Original Research Article

The Assessment of Diagnostic Efficacy of Modified Triple Test in Breast Lump: A Prospective Study

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Abstract:

Introduction: The objective was to study the diagnostic efficacy of components of individual and combined modified triple test in breast lump.

Materials and Methods: This was a prospective, analytic, clinical study had included 72 Female patients with palpable breast lump/lumps above 12 years of age, who were admitted in surgery Outpatient Department and ward from June 2017 to May 2018 with breast lump/lumps. Patients were informed about procedure of clinical breast examination, ultrasonography of bilateral breast with axilla and fine needle aspiration cytology of the breast lump.

Results: Most common age group in this series was 50 to 70 years of age. Mean age was 36.74 ± 14.88 years. The most common symptom was lump in axilla 8 (11.11%) along with breast lump, more on Left side 41 (56.94%), most commonly upper outer quadrant 41 (56.94%), size of lump was in range of > 2 cm to 5 cm in diameter 57 (79.17%) patients. In clinical examination with benign pathology in 36 (50.00%) and malignant pathology were found in 36 (50.00%). Ultrasound of bilateral breast with bilateral axilla yields that 37 (51.39%) patients had malignant pathology and 35 (48.61%) patients have had benign pathology. FNAC yields malignant pathology 39 (54.16%) and lump with benign pathology were found 33 (45.83%). Modified triple assessment with specificity 100.00% sensitivity 88.89%, positive predictive value 100.00%, Negative predictive value 85.65% and Accuracy 93.52% in diagnosis of palpable breast lump.

Conclusion: The diagnostic accuracy of combined clinical breast examination, breast USG and FNAC was comparable and reliable to that of histological examination.

Keywords: Breast Lump, Benign Breast Disease, Malignant Breast Disease, Diagnostic Efficacy, Modified Triple Test.

Introduction

The breast lump was the commonest mode of presentation of disease of the breast. A palpable mass in a woman's breast could be a benign or malignant lesion and it requires a prompt evaluation. Correct preoperative diagnosis of a breast lesion was essential for optimal treatment planning.

The primary aim was to confirm or exclude cancer. A single-modality test was not accurate enough to make the correct diagnosis for a breast lesion. However, the number of modalities together is more accurate and reliable compared to a single-modality test, despite having their own technical limitations. [1] The combination of physical examination mammography and Fine needle aspiration cytology (FNAC) came to be called upon as the "TripleTest" for assessment of breast lumps and has now become the gold standard in the work-up of the same. High resolution breast ultrasound was now proving a useful adjunct to mammography. The wide acceptance of ultrasound as a diagnostic modality has been documented extensively. [2] However, opinions vary about the usefulness of Ultrasonography (USG) breast in the evaluation of masses, and, surgeons are cautioned to be aware of its attributes as well as its deficiencies.

The Modified Triple Test' Utilizes-Physical Examination, Ultrasonography of the breast as the radiological method, FNAC, and it was gaining acceptance with the recent advances in technology and refinements in the interpretative criteria of sonographically characterized masses. [3]

Today, the studies concentrate on whether a benign result of the tests mentioned above makes excision biopsy unnecessary. Most often, this question arises in connection with localized changes in breasts

with Fibrocystic diseases. So the aim of the study was to assess the diagnostic efficacy of modified triple test in breast lump.

Material and Methods

This was a prospective, analytic, clinical study had included 72 Female patients with palpable breast lump/lumps above 12 years of age selected randomly, who were admitted to seven surgical units of Assam Medical College & Hospital (AMCH), Dibrugarh, or attended the Surgery Outpatient Department from June 2017 to May 2018 with having complaint of breast lump/lumps were assessed thoroughly as per modified triple assessment comprised of clinical examination, Ultrasonography of bilateral breast with bilateral axilla and FNAC of the breast lump.

Patients with diagnosed malignancy of the same breast, locally advanced malignancy of breast, history of previous Radiation therapy, acute inflammatory conditions of the breast and male patients with breast lump/lumps were excluded from the study. The study protocol was reviewed by the Institutional Ethical Committee of the AMCH and permitted.

Patients were informed about procedure of clinical breast examination, ultrasonography of bilateral breast with axilla and FNAC of the breast lump after detailed explanation about the purpose of the study, the procedures, in their own language and valid consent had been obtained with assurance of confidentiality, individual privacy.

Detailed history and General physical examination of patients having palpable breast lump was carried out and details was entered in Performa.

The study was undertaken to assess the diagnostic efficacy of modified triple test as a whole and its components which had been correlated with the final histopathological report set as gold standard in present study.

Data Entry and Statistical Analysis: Data were analysed by using statistical formula of Mean, Median, Standard Deviation (SD), Specificity, Sensitivity, PPV, NPV and Accuracy. All data analyses were performed on Microsoft Office Excel and SPSS v27.

Results

In present study as we can observe from below mentioned Figure-1 that most common age group in this series was 50 to 70 years of age. Mean age was 36.74 ± 14.88 years.
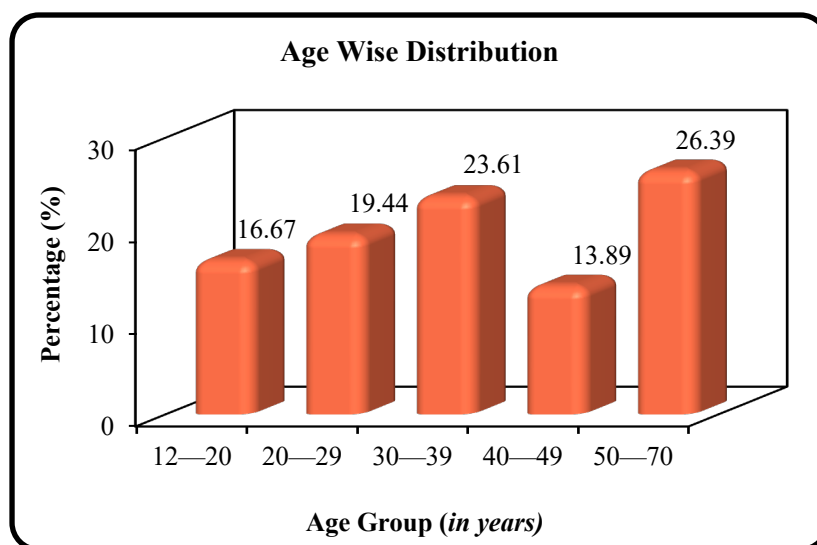

Figure 1: Age Wise Distribution

The most of the patients presented with the breast lump were multiparous 54 patients (75.00%) and 18 patients (25.00%) were nulliparous, 46 patients (63.89%) were premenopausal status whereas 19 patients were (26.39%), postmenopausal.

The most common symptoms and as from the above table and diagram we can see that lump in axilla 8 (11.11%) along with breast lump as additional symptoms followed by with pain 6 (8.33%) over the breast. The duration of symptoms ranges 1 to 6 months in 58.33% patients, followed by 7-12 months in 30.56% patients. The lump was present more on Left side 41 (56.94%) as compared to right side 27 (37.50%) with left to right ratio was 1.51. Bilateral breast lump was found in 4 patients (5.56%).

The most commonly upper outer quadrant 41 (56.94%) was involved quadrant followed by lower inner and outer quadrant 9 (12.50%) and central was least commonly involved in just 2 (2.78%) of cases. The size of lump was in range of > 2 cm to 5 cm in diameter 57 (79.17%) in clinical breast ex-

amination with lump in hard consistency in 36 (50.00%) patients while firm consistency in 30 (41.67%) patients. In clinical examination with benign pathology in 36 (50.00%) and malignant

pathology were found in 36 (50.00%). Ultrasound of bilateral breast with bilateral axilla yields that 37 (51.39%) patients had malignant pathology and 35 (48.61%) patients have had benign pathology.
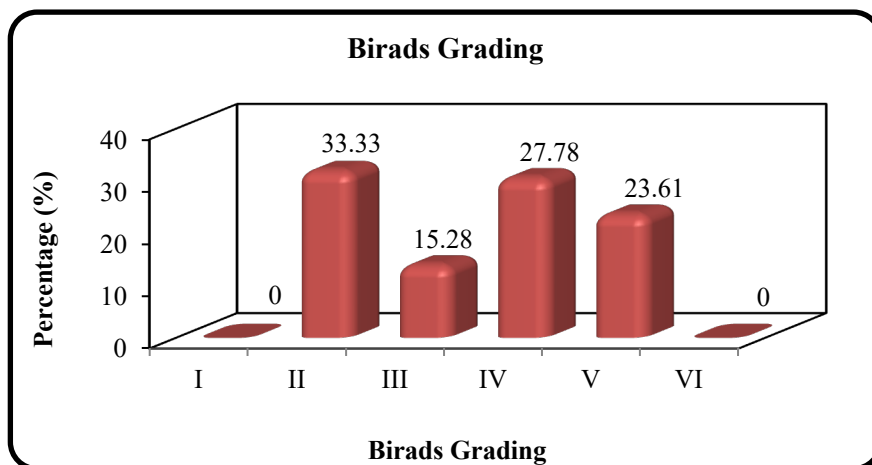

Figure 2: Birads Grading

As figure 2 Ultrasound of bilateral breast with axilla the BIRADS grading category II with maximum 24 (33.33%) yield in breast lump followed by category IV probably malignant 20 (27.78%) followed by 17 (23.61%) as malignant in category V and 11 (15.28%) cases in category III. In present study FNAC yields malignant pathology 39 (54.16%) and lump with benign pathology were found 33 (45.83%).
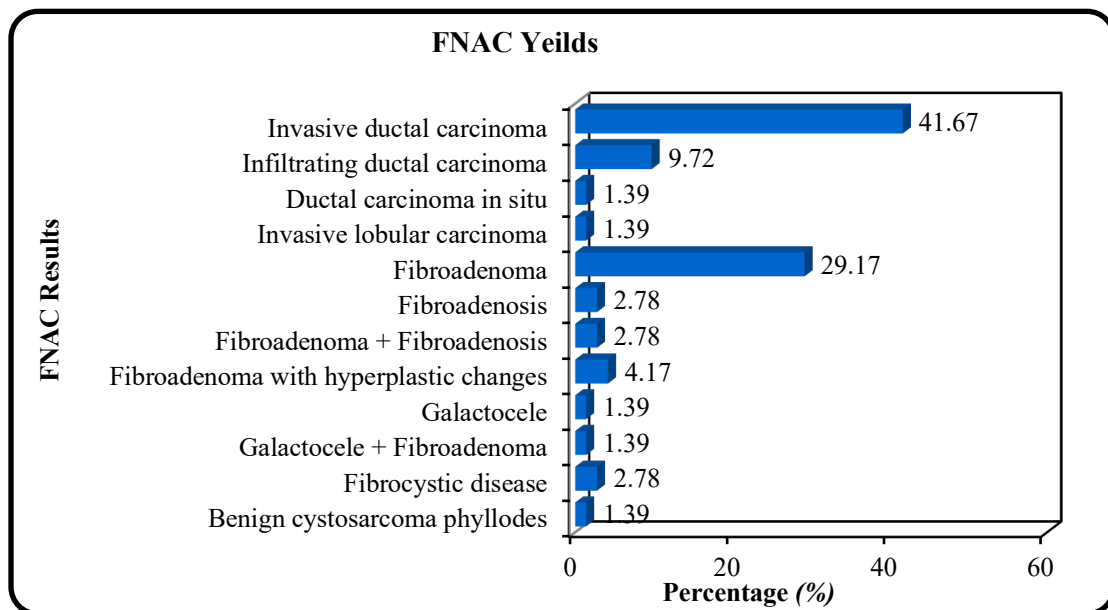

Figure 3: FNAC Yeilds

FNAC yields most commonly found malignant lesions, was Invasive Ductal Carcinoma 30 (41.67%).

The most commonly results of benign pathology was fibroadenoma 21 (29.17%). Also, Invasive lobular carcinoma 1 (1.39%) case, Infiltrating ductal carcinoma in 7 (9.72%) cases, DCIS in 1 case, fibroadenoma with hyperplasia in 3 (4.17%) cases, fibrocystic disease in 2 (2.78%) cases, single (1.39%) case of benign cystosarcoma phylloides, and galactocele as shown in figure-3.

In present study 39 (54.17%) patients with breast lump underwent of Modified radical mastectomy with preoperative diagnosis of malignant pathology followed by 32 (44.44%) excisional biopsy and single (1.39%) lumpectomy for benign pathology and specimen sent for final histopathological assessment which was set as gold standard. In present study HPE yields most commonly found malignant lesions, were IDC 31 (43.06%) cases.

The most commonly results of benign pathology was fibroadenoma 21 (29.17%) cases as also found

in FNAC shows that FNAC had 100% diagnostic accuracy in benign lesions.

Also, Invasive lobular carcinoma 1 (1.39%) case, Infiltrating ductal carcinoma in 8 (11.11%) cases,

DCIS in 2 (2.78%) cases, 2 (2.78%) cases of chronic granulomatous disease of the breast and 1 (1.39%) case of benign cystosarcoma phylloides, and galactocele as in figure 4.
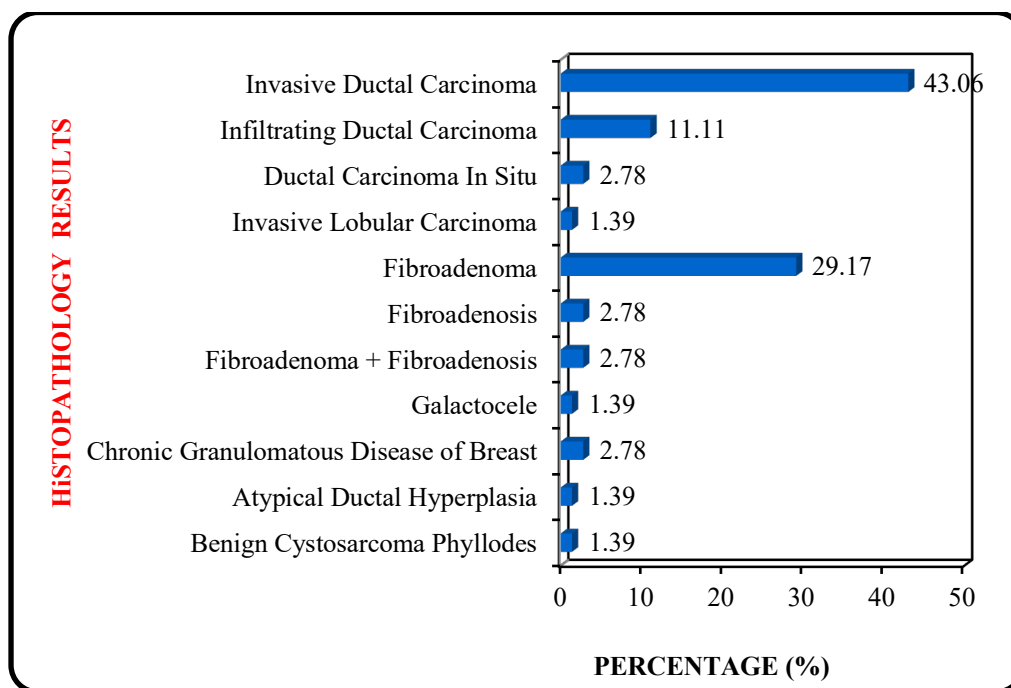

Figure 4: Histopathological Examination.

We concluded from above diagram that modified triple assessment with specificity 100.00% sensitivity 88.89%, positive predictive value 100.00%, Negative predictive value 85.65% and Accuracy 93.52% in diagnosis of palpable breast lump as in table 1.

Table 1: Diagnostic Efficacy of Clinical breast examination, FNAC, USG and Modified Triple Test

	Clinical Breast Examination	FNAC	USG Breast with Bilateral Axilla	Modified Triple Test
Sensitivity	85.71%	92.86%	88.10%	88.89%
Specificity	100%	100%	100%	100%
Positive Predictive Value (PPV)	100%	100%	100%	100%
Negative Predictive Value (NPV)	83.33%	90.91%	85.71%	85.65%
Accuracy	91.67%	95.83%	93.06%	93.52%

In present study as mentioned from above tabulation that modified triple test with specificity 100.00% sensitivity 88.89%, positive predictive value 100.00%, Negative predictive value 85.65% and Accuracy 93.52% in present study. CBE was found least sensitive while FNAC was most sensitive in all variables with USG with intermediate sensitivity and accuracy among the three components of modified triple test.

Discussion

In this study the diagnostic efficacy of modified triple test in breast lump was observed. This was a hospital based prospective study. In present study most common age group in this series was 50 to 70 years. of age. Mean age was 36.74 ± 14.88 years. Youngest patient was 13 years. Of age and oldest patient was 70 years. of age. Akshey Batta et al

[4] in their study they evaluated 100 females with breast masses, the age of the patient in ranged from 16 years to 78 years with the mean age of 38.24 years. In present study out of 72 patients 18 (25%) patients were nulliparous and 54 (75%) patients were multiparous. However, malignant lesions were not detected in all the nulliparous patients.Takkar et al [5] In their study most of the women (98.8%) had their first childbirth before the age of 30 years, only 1.2% were nulliparous, 33% of women in the study group were menopausal. Late menopause (menopause after 55yrs of age) was also a risk factor of development malignancy of breast. This was also having same mechanism as early menopause like more exposure of hormones during excess number of menstrual cycles. AS in present study average age of menopause was 43.10 years and 29 (40.28%) patients belong to age

groups > 40 years. So here late menopause was not risk factor. Clinical breast examination yield that almost half of the patients with lump in hard consistency 36 (50.00%) with malignant pathology as most of the patients had followed by firm consistency 30 (41.67%) with benign of breast lump.

Ebubedike UR, et al [6] in their study one hundred and thirteen patients were recruited during the study period from January 2013 to April 2014. In their study CBE achieved a sensitivity of 82.1%, specificity 67.9%, positive predictive value (PPV) 78%, negative predictive value 73%, overall accuracy 76.1%, false positive rate 32.1%, and false negative rate 17. They found in their study revealed no statistical significant difference between the accuracy of CBE and breast ultrasonography. They recommend that both should be used in the evaluation of palpable breast masses.

In this study Ultrasound of bilateral breast with bilateral axilla as given in above table yields that 37 (51.39%0 patients had benign pathology and 35 (48.61%) patients have had malignant pathology in with the most common lesion as heterogeneous predominantly Hypoechoic 37 (51.39%) cases followed by Hypoechoic 35 (48.61%) in cases with most of the patients fall in the BIRADS category II with maximum 24 (33.33%) yield in breast lump followed by category IV probably malignant 20 (27.78%). Bangaru H et al [7] they conducted a retrospective, record based, study conducted in general surgery department at Malla Reddy institute of medical sciences from August 2013 to July 2017 in 202 cases of breast lumps were evaluated by ultrasonography (USG). USG showed 98.3% sensitivity while specificity, positive and negative predictive values were 71.4%, 93.1% and 91.5% respectively. Degree of agreement between each diagnostic modality and HPE were analyzed. USG was also found to be in good agreement with HPE (kappa 0.76).

Kachewar S. et al [8] they carried out prospective study from May 2010 to April 2012. The MTT was applied to 70 cases out of these 70, The Statistical Analyses of FNAC as a diagnostic test to detect the presence of malignancy in the breast was done. FNAC was 88.37% sensitive and 96.42% specific in diagnosing malignant lesions. Also, FNAC had PPV of 97.43% and a NPV of 84.37% in diagnosing malignant lesion. In their study, it had an accuracy/efficiency of 91.54%.

In present study, 72 female patients with breast lump had been undertaken to FNAC. In FNAC 39 patients were came out with malignant lesion and 33 with benign. When this compared with histopathology the sensitivity 92.86%, specificity 100.00%. Negative predictive value 90.91%. positive predictive value 100.00%, In FNAC most common benign lesion found in present study was

fibradenoma 29.17%, and most common malignant lesion found in present study was invasive ductal carcinoma 41.67%, over all most common lesion was invasive ductal carcinoma. In present study three malignant lesions yield false negative with FNAC results of fibroadenoma with hyperplastic changes and fibrocystic disease cases.

Bhavinder A et al [3] they conducted a prospective study to evaluate the diagnostic efficacy of clinical examination, ultrasonography and FNAC individually and in combination for the diagnosis of palpable breast lump in 50 patients, during the time period of 2007-2009. Sonographic investigation was performed using a linear probe 5-12 MHz in all cases FNAC was done using fine 22 to 23-gauge needle of 2.5-4 cm for aspiration.

All cases were operated and correlated histopathologically. They yield that accuracy of Clinical examination, FNAC, and ultrasound in the diagnosis of benign breast lump were 88.0%, 93.7%, and 94% respect. Sensitivity and specificity of modified triple test (C.E., USG, and FNAC) in comparison to histopathology in the diagnosis of breast carcinoma was 100% and 96.15% respectively.

Sensitivity and specificity of modified triple test (clinical examination, USG and FNAC) in diagnosing a malignant breast lump were 100% and 95.8% respectively. Accuracy of triple assessment was 97.0%. They concluded that use of triple test in diagnose was of breast lump was most accurate instead of using a single modality alone. But in developing countries like India modified triple test was more useful because of its cost effectiveness, wide availability and better diagnostic accuracy.

In present study, the diagnostic efficacy of modified triple assessment in breast lump comprised of combination of all three components used had shown the sensitivity 88.89% specificity 100%, positive predictive value 100% and negative predictive value was 85.65%. In present study diagnostic efficacy of modified triple test in breast lump was near to ~` 100% (93.52%) with highest accuracy was FNAC 95.83%, followed by ultrasound 93.06% and least with the CBE 91.67%.

To conclude, the Modified Triple Assessment was easily reproducible, making it a valid and reliable diagnostic approach as well the as reliably guides towards effective management of palpable breast lumps. This lead to less delay in treatment when malignancy was suspected and when a benign nature of lesion was suspected avoids unnecessary open biopsies.

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