosed as malignancies and turned out in 3 cases to be Fibrocystic Disease and 2 cases were benign cystosarcoma phylloides-both benign lesions. Inconclusive results (n=4) on MTT were also confirmed to be benign lesions. Thus MTT, though had false positives with respect to malignancy but no false negatives (i.e.,) a negative predictive value of 100%. These data are comparable to the original triple test with its sensitivity (65%-96%) and specificity (55%-98%) as reported in various studies (Tables 9-13).

Table 7: Correlation Between Clinical Examination and Histopathology Report

	Clinical Examination	Histopathology Report
Benign	24 (42.1%)	33 (57.9%)
Malignant	19 (33.3%)	24 (42.1%)
Inconclusive	14 (24.6%)	0

Table 8: Correlation Between Ultrasonogram Diagnosis and Histopathological Diagnosis

	Ultrasonogram	Histopathology Report
Benign	25(43.8%)	33(57.9%)
Malignant	29(50.8%)	24(42.1%)
Inconclusive	3(5.3%)	0

Table 9: Correlation of FNAC Diagnosis with Histopathological Diagnosis

	FNAC	Histopathology Report
Benign	24(42.2%)	33(57.1%)
Malignant	27(47.3%)	24(42.1%)
Inconclusive	06(10.5%)	0

Table 10: Correlation of Modified Triple Assessment with Histopathological Diagnosis

	Modified Triple Assessment	Histopathology Report
Benign	29(50.8%)	33(57.9%)
Malignant	24(42.1%)	24(42.1%)
Inconclusive	04(7.1%)	0

FNA / CNB as a single test was a superior diagnostic test than the other two tests, but only when complemented by them could the lesion be characterized in all dimensions for the chosen interventional procedure. When report of triple assessment is inconclusive the likelihood of malignancy increased in ascending order from FNAC, USG to C/E (n=o, n=1, n=5) respectively.

Table 11. Accuracy of Clinical Examination, Ultrasound Breast, FNAC and Modified Triple Assessment

	Clinical examination	Ultrasound breast	FNAC	Modified triple assessment
Sensitivity	75%	92%	100%	100%
Specificity	97%	85%	100%	85%
Positive predictive value	95%	81%	100%	83%
Negative predictive value	84%	93%	100%	100%
P value	<0.001	<0.001	<0.001	<0.001

Breast lumps cause considerable morbidity and palpable masses potentially pose serious concerns prompting immediate evaluation especially in era of breast cancer awareness. This study mainly attempts to analyze the efficacy of triple assessment in the management of breast lumps and it is discussed in relation to clinical, imageological, cytological and demographic compositions using the recent 2 year data. Of the 80 patients randomly referred for the study, 23 patients not fitting the inclusion criteria were excluded. Thus 57 patients with breast lumps were inducted into the study. Thus the final study group (n=57) underwent the MTT followed by excision biopsy, the results of which were available for comparison. Out of 57 cases there were 5 discordant results. these cases were given as malignant lesions by triple assessment and later they proved to be benign lesions on histopathological report. Accurate diagnosis of cancer has been a diagnostic dilemma since long. Currently a combination of three tests, i.e. clinical examination, imaging (USG) and FNAC (pathology) together called as triple assessment is used to accurately diagnose all palpable breast lumps. The triple assessment is taken positive if any of the three components is positive for malignancy and negative only if all of its components are negative for malignancy. In present study the stand alone clinical examination has sensitivity of 75% and specificity of 97% to diagnose malignancy. Same is in agreement with the khode[3] and rajan[4], suman karwal[6]. Regarding clinical presentation observed that minimum and maximum duration of breast lump in present study was from 3 month to 2 yrs.

- Mean size of lump 3.8 cm.
- The lump was located in upper outer quadrant of breast in 50 percent of the patients. Lump was found more often in left breast than right breast.
- The results are in agreement with other studies like khatoon s *et al,* khode *et al,* homesh *et al,* sadiq *et al* ,jayaram[7-10].

Ultrasound was investigative modality used in this study as it can be used for all the age group of patients

especially can be used for women younger than 35 yrs in whom mammography can't be accurate due dense breasts. In present study out 25 cases diagnosed to be malignant in ultrasound 22 turned to be malignant on histopathological examination 3 turned out to be benign. And out of 29 cases diagnosed as benign on ultrasound 28 cases was diagnosed as benign on histopathological examination one case was diagnosed as malignant. 3 cases were deemed as in conclusive on ultrasonography. Of which one case was malignant and 2 cases were benign on histopathological examination. Thus for ultrasound sensitivity of 92%, specificity was 85%, positive predictive value was 81%, negative predictive value was 93%. When compared these results with available literature it was found out to be correlating with the available studies of khode *et al,* rajan v *et al.* The present study showing a sensitivity of 92% means that 8.4 malignant lesions would be missed out of 100 malignant lesions. Thus, a benign result on USG does not completely rule out the possibility of malignancy. In case of a benign report, additional testing modalities should be used to rule out malignancy. A specificity of 85% and a positive predictive value of 81% means that a USG report cannot be completely relied upon for treatment decisions when a malignant result is reported. On FNAC examination out of 24 diagnosed to be malignant all 24 cases were confirmed to be malignant on histopathological examination. And out of 27 cases diagnosed to be benign in FNAC all 27 cases were confirmed to be benign on Histopathological examination. And 6 cases which were give as inconclusive on FNAC turned out be benign on HPE. Thus sensitivity, specificity, positive predictive value, negative predictive value of FNAC is 100%. In diagnoses of malignancy but its efficacy to diagnose benign lump is not 100%. Because 6 cases were inconclusive. This is results when compared with the available literature is found out to be correlating. FNAC is found out to be highly sensitive in diagnosing the breast lump which are malignant. Management of the lumps can be done using the FNAC report by comparing and correlating it with the other available modalities like USG and clinical breast examination. When triple assessment was compared with the histopathlogical report out of 29 cases found to be malignant by triple assessment 24 found to be malignant on HPE and 24 cases found to be benign on triple assessment all are benign on HPE report. Cases which are deemed inconclusive on triple assessment all found out to be benign on HPE. When all the three tests concordant there were no false positive or false negative cases. Were as when any discordant test positive and negative predictive value persists. The sensitivity, specificity, positive and negative predictive value of triple assessment in present study was 100%, 85%, 83%, 100% respectively. The findings in present study agree with those of khoda *et al* rajan v *et al,* suman *et al,* hussain *et al.,* vaithiananthan *et al,* tiwari[11-14]. So triple assessment was proved to be 100% sensitive to diagnose a malignant breast lump and helps in management of the breast lump. When one variable is discordant then also triple assessment provides us with most likely diagnoses which can be utilized for the management. Thus from above study it is understand the triple assessment was immensely helpful in management of the breast lumps. The MTT was 85% specific with malignant lesions. But 5 cases were mis diagnosed as malignancies and turned out in 3 cases to be Fibrocystic Disease and 2 cases were benign cystosarcoma phylloides-both benign lesions. Inconclusive results (n=4) on MTT were also confirmed to be benign lesions. Thus MTT, though had false positives with respect to malignancy but no false negatives (i.e.,) a negative predictive value of 100%. So there is no chance of missing malignancy by triple assessment but has chance of over diagnosis of lumps as malignant. In practical aspect too triple assessment is simplest and most cost effective and easily available tests for evaluation and management of breast masses with proven efficacy as show in present study or various studies which are done across the world. It will significantly help both patient and treating doctor for the effective management of breast lumps. It can be also used as screening modality in women of age greater than 40 yrs of age.

CONCLUSION

The overall conclusion of our study is triple assessment is the gold standard diagnostic tool for the palpable breast lumps in early detection of malignancy avoiding biopsies.

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