



A STUDY OF MODIFIED TRIPLE TEST SCORE FOR ASSESSMENT OF PALPABLE BREAST LUMPS IN FEMALES- A PROSPECTIVE STUDY

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ABSTRACT

Background- Self-breast examination or a Clinical breast examination alone was insufficient in diagnosing potentially malignant breast lesions. So, additional modalities of radiological investigations like x-ray mammography or Sono-mammography can demonstrate such lesions. **Objectives-** To assess the reliability of the Modified Triple test to make an accurate pre-procedural diagnosis of Breast Lumps and to compare modified triple test scores with conventional triple test scores for the diagnosis of breast lumps. **Methods-** It was a Prospective Observational study done at Department of General Surgery, PESIMSR hospital, Kuppam between 18 months (December 2019 – May 2021). All female patients aged between 20 - 60 years presenting with breast lumps to PESIMSR hospital are considered as study population. We tabulated modified triple test scores after obtaining individual scores of all three components. According to the findings, each element in the modified triple test was given scores of 1, 2 and 3. All three component scores was given a final total score. We assessed each component in the score separately based on clinical, ultrasound and FNAC findings. Breast lumps are first broadly categorised into Benign, Malignant and inconclusive lesions. SPSS (version 20.0) was used for analysis. **Results-** Most of the patient belonged to 41-50 years of age (40%) followed by above 50 years (24%) suggest that breast lump are more commonly occurring 4th decade onwards. Around 37% of patients has more than 6 months duration of symptoms. histopathological examination through various modes of surgery like excision and biopsy MRM and subcutaneous mastectomy it was seen 59% has malignant tissue while 41% has benign mass. diagnostic accuracy of MMTS was far more superior than other tests. Sensitivity, Specificity, PPV, NPV, diagnostic accuracy for MMTS (100%, 98%, 98%, 100%, 99%) followed by CTTS as compared to other tests. And this was found to be statistically significant ($p < 0.05$). **Conclusion-** Modified triple test score was the highly sensitive reliable diagnostic tool for diagnosing palpable breast lumps and differentiating benign from malignant breast lumps. Thus, the modified triple test score is as accurate as the conventional triple test score in evaluating breast lumps with equal diagnostic accuracy.

KEYWORDS : Breast lump, mammography, mastectomy, sensitivity, Modified triple test, breast self-examination.

Introduction-

Despite amelioration in science and technology, breast cancer remains humankind's one of the most dreaded maladies.¹ Accurate, timely diagnosis with planned and executed treatment strategies are the cornerstone of the successful treatment of breast cancer.² Self-breast examination or a Clinical breast examination alone was insufficient in diagnosing potentially malignant breast lesions. So, additional modalities of radiological investigations like x-ray mammography or Sono-mammography can demonstrate such lesions. Lesions were then subjected to fine-needle aspiration cytology (FNAC) for pathological confirmation as FNAC continues to be the test of time as a safe, reliable and time-saving procedure.³ X-ray mammographic screening detects small, non-palpable, asymptomatic breast lumps. Main X-ray mammographic signs of breast carcinoma are densities and calcifications. Unfortunately, malignancies are flanked by mammography in about 10% of patients. The foremost causes of this failure is the surrounding radio dense tissue that obscures the tumour, the absence of calcification, smaller size, diffuse infiltrative pattern with little or no desmoplastic response, or a location approximate to the chest wall or in the periphery of the breast tissue. Sono-mammography distinguishes between solid and cystic lesions, and most palpable breast lumps are not detected by mammography is detectable by ultrasound.⁴ Various studies found nearly 100% diagnostic accuracy of the Triple test for diagnosing palpable breast lumps when all three components (i.e., physical examination, mammogram and FNAC) concordantly examined.⁵ A clinician can directly go with definitive therapy without an interventional open biopsy if all the components of the Triple test are malignant. If all three elements are benign, the patient can be managed conservatively.⁶ The triple test is a valid and reliable test, with more diagnostic accuracy for diagnosing breast lumps. Of all the three elements of the triple test, FNAC is the most accurate. Therefore, a patient with a benign triple test report can be followed up safely without surgical intervention.⁷ This study determines to assess the reliability of the Modified Triple test to make an accurate pre-procedural diagnosis of Breast Lumps and to compare modified triple test scores with conventional triple test scores for the diagnosis of breast lumps.

Material and Methods-

It was a Prospective Observational study done at Department of General Surgery, PESIMSR hospital, Kuppam between 18 months (December 2019 – May 2021). All female patients aged between 20 - 60 years presenting with breast lumps to PESIMSR hospital are considered as study population.

INCLUSION CRITERIA

1. All-female patients with age 20-60 years presenting with breast lumps
2. Breast lumps at presentation with a clinically palpable lesion.

EXCLUSION CRITERIA

1. Female patients with advanced carcinoma breast as the diagnosis was evident.
2. Female patients below 20 years
3. Male patients
4. Patients who don't want to participate in the study

Ethical Clearance:

The study design and protocols are reviewed by the Institutional Ethical Committee of the institution and granted clearance.

Study Tools

1. Bedside clinical breast examination
 2. Ultra-sonogram of breast and mammogram of the breast
 3. Fine needle aspiration cytology as part of histological diagnosis.
- The nature of the study, its implications was explained to the patients and informed written consent was obtained.

Methodology- The subjects were registered in this study after applying inclusion and exclusion criteria. Both conventional triple test scores and modified triple test scores are used for participants with breast lumps among two age groups, i.e., those less than 40 years of age and the other group with age 40 years and above accordingly. Detailed history and thorough physical examination of the patient having palpable breast lump is carried out and entered in the proforma. The patients have explained the procedure, and informed consent was obtained before subjecting them to fine needle aspiration cytology of

the breast lump. Ultrasound examination includes breast, axilla, and internal mammary lymph nodes. After this, the attending surgeon performed FNAC / Core needle biopsy, and the sample was sent for histopathological examination. We compared the conventional and modified triple test scores with histopathological diagnosis.

We tabulated modified triple test scores after obtaining individual scores of all three components. According to the findings, each element in the modified triple test was given scores of 1, 2 and 3. All three component scores were given a final total score. We assessed each component in the score separately based on clinical, ultrasound and FNAC findings. Breast lumps are first broadly categorised into Benign, Malignant and inconclusive lesions.

Statistical Analysis-

The data will be entered into MS Excel 2016 version and analyzed using SPSS 20. The categorical data is analysed using the Chi-square test. The prospective study studies the efficacy of the modified triple test scoring system for early diagnosis of palpable breast lumps and management for a treatment plan. Eighty-two patients were selected randomly who fulfilled with framed criteria and were included in the study.

Results-

Table 1- Age wise distribution and Duration of Symptoms of Study Participants

age in years	number of patients	percentage
18-30	16	20%
31-40	13	16%
41-50	33	40%
Above 50	20	24%
Total	82	100%

As per table 1 most of the patient belonged to 41-50 years of age (40%) followed by above 50 years (24%) suggest that breast lump are more commonly occurring 4th decade onwards. Around 37% of patients has more than 6 months duration of symptoms.

Table 2- Variation of Lump Size and Side of Breast Involved

size of lump	number of patients	percentage
Less than 5 cm	39	48%
Greater than 5 cm	43	52%
Total	82	100%

As per table 2 around 52% of patients had lump size of greater than 5cm which was significant. And the most common side involved is right seen in 76% of cases. As per consistency of lump 50% of patients had hard lump followed by firm in 39% patients. Axillary lymph node involvement is absent in 84% of patients.

Table 3- Histopathological Examination

HPE	number of patients	percentage
BENIGN	34	41%
MALIGNANT	48	59%
Total	82	100%

As per table 3 after histopathological examination through various modes of surgery like excision ad biopsy MRM and subcutaneous mastectomy it was seen 59% has malignant tissue while 41% has benign mass.

Table 4 – Modified triple test score findings

Test	benign	suspicious	malignant
CBE	33	8	41
USG	33	6	43
FNAC	31	8	43
MTTS	33	0	49

As per table 4 MTTs findings shows almost similar score for benign mass while MTTs score is high in malignant mass which shows the better impact of diagnosis and it was statistically significant (p<0.05).

Table 5- Diagnostic Characteristics of the Test

Test	Sensitivity	Specificity	PPV	NPV	diagnostic accuracy
CBE	85.42%	94%	95%	82.05%	89.02%

USG	89.50%	97%	98%	86.84%	92.68%
FNAC	89.58%	91%	93%	86.11%	90.24%
MAMMOGRAPHY	84.09%	80%	95%	53.33%	83.33%
CTTS	100%	90%	98%	100%	98%
MTTS	100%	98%	98%	100%	99%

As per table 5 the diagnostic accuracy of MMTS was far more superior than other tests. Sensitivity, Specificity, PPV, NPV, diagnostic accuracy for MMTS (100%, 98%, 98%, 100%, 99%) followed by CTTS as compared to other tests. And this was found to be statistically significant (p<0.05).

Discussion-

Breast carcinoma is one of the common causes of cancer-related deaths in women. Colorectal and lung cancers are responsible for approximately 40% of cancer-related deaths in women. The single most important prognostic factor in ascertaining the treatment outcome in these patients is the stage of malignancy.⁸ Hence early detection of carcinoma enhances the long-time survival rate with a better prognosis. Modified triple test score with the components of clinical examination, FNAC, and ultrasonography was taken into consideration which was equally sensitive with mammography in palpable breast lumps. All three components yielded 100% diagnostic accuracy with reliable scoring. MTTs mainly aims to correct preoperative diagnosis and avoid unnecessary biopsies in a benign lump.^{9,10}

In our study, 82 female patients with palpable breast lumps were studied. The Mean age in my study was 42.69. This was in accordance with a study done by Akshey Batta, P.C. Attri, Pranab Jain et al. where the mean age was 38.24 yrs. with 100 patients included in the study.^{8,9,10} In the study done by Monali Mahadev Patil. et al., 68% of patients had symptoms in less than six months, 22 % had symptoms duration from 7-12 months, and 6% patients presented with symptoms more than two years. 10 Upon comparison, with a study done by Monali Mahadev Patil .et.al, where the right breast is involved in 24 patients (48%), and the left breast involvement was seen in 26 patients, i.e., 52%.¹⁰ In a study done by Akshey Batta, P.C. Attri, Pranab Jain et al., right breast is involved in 43%, and left breast is involved in 51% of patients and bilateral involvement in 6%. In a study done by Monali Mahadev Patil .et.al, out of 37 patients with score 1, 35 had benign lesions and 2 patients had malignant lesions and 13 patients with score 3 had malignant lesions with Sensitivity – 100%, specificity-86.67%, PPV- 94.59%, NPV-100%, with a diagnostic accuracy of 96%. In our study, sensitivity of MTTs is 100 %, specificity-98%, PPV- 98%, NPV- 100 % with diagnostic accuracy of 99 % In study done by Monali Mahadev patil .et.al and other studies sensitivity was 97.14%, specificity-100%, PPV-100% and NPV-93.75% with diagnostic accuracy of 98%,^{10,11,12,13,14}. In our study, conventional triple test score CTTS, sensitivity- 100%, specificity- 90%, PPV-98%, NPV-100% and diagnostic accuracy is 98 %.

Conclusion-

Breast carcinoma is the foremost cause of death in females, so early detection of malignancy carries much more important to decrease morbidity and mortality. Diagnosis of palpable breast lumps by scoring with clinical examination, ultrasound examination and, FNAC examination helped in the accurate diagnosis of palpable breast lumps. Modified triple test score accurately diagnosed palpable breast lumps within accuracy of 100 % by all patients with scores above 6 in my study had malignancy proven in histopathological studies.

This scoring is advantageous to all outpatients presenting to the surgical outpatient department, with additional benefits to patients. This scoring was readily available in all hospitals, had no invasive method, and was cost-effective with accurate diagnoses. This scoring avoided unnecessary open biopsies in patients with benign conditions. As proved in this study, the patient's age, size of breast lump, and late presentation were considered risk factors for malignancy. Modified triple test score was the highly sensitive reliable diagnostic tool for diagnosing palpable breast lumps and differentiating benign from malignant breast lumps. Thus, the modified triple test score is as accurate as the conventional triple test score in evaluating breast lumps with equal diagnostic accuracy.

Source of Funding- None

Conflict of Interest- None declared

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