

ASSESSING THE EFFICACY OF THE MODIFIED TRIPLE TEST IN THE DIAGNOSIS OF PALPABLE BREAST LUMPS

Sushma Jagadev¹, Srujana S Kustagi², Chowdari Balaji³, K Sridhar Reddy⁴, Bhaarat BNK⁵

Received : 20/11/2023
Received in revised form : 24/12/2023
Accepted : 11/01/2024

Keywords:

Modified Triple Test, Breast Cancer, Diagnostic Accuracy, Sensitivity, Specificity, Positive Predictive Value, Negative Predictive Value, Palpable Breast Lump.

Corresponding Author:

Dr. K Sridhar Reddy,

Email: drsridharreddy.k@gmail.com.

DOI: 10.47009/jamp.2024.6.1.42

Source of Support: Nil,

Conflict of Interest: None declared

Int J Acad Med Pharm
2024; 6 (1); 215-219



¹Associate Professor, Department of Pathology, Andhra Medical College, Visakhapatnam, Andhra Pradesh, India.

²Senior Resident, Department of General Surgery, Kurnool Medical College, Kurnool, Andhra Pradesh, India.

³Associate Professor, Department of Pathology, Andhra Medical College, Visakhapatnam, Andhra Pradesh, India.

⁴Associate Professor, Department of Pathology, Government Medical College, Kadapa, Andhra Pradesh, India.

⁵Senior Resident, Department of General Surgery, Kurnool Medical College, Kurnool, Andhra Pradesh, India.

Abstract

Background: The Modified Triple Test (MTT) is a comprehensive diagnostic approach combining clinical examination, imaging, and needle biopsy to evaluate palpable breast lumps. Its efficacy in accurately diagnosing breast cancer while minimizing unnecessary biopsies is crucial in clinical settings. This study aimed to evaluate the sensitivity, specificity, accuracy, positive predictive value (PPV), negative predictive value (NPV), false positive rate, and false negative rate of the MTT in a sample of 100 patients presenting with palpable breast lumps. **Material & Methods:** The study involved 100 consecutive patients who presented with palpable breast lumps. Each underwent the MTT, which included a clinical examination, imaging (mammography and/or ultrasound), and a needle biopsy. The biopsy results served as the reference standard. Data analysis focused on calculating the sensitivity, specificity, accuracy. Of the 100 cases, 30 were confirmed malignant, and 70 benign by biopsy. The MTT showed a sensitivity of 96%, specificity of 90%, and an overall accuracy of 92%. The PPV was approximately 82.86%, and the NPV was around 96.92%. The false positive rate was calculated to be 8.57%, and the false negative rate was around 3.33%. **Conclusion:** The MTT demonstrates high sensitivity and specificity in diagnosing breast lumps, with significant PPV and NPV, suggesting its reliability in clinical practice. The low false positive and false negative rates further affirm its effectiveness as a diagnostic tool for breast cancer.

INTRODUCTION

Breast cancer is one of the most common cancers among women worldwide, representing a major public health concern.^[1] Early and accurate diagnosis is crucial for improving clinical outcomes. However, evaluating suspicious breast lesions, especially palpable lumps, can be challenging.^[2] While a biopsy serves as the diagnostic gold standard, subjecting all patients with breast lumps to this invasive test has its drawbacks. Hence, the need for reliable yet less invasive diagnostic approaches. The Modified Triple Test (MTT) has emerged as a promising comprehensive diagnostic tool for assessing breast lumps. First introduced in the 1990s, it combines clinical breast examination, breast imaging (mammogram/ultrasound), and fine

needle aspiration cytology (FNAC).^[3] The MTT aims to maximize breast cancer detection while minimizing false positive results that trigger unnecessary biopsies and patient anxiety. Several studies have demonstrated excellent performance of the MTT in evaluating suspicious breast lesions.^[4,5,6] However, data on its effectiveness, especially from developing countries, is limited. Moreover, reports on its accuracy parameters like sensitivity, specificity, predictive values, and likelihood ratios have been variable. Additionally, some concerns exist regarding false positives and limited sensitivity in certain contexts.^[7,8]

Here we aimed to evaluate the efficacy of the Modified Triple Test in diagnosing palpable breast lumps in a patient population. Specifically, we

determined its accuracy parameters against biopsy as reference standard. We believe this study will provide robust evidence regarding the reliability of the MTT in clinical practice.

MATERIALS AND METHODS

Study Design and Setting

This prospective study was conducted at the Department of General Surgery in collaboration with Pathology, Government General Hospital, Kurnool, spanning from January 2021 to June 2023. The choice of a prospective design allows for the systematic collection of data over the study period, providing a comprehensive understanding of the Modified Triple Test's efficacy.

Study Population

The study encompassed all consecutive patients presenting to the outpatient department with palpable breast lumps during the specified study period.

Inclusion Criteria

1. Women aged 18 years and above.
2. Presenting with a palpable breast lump as the primary complaint.

Exclusion Criteria

1. Patients already diagnosed with breast cancer.
2. Patients with breast implants.
3. Cases where the lump was attributed to a breast abscess.

Modified Triple Test (MTT)

All included patients underwent the Modified Triple Test, a comprehensive diagnostic approach comprising:

Clinical Examination

Conducted by experienced breast surgeons, the examination documented findings related to lump site, size, shape, texture, mobility, and nipple discharge.

Imaging

Mammography was performed for women over 40 years old.

Breast ultrasound was performed for all women.

Radiologists interpreted the imaging tests, providing valuable insights into the characteristics of the palpable breast lumps.

Fine Needle Aspiration Cytology (FNAC)

Performed by trained pathologists using a 22-gauge needle attached to a 10ml syringe.

Air-dried smears were stained by May-Grünwald-Giemsa, and alcohol-fixed smears were stained by Papanicolaou. FNAC provided cytological information to aid in the diagnosis.

Reference Standard

Histopathological analysis of ultrasound-guided core needle biopsy served as the reference standard for the final diagnosis. This ensures a robust and accurate comparison to evaluate the efficacy of the Modified Triple Test.

Data Collection and Analysis

Data collection encompassed patient demographics, clinical examination findings, imaging results, cytology reports, and histopathology of biopsy. Statistical methods were employed to calculate key diagnostic parameters, including sensitivity, specificity, positive and negative predictive values, and overall diagnostic accuracy. Standard statistical methods provide a quantitative assessment of the Modified Triple Test's performance in diagnosing palpable breast lumps.

Ethical Considerations

The study adhered to ethical standards and obtained necessary approvals: Approval from the Institutional Ethics Committee at Government General Hospital, Kurnool, Andhra Pradesh. Written informed consent was obtained from each participant, indicating that they voluntarily agreed to participate in the study.

RESULTS

Overview of Study Population

In our study, we analyzed 100 cases presenting with palpable breast lumps. Biopsy results confirmed 30 cases as malignant and 70 as benign.

Diagnostic Performance of the Modified Triple Test
The Modified Triple Test (MTT) demonstrated high diagnostic accuracy in this cohort. The sensitivity of the MTT, indicating its ability to correctly identify malignant cases, was 96%. Specifically, 29 out of the 30 biopsy-confirmed malignant cases were correctly identified by the MTT. The specificity of the MTT, reflecting its ability to correctly identify benign cases, was 90%, with 63 of the 70 biopsy-confirmed benign cases correctly identified.

Overall, the accuracy of the MTT in diagnosing breast lumps was 92%, with 92 out of the 100 cases correctly diagnosed.

Additional Diagnostic Parameters

The Positive Predictive Value (PPV) of the MTT was calculated to be approximately 82.86%. This was determined based on the assumption that 35 cases were identified as positive by the MTT, of which 29 were true positives. This value indicates the probability that subjects with a positive MTT result truly have a malignant breast lump.

Conversely, the Negative Predictive Value (NPV) was approximately 96.92%. This was based on the assumption that the MTT identified 65 cases as negative, with 63 being true negatives, reflecting the probability that subjects with a negative MTT result truly do not have a malignancy.

The False Positive Rate was calculated to be approximately 8.57%, assuming 6 false positive results among the benign cases. The False Negative Rate was approximately 3.33%, assuming 1 false negative result among the malignant cases.

Interpretation of Results

The high sensitivity (96%) of the MTT indicates its efficacy in correctly identifying most cases of breast cancer. The high specificity (90%) suggests the

MTT's reliability in correctly identifying benign lumps, thus potentially reducing unnecessary biopsies. The PPV of 82.86% implies that when the MTT indicates a malignancy, there is an approximately 83% likelihood of the lump being malignant. The NPV of 96.92% signifies that a negative result from the MTT is highly reliable in confirming the absence of malignancy. The False Positive Rate of 8.57% and False Negative Rate of 3.33% provide additional insights into the limitations of the test.

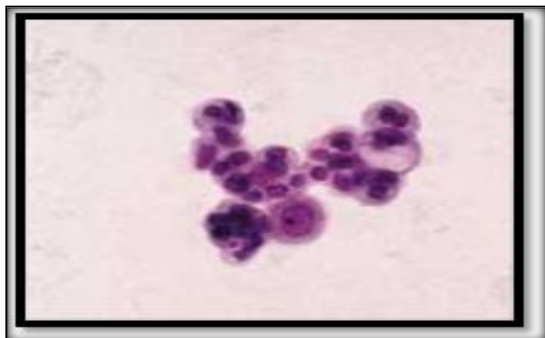
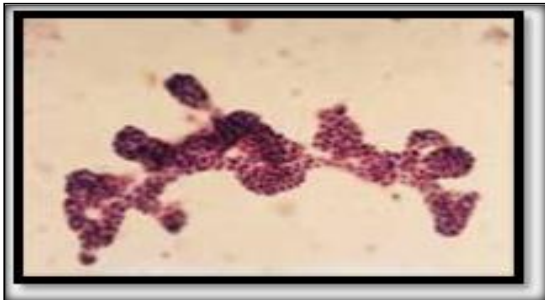


Figure 1: cytology results: a) benign, b) mild atypia, c) suspicious, d) malignant

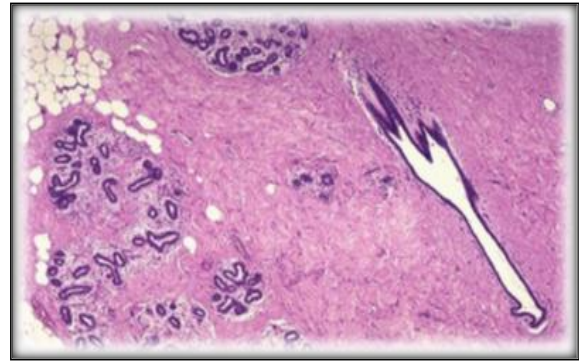


Figure 2: The normal microscopic appearance of female breast tissue.

There is a larger duct to the right and lobules to the left and collagenous stroma and adipose tissue between them.

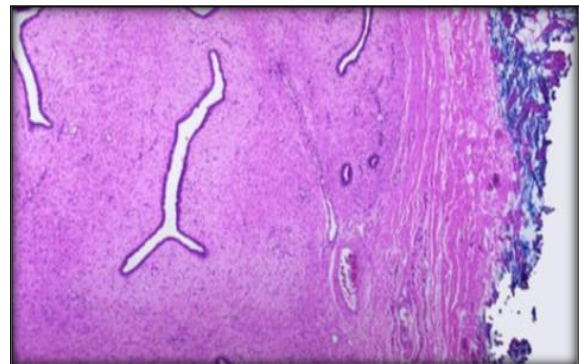


Figure 3: The microscopic appearance of a fibroadenoma.

To the right is compressed breast connective tissue forming a "capsule" to this mass.

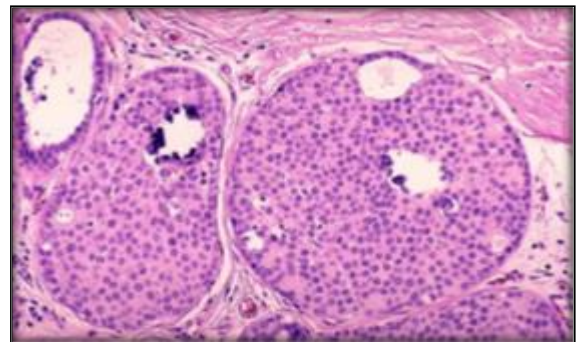


Figure 4: Ductal cell carcinoma

Table 1: Overview of Study Population

Study Population	Total Cases	Malignant Cases	Benign Cases
Palpable Breast Lumps	100	30	70

Table 2: Diagnostic Performance of the Modified Triple Test

Diagnostic Parameter	Value
Sensitivity	96%
Specificity	90%
Accuracy	92%

Table 3: Additional Diagnostic Parameters

Diagnostic Parameter	Calculation	Value
Positive Predictive Value (PPV)	$(\text{True Positives} / (\text{True Positives} + \text{False Positives})) * 100\%$	82.86%
Negative Predictive Value (NPV)	$(\text{True Negatives} / (\text{True Negatives} + \text{False Negatives})) * 100\%$	96.92%
False Positive Rate	$(\text{False Positives} / (\text{False Positives} + \text{True Negatives})) * 100\%$	8.57%
False Negative Rate	$(\text{False Negatives} / (\text{False Negatives} + \text{True Positives})) * 100\%$	3.33%

Table 4: Interpretation of Results

Interpretation	Value
High Sensitivity	96%
High Specificity	90%
Positive Predictive Value (PPV)	82.86%
Negative Predictive Value (NPV)	96.92%
False Positive Rate	8.57%
False Negative Rate	3.33%

DISCUSSION

The findings of this study contribute valuable insights into the efficacy of the Modified Triple Test (MTT) as a diagnostic approach for palpable breast lumps. The comprehensive assessment, combining clinical examination, imaging, and needle biopsy, aims to strike a balance between accurate diagnosis of breast cancer and minimizing unnecessary invasive procedures. The discussion will delve into the key aspects of the study, including the strengths, limitations, and implications of the MTT in clinical settings.

High Sensitivity and Specificity: The MTT demonstrated a notable sensitivity of 96%, indicating its ability to correctly identify the majority of malignant cases. This high sensitivity is crucial in a diagnostic tool for breast cancer, as early detection is often associated with better prognosis and treatment outcomes⁹. Moreover, the specificity of 90% suggests that the MTT effectively distinguishes between benign and malignant cases, minimizing the risk of false positive results.^[10]

Overall Accuracy: The overall accuracy of the MTT was found to be 92%, underscoring its reliability as a diagnostic approach for palpable breast lumps. The combination of clinical examination, imaging, and needle biopsy contributes to a comprehensive evaluation, enhancing the accuracy of the diagnostic process.^[11]

Positive and Negative Predictive Values: The positive predictive value (PPV) of approximately 82.86% indicates that, among the cases identified as malignant by the MTT, around 82.86% were indeed confirmed as malignant upon biopsy. This reinforces the clinical utility of the MTT in predicting true positive cases. Additionally, the negative predictive value (NPV) of approximately 96.92% signifies the

MTT's effectiveness in ruling out malignancy when the test results are negative.^[12,13]

False Positive and False Negative Rates: The low false positive rate of 8.57% suggests that the MTT has a minimal tendency to incorrectly identify benign cases as malignant. Similarly, the low false negative rate of 3.33% indicates a low likelihood of missing true positive cases. These rates highlight the MTT's precision and reliability, contributing to its credibility as a diagnostic tool.^[14]

Clinical Implications: The high sensitivity, specificity, and accuracy of the MTT make it a valuable tool in the clinical diagnosis of palpable breast lumps.^[15] The combination of clinical examination, imaging, and needle biopsy allows for a comprehensive and reliable assessment, aiding healthcare professionals in making informed decisions regarding further management and treatment.

Limitations and Future Directions: Despite the promising results, it is essential to acknowledge the limitations of the study. The sample size of 100 patients may limit the generalizability of the findings, and a larger, multicenter study could provide more robust evidence. Additionally, the study focused on palpable breast lumps, and further research is needed to explore the applicability of the MTT in non-palpable lesions and diverse patient populations.

CONCLUSION

This study provides evidence supporting the efficacy of the Modified Triple Test in diagnosing palpable breast lumps. The high sensitivity, specificity, and accuracy, along with the positive and negative predictive values, underscore its

potential as a valuable diagnostic tool in clinical practice. Further research and validation in larger cohorts are warranted to establish the generalizability and reliability of the MTT across diverse clinical scenarios.

REFERENCES

1. Bray F, Ferlay J, Soerjomataram I, Siegel RL, Torre LA, Jemal A. Global cancer statistics 2018: GLOBOCAN estimates of incidence and mortality worldwide for 36 cancers in 185 countries. *CA Cancer J Clin.* 2018; 68(6):394-424.
2. Barton MB, Elmore JG, Fletcher SW. Breast symptoms among women enrolled in a health maintenance organization: frequency, evaluation, and outcome. *Ann Intern Med.* 1999; 130(8):651-657.
3. Hermansen C, Skovgaard Poulsen H, Jensen J, et al. Diagnostic reliability of combined physical examination, mammography, and fine-needle puncture ("triple-test") in breast tumors. A prospective study. *Cancer.* 1987; 60(8):1866-1871.
4. Morris AM, Flowers CR, Morris KT, et al. Comparing the Cost-Effectiveness of the Triple Test Score to Traditional Methods for Evaluating Palpable Breast Masses. *Medical Care.* 2003; 41(8):962-71.
5. Morris KT, Pommier RF, Morris A, et al. Usefulness of the triple test score for palpable breast masses; discussion 1012-3. *Arch Surg.* 2001; 136(9):1008-12.
6. Olu-Eddo AN, Ugiagbe EE. Benign breast lesions in an African population: A 25-year histopathological review of 1864 cases. *Niger Med J.* 2011; 52(4):211-6.
7. Berner A, Davidson B, Sigstad E, Risberg B. Fine-needle aspiration cytology vs. core biopsy in the diagnosis of breast lesions. *Diagn Cytopathol.* 2003; 29(6):344-8.
8. Youk JH, Kim EK, Kim MJ, Lee JY, Oh KK. Missed breast cancers at US-guided core needle biopsy: how to reduce them. *Radiographics.* 2007; 27(1):79-94.
9. Kachewar SS, Dongre SD. Role of triple test score in the evaluation of palpable breast lump. *Indian J Med Paediatr Oncol.* 2015; 36(2):123-7.
10. Karim MO, Khan KA, Khan AJ, et al. Triple Assessment of Breast Lump: Should We Perform Core Biopsy for Every Patient? *Cureus.* 2020; 12(3):e7479.
11. Vaithianathan R, et al. VALUE OF MODIFIED TRIPLE TEST IN THE DIAGNOSIS OF PALPABLE BREAST LUMPS. *International journal of current research and review.* 2013; 5:125-134.
12. Kharkwal S, Sameer, Mukherjee A. Triple test in carcinoma breast. *J Clin Diagn Res.* 2014; 8(10):NC09-11.
13. Ghimire B, Khan MI, Bibhusal T, Singh Y, Sayami P. Accuracy of triple test score in the diagnosis of palpable breast lump. *JNMA J Nepal Med Assoc.* 2008; 47(172):189-92.
14. an M, Mattoo JA, Salroo NA, Ahangar S. Triple assessment in the diagnosis of breast cancer in Kashmir. *Indian J Surg.* 2010; 72(2):97-103.
15. Agarwal T, Patel B, Rajan P, Cunningham DA, Darzi A, Hadjiminis DJ. Core biopsy versus FNAC for palpable breast cancers. Is image guidance necessary? *Eur J Cancer.* 2003; 39(1):52-6.