

“Diagnostic Accuracy And Predictive Value Of Modified Triple Test Components Against Histopathology In Breast Lump Evaluation”

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Keywords	Abstract
Breast Neoplasms; Diagnostic Accuracy; Fine-Needle Aspiration; Ultrasonography; Histopathology	Background: Breast lumps are a common clinical presentation in women, requiring accurate and timely differentiation between benign and malignant pathology. The Modified Triple Test Score (MTTS), which includes Clinical Breast Examination (CBE), radiological imaging, and cytopathology, serves as a cost-effective, structured diagnostic tool. Its validation against histopathology may optimize decision-making, particularly in resource-constrained settings. Objectives: To determine the diagnostic accuracy and predictive value of each MTTS component and the overall score by comparing them with final histopathological examination (HPE) results in patients with palpable breast lumps. Methods: This prospective observational study was conducted from January 2023 to March 2024 at a tertiary care hospital in Dehradun. Sixty female patients aged over 18 years with palpable breast lumps underwent clinical examination, sonomammography, and FNAC/core biopsy. Each MTTS component was scored (1–3), with a total score ranging from 3 to 9. Scores of 3–4 were considered benign, and ≥ 6 as malignant. Final diagnoses were confirmed by histopathology. Diagnostic metrics including sensitivity, specificity, PPV, NPV, and accuracy were calculated. Results: Among 60 patients, 39 (65%) were histologically benign and 21 (35%) malignant. CBE and pathological assessments both achieved 100% sensitivity, specificity, and accuracy. Radiology showed 57.14% sensitivity and 100% specificity. MTTS demonstrated 100% sensitivity but low specificity (46.15%) and overall accuracy of 65%. Suspicious FNAC cases were all benign, highlighting potential overestimation. Conclusion: MTTS is a highly sensitive tool for evaluating breast lumps but may overestimate malignancy due to low specificity. CBE and pathology

	remain the most accurate components. MTTS can aid early triage, but refinement in scoring may improve predictive accuracy.
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Introduction

Breast lumps remain one of the most common clinical concerns among women, often prompting surgical evaluation due to the associated risk of malignancy. Although the majority are benign, timely and accurate differentiation is critical to prevent both diagnostic delays and unnecessary surgical interventions¹. Globally, breast cancer continues to be the leading malignancy in women, with an estimated 2.3 million new cases and over 670,000 deaths reported in 2023 alone, underscoring the urgent need for early diagnostic precision in suspected breast lesions^{1,2}.

In India, breast cancer accounts for nearly 14% of all female cancers, with rising incidence particularly in urban populations due to lifestyle changes, delayed childbirth, and limited access to screening programs³. To address this diagnostic challenge, the Triple Assessment—which combines Clinical Breast Examination (CBE), imaging (such as ultrasound or mammography), and cytological evaluation (FNAC or core biopsy)—has become a cornerstone in initial breast lump evaluation⁴. However, variability in interpretation and subjectivity in assessment have posed limitations.

The Modified Triple Test Score (MTTS) was introduced to enhance objectivity by assigning standardized scores to each component, providing a composite risk stratification that aids in guiding further management⁵. MTTS offers a potentially powerful, reproducible, and low-cost alternative for use in busy or resource-limited clinical settings.

Despite its adoption, few studies have thoroughly correlated MTTS with final Histopathological Examination (HPE) findings—the gold standard for diagnosis that not only confirms malignancy but also provides detailed subtyping crucial for treatment planning⁶. Particularly in developing healthcare settings, validating such predictive tools against histopathology is essential for safe surgical decision-making.

The purpose of the study was to evaluate the diagnostic accuracy and predictive value of Modified Triple Test Score (MTTS) components against post-excisional histopathology in patients with breast lumps, aiming to establish MTTS as a reliable tool in preoperative assessment.

Aim and objectives

To evaluate the diagnostic accuracy and predictive value of MTTS components compared to histopathology in breast lump assessment.

Materials and Methods

This prospective observational study was conducted to evaluate the diagnostic accuracy and predictive value of the Modified Triple Test (MTT) components—Clinical Breast Examination (CBE), radiological imaging, and pathological assessment—against the final histopathological examination (HPE) in patients presenting with palpable breast lumps. The study was carried out in the Departments of General Surgery and Surgical Oncology at Shri Mahant Indires Hospital, Dehradun, from January 2023 to March 2024.

A total of 60 female patients, aged above 18 years, who presented with clinically palpable breast masses, were enrolled after obtaining informed written consent. All eligible patients were adequately counselled regarding the purpose and nature of the study. Confidentiality and ethical standards were strictly maintained throughout.

Inclusion Criteria

- Female patients aged >18 years.

- Presence of a palpable breast mass.

Exclusion Criteria

- Previously diagnosed cases of carcinoma breast.
- Patients unwilling to undergo invasive or surgical procedures.

Each participant underwent triple assessment:

1. Clinical Breast Examination (CBE)
2. Radiological imaging (sonomammography)
3. Pathological evaluation (Fine Needle Aspiration Cytology or core biopsy)

Each component was scored using the Modified Triple Test system:

- **Score 1** for benign findings
- **Score 2** for suspicious findings
- **Score 3** for malignant findings

The total score, referred to as the Modified Triple Test Score (MTTS), ranged from 3 to 9. A total score of 3–4 was considered benign, and a score of 6 or more was considered malignant. These scores were then compared with the post-excisional histopathological findings, which served as the gold standard for final diagnosis.

Breast examination.

Positions include the patient seated or standing (A) with arms at sides; (B) with arms raised over the head, elevating the pectoral fascia and breasts; (C) with hands pressed firmly against hips; or (D) with palms pressed together in front of the forehead, contracting the pectoral muscles. (E) Palpation of axilla; arm supported as shown, relaxing the pectoral muscles. (F) Patient supine with pillow under the shoulder and with the arm raised above the head on the side being examined. (G) Palpation of breast in a circular pattern from the nipple outward.

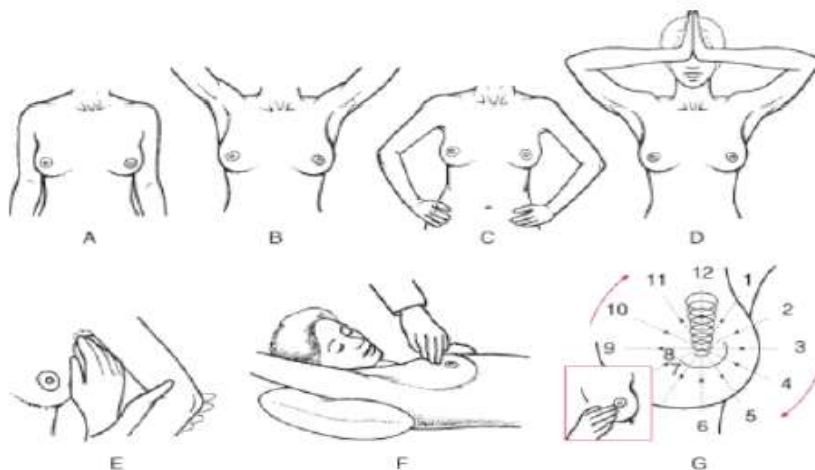


Figure 1: Clinical Breast Examination

BI-RADS CATEGORIES	
BI-RADS 0 (incomplete):	Recommend additional imaging -- mammogram or targeted ultrasound
BI-RADS 1 (negative):	Routine breast MR screening if cumulative lifetime risk $\geq 20\%$
BI-RADS 2 (benign):	Routine breast MR screening if cumulative lifetime risk $\geq 20\%$
BI-RADS 3 (probably benign):	Short-interval (6-month) follow-up
BI-RADS 4 (suspicious):	Tissue diagnosis
BI-RADS 5 (highly suggestive of malignancy):	Tissue diagnosis
BI-RADS 6 (known biopsy-proven malignancy):	Surgical excision when clinically appropriate

Figure 2: BI-RADS Categories

Cytology categories	Explanation
C1	Inadequate
C2	Benign
C3	Atypical, probably benign
C4	Suspicious, favor malignancy
C5	Malignant

Figure 3: Cytology Categories

Statistical Analysis

Data were tabulated using Microsoft Excel and analyzed using SPSS version 23. Student's t-test was used for comparing continuous variables, while associations between categorical variables were evaluated using the Chi-square test or Fisher's Exact Test, as appropriate. A p-value <0.05 was considered statistically significant.

Ethical approval was obtained from the Institutional Ethics Committee prior to the commencement of the study, and all patients provided voluntary, informed consent before participation.

Results

Table 1: Distribution of study subjects according as per final HPE Results

HPE Results	Frequency (n)	Percentage (%)
Benign	39	65.0
Malignant	21	35.0
Total	60	100

Distribution of Study Subjects According to Final HPE Results

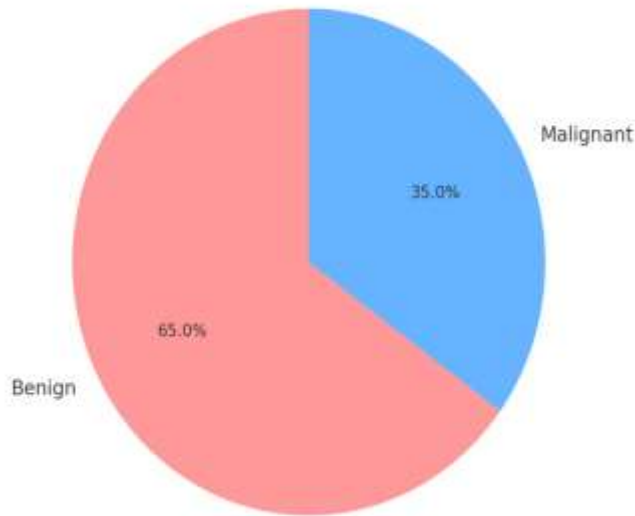


Figure 1: Distribution of Study Subjects According to Final HPE Results

Table 2: Comparison of Clinical Breast Examination, Radiological, and Pathological Findings (FNAC/Biopsy) with HPE Findings

Variable	Category	HPE Findings				Total		X ² , df, p-value
		Benign		Malignant				
		No.	%	No.	%	No.	%	
Clinical Breast Examination Findings	Benign	18	100.0	0	0.0	18	30.0	X ² = 60.00 df = 2 p-value = 0.000
	Suspicious	21	100.0	0	0.0	21	35.0	
	Malignant	0	0.0	21	100.0	21	35.0	
	Total	39	65.0	21	35.0	60	100	
Radiological Findings	Benign	18	100.0	0	0.0	18	30.0	X ² = 32.31 df = 2 p-value = 0.000
	Suspicious	21	70.0	9	30.0	30	50.0	
	Malignant	0	0.0	12	100.0	12	20.0	
	Total	39	65.0	21	35.0	60	100	
Pathological Findings (FNAC/Biopsy)	Benign	9	100.0	0	0.0	9	15.0	X ² = 60.00 df = 2 p-value = 0.000
	Suspicious	30	100.0	0	0.0	30	50.0	
	Malignant	0	0.0	21	100.0	21	35.0	
	Total	39	65.0	21	35.0	60	100	

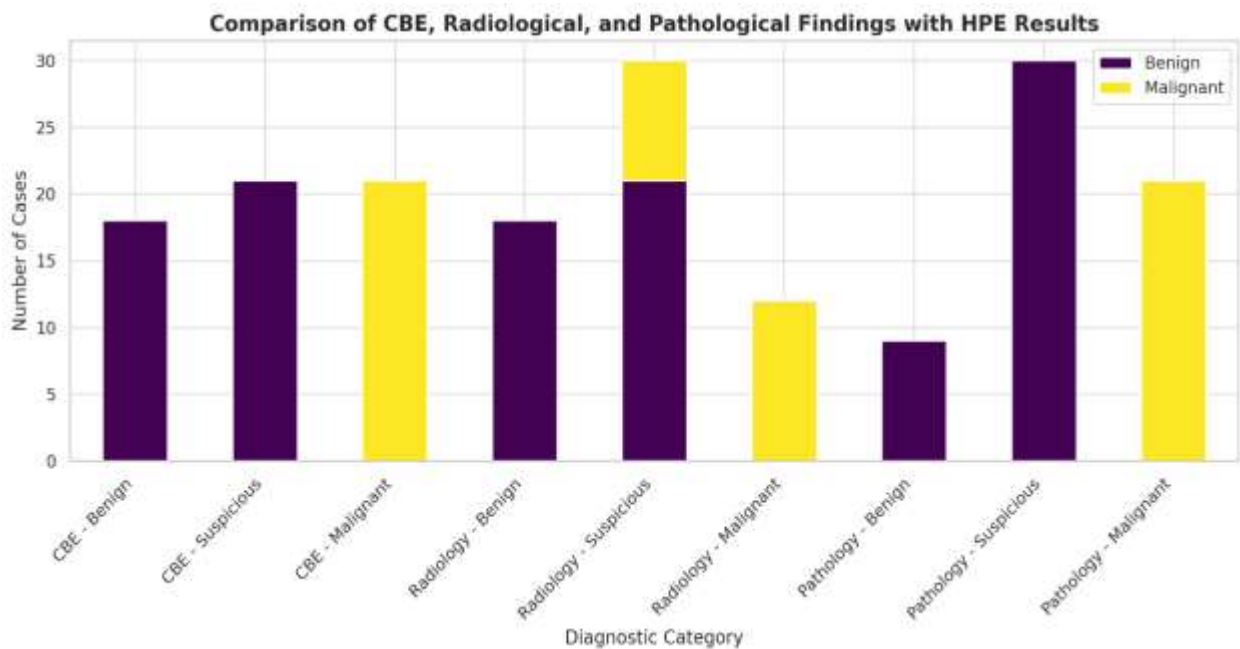


Figure 2: Comparison of CBE, Radiological, and Pathological Findings with HPE Results

Table 3: Comparison of Modified Triple Test Score with HPE Findings

Modified Triple Test Score	HPE Findings				Total		X ² , df, p-value
	Benign		Malignant				
	No.	%	No.	%	No.	%	
Benign (MTTS = 3-4)	18	100.0	0	0.0	18	30.0	X ² = 13.846 df = 2 p-value = 0.000
Malignant (MTTS ≥ 6)	21	50.0	21	50.0	42	70.0	
Total	39	65.0	21	35.0	60	100	

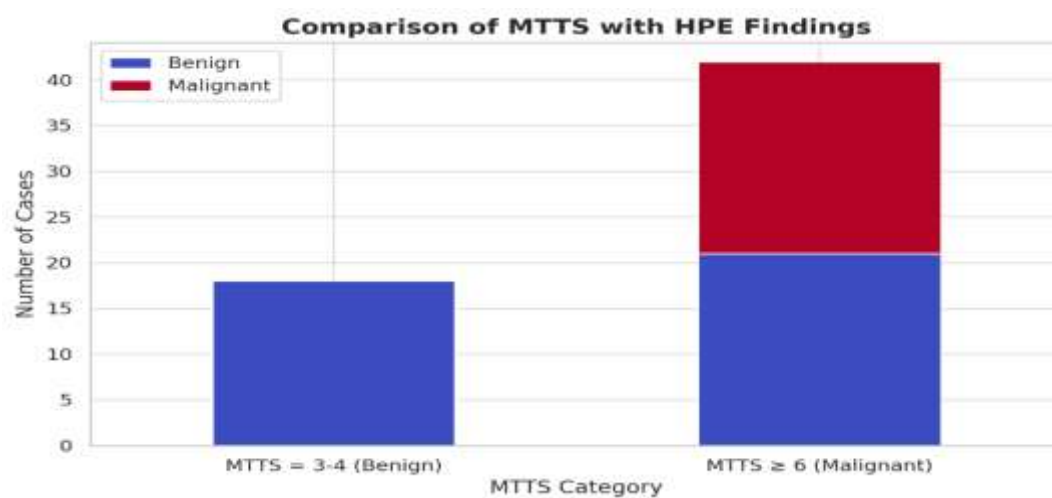


Figure 3: Comparison of MTTS with HPE Findings

Table 4: Comparison of CBE, Radiological Examination, Pathological Examination and MTTs with HPE Report

Variable	Category	CBE	Radiological Examination	Pathological Examination	MTTS
Observation	True Positive	21	12	21	21
	False Positive	0	0	0	21
	False Negative	0	9	0	0
	True Negative	39	39	39	18
Correlation (%)	Sensitivity	100%	57.14%	100%	100%
	Specificity	100%	100%	100%	46.15%
	PPV	100%	100%	100%	50%
	NPV	100%	81.25%	100%	100%
	Accuracy	100%	85%	100%	65%

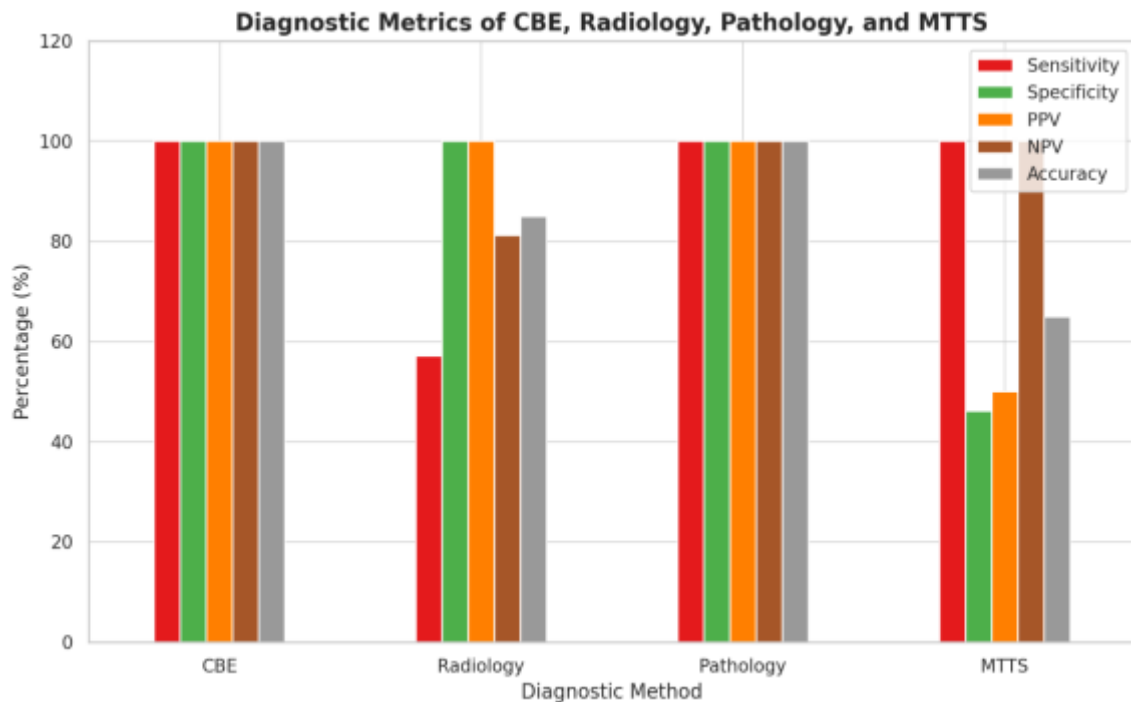


Figure 4: Diagnostic Metrics of CBE, Radiology, Pathology, and MTS

Discussion

In the present study, histopathological examination (HPE) revealed that 65% of breast lumps were benign and 35% malignant, aligning with findings by Kumari Varsha et al.⁷ (18% malignancy) and Akinnibosun-Raji et al.⁸ (30.4% malignancy). Sushma Jagadev et al.⁹ also observed a similar malignancy rate of 30%. However, Rohan S. More et al.¹⁰ and Mahwish Niaz et al.¹¹ reported lower malignancy rates (12.6% in Niaz et al.¹¹), possibly due to differences in population size or diagnostic criteria.

Clinical Breast Examination (CBE) showed perfect concordance with HPE, achieving 100% sensitivity, specificity, and accuracy, comparable to Jagadev et al.⁹ (96% sensitivity, 90% specificity) and More et al.¹⁰ (73.08% sensitivity, 98.65% specificity). Pathological evaluation via FNAC or core biopsy also mirrored HPE results in benign and malignant cases, supporting high diagnostic reliability. Interestingly, all 30 cases reported as 'suspicious' on FNAC turned out benign—an uncommon finding not mirrored in studies like Niaz et al.¹¹, who reported 30.6% malignancy in C3 lesions—suggesting possible over-caution in cytology interpretation in our setting.

Radiological findings showed 100% accuracy in clear benign/malignant categories, but only 30% of 'suspicious' lesions were malignant. The sensitivity was 57.14% with 100% specificity and 85% overall accuracy—similar to Akinnibosun-Raji et al.⁸ (79.5% sensitivity) and More et al.¹⁰ (57.69% sensitivity, 98.64% specificity), indicating high specificity but limited sensitivity in ambiguous imaging cases.

Modified Triple Test Score (MTTS) showed 100% sensitivity but only 46.15% specificity, with 50% PPV and 65% accuracy. Although these findings align in part with Jagadev et al.⁹ (92% accuracy) and More et al.¹⁰ (100% sensitivity, 98.65% specificity), the lower specificity here highlights overestimation of malignancy by MTTS. This unique trend suggests the scoring system may need refinement, especially in settings where unnecessary biopsies could burden resources. The perfect accuracy of CBE and pathology underscores their value as reliable tools, while the limitations of MTTS emphasize the need for more nuanced scoring or adjunctive imaging strategies.

The limitations of the study include a relatively small sample size, which may affect the generalizability of the findings. The exclusion of mammography limited the radiological assessment, especially in older patients. The study setting in a single tertiary care center may not reflect outcomes in primary or rural healthcare setups. Additionally, observer bias in clinical and cytological interpretation cannot be fully ruled out despite standardization.

The strengths of the study include its prospective design, uniform diagnostic criteria, and direct histopathological correlation, ensuring high internal validity. It involved a multidisciplinary approach with experienced clinicians and pathologists, which enhanced diagnostic accuracy. The use of standardized MTTS scoring across all subjects provided consistency. Comprehensive comparison of all triple test components with histopathology enabled robust evaluation of each modality's diagnostic performance.

Conclusion

We concluded that the Modified Triple Test Score (MTTS) is highly sensitive in evaluating breast lumps but has limited specificity. Clinical Breast Examination and pathological assessment demonstrated perfect diagnostic accuracy when compared with histopathology, confirming their reliability as primary diagnostic tools. Radiology showed moderate sensitivity but excellent specificity. Our study underscores the importance of integrating clinical judgment with objective tests for accurate preoperative evaluation of breast lesions.

Conflict of Interest: None.

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Ethical Approval: Obtained.

Consent: Written consent secured.

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