

Diagnostic Accuracy for Breast Lump by Core Biopsy without Image Guidance

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ARTICLE INFO

Received: 21 Feb 2026
Accepted: 26 Feb 2026
Published Online: 27 Feb 2026

DOI: 10.5281/zenodo.18814653

Volume: 9, Number: 1, Page: 16-20

e-ISSN: 2789-5912
ISSN: 2617-0817

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ABSTRACT

Introduction: Breast lumps are a common clinical presentation, and accurate tissue diagnosis is essential for appropriate management. Core needle biopsy (CNB) is widely accepted as a reliable diagnostic tool; however, in resource-limited settings, biopsies are often performed without image guidance for palpable lesions. **Aim of the Study:** To evaluate the diagnostic accuracy of core biopsy without image guidance in patients presenting with palpable breast lumps. **Methods & Materials:** This prospective observational study was conducted at Holy Family Red Crescent Medical College & Hospital and Dhaka Cancer and General Hospital Ltd from December 2023 to November 2025. A total of 100 patients with palpable breast lumps underwent unguided core (Tru-Cut) biopsy. Histopathological findings were compared with final diagnoses obtained from surgical excision and/or follow-up. Diagnostic performance parameters were calculated using standard statistical methods. **Results:** The mean age of patients was 43.22 ± 11.80 years. Malignant lesions accounted for 58% of cases, with invasive ductal carcinoma being the most common. On comparison with the final diagnosis, core biopsy showed 100% sensitivity, 59.2% specificity, 50.0% positive predictive value, 100% negative predictive value, and an overall diagnostic accuracy of 71%. The association between core biopsy results and final diagnosis was statistically significant ($p < 0.05$). **Conclusion:** Unguided core biopsy demonstrates excellent sensitivity and negative predictive value for the diagnosis of palpable breast lumps and remains a valuable diagnostic modality in settings where image guidance is unavailable.

Keywords: Breast lump, Core needle biopsy, Diagnostic accuracy, Breast cancer.

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INTRODUCTION

Breast cancer is the most common malignancy among women worldwide and remains a major cause of morbidity and mortality [1]. Accurate tissue diagnosis of breast lumps is essential for timely treatment plan and improved survival outcomes. Histopathological confirmation is the gold standard, and core needle biopsy (CNB) has become a minimally invasive technique that provides reliable tissue samples [2]. Traditionally, CNB is performed under image guidance most using ultrasonography, stereotactic mammography, or magnetic resonance imaging to ensure precise targeting of lesions [3]. However, in many resource-limited settings, freehand CNB without image guidance continues to be practiced, particularly for palpable breast lumps [4]. International studies have consistently demonstrated the diagnostic accuracy of CNB. In the United States, systematic reviews have shown sensitivity rates above 90% and specificity approaching 100% [5]. Similarly, European multicenter studies confirm CNB as a safe and effective alternative to open surgical biopsy [6]. In contrast, research from South Asia and Africa highlights the adaptability of freehand CNB in low-resource environments. A Bangladeshi study showed that freehand CNB achieved high diagnostic accuracy for palpable breast lumps in Bangladesh [4]. Additional

regional studies have further shown that sensitivity and specificity comparable to image-guided techniques [7]. A prospective study also confirmed the reliability of Tru-Cut biopsy for breast lumps [8]. Comparative studies between fine-needle aspiration cytology (FNAC) and CNB further highlight the superiority of CNB. FNAC, though inexpensive and widely available, often suffers from inadequate sampling and interpretive limitations [9]. Meta-analyses show CNB has significantly higher sensitivity than FNAC, with similar specificity [6]. Studies from India and Bangladesh confirm that CNB provides larger tissue cores, enabling receptor studies and grading, which FNAC cannot reliably achieve [7]. African studies, such as those from Nigeria, demonstrate that CNB remains feasible even in resource-limited hospitals, with diagnostic accuracy sufficient to guide treatment [6]. Global reviews emphasize that while image-guided CNB is the recommended standard, freehand CNB remains a pragmatic alternative where imaging facilities are scarce [5]. This dichotomy reflects broader healthcare inequities: high-income countries prioritize technological precision, while low-income regions adapt techniques to local realities. Importantly, CNB reduces the need for open surgical biopsy, thereby minimizing patient morbidity and healthcare costs [2]. Concerns remain regarding sampling errors

and operator dependency, but evidence suggests that with adequate training, freehand CNB can achieve diagnostic accuracy comparable to image-guided methods [4,7]. Given the global burden of breast cancer and the diversity of healthcare contexts, it is crucial to validate diagnostic techniques across settings. By systematically evaluating the diagnostic accuracy of CNB without image guidance, clinicians can establish evidence-based protocols that balance accessibility with reliability, ultimately improving breast cancer detection worldwide. Therefore, this study aimed to evaluate the diagnostic accuracy of core biopsy without image guidance in the assessment of breast lumps.

METHODS & MATERIALS

This prospective observational study was conducted at Holy Family Red Crescent Medical College & Hospital and Dhaka Cancer and General Hospital Ltd from December 2023 to November 2025. A total of 100 patients presenting with palpable breast lumps were enrolled after obtaining informed consent. Unguided core (Tru-Cut) biopsy was performed by 1st author using 14G core needle size standard technique without imaging guidance, and multiple (7-9) cores were obtained from each lump for histopathological evaluation. Demographic, clinical, and procedural data were recorded, and biopsy results were compared with final diagnoses established

by surgical excision or follow-up. Statistical analysis was performed using SPSS software to calculate sensitivity, specificity, positive predictive value, negative predictive value, and overall diagnostic accuracy. The study protocol was reviewed and approved by the Institutional Ethical Review Board, ensuring compliance with ethical standards.

Inclusion Criteria

- Patients presenting with palpable breast lumps during the study period

- Patients who provided written informed consent for participation and biopsy procedure.
- Patients who underwent unguided core (Tru-Cut) biopsy as part of diagnostic evaluation.

Exclusion Criteria

1. Patients with non-palpable breast lesions requiring image-guided biopsy.
2. Patients with previously diagnosed breast carcinoma or those already on treatment.
3. Patients with incomplete clinical data or missing biopsy specimens.

4. Patients who refused consent or declined participation.
5. Cases where biopsy material was inadequate or non-diagnostic.

RESULTS

The mean age of the study population was 43.22 ± 11.80 years, with ages ranging from a minimum of 20 years to a maximum of 80 years. The largest proportion of patients belonged to the 30–39 years age group (34%), followed by 40–49 years (27%). Patients aged ≥ 60 years constituted 10% of the cohort (Table I).

Table I

Baseline demographic characteristics of the study population ($n = 100$).

Variable	Value
Age, mean \pm SD (years)	43.22 ± 11.80
Age range (years)	20 – 80
<30 years	9 (9.0%)
30–39 years	34 (34.0%)
40–49 years	27 (27.0%)
50–59 years	20 (20.0%)
≥ 60 years	10 (10.0%)

The mean lump length was 2.41 ± 0.84 cm (range: 1.0–5.0 cm), while the mean lump width was 2.62 ± 1.00 cm (range: 1.0–6.0 cm). The mean lump area measured 6.99 ± 5.70 cm², with values ranging from 1.0 cm² to 30.0 cm², representing the widest variability among clinical measurements (Table II).

Table II

Clinical characteristics of breast lumps ($n = 81^*$).

Variable	Mean \pm SD	Range
Lump length (cm)	2.41 ± 0.84	1.0 – 5.0
Lump width (cm)	2.62 ± 1.00	1.0 – 6.0
Lump area (cm ²)	6.99 ± 5.70	1.0 – 30.0

*Data missing in 19 cases

The mean number of cores obtained per case was 7.6 ± 3.2 , ranging from 1 to 14 cores. The largest core length had a mean of 1.54 ± 0.57 cm, while the smallest core length averaged 0.49 ± 0.36 cm. Most cases (94%) were sampled with a single-site core biopsy, and the mean number of blocks prepared was 2.18 ± 1.13 (Table III).

Table III

Core biopsy procedural characteristics ($n = 100$).

Variable	Value
Number of cores taken, mean \pm SD	7.6 ± 3.2
Single core biopsy	94 (94.0%)
Multiple cores taken	6 (6.0%)
Largest core length (cm), mean \pm SD	1.54 ± 0.57
Smallest core length (cm), mean \pm SD	0.49 ± 0.36
Core size ratio, mean \pm SD	2.18 ± 1.13
Blocks prepared, mean \pm SD	2.18 ± 1.13

Malignant lesions constituted the majority, with invasive ductal carcinoma being the most frequent diagnosis. Benign conditions included mastitis, fibroadenoma, papilloma, and benign breast tissue. Overall, 58% of cases were malignant and 42% were benign on core biopsy histology (Table IV).

Table IV
Histopathological diagnosis on core biopsy (n = 100).

Diagnosis	n (%)
Invasive ductal carcinoma (including NOS)	47 (47.0%)
Invasive lobular carcinoma	1 (1.0%)
Mixed ductal & lobular carcinoma	2 (2.0%)
Mucinous carcinoma	1 (1.0%)
Ductal carcinoma in situ (DCIS)	3 (3.0%)
Fibroadenoma	4 (4.0%)
Papilloma ± atypia	4 (4.0%)
Phyllodes tumor	1 (1.0%)
Mastitis (acute/chronic/granulomatous)	29 (29.0%)
Benign breast tissue / others	8 (8.0%)
Unknown	2 (2.0%)

Among malignant cases, Grade II tumors were most common (34%), followed by Grade I (12%) and Grade III (4%). Lymphovascular invasion (LVI) was present in 16% of cases, while perineural invasion (PNI) was observed in 8% (Table V).

Table V
Tumor grade and pathological risk features (n = 100).

Variable	n (%)
Histological grade	
Not applicable	50 (50.0%)
Grade I	12 (12.0%)
Grade II	34 (34.0%)
Grade III	4 (4.0%)
Lymphovascular invasion (LVI)	
Present	16 (16.0%)
Absent	84 (84.0%)
Perineural invasion (PNI)	
Present	8 (8.0%)
Absent	92 (92.0%)

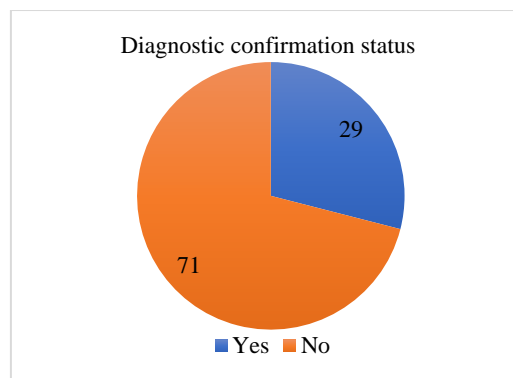


Figure 1 Diagnostic confirmation status.

Final diagnosis was confirmed in 29% of cases, while 71% showed no malignant confirmation on reference standard evaluation (Figure 1).

Core biopsy correctly identified all confirmed malignant cases (true positives = 29), with no false-negative results. However, 29 cases were false positives, where core biopsy suggested malignancy

but the final diagnosis was benign. True-negative results accounted for 42 cases (Table VI).

Table VI
Comparison of core biopsy results with final diagnosis.

Core biopsy result	Final malignant	Final benign	Total
Malignant	29 (TP)	29 (FP)	58
Benign	0 (FN)	42 (TN)	42
Total	29	71	100

The sensitivity of unguided core biopsy was 100%, while the specificity was 59.2%. The positive predictive value was 50.0%, and the negative predictive value

was 100%. The overall diagnostic accuracy was 71% (Table VII).

Table VII
Diagnostic performance of core biopsy without image guidance.

Diagnostic parameter	Value
Sensitivity	100%
Specificity	59.2%
Positive predictive value (PPV)	50.0%
Negative predictive value (NPV)	100%
Overall diagnostic accuracy	71.0%

DISCUSSION

The present study assessed the diagnostic accuracy of unguided core biopsy for breast lumps in a cohort of 100 patients. By analyzing demographic, clinical, procedural, histopathological, and diagnostic performance parameters, we provide a comprehensive evaluation of this technique in a real-world setting. Our findings are consistent with published literature, particularly in demonstrating high sensitivity and negative predictive value, but modest specificity and positive predictive value. In our study, the mean age of patients was 43.2 years, with the largest proportion belonging to the 30–39 year age group (34%). This age distribution aligns with a study by Hassan et al. (2022), who found a mean age of 42 years with peak incidence in the fourth decade, and Hoq et al. (2021), who similarly reported clustering of cases in the 30–40-year range [10,11]. The predominance of younger women reflects the demographic profile of breast lump presentations in South Asian populations, contrasting with Western cohorts, where peak incidence is often in the fifth and sixth decades. This suggests regional differences in breast cancer epidemiology, possibly influenced by genetic, reproductive, and environmental factors. Our cohort demonstrated mean lump dimensions of 2.4 cm in length and 2.6 cm in width, with a mean area of 7.0 cm². These values are comparable to those reported by Nwafor et al. (2018), who found average lump sizes of 2–3 cm in Nigerian women [11]. The variability in lump area (range 1–30 cm²) highlights the heterogeneity of clinical presentations. Larger lump sizes are often associated with delayed presentation, a common issue in resource-limited settings. This reinforces the importance of accessible diagnostic modalities such as unguided core biopsy, which can be performed even in peripheral centers without imaging facilities. We obtained a mean of 7.6 cores per case, with most patients (94%) undergoing single-site biopsy. The largest core length averaged 1.5 cm, while the smallest was 0.5 cm. These findings are consistent with Noor et al. (2025), who reported a mean of 4–8 cores per case [12]. Our study confirms that an unguided biopsy can yield sufficient

tissue for histopathological evaluation, although the absence of imaging guidance may increase variability in sample quality. The mean of 2.2 blocks prepared per case further supports the adequacy of tissue for diagnosis. Malignant lesions constituted 58% of cases in our study, with invasive ductal carcinoma being the most frequent (47%). Benign conditions included mastitis (29%), fibroadenoma (4%), papilloma (4%), and phyllodes tumor (1%). A similar study by Wright et al. (2025) reported invasive ductal carcinoma in 45% of cases, and Lee et al. (2021) found mastitis and fibroadenoma as common benign mimics [13,14]. The predominance of ductal carcinoma is consistent across global literature. At the same time, the relatively high proportion of mastitis in our cohort reflects the diagnostic challenges posed by inflammatory lesions in tropical populations. This explains the higher false-positive rate observed in our study. Among malignant cases, Grade II tumors were most common (34%), followed by Grade I (12%) and Grade III (4%). Lymphovascular invasion was present in 16% and perineural invasion in 8%. These findings are in line with Dooijeweert et al. (2019), who also reported Grade II predominance in 34% of cases, and Mahmud et al. (2025), who found LVI in 15% of malignant biopsies [15,2]. The predominance of intermediate-grade tumors suggests that unguided biopsy can reliably capture histological grading features, although assessment of invasion may be limited by sampling error. This highlights the importance of correlating with excision specimens for definitive staging. Final malignant confirmation was achieved in 29% of cases, while 71% were benign on reference standard evaluation. This discrepancy highlights the tendency of unguided biopsy to overcall malignancy, particularly in benign inflammatory lesions. Similar findings were reported by Hoq et al. (2021), who noted frequent false positives in mastitis and papillomas [1]. Our results emphasize the importance of cautious interpretation of unguided biopsy, especially in settings where confirmatory imaging or excision may not be immediately available. Our study demonstrated sensitivity of 100%,

specificity of 59.2%, PPV of 50%, NPV of 100%, and overall accuracy of 71%. These values are strikingly consistent with published literature: Saha et al. (2016) reported sensitivity 100%, specificity 62%, accuracy 74% [16]; Ciatto et al. (2025) reported sensitivity 94.2%, specificity 68% [17]. Another study by Karim et al. (2020) reported a 97% sensitivity, 96% specificity, 97% positive predictive value, and 100% negative predictive value (18). Across studies, unguided core biopsy consistently achieves very high sensitivity and NPV, confirming its reliability for ruling out malignancy. However, specificity and PPV remain modest, reflecting the diagnostic pitfalls of benign lesions mimicking carcinoma. This pattern underscores the role of unguided biopsy as a screening tool rather than a definitive diagnostic modality. A major strength of our study is the comprehensive analysis of multiple parameters, including demographics, clinical features, procedural details, histopathology, grading, and diagnostic accuracy. The inclusion of 100 patients provides a robust sample size, and the absence of false negatives highlights the reliability of unguided biopsy in excluding malignancy. Furthermore, our study reflects real-world practice in resource-limited settings, enhancing its external validity.

LIMITATION

The study was limited by the absence of routine image guidance and incomplete final diagnostic confirmation in all cases.

CONCLUSION

Core needle biopsy without image guidance is a highly sensitive and practical diagnostic tool for the histopathology of palpable breast lumps. Although specificity is comparatively lower, the technique reliably excludes malignancy and provides adequate tissue for histopathological evaluation and for further IHC (Immunohistochemistry). In resource-constrained healthcare settings, unguided core biopsy can effectively reduce the need for open surgical biopsy and facilitate early clinical decision-making.

RECOMMENDATION

Unguided core biopsy can be adopted as a standard initial diagnostic approach for palpable breast lumps in resource-limited centers, provided that procedures are performed by trained clinicians. Where available, suspicious or equivocal cases should be further evaluated with image-guided biopsy or surgical excision. Future multicenter studies with larger sample sizes and complete histological follow-up are recommended to further validate diagnostic accuracy and improve specificity.

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