

COMPARATIVE EVALUATION OF FINE NEEDLE ASPIRATION CYTOLOGY AND TRU-CUT BIOPSY IN THE DIAGNOSIS AND GRADING OF BREAST LESIONS: A PROSPECTIVE OBSERVATIONAL STUDY

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Abstract

Background

Accurate pathological diagnosis of suspicious breast lesions is essential for appropriate therapeutic planning. Fine needle aspiration cytology (FNAC) is a rapid and minimally invasive technique, whereas Tru-cut biopsy provides superior tissue architecture and histological grading. This study compared the diagnostic utility and grading concordance of FNAC with Tru-cut biopsy in clinically suspicious breast lesions.

Methods

A prospective observational study was conducted on 70 consecutive patients with clinically suspicious breast lesions between July 2024 and December 2025. All patients underwent both FNAC and Tru-cut biopsy. Cytological grading was performed using the Robinson grading system, while histological grading was assessed using the Nottingham modification of the Scarff–Bloom–Richardson grading system. Agreement between the two techniques was evaluated using Cohen's kappa coefficient.

Results

The highest proportion of patients belonged to the 41–50-year age group (41.4%), and females constituted 98.6% of the study population. The upper outer quadrant was the commonest site of involvement (52.9%). FNAC diagnosed malignancy in 65 (92.9%) cases, whereas Tru-cut biopsy identified 68 (97.1%) malignant lesions, with no statistically significant difference in overall diagnostic distribution ($p = 0.38$). Invasive ductal carcinoma (NOS) was the predominant histological subtype. Grade II tumours were the most frequent on both FNAC (61.5%) and Tru-cut biopsy (63.1%). FNAC grading showed 93.8% concordance with Tru-cut biopsy grading, demonstrating excellent agreement ($\kappa = 0.896$, $p < 0.001$).

Conclusion

FNAC demonstrated excellent concordance with Tru-cut biopsy for the diagnosis and cytological grading of suspicious breast lesions. While Tru-cut biopsy remains indispensable for definitive histopathological evaluation and tumour characterization, FNAC continues to be a valuable, rapid, minimally invasive, and cost-effective first-line diagnostic modality, particularly in resource-limited settings.

Keywords: Breast Neoplasms; Fine-Needle Aspiration; Core Needle Biopsy; Cytological Techniques; Histopathology; Diagnostic Concordance.

How to cite this article: Bhatia K, Madan M, Sharma M, Gill PK. Comparative Evaluation of Fine Needle Aspiration Cytology and Tru-Cut Biopsy in the Diagnosis and Grading of Breast Lesions: A Prospective Observational Study. *Int J Drug Deliv Technol.* 2026;16(69s): 2119-2124. DOI: 10.25258/ijddt.16.69s.208

INTRODUCTION

Breast cancer is the most frequently diagnosed malignancy and the leading cause of cancer-related mortality among women worldwide. According to the Global Cancer Statistics (GLOBOCAN 2022), breast cancer accounted for approximately 2.3 million new cases and over 665,000 deaths, highlighting its

substantial public health burden. In India, the incidence of breast cancer has steadily increased over the past decade, and it has surpassed cervical cancer to become the most common cancer among women. Early diagnosis remains the cornerstone for improving survival, reducing treatment-related morbidity, and enabling breast-conserving therapeutic strategies.[1,2]

The evaluation of a suspicious breast lesion relies on the triple assessment, comprising clinical examination, imaging, and pathological confirmation. Tissue diagnosis is indispensable because clinical and radiological findings alone cannot reliably distinguish benign from malignant lesions. Among minimally invasive diagnostic techniques, fine needle aspiration cytology (FNAC) and core needle (Tru-cut) biopsy are the most widely employed owing to their safety, cost-effectiveness, and ability to provide preoperative diagnosis.[3]

FNAC is a rapid outpatient procedure that provides cytomorphological assessment with minimal patient discomfort and excellent diagnostic accuracy in experienced hands. It facilitates prompt clinical decision-making and reduces unnecessary surgical interventions for benign lesions. However, FNAC has inherent limitations, including inadequate sampling, inability to assess tissue architecture, difficulty in differentiating in situ from invasive carcinoma, and restricted utility for biomarker evaluation.[4] In contrast, Tru-cut biopsy retrieves intact tissue cores that preserve architectural details, allowing definitive histopathological diagnosis, tumour grading, assessment of invasion, and immunohistochemical evaluation of predictive biomarkers such as estrogen receptor (ER), progesterone receptor (PR), HER2, and Ki-67. Consequently, Tru-cut biopsy has become the preferred method for evaluating suspicious breast lesions in contemporary oncological practice.[2,5]

Despite the growing preference for Tru-cut biopsy, FNAC continues to be extensively used in resource-constrained settings because of its simplicity, affordability, and rapid turnaround time. Determining the diagnostic concordance between these two techniques is therefore clinically important, particularly in institutions where both modalities are available. Comparative evaluation of FNAC and Tru-cut biopsy provides valuable information regarding their diagnostic accuracy, complementary roles, and suitability in different clinical scenarios, thereby facilitating evidence-based management of patients presenting with suspicious breast lesions.

MATERIALS AND METHODS

Study Design and Setting

This prospective observational study was conducted in the Department of Pathology, Sri Guru Ram Das Institute of Medical Sciences and Research, Amritsar, Punjab, India, over an 18-month period from July 2024 to December 2025. The study was approved by the Institutional Ethics Committee, and written informed consent was obtained from all participants before enrolment.

Study Population

The study included consecutive patients presenting with clinically suspicious breast lumps who were referred for Tru-cut biopsy. All enrolled patients underwent both fine needle aspiration cytology (FNAC) and Tru-cut biopsy of the same breast lesion. Cytological findings were compared with histopathological findings, with Tru-cut biopsy considered the reference (gold standard)

for diagnostic evaluation.

Inclusion Criteria: Patients of either sex presenting with breast lumps clinically suspicious for malignancy.

Exclusion Criteria: Uncooperative patients or those refusing the procedure. Patients with significantly deranged coagulation parameters (prothrombin time/international normalized ratio) predisposing to bleeding complications.

Fine Needle Aspiration Cytology

FNAC was performed under aseptic precautions using a 22-gauge needle attached to a 20-mL syringe mounted on a syringe holder. After immobilization of the breast lump, multiple passes were made using negative pressure to obtain representative cellular material. Smears were immediately prepared, air-dried for May-Grünwald-Giemsa (MGG) staining and alcohol-fixed for Papanicolaou (Pap) staining. Cytomorphological diagnosis was established by experienced pathologists. Cytological grading of malignant lesions was performed according to the Robinson grading system, based on cell dissociation, cell size, cell uniformity, nucleoli, nuclear margins, and chromatin pattern, with total scores categorized as Grade I (6–11), Grade II (12–14), and Grade III (15–18).

Tru-cut Biopsy

Following local infiltration with 2% lignocaine, Tru-cut biopsy was performed under aseptic conditions using a core biopsy needle through a small skin incision. Multiple tissue cores (5–8 passes) were obtained from different areas of the lesion to ensure adequate sampling. Specimens were fixed in 10% neutral buffered formalin, processed routinely, embedded in paraffin, sectioned, and stained with hematoxylin and eosin (H&E). Histopathological diagnosis and tumour grading were performed using the Nottingham modification of the Scarff-Bloom-Richardson grading system.

Outcome Measures

The primary outcome was to determine and compare the diagnostic accuracy of FNAC with Tru-cut biopsy in the evaluation of clinically suspicious breast lesions.

The secondary outcomes included:

Determination of the cytomorphological spectrum of breast lesions on FNAC.

Determination of the histopathological spectrum of breast lesions on Tru-cut biopsy.

Assessment of concordance between FNAC and Tru-cut biopsy findings.

Statistical Analysis

Data were analysed using IBM SPSS Statistics version 26.0 (IBM Corp., Armonk, NY, USA). Categorical variables were expressed as frequencies and percentages. The diagnostic distribution obtained by FNAC and Tru-cut biopsy was compared using the chi-square test. Agreement between FNAC and Tru-cut biopsy grading was assessed using Cohen's kappa coefficient. A p value <0.05 was considered statistically significant.

RESULTS

A total of 70 patients with clinically diagnosed breast lesions were included in the study. The mean age

distribution peaked in the 41–50-year age group (41.4%), followed by 51–60 years (25.7%). Females constituted 98.6% of the study population. The left breast was slightly more frequently involved (55.7%), and the upper outer quadrant was the commonest site (52.9%). Most patients presented with breast lumps measuring 2–5 cm (51.4%), while 45.7% had associated axillary lymphadenopathy (Table 1; Figure 1).

Table 1. Baseline demographic and clinical characteristics of study participants (N = 70)

Variable	n (%)
Age group (years)	
21–30	2 (2.9)
31–40	15 (21.4)
41–50	29 (41.4)
51–60	18 (25.7)
61–70	5 (7.1)
71–80	1 (1.4)
Gender	
Female	69 (98.6)
Male	1 (1.4)
Side of lesion	
Right	31 (44.3)
Left	39 (55.7)
Central	5 (7.1)
Diffuse	3 (4.3)
Lump size	
<2 cm	0
2–5 cm	36 (51.4)
>5 cm	34 (48.6)
Axillary lymphadenopathy	
Present	32 (45.7)
Absent	38 (54.3)

*Patients may have had more than one associated clinical feature.

PRESENTING COMPLAINTS OF STUDY PARTICIPANTS (N = 70)

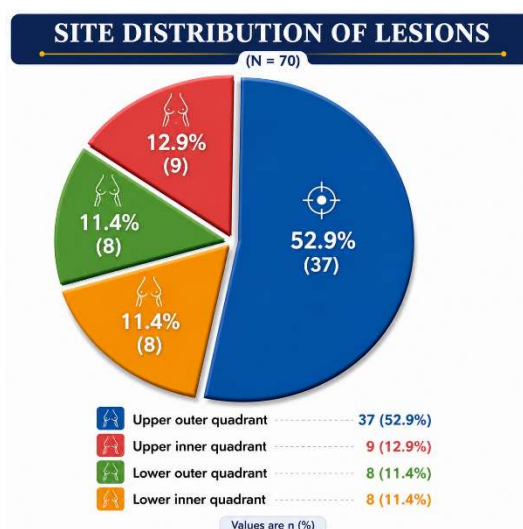
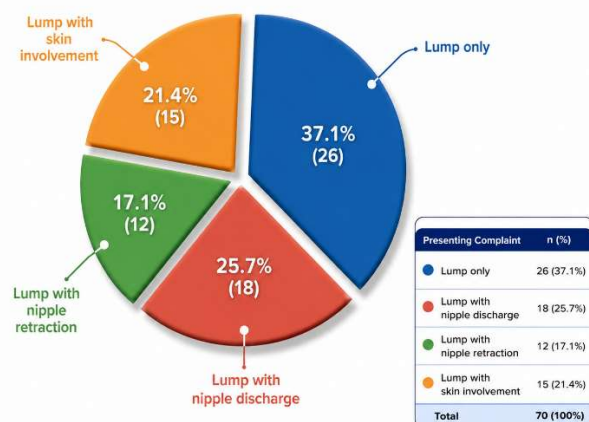


Figure 1: Distribution of presenting complaints and anatomical site of breast lesions among the study participants.

FNAC diagnosed malignancy in 65 (92.9%) cases, whereas Tru-cut biopsy confirmed malignancy in 68 (97.1%) cases. Three FNAC samples were non-diagnostic. There was no statistically significant difference between the overall diagnostic distribution obtained by the two methods ($p=0.38$ Table 2).

Table 2. Comparison of morphological diagnosis by FNAC and Tru-cut biopsy

Diagnosis	FNAC n (%)	Tru-cut biopsy n (%)
Malignant	65 (92.9)	68 (97.1)
Fibroadenoma	1 (1.4)	1 (1.4)
Phyllodes tumour	1 (1.4)	1 (1.4)
Non-diagnostic	3 (4.3)	0
Total	70	70

Comparison: χ^2 test, $p = 0.38$

Invasive ductal carcinoma (NOS) was the predominant malignant lesion identified by both techniques. Grade II tumours were the most frequent on both FNAC (61.5%) and Tru-cut biopsy (63.1% Table 3).

Table 3. Histological subtype and tumour grading

Variable	FNAC n (%)	Tru-cut biopsy n (%)
Histological subtype		
Ductal carcinoma, NOS	65	67
Mucinous carcinoma	0	1
Tumour grade		
Grade I	5 (7.7)	6 (9.2)
Grade II	40 (61.5)	41 (63.1)
Grade III	20 (30.8)	18 (27.7)

Among the 65 malignant cases, FNAC grading was concordant with Tru-cut biopsy grading in 61 (93.8%)

cases, while discordance was observed in 4 (6.2%) cases. Cohen's kappa coefficient demonstrated excellent agreement between FNAC and Tru-cut biopsy grading ($\kappa = 0.896$, $p < 0.001$), indicating a high level of concordance between the two diagnostic modalities (Table 4).

Table 4. Agreement between FNAC and Tru-cut biopsy grading

Parameter	Value
Cases compared	65
Concordant grading	61 (93.8%)
Discordant grading	4 (6.2%)
Cohen's κ	0.896
p-value	<0.001

DISCUSSION

The present prospective observational study evaluated the comparative role of fine needle aspiration cytology (FNAC) and Tru-cut biopsy in the diagnosis and grading of breast lesions. Both techniques demonstrated excellent concordance in the evaluation of malignant breast lesions, highlighting their complementary roles in contemporary breast pathology. While FNAC provides rapid cytomorphological assessment with minimal invasiveness, Tru-cut biopsy offers superior architectural preservation, enabling definitive histopathological diagnosis and tumour grading.

Breast carcinoma predominantly affected patients in the 41–50-year age group (41.4%), followed by those aged 51–60 years (25.7%). Similar age distributions have been reported by Sharma et al. [6]; Makwana et al. [7] and the National Cancer Registry Programme (NCRP), demonstrating that breast cancer in India commonly presents nearly a decade earlier than in many Western populations. Earlier disease onset has been attributed to demographic variation, reproductive factors, lifestyle changes, increasing obesity, and improved awareness leading to earlier clinical evaluation. The predominance of patients in the economically productive age group emphasizes the importance of timely diagnosis and effective screening strategies.

Females accounted for 98.6% of cases, with only one male patient included in the study. Male breast cancer remains an uncommon entity, accounting for approximately 1% of all breast malignancies worldwide. The present findings are therefore consistent with the established epidemiological pattern reported in contemporary literature. [8-10]

Clinically, a palpable breast lump was the predominant presenting complaint, either alone or in combination with nipple discharge, nipple retraction, or skin involvement. These findings reinforce that a breast lump remains the most frequent symptom prompting pathological evaluation. Advanced clinical manifestations such as nipple retraction and skin involvement generally reflect locally advanced disease, underscoring the continued challenge of delayed presentation in low- and middle-income countries.

The left breast was slightly more frequently involved

than the right breast, while the upper outer quadrant represented the commonest anatomical location of the lesion (52.9%). This distribution closely parallels observations reported by Rahman et al.[11]; Sundaram et al.[12]. The predominance of the upper outer quadrant is biologically plausible because this region contains the greatest concentration of terminal duct-lobular units, from which the majority of breast carcinomas originate.

FNAC identified malignancy in 92.9% of patients, whereas Tru-cut biopsy confirmed malignancy in 97.1% of cases. Although the difference was not statistically significant, three cases remained non-diagnostic on FNAC, illustrating one of the recognised limitations of cytology. Sampling inadequacy, hypocellular lesions, fibrosis, and mucin-rich tumours may reduce cytological yield and contribute to indeterminate results. In contrast, Tru-cut biopsy preserves tissue architecture, allowing more reliable differentiation of invasive lesions and facilitating histological classification. Consequently, both investigations should be viewed as complementary rather than competing diagnostic techniques within the framework of triple assessment.

Invasive ductal carcinoma (no special type) constituted the overwhelming majority of malignant lesions in the present study, whereas only one case of mucinous carcinoma was identified on Tru-cut biopsy. These observations are consistent with Tan et al.[13]; Hamdy et al. [14], where invasive ductal carcinoma accounts for nearly 70–80% of all invasive breast cancers [15]. The mucinous carcinoma missed on FNAC illustrates the limitations of cytological sampling in certain histological variants and highlights the additional diagnostic value provided by tissue biopsy.

Tumour grading is an important determinant of prognosis and therapeutic decision-making. In the present study, Grade II tumours predominated on both FNAC (61.5%) and Tru-cut biopsy (63.1%), followed by Grade III lesions. Similar distributions have been reported by Ajitha et al.[16]; Tripathi et al.[17] and Rahman et al.[11] indicating that moderately differentiated carcinomas represent the most frequent histological grade encountered in routine practice. The close agreement between cytological and histopathological grading suggests that Robinson's cytological grading system reliably reflects tumour differentiation before definitive surgery.

One of the most significant findings of the present study was the excellent concordance between FNAC and Tru-cut biopsy grading. Agreement was observed in 93.8% of malignant cases, with a Cohen's kappa coefficient of 0.896 ($p < 0.001$), indicating almost perfect agreement. Comparable levels of concordance have been reported by Rupom et al.[18] Reliable preoperative cytological grading may aid multidisciplinary treatment planning, particularly in selecting patients for neoadjuvant therapy while awaiting definitive histopathological assessment.

Overall, the findings demonstrate that FNAC remains a valuable first-line diagnostic investigation because of

its simplicity, rapid turnaround time, low cost, and excellent agreement with histopathological grading. Nevertheless, Tru-cut biopsy continues to provide indispensable information regarding tissue architecture, tumour subtype, and definitive grading, making it the preferred modality whenever complete pathological characterization is required.

Limitations

The present study was conducted at a single tertiary care centre with a relatively small sample size and a predominance of malignant lesions, which may limit the generalizability of the findings. In addition, immunohistochemical and molecular profiling were not incorporated. Larger multicentric studies integrating biomarker evaluation and long-term clinical outcomes are warranted to further validate the comparative performance of FNAC and Tru-cut biopsy.

CONCLUSION

FNAC demonstrated excellent agreement with Tru-cut biopsy in the diagnosis and grading of suspicious breast lesions, supporting its role as an effective first-line diagnostic investigation. Although Tru-cut biopsy remains the reference standard because of its ability to evaluate tissue architecture and facilitate tumour grading, FNAC offers rapid, minimally invasive, and economical preliminary diagnosis with high concordance. Integrating both modalities within the triple assessment approach can improve diagnostic confidence, expedite clinical decision-making, and optimize the management of patients presenting with suspicious breast lesions.

Funding: None.

Conflict of Interest: The authors declare no conflict of interest.

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