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Original Research Article

Evaluation of Diagnostic Accuracy of Triple Assessment in Palpable Breast Lumps: A Comparative Study of Clinical, Radiological, and Histopathological Methods

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Abstract:

This prospective observational study investigates the diagnostic accuracy of the triple assessment (clinical examination, radiological evaluation, and histopathological analysis) for palpable breast lumps in females. Utilizing data collected from 100 patients over three years (2020-2023), the study assesses the sensitivity, specificity, and accuracy of each diagnostic method and compares them against histopathological evaluation (HPE). Results show high diagnostic concordance, supporting the triple assessment's efficacy in detecting malignancy. This study aims to reinforce the use of triple assessment for early and accurate diagnosis of breast lumps, ultimately aiding in precise treatment planning.

Keywords: Breast Lump, Triple Assessment, Breast Cancer, Clinical Examination, Mammography, FNAC, Core Needle Biopsy, Histopathology.

Introduction

Breast lumps are among the most common reasons for surgical consultation in females, often raising concerns about malignancy. [1] Breast cancer is now the most frequently diagnosed cancer globally, accounting for 11.7% of all cancer diagnoses, surpassing even lung carcinoma.[2] Historically, breast carcinoma diagnoses relied solely on physical examination and were often followed by radical surgical excisions. [3]

However, advancements in diagnostic imaging and minimally invasive procedures, such as ultrasonography, mammography, fine needle aspiration cytology (FNAC), and core needle biopsy (CNB), have significantly improved diagnostic precision and management strategies.[4]

The triple assessment method, combining clinical examination, radiology, and histopathology, provides a comprehensive framework for evaluating breast lumps.[5] Each component contributes uniquely to the diagnostic process, ensuring reliable results and reducing the need for immediate invasive procedures. This study aims to assess the accuracy, sensitivity, and specificity of each component within the triple assessment framework and to establish its diagnostic reliability in palpable breast lumps.

Materials and Methods

Study Design: This prospective observational study was conducted between 2020 and 2023.

Sample Size: 100 females with clinically palpable breast lumps.

Inclusion Criteria: Females above 18 years with palpable breast lumps.

Exclusion Criteria: Proven breast malignancies undergoing treatment, recurrent lumps, and patients unwilling to proceed with evaluation.

Methodology:

Each patient underwent a structured diagnostic approach, including:

Clinical Examination: Comprehensive history and physical examination were performed to assess initial signs of benign or malignant conditions.

Radiological Assessment: Mammography: Utilized primarily in patients over 35, using craniocaudal and mediolateral oblique views.

Ultrasonography: For patients under 35, particularly to differentiate solid and cystic lesions.

Histopathological Evaluation:

FNAC: A minimally invasive method involving tissue aspiration for cytological examination.

Core Needle Biopsy (CNB): Provided a more comprehensive tissue sample for histopathology, aiding in pre-surgical decision-making.

Data were collected regarding patient demographics, clinical findings, radiologic outcomes, and histopathological results. Diagnostic performance metrics, including sensitivity, specificity, positive predictive value (PPV), and negative predictive value (NPV), were calculated for each modality.

Statistical Analysis: Descriptive statistics were calculated for demographic data. The sensitivity, specificity, and diagnostic accuracy of each assessment method were evaluated using histopathology as the gold standard. Statistical significance was assessed using Cohen's Kappa for inter-method agreement, with p-values <0.05 considered statistically significant.

Results

Table 1: Age wise distribution of breast lumps.

Age Group	Frequency	Percent
< 20	5	5.0%
21 – 30	9	9.0%
31 – 40	14	14.0%
41 – 50	29	29.0%
51 – 60	26	26.0%
61 – 70	15	15.0%
71 – 80	1	1.0%
81 – 90	1	1.0%

The above table shows that the age group 41–50 has the highest frequency at 29%, followed by 51–60 at 26%, indicating that most individuals fall within these age ranges. Younger and older age groups (<20 and 71–90) have the lowest representation, each comprising 5% or less of the total.

Table 2: Comparison between Clinical examination, Radiological investigation, FNAC and Triple Assessment with HPE

Diagnostic Methods		HPE		Total	Cohen Kappa (p value)
		Benign	Malignant		
Clinical Examination	Benign	25	1	26	0.974 (0.001)
	Malignant	0	74	74	
	Total	25	75	100	
Sono Mammography	Benign	25	2	27	0.948 (0.001)
	Malignant	0	73	73	
	Total	25	75	100	
FNAC	Benign	24	0	24	0.973 (0.001)
	Malignant	1	75	76	
	Total	25	75	100	
Triple Assessment	Benign	24	0	24	0.973 (0.001)
	Malignant	1	75	76	
	Total	25	75	100	

The above table compares the accuracy of different diagnostic methods (Clinical Examination, Sono Mammography, FNAC, and Triple Assessment) in identifying benign versus malignant cases, as confirmed by histopathological examination (HPE).

Each method has high agreement with HPE, indicated by Cohen's Kappa values close to 1 (all with a p-value of 0.001, showing statistical significance). Clinical Examination and FNAC show the highest agreement (0.974 and 0.973, respectively), while Sono Mammography has a slightly lower agreement (0.948). Overall, each method demonstrates strong reliability in diagnosing malignancy, with minimal benign-to-malignant misclassifications.

Table 3: Diagnostic Analysis of Different diagnostic methods

Statistics	Clinical Examination	Sono Mammography	FNAC	Triple Assessment
Sensitivity	98.67%	97.33%	100.00%	100.00%
Specificity	100.00%	100.00%	96.00%	96.00%
Positive Predictive Value	100.00%	100.00%	98.68%	98.68%
Negative Predictive Value	96.15%	92.59%	100.00%	100.00%
Accuracy	99.00%	98.00%	99.00%	99.00%

The above table summarizes key diagnostic performance metrics (sensitivity, specificity, positive predictive value, negative predictive value, and accuracy) for four different diagnostic methods: Clinical Examination, Sono Mammography, FNAC (Fine Needle Aspiration Cytology), and Triple Assessment. FNAC and Triple Assessment both demonstrate 100% sensitivity, indicating that these methods correctly identified all true positive cases. Followed by Clinical Examination (98.67%) and Sono Mammography (97.33%) also show high sensitivity, but with slightly lower performance compared to FNAC and Triple Assessment.

Clinical Examination and Sono Mammography both show 100% specificity, meaning that they were highly effective at correctly identifying cases that do not have the disease, with no false positives. Followed by, FNAC (96.00%) and Triple Assessment (96.00%) exhibit slightly lower specificity. Clinical Examination and Sono Mammography show 100% PPV, meaning that all positive test results from these methods were true positives. Followed by, FNAC and Triple Assessment also show high PPV (98.68%).

FNAC and Triple Assessment show 100% NPV, meaning that a negative result from these methods guarantees that the individual does not have the disease. Followed by, Clinical Examination (96.15%) and Sono Mammography (92.59%) have slightly lower NPV values, indicating that there is a small chance of a false negative result. Clinical Examination, Sono Mammography, FNAC, and Triple Assessment demonstrate high accuracy, with values ranging from 98.00% to 99.00%.

Discussion

100 patients with clinically palpable breast lumps presenting to outpatient department of Dr.D Y Patil Hospital, Nerul from 2020 to 2023 were included in this study. Each patient was initially evaluated by physical examination followed by radiological evaluation with ultrasonography or sonomammography, depending on the age of the patient. This was then followed by invasive tissue diagnosing investigations which included FNAC, thus following the triple assessment guideline. This was then followed by TRUCUT biopsy and each patient finally underwent surgical excision of the lump. The aim was to find the diagnostic accuracy of each component along with sensitivity and specificity of each. In this study, physical examination had 98.7% sensitivity which was similar to a study published by Arden Morris et.al [6] on 259 patients and with study by Chandni Ravi et.al [7] in 2012 in which the sensitivity was 94.5%, however this study has diagnostic accuracy of 99% which greatly differs from the results given by Arden Morris et.al [6] in 1998. In this study, every patient underwent radiological evaluation pre-operatively which included sonography in patients less than 35 years of age and sono-mammography in patients above 35 years of age.

This study had sensitivity of 97.3% which is comparable 96% seen by study published by Arden Morris et.al [6], 90.9% seen in study by Kwak et.al [8], 81.3% in study by Karim et.al [9] . however, other studies had drastically low sensitivity for radiological investigations like 75% seen in study by Sachin Prasad et.al (10), 70% seen in study by Purasiri et.al [11] in 1996, and 61% seen in study by Clarke D et.al [12].

This study had sensitivity of 100% with diagnostic accuracy of 99% with FNAC in diagnosing the patient which was comparable to the study by Arden Morris et.al [6] where sensitivity was 100% and study by Kwak et.al [8] in which the sensitivity was 98.6% with diagnostic accuracy of 94.4%, this was however in contrast to the results seen in study by Clarke D et.al [12] which showed sensitivity of mere 53%. Core needle biopsy in this study has sensitivity of 100%, specificity of 100% with 100% positive predictive value of 100%. This coincides with the findings of study by Clarke D et al [12], 2001 in which sensitivity was 97% and while in a study by Karim M et. al [9], the sensitivity was 95.5% for core needle biopsy. The results of the three tests, that is, physical examination, radiological evaluation and FNAC were combined to together for triple assessment of breast. In this study, the sensitivity of triple assessment was 100% with diagnostic accuracy of 100% and positive predictive value of 100%. This was comparable with the results seen in other studies like study by L Irwig et.al [13] in 2001 had sensitivity of 99.6%, Katherine Morris et.al [14], 2001 had sensitivity of 100%, Ibrar A et.al [15], 2007 showed sensitivity of 100%.

Conclusion

Triple assessment, comprising clinical examination, radiologic imaging, and histopathologic evaluation,

is a highly accurate diagnostic approach for evaluating palpable breast lumps. This study confirms that combining these three modalities yields near-perfect diagnostic accuracy, supporting its use as a standard protocol in clinical settings. Further studies with larger sample sizes and in varied demographic settings are needed to generalize these findings. Advances in imaging technology and biopsy techniques may further enhance diagnostic precision, potentially reducing the need for invasive surgery in benign cases.

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