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RESEARCH ARTICLE

COMPARISION OF TRIPLE ASSESSMENT AND HISTOPATHOLOGY RESULTS IN DIAGNOSING BREAST LUMP

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Abstract

Background: Breast lumps constitute a major public health concern, given their potential to signify malignancy and the psychosocial distress they cause. Early and accurate diagnosis is paramount for timely intervention and optimal outco mes. Triple assessment comprisingclinical examination, imaging (mammogra phy and/or ultrasound), and cytopathological evaluationhas long been advocate d for its high diagnostic accuracy. However, histopathological examination of excised tissue remains the definitive standard, creating an ongoing debate about how precisely triple assessment aligns with final histopathology.

Methods: We conducted a Retrospective, observational study conducted over two years (March 2023–April 2025) at Basaweshwar Teaching and General Hospital. Women aged 15 years and above presenting with a palpable breast lump were recruited. Each patient underwent clinical examination, imaging (mammography and/or ultrasound), and fine-needle aspiration cytology (FNAC) as part of the triple assessment. Histopathological evaluation of surgical specimens followed for definitive diagnosis. Data were statistically analyzed to calculate sensitivity, specificity, positive predictive value (PPV), negative predictive value (NPV), and overall diagnostic accuracy.

Results: Among 80 enrolled patients, the mean age was 40.2 years, with the majority presenting with a single, unilateral lump. Triple assessment was highly sensitive (94.4%) and specific (98.4%) PPV of 94.4%, NPV of 98.4%, and accuracy of 98.75%. False negatives occurred primarily in younger patients with dense breast tissue and,also likely due to overlap in cytological features of fibroepithelial lesions (e.g., fibroadenoma vs. phyllodes tumor). There were no false positives. The correlation between triple assessment and histopathological outcomes was statistically significant ($p<0.001$).

Conclusion: Our study demonstrates that triple assessment remains a reliable diagnostic algorithm for breast lumps, closely mirroring definitive histopathology results. While histopathology is the gold standard, the high concordance underscores triple assessment's value in prompt clinical decision-making, particularly in resource-limited settings.

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Introduction:-

Breast pathologies are among the most encountered conditions in clinical practice, with breast cancer ranking as one of the leading causes of cancer-related morbidity and mortality worldwide [1]. Accurate and prompt diagnosis of breast lumps is therefore crucial, both to alleviate patient anxiety and to expedite appropriate treatment [2]. The diagnostic approach to a breast lump typically incorporates multiple modalities, namely clinical examination, radiological imaging, and pathological assessment. Collectively, these three processes are referred to as the "triple assessment" [3].

Historically, each component of the triple assessment has its own merits and limitations. Clinical examination is an essential starting point: experienced clinicians can often differentiate benign from malignant lumps using palpatory findings such as lump texture, mobility, and associated changes in the overlying skin or nipple [4]. Imaging adds another layer of diagnostic accuracy, with mammography recognized as the primary imaging modality for women over 40 years of age. Younger women may receive breast ultrasound due to higher breast density, which can limit mammographic detection [5]. To overcome these challenges, a modified triple test (MTT) has been proposed, replacing mammography with ultrasound (USG) to improve diagnostic accuracy, especially in premenopausal women [6].

The final pillar of the triple assessment involves cytopathological or histopathological evaluation. Fine-needle aspiration cytology (FNAC) is frequently employed as a minimally invasive procedure, providing rapid insight into the nature of the lesion. However, FNAC can occasionally yield inconclusive or indeterminate results, often necessitating a core needle biopsy for more definitive findings [7]. Ultimately, a surgical specimen's histopathological report is considered the gold standard because of its superior ability to delineate tumour architecture and subtype [8].

Despite the ubiquity of triple assessment, questions remain regarding the extent to which it correlates with final histopathological results. Discrepancies may arise due to subjective variation in clinical assessment, technical issues in imaging or sampling, or interpretative challenges. The present study seeks to evaluate the diagnostic concordance between triple assessment and final histopathology for breast lumps, thereby shedding light on the reliability, potential pitfalls, and clinical significance of employing a triple assessment protocol. By delineating the strengths and limitations of triple assessment, we aim to contribute evidence that can inform both clinicians and policymakers seeking to optimize breast lump diagnostics and resource allocation.

Materials and Methods:-

Study Design and Setting:

This Retrospective, observational study was carried out in the Department of Surgery at basaweshwar teaching and general hospital attached to Mahadevappa Rampure Medical College over a period of two years from March 2023 to April 2025. Ethical clearance for the study was obtained from the Institutional Review Board before participant enrolment. Written informed consent was secured from each participant, ensuring adherence to ethical principles.

Patient Selection:

Inclusion Criteria:

1.Women aged 15 years and above presenting with a palpable breast lump were considered eligible.

Exclusion criteria:

1.Pregnant or lactating women,

2.Patients with recurrent breast cancer or a history of prior breast surgery, and

3.Those who opted out of surgical intervention. Patients with suspicious findings who declined biopsy or surgical consultation were also excluded.

Methodology:-

After recording baseline demographic information, a detailed history was taken from each participant, focusing on duration of the lump, any recent changes in its size, breast pain, family history of breast disease, and previous breast evaluations.

1. **Clinical Examination**: All participants underwent a standardized clinical breast examination performed by two independent surgeons. Observations included lump location, size (measured in centimetres), mobility, surface characteristics, and any skin or nipple abnormalities. Clinical findings were categorized as benign, suspicious, or malignant based on a consensus of the two examiners.

2. **Imaging**: Mammography was performed for women aged 40 years and older, while younger women underwent targeted breast ultrasound. In select cases with equivocal findings, both mammography and ultrasound were performed. Imaging results were classified according to the Breast Imaging Reporting and Data System (BI-RADS) by American College of Radiology.
   For the purposes of this study, BI-RADS 1-2 were grouped together as benign lesions and BI-RADS 3-4b were suspicious and BI-RADS 4c-6 were grouped together as malignant lesions. The USG findings were categorized into benign ,suspicious and malignant lesions..
3. **Cytopathology**: Fine-needle aspiration cytology (FNAC) was performed using a 22-gauge needle under ultrasound guidance when necessary. patients were subjected to FNAC after obtaining informed consent. Direct smears prepared were fixed in 95% ethyl alcohol for at least 30 minutes or overnight and fixed smears were stained using PAP and H&E stain while air dried smears were stained with May Grunwald Giemsa (MGG) stain. The cytology smears were categorized into diagnostic categories (C1- C5) proposed by National Cancer Institute (NCI) in 1996. Final cytology diagnosis was categorized into benign (category C2) suspicious (category C3) and malignant (category C4,C5) lesions.

Triple Assessment Categorization:
Clinical examination, imaging, and cytopathology findings were synthesized to arrive at a composite triple assessment result. For instance, if any single component indicated suspicion for malignancy while others suggested benign changes, the overall interpretation was considered "suspicious." If two or more components concurred on malignancy, the triple assessment was deemed positive for malignancy.

Definitive Histopathology:
Surgical excision (lumpectomy or mastectomy) was performed based on clinical judgment, patient preference, and the triple assessment outcome. Final histopathology was conducted on the excised specimens. Tissue blocks were stained with haematoxylin and eosin, and additional immunohistochemical stains were applied as indicated. The histopathological diagnosis was considered the gold standard reference.

Statistical Analysis:
Data were analysed using appropriate statistical software (SPSS version 25). The sensitivity, specificity, positive predictive value (PPV), and negative predictive value (NPV) of triple assessment were computed. Agreement between triple assessment and definitive histopathology was measured using Cohen's kappa. A p-value <0.05 was deemed statistically significant.

Results:-

Overview of Study Population:
A total of 80 patients fulfilling the inclusion and exclusion criteria were enrolled. The mean age of participants was 40.2 years (range: 15–72 years). Among them, 61 patients(76.2%) were premenopausal, and 19 patients(23.7%) were postmenopausal. A majority 52 patients (65%) presented with a lump in the right breast. Nearly 48 patients (60%) of lumps were located in the upper outer quadrant—a common site for both benign and malignant breast lesions.
The first observation gleaned from clinical examination revealed that approximately 56 (70%) cases were characterized as benign and 14 (17.5%) as malignant, while 10 (12.5%) were deemed suspicious. Mammography or ultrasound imaging delineated roughly 16 (20%) masses as malignant (BI-RADS 4 or 5). On cytopathological assessment, 57 (71.25%) were reported as benign, 17(21.2%) as malignant, and 6 (7.5%) as atypical or suspicious.

Clinical Breast Examination:
On the basis of clinical breast examination 70% of patients breast lump felt benign ,12.5% of patients breast lump were suspicious, and 17.5% were malignant with features of fixity and skin dimpling

Table 1:-Grading of breast lesions on Clinical breast examination.

Clinical Breast examination	Clinical Examination	%age
Benign	56	70
Suspicious	10	12.5
Malignant	14	17.5
Total	**80**	**100**

Mammography/Ultrasonography:
In this study , population of women less than 40 yrs with breast lump were more (61 cases) hence ultrasound modality used in contrast to women over 40 yrs(19 cases) where mammography was used, due to decreased sensitivity in denser breast.

Table 2:- Grading of breast lesions on imaging.

BI-RADS Category	Mammographic Diagnosis (Cases)	Ultrasonography (Cases)	Total per Category
Benign (BI-RADS 1-2)	2	42	44 (55%)
Suspicious (BI-RADS 3-4b)	6	14	20 (25%)
Malignant (BI-RADS 4c-6)	11	5	16 (20)

FNAC (Cytopathology):
On the basis of FNAC findings 18 (22.5%) of cases were found out to be having carcinoma breast and, 2(2.5%) were found to have atypical cells and termed suspicious were needed to be investigated further and 60(75%) were having benign disease.

Table 3:- Results of breast lesions on FNAC.

FNAC (Cytopathology)	No. of cases	%age
Benign	60	75
Suspicious	2	2.5
Malignant	18	22.5
Total	**80**	**100**

Distribution of patients on all the four modalities [Clinical breast examination +mammography+FNAC and histopathology]
On the basis of the results of each investigational modality three categories for each as follows: benign, suspicious and malignant. FNAC was out to give more similar results as compared to histopathology whereas clinical breast examination tends to vary in results as compared to histopathology when considered alone.

Table 4:- Distribution of type of lesions on CBE, imaging, FNAC and HPE.

Category	Clinical breast examination	Sonomammography	FNAC	Histopathology
Benign	56	44	60	62
Suspicious	10	20	2	0
Malignant	14	16	18	18

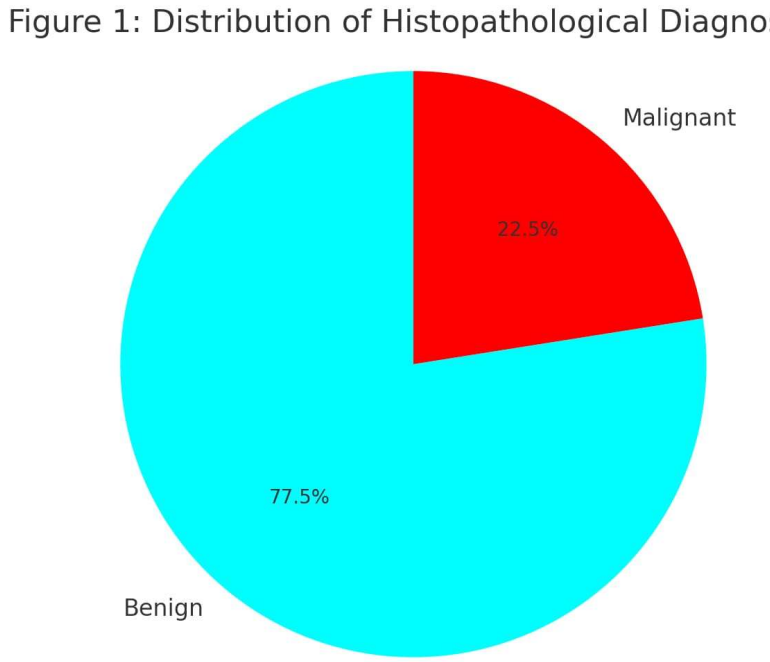

Figure 1:- Distribution of Histopathological Diagnosis

On Histopathology ,Out of 80 specimens, 62 cases(77.5%) were benign, 18 cases(22.5%) were malignant

Diagnostic efficacy of triple test according to histopathological diagnosis (Gold standard)
On comparison of modality of triple assessment (CBE, USG/Mammo and FNAC) with histopathology, showed statistically significant correlation with p value of <0.002.

True positive(TP)- Test and histopathology both show malignant
True negative(TN)- Test and histopathology both show benign
False positive(FP)- Test show malignant or suspicious, but histopathology shows benign
False negative(FN)- Test shows benign ,but histopathology shows Malignant.

Modality of triple assessment		No. of cases	Histopathology		P- Value
			Benign	Malignant	
Clinical Breast Examination	Benign	56	62	4	
	Suspicious	10	-	-	
	Malignant	14	0	14	
Sonomammography/ Mammography	Benign	44	62	2	
	Suspicious	20	-	-	
	Malignant	16	0	16	
FNAC	Benign	60	62	0	
	Suspicious	2	-	-	
	Malignant	18	0	18	
Triple assessment test	Benign	62	62	0	
	Suspicious	1	-	-	<0.002
	Malignant	17	0	18	

In clinical breast examination, 14 cases which were malignant were proven to be same in histopathology(**TP-14**), whereas out of 56 benign and 10 suspicious cases , 62 were benign and 4 cases turned out to be malignant in histopathology.(**FN-4**).

In sonomammography/ Mammography, 16 cases were malignant proved ro be the same in histopathology(**TP-16**) ,there were 20 suspicious cases probably because majority of the cases were fibroadenoma which comes under BI-RADS 3 or 4 which were according to the study were categorized in suspicious .

Out of 44 benign and 20 suspicious cases in sonomammography/ Mammography, 62 were confirmed benign in histopathology , whereas 2 cases turned out to be malignant (**FN-2**).
In cytopathology 18 cases were proven to be malignant in histopathology(**TP- 18**), whereas out of 60 benign and 2 suspicious cases ,1 case turned out to be benign in histopathology (**FP-1**) ,

This can be explained as both fibroadenoma and phyllodes tumours are 'fibroepithelial lesions' in FNAC as it is cannot reliably differentiate between phyllodes tumour and fibroadenoma with high confidence as well cannot grade phylloids(Benign vs malignant), making histopathology as definitive tool for diagnosing

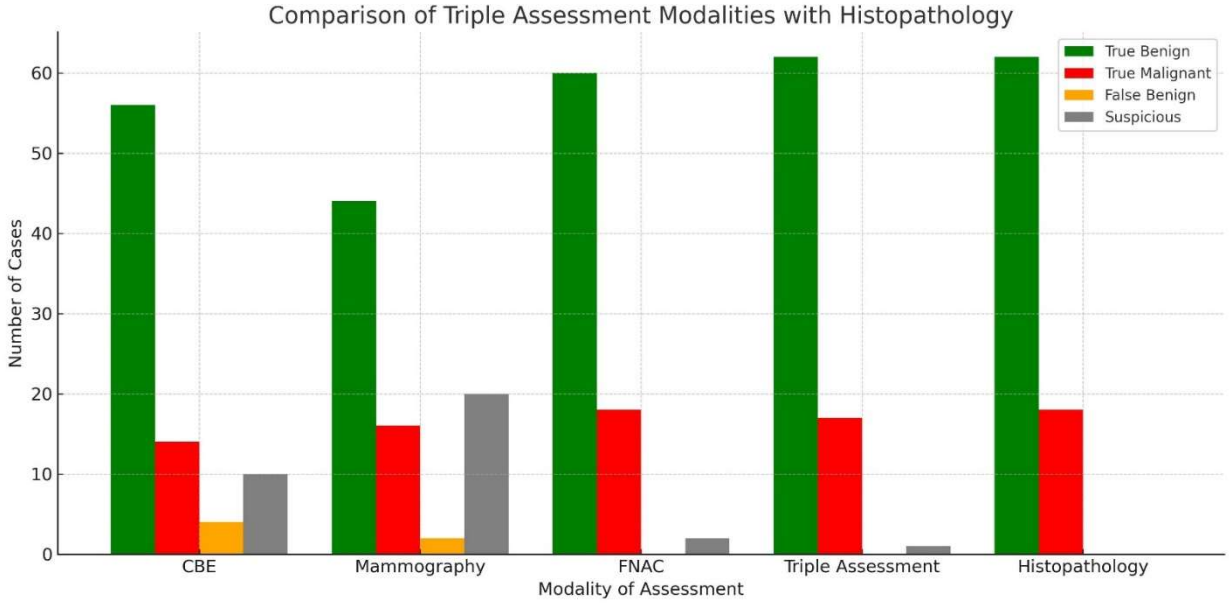

Figure 2:-Comparision of triple assesement vs HPE.

Here's the bar graph showing the performance of each modality in the triple assessment (CBE, Mammography, FNAC, and Triple Assessment Test) against histopathology. It displays:

1. True Benign (green): Cases correctly identified as benign.
2. True Malignant (red): Cases correctly identified as malignant.
3. False Benign (orange): Malignant cases misclassified as benign. Indicating False positive,seen in clinical examination and imaging modality, which were nil in FNAC.
4. Suspicious (gray): Indeterminate cases, seen more in imaging modalities

Lesions turning out malignant after being classified as benign or suspicious(False negative results) is often due to:
-Small or deep seatedtumours that are not palpable,
-Dense breast tissue which can obscure masses,
-Technical limitations of individual diagnostic modalities.

This visual clearly shows that the Triple Assessment Test has the best alignment with histopathology, with no false benign cases and the highest true benign and true malignant counts combined.

Statistical Evaluation of Triple Assessment:
The triple assessment test showed high sensitivity when compared to each modality of triple test

Statistics	Clinical Examination	Sono Mammography/ Mammography	FNAC	Triple Assessment
Sensitivity	77.8%	88.9%	94.4%	94.4%
Specificity	100%	100%	98.3%	98.4%
Positive Predictive Value	100%	100%	94.4%	94.4%
Negative Predictive Value	93.3%	95.6%	98.3%	98.4%
Accuracy	94.6%	96.7%	97.4%	98.75%

Cytopathology demonstrated the highest sensitivity . Imaging outperformed clinical examination, though all three components individually showed reasonable accuracy. When combined, the synergy of these modalities improved overall diagnostic confidence

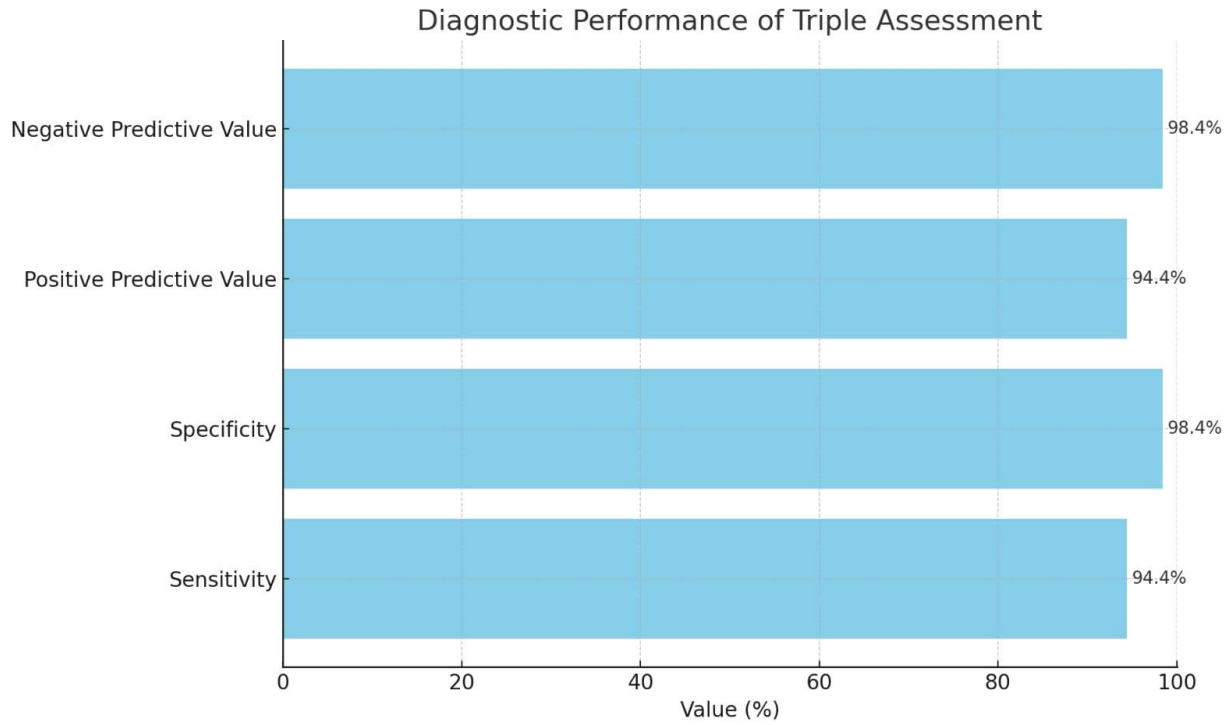

Figure 3:- Diagnostic performance of triple assesement.

A high sensitivity of 94.4% reflects the method's capability to detect the majority of malignant lesions. The specificity of 98.4% indicates a low rate of labelling benign lesions as malignant. Similarly, the high NPV suggests a negligible probability of undetected malignancy when the triple assessment concludes a lesion is benign.

Table 3:- Distribution of Benign and Malignant Lesions based on HPE.

Lesion Type	**Frequency (n=80)**	**Percentage (%)**
Fibroadenoma	32	40
Fibrocystic Changes	12	15
phylloidstumor(Benign)	5	6
Abscess	7	8
Traumatic fat necrosis	4	5
Duct ectasia	2	2.5

Invasive Ductal Carcinoma	8	10
Invasive Lobular Carcinoma	3	3.75
Ductal carcinoma in situ	6	7.5
Malignant phylloids	1	1.25

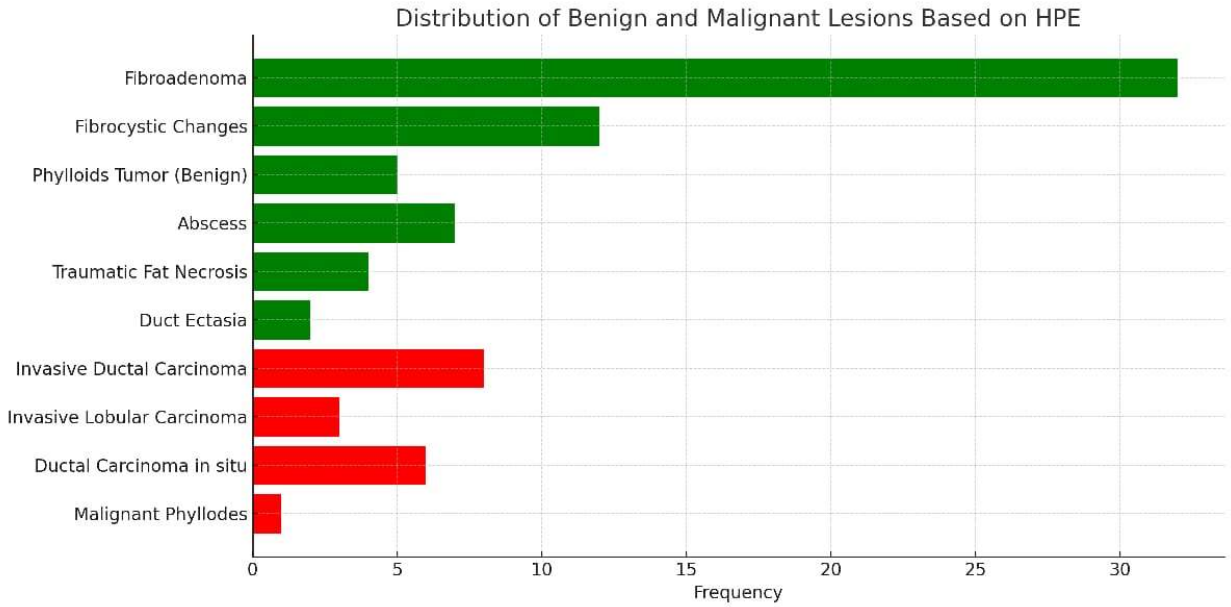

Figure 4:- Green indicates Benign ,Red indicates Malignant lesions.

Discussion:-

Triple assessment has become a cornerstone in the diagnostic process of breast lumps because it effectively harmonizes three distinct yet complementary methodologies: clinical examination, radiological imaging, and pathological analysis [9]. Our findings reinforce the consensus that triple assessment offers a high degree of diagnostic reliability, closely aligning with histopathological conclusions. In this study, the sensitivity and specificity values (94.4% and 98.4%, respectively) are comparable to other investigations reporting the robust performance of triple assessment in breast centres worldwide [10,11].

These data suggest that, while histopathological evaluation remains the gold standard, triple assessment is a pragmatic and resource-efficient means to guide clinical decision-making. High negative predictive value (98.4%) in our results implies that a triple assessment diagnosis of “benign” can reassure patients, potentially circumventing unnecessary, more invasive procedures [12]. This aspect is of particular importance in resource-limited settings, where the availability of advanced diagnostic tools may be limited. By the same token, the relatively modest number of false positives underscores the low risk of subjecting patients to overtreatment for benign pathologies [13].
Nonetheless, discrepancies between triple assessment and final histopathology were noted. Younger, premenopausal women exhibited a slightly lower concordance, likely driven by challenges in imaging dense breast tissue, an obstacle also emphasized in previous studies [14]. Such results underline the necessity for a tailored diagnostic strategy—particularly in equivocal or suspicious cases—where advanced imaging techniques (e.g., MRI) or more thorough sampling with core needle biopsy may be warranted.

An intriguing outcome of our study was the relatively small butnumber of false negatives . These cases predominantly involved clinically subtle lesions and borderline cytological features. As such, clinicians must remain vigilant, especially in individuals who present with significant risk factors such as a strong family history or genetic predisposition.

Moreover, the integration of molecular diagnostic techniques into routine breast evaluation may further refine the diagnostic pathway. Genetic and proteomic profiling could, in future, supplement triple assessment, making an already robust approach even more accurate and personalized. Finally, while our data reflect the potential for broad applicability, one must remember the study's local context and sample size. The results highlight the need for multi-institutional studies with larger patient cohorts to corroborate these findings and potentially generalize them to heterogeneous populations [9,11].

In conclusion, our study reaffirms that triple assessment stands as a highly effective diagnostic algorithm for breast lumps, with performance metrics that approximate the definitive histopathological outcomes. It provides reliable guidance in distinguishing benign from malignant lesions, enabling timely clinical decisions that are central to optimal patient care.

Conclusion:-

In this study, triple assessment demonstrated high diagnostic concordance with final histopathological findings for breast lumps. Our results indicate that the combination of clinical examination, imaging, and cytopathological evaluation consistently identifies malignancies while minimizing unnecessary invasive procedures. Nevertheless, vigilance is required for younger patients and atypical presentations, which may warrant additional diagnostic layers. Overall, triple assessment remains an invaluable strategy in breast care, streamlining the diagnostic pathway and contributing to prompt, evidence-based management.

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