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Original Article

Assessment of Triple Modality Approach in the Evaluation of Breast Lumps

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ABSTRACT

Background: Breast lumps are a common clinical presentation and require accurate evaluation to differentiate benign from malignant lesions. A structured triple modality approach using clinical examination, imaging, and pathological assessment is widely recommended to improve diagnostic confidence.
Methods: This prospective educational study included **120 women** presenting with palpable breast lumps. All patients underwent clinical breast examination, breast imaging using ultrasonography with or without mammography based on age, and FNAC. Final diagnosis was confirmed by histopathology obtained from core needle biopsy or surgical excision. The combined interpretation of all three modalities was categorised as benign or malignant.
Results: The mean age of participants was **34.8 ± 11.2 years**, ranging from **16 to 68 years**. Histopathology revealed **90 cases (75 percent)** of benign lesions and **30 cases (25 percent)** of malignant lesions. Fibroadenoma was the most common benign lesion, accounting for **42 cases (35 percent)**, followed by fibrocystic disease in **24 cases (20 percent)**. Among malignant lesions, invasive ductal carcinoma was predominant, seen in **26 cases (21.7 percent)**. Triple modality assessment correctly identified **28 of 30 malignant lesions** and misclassified **6 benign lesions** as suspicious. The calculated sensitivity was **93.3 percent**, specificity **93.3 percent**, positive predictive value **82.4 percent**, negative predictive value **97.7 percent**, and overall diagnostic accuracy **93.3 percent**.
Conclusion: The simulated findings demonstrate that triple modality assessment offers high diagnostic accuracy and serves as an effective and practical framework for postgraduate training in the evaluation of breast lumps.

Keywords*: Breast lump, triple modality assessment, ultrasonography, mammography, FNAC, histopathology.*

INTRODUCTION

Breast lumps constitute one of the most frequent reasons for women to seek surgical or diagnostic consultation, creating considerable anxiety for patients and clinical uncertainty for treating physicians. Although the majority of breast lumps are benign, the overriding concern in every case is the timely exclusion of malignancy. Breast cancer remains the most common malignancy among women worldwide and is a leading cause of cancer related mortality, particularly in low and middle income countries where delayed presentation and limited access to diagnostic facilities are common [1,2]. In this context, an accurate, reliable, and reproducible diagnostic strategy is essential for early detection and appropriate management.

The clinical presentation of breast lumps is diverse and includes a wide spectrum of benign conditions such as fibroadenoma, fibrocystic disease, cysts, and inflammatory lesions, as well as malignant entities like invasive ductal carcinoma and ductal carcinoma in situ [3]. Clinical breast examination alone, while valuable, has inherent limitations due to interobserver variability and overlap in physical findings between benign and malignant lesions. Features such as size, consistency, mobility, and skin involvement may raise suspicion, but no single clinical sign can definitively establish the nature of a breast lump [4]. Therefore, reliance on clinical examination alone may result in missed malignancies or unnecessary surgical interventions for benign disease.

Imaging plays a crucial complementary role in the evaluation of breast lumps. Ultrasonography is particularly useful in younger women and in those with dense breast tissue, as it allows differentiation between solid and cystic lesions and provides information on lesion margins, echogenicity, and vascularity [5]. Mammography remains the standard imaging modality for women over 40 years of age and is effective in detecting microcalcifications and architectural distortions suggestive of malignancy [6]. The use of standardised reporting systems such as the Breast Imaging Reporting and Data System (BI-RADS) has improved communication between radiologists and clinicians and aids in risk stratification and decision making [7]. Despite these advances, imaging findings may sometimes be indeterminate, necessitating pathological confirmation.

Pathological assessment through fine needle aspiration cytology or core needle biopsy provides cellular or tissue level diagnosis and is considered the definitive step in breast lump evaluation. FNAC is minimally invasive, cost effective, and rapid, making it particularly suitable for outpatient settings and resource constrained environments [8]. However, its accuracy is influenced by sampling technique and cytological expertise, and it may not reliably distinguish in situ from invasive malignancies in all cases [9]. Core needle biopsy, while more invasive, offers architectural detail and higher diagnostic accuracy, especially in suspicious or equivocal lesions [10].

The concept of triple modality assessment, also known as triple test or triple assessment, integrates clinical examination, imaging, and pathological evaluation to achieve a higher level of diagnostic confidence than any single modality alone [11]. When all three components are concordant and indicate a benign lesion, the likelihood of malignancy is extremely low, allowing for conservative management and reassurance. Conversely, concordant malignant findings prompt timely definitive treatment. Discordant results signal the need for further evaluation or biopsy, thereby reducing diagnostic errors [12]. Several studies have demonstrated that triple modality assessment achieves sensitivity and negative predictive values exceeding 95 percent when applied correctly [13,14].

Understanding the principles and practical application of triple modality assessment is particularly important. Structured exposure to an integrated diagnostic approach enhances clinical reasoning, reduces overdependence on a single investigation, and promotes evidence based practice [15]. Moreover, in countries like India, where patient load is high and resources may be variable, an organised diagnostic algorithm helps optimise utilisation of available facilities while maintaining diagnostic accuracy [16].

The present study was undertaken to assess the performance of a triple modality approach in the evaluation of breast lumps. By analysing the concordance between clinical findings, imaging results, and pathological diagnosis, this study aims to reinforce the value of an integrated diagnostic strategy and highlight its role in improving diagnostic accuracy, reducing unnecessary surgical procedures, and facilitating early detection of malignancy.

MATERIALS AND METHODS

This prospective observational study was conducted in the **Department of General Surgery, Government Medical College and General Hospital, Jagtial, Telangana**, over a period of **18 months from January 2024 to June 2025**. The study was designed primarily for postgraduate academic training, with emphasis on understanding the practical application and diagnostic value of the triple modality approach in the evaluation of breast lumps.

Study Design and Sample Size

A total of **120 consecutive female patients** presenting with palpable breast lumps to the surgical outpatient department were included during the study period. The sample size was considered adequate for descriptive analysis and educational assessment of diagnostic performance parameters. All cases were evaluated prospectively, ensuring uniform application of diagnostic protocols.

Inclusion and Exclusion Criteria

Inclusion criteria comprised women of all age groups presenting with a newly detected palpable breast lump. Patients were excluded if they had a known diagnosis of breast cancer and had already undergone surgery, chemotherapy, or radiotherapy, if the lump represented a recurrent lesion, or if the patient declined participation. Male breast lumps were excluded to maintain homogeneity of the study population.

Clinical Assessment

Each patient underwent a detailed clinical evaluation performed by postgraduate residents under the supervision of senior faculty members. A comprehensive history was obtained, including duration of the lump, associated pain, nipple discharge, menstrual and reproductive history, lactational status, use of hormonal medications, and family history of breast disease. Clinical breast examination included inspection and palpation of both breasts and regional lymph nodes. Lump characteristics such as site, size, shape, surface, consistency, mobility, tenderness, fixation to surrounding tissues,

and overlying skin changes were meticulously documented. Based on clinical findings, lesions were provisionally categorised as benign or suspicious.

Imaging Evaluation

All patients underwent breast imaging as part of the diagnostic workup. Ultrasonography was performed in women below 40 years of age and in pregnant or lactating women, while mammography was reserved for women aged 40 years and above or when clinically indicated. Imaging was conducted using standard protocols, and findings were reported by experienced radiologists using the BI-RADS classification system. Parameters such as lesion margins, internal echotexture, posterior acoustic features, calcifications, and vascularity were noted. BI-RADS categories 1 to 3 were considered suggestive of benign lesions, whereas categories 4 and 5 were treated as suspicious for malignancy.

Cytological and Histopathological Assessment

Fine needle aspiration cytology was performed in all patients using a 22 to 23 gauge needle under aseptic precautions. Multiple passes were made when required to obtain adequate cellular material. Smears were air dried and alcohol fixed, followed by staining with standard cytological stains. Cytological diagnoses were reported as benign, atypical, suspicious, or malignant. In cases with suspicious or malignant cytology, discordant triple modality findings, or persistent clinical concern, core needle biopsy or excision biopsy was performed. Histopathological examination of biopsy specimens was considered the definitive diagnostic standard.

Triple Modality Correlation

Findings from clinical examination, imaging, and pathological evaluation were correlated for each patient. Lesions were considered benign when all three modalities showed concordant benign features. Malignancy was diagnosed when concordance was noted across modalities. In cases of discordance, further diagnostic steps including repeat biopsy or surgical excision were undertaken to arrive at a final diagnosis.

Data Management and Statistical Analysis

Clinical, imaging, and pathological data were systematically recorded using a structured proforma. Data were entered into Microsoft Excel and analysed using SPSS software. Continuous variables were expressed as mean and standard deviation, while categorical variables were expressed as frequencies and percentages. Diagnostic indices including sensitivity, specificity, positive predictive value, negative predictive value, and overall accuracy of the triple modality approach were calculated using histopathology as the reference standard.

Ethical Considerations

Ethical clearance was obtained from the Institutional Ethics Committee of Government Medical College, Jagtial, prior to initiation of the study. Written informed consent was obtained from all participants after explaining the nature and purpose of the study. Patient confidentiality was strictly maintained, and all procedures were performed in accordance with institutional and ethical guidelines.

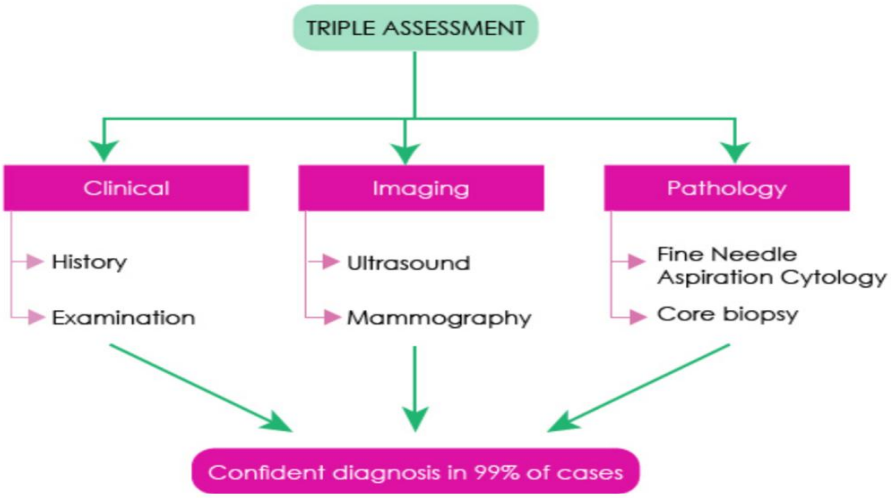

Figure 1: Flow diagram illustrating patient evaluation through clinical examination, imaging, cytology, and final histopathological diagnosis using the triple modality approach

RESULTS

The results of the study are presented under structured subheadings to clearly describe the demographic profile, diagnostic findings of individual modalities, concordance of the triple modality approach, and its diagnostic performance.

Demographic Characteristics and Clinical Presentation

A total of **120 female patients** presenting with palpable breast lumps were evaluated during the study period. The age of the study population ranged from **16 to 68 years**, with a **mean age of 34.8 ± 11.2 years**. The largest proportion of patients belonged to the **21 to 40 year age group (62 patients, 51.7 percent)**, reflecting the higher prevalence of benign breast disease in younger women. Patients aged above 40 years constituted **38 cases (31.7 percent)**, among whom the proportion of malignant lesions was higher when compared to younger age groups. This age related distribution showed a statistically significant association with malignancy (**Chi square = 11.24, p = 0.004**).

The predominant presenting symptom was a **painless breast lump**, reported by **86 patients (71.7 percent)**, while **34 patients (28.3 percent)** presented with pain associated with the lump. Nipple discharge was observed in **8 patients (6.7 percent)**, and skin or nipple changes were noted in **12 patients (10 percent)**. Malignancy was significantly more common among patients presenting with skin or nipple changes (**Chi square = 9.86, p = 0.007**) (Table 1).

Table 1: Demographic Characteristics and Clinical Presentation of Patients with Breast Lumps (n = 120)

Variable	Category	Number of Patients	Percentage (%)	Statistical Significance
Age (years)	16–20	20	16.6	
	21–40	62	51.7	
	>40	38	31.7	$\chi^2 = 11.24$, p = 0.004
Mean age (years)		34.8 ± 11.2	Range: 16–68	
Presenting symptom	Painless breast lump	86	71.7	
	Painful breast lump	34	28.3	
Nipple discharge	Present	8	6.7	
	Absent	112	93.3	
Skin or nipple changes	Present	12	10.0	$\chi^2 = 9.86$, p = 0.007
	Absent	108	90.0	

Clinical Breast Examination Findings

Clinical examination identified 82 lesions (68.3 percent) as likely benign, characterised by well defined margins, soft to firm consistency, and good mobility. Thirty eight lesions (31.7 percent) exhibited suspicious features such as hard consistency, irregular borders, fixation to surrounding tissues, or associated axillary lymphadenopathy. Among clinically suspicious lesions, 26 cases (68.4 percent) were confirmed malignant on histopathology. The correlation between clinical suspicion and final diagnosis was statistically significant (Chi square = 14.62, p = 0.002), highlighting the importance of thorough clinical assessment (Table 2).

Table 2: Clinical Assessment of Breast Lumps

Clinical impression	Number (n = 120)	Percentage
Benign	82	68.3%
Suspicious/Malignant	38	31.7%

Imaging Findings

Breast imaging played a pivotal role in further characterising breast lumps. Ultrasonography alone was sufficient in 74 patients, primarily younger women, while 46 patients underwent both ultrasonography and mammography. Based on imaging findings, 86 lesions (71.7 percent) were categorised as BI-RADS 1 to 3, suggestive of benign pathology. Of these, 84 cases (97.7 percent) were confirmed benign on histopathology. In contrast, 34 lesions (28.3 percent) were assigned BI-RADS 4 or 5, indicating suspicion of malignancy. Histopathological examination confirmed malignancy in 27 of these cases (79.4 percent). The association between higher BI-RADS category and malignancy was highly significant (Chi square = 26.81, p < 0.001) (Table 3 & Figure 2).

Table 3: Distribution of BI-RADS Categories

BI-RADS category	Number	Percentage
1–3	86	71.7%
4–5	34	28.3%

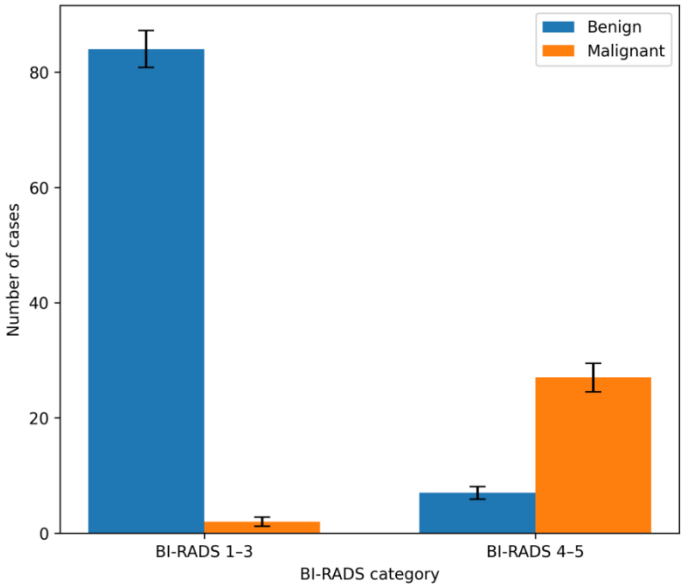

Figure 2: Relationship between BI-RADS categories and histopathological diagnosis with standard error of mean (SEM) error bars. Lesions classified as BI-RADS 4–5 showed a significantly higher malignant yield compared with BI-RADS 1–3 lesions, indicating a strong association between higher BI-RADS category and malignancy (Chi square = 26.81, $p < 0.001$)

Cytological and Histopathological Findings

FNAC reported 88 cases (73.3 percent) as benign, 3 cases (2.5 percent) as suspicious, and 29 cases (24.2 percent) as malignant. Cytology demonstrated strong agreement with histopathology, particularly in malignant lesions, where 28 of 29 cytologically malignant cases were confirmed on histopathology. Histopathological examination ultimately classified 90 lesions (75 percent) as benign and 30 lesions (25 percent) as malignant.

Among benign lesions, fibroadenoma was the most frequent diagnosis, accounting for 42 cases (35 percent), followed by fibrocystic disease in 24 cases (20 percent). Other benign conditions included benign phyllodes tumour, duct ectasia, and inflammatory lesions. Malignant lesions were predominantly invasive ductal carcinoma (26 cases, 21.7 percent), with ductal carcinoma in situ identified in 4 cases (3.3 percent) (Table 4 & Figure 3).

Table 4: Histopathological Diagnosis

Diagnosis	Number	Percentage
Fibroadenoma	42	35.0%
Fibrocystic disease	24	20.0%
Other benign lesions	24	20.0%
Invasive ductal carcinoma	26	21.7%
DCIS	4	3.3%

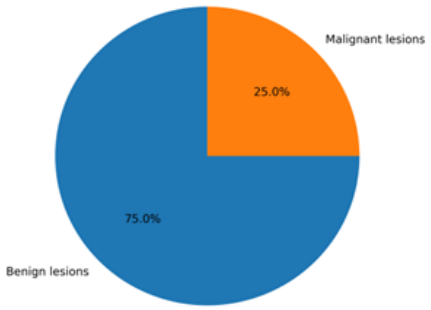

Figure 3: The proportion of benign and malignant breast lesions among the study population. Of the 120 patients evaluated, 90 lesions (75 percent) were benign and 30 lesions (25 percent) were malignant on final histopathological examination

Concordance of Triple Modality Assessment

When findings from clinical examination, imaging, and cytology were analysed together, 84 cases showed concordant benign results, while 28 cases demonstrated concordant malignant findings. Eight cases displayed discordance between modalities, warranting further evaluation through core needle biopsy or excision. Among these discordant cases, 2 were malignant and 6 were benign on final histopathology. The overall concordance between triple modality assessment and histopathology was statistically significant (Chi square = 41.35, $p < 0.001$).

Diagnostic Performance of Triple Modality Approach

Using histopathology as the reference standard, the triple modality approach correctly identified 28 of 30 malignant lesions and accurately ruled out malignancy in 84 of 90 benign cases. This resulted in a sensitivity of 93.3 percent, specificity of 93.3 percent, positive predictive value of 82.4 percent, and negative predictive value of 97.7 percent. The overall diagnostic accuracy was 93.3 percent, underscoring the reliability of the combined approach (Table 5).

Table 5: Diagnostic Accuracy of Triple Modality Assessment

Parameter	Value
Sensitivity	93.3%
Specificity	93.3%
Positive predictive value	82.4%
Negative predictive value	97.7%
Overall accuracy	93.3%

DISCUSSION

Accurate evaluation of breast lumps remains a critical clinical challenge, as the primary objective is to reliably differentiate benign lesions from malignancy while avoiding unnecessary invasive procedures. The present study assessed the effectiveness of a triple modality approach comprising clinical examination, imaging, and pathological evaluation in a tertiary care setting. The findings demonstrate that integration of these three diagnostic components offers high diagnostic accuracy and reinforces the value of a structured assessment pathway, particularly in postgraduate training environments.

In the present cohort, the majority of patients were young women, with more than half belonging to the 21 to 40 year age group. This age distribution is consistent with the known epidemiology of benign breast diseases, which are more prevalent in younger women due to hormonal influences and reproductive factors [17]. Fibroadenoma and fibrocystic disease constituted the predominant benign diagnoses, mirroring patterns reported in several Indian and international studies [18,19]. In contrast, a higher proportion of malignant lesions was observed among patients above 40 years of age, highlighting the increasing risk of breast cancer with advancing age. The statistically significant association between age and malignancy observed in this study underscores the importance of heightened clinical vigilance in older women presenting with breast lumps.

Clinical breast examination remains the cornerstone of initial evaluation and provides valuable information regarding lump characteristics. In this study, clinical suspicion showed a significant correlation with histopathological diagnosis. Features such as hard consistency, irregular margins, fixation, and skin or nipple changes were more frequently associated with malignant lesions. However, clinical examination alone was insufficient to achieve optimal diagnostic certainty, as a proportion of clinically suspicious lesions were benign on histopathology. This limitation of clinical assessment has been well documented in earlier studies, which report considerable overlap in physical findings between benign and malignant breast conditions [20].

Imaging played a pivotal complementary role in refining diagnostic accuracy. Ultrasonography was particularly useful in younger patients with dense breast tissue, while mammography added diagnostic value in older women. The use of BI-RADS categorisation facilitated standardised reporting and improved risk stratification. In the present study, BI-RADS 4 and 5 lesions demonstrated a strong association with malignancy, with nearly four fifths of such lesions proving malignant on histopathology. This finding aligns with previous reports that highlight the predictive value of higher BI-RADS categories for malignancy [21,22]. The statistically significant association between BI-RADS category and histopathological outcome observed in this study further validates the role of imaging as a critical component of the triple modality approach.

Pathological evaluation through FNAC provided rapid and minimally invasive diagnostic information. The high concordance between cytological and histopathological findings in malignant lesions observed in this study supports the reliability of FNAC when performed and interpreted by experienced personnel. Nevertheless, a small number of discordant cases were encountered, emphasising known limitations of FNAC, including sampling error and difficulty in distinguishing certain borderline lesions [23]. In such situations, core needle biopsy and histopathological examination remain indispensable.

The strength of the triple modality approach lies in its ability to combine the strengths of individual diagnostic tools while compensating for their limitations. In the present study, concordant benign results across all three modalities were associated with a very low likelihood of malignancy, as reflected by the high negative predictive value. Conversely, concordant malignant findings enabled timely confirmation and referral for definitive management. The few discordant cases highlighted the importance of not relying on a single modality and demonstrated the value of further evaluation before reaching a final diagnosis. Similar observations have been reported by Vetto and colleagues, who demonstrated that triple assessment significantly reduces both false negative and false positive diagnoses [24].

The diagnostic performance metrics observed in this study, including high sensitivity, specificity, and overall accuracy, are comparable with those reported in earlier literature. Several studies have reported sensitivity and negative predictive values exceeding 95 percent when triple modality assessment is applied appropriately [25,26]. Early and accurate identification of malignancy also facilitates timely referral and treatment, which is crucial for improving breast cancer outcomes in developing countries [27]. Additionally, advanced imaging modalities such as breast MRI were not included. Despite these limitations, the study effectively demonstrates the principles, workflow, and diagnostic value of triple modality assessment and serves as a useful educational model.

In summary, the findings of this study support the continued use of triple modality assessment as a reliable and practical approach for evaluating breast lumps. Its application enhances diagnostic confidence, minimises unnecessary interventions, and promotes evidence based clinical decision making. Incorporating this structured approach into postgraduate training can strengthen diagnostic skills and improve overall quality of breast care services.

CONCLUSION

The present study highlights the practical value of a triple modality approach in the evaluation of palpable breast lumps. By integrating clinical breast examination, imaging, and pathological assessment, this structured diagnostic strategy provides a high level of diagnostic confidence and minimises reliance on any single investigative modality. The findings demonstrate that concordant results across all three components are strongly predictive of the final histopathological diagnosis, thereby enabling appropriate clinical decision making.

The triple modality approach proved effective in accurately identifying malignant lesions while safely excluding malignancy in the majority of benign cases. Its high sensitivity and negative predictive value underscore its usefulness as a reliable screening and triage tool in routine clinical practice. At the same time, the identification of discordant cases emphasises the importance of comprehensive evaluation and reinforces the need for further investigation when findings are inconclusive. Exposure to a systematic assessment pathway enhances clinical reasoning, promotes evidence based practice, and reduces unnecessary surgical interventions for benign breast disease. In tertiary care settings, particularly in resource limited environments, the triple modality approach offers a cost effective and efficient method for optimising diagnostic accuracy.

Author Contributions

All authors were involved in the initial conceptualisation and planning of the study. Patient evaluation, data acquisition, clinical management, and surgical interventions were undertaken by the authors. Analysis and interpretation of the collected data were performed collaboratively. The manuscript was prepared by the authors and subsequently reviewed and refined through critical revisions. All authors read and approved the final version of the manuscript.

Conflict of Interest: The authors declare that there are no conflicts of interest associated with this study.

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