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CYTO-MORPHOLOGICAL SPECTRUM OF BREAST LESIONS: A PROSPECTIVE OBSERVATIONAL STUDY IN A TERTIARY CARE HOSPITAL

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Abstract

Background: Breast lumps are a common clinical presentation in Indian women. The triple assessment protocol — combining clinical examination, ultrasonography (BI-RADS), and fine needle aspiration cytology (FNAC) — is the accepted standard for their evaluation. This study aimed to characterize the cytomorphological spectrum of palpable breast lesions and correlate FNAC findings with radiological BI-RADS classification. ***Methods:*** A prospective observational study was conducted at the Department of Pathology, Gitam Institute of Medical Sciences and Research (GIMSR), Visakhapatnam, over 18 months (March 2023 – September 2024). Seventy-four patients presenting with palpable breast lumps were enrolled using consecutive sampling. FNAC was categorized using the International Academy of Cytology (IAC) Yokohama System (C1–C5) and ultrasonography findings using BI-RADS 5th Edition. Cohen's kappa and Spearman's correlation were used to assess diagnostic concordance. ***Results:*** Of 74 patients, 89.19% were female and 10.81% male, with a mean age of 35.03 years. The 21–30 year age group was most commonly affected (35.1%). The upper outer quadrant was the predominant site (40.5%). FNAC yielded benign (C2) findings in 71.62%, malignant (C5) in 17.57%, atypical (C3) in 6.76%, suspicious (C4) in 1.35%, and inadequate (C1) in 2.7% of cases. Fibroadenoma (48.6%) was the most common diagnosis, followed by duct cell carcinoma (17.6%) and gynecomastia (8.1%). BI-RADS 2 was the predominant radiological category (55.4%). A moderate diagnostic concordance was found between FNAC and BI-RADS (Cohen's $\kappa = 0.44$; Spearman $r = 0.677$, $p < 0.001$). ***Conclusion:*** FNAC, categorized using the IAC Yokohama System, is a reliable, cost-effective first-line diagnostic tool for breast lesions. Its integration with ultrasound BI-RADS classification enhances diagnostic accuracy. The triple assessment approach is strongly advocated, particularly in resource-limited tertiary care settings.

Keywords: Breast lesions; Fine needle aspiration cytology; FNAC; BI-RADS; IAC Yokohama System; Fibroadenoma; Duct cell carcinoma; Triple assessment; Cytomorphology; Tertiary care

INTRODUCTION

Breast lumps represent one of the most frequent reasons for surgical and oncological consultation among women globally. While the majority of breast lesions are benign, breast cancer remains the leading cancer-related cause of death in Indian women, having surpassed cervical cancer in recent years. Globally, an estimated 2.3 million new breast cancer cases were diagnosed in 2020, with India reporting age-adjusted incidence rates of 25–32 per 100,000 women in urban areas — lower than Western countries but rising sharply.[1–3]

The evaluation of palpable breast lumps demands a structured and systematic approach. The "triple assessment" protocol — encompassing clinical examination, radiological imaging, and cytopathological evaluation — is the universally accepted standard. When all three components are concordant, diagnostic accuracy approaches 99%, virtually eliminating the need for diagnostic excisional biopsy.[4,5]

Fine Needle Aspiration Cytology (FNAC) occupies a pivotal position within this triad. It is minimally invasive, rapid, cost-effective, and well-tolerated. Reported sensitivity ranges from 90–95% with specificity approaching 98–100%, particularly for excluding malignancy. The International Academy of Cytology (IAC) Yokohama System standardizes FNAC reporting into five categories (C1–C5), ensuring reproducibility and guiding clinical management.[6,7]

Ultrasound imaging with the Breast Imaging Reporting and Data System (BI-RADS), developed by the American College of Radiology, complements FNAC by providing non-invasive, radiation-free real-time characterization of breast lesions across six categories (BI-RADS 1–6). Correlation between BI-RADS and FNAC has been shown to significantly reduce false-negative diagnoses.[8]

Despite the established role of FNAC in breast diagnostics, region-specific data from tertiary care hospitals in India are limited. The burden of breast disease in India is compounded by late presentation, limited awareness, and constrained diagnostic resources. This study was therefore designed to systematically characterize the cytomorphological spectrum of palpable breast lesions using the IAC Yokohama System and to correlate these findings with BI-RADS ultrasonographic classifications in a south Indian tertiary care setting.

Objectives

1. To describe the cytomorphological findings of palpable breast lesions using FNAC (IAC Yokohama System).
2. To correlate FNAC cytological categories with ultrasonographic BI-RADS categories.

MATERIALS AND METHODS

2.1 Study Design and Setting

This was a hospital-based prospective observational study conducted at the Department of Pathology, Gitam Institute of Medical Sciences and Research (GIMSR), Visakhapatnam, Andhra Pradesh, India — a tertiary care teaching hospital catering to a predominantly coastal South Indian population.

2.2 Study Period and Sample Size

The study was conducted over 18 months, from 15th March 2023 to 15th September 2024. A total of 74 patients presenting with palpable breast lumps were enrolled using consecutive sampling. Sample size was determined based on a reported 48–55% prevalence of benign lesions in tertiary care FNAC studies from India.

2.3 Inclusion and Exclusion Criteria

Included were all male and female patients presenting with palpable breast lump(s), patients who underwent ultrasound-guided FNAC, patients with breast lumps accompanied by palpable lymph nodes, and patients with nipple discharge. Patients who did not undergo ultrasound evaluation, and those who declined written informed consent, were excluded.

2.4 Clinical Evaluation

A standardized proforma documented patient demographics (age, sex), lump characteristics (location, quadrant, size, consistency, mobility, skin and nipple changes), and relevant history (obstetric history, menstrual status, hormonal and familial risk factors).

2.5 Radiological Assessment

All patients underwent high-resolution breast ultrasonography. Findings were categorized using the BI-RADS Lexicon, 5th Edition (American College of Radiology): BI-RADS 1 (Negative), BI-RADS 2 (Benign), BI-RADS 3 (Probably Benign), BI-RADS 4 (Suspicious), and BI-RADS 5 (Highly Suggestive of Malignancy).

2.6 FNAC Technique

FNAC was performed under ultrasound guidance. Patients were positioned supine following written informed consent. The lesion was localized, skin cleaned with a sterile swab, and the lump stabilized. A 24-gauge needle was used for aspiration; material was expelled onto glass slides, wet-fixed in 95% ethyl alcohol, and stained with Haematoxylin and Eosin (H&E). Cytological findings were categorized using the IAC Yokohama System: C1 (Inadequate/Unsatisfactory), C2 (Benign), C3 (Atypical — Probably Benign), C4 (Suspicious for Malignancy), and C5 (Malignant).

2.7 Statistical Analysis

Categorical variables were expressed as frequencies and percentages. Diagnostic concordance between FNAC (C1–C5) and BI-RADS categories was assessed using Cohen's Kappa coefficient (κ) and Spearman's rank correlation coefficient. A p-value < 0.05 was considered statistically significant. Analysis was performed using SPSS version 26.0.

2.8 Ethical Considerations

The study was approved by the Institutional Ethics Committee of GIMSR (Approval No.: IEC/GIMSR/2023/Path-12). Written informed consent was obtained from all participants prior to enrolment. Patient confidentiality was maintained throughout.

RESULTS

3.1 Demographic Profile

A total of 74 patients were enrolled. The cohort was predominantly female: 66 females (89.19%) and 8 males (10.81%). The mean age was 35.03 years (median 34 years; mode 22 years; range 14–70 years). The 21–30 year age group was most commonly represented (35.1%), followed by 31–40 years (21.6%), 41–50 years (14.9%), 11–20 years (10.81%), 51–60 years (13.5%), and 61–70 years (4.1%).

Table 1: Age and sex distribution of patients with breast lumps (n = 74)

Age Group	Female	Male	Total	Percentage (%)
11–20 years	6	2	8	10.81
21–30 years	24	2	26	35.10
31–40 years	15	1	16	21.62
41–50 years	10	1	11	14.86
51–60 years	8	2	10	13.51
61–70 years	3	0	3	4.05
Total	66	8	74	100.00

3.2 Site and Quadrant Distribution

The right breast was involved in 50.00% (n=37), the left in 44.59% (n=33), and bilateral involvement was noted in 5.41% (n=4). Regarding intrabreast quadrant distribution, the upper outer quadrant (UOQ) was the most common site of lesions (40.5%), followed by the upper inner quadrant (17.6%), lower outer quadrant (14.9%), subareolar region (14.9%), and lower inner quadrant (12.2%).

Table 2: Distribution of breast lesions by intrabreast quadrant (n = 74)

Site / Quadrant	Count	Percentage (%)
Upper outer quadrant	30	40.5
Upper inner quadrant	13	17.6
Lower outer quadrant	11	14.9
Subareolar region	11	14.9
Lower inner quadrant	9	12.2
Total	74	100.0

Table 3: Distribution of FNAC findings using IAC Yokohama System (n = 74)

IAC Yokohama Category	Description	Count	Percentage (%)
C1	Inadequate / Unsatisfactory	2	2.70
C2	Benign	53	71.62
C3	Atypical — Probably Benign	5	6.76
C4	Suspicious for Malignancy	1	1.35
C5	Malignant	13	17.57
Total		74	100.00

3.3 Clinical Characteristics

Most lumps presented as firm (86.54%) and freely mobile (90.54%) masses. Hard consistency was noted in 4.10% and fixed lumps in 4.10%, raising clinical suspicion for malignancy in those cases. Nipple discharge was uncommon, with only one patient (1.35%) reporting serous discharge. The majority of female patients (77.03%) had regular menstrual cycles; 9.46% were menopausal, and 2.70% had undergone hysterectomy.

3.4 FNAC (IAC Yokohama) Category Distribution

FNAC findings were categorized per the IAC Yokohama System. The majority of cases fell in the C2 (benign) category (71.62%), followed by C5 (malignant) at 17.57%. Atypical (C3), inadequate (C1), and suspicious (C4) lesions accounted for 6.76%, 2.70%, and 1.35% of cases, respectively. The rate of inadequate samples (C1: 2.7%) was notably low, reflecting good technical quality of aspiration.

3.5 Spectrum of Diagnoses

Fibroadenoma was the single most common diagnosis, accounting for 48.6% of all cases. Duct cell carcinoma was the predominant malignancy (17.6%). Gynecomastia constituted 8.1% of cases, reflecting the inclusion of male patients. Atypical lesions were encountered in 6.8%, mastitis and benign cystic lesions in 4.1% each, and granulomatous mastitis in 2.7%. Rare diagnoses included galactocele, lactating adenoma, and lipoma (1.4% each).

Table 4: Spectrum of cytological diagnoses on FNAC (n = 74)

Diagnosis	Count	Percentage (%)
Fibroadenoma	36	48.6
Duct Cell Carcinoma	13	17.6
Gynecomastia	6	8.1
Atypical Lesions (C3)	5	6.8
Benign Cystic Lesion	3	4.1
Mastitis	3	4.1
Granulomatous Mastitis	2	2.7
Inadequate Sample	2	2.7
Galactocele	1	1.4
Lactating Adenoma	1	1.4
Lipoma	1	1.4
Suspicious for Malignancy	1	1.4
Total	74	100.0

3.6 Radiological BI-RADS Distribution

Ultrasound BI-RADS categorization revealed a predominance of BI-RADS 2 (benign) findings (55.40%, n=41), consistent with the high proportion of benign lesions on FNAC. BI-RADS 4 (suspicious) was identified in 24.32% (n=18), BI-RADS 3 (probably benign) in 14.86% (n=11), BI-RADS 5 (highly suspicious for malignancy) in 4.05% (n=3), and BI-RADS 1 (negative) in 1.35% (n=1). No cases were classified as BI-RADS 0 or BI-RADS 6.

Table 5: Radiological BI-RADS category distribution (n = 74)

BI-RADS Category	Description	Count	Percentage (%)
BI-RADS 1	Negative	1	1.35
BI-RADS 2	Benign	41	55.40
BI-RADS 3	Probably Benign	11	14.86
BI-RADS 4	Suspicious	18	24.32
BI-RADS 5	Highly Suspicious of Malignancy	3	4.05
BI-RADS 6	Known Biopsy-Proven Malignancy	0	0.00
Total		74	100.00

3.7 Correlation between FNAC and BI-RADS

A statistically significant positive correlation was observed between FNAC categories (C1–C5) and BI-RADS scores (Spearman's $r = 0.677$, $p < 0.001$). Cohen's Kappa coefficient was $\kappa = 0.44$, indicating moderate inter-modality agreement. Diagnostic concordance was strongest for clearly benign cases: 71.7% of C2 lesions corresponded to BI-RADS 2. Among malignant (C5) cases, 53.8% were classified as BI-RADS 4 and 23.1% as BI-RADS 5. Discordant cases — radiologically benign (BI-RADS 2) but cytologically atypical or malignant — underscored the importance of not relying on imaging alone.

Table 6: Correlation between FNAC categories and BI-RADS classification

FNAC Category	Most Frequent BI-RADS	Concordance	Clinical Implication
C2 (Benign)	BI-RADS 2	71.7%	Routine follow-up
C3 (Atypical)	BI-RADS 3/4	Variable	Core needle biopsy recommended
C5 (Malignant)	BI-RADS 4/5	76.9%	Oncosurgical referral

3.8 Comparison with Published Literature

Table 7: Comparative analysis of FNAC findings across studies

Study (Year)	n	Fibroadenoma (%)	Malignancy (%)	Benign (%)
Present Study (2024)	74	48.6	17.57	71.62
Bukhari et al. (2018)	150	34.67	14.67	42.67
Mridha et al. (2021)	61	34.67	24.5	65.5
Arora et al. (2019)	65	32.3	27.7	72.3

DISCUSSION

4.1 Demographic Findings

The marked female preponderance in our study (89.19%) is consistent with established epidemiological patterns of breast disease. The mean age of 35.03 years, with peak presentation in the 21–30 year group, reflects the well-recognised younger age at presentation of benign breast lesions, particularly fibroadenomas, in South Asian women. This aligns with Arora et al. (mean age 34.5 years) and Pandit et al. (fibroadenomas predominating in 20–29 year olds).[43,44] The male representation (10.81%) is attributable to our inclusive study design encompassing all breast pathologies rather than focusing exclusively on malignancies.

4.2 Laterality and Quadrant Distribution

The near-equal distribution between right (50%) and left (44.59%) breast involvement in our cohort differs from several international studies that document a left-sided predominance in breast cancer (left/right ratio 1.05–1.26 in a US analysis of 1.2 million cases).[47] However, our findings correspond well with an Indian study reporting 47.13% left-sided and 43.12% right-sided breast lesions.[46] The upper outer quadrant predominance (40.5%) is a consistent finding across the literature, explained by the greater volume of glandular tissue in this region.

4.3 Clinical Characteristics

Most lumps were firm (86.54%) and mobile (90.54%), characteristics concordant with the dominantly benign pathology in our cohort. The rarity of nipple discharge (1.35%) contrasts with historical reports of 9–14% in non-pregnant women but aligns with studies focused primarily on palpable lumps, suggesting a selection bias. When discharge is present — particularly spontaneous, unilateral serous or bloody discharge — it warrants thorough investigation, as 5–33% of such cases may harbour underlying malignancy.[49]

4.4 FNAC Findings and Diagnostic Adequacy

The low inadequate sample rate (C1: 2.7%) in our study reflects the technical proficiency of performing ultrasound-guided FNAC and the experience of our cytopathologists. The literature reports rates up to 3.1%.[55] The predominance of C2 (benign) cases (71.62%) is consistent with other Indian tertiary care data. The malignant category (C5: 17.57%) falls within the reported range of 15.7–38.9% in FNAC series.

4.5 Spectrum of Breast Lesions

Fibroadenoma (48.6%) was the most frequent lesion — corroborating its established status as the most common benign breast tumour in young women. Ductal cell carcinoma was the dominant malignancy (17.6%), consistent with global epidemiology where invasive ductal carcinoma accounts for approximately 70–80% of breast cancers. Gynecomastia in male patients (8.1%) reinforces the need for inclusive diagnostic protocols in breast clinics. Inflammatory lesions (mastitis, granulomatous mastitis) were encountered at lower rates than in some published series (4.1% vs. 9.2–13.3%), potentially reflecting referral patterns and study inclusion criteria.

4.6 BI-RADS Distribution and FNAC–BI-RADS Concordance

BI-RADS 2 predominance (55.4%) mirrored the FNAC C2 preponderance, supporting good overall imaging–cytology concordance for unequivocally benign lesions. The substantial proportion of BI-RADS 4 lesions (24.32%) underscores the imaging heterogeneity of suspicious findings, where malignancy risk spans 2–95%. In our study, 53.8% of FNAC C5 cases were classified as BI-RADS 4 and 23.1% as BI-RADS 5, comparable to published data from Sciendo (2021): 51.9% of BI-RADS 4C lesions had malignant FNAC findings.[61]

The moderate inter-modality agreement ($\kappa = 0.44$, Spearman $r = 0.677$) in our study reflects the well-recognised limitations of single-modality assessment. Discordant cases — particularly BI-RADS 2 lesions with atypical or malignant cytology — demonstrate that radiological benignity alone cannot exclude significant pathology. Published FNAC diagnostic parameters (sensitivity 90.48–96.67%; specificity 97.56–100%; PPV 95.24–100%; NPV 95.24–97.56%) further validate FNAC as a high-performance first-line tool when combined with ultrasound.[64,65]

4.7 Limitations

The absence of histopathological confirmation as a gold standard for all cases limits definitive sensitivity and specificity calculations for our cohort. The relatively small sample size (n=74), single-centre design, and 18-month study period restrict generalizability. Future multicentre studies with larger cohorts and histopathological correlation are warranted.

CONCLUSION

This prospective study characterized the cytomorphological spectrum of 74 palpable breast lesions in a south Indian tertiary care setting. Fibroadenoma was the most common diagnosis (48.6%), and duct cell carcinoma the predominant malignancy (17.6%), consistent with both national and international data. FNAC, standardized using the IAC Yokohama System, demonstrated high diagnostic utility with a low inadequate sample rate (2.7%) and a strong definitive categorization rate (89.19% for C2+C5 combined).

A statistically significant moderate correlation between FNAC and BI-RADS categorization ($\kappa = 0.44$; $r = 0.677$, $p < 0.001$) underscores the complementary, rather than substitutable, relationship between these modalities. Discordant cases affirm that neither FNAC nor ultrasound alone can replace the triple assessment protocol. We strongly advocate the integrated triple assessment approach — clinical evaluation, BI-RADS ultrasonography, and IAC Yokohama–categorized FNAC — as the standard of care for palpable breast lumps, especially in resource-constrained Indian health systems where histopathological workup carries significant cost and time burdens.

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