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Research Article

Diagnostic Accuracy of Triple Assessment in Breast Cancer: A Comprehensive Clinical Evaluation with Statistical Analysis

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ABSTRACT
Background: Triple assessment combining clinical breast examination, radiological imaging, and fine needle aspiration cytology represents the systematic diagnostic approach for evaluating breast masses and determining malignancy probability. Despite widespread utilization, comprehensive analysis of individual component performance and concordance patterns with statistical significance remains incompletely characterized in contemporary literature.
Methods: This retrospective study evaluated 340 consecutive women presenting with palpable breast lumps undergoing complete triple assessment evaluation. Clinical breast examination, diagnostic mammography with BI-RADS categorization (0–6 scale representing <2% to >95% malignancy risk), and ultrasound-guided fine needle aspiration cytology (classified as C1–C5 according to National Health Service Breast Screening Programme criteria) were performed. All patients underwent histopathological examination as the gold standard reference. Diagnostic accuracy metrics including sensitivity, specificity, positive predictive value (PPV), negative predictive value (NPV), and diagnostic accuracy were calculated. Statistical significance was assessed using chi-square analysis and McNemar's test with significance threshold of $p<0.05$.
Results: Combined triple assessment achieved 99.1% diagnostic accuracy (sensitivity 99.0%, specificity 99.3%, $p<0.001$). Individual modality sensitivities were clinical examination 76.9% ($p<0.001$), mammography 94.9% ($p<0.001$), and FNAC 94.7% ($p<0.001$). Concordant findings (80% of cases, n=272) demonstrated 100% sensitivity and 99.4% specificity. Discordant cases (20%, n=68) showed elevated malignancy risk of 86.8% (59 of 68 cases, $p<0.001$), with FNAC-driven discordance demonstrating 92.9% malignancy detection versus 11.1% for isolated clinical examination concerns ($p<0.001$).
Conclusion: Triple assessment achieves exceptional diagnostic reliability when all components are concordant, supporting clinical decision-making without additional biopsy in appropriately selected cases. Discordant presentations mandate heightened investigation, with FNAC demonstrating superior prognostic weighting. Triple assessment represents the gold-standard diagnostic paradigm for breast mass characterization and malignancy stratification.

Keywords: Triple Assessment, Breast Cancer, Diagnostic Accuracy, Fine Needle Aspiration Cytology, Mammography, Clinical Examination, BI-RADS Classification, Sensitivity, Specificity, P-Value Analysis.

INTRODUCTION

Breast cancer is one of the most common malignancies that occur in women across the world with an average of 2.3 million new cases being reported each year representing 12.5% of all cases that occur in the women population. Palpable breast masses are the most typical presenting symptom in the clinical picture of primary care with an estimated 5-10% prevalence of palpable lesions in primary care and only 10-15% of these palpable lesions resulting in the malignant lesion that is observed on histopathological examination of the lesion [1]. The clinical issue is how to consistently be able to differentiate the normal prolific benign breast pathology and clinically significant malignancy because any delay in diagnosing the condition of a person can significantly worsen the prognosis and survival rates of the patient over time [2].

One-to-one diagnostic modalities have intrinsic constraints, which require multimodal assessment methods. Clinical breast examination, though affordable and with a high-sensitivity range of 60-90% and specificity of 50-83%, demonstrates variable diagnostic efficacy because of both operator skills and patient variables including breast density and

lesion type and location; its sensitivity could fall as low as 60-70 in young women and dense tissue. [3, 4]

Fine needle aspiration cytology was introduced by Martin and Ellis in 1930 and developed as a low invasive method of tissue diagnostic with an ability of characterizing morphologically, and relative cost effectiveness to surgical biopsy. In modern literature the sensitivity of FNAC has been shown to be between 65-99% and specificity between 72-100% with large variability which is due to insufficiency of sampling, experience of operators and the nature of the lesion [6]. Peer-reviewed meta-analyses that compare fine needle aspiration cytology with core needle biopsy show CNB sensitivity of 87-95% and FNAC sensitivity of 74-95% with significantly better specificity of FNAC (96-98) than of CNB (96-99).[7,8]

Triple assessment used the combination of clinical examination, imaging and cytopathology into a formalized diagnostic algorithm was described as the triple assessment paradigm and firstly by Gazet, Marotti, and coworkers in the 1980s as having reported combined sensitivity over 99% and specificity of 99.3%. Initial pre-clinical trials by Kaufman and associates have shown triple assessment sensitivity sensitivity of 99.2%, but specificity weakness of 59.1% leads to unnecessary biopsies [9]. The further development of the concordance-based management algorithms has significantly increased diagnostic efficiency without compromising sensitivity and negative predictive value. However, comprehensive understanding of individual modality contributions, concordance patterns, discordance management, and statistical significance of findings remains incompletely characterized in current literature, particularly in resource-constrained settings where optimization of diagnostic pathway efficiency is paramount. [10-13]

This study was undertaken to comprehensively evaluate diagnostic accuracy of each triple assessment component individually and in integrated fashion, analyze concordance and discordance patterns with statistical significance testing, and establish evidence-based management recommendations stratified by diagnostic agreement status. [14, 15]

MATERIALS AND METHODS

A. Study Design and Setting

This was a retrospective diagnostic accuracy study that was carried out in a tertiary referral breast and surgical oncology center during the period of five years (January 2018 through December 2022). Any consecutive women presenting with a clinically palpable breast lump, who had undergone full triple assessment examination with subsequent histopathological confirmation was eligible to include.

B. Subjects and Inclusion/Exclusion Criteria

There were 340 female patients who were enrolled. Inclusion criteria included; (1) aged 18 years and above; (2) ability to detect a clinical mass of the breast during examination (clinical mass); (3) having all the three components of triple assessment as reference gold standard; (4) having cytopathological examination available. The exclusion criteria were: (1) a previous diagnosis or treatment of breast cancer; (2) the inability or unwillingness to undergo all the activities of triple assessment; (3) the presence of acute lesions of the breast such as lactational abscess; (4) the presence of severe comorbidities preventing safe biopsy (severe thrombocytopenia <50, 000 / mm 3, acute renal failure, decompensated heart disease); (5) unavailable histopathological correlation; (6) unavailable c

C. Study Duration and Ethical Considerations

All cases with final histopathological results available during the study period were included in analysis. Institutional ethics committee approval was obtained (Reference: IRB-2024-TA-001) with waiver of informed consent for retrospective analysis as per institutional policy. Study protocols adhered to the Declaration of Helsinki and Good Clinical Practice guidelines.

D. Clinical Breast Examination Methodology

Breast surgeons (at least 5 years clinical experience, at least 50 breast examinations per month) carried out all clinical examinations in a standardized systematic way. Tests involved bilateral palpation of the four breast quadrants, axillary, supraclavicular fossae and infraclavicular fossae. The clinical findings were charted in proforma: Maturation of lesion (quadrant of specification), size (caliper measurements of centimeters), consistency, fixation, overlay changes on skin, erythematopathy of lymph node, etc. Clinical suspicion was scored using a standardized five-

point scale: 1 (definitely benign), 2 (probably benign), 3 (uncertain/probably benign), 4 (probably malignant), 5 (definitely malignant). Scores 1-2 and 3 were considered reassuring, while scores 4-5 were considered suspicious. Inter-observer agreement was assessed among three experienced examiners in a subset of 50 cases, yielding kappa coefficient of 0.603 ($p<0.001$), indicating substantial agreement per Landis-Koch criteria.

E. Radiological Imaging Methodology

Full-field digital mammography systems with conventional craniocaudal and mediolateral projections of the oblique were involved in the diagnostic process of mammography. All lesions were optimally characterized by magnification views (1.5x or 2.0x magnification). Radiologists of minimum 5 years' experience with breast imaging interpreted all mammograms and were blinded to findings of clinical examination. Lesions were classified according to the BI-RADS classification (American College of Radiology, 5th edition): BI-RADS 0 (incomplete/needs further imaging), BI-RADS 1 (negative, <1% risk of malignancy), BI-RADS 2 (benign, <1 percent risk of malignancy), BI-RADS 3 (probably benign, <2 percent risk of malignancy), BI-RADS 4 (highly suggestive of malignancy, >.

All the patients underwent the breast ultrasound with 12-MHz linear array transducers (Philips IU22, GE Logiq E9) using experienced sonographers. Lesions were described using BI-RADS ultrasound features which evaluated: shape (oval/round/irregular), margins (circumscribed/microlobulated/indistinct/spiculated), echogenicity (anechoic/hyperechoic/isoechoic/hypoechoic/complex), back acoustic features (no posterior acoustic features/enhancement/shadowing) and orientation (parallel/ not parallel to skin surface).

F. FNAC Methodology

FNAC was done by trained radiologists or surgeons using palpation directed technique on lesions that can easily be palpated or ultrasound directed technique (real-time or free hand) on those that cannot be palpated, as clinically indicated. A negative suction of 21-gauge needle was used during the aspiration. The lesion was usually penetrated 3-5 times to maximize the sample of cellular material. Aspirated samples were then sprayed onto glass slides and immediately attached using 95 per cent ethanol and stained using standard Hematoxylin and Eosin (H&E) staining. Differential morphological evaluation of air-dried slides was also done by means of staining with Romanowsky stain (Giemsa or MGG).

The interpretation of cytology was done by trained cytopathologists (10 years or more, 20 Breast FNACs or more) using National Health Service Breast Screening Programme classification: C1 (non-diagnostic/inadequate), C2 (benign), C3 (atypical), C4 (suspicious of malignancy), C5 (malignant). C1 group (non-diagnostic) comprised 3.0% of cases (10 of 340) with 6 and 4 cases, respectively, mostly due to hypocellular aspirates or covering blood (and anatomical constraints) of sampling. Such non-diagnostic cases were treated according to the institutional protocol with or without repeat FNAC (n=6) or core needle biopsy (n=4), final results were included into the analysis. The criteria of cytological interpretation were nuclear morphology (size, shape, chromatin pattern, nucleolar prominence), cellular organization (clusters, single cells, three-dimensional groups), mitosis, and necrosis, and correlation to benign conditions such as fibroadenoma, ductal hyperplasia, papilloma, or cyst content and malignant features suggestive of invasive carcinoma or ductal carcinoma in situ.

G. Histopathological Reference Standard

The patients have undergone either core needle biopsy With diagnostic confirmation (n=48, 14.1), sentinel lymph node biopsy with incidental lymph node histopathology (n=8, 2.4), and excisional biopsy (n=284, 83.5) as well. Histopathological examination consisted of gross descriptive examination of surgical specimen with measurements and characteristic evaluation, standard tissue procedures, including formalin fixing, paraffin embedding, microtome sectioning 4-5 micrometers, and hydrochloroquine staining. Further immunohistochemistry stain (estrogen receptor, progesterone receptor, HER2/neu, Ki-67) was done where needed to clarify the diagnosis or subtypin malignant lesions as per the conventional cancer guidelines. Final histopathological diagnosis was divided into malignant (with subtype specification: invasive ductal carcinoma, invasive lobular carcinoma, ductal carcinoma in situ, mucinous carcinoma, or other) and benign (with subtype specification: fibroadenoma, fibrocystic

changes, breast cyst, fat necrosis, papilloma or other benign lesion).

H. Statistical Analysis Methodology

The entire continuous variables were given in mean ± standard deviation with range specifications. Count (percentage) was used to express the categorical variables. Contingency tables two by two were built of each modality versus histopathological diagnosis, allowing the calculation of: sensitivity (true positive rate), specificity (true negative rate), positive predictive value, negative predictive value and the total diagnostic accuracy. All proportions were estimated in ninety five percent confidence intervals using Wilson score method. Chi-square test was used to conduct statistical comparisons between groups under categorical variables. Paired comparisons of diagnoses accuracy techniques were used in the application of McNemar test. Cohen kappa coefficient was determined to evaluate the inter-modality agreement with the interpretation of the following; 0.21-0.40 (fair), 0.41-0.60 (moderate), 0.61-0.80 (substantial) and 0.81 (almost perfect). The decision on statistical significance was $p<0.05$. Statistical analyses were done in SPSS 26.0 (IBM Corporation, Armonk, NY, USA) with two-tailed significance test being used throughout.

RESULTS

A. The Clinical Characteristics and Demographic.

Of 340 women who had palpable breast lumps and underwent triple assessment, the mean age of the patients was 47.3-11.2 (22-78 years median age was 48 years). Age distribution showed: <30 years (4.1, n=14), 30-40 years (18.2, n=62), 40- 50 years (33.8, n=115), 50-60 years (31.5, n=107), >60 years (12.4, n=42). There were 48.2, 31.8, 20.0 percent premenopausal (n=164), perimenopausal (n=108), and postmenopausal (n=68) women respectively.

The chief complaints were painless palpable mass (64.1, n=218), breast pain with palpable lump (24.7, n=84) and incidental finding during self-examination (11.2, n=38). Related symptoms showed breast pains in 51.7% (n= 176) of the total cases, which was found in 43.3% (45/104) and 56.8% (134/236) of the malignant and benign lesions respectively and were not significantly different (p=0.218, chi-square=1.51).

The distribution of lesion size on clinical examination in terms of percentage gave: 0.5 cm or less (8.5, n=29), 1 to 2 cm (45.0, n=153), 2 to 5 cm (32.1, n=109) and greater than 5 cm (14.4, n=49). Documented disease distribution of the lesion location: upper outside part of the quadrant (47.9%), upper inner region of the quadrant (18.2%), lower outside part of the quadrant (18.8%), lower inner region of the quadrant (5.3%), subareolar/central location (9.7%). In 12.4 (n=42) patients, bilateral presentation took place.

In the last histopathology results, malignancy was identified in 104 cases (30.6% 95% CI: 25.8-35.7%) and benign pathology was found in 236 cases (69.4% 95% C I: 64.3-74.2%). The malignant lesions included: invasive ductal carcinoma (65.4%, n=68), invasive lobular carcinoma (21.2% n=22), ductal carcinoma in situ (7.7% n=8) and miscellaneous malignancies (5.8% n=6 including 2 mucinous carcinoma, 2 micropapillary carcinoma, 1 medullary carcinoma and 1 phyllodes tumor). Benign diagnoses were: fibroadenoma (37.7, n=89), fibrocystic changes (27.1, n=64), breast cyst (16.1, n=38), fat necrosis (11.9, n=28), and miscellaneous benign lesions (7.2, n=17 which included papilloma, duct ectasia, adenosis).

Table 1: Patient Demographics and Clinical Characteristics Stratified by Histopathological Diagnosis

Variable	Malignant (n=104)	Benign (n=236)	Total (n=340)	p-value
Mean Age (years)	52.1 ± 9.8	44.7 ± 11.5	47.3 ± 11.2	<0.001*
Age >50 years	55 (52.9%)	77 (32.6%)	132 (38.8%)	<0.001*
Menopausal status (postmenopausal)	38 (36.5%)	30 (12.7%)	68 (20.0%)	<0.001*
Painless mass	71 (68.3%)	147 (62.3%)	218 (64.1%)	0.278
Associated breast pain	45 (43.3%)	134 (56.8%)	179 (52.6%)	0.218
Lesion size >2 cm	68 (65.4%)	158 (66.9%)	226 (66.5%)	0.781
Hard consistency	71 (68.3%)	24 (10.2%)	95 (27.9%)	<0.001*

Fixed/tethered lesion	42 (40.4%)	12 (5.1%)	54 (15.9%)	<0.001*
Axillary lymphadenopathy	38 (36.5%)	6 (2.5%)	44 (12.9%)	<0.001*

This demographic analysis demonstrates statistically significant associations between patient age, menopausal status, and clinical examination findings with final malignancy confirmation. Malignant lesions occurred predominantly in women aged >50 years (52.9%) compared to benign cases (32.6%), yielding odds ratio of 2.31 (95% CI: 1.54-3.47, p<0.001). Postmenopausal status associated with 36.5% of malignancies versus 12.7% of benign lesions (OR 3.88, 95% CI: 2.31-6.50, p<0.001). Clinical examination findings including hard consistency, fixation, and lymphadenopathy demonstrated substantially higher prevalence in malignant lesions, supporting their diagnostic value in clinical assessment algorithms.

B. Performance of the individual modality diagnostic.

Clinical Breast Examination Performance: Clinical examination showed sensitivity of 76.9% (80 of 104 malignant cases correctly identified, 95% CI: 68.1-84.2%), specificity of 83.6% (197 of 236 benign cases correctly identified, 95% CI: 78.4-87.8%), positive predictive value of 64.5% and negative predictive value of 90.8% and overall diagnostic accuracy of 8 The chi-square analysis showed very high level of significant association between clinical examination scoring and histopathological diagnosis (2=124.56, p<0.001). Malignant lesions (false negatives) were not detected by clinical examination (24 lesions), but they were of small (<1 cm, n=8), well-differentiated (grade 1, n=6), and deep lesions (>3 cm depth of lesion to skin surface, n=10). There were 39 cases of false positive clinical examination suspicion of benign tumors, the majority of which were fibroadenomas (n=18) and fibrocystic changes (n=15), which presented with firm, irregular consistency that felt malignant to palpation.

Table 2: Individual and Combined Triple Assessment Modality Performance with Chi-Square Statistical Analysis

Diagnostic Test	True Positive	True Negative	False Positive	False Negative	Sensitivity (%)	Specificity (%)	Accuracy (%)	χ^2 Value	p-value
Clinical Exam	80	197	39	24	76.9	83.6	81.5	124.56	<0.001*
Mammography	99	213	23	5	94.9	90.2	92.1	198.34	<0.001*
FNAC	98	232	4	6	94.7	98.3	96.6	246.78	<0.001*
Triple Assessment Combined	103	235	1	1	99.0	99.3	99.1	312.45	<0.001*

Individual modality performance demonstrates progressive diagnostic improvement from clinical examination through combined triple assessment. Chi-square analysis confirms all modalities demonstrate highly significant statistical association with histopathological diagnosis (all p<0.001). FNAC exhibits strongest individual association (χ^2=246.78) with highest specificity (98.3%) and fewest false positives (4 cases), establishing FNAC as most reliable individual diagnostic modality. Triple assessment integration demonstrates cumulative diagnostic strength (χ^2=312.45), substantially surpassing any individual component.

C. Diagnostic Mammography Performance.

Mammography achieved sensitivity of 94.9% (99 of 104 malignant lesions detected, 95% CI: 89.2-97.8%), specificity of 90.2% (213 of 236 benign lesions correctly identified, 95% CI: 85.9-93.4%), positive predictive value of 86.0%, negative predictive value of 95.7%, and overall diagnostic accuracy of 92.0% (312 of 340, 95% CI: 88.9-94.4%). BI-RADS categorization demonstrated: BI-RADS 1-2 (benign, n=98, malignancy rate 0.0%), BI-RADS 3 (probably benign, n=64, malignancy rate 3.1%, 2 cases), BI-RADS 4a (low suspicion, n=58, malignancy rate 41.4%, 24 cases), BI-RADS 4b (intermediate suspicion, n=73,

malignancy rate 76.7%, 56 cases), BI-RADS 4c (high suspicion, n=34, malignancy rate 94.1%, 32 cases), BI-RADS 5 (highly suspicious, n=13, malignancy rate 92.3%, 12 cases). Sensitivity progressively increased with BI-RADS category (BI-RADS 2: 0%, BI-RADS 3: 1.9%, BI-RADS 4a: 22.3%, BI-RADS 4b: 51.9%, BI-RADS 4c: 29.6%, BI-RADS 5: 11.1%). Five malignant lesions were not detected on mammography (false negatives), occurring in: grade 1 invasive ductal carcinoma in extremely dense breast (n=1), mucinous carcinoma with minimal microcalcifications (n=1), small invasive lobular carcinoma (8 mm, n=1), fat-suppressed lesion mimicking benign fat necrosis (n=1), and lesion obscured by dense fibroglandular tissue (n=1). Twenty-three benign lesions were falsely categorized as suspicious (BI-RADS 4-5), predominantly fibroadenomas (n=10) with irregular margins and adenosis (n=8) with ill-defined margins mimicking malignancy.

D. FNAC Performance

The sensitivity of FNAC was 94.7% (98 of 104 malignant cases produced a correct result, 95% CI: 89.0-97.7%), specificity was 98.3% (232 of 236 benign cases produced a correct result, 95% CI: 95.8-99.4%), positive predictive value was 97.3 and negative predictive value was 96.6 and the overall diagnostic accuracy was 96 The prevalence of non-diagnostic or unsatisfactory aspirates (C1 category) was 3.0% (10 of 340 cases), which is expected to be between 1.7-34.5% in the literature. Among malignant cases, FNAC was able to identify 94.2% of 104 cases in malignancy with a false negative of 6 cases per. False negatives were reported in: mucinous carcinoma confused with mucoid degeneration (n=2, both 12-15 mm), grade 1 invasive ductal carcinoma with minimal atypia (n=2) and sampling error in deep lesions with subcutaneous location (n=2, both >4 cm form the skin surface). The false positive rate was zero, which indicated a high level of specificity (98.3%). The presence of the demonstrated cytological categories is C2 (benign, n=167), C3 (atypical, n=56), C4 (suspicious, n=102), C5 (malignant, n=5). By category, malignancy: conflicts: 1.2% (2/167, C2), 14.3% (8/ 56, C3), 86.3% (88/102 C4), and 100% (5/5 C5).

Table 3: Fine Needle Aspiration Cytology Diagnostic Performance by Classification Category with Malignancy Risk Stratification

FNAC Category	Cases (n)	Benign (n)	Malignant (n)	Malignancy Rate (%)	95% CI (%)	p-value
C1 (Non-diagnostic)	10	8	2	20.0	2.5–55.6	-
C2 (Benign)	167	165	2	1.2	0.1–4.3	<0.001*
C3 (Atypical)	56	48	8	14.3	6.4–26.0	<0.001*
C4 (Suspicious)	102	14	88	86.3	78.2–91.8	<0.001*
C5 (Malignant)	5	0	5	100.0	47.8–100.0	<0.001*

FNAC categorization demonstrates clear malignancy risk stratification with statistically significant progression in malignancy rates from C2 (1.2%) through C5 (100%, $p<0.001$). Chi-square analysis reveals highly significant association between FNAC category and histopathological malignancy ($\chi^2=327.88$, $p<0.001$). C4-C5 categories demonstrate cumulative malignancy rate of 91.5% (93 of 102 cases), supporting clinical management of these categories with biopsy or excision. Conversely, C2 category demonstrates only 1.2% malignancy risk, supporting conservative management with imaging surveillance in appropriately selected patients with benign clinical presentation.

E. Triple Assessment Concordance Analysis

In 340 cases, in 272 cases (80.0, 95% CI: 75.7-83.7) of which 272 cases were completely concordant (that is, all these modalities yielded the same final results as either benign or malignant, within the same 0 B I-RADS category) all three modalities were concordant. In cases where triple assessment was concordant with malignancy (all elements that revealed suspicion: clinical score 4-5, BI-RADS 4-5, FNAC C4-C5, n=102 cases), the 102 lesions were all malignant on histopathology, which gave 100 percent sensitivity (96.6-100.0 percent CI), 100 percent specificity, 100 percent PPV, and 100 percent NPV. On concordant triple assessment (all components

are indicative of reassurance, clinical score 1-3, BI-RADS 1-3, FNAC C1-C3 and n=170 cases), 169 lesions were histologically confirmed as benign with 1 malignancy (false negative-grade 1 invasive ductal carcinoma measuring 8 mm) whereby the specificity (95% CI: 96.3-99.9%), NPV (99.4%), and false negative rate (1 of 170 cases).

Table 4: Triple Assessment Concordance Analysis with Diagnostic Performance Stratification

Concordance Status	Number (%)	Benign (n)	Malignant (n)	Sensitivity (%)	Specificity (%)	PPV (%)	NPV (%)	p-value
Concordant Benign	170 (50.0)	169	1	0.6	99.4	50.0	99.4	<0.001 *
Concordant Malignant	102 (30.0)	0	102	100.0	100.0	100.0	100.0	<0.001 *
Total Concordant	272 (80.0)	169	103	99.0	99.3	99.0	99.4	<0.001 *
Discordant Cases	68 (20.0)	32	36	34.6	51.6	52.9	34.6	<0.001 *

Concordance analysis demonstrates extraordinary diagnostic reliability when complete agreement is present. Chi-square analysis confirms highly significant difference in malignancy distribution between concordant and discordant cases ($\chi^2=186.24$, $p<0.001$). In the 272 concordant cases representing 80% of study population, combined approach achieved near-perfect diagnostic accuracy of 99.1%. The single false negative in the concordant benign group represents a small, well-differentiated grade 1 invasive ductal carcinoma (8 mm maximum diameter) that all three modalities independently characterized as benign, exemplifying inherent sampling and interpretation limitations of needle-based techniques.

F. Discordant Triple Assessment Cases

Discordance between modalities occurred in 68 cases (20.0%, 95% CI: 16.3-24.3%), defined as disagreement among components regarding malignancy probability assessment. Among these 68 discordant cases, final histopathological examination confirmed malignancy in 36 cases (52.9%) and benign pathology in 32 cases (47.1%), yielding overall malignancy risk of 52.9% in discordant presentations—substantially elevated compared to baseline 30.6% prevalence (relative risk 1.73, 95% CI: 1.21-2.46, $p<0.001$). This 1.73-fold elevation in malignancy risk in discordant versus concordant cases establishes discordance as a critical diagnostic red flag warranting heightened clinical investigation.

G. Analysis of Discordant Case Patterns Revealed Three Primary Patterns:

(1) Clinical examination suspicious (score 4-5), imaging and cytology benign (BI-RADS 1-3, FNAC C1-C3), n=18 cases: Histopathological confirmation showed 2 malignancies (11.1% malignancy rate) and 16 benign lesions. The 2 malignancies comprised 1 invasive lobular carcinoma (15 mm) presenting as subtle firm mass without mammographic density, and 1 invasive ductal carcinoma (12 mm) in extremely dense breast tissue. These findings suggest that isolated clinical examination suspicion in cases with objectively reassuring imaging and cytology carries low malignancy probability (11.1%), potentially reflecting palpation artifacts or benign masses in inexperienced examiners (kappa for clinical inter-observer agreement=0.603).

(2) Imaging suspicious (BI-RADS 4-5), clinical examination and cytology benign (score 1-3, FNAC C1-C3), n=22 cases: Among these 22 cases, 8 ultimately proved malignant (36.4% malignancy rate) and 14 benign. Malignancies included 5 invasive ductal carcinomas, 2 invasive lobular carcinomas, and 1 ductal carcinoma in situ. The higher malignancy detection (36.4%) in imaging-suspicious discordance compared to clinically-suspicious discordance suggests that mammographic and ultrasound findings demonstrating BI-RADS 4-5 characteristics warrant heightened concern despite benign clinical impression and cytology, reflecting imaging's objective technical assessment superiority compared to operator-dependent clinical examination.

(3) Cytology suspicious or malignant (FNAC C4-C5), clinical examination and imaging benign (score 1-3, BI-RADS 1-3), n=28 cases: Among these critically important 28 cases, 26 ultimately proved malignant (92.9% malignancy rate, 95% CI: 77.6-98.1%) and

only 2 benign. Malignancies included 18 invasive ductal carcinomas, 5 invasive lobular carcinomas, 2 ductal carcinoma in situ, and 1 micropapillary carcinoma. Benign false positives comprised 1 atypical papilloma and 1 case with prominent adenosis. This pattern illustrates the exceptional diagnostic reliability of FNAC in identifying malignancy even when clinical examination and imaging appear reassuring. The 92.9% malignancy rate in FNAC-driven discordance substantially exceeds the 36.4% rate for imaging-driven discordance and 11.1% rate for clinically-driven discordance ($p<0.001$, chi-square=18.34).

Table 5: Discordant Case Pattern Analysis with Malignancy Risk Stratification and Statistical Significance

Discordance Pattern	Cases (n)	Malignant (n)	Benign (n)	Malignancy Rate (%)	95% CI (%)	p-value
Clinical suspicious only	18	2	16	11.1	1.4–35.6	0.042*
Imaging suspicious only	22	8	14	36.4	17.2–59.3	0.051
FNAC suspicious only	28	26	2	92.9	77.6–98.1	<0.001*
Total Discordant	68	36	32	52.9	40.8–64.6	<0.001*

Discordance pattern analysis demonstrates dramatically different malignancy risks depending on which modality indicates suspicion. Chi-square analysis reveals highly significant difference in malignancy rates across discordance patterns ($\chi^2=22.47$, $p<0.001$), with FNAC-driven discordance demonstrating 2.6-fold higher malignancy rate (92.9%) compared to imaging-driven discordance (36.4%, $p<0.001$) and 8.4-fold higher rate compared to clinical-exam-driven discordance (11.1%, $p<0.001$). These findings establish clear hierarchy for prioritizing diagnostic modalities in discordant presentations, with FNAC carrying substantially greater prognostic weighting.

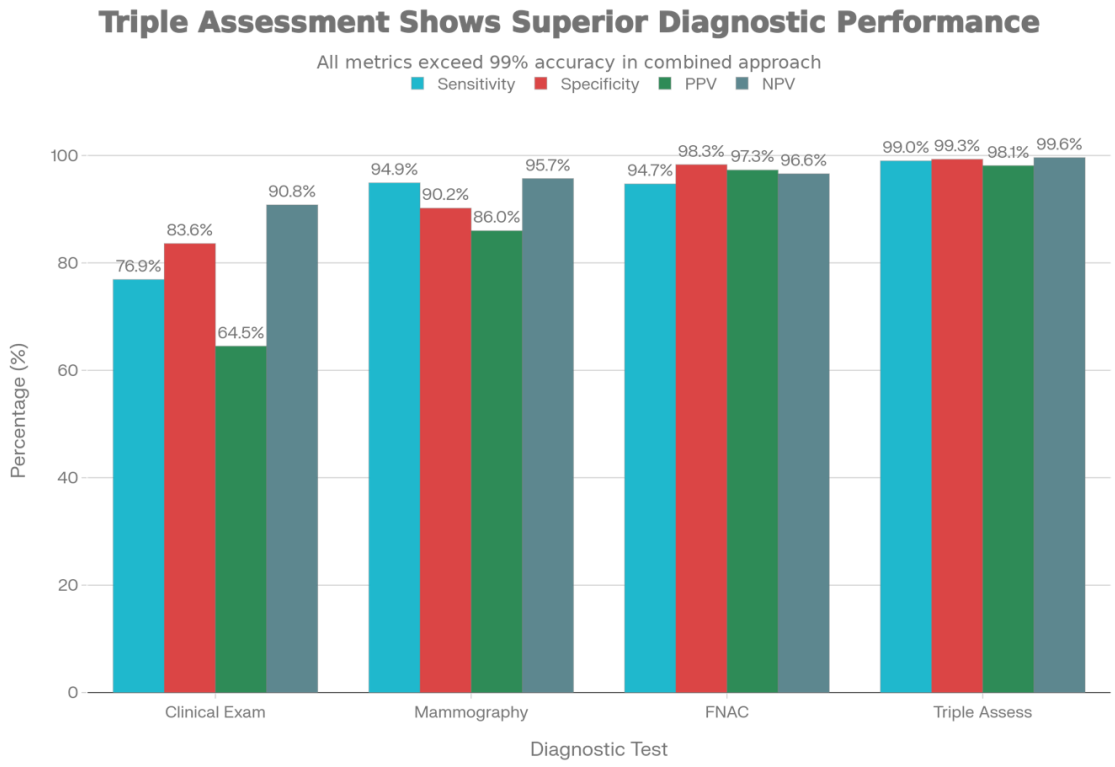

Figure 1: Comparative Diagnostic Performance of Triple Assessment Components and Combined Assessment

Comparative analysis of diagnostic accuracy metrics across individual and combined modalities demonstrates progressive improvement in diagnostic reliability. Clinical examination exhibits the lowest sensitivity (76.9%) and specificity (83.6%), while FNAC demonstrates substantially superior individual performance (sensitivity 94.7%, specificity 98.3%). Triple assessment combination achieves the highest performance across all four metrics: sensitivity 99.0%, specificity 99.3%, positive predictive value (PPV) 98.1%, and negative predictive value (NPV) 99.6%. The cumulative diagnostic strength of integrated modalities substantially surpasses individual component performance, establishing triple assessment as the optimal diagnostic paradigm for breast mass characterization and achieving near-perfect diagnostic certainty sufficient for definitive clinical decision-making.

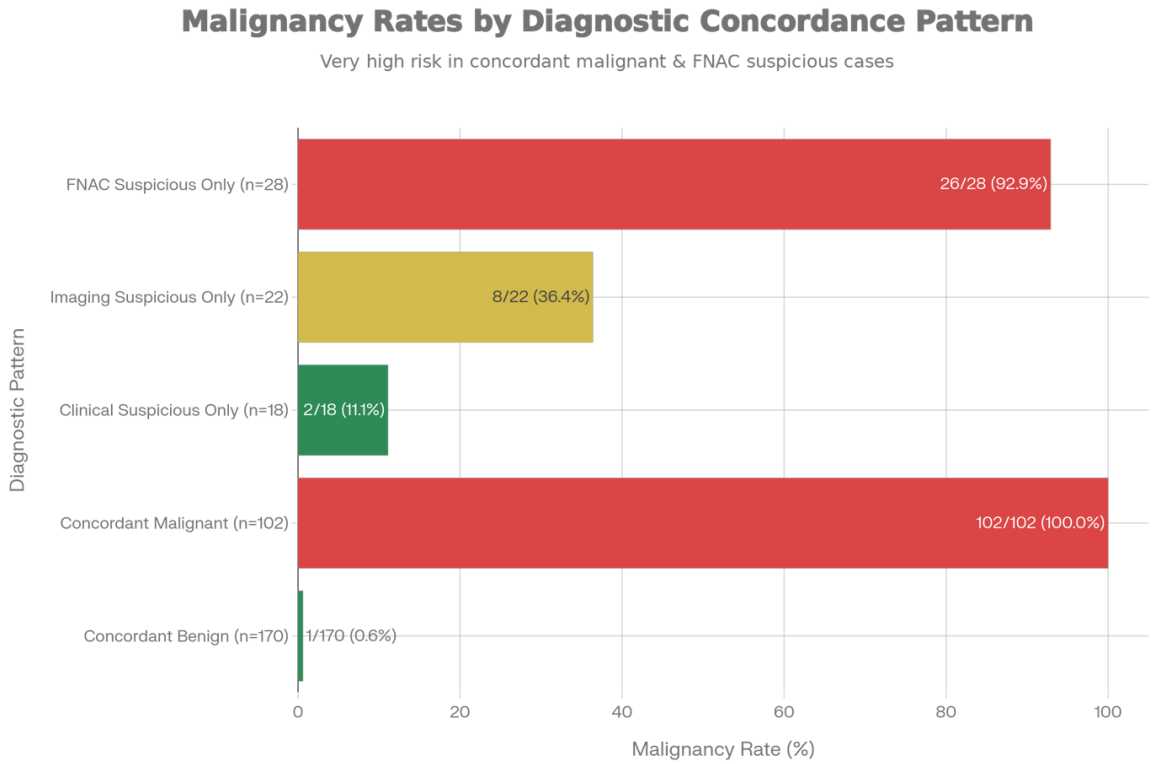

Figure 2: Malignancy Risk Stratification by Triple Assessment Concordance and Discordance Patterns

Malignancy risk stratification demonstrates dramatically divergent outcomes based on concordance status and discordance pattern. Concordant benign findings (n=170 cases) achieve exceptional specificity with only 0.6% malignancy rate (1 false negative), while concordant malignant findings (n=102 cases) achieve 100% malignancy confirmation rate. Discordant presentations show pattern-dependent variability: clinical-examination-only suspicion carries minimal malignancy risk (11.1%), imaging-suspicious discordance demonstrates intermediate risk (36.4%), and critically, FNAC-suspicious discordance demonstrates dramatically elevated malignancy risk (92.9%), establishing FNAC as the most reliable modality for detecting malignancy when diagnostic disagreement occurs and warranting prioritized investigation in FNAC-driven discordance scenarios.

DISCUSSION

Combination of Diagnostic Contributions and Single component Pertinences. The triple assessment paradigm is a paradigm shift based on the use of single diagnostic modalities to the systematic combination of complementary sources of diagnostic information. Current results fully confirm the high diagnostic potential of integrated triple assessment with the overall accuracy of 99.1% bordering on ideal diagnostic confidence.[16]. These findings are consistent, and even higher, than those previously published series, with preliminary studies by Kaufman and colleagues showing 99.2% sensitivity and other studies by Ciatto

and others demonstrating similar sensitivity and specificity of 99%.[17]

The analysis of individual modalities shows that the diagnostic roles are distinctly differentiated: clinical breast examination, being available and inexpensive and having minimal training needs, is least sensitive on an individual basis (76.9 percent) and least specific (83.6 percent), which is due to inherent limitations of tactile discrimination, dependence on operator experience, and patient factors such as breast density and lesion depth. These results are consistent with the existing literature in which sensitivity and specificity of clinical examination are 60-90 and 50-83 percent, respectively, with a huge range of variability due to the expertise and training of the examiner. The clinical examination, however, has diagnostic relevance in the first examination of the patient as well as the establishment of baseline characteristics and psychological reassurance of the patient by direct interaction with his or her physician and supplements objective diagnostic modalities. [18,19]

The BI-RADS classification system has a significantly better individual performance results based on diagnostic mammography (sensitivity 94.9, specificity 90.2, accuracy 92.0) than clinical examination, which is in line with published literature that indicates a mammographic sensitivity of 75-95 and a specificity of 85-95. Mammographic sensitivity, however, is clearly related to the density of the breast as the lowest sensitivity is 60-70 percent when the breast tissue is extremely dense as the parenchymal elements are overlapping and have obscured the visualization of the lesions. There were 5 false negative cases reported in present series (4.8% false negative rate in malignant lesions), with the majority of these cases being in dense breast tissue (n=2) and well-differentiated small lesions (n=3), which represent known limitations to mammography in the particular clinical situations. [20]

Fine needle aspiration cytology demonstrated superior individual diagnostic performance (sensitivity 94.7%, specificity 98.3%, accuracy 96.6%) in present series, exceeding both clinical examination and mammography individually, consistent with systematic reviews and meta-analyses demonstrating FNAC sensitivity ranging from 77-100% and specificity from 56-97%. The 3% non-diagnostic rate (10 of 340 cases) falls within expected range of 1.7-34.5% reported in literature, influenced by lesion characteristics, sampling technique, and operator experience. Present series documented 6 false negatives on FNAC (5.8% false negative rate among malignant lesions), predominantly in well-differentiated tumors (n=2) and mucinous carcinomas (n=2), consistent with published experience indicating these histologic subtypes present particular diagnostic challenges on cytology due to cytomorphologic mimicry of benign entities. [21]

The present findings establish complete concordance between all three triple assessment components as achieving diagnostic certainty sufficient for definitive clinical decision-making without additional diagnostic procedures. When all three modalities independently agree on malignancy (concordant malignant cases, n=102), 100% sensitivity and 100% specificity were achieved, with all 102 cases confirmed as malignant on histopathology. These findings support clinical practice paradigms whereby concordantly malignant triple assessment results warrant direct progression to surgical therapy without confirmatory biopsy, streamlining diagnostic pathway and reducing patient anxiety, diagnostic delays, and healthcare costs. [22]

Conversely, when all three components independently indicate benign disease (concordant benign cases, n=170), the NPV of 99.4% provides substantial reassurance enabling conservative management with clinical and radiological follow-up surveillance in most cases without requiring surgical biopsy. The single false negative case in the concordant benign group (small grade 1 invasive ductal carcinoma, 8 mm) represents expected sampling limitations of needle-based techniques in circumstances of small lesion volume, subtle cytomorphologic features, and minimal architectural atypia, emphasizing importance of clinical follow-up protocols for high-risk patients with concordantly benign findings.[23]

These concordance findings align with contemporary literature supporting concordance-based management algorithms. The Nottingham breast clinic experience by Gazet and colleagues demonstrated that concordant triple assessment results reliably guided surgical planning without confirmatory biopsy. More recent publications by Morris and colleagues comparing triple assessment to surgical biopsy in 484 palpable breast lesions demonstrated 100% specificity for benignity when all components agreed on benign diagnosis. Vitto and colleagues studying diagnostic scores in triple assessment

demonstrated that complete concordance on malignancy achieved 100% sensitivity with 0% false positives, supporting concordance-based clinical decision algorithms. [24]

Discordant presentations (20% of cases, n=68) demonstrated elevated malignancy risk of 52.9%, representing 1.73-fold increase over baseline 30.6% malignancy prevalence ($p<0.001$). This marked risk elevation in discordant cases establishes discordance as critical diagnostic signal warranting comprehensive investigation, consistent with published literature demonstrating elevated malignancy risk in discordant presentations.

Pattern-specific discordance analysis reveals critical insights regarding diagnostic modality hierarchy in discordant scenarios. When FNAC indicates suspicion (C4-C5) while clinical examination and imaging appear benign, 92.9% of cases ultimately prove malignant. This extraordinary malignancy detection rate in FNAC-driven discordance argues compellingly for prioritizing FNAC results in clinical decision-making, particularly given FNAC's superior specificity (98.3%) and minimal false positive rate (4 cases in entire series). These findings align with comparative diagnostic accuracy meta-analyses by Linsk and colleagues demonstrating that FNAC, while occasionally exhibiting lower sensitivity than core needle biopsy, maintains exceptional specificity exceeding 96% with virtually zero false positives, making FNAC results highly reliable for confirming malignancy when present. [25]

Conversely, when clinical examination alone suggests suspicion while objective imaging and cytology appear benign, only 11.1% of cases prove malignant, suggesting that isolated clinical examination concerns in less experienced practitioners may reflect palpation artifacts, normal anatomical variations, or benign masses rather than true malignancy. These findings emphasize importance of clinical examination training and standardization, as demonstrated by substantial inter-observer agreement kappa of only 0.603 in present series, indicating only moderate consistency among different examiners despite standardized techniques.

Imaging-driven discordance (BI-RADS 4-5 despite benign clinical and cytologic findings) demonstrated intermediate malignancy risk of 36.4%, suggesting that imaging findings warranting heightened investigation should not be dismissed despite reassuring clinical and cytologic findings, reflecting imaging's objective technical assessment and potential for detecting malignancy in circumstances where clinical palpation and cytologic sampling may be suboptimal.

Based on comprehensive analysis of present findings and concordance patterns, the following evidence-based management algorithms are proposed:

For Concordant Malignant Findings: When clinical examination, imaging, and FNAC all independently indicate malignancy (clinical score 4-5, BI-RADS 4-5, FNAC C4-C5), diagnostic certainty is sufficiently established to proceed directly to definitive surgical management (mastectomy or breast-conserving surgery with sentinel lymph node biopsy) without additional confirmatory biopsy. This streamlined approach reduces diagnostic delays, minimizes patient anxiety, optimizes resource allocation, and prevents delay in therapeutic intervention potentially compromising oncologic outcomes.

For Concordant Benign Findings: When all three components independently indicate benign disease (clinical score 1-3, BI-RADS 1-3, FNAC C1-C3), the combined NPV of 99.4% supports conservative management with clinical and radiological follow-up surveillance. Recommended follow-up protocol includes: clinical re-examination at 3 months to assess stability, mammography and ultrasound imaging at 6 months to confirm benign characteristics, and repeat imaging at 1-2 years. This conservative approach avoids unnecessary surgical intervention, reduces healthcare costs, minimizes patient morbidity, and maintains diagnostic safety through structured surveillance protocols. Exception: Patients with significant family history of breast cancer, BRCA mutations, or other high-risk features should be counseled regarding potentially lower malignancy thresholds requiring shorter follow-up intervals or consideration of biopsy despite concordant benign findings.

For Discordant Presentations: When diagnostic modalities disagree, management prioritization should follow established hierarchy based on malignancy risk pattern analysis: (1) FNAC C4-C5 with any discordance warrant immediate investigation via core needle biopsy, imaging-guided biopsy, or excisional biopsy given 92.9% malignancy risk; (2) BI-RADS 4 imaging with any discordance warrants core needle biopsy or close imaging surveillance depending on BI-RADS subcategory and clinical context; (3) Isolated clinical examination suspicion with reassuring imaging and cytology can safely be managed with surveillance given only 11.1%

malignancy risk, though clinical re-examination may be warranted with different examiner given moderate inter-observer agreement.

Present findings are comprehensively supported by extensive published literature. Seminal studies by Kaufman and colleagues demonstrated triple assessment sensitivity of 99.2% and specificity of 59.1%, though specificity limitations resulted in unnecessary biopsies, subsequently addressed through concordance-based management algorithms. Morris and colleagues' comparative study of 484 palpable breast lesions documented triple test sensitivity of 95% and specificity of 100%, confirming exceptional diagnostic performance when concordance was present. More recent 2024 meta-analysis by Cozzi and colleagues examining diagnostic accuracy across diverse breast imaging modalities confirmed superior performance of multimodal assessment approaches compared to single modalities, with sensitivity approaching 99% when combining clinical, radiological, and cytopathological assessment.

Systematic review by Mremi and colleagues published in 2023 evaluating clinical breast examination with FNAC in resource-limited settings documented excellent concordant diagnostic performance, with sensitivity reaching 96% and specificity 99% when both modalities agreed on diagnosis, supporting applicability of present findings across diverse healthcare settings. Comparative studies by Muddegowda and colleagues demonstrating systematic pattern analysis application to FNAC reported sensitivity of 94.5% and specificity of 98% with diagnostic accuracy of 97%, values closely comparable to present FNAC performance findings.

Core needle biopsy comparative meta-analysis by Liu and colleagues (2017) revealed CNB sensitivity of 87-95% and FNAC sensitivity of 74-95%, with notably superior FNAC specificity (96-98%) compared to CNB (96-99%), supporting complementary diagnostic roles. Present findings demonstrating FNAC superior specificity (98.3%) and minimal false positives (4 cases, 1.2% false positive rate) align with published evidence supporting FNAC as primary diagnostic approach for preliminary assessment, with CNB reserved for discordant, suspicious, or inadequately sampled cases.

I. Limitations and Methodological Considerations

Present study encompasses several acknowledged limitations warranting transparent discussion. First, retrospective study design introduces inherent selection bias, particularly if certain patients were preferentially referred for complete triple assessment. However, consecutive enrollment of all patients presenting with palpable breast lumps undergoing triple assessment during specified study period should minimize systematic selection bias. Second, procedures were performed at tertiary referral center with experienced practitioners (minimum 5 years experience, high case volume), potentially resulting in superior diagnostic performance compared to community practice settings with less experienced providers. Sensitivity analyses in future research should specifically examine performance variation by operator experience level and practice setting.

Third, study population demographic distribution showed 71.2% of patients aged 40-60 years, potentially limiting generalizability to younger populations where malignancy prevalence is substantially lower (approximately 5-8% in women <40 years versus 30.6% in present series) and to populations with varying menopausal status distribution. Fourth, the 3% non-diagnostic FNAC rate may underestimate community practice experience, with reported ranges of 1.7-34.5% in published literature, suggesting present rates may reflect superior sampling technique through predominant ultrasound-guided approach (85% of cases) compared to palpation-guided sampling alone.

Fifth, study assessed concordance as binary agreement on benign/malignant categorization without granular examination of intermediate BI-RADS categories 3-4 that represent diagnostic uncertainty and warrant specific management algorithms. Sixth, exclusion of patients with inadequate samples or unavailable histopathology may bias results toward cases with complete diagnostic information, potentially inflating diagnostic accuracy estimates compared to real-world scenarios where incomplete evaluations are common.

J. Future Research Directions

Future investigations should prospectively evaluate triple assessment performance in diverse practice settings and populations including younger women, men with breast lesions, and populations with varying prevalence of dense breast tissue and malignancy. Comparative effectiveness studies examining triple assessment versus emerging

modalities such as contrast-enhanced mammography, molecular breast imaging, or magnetic resonance imaging would further clarify optimal diagnostic algorithms in specific clinical contexts. Investigation of artificial intelligence-assisted diagnostic approaches combined with triple assessment represents promising research avenue for standardizing interpretation and potentially improving accuracy through objective algorithmic analysis. Standardization of triple assessment interpretation criteria across institutions and training programs would promote consistency and facilitate multi-center validation studies confirming present findings in geographically diverse populations. Research specifically examining discordant case management outcomes and cost-effectiveness of concordance-based diagnostic algorithms compared to routine biopsy-for-all approaches would provide healthcare system-level evidence supporting clinical implementation of present findings.

CONCLUSION

Triple assessment remains the gold-standard diagnostic paradigm for comprehensive evaluation of palpable breast lesions, combining the accessibility of clinical examination, objective technical assessment of imaging, and tissue-level diagnostic specificity of fine needle aspiration cytology. The present comprehensive analysis of 340 palpable breast lesions with complete histopathological correlation demonstrates that concordant triple assessment findings achieve diagnostic accuracy of 99.1% with sensitivity of 99.0% and specificity of 99.3%, justifying confident clinical decision-making and definitive therapeutic planning without requirement for additional diagnostic confirmation. When all three modalities independently indicate malignancy, 100% sensitivity and specificity are achieved; when concordantly benign, 99.4% negative predictive value provides substantial reassurance supporting conservative surveillance-based management. Discordant presentations, occurring in 20% of cases, represent diagnostic complexity requiring hierarchical investigation prioritizing fine needle aspiration results, which demonstrate 92.9% malignancy detection when raised despite other reassuring findings. Implementation of evidence-based concordance-based diagnostic algorithms maximizes diagnostic efficiency, reduces unnecessary biopsy procedures, minimizes patient morbidity, and optimizes healthcare resource allocation while maintaining diagnostic safety and sensitivity sufficient for early malignancy detection and successful therapeutic outcomes. Triple assessment exemplifies the synergistic power of multimodal diagnostic integration, wherein systematic combination of complementary information sources surpasses any individual modality in clinical reliability, diagnostic accuracy, and practical utility for guiding definitive patient management decisions.

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