

**Original research article**

**To Study the Assessment of Palpable Breast Lump by the Use of Modified Triple Test in A Tertiary Care Hospital**

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**Abstract**

**Introduction:** Carcinoma breast is the leading cause of morbidity and mortality in women, both in the developed and developing countries. The occurrence of breast cancer is increasing in the developing world due to increased life expectancy, adoption of western lifestyles, urbanization and diagnosis in very late stages.

**Aim:** The aim of this study was assessment of palpable breast lumps for detection of malignancy using a modified triple test and comparison with histopathological examination as reference standard.

**Methods:** Female patients with breast lump were included in this study. Modified Triple Test will be assigned a score of 1, 2, or 3 point for a benign, inconclusive or malignant result, respectively. The present study was commenced to evaluate the role of MTT in preoperative diagnosis of palpable breast lesions keeping histopathological examination as gold standard.

**Results:** A total of 120 cases of breast lumps were studied. all of the patients who were suspected to have malignancy by Modified triple test had malignancy on histological analysis and specificity was 100%, that proved it as a best initial test for diagnosis of malignancy preoperatively.

**Conclusion:** The modified triple test in our study was an accurate predictor of malignancy. It helps us to plan the surgical treatment earlier, accurately.

**Keywords:** MTT (Modified Triple Test), palpable breast lumps, fine needle aspiration cytology.

**Introduction**

Breast carcinoma is one of the common causes of morbidity and mortality among women worldwide. Considering all types of cancer, breast cancer accounts for one in every four women. In India, the age-standardized incidence rate of breast malignancies varies from 9- 32 per one lakh women. More than one million new cases are diagnosed every year in India. Mortality due to breast cancer is also high due to low rates of early-stage detection and poor treatment outcome <sup>[1]</sup>. Developing countries have limitations in resources and infrastructure that challenge the objective of improving breast cancer outcomes through timely recognition, diagnosis and management <sup>[2]</sup>.

Breast masses have a variety of etiologies, i.e. benign and malignant. A palpable breast mass accidentally found in young women is a common cause of anxiety, though the majority of these lesions are benign <sup>[3]</sup>.

A lump in the breast is of great concern to the patient and is also a challenge to the diagnostic acumen and judgment of the surgeon. With growing awareness in the general population, especially about breast cancer, a lump in the breast causes physical, emotional and psychological trauma to the patient and the family members. Therefore, a distinction between benign and malignant is of paramount importance for the patient and its proper management. Any breast lesion is worrisome to the patient and is also a challenge when it comes to diagnosis and the decision of the surgeon.

The triple test was first described by Johansen in 1970 for the assessment of palpable breast masses by physical examination, mammography, and fine needle aspiration cytology <sup>[4]</sup>.

Many breast masses do not show typical features on physical examination; therefore, imaging becomes significant in almost all cases to classify the palpable lesion and screen the remaining breast tissue for any other lesions if the patient is 40 years older or more <sup>[5]</sup>. Ultrasonography can help differentiate between solid and cystic masses of the breast. Ultrasonography is considered superior to mammography when it comes to imaging dense breasts <sup>[6]</sup>.

Presently clubbing of all three tests, i.e., clinical examination, mammography, or ultrasonography and pathology, is referred to as a triple assessment test used to diagnose all breast abnormalities. It is simple, less traumatic, and cost-effective. When the three assessments are performed effectively and produce concordant results, diagnostic accuracy can reach 100% <sup>[7]</sup>. These methods of investigation, when used

alone, give less reliable outcomes, but when combined, accuracy and chances of correct diagnosis increase<sup>[8]</sup>.

A triple assessment collective approach or clinics are a great example of a multidisciplinary approach as it involves surgeons/physicians to whom the first patient presents, radiologists and clinical pathologists as a team. Where all three investigations are available under one roof, communication between all professionals must be encouraged and practiced to reach the most likely diagnosis in such a setting<sup>[9]</sup>.

The modified triple test aims to allow the surgeon to avoid unnecessary open biopsy and to proceed with definitive therapy if a malignant breast lump is present. The modified triple test is a reliable test, with a high accuracy for the diagnosis of breast lumps. Although FNAC is the most accurate. A patient with a concordant benign triple test report can be safely followed up without the need for a biopsy<sup>[10]</sup>.

### **Aim and Objectives**

The aim of the study is to assess reliability of each components of modified triple test in making pre procedural diagnosis of palpable breast lump, so that unnecessary invasive procedures can be avoided. Objective of this study is to assess the effectiveness of Modified Triple test (MTT) in evaluation of breast diseases. To compare MTT (as a combined diagnostic modality) to each of its components.

### **Material and Methods**

This hospital based prospective study was carried out from January 2021 to June 2022 for a period of 18 months. After applying inclusion and exclusion criteria and after obtaining their informed written consent on female patients above 15 years of age with breast lump presenting to the department of General Surgery, AIMS Bathinda after getting approval from the Research committee, AIMS and Ethics committee, Adesh University. Male patients and lump associated with fungation were excluded from the study.

### **Methods**

Each patient was put through the Modified Triple Test. Each component of MTT assessed and graded as malignant, benign or inconclusive. To better evaluate lesions, MTT was assigned a score of 1, 2, or 3 point for a benign, inconclusive, or malignant result, respectively. Individual element scores were added together to yield a total MTT score for each lesion. This system results in a minimum score of 3 for a concordant benign test result and a maximum score of 9 for concordant malignant test result. MTT score were correlated with the conclusive diagnosis which was the histopathological results of tissue specimens obtained from open biopsy, lumpectomy or mastectomy of the breast mass under study.

### **Statistical Analysis**

All the data were recorded in a Microsoft Excel Sheet and analyzed using SPSS-26 Software. Parametric data were analysed using t test and chi square test was applied for nonparametric data. Diagnostic accuracy of MTT and all its modalities was calculated with sensitivity, specificity PPV and NPV. The modified triple test (MTT) was scored as concordant if the elements had either all malignant or all benign results. It was non-concordant if the elements had neither all malignant nor all benign results. Level of significance was considered  $p < 0.05$  as significant and  $p > 0.05$  as insignificant.

### **Results**

The results encompassed the detailed information of patients attending surgical OPD with the breast lump, above 15 years of age. The total of 120 patients were selected as considering inclusion & exclusion criteria as discussed earlier. Modified Triple Test assessment was done in 120 cases of palpable breast lump in females. The results were compared with gold standard histopathology reports in view of carcinoma breast to analyze that how accurately carcinoma breast can be diagnosed on basis of MTT assessment.

The youngest patient in the study was 28, and the oldest was 62 years. The mean age of the patients is  $43.35 \pm 9.12$  years. The maximum number of cases, i.e., 43 (35.8%), occurred in the 31-40 years of age group. The mean duration of symptom in patients were  $5.45 \pm 2.05$  months. Out of 120 patients, maximum women, i.e., 70 (58.3%), are in the premenopausal period. The mean size of the lump is  $3.21 \pm 0.81$  cm. The smallest size found is 2cm, and the largest was seen at 5cm. on histopathological examination, 41 (34%) cases were found malignant, and the maximum percentage of cases were lying in benign cases, i.e., 66%. malignant breast disorders were found in 41 (34% of total cases) patients, in which, invasive ductal carcinoma had the lead with 32 (78%) of total malignant cases followed by 3 cases of Ductal Carcinoma in situ (7.3%). Invasive Papillary Neoplasm and Mucinous Carcinoma of 2 case (4.9%) each. Our study more or less found the same results as in the study done by Sulhyan KR *et al.*<sup>[11]</sup>.

On clinical breast examination, out of 45 malignant patients, 39 were confirmed, and six were declared benign. Seventy-five patients were found benign, out of which 73 were confirmed benign. However, 2 cases were graded as malignant. Which is statistically highly significant ( $p < 0.001$ ). (Table 1)

**Table 1:** Grading of clinical breast examination versus histopathology report

Clinical Examination	Histopathology Examination		No of Patients	p value
	Malignant	Benign		
Malignant(Hard)	39(86.6)	6(13.3)	45	<0.001
Benign(Firm)	2(2.6)	73(97.3)	75	

In ultrasonographic findings, all 41 patients as malignant and 73 patients as benign were confirmed in histopathological examination. However, 6 cases were found inconclusive in USG findings, which were declared as benign in histopathological examination ( $p<0.001$ ). (Table 2).

**Table 2:** Grading of imaging vrsus histopathology reports

USG Finding	Histopathology Examination		No of patients	p Value
	Malignant	Benign		
Malignant	41(100)	0	41	<0.001
Benign	0	73(100)	73	
Inconclusive	0	6(100)	6	

When we correlate the FNAC with histopathology, we found statistically highly significant difference in findings. 38 malignant patients were confirmed, and out of 72 benign patients, one patient was found malignant. However, two were malignant, and eight were graded as benign in 10 inconclusive results. (Table 3).

**Table 3:** Grading of FNAC vrsus histopathology reports

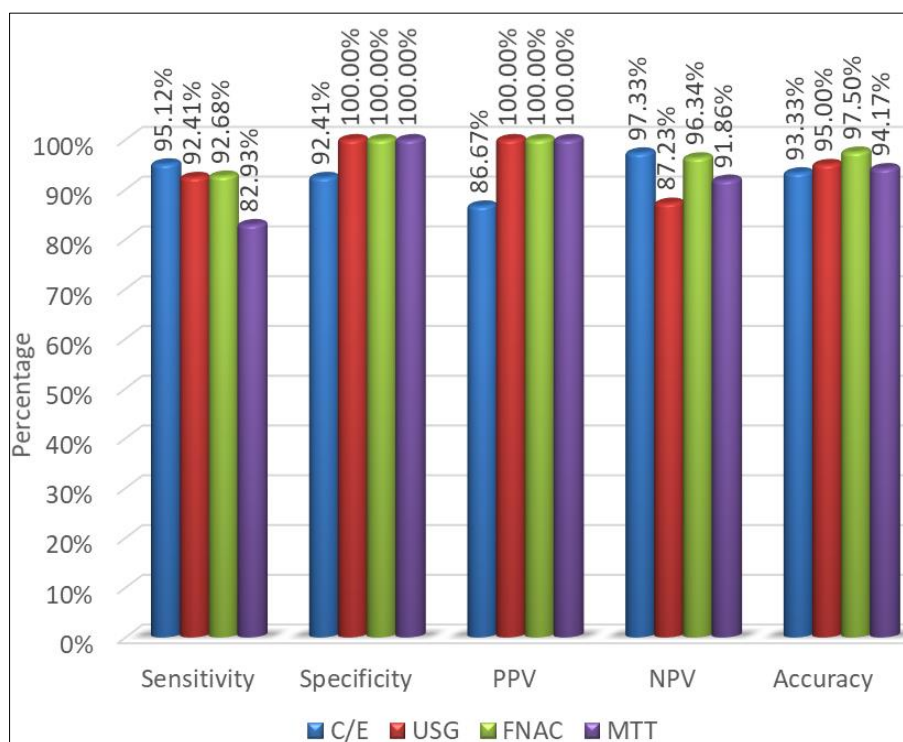
FNAC	Histopathology Examination		No of patients	p Value
	Malignant	Benign		
Malignant	38(100)	0	38	<0.001
Benign	1(1.38)	71(98.61)	72	
Inconclusive	2(20)	8(80)	10	

The MTT was concordant in 98 cases. Out of 22 non-concordant cases of MTT, seven patients were later proven to be malignant, and 15 were proven benign on histopathology ( $p<0.001$ ). (Table 4).

**Table 4:** Modified Triple Test in Diagnosing Carcinoma Breast as Compare to Histopathology

MTT	Histopathology Examination		No of patients	p Value
	Malignant	Benign		
Malignant	34(100)	0	34	<0.001
Benign	0	64(100)	64	
Inconclusive	7(31.82)	15(68.18)	22	

On comparison of each components of MTT and with histopathology, sensitivity of the CBE, USG and FNAC is 95.12%, 92.41% and 92.68% respectively but as combined reliability of MTT it is 82.93%. Specificity and positive predictive value of USG, FNAC and MTT was found to be 100%. In case of CBE it was 92.41% and 86.67%. Negative predictive value CBE, USG and FNAC is 97.33%, 87.23% and 97.50% respectively. In case of MTT it was found to be 91.86%. Accuracy of each component is somewhere between 93.33% to 97.50%. (Figure).



**Fig 1:** Comparative Analysis of MTT (As a Combined Diagnostic Modality) and its Each Components in Diagnosing Carcinoma Breast

### Discussion

In the present study, sensitivity, specificity, PPV, and NPV for clinical examination is found to be 95.12%, 92.41%, 86.67% and 97.33%, respectively with an accuracy of 93.33%. Almost similar results were seen in the study done by Sharma P *et al.*,<sup>[12]</sup>. However, a slight variation is seen in the study of Khoda *et al.*<sup>[13]</sup> in which the sensitivity, specificity and accuracy for clinical breast examination as 66.6%, 100% and 90%, respectively.

Sensitivity, specificity, PPV, and NPV for clinical breast examination are 92.41%, 100%, 100% and 87.23%, respectively, with an accuracy of 95%.

Our results were close to another study by Khoda *et al.*,<sup>[13]</sup> in which only the negative predictive value is different, i.e., 97.3%.

In the present study, sensitivity, specificity, PPV, and NPV for FNAC are 92.68%, 100%, 100%, and 96.34%, respectively, with an accuracy of 97.5%. The same results were found in the study done by Khoda *et al.*<sup>[13]</sup> Although 92.29% sensitivity and 86.67% specificity, 94.29% PPV, and 86.67% NPV with 92% accuracy was seen in the study done by Patil M *et al.*<sup>[14]</sup> which is slightly different with our study.

Sensitivity, specificity, PPV, and NPV for the modified triple test mean the combination of all three modalities were found to be 82.93%, 100%, 100%, and 91.86%, respectively, with an accuracy of 94.17%. Specificity, PPV & NPV was found to be the same in the study done by Patil M *et al.*<sup>14</sup>, Khoda *et al.*<sup>[13]</sup> and Sharma P *et al.*<sup>[12]</sup>, as revealed in our study, But the sensitivity of the MTT was found very less as compared to those studies.

### Conclusion

Triple assessment was done in 120 cases of palpable breast lump in females. The results were compared with gold standard histopathology reports in view of carcinoma breast to analyze that how accurately carcinoma breast can be diagnosed on basis of triple assessment. Modified triple test score (MTTS) is a very cost effective and non invasive technique and can be relied upon for evaluation of palpable breast lumps. This approach avoids open biopsy in the majority of cases.

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