

## COMPARATIVE STUDY OF DIAGNOSTIC ACCURACY OF INCONCLUSIVE FINE NEEDLE ASPIRATION CYTOLOGY WITH TRUCUT BIOPSY AND POSTOPERATIVE HPE SPECIMEN REPORT OF BREAST LUMPS

Deepak Vellingiri Raj C<sup>1</sup>, Gopinath C<sup>2</sup>, Vijayshankar R<sup>2</sup>

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Corresponding Author:

**Dr. Vijayshankar R.**

Email: vijayshankar.dr@gmail.com

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<sup>1</sup>Senior Resident, Department of General Surgery, Government Erode Medical College and Hospital, Tamilnadu, India

<sup>2</sup>Assistant Professor, Department of General Surgery, Coimbatore Medical College and Hospital, Tamilnadu, India

### Abstract

**Background:** Breast cancer is the second most common malignancy in Indian women. Fine-needle aspiration cytology (FNAC) and Tru-cut biopsy are widely used for preoperative diagnosis of thyroid cancer. FNAC provides rapid prognostic understanding, whereas Tru-cut biopsy offers precise tumour grading. This study evaluated the diagnostic accuracy of these models in distinguishing between benign and malignant breast lesions. **Materials and Methods:** This prospective study included 50 female patients presenting with a breast mass who underwent clinical evaluation, imaging (ultrasonography and mammography), and FNAC. Based on these findings, the patients underwent excisional biopsy, simple mastectomy, or modified radical mastectomy. Histopathological examination of excised specimens was performed, and biopsy reports were analysed to assess the clinical correlation and diagnostic accuracy of FNAC and Tru-cut biopsy. **Result:** Of the 50 patients, the highest proportion (44%) was aged 41-50 years. Breast lumps were mostly located in the upper outer quadrant (38% of cases). FNAC identified malignancy in 52% of the cases, whereas Tru-cut biopsy and HPE confirmed a higher malignancy rate of 62%. FNAC misclassified 10% of benign cases as malignant (p=0.001), whereas Tru-cut biopsy showed complete concordance with HPE. In terms of diagnostic performance, FNAC had a sensitivity of 83.87%, specificity of 100%, and NPV of 79.17%, whereas Tru-cut biopsy showed superior accuracy with 100% sensitivity, specificity, and NPV. Overall, the diagnostic accuracy was 90% for FNAC and 100% for Tru-cut biopsy. **Conclusion:** Our study concluded that Tru-cut biopsy has higher accuracy and sensitivity than FNAC, with similar specificity. Its reliability and ability to assess tumour characteristics make it the preferred preoperative diagnostic modality.

## INTRODUCTION

Breast cancer is the second most prevalent malignancy in Indian women. The cumulative incidence in females is 1-2% up to 64 years of age. Fine needle aspiration cytology (FNAC) is increasingly employed for the preoperative diagnosis of breast cancer to determine prognostic factors for optimal treatment planning.<sup>[1]</sup> Both palpable and non-palpable lesions can undergo breast FNAC using imaging modalities such as mammography and ultrasonography. The advantages include its capacity for the rapid and accurate diagnosis of cystic diseases, as well as its potential for therapeutic applications. The subtypes of benign and malignant breast lesions can now be identified using cytological

examination. It has shown that FNAC can provide additional data, such as the intrinsic characteristics of the tumour, which facilitates the prediction of tumour elements including DNA content, mitotic index, and nuclear gradation.<sup>[2]</sup> As such, it functions as a crucial preoperative assessment process in conjunction with imaging and clinical correlation, collectively termed the "Triple test".<sup>[3]</sup> Nuclear grade and histological type are the two principal morphological prognostic markers of breast cancer. Cytological grading is significant in predicting the histopathological grade, as it has demonstrated a positive correlation with the histological grade. Consequently, the cytological grade would provide pertinent information on the biological behaviour of the tumour and could be a valuable factor to consider when selecting

neoadjuvant therapy.<sup>[4]</sup> For prognostic purposes, the FNA tissue grade should be included in the FNAC report, as recommended by the Bethesda National Cancer Institute. Furthermore, emphasis should be placed on the cytological grading method, which closely corresponds to the grading system applied to histological material. FNAC has been extensively used to diagnose breast lesions over the past 25 years. Recently, Tru-cut biopsy has been implemented for the diagnosis of breast cancer in our institution. This implementation may be attributed to the fact that compared with FNAC, a Tru-cut biopsy facilitates more accurate tumour grading and determination of ER and PR receptor status. The treating physician subsequently utilises this information to determine the appropriateness of chemotherapy as the primary treatment modality for breast cancer.<sup>[5]</sup>

The primary objective of a Tru-cut biopsy is to eliminate the need for an open surgical biopsy by providing a definitive preoperative diagnosis of breast lesions. Given its advantages, it remains employed as a forensic technique when FNAC is unable to yield a diagnosis.<sup>[6]</sup> Notwithstanding the utilisation of Tru-cut biopsy, certain types of lesions continue to present clinical challenges and necessitate bulk excision. These comprise fibroepithelial lesions in cellular stroma, phyllodes tumours, mucinous lesions, spindle cell lesions, radial scars, and atypical proliferative lesions such as lobular neoplasia and atypical ductal hyperplasia.<sup>[4]</sup> Thus, this study aimed to ascertain the degree of correlation between the preliminary diagnoses obtained from breast lumps using FNAC and Tru-cut procedures and the definitive histological findings.

#### Aim

This study aimed to assess the diagnostic precision of Tru-cut biopsy and fine-needle aspiration cytology in distinguishing between benign and malignant lesions of palpable breast lumps using cytological and histopathological correlations.

## MATERIALS AND METHODS

This prospective study included 50 female patients from the Department of General Surgery, Coimbatore Medical College Hospital, Coimbatore, between March 2022 and September 2022. The Institutional Ethics Committee (IEC No.062/2023) approved this study before its initiation, and informed consent was obtained from all patients.

#### Inclusion criteria

Female patients aged 18-70 years with palpable breast masses of varying durations were included.

#### Exclusion criteria

Female patients with recurrent malignancy, those presenting with an acute and tender breast mass such as breast abscess, and those exhibiting frank malignant neoplasm with cutaneous ulceration were excluded.

#### Methods

Patients presenting to the outpatient department with a breast mass underwent history taking and clinical examination. Based on these findings, a preliminary diagnosis was established, and the patients were admitted for further evaluation. Diagnostic investigations, including breast ultrasonography, mammography, and FNAC, were performed. Patients then underwent an anaesthesia assessment to determine their suitability for surgery. Depending on the clinical indications, procedures such as excision biopsy, simple mastectomy, or modified radical mastectomy (MRM) were performed. The excised specimen was submitted for histopathological analysis. Biopsy reports were collected and analysed for clinical correlation and decision-making.

**Statistical analysis:** Data were presented as frequency and percentage. Categorical variables were compared using Pearson's chi-square tests. Cross tabs were created to determine the sensitivity, specificity, positive predictive value (PPV), negative predictive value (NPV), and overall diagnostic accuracy. The agreement between FNAC, Tru-cut biopsy, and HPE findings was assessed using cross-tabulations. Statistical significance was defined as P values less than 0.05 using a two-tailed test. Data analysis was conducted using IBM SPSS version 21.0

## RESULTS

Regarding age distribution, most patients (44%) were between 41-50 years, followed by 28% in the 31-40 years age group. A smaller proportion (14%) of patients were aged 51-60 years, while 10% were older than 60 years, and only 4% were under 30 years. Regarding the distribution of breast lumps, the upper outer quadrant was the most frequently affected site (38%), followed by the lower outer quadrant (20%). The lower inner and upper inner quadrants were involved in 16% and 14% of patients, while the central quadrant was involved in 12% of patients [Table 1].

**Table 1: Demographic and clinical characteristics**

|               |             | N (%)   |
|---------------|-------------|---------|
| Age           | <30         | 2(4%)   |
|               | 31-40       | 14(28%) |
|               | 41-50       | 22(44%) |
|               | 51-60       | 7(14%)  |
|               | >60         | 5(10%)  |
| Lump quadrant | Upper outer | 19(38%) |
|               | Lower outer | 10(20%) |
|               | Upper inner | 7(14%)  |
|               | Lower inner | 8(16%)  |

|  |         |        |
|--|---------|--------|
|  | Central | 6(12%) |
|--|---------|--------|

FNAC findings showed that 48% of the patients had benign tumours, while 52% had malignant tumours. Tru-cut biopsy findings indicated malignancy in 62% of patients, with the remaining 38% classified as

benign. Similarly, histopathological examination (HPE) confirmed malignancy in 62% of the patients, while 38% were benign [Table 2].

**Table 2: Histopathological and cytological findings.**

|                  |            | N (%)   |
|------------------|------------|---------|
| FNAC findings    | Benign     | 24(48%) |
|                  | Malignancy | 26(52%) |
| Tru-cut findings | Benign     | 19(38%) |
|                  | Malignancy | 31(62%) |
| HPE findings     | Benign     | 19(38%) |
|                  | Malignancy | 31(62%) |

Among patients diagnosed with malignancy on HPE, 4% were under 30 years, 20% were between 31-40 years, 12% were between 41-50 years, and 2% were between 51-60 years. No malignancy was reported in patients aged > 60 years.

Among patients with benign tumours, 8% were between 31-40 years, while the highest proportion

(32%) was observed in the 41-50 years group. Additionally, 12% of patients with benign disease were between 51-60 years, and 10% were above 60 years of age, with no benign findings in patients under 30 years of age [Table 3].

**Table 3: Comparison of age distribution with HPE Findings**

|     |       | N (%)         |            |
|-----|-------|---------------|------------|
|     |       | HPE malignant | HPE benign |
| Age | <30   | 2(4%)         | 0          |
|     | 31-40 | 10(20%)       | 4(8%)      |
|     | 41-50 | 6(12%)        | 16(32%)    |
|     | 51-60 | 1(2%)         | 6(12%)     |
|     | >60   | 0             | 5(10%)     |

FNAC findings showed that all 26 patients diagnosed with malignancy (52%) were confirmed to have malignancies on HPE, while 19 patients (38%) diagnosed as benign remained benign. However, 5 patients (10%) initially classified as benign on FNAC were found to be malignant on HPE, with a significant difference (p=0.001).

Tru-cut biopsy results confirmed that all 31 patients (62%) diagnosed with malignant tumours were malignant on HPE, and all 19 patients (38%) diagnosed as benign were concordant with HPE findings. No malignancies were misclassified as benign on Tru-cut biopsy, showing a significant difference (p=0.001) [Table 4].

**Table 4: Comparison of FNAC and Tru-cut findings with HPE findings**

|         |            | N (%)         |            | P value |
|---------|------------|---------------|------------|---------|
|         |            | HPE malignant | HPE benign |         |
| FNAC    | Malignancy | 26(52%)       | 0          | 0.001   |
|         | Benign     | 5(10%)        | 19(38%)    |         |
| Tru-cut | Malignancy | 31(62%)       | 0          | 0.001   |
|         | Benign     | 0             | 19(38%)    |         |

The sensitivity of FNAC was 83.87%, whereas that of Tru-cut biopsy was 100%. Both methods exhibited 100% specificity. In terms of predictive values, FNAC and Tru-cut biopsy both had a PPV of 100%. However, the NPV of FNAC was lower at 79.17%

compared to 100% for Tru-cut biopsy. The overall diagnostic accuracy of FNAC was 90%, while Tru-cut biopsy achieved a diagnostic accuracy of 100% [Table 5].

**Table 5: Comparative diagnostic performance of FNAC and Tru-cut biopsy**

|             | FNAC   | TRU-CUT |
|-------------|--------|---------|
| Sensitivity | 83.87% | 100%    |
| Specificity | 100%   | 100%    |
| PPV         | 100%   | 100%    |
| NPV         | 79.17% | 100%    |
| Accuracy    | 90%    | 100%    |

## DISCUSSION

In our study, most patients belonged to the middle-aged group (41-50 years), with fewer patients in the younger and older age groups. The upper outer quadrant (38%) was the most affected site, followed by the lower outer quadrant (20%), whereas the other quadrants had a relatively lower frequency of involvement. This aligns with the retrospective analysis by Shrivastava, who reported that the upper outer quadrant was the most affected site for breast cancer in 61.4% of patients, followed by the lower outer quadrant in this Indian cohort.<sup>[7]</sup> A study by Shah et al. reported that the upper outer quadrant was the most affected site of breast cancer, followed by the lower outer quadrant, with younger patients more likely to have advanced-stage tumours in the upper outer quadrant.<sup>[8]</sup>

In our study, FNAC identified a nearly equal proportion of benign (48%) and malignant cases (52%), whereas Tru-cut biopsy classified a higher number of cases as malignant (62%), which was in complete agreement with HPE. The middle-aged group had the highest proportion of malignant HPE cases, whereas fewer cases were observed in the younger and older age groups. Among patients diagnosed with benign lesions, the majority were middle-aged, followed by older patients, whereas no benign cases were observed in the youngest group. A single-centre observational study by Ibrahim et al. reported that more than half ( $n = 26/50$ ; 52%) of malignant cases were diagnosed before 50 years of age, and only one case was reported at 16 years of age. The most non-malignant cases (85.5% of inflammatory and 85.3% of benign cases) were seen before 50 years.<sup>[9]</sup> A study by Osime and Ohanaka reported that benign breast lesions were most common in the third decade, while malignant lesions occurred most in the fourth decade, and all cases after age 60 were malignant.<sup>[10]</sup>

In our study, a comparison of FNAC and Tru-cut biopsy with HPE findings showed that FNAC correctly identified all malignant cases but misclassified a small number of malignant cases as benign. In contrast, Tru-cut biopsy accurately diagnosed all malignant and benign cases, showing complete agreement with the HPE findings. Diagnostic performance analysis revealed that FNAC had high specificity (100%) and a strong ability to correctly identify malignant cases; however, its sensitivity (83.7%). Tru-cut biopsy demonstrated superior sensitivity (100%), specificity (100%), and overall diagnostic accuracy (100%), making it a more reliable preoperative diagnostic tool for distinguishing between benign and malignant breast lesions.

A study by Singh Bhadauria et al. reported that Tru-cut biopsy is more accurate than FNAC in diagnosing breast lesions, with FNAC sensitivity, specificity, and diagnostic accuracy of 95%, 100%, and 96%, and Tru-cut biopsy sensitivity, specificity, and diagnostic

accuracy of 100%, 100%, and 100%.<sup>[11]</sup> A comparative study by Pravalika et al. reported that FNAC correctly identified all malignant cases but misclassified some as benign, whereas Tru-cut biopsy accurately diagnosed all malignant and benign cases. Tru-cut biopsy showed superior diagnostic performance compared to FNAC, with higher sensitivity (85.7% vs. 76.92%) and specificity (100% vs. 96.2%). It also had a greater positive predictive value (100% vs. 90.9%) and negative predictive value (92.85% vs. 89.65%).<sup>[12]</sup>

A study by Hossain et al. reported that Tru-cut biopsy is more accurate than FNAC in diagnosing breast lesions than HPE. Tru-cut biopsy demonstrated superior diagnostic performance compared to FNAC, with higher sensitivity (98.1% vs. 75%), while both had 100% specificity. The positive predictive value was 100% for both, but the negative predictive value was higher for the Tru-cut biopsy (88.9% vs. 38.1%). Overall, Tru-cut biopsy achieved a diagnostic accuracy of 98.3%, whereas FNAC, had an accuracy of 78.3%.<sup>[13]</sup> A study by Ajitha et al. reported that Tru-cut biopsy is more accurate than FNAC in diagnosing benign and malignant breast lumps with the Sensitivity of FNAC and TRU-CUT biopsy being 86.84% and 97.14%.<sup>[14]</sup>

A study by Shashirekha et al. reported that Tru-cut biopsy is more accurate than FNAC in diagnosing breast cancer, with a complete agreement with HPE. The Sensitivity of FNAC and TRU-CUT biopsy was 84.34% and 97.1%.<sup>[15]</sup> A study by Kar et al. reported that FNAC correctly identified all malignant cases but misclassified some, whereas Tru-cut biopsy accurately diagnosed all malignant and benign cases. With FNAC, the overall accuracy rate was estimated to be approximately 96.3%. The adequacy of the Tru-cut biopsy was 91–95%, and its accuracy was approximately 98%.<sup>[16]</sup>

### Limitations

The small sample size of this study may have impacted the generalisability of the results. It focused on palpable breast lumps, limiting its applicability to non-palpable lesions requiring image-guided biopsy. FNAC could not assess the receptor status, tumour grade, and lymphovascular invasion. Although Tru-cut biopsy showed superior diagnostic performance, challenges such as discomfort, higher cost, and expertise requirements may limit its use in resource-limited settings.

## CONCLUSION

Our study concluded that Tru-cut biopsy has a higher accuracy rate and sensitivity, and equal specificity compared with FNAC. Tru-cut biopsy is a primary diagnostic modality for the preoperative diagnosis of benign and malignant tumours. Tru-cut biopsy is an active and reliable diagnostic procedure. However, FNAC is inadequate in providing additional information on receptor status, tumour level, and morphology. Its limitations in assessing

lymphovascular penetration make Tru-cut biopsy the preferred primary diagnostic modality for this condition. Future studies should include a larger cohort to validate these findings. Comparative analyses with image-guided FNAC and Tru-cut biopsy for non-palpable lesions would enhance its applicability.

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