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Diagnostic Accuracy of Tru-Cut Biopsy for the Evaluation of Suspicious Breast Lump

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ABSTRACT

Introduction:*Breast lumps are a common clinical finding in women and may represent a spectrum of benign to malignant lesions. Early and accurate diagnosis is critical for timely management and improved patient outcomes. Tru-Cut (core needle) biopsy is a minimally invasive technique that allows for preoperative tissue diagnosis, guiding treatment decisions while avoiding unnecessary excisional procedures.This study aims to assess the diagnostic accuracy of Tru-cut biopsy for the evaluation of a suspicious breast lump.*

Methods:*This cross-sectional diagnostic accuracy study was conducted in the Department of Surgery, Sylhet MAG Osmani Medical College Hospital, Sylhet, from July 2023 to July 2024, with a sample size of 86 patients.Histopathological diagnosis of resected specimens was considered the gold standard for calculating the sensitivity and specificity of Tru-Cut biopsy.Data were analyzed using SPSS version 25.*

Result:*In this study of 86 patients with suspicious breast lumps, Tru-Cut biopsy correctly diagnosed 81 cases when compared with final histopathology, yielding a sensitivity of 93.9%, specificity of 90.0%, positive predictive value of 96.9%, negative predictive value of 81.8%, and overall diagnostic accuracy of 93%. Invasive ductal carcinoma was the most common malignancy, and the upper outer quadrant was the most frequently involved site.*

Conclusion:*Tru-Cut biopsy is a highly accurate, safe, and minimally invasive method for the evaluation of suspicious breast lumps. In this study, it demonstrated excellent sensitivity, specificity, and overall diagnostic accuracy when compared with final histopathology, confirming its reliability as a preoperative diagnostic tool.*

Keywords:*Tru-Cut Biopsy, Diagnostic Accuracy,Suspicious Breast Lump, Histopathology*

I. INTRODUCTION

Breast cancer is the most common type of cancer among women in the world. One in eight females is a patient of breast cancer at some point in life. 22.5 out of every 100000 women in Bangladesh are affected by breast cancer [1].Tru Cut Biopsy, in recent years, is the preferred procedure for the diagnosis of a suspicious breast lump. It causes minimal morbidity, is less time-consuming, cost-effective, and provides an accurate tissue diagnosis of palpable breast lumps before definitive treatment [2].It provides adequate tissue for a pathologist to make an accurate histopathological diagnosis, along with history, clinical examination findings, and imaging results, which guide the surgeon and the oncologist to plan for an ideal therapeutic strategy, including surgical decision-making and further use of neoadjuvant therapy [3].The advantages of Tru Cut Biopsy are well documented in many meta-analyses and retrospective studies over fine needle aspiration or surgical excision biopsies [4]. Tru Cut Biopsy provides a suitable-sized tissue mass for assessment of both cytomorphology and architecture for diagnostic and prognostic purposes. It shows variable ranges of sensitivity, specificity, and accuracy [5]. Breast cancer is sometimes difficult to determine whether a suspicious palpable breast lump is benign or malignant simply from clinical assessment. Some authors recommended combining the two techniques to improve the diagnostic yield by reducing false positive and false negative rates. As a part of the triple assessment, in recent times, a gradual trend of increase in the rate of Tru Cut Biopsy is seen replacing the previously rampant use of the FNAC [6]. It is now the first preferred procedure for the diagnosis of highly

suspicious breast lesions before operation because of less invasiveness compared to excisional biopsy, but it provides enough tissue for pathologists to establish a correct diagnosis and further management plan [7]. For histopathological diagnosis,Tru Cut biopsy is superior to FNAC in the confirmation of breast cancer in a suspicious breast lump. A study found that FNAC can miss up to 20% malignant breast lump, whereasTru Cut biopsy have a false negative result up to 5% [8]. Excisional biopsy is the gold standard procedure for diagnosis of breast lesions, although Tru Cut Biopsy has replaced excisional biopsy in recent years, which has some advantages like preoperative planning, just as efficient as open biopsy, decreases patient morbidity, and obviates unnecessary breast surgery [9]. FNAC reports still have a percentage of uncertainty, and also lack important information about the histopathological type, grade, receptors, and intrinsic behavior of the tumor. An author found that the sensitivity of FNAC and Tru Cut Biopsy was 84.34% and 97.1%, respectively [10].Tru Cut Biopsy seems superior to FNAC in detecting suspicious malignant breast lumps because of the possibility to define the lesion's receptor status, as well as superior to open biopsy in terms of safety, costs, post-operative pain, and complications [11]. FNAC sometimes fails to separate atypical ductal hyperplasia (ADH) from ductal carcinoma in situ (DCIS) and differentiate DCIS from invasive carcinoma, which affects the patient's treatment. These limitations have contributed to the increase in the use of Tru Cut Biopsy. Sampling errorsare also less common with Tru-Cut Biopsy [12]. This study aims to assess the diagnostic accuracy of Tru-cut biopsy for the evaluation of a suspicious breast lump.

II. METHODS

This cross-sectional diagnostic accuracy study was conducted in the Department of Surgery, Sylhet MAG Osmani Medical College Hospital, Sylhet, from July 2023 to July 2024, with a sample size of 86 patients. Purposive sampling was used. All female patients aged 18 years or above presenting with a clinically palpable suspicious breast lump and who provided informed written consent were included. Patients with breast infections, ulcerated breast lumps, those refusing Tru-Cut biopsy, or not meeting the inclusion criteria were excluded.Suspicious breast lumps were identified clinically (hard or firm consistency, irregular border, non-tender, fixed to surrounding structures, skin changes, nipple retraction, palpable axillary lymph nodes) and radiologically (irregular, speculated, hypoechoic, or microcalcified lesions on ultrasonography or mammography).A Tru-Cut biopsy was performed under aseptic precautions. After manual localization and immobilization, 2% lignocaine was infiltrated. A skin stab was made with a No. 11 blade, and a 16-gauge Tru-Cut needle was used to obtain six core specimens from different angulations. Specimens were placed in 10% formalin and sent to the Department of Pathology for histopathological examination.Following surgery, resected specimens were similarly processed, and histopathology was performed. Histopathological diagnosis of resected specimens was considered the gold standard for calculating the sensitivity and specificity of Tru-Cut biopsy.Data were collected using a predesigned structured questionnaire. Categorical variables were expressed as frequencies and percentages, and continuous variables as mean ± standard deviation. Data were analyzed using SPSS version 25. Ethical approval for the study was obtained from the Institutional Ethical Committee of Sylhet MAG Osmani Medical College before commencement.

III. RESULTS

Table 1: Age Distribution of Study Population (n = 86)

Age Group (years)	Frequency	Percentage (%)
18–30	12	13.9
31–40	22	25.6
41–50	28	32.6
51–60	16	18.6
>60	8	9.3
Total	**86**	**100**

Most patients were in the 41–50 years age group (32.6%), which is consistent with earlier studies showing a higher prevalence of breast malignancy in perimenopausal women. [Table 1]

Table 2: Clinical Presentation of Suspicious Breast Lump (n = 86)

Clinical Feature	Frequency	Percentage (%)
Painless lump	70	81.4
Nipple retraction	22	25.6

Skin changes (dimpling, peaud'orange)	18	20.9
Fixed to the surrounding structure	15	17.4
Palpable axillary lymph node	28	32.6

Painless breast lump was the most common presenting feature (81.4%), followed by palpable axillary lymphadenopathy (32.6%). These findings closely match those of similar diagnostic accuracy studies where a painless lump was the predominant symptom. [Table 2]

Table 3: Distribution of Breast Lumps by Side and Quadrant (n = 86)

Location of Lump	Frequency	Percentage (%)
Side		
Right Breast	50	58.1
Left Breast	36	41.9
Quadrant		
Upper Outer Quadrant	48	55.8
Upper Inner Quadrant	12	13.9
Lower Outer Quadrant	10	11.6
Lower Inner Quadrant	8	9.3
Central	8	9.3

The upper outer quadrant was the most frequent site (55.8%), which is consistent with prior literature reporting this quadrant as the most common location for breast carcinoma due to its higher glandular density. [Table 3]

Table 4: Histopathological Findings of Tru-Cut Biopsy (n = 86)

Histopathological Diagnosis	Frequency	Percentage (%)
Invasive ductal carcinoma	58	67.4
Invasive lobular carcinoma	6	7.0
Ductal carcinoma in situ (DCIS)	4	4.7
Benign lesions (fibroadenoma, fibrocystic change)	12	14.0
Suspicious / Inconclusive	6	7.0

Invasive ductal carcinoma was the most common histopathological finding (67.4%), similar to findings from other regional studies where IDC comprised 65–75% of breast malignancies. [Table 4]

Table 5: Correlation Between Tru-Cut Biopsy and Final Histopathology (n = 86)

Final Histopathology	Tru-Cut Positive	Tru-Cut Negative	Total
Malignant	62	4	66
Benign	2	18	20
Total	**64**	**22**	**86**

Out of 66 malignant cases, Tru-Cut biopsy correctly diagnosed 62. There were 2 false positives and 4 false negatives. [Table 5]

Table 6: Diagnostic Accuracy of Tru-Cut Biopsy(n = 86)

Parameter*	Value (%)
Sensitivity	93.9
Specificity	90.0
Positive Predictive Value (PPV)	96.9
Negative Predictive Value (NPV)	81.8
Diagnostic Accuracy	93.0

*Sensitivity, specificity, PPV, and NPV were calculated using a 2×2 contingency table (Table 5), taking the histopathology of surgically resected specimens as the gold standard.The association between Tru-Cut biopsy results and final histopathology was assessed using the Chi-square test. A p-value < 0.05 was considered statistically significant.

Tru-Cut biopsy showed high diagnostic accuracy with excellent sensitivity and specificity. [Table 6]

IV. DISCUSSION

In this study of 86 patients with clinically and radiologically suspicious breast lumps, Tru-Cut (core) biopsy demonstrated high diagnostic performance (sensitivity 93.9%, specificity 90.0%, PPV 96.9%, NPV 81.8%, overall accuracy 93%). These results confirm that Tru-Cut biopsy is a reliable preoperative diagnostic tool that provides adequate tissue for histopathological diagnosis and receptor assessment while avoiding unnecessary excisional procedures.Our sensitivity and specificity are comparable to several published single-centre series. Rikabi and Hussain reported a sensitivity of 95.1% and a specificity of 100% in 275 TCBs, highlighting excellent diagnostic reliability when sampling is adequate [13]. Alshaekely et al., in a retrospective series of 187 ultrasound-guided Tru-Cut biopsies, reported a sensitivity of 88.7% and specificity of 100% for detecting clinically significant pathology [14]. Mahbuba Khatun et al. in Bangladesh found high concordance (97.2%) between Tru-Cut and surgical histology, with sensitivity ≈95.7% and specificity ≈96.9% [3].Larger systematic reviews and meta-analyses support the high diagnostic accuracy of image-guided large-core needle biopsy. Verkooijen et al. found a pooled sensitivity near 97% and high agreement with surgical histology, concluding that image-guided large-core biopsy is a reliable alternative to needle-localized open biopsy for non-palpable lesions [15]. Apesteguía and Pina reported similar findings in ultrasound-guided CNB, noting that sensitivity typically reaches the mid-90s when combined with clinical and imaging data [16]. Dimitrov et al. reported a sensitivity of 98.7% and specificity of 100% in their series, emphasizing that adequate cores and proper technique minimize false negatives [12].Variation between studies (including ours) in sensitivity and NPV can be explained by lesion size and location, needle gauge, number of cores obtained, use of imaging guidance, and the proportion of benign versus malignant lesions. In our series, a few false negatives likely reflected sampling error and tumor heterogeneity, consistent with observations in previous studies [13–16]. False positives were rare, reflecting the generally high specificity of Tru-Cut biopsy.To optimize sensitivity and reduce false negatives, routine ultrasound guidance, obtaining 4–6 cores per lesion, and careful radiologic–pathologic correlation are recommended.

Limitations of The Study

The study was conducted in a single hospital with a small sample size. So, the results may not represent the whole community.

V. CONCLUSION

Tru-Cut biopsy is a highly accurate, safe, and minimally invasive method for the evaluation of suspicious breast lumps. In this study, it demonstrated excellent sensitivity, specificity, and overall diagnostic accuracy when compared with final histopathology, confirming its reliability as a preoperative diagnostic tool.

VI. RECOMMENDATION

Based on the high diagnostic accuracy observed, Tru-Cut biopsy should be routinely employed for the evaluation of clinically and radiologically suspicious breast lumps. To further improve sensitivity and minimize false negatives, it is recommended to use ultrasound guidance, obtain multiple cores per lesion, and ensure close radiologic–pathologic correlation.

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