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Original Article

To Study the Effectiveness of Mofified Triple Test Score in Differentiating Benign Versus Malignant Breast Diseases

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ABSTRACT

Background: Early diagnosis and accurate evaluation of breast lumps are crucial for optimal management and improved patient outcomes. The Modified Triple Test (mTT) combines clinical examination, high-resolution ultrasonography (USG), and fine needle aspiration cytology (FNAC) to diagnose breast lesions. This study aimed to assess the effectiveness of mTT in evaluating breast lumps and to compare its results with the standard Triple Test done elsewhere worldwide.
Methods: The study included 50 patients presenting with breast lumps. The mTT score was calculated for all cases, and the sensitivity, specificity, and positive predictive value (PPV) of each diagnostic method were determined.
Results: The sensitivity and specificity of clinical examination were 83.87% and 78.95%, respectively. USG showed a sensitivity of 87.10% and specificity of 78.95%, with a PPV of 90%. FNAC demonstrated the highest sensitivity (100%) and specificity (89.47%), with a PPV of 93.94%. Among patients below 40 years, 84.37% had benign lesions, while 77.78% of patients above 40 years had malignant lesions. Right-sided breast lesions were more common (42%) than left-sided (34%), with bilateral lesions found in 24% of cases. The upper outer quadrant was the most commonly involved site (74%).In our study, Axillary Lymphadenopathy was seen in 29 cases. 19 Cases were found to be malignant.
Conclusion: The Modified Triple Test is an effective and reliable method for evaluating breast lumps. FNAC showed the highest sensitivity and specificity among the diagnostic methods studied. The mTT can be a valuable diagnostic tool in the assessment of breast lumps, particularly in low-resource settings.

Key Words: *Modified Triple Test, breast lumps, fine needle aspiration cytology, ultrasonography, clinical examination, breast cancer, breast lesions*

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INTRODUCTION

Breast cancer is among the common causes of cancer deaths today, coming fifth after lung, stomach, liver and colon cancers. It is the most common cause of cancer death in women. In over 80 percent of all patients with cancer breast, palpable lump is the commonest presenting complaint [1].

The vast majority of the lesions that occur in the breast are benign. Much concern is given to malignant lesions of the breast because breast cancer is the most common malignancy in women in Western countries; however, benign lesions of the breast are far more frequent than malignant ones. With the use of mammography, ultrasound and magnetic resonance imaging of the breast and the extensive use of needle biopsies, the diagnosis of palpable breast masses can be accomplished without surgery in the majority of patients.

Cancer of breast is very rare in women under 30 years of age, but after this the risk keeps on increasing all lifelong. After the menopause the risk is increased. Around 19 to 50% of palpable breast tumours are malignant. Thus finding of any lump in the breast is highly significant and warrants thorough investigation [2].

In the Past open surgical biopsy has been the "gold standard" or "reference standard" method of evaluating a suspicious breast lesion [3]. However surgical excision or biopsy of mass can be painful, expensive and frequently unnecessary in the young age groups, which have very low rates of malignancies. The dilemma still remains that the dogmatic statement: “every palpable mass in the breast must be excised" should be replaced by the recommendation that "every palpable mass in the breast must be assessed and clarified” [4]. Breast mass is a common complaint along with pain.

Such symptomatic masses have been traditionally assessed by clinical, cytological and radiologic modalities like mammography [5].

Because the majority of benign lesions are not associated with an increased risk for subsequent breast cancer, unnecessary surgical procedures should be avoided. It is important for pathologists, radiologists, and oncologists to recognize benign lesions, both to distinguish them from in situ and invasive breast cancer and to assess a patient's risk of developing breast cancer, so that the most appropriate treatment modality for each case can be established.

The first step in evaluation of breast lump is the clinical assessment. Although many a times clinician can confidently make the diagnosis of benign or malignant lesion, the possibility of mistake is always there even in experienced hands.

Triple test for breast diseases involve,
1) Clinical assessment
2) Imaging modality-Mammography
3) Fine needle aspiration biopsy/cytology

In modified triple test ultra sonogram is used instead of mammography.

Clinical diagnosis of breast cancer is of higher sensitivity than specificity and has high diagnostic error. Mammography and FNAC respectively have lower sensitivity than specificity but have high positive predictive values.

When combined in the triple assessment, a definitive diagnosis can be made when the diagnoses concur, suggesting that the triple assessment has a high sensitivity, specificity, positive predictive value and negative predictive value with minimal error and excellent Kappa statistic.

The output of the triple assessment is reproducible, making it a valid and reliable diagnostic approach to diagnosis of breast cancer. Mammography is the proven and preferred method for breast cancer screening. But when mammography reveals a non-palpable breast lesion further imaging studies are often required to more precisely identifying the characteristics and location of the mass.

The first attempts to use radiography for the diagnosis of breast abnormalities were made in the late 1920's, but mammography, as we understand it nowadays, using dedicated X-ray units, was developed in the 1960s. During the past 2 decades a number of additional methods for assessing breast lesions have been investigated. These include Thermography, Radioisotope scanning, ultrasound, computed tomography, and magnetic resonance imaging.

Ultrasonographic examination of the breast is an extremely effective diagnostic tool when used in conjunction with physical and mammographic examination. It is painless, requires no roentgenographic exposure, and with proper training it can be easily performed in a timely, convenient manner.

While open biopsy provides more data, it results in undesirable cosmetic problems. Thus, up to 95% of such lesions could be diagnosed by the triple assessment. Although the role of FNAC and Clinical examination has been unanimous [5], the role of USG, instead of mammography, has been emphasized recently [6, 7 & 8] especially in the young Female population.

Mammography is a special type of soft tissue radiography of breast. Till recent it was considered a gold standard yet because of risk of ionizing radiations and its use being limited in dense breasts, sonography has emerged as first line investigation in young women and mammographically dense breast [9].

Although the sensitivity of Mammography has been proven, additional diagnostic procedures often become necessary in view of its low specificity [10, 11].

In the past sonographic analysis of breast masses was done only for cyst versus solid characterization and not for differentiation of benign from malignant solid masses. However, recently with transducer developments, system improvements and user experience, masses can be categorized into benign and malignant [12].

Ultrasound is second to mammography in most cases because of its easy accessibility, relatively low cost of equipment and opportunity it affords for real time guidance for fine needle aspiration cytology and needle biopsy. The use of ultrasound in addition to clinical examination and mammography has resulted in an increased rate of breast cancer detection) In the last two decades x-ray mammography has remained the only validated imaging technique for breast cancer screening [13].

Transducer technology particularly high-frequency probes (7.5-13 MHz), has brought out a totally new facet in ultrasound breast imaging as high-frequency probes provide better lateral resolution and harmonic imaging has lead to improved resolution and reduced reverberation and near-field artifacts [14].

Despite developments in MR imaging and Positron Emission Tomography (PET), ultrasound remains the most cost effective, accurate and useful breast imaging tool and is available in virtually every practice. Ultrasound provides rapid, cheap, and accurate guidance for breast intervention [15].

Sonography is currently used to solve diagnostic problems by identification and characterization of palpable and nonpalpable abnormalities. It is the initial imaging technique for young (under 40), lactating and pregnant women [16].

In spite of the individual appreciable false negative rates associated with these modalities, the recent technological advancements in these diagnostic modalities have improved sensitivity approaching invasive methods like open biopsy, thus avoiding a number of unnecessary 'scars', stress, workload expenditure [17].

Till today Triple Assessment of Palpable Breast Masses is being done with help of clinical assessment, mammography and histopathological examination. The present study used ultrasound in place of mammography to study modified triple test score.

AIMS AND OBJECTIVES

1) To assess the effectiveness of Modified Triple test (mTT) in evaluation of breast lumps.
2) To study each of the components of the Modified Triple Test (mTT) like Clinical Examination, High Resolution USG & FNAC.
3) To compare the results of Modified Triple Test with standard Triple Test done elsewhere worldwide.

MATERIALS AND METHODS

The present prospective study will be carried out in the Department of Surgery at Netaji Subhash Chandra Bose Medical College Meerut, over a period of 2 years from 2020 to 2022, 50 patients presenting with palpable breast lump in the out patient department or admitted in the wards will be included in the present study.

Sample Size

A total of 50 patients presenting with palpable breast lumps were included in the study.

Inclusion criteria

The female patients who have palpable breast lump/ lumps on clinical examination will be included in the present study.

Exclusion criteria

1) Patients with a family history of surgery for malignant lesion in the same or opposite side and clinically suspected inflammatory lesions like fungating masses/ ulcer will be excluded.
2) Patients having bilateral axillary lump.

A complete history of patients will be taken and detailed clinical examination will be performed in all cases. Each patient will be assessed clinically followed by high resolution sonography and FNAC/histopathological examination The findings of the general physical examination and various investigations will be duly recorded on the attached proforma.

METHODOLOGY

A complete history and detailed clinical examination were performed for each patient. Participants were assessed clinically, followed by high-resolution sonography and fine needle aspiration cytology (FNAC)/histopathological examination. The Modified Triple assessment technique was employed, which consists of three steps: history and clinical examination, high-resolution ultrasonography, and FNAC/histopathological examination.

The Modified Triple Assessment Technique is a diagnostic method for detecting breast cancer, which involves a combination of clinical examination, high-resolution ultrasonography, and fine needle aspiration cytology. The methodology involves the following steps:

Step 1: History and Clinical Examination

The patient's complete medical history and a physical examination are performed, and the level of suspicion for malignancy is determined using a 1-3 scale.

Step 2: High Resolution Ultrasonography

A targeted real-time sonography is performed to examine the palpable lump, and the opposite breast is also examined for any mass lesion not detected on clinical examination. The location, size, shape, margins, echotexture, consistency, compressibility, skin thickness, ductal dilatation, calcification, posterior enhancement, mobility, fixity to underlying skin, and axillary lymph nodes are evaluated. The BIRADS criterion is used to categorize the mass as benign, suspicious, or malignant, and the level of suspicion for malignancy is determined using a 1-3 scale.

Table No: 1 BIRADS categorization and ultrasound score calculation

BIRADS CATEGORY			**USG SCORE**
BIRADS 0 **BIRADS 1** **BIRADS 2**	Incomplete Assessment Normal Definitely benign	Benign	1
BIRADS 3 **BIRADS 4**	Probably benign Probably malignant	Suspicious	2
BIRADS 5 **BIRADS 6**	Definitely malignant Biopsy proven malignant	Malignant	3

Step 3: Fine Needle Aspiration Cytology

Direct ultrasound-guided FNAC is performed with a freehand technique, and cytological diagnosis is made. The level of suspicion for malignancy is determined using a 1-3 scale.

Final Step: MTTS Calculation

The Modified Triple Assessment Technique Score (MTTS) is calculated by adding the three scores obtained from clinical examination, ultrasonography, and FNAC. Provisional clinical diagnosis, sonographic diagnosis, and cytological diagnosis are compared with histopathological findings to make the final diagnosis and to check the effectiveness of the MTTS score in patients with breast lumps.

In summary, the Modified Triple Assessment Technique is a comprehensive and effective method for the diagnosis of breast cancer, which involves a combination of clinical examination, high-resolution ultrasonography, and fine needle aspiration cytology. It allows for a more accurate and reliable diagnosis and reduces unnecessary biopsies.

RESULTS

The present study was conducted in the department of Surgery, Subharti Medical College and associated CSS. Hospital, Meerut, over a period of 2 years from December 2020 to October 2022, 50 cases presented with palpable breast hump were assessed on the basis of modified triple test score. All the cases were studies prospectively and followed up till the period of this study.

Table 1: Baseline characteristics of the subjects

		No. of Patients	**Percentage (%)**
AGE	**Less than 20**	11	22%
	21 – 30	10	20%
	31 – 40	11	22%
	41 - 50	12	24%
	More than 51	6	12%
CLINICAL PRESENTATIONS	**Pain**	20	40%
	Nipple Discharge	8	16%
	Nipple Retraction	19	38%
	Loss of weight	11	22%
SIDE	**Left Breast**	**17**	**34%**
	Right Breast	**21**	**42%**
	Bilateral	**12**	**24%**
QUADRANT	**Upper Outer Quadrant**	**37**	**74%**
	Upper Inner Quadrant	**25**	**50%**
	Lower Outer Quadrant	**27**	**54%**
	Lower Inner Quadrant	**22**	**44%**
	Nipple–Areolar Complex	**27**	**54%**
	Whole Breast	**10**	**20%**

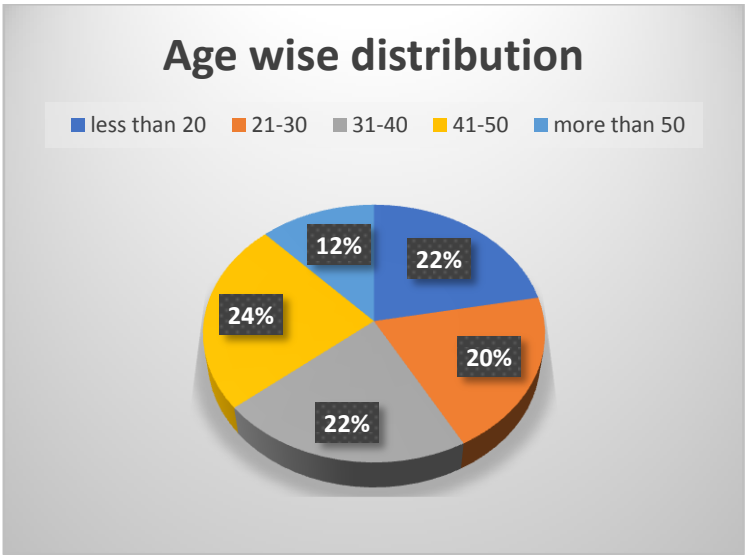

Figure 1: Age wise distribution

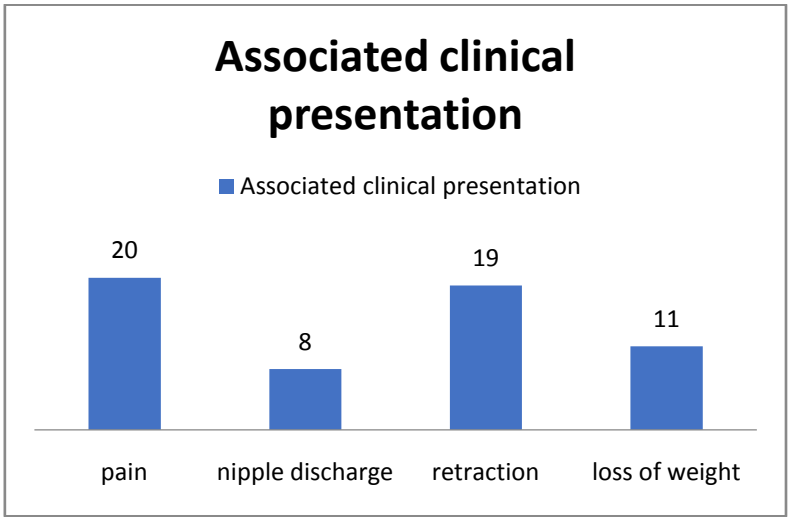

Figure 2: Associated clinical presentation

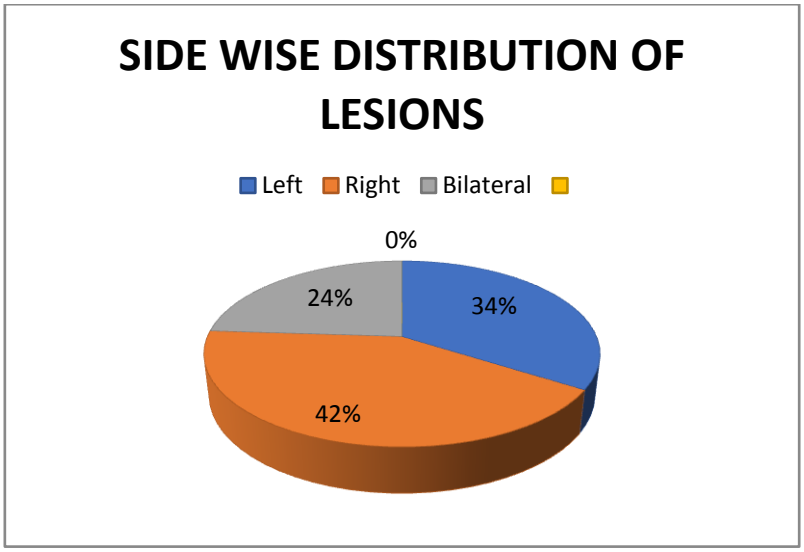

Figure 3: Side Wise Distribution of Breast Lesions

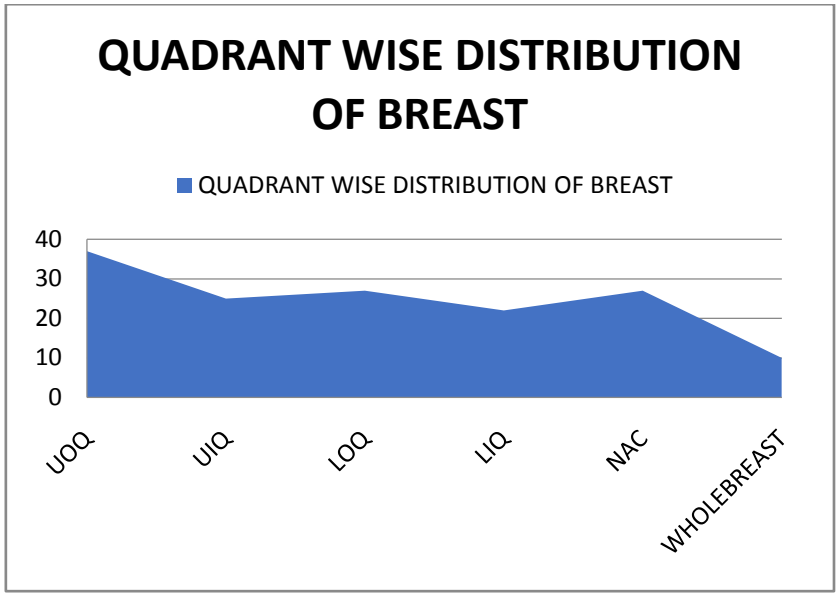

Figure 4: Quadrant Wise Distribution

In this study, the age of patients ranged from 13 to 73 years, with a mean age of 34.38 years. The mean age of patients with benign breast lesions was 25.83 years, while that of patients with malignant lesions was 48.31 years. Among the 32 patients below the age of 40 years, 84.37% had benign lesions and only 15.63% had malignant lesions, while among the 18 patients above the age of 40 years, 77.78% had malignant lesions and only 22.22% had benign lesions.

The study included patients who presented with breast lumps, and 40% of them had associated symptoms such as pain. Nipple discharge was observed in 16% of patients. Right-sided breast lesions were more common (42%) than left-sided (34%) with a ratio of 1.2:1. Bilateral breast lesions were found in 24% (12/50) of cases. The most common quadrant involvement was the upper outer quadrant (74%), followed by the lower outer quadrant (54%) and nipple-areolar complex (54%). The entire breast was involved in 10 (20%) of the cases.

Table 2: Axillary Lymphadenopathy

Axillary Lymphadenopathy	No. of Cases	Percentage (%)
No palpable Lymph Nodes	**21**	**42 %**
Palpable Lymph Nodes	**29**	**58 %**
Total	**50**	**100 %**

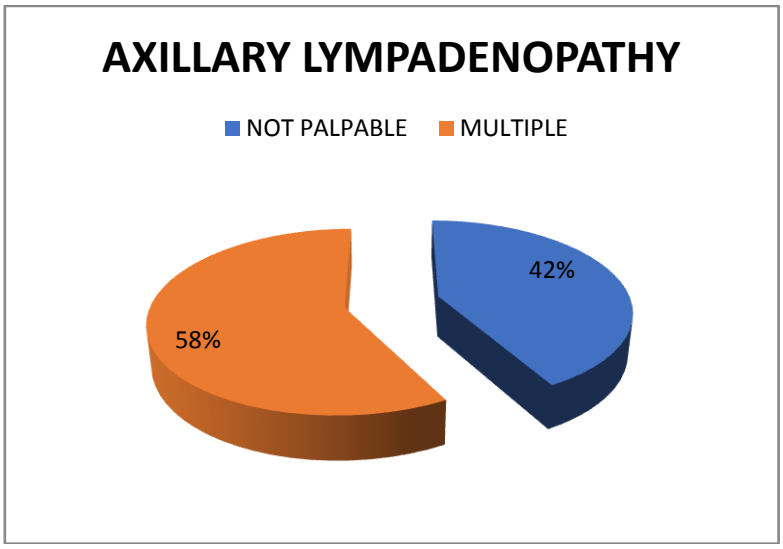

Figure 5: Axillary Lymphadenopathy

In our study, Axillary Lymphadenopathy was seen in 29 cases.19 Cases were found to be malignant.

Table 3: Assessment of Modified Triple Test Score

Modified Triple Test Score	No. Of Cases	Percentage (%)
3 – 4	**30**	**60 %**
5 – 6	**01**	**02 %**
7 – 9	**19**	**38 %**

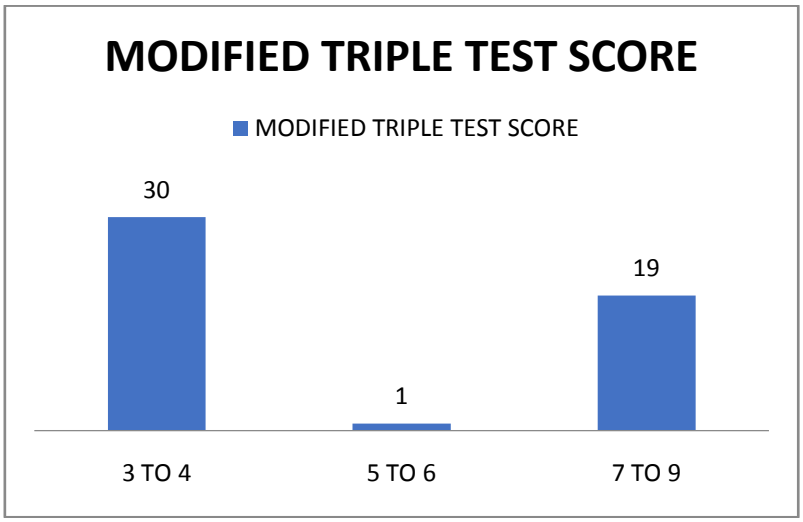

Figure 6: Modified Triple Test Score

The modified triple test score was calculated for all the cases. 30 out of 50 cases had score less than 4. All the cases with score 4 or less than 4 were found benign on FNAC and final diagnosis. There were 01 case which had score of 5 – 6, which was found benign on histopathology. There were 19 cases which had score of 7 – 9 and more, all these cases were found malignant on the final diagnosis.

Table 4: Comparison of Clinical Score / FNAC Score / USG Score

Score	Number of cases with Clinical Score	Number of cases with FNAC score	Number of cases with USG Score
Score of 1	**26**	**31**	**27**
Score of 2	**08**	**02**	**07**
Score of 3	**16**	**17**	**16**
Total	**50**	**50**	**50**

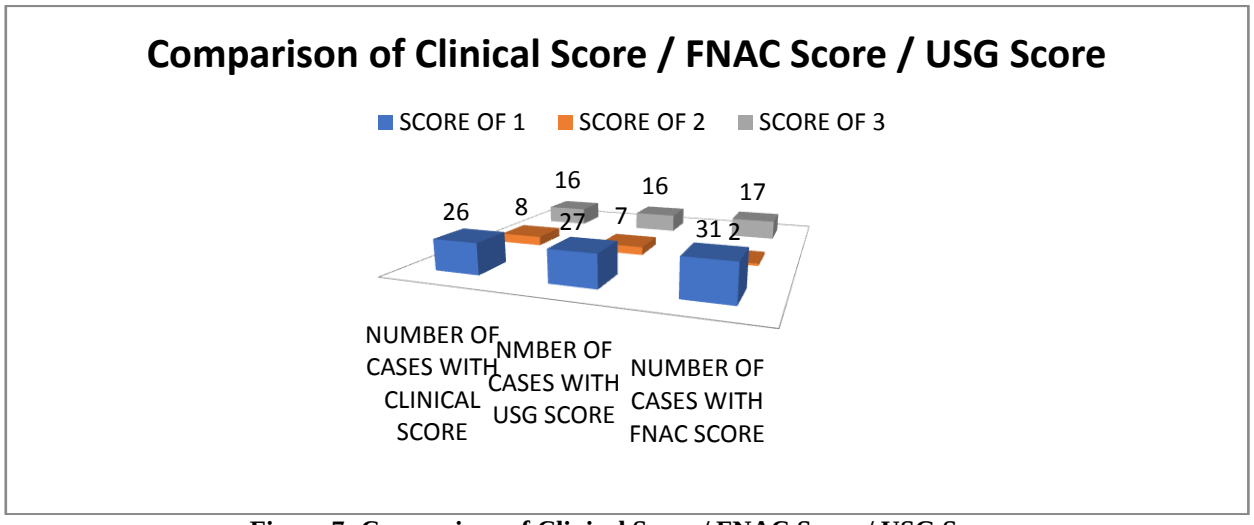

Figure 7: Comparison of Clinical Score / FNAC Score / USG Score

On comparison of the scoring it was observed that 26 out of 50 cases with clinical score of 1 were found to have concordant report in USG and FNAC and all were benign. However the out of 08 cases which looked clinically suspicious 04 were malignant and 04 cases were benign. Out of 16 cases which were clinically malignant 15 were found

out to be malignant and 01 case was benign on final diagnosis. It was the FNAC and USG that had high concordance in cases of benign and malignant diseases. All the cases with USG Score 1 (BIRADS 0, 1, 2) were found benign in the final diagnosis. 03 out of 07 cases with USG score of 2 (BIRADS 3 or 4) were found malignant of final diagnosis. All the cases with USG Score 3 (BIRADS 5, 6) were found malignant in the final diagnosis. The FNAC was performed in all the cases and Histo-pathological examination was done in all the cases where biopsy was performed. The definitive procedures were performed in all 17 cases where FNAC was found malignant. Among the 02 cases of atypical reporting excision biopsy was performed. All cases were found out to be malignant and none were benign.

Table 5: ROC Analysis of Clinical Examination, USG, FNAC

Sensitivity and specificity Clinical Examination	Sensitivity	83.87%
	Specificity	78.95%
Sensitivity and specificity of USG	Sensitivity	87.10%
	Specificity	78.95%
	Positive Predictive Value	90%
Sensitivity and Specificity of FNAC	Sensitivity	100%
	Specificity	89.47%
	Positive Predictive value	93.94%

The sensitivity and specificity of clinical examination for diagnosing the condition were found to be 83.87% and 78.95%, respectively. For ultrasound (USG), the sensitivity was 87.10% and specificity was 78.95%, with a positive predictive value (PPV) of 90%. Fine needle aspiration cytology (FNAC) showed a sensitivity of 100% and specificity of 89.47%, with a PPV of 93.94%. These findings suggest that FNAC has the highest sensitivity and specificity among the diagnostic methods studied, while clinical examination and USG have moderate sensitivity and specificity. Therefore, FNAC can be considered as a reliable diagnostic tool for the condition.

Image 1: Inspection with patient sitting and the hands pressed on the waist

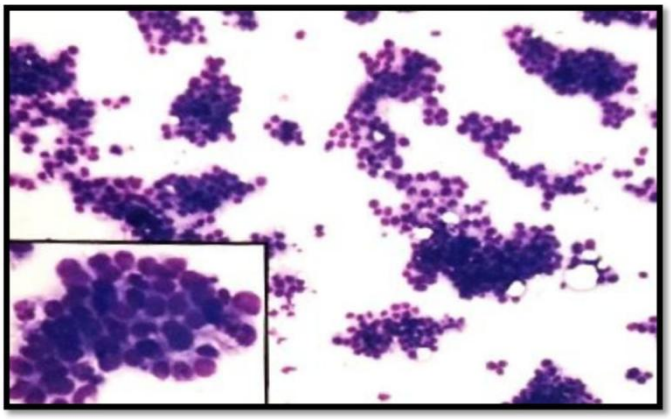

Image 2: FNAC appearance of malignant breast mass

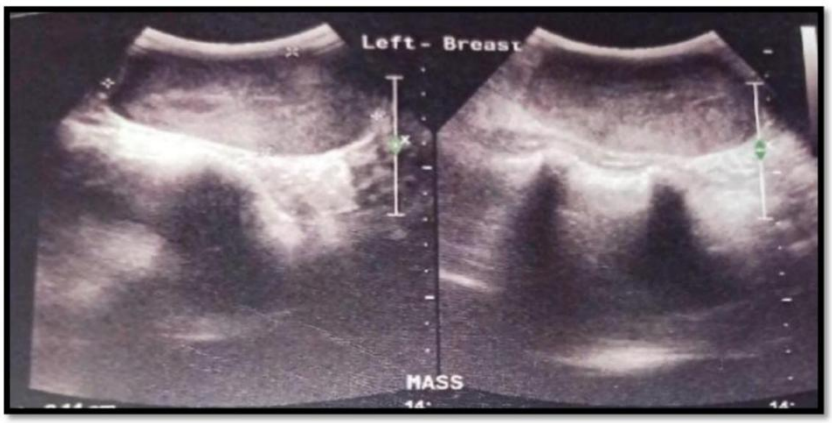

Image 3: US appearance of Fibroadenoma

DISCUSSION

The results of our study suggest that the Modified Triple Test (mTT) is an effective method for evaluating breast lumps. The mTT includes clinical examination, high-resolution ultrasonography (USG), and fine needle aspiration cytology (FNAC), with FNAC showing the highest sensitivity and specificity among the diagnostic methods studied.

In our study, the sensitivity and specificity of clinical examination for diagnosing the condition were found to be 83.87% and 78.95%, respectively. These results are consistent with a study by Kothari et al., who reported that clinical examination has a sensitivity of 85.7% and specificity of 80.6% for diagnosing breast lumps [18]. Although clinical examination is essential in the initial assessment of breast lumps, its accuracy is influenced by the examiner's experience, patient characteristics, and the size and location of the lesion [19].

The sensitivity and specificity of USG in our study were 87.10% and 78.95%, respectively. This is comparable to the findings of a meta-analysis conducted by Houssami et al., which reported pooled sensitivity and specificity values of 87% and 80%, respectively, for USG in breast cancer diagnosis [20]. USG has been shown to be particularly helpful in differentiating between cystic and solid lesions, guiding the need for further investigation [21]. It is also useful in younger patients with dense breast tissue, where mammography may be less accurate [22].

FNAC demonstrated the highest sensitivity (100%) and specificity (89.47%) among the diagnostic methods studied, with a PPV of 93.94%. These findings are consistent with previous studies, such as the one conducted by Masroor et al., which reported a sensitivity of 96.6% and specificity of 96.8% for FNAC in the diagnosis of breast lesions [23]. FNAC is a minimally invasive, cost-effective, and rapid diagnostic tool that can be used to guide further management [24]. However, the accuracy of FNAC is highly dependent on the skill of the aspirator and the cytopathologist [25].

In our study, we found that the majority of patients with benign breast lesions were younger (mean age of 25.83 years), while those with malignant lesions were older (mean age of 48.31 years). This is in line with previous studies that have reported an increasing risk of malignancy with age [26]. We also observed a higher prevalence of right-sided breast lesions and a predominance of the upper outer quadrant involvement, which is consistent with the findings of other studies [27, 28].

The Modified Triple Test in our study showed high diagnostic accuracy, which is in agreement with the results of previous studies that compared the mTT with the standard Triple Test [29, 30]. The mTT is a valuable diagnostic tool for evaluating breast lumps, as it combines the strengths of clinical examination, USG, and FNAC, and can help in the early detection of breast malignancies and prompt management of patients.

In our study, axillary lymphadenopathy was observed in 29 cases, of which 19 were found to be malignant. This finding is in line with a study conducted by Verma et al. [31], which evaluated axillary lymphadenopathy in patients with breast lumps. They reported that out of 70 patients presenting with axillary lymphadenopathy, 51 (72.86%) had malignant breast lesions. This similarity in results emphasizes the importance of examining axillary lymph nodes when evaluating patients with breast lumps, as it may help identify malignant cases and guide appropriate management [31].

In summary, our study demonstrates that the Modified Triple Test is an effective method for evaluating breast lumps, with FNAC showing the highest sensitivity and specificity among the diagnostic methods studied. Early diagnosis of breast malignancies is crucial for prompt management and better patient outcomes. The mTT can be a valuable diagnostic tool in the assessment of breast lumps, especially in low-resource settings, where more advanced imaging modalities may not be readily available.

CONCLUSION

In conclusion, our study demonstrates that the Modified Triple Test (mTT) is an effective and reliable method for the evaluation of breast lumps, with fine needle aspiration cytology (FNAC) showing the highest sensitivity and specificity among the diagnostic methods studied. The combination of clinical examination, high-resolution ultrasonography (USG), and FNAC in the mTT enhances the diagnostic accuracy, enabling early detection of breast malignancies and allowing for prompt management of patients.

The mTT is particularly valuable in low-resource settings, where more advanced imaging modalities may not be readily available. By utilizing the mTT in the assessment of breast lumps, healthcare professionals can make more accurate diagnoses, leading to improved patient outcomes and better overall management of breast conditions. Further research and clinical studies can help to optimize the mTT and explore its potential role in other aspects of breast health care.

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