

Original Research Article

A study on diagnostic accuracy of modified triple assessment in palpable breast lumps

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ABSTRACT

Background: Breast (mammary gland) is a distinguishing feature of class Mammalia. Patients commonly present, complaining of a lump in the breast, pain, and nipple discharge. Although the most common cause of symptoms is benign breast diseases. But as the life expectancy is increasing incidence of carcinoma breast is also increasing. 1.To assess the individual component diagnostic accuracy of MTT.

Methods: This was a cross-sectional study involving 50 female patients with palpable breast lumps attending the Surgical Out-Patient of the Department of General Surgery, Government Royapettah Hospital, Kilpauk medical college, Chennai between June 2020 and May 2021 over 12 months, who underwent clinical breast examination (CBE), ultrasonography (USG), and fine-needle aspiration cytology (FNAC).

Results: In the study population, the breast tumor is common on the left side account for about overall 53% age of patients. The bilateral tumors are the least common. Fibroadenoma is the most common benign tumor. In our study also similar results were obtained. The next common benign tumor among the study group is a fibrocystic disease of the breast. Analysis of the above results shows that though FNAC has a sensitivity of 90%, it has a positive predictive value of 100%. The study shows that the combined results of the Modified Triple Test are comparable to the histopathological diagnosis of the biopsy specimen.

Conclusions: Our study includes assessment of combined diagnostic accuracy of Modified Triple Test in women of more than 30 years of age with a palpable breast lump.

Keywords: Breast lumps, Clinical breast examination, Fine-needle aspiration cytology, Modified triple test, Ultrasonography

INTRODUCTION

A breast lump is one of the most common complaints in women attending the surgical outpatient department. Even though most of the lumps were benign, all cases need to be assessed properly to rule out malignancy. In India, Carcinoma breast is the second most common malignancy in women. Incidence keeps increasing every year which ranges between 19-34%. Incidence of breast cancer shows an “age shift” over the past two decades in India that its incidence increased from 7 to 16% in the age group of

30-40 years.¹ Advanced-stage breast cancer is associated with high morbidity and mortality. Hence early-stage disease should be promptly differentiated from benign disease for appropriate management at the earliest with proper assessment. Assessment of breast lump should be an ordered one. So, a sequential evaluation named “triple test” was formalized. This was introduced to avoid expensive potentially morbid negative open biopsy and also to let the clinician proceed directly for definitive management without further investigations. The triple test

proved to be a gold standard diagnostic modality in breast lump.

Components of triple test: clinical examination, imaging and FNAC. Clinical assessment should be the initial one but it is not very certain to make a clear-cut diagnosis. Hence demand to proceed with the next diagnostic test, the Imaging study- Mammogram.² In 1950, Robert Egan at the University of Texas introduced Mammogram. In 1966 Philip Strax demonstrated a mammogram as a screening procedure. Mammogram is a low energy X-ray [30 kvp] with high mAs used to image the breast. Like another X-ray it emits ionizing radiation but of low energy. It has a high false-negative rate that is missed cancer rate of 10%, especially in dense breast.³ In women of reproductive age group breast is dense owing to the increased glandular component, where the sensitivity of mammogram is less and hence Ultrasound imaging of breast came into vogue which replaced mammogram in the conventional triple test. Then “modified triple test” was put into practice with USG replacing Mammogram as an imaging modality in women less than 40 years of age.⁴ In recent year’s ultrasound with advanced technology proved to be an effective adjuvant to diagnosis. With invent of FNAC entire outlook in the management of breast lump changed, it serves as an effective tool in confirming the diagnosis. FNAC is safe, minimally invasive, painless, and technically easy procedure that can be carried out for assessing all the patient with palpable breast.⁵ This study was done to know the efficacy of individual components and also the overall efficacy of modified triple test in accurately diagnosing a palpable breast lump in a woman with more than 30 years of age.

METHODS

This was a cross-sectional study involving 50 female patients with palpable breast lumps attending the Surgical Out-Patient of the Department of General Surgery, Government Royapettah Hospital, Kilpauk medical college, Chennai. between June 2020 and May 2021 over 12 months, who underwent clinical breast examination (CBE), ultrasonography (USG), and fine-needle aspiration cytology (FNAC). After obtaining institutional ethical committee based on Inclusion criteria: Female patients with a palpable breast lump, Age group of more than 30 years. Exclusion criteria: Male patients, Female patients with clinically evident advanced stage breast disease. As per the inclusion and exclusion criteria, study people were selected. Total numbers of 50 patients were included in the study. Initially, the complete clinical examination (performed) after getting informed consent. Ultrasound Imaging of both breast and axilla, imaging study was done before any invasive procedure to avoid possible architectural distortion. Finally, the tissue diagnosis with FNAC/CNB is based on 5 tier system of FNAC reports. All patients at the end of MTT are categorized as Benign, Suspicious, and Malignant with each component of MTT. Those who are diagnosed as clear-cut benign tumors (score <4) on three tests were subjected to incisional biopsy and

others with a suspicious or malignant lesion (score 5 and 6) were to proceed with excisional biopsy or definitive surgical procedure. Finally, all the individual components and combined results of the modified triple test, explored against the HPE report of incisional /excisional biopsy/definitive procedure – modified radical mastectomy specimen. We used the Chi-Square test, ANOVA, and Post-Hoc test as appropriate. $p < 0.05$ was considered statistically significant. The results were presented as means and SD.

Statistical analysis

The final histopathological report was considered as the reference standard and reports were then grouped into "benign" and "malignant" for analysis. Data were entered in a pro forma. Variables were cross-tabulated against the HPE report, the reference standard. Sensitivity, specificity, positive predictive value, negative predictive value, and accuracy were determined for each modality separately and then combined. Statistical calculation comprised of sensitivity, specificity, positive predictive value, negative predictive value, and accuracy of triple test, for evaluating breast pathology, considering histopathology as standard.

RESULTS

In this section, the data analysis encompassed the detailed information of patients attending surgical OPD with the breast lump, above 30 years of age. A total of 50 patients were selected as per the criteria as discussed earlier. Each patient is concerned with various data and their study results concerning the modified triple test were analyzed in detail.

Table 1: Age distribution.

Age range	Total No. of Patients
30 to 39 years	19
40 to 49 years	14
50 to 59 Years	13
60 and above	04

Table 2: Comparison between parity of patients with percentage of benign and malignant breast lump.

Parity	No. of patients (%)		
	Benign	Malignant	Total
Nulli parous	4 (44.44)	5 (55.55)	9 (100)
Multiparous	35 (85.37)	6 (14.63)	41 (100)
Total	39 (78)	11 (22)	50 (100)

(Table 1) In this study population, based on the age group, the 30 years patients as the youngest and 64 years is being the oldest. The mean age of the study group is 45 (44.76) and its standard deviation is 9.5 i.e., 45 ± 9 years.

Table 3: Location of tumor and percentage.

Tumor sites	Percentage of patients
Right Side	45
Left Side	53
Bilateral	02

Table 4: Quadrant involvement.

Quadrant	Percentage of patients
Upper Outer (U/O)	64
Upper Inner (U/ I)	14
Lower Outer (L/O)	09
Lower Inner (L/I)	04
Central (C)	09

Table 5: Histopathological report.

Cytology	no. of patients
Fibroadenoma	24
Fibro cystic disease	11
Cystosarcoma phyllodes	02
Proliferative without atypia	02
Ductal carcinoma in situ	01
Ductal carcinoma	06
Lobular Carcinoma	03
Mucoid Carcinoma	01

Parity study compared the occurrence of benign and malignancy disease among nulliparous and multiparous women results were reported as percentage and total numbers of patients (Table 2). From this table, among 9 nulliparous women, 5 were found to be breast carcinoma. The calculated p value for parity study is 0.017 and it is shown that malignancy is common among nulliparous. However, the comparison of the menstrual status of women shows that premenopausal women prevailing benign tumor are common, whereas in the case of perimenopausal and postmenopausal women being malignant tumor is a common one. For the menstrual status, the calculated p value is 0.044 is significant.

In the study population, the breast tumor is common at left side account for about overall 53% (Table 3).

Table 4 shows During the population study, the location of the most prevailing tumor was also examined. Based on the results, most of the patient's tumors were observed at U/O and the least patient at L/I. This fact is due to estrogen receptors more prevailing at the U/O quadrant which is reported as 64 %. In this comparison, the L/O quadrant plays a median role between L/I and U/O quadrants.

Table 6: Final biopsy specimen results.

Clinical examination	Biopsy report		Total
	Malignant	Benign	
Malignant (+)	08 (a)	01 (c)	09
Benign (-)	01 (b)	37 (d)	38

Fibroadenoma is the most common benign tumor. In our study also similar results were obtained (Table 5). The next common benign tumor among the study group is a fibrocystic disease of the breast. One of our study patients has ductal carcinoma in situ of the malignant cases, ductal carcinoma is the commonest which is comparable to the previous study results mentioned in the literature.

Table 7: Comparison between ultrasound results against final biopsy report.

Ultrasound	Biopsy Report		Total
	Malignant	Benign	
Malignant (+)	08(a)	-(c)	08
Benign (-)	- (b)	39 (d)	39

Comparison of clinical input against final biopsy reports, sensitivity: 88.89%, specificity: 97.37%, PPV: 88.89%, NPV: 97.37% (Table 6). It was inferred from the study that clinical examination has a sensitivity of 89% which means that around 11% of the breast carcinoma cases are missed clinically. Despite this, clinical examination is a reliable method to assess the breast lump as it has high specificity and negative predictive value.

Table 8: Comparison between FNAC result and final biopsy report results.

FNAC	Biopsy report		Total
	Malignant	Benign	
Malignant (+)	10(a)	-(c)	10
Benign (-)	01 (b)	38 (d)	39

Results of ultrasound breast are highly operator dependent (Table 7). The results of the study show that the radiologists are experienced and skilled enough. Ultrasound breast has high sensitivity and a negative predictive value of 100%.

Analysis of the above results shows that though FNAC has a sensitivity of 90%, it has a positive predictive value of 100% (Table 8). So those who are diagnosed to be positive for malignancy can be taken up for definitive surgical management without any further investigations for confirmation of diagnosis.

Table 9: Comparison between combined results of MTT against final biopsy report.

	C/E	USG	FNAC	MTT
Sensitivity	88.89	100	90	100
Specificity	97.37	99.7	100	97.37
PPV	88.89	98.9	100	91.67
NPV	97.37	100	97.44	100

The study shows that the combined results of the Modified Triple Test are comparable to the histopathological diagnosis of the biopsy specimen (Table 9). Hence the modified triple test can be used as a reliable and fairly accurate means of diagnosis of breast carcinoma. After analyzing the results of all the individual and combined components of the modified triple test we can infer the following. Clinical examination alone has a sensitivity of 89%, but when combined with USG and FNAC the overall sensitivity rises to 91%. Ultrasound examination has a high sensitivity of 100% and hence is a reliable method that can be used for screening of breast lump. Among the three components, fine needle aspiration cytology is highly accurate with specificity and a positive predictive

DISCUSSION

Breast carcinoma mortality was greatly reduced after the introduction of mammogram screening. Ultrasound role was established in the assessment of breast lump because of limitations of Mammogram. Ultrasound sound waves with no risk of Radiation exposure can be safely used to image the breast, high frequency probes are used. Sound waves from the probe pass through the body, the transducers collect the sound waves that bounce back and the computer then uses these waves to create an image.⁶ Our present study was conducted on 50 female patients with a palpable breast lump each of whom underwent fine-needle aspiration cytology of the lump followed by excisional surgery either in the form of a lumpectomy or a definitive surgical procedure like a mastectomy, depending on the diagnosis at aspiration cytology. The aspiration cytology findings were then matched with the final histology report to see how accurate FNAC was as compared to open biopsy i.e., to assess the cyto-histologic correlation. None of our patients was subjected to a core biopsy and its correlation with FNAC was not a part of our study.⁷ Our study also did not attempt to draw any conclusions as to whether one diagnostic modality could replace the other. Patients were selected regardless of their religion, occupation, and financial status. All these patients underwent an FNAC and patients who did not follow up after FNAC were not included in this study.⁸ Every patient included in this study was admitted and underwent a definitive surgical procedure as demanded by the FNAC report. It varied from excision biopsy to a modified radical mastectomy. The procedure of FNAC was performed by trained personnel in the pathology department following a uniform protocol. All pathology specimens underwent a histopathological study, the final report was compared with that of FNAC and the correlation was sought. The

results obtained were tabulated and conclusions are drawn based on statistical tests.⁹ Though many aspects relating to the patient profile were tabulated and compared with those in other similar studies, the most important aspect of this study was to conclude the cytohistological correlation in these patients. In our study, results of imaging of breast gave a sensitivity of 100% and specificity of 99.7% with negative predictive value of 100%, which are on the higher side of the available literature. The reason may be breast imaging is an operator-dependent process and technical team expertise and it also reflects good resolution of Ultra sound machine.¹⁰ FNAC results in our study have given the sensitivity of 90.0% and specificity of 100% with negative predicted value of 97.4%, which is following most of the available literature.¹¹ In our study, combined assessment with clinical examination and FNAC yielded a sensitivity of 89.45% and specificity of 95.68% which is in agreement with Donegan et al sensitivity 93.33% specificity 87.50% in the view of higher diagnostic accuracy than single diagnostic modality.¹² Hermansen et al used a scoring system for triple tests in their study, they have included 113 patients. Benign lesions have given a score of 1, suspicious lesions 2, and malignant lesions 3 on each modality. The final score was obtained by adding individual scores. Results were then compared with histopathological reports. The triple test was found to have an accuracy of 100%. They suggested that breast pathologies with a score less than four are benign, those with a score of five should undergo biopsy, and lesions with a six and higher score can undergo definitive treatment. Thus unnecessary biopsies can be avoided.¹³ Bassett et al also determined the accuracy of triple assessment in characterizing breast lesions. They scored results of the triple assessment as concordant and non-concordant. If all elements were either benign or malignant then findings were considered as concordant and non-concordant if the elements were neither all malignant nor benign. The study concluded that triple assessment is less time-consuming, minimally invasive, and cheap, however, it should only be employed in settings where good imaging modalities and trained staff are available.¹⁴ Shetty et al conducted a prospective study to calculate the accuracy of triple assessment in diagnosing breast cancer. It was found that all these modalities had less accuracy when employed alone but in combination, triple assessment gave 100% sensitivity and high specificity.¹⁵ In other words, if all three modalities give negative results, breast cancer is excluded and the patient can be safely discharged. We suggest that instead of putting the patient through pain and agony of biopsy, the three modalities of triple assessment (P, M and/or U, and FNAC) can be safely done to assess the status of cancer, and it can be a potential alternative to core biopsy.

CONCLUSION

Our study includes assessment of individual and combined diagnostic accuracy of Modified Triple Test in women of more than 30 years of age with a palpable breast lump. Study goes on with initial assessment with clinical

examination, then imaging with Ultrasound, and finally, cytological interpretation of FNAC slides. Clinician, Radiologist, and the pathologist had fine collaboration during the study. The diagnostic accuracy of MTT indirectly indicates the experience and skill of the clinician, radiologist, and pathologist. On data analysis the study results showed that clinical examination is least sensitive in diagnosing the malignancy, hence breast lump requires further investigations which in combination with the other two-component the sensitivity increased to 100%. Advanced technology Ultrasonogram good in the characterization of a breast lump which had high sensitivity and NPV of 100%. FNAC had a high specificity and positive predictive value of 100% which was highly comparable to previous study results.

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