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Study of Clinico-Radiological Examination and Histopathological Examination in Management of Breast Lump

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Abstract

Background: Breast lumps are among the most common presenting complaints in surgical outpatient departments, encompassing a wide spectrum from benign fibrocystic disease to invasive malignancy. Accurate early differentiation is critical to prevent diagnostic delays, reduce unnecessary surgery, and optimize patient outcomes. The triple assessment – comprising clinical breast examination (CBE), radiological imaging (ultrasonography [USG]/mammography), and fine needle aspiration cytology (FNAC) – is the internationally recommended standard for evaluating breast lumps. However, institution-specific data validating its performance in the Indian clinical context remain sparse. **Materials and Methods:** This prospective observational study enrolled 50 patients with palpable breast lumps at SGT Medical College, Gurugram, between 2024 and 2026. All patients underwent structured CBE, radiological assessment (USG ± mammography) classified by the Breast Imaging Reporting and Data System (BI-RADS), and FNAC classified by the C1–C5 cytology grading system. Histopathological examination (HPE) served as the reference standard. Sensitivity, specificity, positive predictive value, negative predictive value, accuracy, and Cohen's kappa (κ) were computed. **Results:** Of 50 patients (mean age 38.6 ± 9.4 years), 32 (64%) had benign and 18 (36%) had malignant lesions on HPE. Key malignancy-associated clinical features included puckering/dimpling (66.7% vs. 9.4%; $P < 0.001$), peau d'orange (50.0% vs. 3.1%; $P < 0.001$), and axillary lymphadenopathy (72.2% vs. 9.4%; $P < 0.001$). All BI-RADS 5 lesions (100%) were histologically malignant. FNAC: Sensitivity 94.4%, specificity 90.6%, accuracy 92.0%. Kappa values: Clinical $\kappa = 0.71$, radiology $\kappa = 0.79$, FNAC $\kappa = 0.84$, triple assessment $\kappa = 0.88$. **Conclusion:** Integrated triple assessment achieves near-perfect concordance with histopathology ($\kappa = 0.88$) and represents the optimal diagnostic strategy for breast lumps. FNAC is the most accurate single modality. Multicentric studies with larger cohorts are warranted.

Keywords: Breast imaging reporting and data system, Breast cancer India, Breast lump, Fine needle aspiration cytology, Histopathology, Mammography, Triple assessment, Ultrasonography

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Introduction

Breast lumps constitute one of the most frequent reasons for surgical consultation worldwide, accounting for a substantial proportion of outpatient presentations. Their clinical significance arises from the broad pathological spectrum they represent – ranging from entirely benign entities such as fibroadenoma, fibrocystic disease, and duct ectasia, to pre-malignant and frankly malignant neoplasms including ductal carcinoma *in situ* and invasive ductal carcinoma.[1,2] The imperative of accurate diagnosis lies in the divergent management these conditions demand: Unnecessary excision for misdiagnosed benign disease or delayed curative treatment for unrecognized malignancy, both carry significant clinical and psychological costs.[3]

Breast cancer remains the most commonly diagnosed malignancy among women globally.[4] In India, its incidence has steadily climbed over the past two decades, particularly in urban center, having surpassed cervical cancer as the leading female malignancy in many metropolitan regions. The Indian Council of Medical Research National Cancer Registry Programme estimated approximately 178,361 new cases of female breast cancer in India in 2022, with projections continuing to rise through 2025.[5] Despite advances in multimodal therapy, late-stage presentation – attributable to delayed diagnosis and limited screening – continues to adversely impact survival outcomes.[4,5] Globally, breast cancer continues to impose a substantial disease burden among women, while benign breast diseases constitute a considerable proportion of breast-related presentations. Evidence from breast cancer screening studies further emphasizes the importance of timely detection and structured diagnostic evaluation.[6–8]

The triple assessment framework, integrating clinical breast examination (CBE), breast imaging (ultrasonography [USG] and/or

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mammography), and tissue cytology through fine needle aspiration cytology (FNAC), has been established as the gold standard for evaluating palpable breast lumps. When all three components are concordantly benign or malignant, the diagnostic accuracy approaches 100%. However, discordance between modalities – encountered in approximately 5–15% of cases – necessitates careful clinical judgment, often leading to escalated investigation or surgical biopsy.[9-11] Age-based approaches to palpable breast lumps emphasize tailoring the diagnostic evaluation to patient age and clinical context,[12] while ultrasonography provides valuable diagnostic information for differentiating benign and malignant breast lesions.[13] The combined use of clinical examination, imaging, and pathological assessment has similarly been shown to improve diagnostic confidence in the management of palpable breast lumps.[14]

While published data from tertiary care centers in metropolitan India confirm the utility of triple assessment, institution-specific studies from teaching hospitals serving semi-urban populations remain limited.[15,16] Regional differences in patient demography, disease distribution, available technology, and operator expertise can substantially influence diagnostic performance. This prospective study was therefore conducted at SGT Medical College, Gurugram, to evaluate the individual and combined diagnostic accuracies of CBE, radiological imaging, and FNAC against histopathological examination (HPE) in patients presenting with palpable breast lumps, and to quantify inter-modality agreement. Recent advances in the understanding of breast cancer pathogenesis and treatment further emphasize the importance of accurate early diagnosis and appropriate risk stratification.[17] Although clinical breast examination remains an accessible component of breast assessment, its diagnostic performance is strengthened when integrated with complementary diagnostic modalities.[18] Breast ultrasonography also remains an important adjunct in selected patients, particularly where mammographic assessment may be limited by dense breast tissue.[19]

Aims and Objectives

Primary aim

To evaluate and compare the diagnostic accuracy of CBE, radiological imaging (USG and mammography) and FNAC against HPE as the reference standard in patients presenting with palpable breast lumps.

Specific objectives

i. To characterize clinico-radiological features significantly associated with benign and malignant breast pathology
ii. To assess the individual diagnostic performance of each modality
iii. To determine inter-modality concordance with histopathology using Cohen's kappa coefficient
iv. To establish the incremental diagnostic value of the combined triple assessment approach.

Materials and Methods

Study Design and Setting

This was a prospective observational study conducted at the Department of General Surgery, SGT Medical College, Hospital and Research Institute, Budhera, Gurugram, Haryana, India, from April 2024 to 2026. Ethical approval was obtained from the Institutional Ethics Committee of SGT University, and written informed consent was obtained from all participants.

Study Population

Adult female patients (≥18 years) presenting with a clinically palpable breast lump were screened for eligibility. Inclusion criteria: Any female ≥18 years with a palpable breast mass, willing to undergo all three diagnostic modalities, and subsequent surgical excision/biopsy. Exclusion criteria: Prior breast malignancy or breast surgery, neoadjuvant chemotherapy or hormonal therapy, pregnancy or lactation, non-palpable incidentally detected lesions, and refusal of consent. Fifty eligible patients were enrolled by consecutive sampling.

CBE

Each patient underwent a standardized CBE by the operating surgeon. Inspection was performed in four positions: Arms by side, arms raised above the head, hands on hips with pectoral contraction, and patient leaning forward from the waist.[20] Features recorded included breast position, size/contour symmetry, skin changes (puckering, dimpling, erythema, peau d'orange, engorged veins, skin thickening), nipple and areolar changes, and axillary/supraclavicular fossa assessment. Lump characteristics documented on palpation were quadrant of location, number, size and shape, surface texture, margin definition, consistency, fluctuation, and fixity to skin, nipple, or chest wall.[21,22] Based on integrated CBE findings, a clinical impression was categorized as "clinically benign" or "clinically malignant."

Radiological Assessment

Breast USG was performed in all patients using a high-frequency linear transducer (7.5–12 MHz). Ultrasound parameters evaluated were location, shape, margin, orientation, echogenicity, internal echo pattern, posterior acoustic features, calcifications, and Doppler vascularity pattern. Mammography (craniocaudal and mediolateral oblique views) was performed in women ≥40 years or where clinically indicated.[23] All radiological findings were classified according to the American College of Radiology Breast Imaging Reporting and Data System (BI-RADS), categories 2–5.[24] The combined radiological impression was categorized as "radiologically benign" (BI-RADS 2–3) or "radiologically malignant" (BI-RADS 4–5).

FNAC

FNAC was performed under sterile conditions using a 23-gauge needle with a 10-mL syringe, with or without image guidance. Cytology reports were issued according to the UK RCPath five-category system: C1 (Inadequate), C2 (Benign), C3 (Atypia, probably benign), C4 (Suspicious of malignancy), and C5 (Malignant).[16] For binary classification, C4 and C5 were considered "cytology malignant" and C1–C3 as "cytology benign."

HPE

HPE was performed on excised surgical specimens (wide local excision, lumpectomy, or modified radical mastectomy as

appropriate), stained with hematoxylin and eosin. HPE findings were classified as benign or malignant and served as the reference standard for all diagnostic comparisons.

Statistical Analysis

Data were analyzed using the Statistical Package for the Social Sciences version 25.0 (IBM Corp., Armonk, NY). Categorical variables are presented as frequencies and percentages and continuous variables are presented as mean ± standard deviation and median with interquartile range (IQR). The Chi-square test (or Fisher's exact test where applicable) assessed associations between diagnostic features and HPE outcome. Sensitivity, specificity, positive predictive value (PPV), negative predictive value (NPV), and overall accuracy were calculated for each modality. Cohen's kappa coefficient (κ) quantified inter-modality agreement, interpreted as: <0.20 slight, 0.21–0.40 fair, 0.41–0.60 moderate, 0.61–0.80 substantial, 0.81–1.00 almost perfect. A $P < 0.05$ was considered statistically significant.

Results

Demographic and Clinical Profile

Fifty patients completed the study. The mean age was 38.6 ± 9.4 years (median 37 years; IQR 31–45; range 19–63 years). Age distribution showed that 24% were ≤30 years, 36% in the 31–40-year group, 26% in the 41–50-year group, and 14% were >50 years, reflecting a predominance of reproductive-age women [Table 1]. Duration of symptoms: 30% presented within 3 months, 40% between 4 and 6 months, and 30% after more than 6 months, indicating moderate delay in health-seeking behavior. On HPE, 32 patients (64%) had benign lesions and 18 patients (36%) had malignant lesions.

Clinical Examination Findings

Abnormal breast position (elevation or displacement) was present in 18% of patients, predominantly in malignant cases. Key clinical signs significantly associated with malignancy are summarized in Table 2. Puckering or dimpling was present in 66.7% of malignant cases compared to 9.4% of benign cases ($P < 0.001$).[15,24] Peau d'orange was observed in 50.0% of malignant cases compared to only 3.1% of benign cases ($P < 0.001$).[25,26] Nipple retraction/abnormalities (61.1% vs. 15.6%; $P < 0.001$), areolar changes (55.6% vs. 12.5%; $P < 0.001$), arm edema or chest wall fixation (55.6% vs. 6.3%; $P < 0.001$), and palpable axillary lymphadenopathy (72.2% vs. 9.4%; $P < 0.001$) were all strongly associated with malignancy.[26,27] Among palpated lump characteristics, irregular surface (72.2% vs. 15.6%), ill-defined margins (66.7% vs. 6.3%), hard consistency (61.1% vs. 0%), and fixity to skin or chest wall (72.2% vs. 6.2%) were all highly significant (all $P < 0.001$).[15,24,27]

Table 1: Age group distribution of study participants (*n*=50)

Age group (years)	*Number*	*Percentage*
≤30	12	24
31–40	18	36
41–50	13	26
>50	7	14
Total	50	100

Table 2: Key clinical signs and their association with histopathology

Clinical feature	*Benign (n=32) (%)*	*Malignant (n=18) (%)*	*P-value*
Puckering/dimpling	3 (9.4)	12 (66.7)	<0.001
Peau d'orange	1 (3.1)	9 (50.0)	<0.001
Nipple retraction/abnormality	5 (15.6)	11 (61.1)	<0.001
Areolar changes	4 (12.5)	10 (55.6)	<0.001
Arm edema/chest wall fixation	2 (6.3)	10 (55.6)	<0.001
Axillary lymphadenopathy	3 (9.4)	13 (72.2)	<0.001
Irregular lump surface	5 (15.6)	13 (72.2)	<0.001
Ill-defined margins	2 (6.3)	12 (66.7)	<0.001
Hard consistency	0 (0)	11 (61.1)	<0.001
Fixity to skin/chest wall	2 (6.2)	13 (72.2)	<0.001

Ultrasonographic Findings

Irregular shape was observed in 77.8% of malignant lesions compared to 15.6% of benign lesions ($P < 0.001$).[15,28] Non-parallel (taller-than-wide) orientation was present in 72.2% of malignant cases versus 12.5% of benign cases ($P < 0.001$).[24,29] Spiculated or microlobulated margins were seen in 83.3% of malignant lesions ($P < 0.001$).[27,30] Posterior acoustic shadowing was present in 66.7% of malignant lesions versus 15.6% of benign lesions ($P < 0.001$).[15,30] Microcalcifications were detected in 61.1% of malignant lesions compared to 9.4% of benign lesions ($P < 0.001$).[30,31] Central vascularity on Doppler was significantly more prevalent in malignant lesions (44.4% vs. 9.4%; $P = 0.002$) [Table 3].[27]

Mammographic Findings

Irregular mammographic shape was observed in 66.7% of malignant cases versus 18.8% of benign cases ($P < 0.001$).[15,28] Spiculated or indistinct margins were significantly associated with malignancy ($P < 0.001$).[30] Architectural distortion was observed in 66.7% of malignant lesions versus 9.4% of benign lesions ($P < 0.001$).[30] Microcalcifications on mammography were

Table 3: Ultrasonographic features versus histopathology

Ultrasound feature	*Benign (n=32) (%)*	*Malignant (n=18) (%)*	*P-value*
Irregular shape	5 (15.6)	14 (77.8)	<0.001
Non-parallel orientation	4 (12.5)	13 (72.2)	<0.001
Spiculated/microlobulated margin	5 (15.6)	15 (83.3)	<0.001
Heterogeneous internal echoes	6 (18.7)	14 (77.8)	<0.001
Hypoechoic pattern	13 (40.6)	13 (72.2)	0.030
Posterior acoustic shadowing	5 (15.6)	12 (66.7)	<0.001
Microcalcifications	3 (9.4)	11 (61.1)	<0.001
Central Doppler vascularity	3 (9.4)	8 (44.4)	0.002

Table 4: BI-RADS category versus histopathological diagnosis

BI-RADS category	*Benign (n=32) (%)*	*Malignant (n=18) (%)*	*Total (n=50) (%)*
2 - Benign	14 (43.8)	0 (0)	14 (28)
3 - Probably benign	10 (31.3)	1 (5.6)	11 (22)
4A - Low suspicion	6 (18.8)	1 (5.6)	7 (14)
4B - Intermediate suspicion	2 (6.3)	4 (22.2)	6 (12)
4C - High suspicion	0 (0)	4 (22.2)	4 (8)
5 - Highly suggestive	0 (0)	8 (44.4)	8 (16)
Total	32 (100)	18 (100)	50 (100)

Chi-square test; *P*<0.001. BI-RADS: Breast imaging reporting and data system

present in 55.6% of malignant cases versus 12.5% of benign cases ($P = 0.004$).[15,31] Spiculation was present in 72.2% of malignant lesions versus 6.3% of benign lesions ($P < 0.001$).[30] Skin thickening was observed in 50.0% of malignant cases compared to 9.4% of benign cases ($P = 0.002$).[24,26]

BI-RADS Classification and Histopathological Correlation

The distribution of BI-RADS categories was Category 2 ($n = 14$, 28%), Category 3 ($n = 11$, 22%), Category 4A ($n = 7$, 14%), Category 4B ($n = 6$, 12%), Category 4C ($n = 4$, 8%), and Category 5 ($n = 8$, 16%). Concordance with histopathology was highly significant ($P < 0.001$): 100% of BI-RADS 2 lesions were histologically benign; 90.9% of BI-RADS 3 lesions were benign; and 100% of both BI-RADS 4C and BI-RADS 5 lesions were malignant [Table 4].[24,25,32] This demonstrated a statistically robust progressive correlation between increasing BI-RADS category and malignancy.[24]

Cytological (FNAC) Findings

The FNAC cytology distribution was C1 – Inadequate ($n = 3$, 6%), C2 – Benign ($n = 27$, 54%), C3 – Atypia ($n = 6$, 12%), C4 – Suspicious ($n = 5$, 10%), and C5 – Malignant ($n = 9$, 18%). The C5 category showed 100% correlation with malignant histopathology.[27,33] No malignant case was classified as C1. The association between cytology category and HPE outcome was highly significant ($P < 0.001$).[27]

Comparative Diagnostic Performance

Clinical examination correctly classified 83.3% of malignant lesions (sensitivity) and 87.5% of benign lesions (specificity), achieving an overall accuracy of 86.0%.[15,24] Radiology demonstrated sensitivity 88.9%, specificity 90.6%, and accuracy 90.0%.[15,32] FNAC achieved the highest sensitivity (94.4%), specificity (90.6%), and accuracy (92.0%) among individual modalities[27,33] [Table 5].

Table 5: Comparative diagnostic performance of clinical, radiological, and cytological assessment

Parameter	*Clinical (%)*	*Radiology (%)*	*Cytology (FNAC) (%)*
Sensitivity	83.3	88.9	94.4
Specificity	87.5	90.6	90.6
PPV	78.9	84.2	85.0
NPV	90.3	93.5	96.7
Accuracy	86.0	90.0	92.0

PPV: Positive predictive value, NPV: Negative predictive value

Table 6: Cohen's kappa agreement between each modality and histopathology

Modality pair	*κ value*	*95% CI*	*Interpretation*
Clinical examination versus HPE	0.71	0.55–0.87	Substantial agreement
Radiology versus HPE	0.79	0.64–0.92	Substantial agreement
Cytology (FNAC) versus HPE	0.84	0.71–0.95	Almost perfect agreement
Triple assessment versus HPE	0.88	0.76–0.97	Almost perfect agreement

CI: Confidence interval, HPE: Histopathological examination

Inter-Modality Agreement with Histopathology

Clinical examination showed substantial agreement with HPE ($\kappa = 0.71$; 95% CI 0.55–0.87).[24,33] Radiology showed substantial agreement ($\kappa = 0.79$; 95% CI 0.64–0.92).[15,32] FNAC showed almost perfect agreement ($\kappa = 0.84$; 95% CI 0.71–0.95).[27,33] The combined triple assessment demonstrated the highest agreement of all ($\kappa = 0.88$; 95% CI 0.76–0.97) [Table 6].[10,33]

Discussion

This prospective study corroborates and extends the established evidence supporting the triple assessment approach for breast lump evaluation, while providing institution-specific data relevant to the semi-urban North Indian context.[10,15,24]

Demographic Profile and Pathological Spectrum

The mean age of the study participants was 38.6 ± 9.4 years, and the largest proportion of patients (36%) belonged to the 31–40-year age group. This age distribution is broadly comparable to that reported in previous Indian studies. Goyal *et al*.[15] in a 50-patient prospective study similarly reported the highest presentation frequency in the third decade, attributing this to the peak incidence of benign breast disease – particularly fibroadenoma – in this age group. Ibikunle *et al*.[27] in a retrospective series of 289 patients found 76.7% benign lesions predominantly in women aged 18–40 years, paralleling our benign proportion of 64%. The progressive increase in malignancy with advancing age is well supported by Laul *et al*.[26] who demonstrated a significant shift toward malignant diagnoses in women above 40–60 years across 275 patients. Datta *et al*.[29] in 180 female patients similarly confirmed that malignant lumps were most common in the 41–60-year age group. The 40% of patients presenting with delays of 4–6 months highlight a persistent public health challenge requiring targeted health education and community breast awareness programs.[15,26]

Diagnostic Value of CBE

CBE achieved 83.3% sensitivity and 87.5% specificity in our study, yielding kappa = 0.71 with HPE. Ravi and Rodrigues[24] reported sensitivity 95% and specificity 88% for CBE in a comparable Indian series, while Sarangan *et al*.[31] described a slightly lower sensitivity of 80%, reflecting inter-examiner variability. The clinical signs most strongly associated with malignancy in our study – puckering/dimpling ($P < 0.001$), peau d'orange ($P < 0.001$), axillary lymphadenopathy ($P < 0.001$), hard consistency ($P < 0.001$), and fixity ($P < 0.001$) – are pathophysiologically explained by desmoplastic stromal reaction, dermal lymphatic invasion, and regional lymph node metastasis, respectively.[15,24,26] Laul *et al*.[26] identified retraction/puckering in 75% of malignant cases, and Goyal *et al*.[15] reported puckering in 72% of their malignant cohort, consistent with our 66.7%. Despite its inherent operator-dependence and subjectivity, CBE remains an indispensable, low-cost, first-line tool, particularly in resource-constrained settings.[22,34]

Ultrasound and Mammographic Performance

Combined radiology achieved sensitivity 88.9%, specificity 90.6%, accuracy 90.0%, and kappa = 0.79 with HPE. Several USG features

demonstrated robust discriminatory power for malignancy: Irregular shape (77.8%; $P < 0.001$), non-parallel orientation (72.2%; $P < 0.001$), spiculated/microlobulated margins (83.3%; $P < 0.001$), posterior acoustic shadowing (66.7%; $P < 0.001$), and microcalcifications (61.1%; $P < 0.001$). These findings are consistent with the internationally established ultrasound BI-RADS lexicon and with results from Goyal *et al*.,[15] Datta *et al*.,[29] and Mohan *et al*.[30] Central Doppler vascularity was significantly more prevalent in malignant lesions (44.4% vs. 9.4%; $P = 0.002$), reflecting pathological tumor neoangiogenesis, a finding similarly described by Sarangan *et al*.[31]

Mammographic architectural distortion (66.7% vs. 9.4%; $P < 0.001$), spiculation (72.2% vs. 6.3%; $P < 0.001$), and skin thickening (50.0% vs. 9.4%; $P = 0.002$) were highly significant discriminators. The BI-RADS system demonstrated excellent progressive concordance with malignancy, consistent with findings from Sawant *et al*.[32] across 200 female subjects and Sudha Rani *et al*.[25] across 880 women, where BI-RADS 4–5 accuracy was 92.85%. Dense breast tissue was more common in malignant cases (55.6% vs. 34.4%), though the difference did not reach statistical significance ($P = 0.21$), consistent with the known confounding effect of density on mammographic interpretation reported by Ravi and Rodrigues[24] underscoring the complementary role of USG in younger women with dense parenchyma.[15,23] Breast ultrasonography is therefore an important complementary imaging modality for characterizing palpable breast abnormalities and distinguishing cystic from solid lesions.[35]

FNAC

FNAC demonstrated the highest diagnostic accuracy: Sensitivity 94.4%, specificity 90.6%, PPV 85.0%, NPV 96.7%, and overall accuracy 92.0%, with kappa = 0.84 (almost perfect agreement) with HPE. C5 cytology showed 100% correlation with histological malignancy. These figures are consistent with Ibikunle *et al*.,[27] who reported FNAC sensitivity of 99.4% and specificity 100% across 289 patients, and Datta *et al*.,[29] who observed 99% sensitivity. Three cases of inadequate sampling (C1, 6%) represent a recognized limitation of FNAC, particularly in fibrotic or poorly cellular lesions.[11,16] The NPV of 96.7% for FNAC provides high confidence in excluding malignancy when cytology is benign.[11]

Triple Assessment and Clinical Implications

The combined triple assessment yielded the highest inter-modality agreement with HPE ($\kappa = 0.88$; 95% CI 0.76–0.97), confirming its superiority over any single modality.[10,33] This finding replicates the data of Kakarla *et al*.,[33] who reported $\kappa = 0.911$ for triple assessment. Each modality contributes unique and complementary diagnostic information: CBE identifies surface characteristics and nodal involvement; USG/mammography characterize internal morphology, vascularity, and calcification patterns with objective BI-RADS stratification; and FNAC provides direct cytological evidence of malignancy.[9,10] In clinical practice, actionable recommendations from our data include as follows: (i) All patients with BI-RADS ≥4B should proceed directly to tissue sampling; (ii) discordant clinical and imaging findings should prompt mandatory FNAC or core needle biopsy; (iii) C3 cytology should not be managed conservatively without imaging correlation, given that 16.7% of our malignant cases were classified C3;[11,16] and (iv) the combination of hard consistency, ill-defined margins, spiculated/irregular shape on USG, and BI-RADS ≥4 forms a robust high-risk profile warranting expedited oncological referral.[10,32]

Limitations

This study has several limitations: The sample size of 50 patients limits subgroup analyses and generalizability; the single-center design introduces potential selection bias; core needle biopsy was not included as a comparison modality; CBE inter-examiner variability was not formally quantified; and long-term follow-up data were not collected. Future multicentric prospective studies with larger sample sizes, standardized operator training, and integration of newer imaging modalities (elastosonography, contrast-enhanced mammography, magnetic resonance imaging) are necessary to further refine the triple assessment protocol.

Conclusion

The integrated triple assessment approach – CBE, radiological imaging with BI-RADS classification, and FNAC – provides the highest diagnostic accuracy and reliability for differentiating benign from malignant breast lumps, achieving near-perfect concordance with histopathology ($\kappa = 0.88$).[10,33] Among individual modalities, FNAC demonstrated superior sensitivity (94.4%) and accuracy (92.0%) and should be regarded as the pivotal diagnostic procedure.[22,27] Systematic application of standardized clinical and radiological criteria – particularly BI-RADS classification and recognized malignancy-associated features – significantly enhances pre-operative diagnostic precision.[15,24,32] We advocate for the routine, protocolized use of triple assessment in all patients presenting with breast lumps, with histopathological confirmation guiding definitive management. Multicentric studies with larger cohorts are warranted to validate and refine these findings in the diverse Indian clinical landscape.[5,10]

Ethical Approval

This study was approved by the Institutional Ethics Committee of SGT University, Gurugram. Written informed consent was obtained from all participants. The study was conducted in accordance with the Declaration of Helsinki.

Author Contributions

SS: Study conception, data collection, clinical examinations, manuscript writing. DN: Study supervision, surgical procedures, manuscript review and revision. RA: Radiological assessments, BI-RADS classification, imaging data interpretation. KSG: Study design, departmental oversight, final approval of manuscript. All authors have read and approved the final version of the manuscript.

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