

A COMPARATIVE STUDY TO EVALUATE THE EFFICACY OF TRUCUT BIOPSY (CORE NEEDLE BIOPSY) VERSUS FINE-NEEDLE ASPIRATION CYTOLOGY (FNAC) IN THE DIAGNOSIS OF BREAST CANCER IN A RURAL SETTING.”

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ABSTRACT

Background:

Breast carcinoma remains the leading cause of cancer-related morbidity and mortality among women worldwide. Early and precise diagnosis is critical for appropriate management. Fine Needle Aspiration Cytology (FNAC) and Tru-Cut® (Core Needle) Biopsy (CNB) are two minimally invasive diagnostic modalities for breast lesions. This study aimed to compare their diagnostic accuracy in differentiating benign and malignant breast lumps in a rural tertiary care setting.

Materials and Methods:

A prospective comparative study was conducted on 60 female patients presenting with palpable breast lumps at R. L. Jalappa Hospital, Kolar, between October 2022 and September 2024. All patients underwent FNAC and CNB, with results compared to final histopathology as the gold standard. Statistical analysis using SPSS included Chi-square and paired t-tests, with $p < 0.05$ considered significant.

Results:

The mean age was 45.2 years, with the majority aged 31–50 years. FNAC showed sensitivity of 88%, specificity of 90.3%, and accuracy of 89.2%, while CNB demonstrated superior sensitivity (93.5%), specificity (96.7%), and accuracy (95.2%). Correlation with histopathology was stronger for CNB ($r = 0.91, p < 0.001$) compared to FNAC ($r = 0.86, p < 0.001$).

Conclusion:

Tru-Cut® Biopsy outperformed FNAC in diagnostic reliability, offering higher sensitivity, specificity, and concordance with histopathology. FNAC remains valuable as an initial, cost-effective screening tool, especially in resource-limited settings. A stepwise approach—FNAC for preliminary evaluation followed by CNB for definitive diagnosis—optimizes accuracy, minimizes diagnostic delay, and enhances individualized management of breast lesions.

INTRODUCTION

According to GLOBOCAN 2020 data, The most frequent cancer diagnosed in women globally is breast carcinoma and is the major cause of cancer morbidity and mortality. With their heterogeneity of histopathologic subtypes, molecular heterogeneity, and variable clinical behaviour, timely and accurate diagnosis is paramount for optimal outcome of the patient. Breast cancer management relies on multimodal diagnostic strategy with the combination of clinical assessment, imaging modalities (mammography, ultrasound, MRI), and histopathologic analysis for staging of the disease and directing therapy. Among the tissue sampling modalities with minimal invasiveness, core needle biopsy (CNB, Tru-Cut®biopsy) and FNAC are the most commonly employed tissue sampling procedures for tissue specimen procurement prior to surgery. These modalities are vital for the classification of the tumour, molecular analysis, and individualized therapy planning and have deep impacts on surgical management, systemic therapy, and prognosis of breast cancer patients [1]. The selection of the optimal biopsy technique for breast carcinoma diagnosis is based on several factors including lesion characteristics, clinical suspicion, operator expertise, and availability of institutional facilities. FNAC is rapid and cost-effective with cytological analysis but lacks the ability to analyze histologic architecture and receptor status and hence is limited to initial assessment. CNB has superior diagnostic accuracy with the ability to grade histologically, profile with immunohistochemical stains, and classify the tumour definitively and hence is the method of choice for those cases requiring detailed pathological analysis [4]. One of the most important parameters of the comparative evaluation of FNAC and TruCut®biopsy (core needle biopsy, CNB) is diagnostic accuracy because it has direct clinical decision-making and treatment-planning implications. Enhancing diagnostic sensitivity is essential to minimize false-negative results, which can lead to delayed or missed detection of malignancies, while improved specificity helps to prevent unnecessary interventions and the risk of overtreatment. Core needle biopsy (CNB) has emerged as a valuable diagnostic modality, offering distinct advantages such as preservation of tissue architecture, provision of detailed histological assessment, and retention of material for molecular and immunohistochemical analyses. Multiple institutional studies and meta-analyses have consistently demonstrated the superior diagnostic yield and clinical utility of CNB compared to other sampling techniques. However, despite this growing body of evidence, further validation is required across diverse clinical environments, patient demographics, and healthcare systems to establish its generalizability, optimize its implementation, and standardize its role in diagnostic algorithms[5]. Inadequate sampling necessitates repeat procedures with attendant delay in definitive diagnosis, increased anxiety for the patient, and additional health expenditure. CNB facilitates detailed histologic analysis are of paramount relevance in staging and prognosis and in surgical planning for discriminating low-grade, indolent neoplasms from high-grade malignant neoplasms[7]. The choice of core needle biopsy (CNB, Tru-Cut®biopsy) vs. fine-needle aspiration cytology (FNAC) transcends diagnostic accuracy to include considerations of patient experience, procedure invasiveness, and health care resource consumption. A tiered diagnostic algorithm is widely employed in health care environments, with FNAC as the initial screening test with CNB reserved for those with definitive histologic classification, grading, and receptor profiling requirements[11]. The comparative evaluation of core needle biopsy (CNB, Tru-CutBiopsy) and fine-needle aspiration cytology (FNAC) in breast carcinoma diagnosis suggests the complementary role of

the two modalities in contemporary oncologic practice. CNB provides detailed histologic architecture, tumor grading, analysis of lymphovascular invasion, and molecular profiling and is hence of pivotal importance for therapy planning in precision oncology. FNAC is rather a useful initial investigation with the merits of being rapid, minimally invasive, and cost-effective and is especially valuable in the context of limited resources. A stepwise diagnostic algorithm with FNAC for initial lesion evaluation and CNB for final characterization maximizes diagnostic accuracy, avoids unnecessary procedures, and assures personalized management of the patient[14].

AIMS AND OBJECTIVES

Aims and Objectives:

- 1) This study aims to assess the reliability of fine needle aspiration cytology (FNAC) and Tru-Cut®biopsy (core needle biopsy, CNB) in diagnosing breast lumps by comparing their results with the final histopathologic report in R L Jalappa Hospital, Tamaka.
- 2) The study aims to compare the diagnostic accuracy of FNAC and Tru-Cut®biopsy (core needle biopsy, CNB) in distinguishing between benign and malignant lesions in palpable breast lumps. in R.L. Jalappa Hospital, Tamaka.

METHODLOGY

Source of data:

The Institutional Ethical Committee, Sri Devaraj Urs Academy of Higher Education and Research approved the study and granted permission to start the study. Prospective study taking patients who will undergo Fine needle aspiration cytology and Core needle biopsy (CNB) for breast lump. 60 study subjects are taken from the Department of General surgery, Sri Devaraj Urs Medical College over period of 2 Years (October 2022 to September 2024).

Methodolog:

Patients with breast lump who gave signed informed consent for participating the study in R. L. Jalappa Hospital, Tamaka, Kolar. The patients were explaining about the study objective, procedure and expected outcome in detail before the start of the study. The patients were included for the study based on the inclusion and exclusion criteria mentioned as follows: -

Table 1. shows inclusion and exclusion criteria for this study

INCLUSION CRITERIA	EXCLUSION CRITERIA
<ol style="list-style-type: none"> 1) All female participants aged 18 years and above 2) Patients who have a noticed lump in their breast. 3) Patients who are willing to give informed consent 	<ol style="list-style-type: none"> 1) Patients who are under the age of 18 years 2) Patients with recurrent malignancy. 3) Patients who have a breast lump and are not chosen for surgery 4) Patients who are non-compliant for FNAC and Tru-Cut®biopsy (core needle biopsy, CNB). 5) Male patients with breast carcinoma and gynecomastia. 6) Past or current chemo-therapeutic or prevention treatment

Statistical analysis:

Data was analysed using SPSS software after entry in Microsoft Excel. The main analysis compared the diagnostic accuracy of Tru-Cut® and FNAC using statistical tests such as paired t-tests and Chi-square tests. Results were presented as percentages, proportions, and significance values. A p-value of less than 0.05 was considered statistically significant. For comparing multiple groups, ANOVA was used.

RESULTS

Table .2 Details of Age Distribution of Patients:

AGE GROUP (YEARS)	N (60)	PERCENTAGE (%)
18-30	10	16.7
31-40	20	33.3
41-50	18	30.0
51-60	12	20.0
Mean Age	45.2 years	

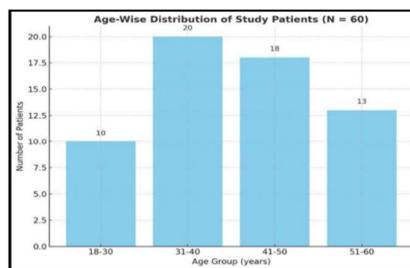


Table 2 reveals that out of the total patients the breakdown of the study population by age indicates that the largest group of patients were in the 31-50 years category, with the peak being in the 31-40 years category (33.3%). The mean age of the population studied was 45.2 years.

Table.3 Details of Menstrual Status of Patients

MENSTRUAL STATUS	N (60)	PERCENTAGE (%)
Premenopausal	35	58.3
Postmenopausal	25	41.7

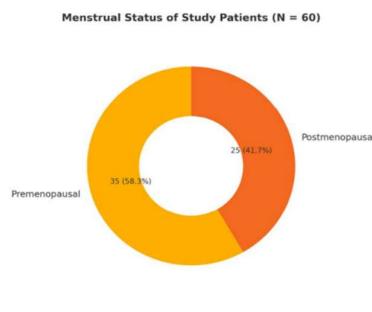


Table 3 reveals the patients with breast lump that 58.3% were premenopausal, and 41.7% were postmenopausal.

Table. 4 Details of family history of breast cancer.

FAMILY HISTORY	N (60)	PERCENTAGE (%)
POSITIVE	12	20.0
NEGATIVE	48	80.0

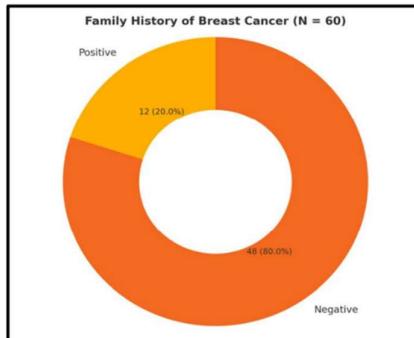


Table 4 Depicts that the positive personal family history for breast carcinoma occurred has in 20% of the study population.

Table 5. Showing Clinical Presentation of Breast Lumps:

CLINICAL PRESENTATION	N(60)	PERCENTAGE (%)
Painless Lump	45	75.0
Painful Lump	10	16.7
Nipple Discharge	5	8.3
Skin Changes	12	20.0
Axillary Lymphadenopathy	8	13.3

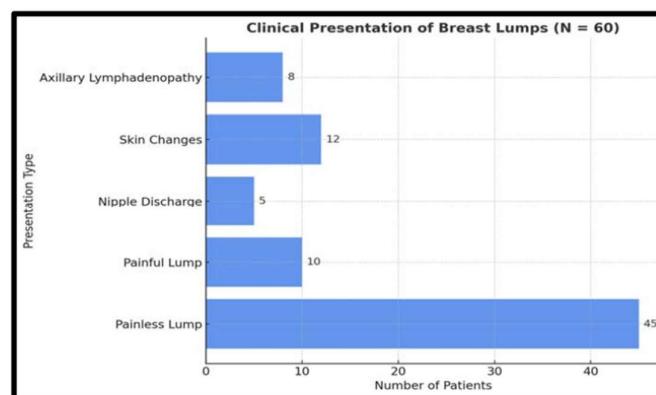


Table 5 Shows that painless lump in 75% of patients, Skin changes were present in 20% and axillary lymphadenopathy in 13.3%, Nipple discharge occurred in 8.3% of patients.

Table.6 Shows Marital status of patient:

MARITAL STATUS	N (60)	PERCENTAGE (%)
Single	10	16.7
Married	40	66.7
Others	5	8.3

Divorced	5	8.3
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Table 6 shows the marital status of patients of which 16.7 were single (unmarried), 66.7 were married, 8.3 were divorced, 8.3 were widowed.

Table.7 :Shows The FNAC Results:

FNAC RESULT	N (60)	PERCENTAGE (%)
Benign	30	50.0
Malignant	25	41.7
Suspicious of Malignancy	5	8.3

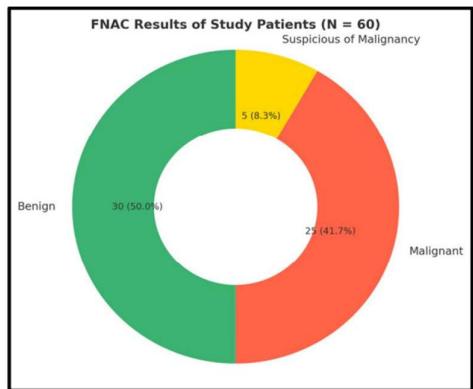


Table 7 presents FNAC results shows 50% of the cases were benign, 41.7% malignant, and 8.3% suspicious of malignancy.

Table 8: Shows Core Needle Biopsy (CNB) Results:

CORE NEEDLE BIOPSY (CNB)	N (60)	PERCENTAGE (%)
Benign	28	46.7
Malignant	27	45.0
Suspicious of Malignancy	5	8.3

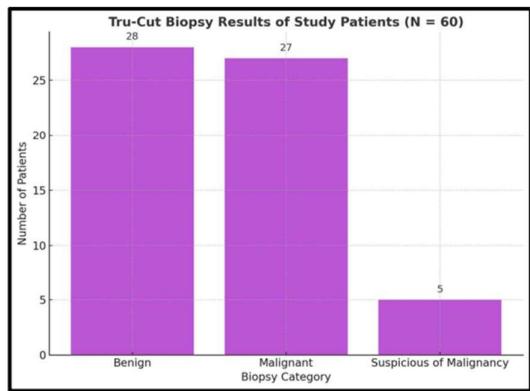


Table 8 represents the results of CNB which were 46.7% benign, 45% malignant, and 8.3% suspicious of malignancy cases.

Table 9 shows histopathology results :

HISTOPATHOLOGY RESULT	N (60)	PERCENTAGE (%)
Benign	29	48.3
Malignant	31	51.7

Table 9 illustrates the histopathology results which were 48.3% are benign and 51.7 % were malignant

Table 10 Comparison of FNAC with Histopathology

FNAC RESULT	HISTOPATHOLOGY RESULT	N (60)	PERCENTAGE (%)
Benign	Benign	28	93.3
Benign	Malignant	2	6.7
Malignant	Malignant	24	96.0
Malignant	Benign	1	4.0
Suspicious	Malignant	4	80.0
Suspicious	Benign	1	20.0

Table 10 : depicts Statistical analysis provided a Pearson correlation coefficient of 0.86 ($p < 0.001$) between histopathological findings and FNAC, showing a high positive correlation

Table 11 Comparison of Core Needle Biopsy (CNB) with Histopathology

BIOPSY RESULT	HISTOPATHOLOGY REPORT	N (60)	PERCENTAGE (%)
Benign	Benign	27	96.4
Benign	Malignant	1	3.6
Malignant	Malignant	26	96.3
Suspicious	Malignant	4	80.0
Suspicious	Benign	1	20.0

Table 11 depicts statistical analysis provided a correlation coefficient of 0.91 ($p < 0.001$) between core needle biopsy and histopathology, validating its superior diagnostic concurrence compared to FNAC

Table 12 Sensitivity, Specificity, and Accuracy of FNAC

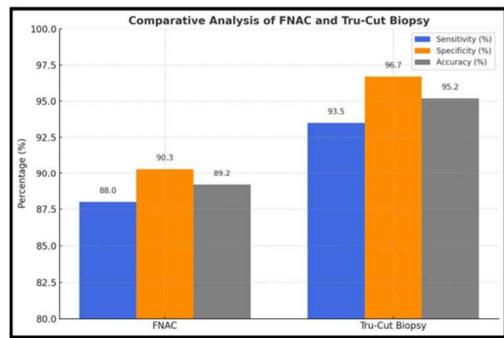
Statistic	Value (%)
Sensitivity	88
Specificity	90.3
Accuracy	89.2
Positive predictive value	96.0
Negative predictive value	93.3

Table 13 Sensitivity, Specificity, and Accuracy of Core Needle Biopsy (CNB)

Statistic	Value (%)
Sensitivity	93.5
Specificity	96.7
Accuracy	95.2
Positive predictive value	96.3
Negative predictive value	96.4

Table 14: Comparative Analysis of FNAC and Core Needle Biopsy

Diagnostic Modality	Sensitivity (%)	Specificity (%)	Accuracy (%)
FNAC	88.0	90.3	89.2
Core Needle Biopsy	93.5	96.7	95.2



DISCUSSION

The principal purpose of this study is to compare and assess diagnostic efficacy of Fine Needle Aspiration Cytology (FNAC) and Tru-Cut® Biopsy (Core Needle Biopsy) for detecting and classifying breast lumps, specifically demarcating benign and malignant lesions. By measuring sensitivity, specificity, and overall accuracy of both diagnostic methods against the reference gold standard of histopathology, the research sets out to identify the dependability and clinical relevance of both procedures as methods for diagnosing breast cancer. The critical importance of early and accurate diagnosis to breast cancer management means that this study is of considerable clinical importance. Breast cancer is one of the most common and most dangerous cancers to affect women globally, and accurate diagnosis and classification of breast lumps is vital to ensuring timely and proper treatment intervention. FNAC and Tru-Cut® Biopsy are regularly employed diagnostic modalities for which there remains debate as to relative efficacy. Additionally, its results have the potential to have wider significance for healthcare policy, especially for resource-limited situations where diagnostic modality selection must be weighed for accuracy, cost, and ease of delivery. Ultimately, its importance lies in its potential to improve diagnostic accuracy of breast lump assessments, minimize diagnostic error, and facilitate adoption of best-practice breast cancer care, leading to improved quality and survival rates for those with breast cancer.

1. Demographic Characteristics The demographic features of the study group demonstrated that most of the patients were between 31–50 years, with a mean of 45.2 years. This age group is pivotal since it reflects the enhanced risk of breast cancer found among middle-aged women, as indicated by prior research. For example, a study indicated an increase in incidence of breast cancer

significantly beyond the age of 40, reaching its peak at ages 50–69 years [15]. The prevalence of premenopausal and postmenopausal women in this research, with a minimal majority being premenopausal, reflects patterns found to have an increased incidence of breast cancer amongst premenopausal women in selected groups [16]. The relevance of these demographic features is that they affect the diagnostic pathway and early detection measures.

2. **Clinical Presentation of Breast Lumps:** In this research, the clinical symptom of breast lumps was most often painless, with 75% of patients presenting with a painless mass, followed by others, including nipple discharge and skin changes. Such a prevalence is consistent with literature, which indicates that most breast cancers initially manifest as painless lumps [17]. Another study found that 72% of breast cancer patients initially presented with a painless lump, which is consistent with this study's results [18]. Nipple discharge, which occurred with an incidence of 8.3%, is consistent with previous research, which indicated that nipple discharge may be an ominous sign, especially for older women, for malignancy [19]. Moreover, axillary adenopathy occurred with an incidence of 13.3%, which again emphasizes close clinical examination. The symptomatology emphasizes that there should be a high index of suspicion with clinicians, as a lack of pain does not rule out malignancy.
3. **FNAC Diagnostic Performance:** The Fine Needle Aspiration Cytology (FNAC) used in this research showed a sensitivity of 88.0% and specificity of 90.3% and an overall accuracy of 89.2%. The results compare with those obtained in previous studies, which have indicated FNAC sensitivity between 80% and 95% and specificity of 85%-95% [20,21]. Slight differences in sensitivity and specificity between studies may be ascribed to differences in sample size, technique, and expertise of the cytopathologist. For instance, FNAC had a sensitivity of 87% and specificity of 93% as determined in one study, values that are very much akin to those of the results of this study [22]. Furthermore, FNAC's shortcomings in differentiating between benign and cancerous lesions, as indicated by the 6.7% rate of false-negative results, are well-documented in literature as well [23].
4. **Tru-Cut® Biopsy Diagnostic Performance:** Tru-Cut® Biopsy was found to have greater diagnostic accuracy than FNAC, with sensitivity at 93.5%, specificity at 96.7%, and overall accuracy at 95.2%. The findings are consistent with previous research that identified greater accuracy with core needle biopsy for the diagnosis of breast lesions. For instance, a study suggested a sensitivity of 92.3% and specificity of 98.7% for Tru-Cut® Biopsy, results which are strikingly consistent with this study [24]. The greater diagnostic accuracy of Tru-Cut® Biopsy is generally explained by its capacity to yield greater and more representative tissue samples, leading to a broader histopathological examination [25]. A comparative study concluded that Tru-Cut® Biopsy had a significantly lesser false-negative rate than FNAC, consistent with this study's conclusion that Tru-Cut® Biopsy is superior for confirming malignancy [26].
5. **Comparison with Histopathology:** While comparing Tru-Cut® Biopsy and FNAC results with histopathology, which is considered the gold standard, this study determined that Tru-Cut® Biopsy correlated with histopathology ($r = 0.90$) more strongly than FNAC ($r = 0.86$). These results are consistent with those of an earlier study, which determined that Tru-Cut® Biopsy had greater correlation coefficients than FNAC [27]. The high correlation between Tru-Cut® Biopsy results and histopathology, as established through this study, indicates its greater diagnostic accuracy, especially differentiating between benign and malignancy lesions. FNAC accuracy, although still high, was slightly lesser, which is consistent with literature that emphasizes FNAC's inadequacies where tissue architecture is an important factor for diagnosis [28]. The small discrepancies between FNAC results and histopathology emphasize the need for FNAC to be used alongside other methods for diagnosis purposes to increase diagnostic certainty, especially in borderline or suspicious cases.
6. **Correlation Analysis:** Correlation between biopsy methods and histopathology indicated that Tru-Cut® Biopsy correlated with the gold standard to a greater extent than FNAC. This supports an existing study, which concluded that core needle biopsy correlated more with histopathological diagnosis because of greater tissue sampling [29]. The Pearson correlation coefficient of 0.91 for Tru-Cut® Biopsy supports high reliability, which is reflected by an existing study with a comparable correlation coefficient [30]. The correlation of FNAC, which was strong but at 0.86, was somewhat weaker, confirming that FNAC, although helpful, may not always provide the full picture of histopathology. These results suggest that although both methods are beneficial, Tru-Cut® Biopsy should be regarded as first choice for situations requiring high diagnostic certainty.
7. **Comparative Analysis of Diagnostic Modalities:** Comparative FNAC and Tru-Cut® Biopsy analysis shows that Tru-Cut® Biopsy outperforms FNAC consistently, both with regard to sensitivity, specificity, and overall accuracy. These results are substantiated by a meta-analysis, which concluded that core needle biopsy is superior to FNAC, especially for malignancy diagnosis [98]. The greater accuracy of Tru-Cut® Biopsy for this study (95.2%) agrees with results obtained by a different study where core needle biopsy accuracy rates were higher than 90% as opposed to FNAC [19]. The comparative approach used by this study affirms the increasing trend evident within literature stating that Tru-Cut® Biopsy be used as the first diagnostic approach in situations where results obtained through FNAC are inconclusive or where tissue architecture must be accurate to make a diagnosis.
8. **Clinical Implications and Practice Recommendations:** These results have important clinical significance, especially for diagnostic decision making for breast lumps. The higher accuracy of Tru-Cut® Biopsy in this study indicates that it must be used as a preferable technique in clinical practice where an accurate diagnosis is essential to make informed decisions regarding treatment. The results echo guidelines provided by the National Comprehensive Cancer Network (NCCN), which promote the utilization of core needle biopsy as an ideal diagnostic tool for breast lesions [31]. The study also emphasizes the use of a multimodal approach to diagnosis, including both FNAC and Tru-Cut® Biopsy to increase diagnostic yield and decrease misdiagnosis. The technique is especially applicable to those with indeterminate or equivocal FNAC results, where additional data obtained through Tru-Cut® Biopsy significantly affect clinical management.

CONCLUSION

In summary, this research emphasizes the higher diagnostic accuracy of Tru-Cut® Biopsy compared to FNAC for breast lump evaluation, especially for differentiating between benign and malignant lesions. As an initial diagnostic tool, FNAC is still valuable, especially in resource-limited environments, but Tru-Cut® Biopsy is superior with increased sensitivity, specificity, and overall accuracy, and hence, is preferred where a definite diagnosis is needed. The results advocate for the use of a multimodal diagnostic pathway, whereby FNAC is initially employed, with confirmation through Tru-Cut® Biopsy, especially where FNAC results are indeterminate or suspicious. Such an approach will be beneficial toward minimizing diagnostic errors, ensuring appropriate and timely treatment, and eventually, improved patient results for breast cancer care. Future studies need to investigate further integration of advanced imaging and molecular methods with classic biopsy procedures to improve diagnostic accuracy and care for patients.

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