International Journal of Research in Medical Sciences
Sakalle S et al. Int J Res Med Sci. 2025 Oct;13(10):4183-4190
www.msjonline.org
pISSN 2320-6071 | eISSN 2320-6012
DOI: https://dx.doi.org/10.18203/2320-6012.ijrms20253162

Original Research Article

Concordance between trucut needle biopsy and surgical specimen for estrogen receptor, progesterone receptor and human epidermal growth factor receptor status in breast cancer

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Received: 07 July 2025
Revised: 11 August 2025
Accepted: 11 September 2025

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ABSTRACT

Background: Breast cancer is the most common malignancy among women worldwide, contributing significantly to cancer-related morbidity and mortality. Estrogen receptor (ER), progesterone receptor (PR), and human epidermal growth factor receptor (HER2/neu) status are crucial for prognosis and treatment planning. Trucut needle biopsy is widely used for preoperative biomarker assessment; however, discrepancies with surgical specimen results may affect clinical decisions.

Methods: A cross-sectional study was conducted at Gandhi Medical College and Hamidia Hospital, Bhopal, from August 2022 to January 2024, including 32 cases of invasive ductal carcinoma. Immunohistochemistry was performed on trucut biopsies and surgical specimens to assess ER, PR, and HER2/neu expression. Concordance rates, sensitivity, specificity, positive predictive value (PPV), and negative predictive value (NPV) were calculated. Statistical analysis used SPSS, with $p<0.05$ considered significant. Factors influencing discordance, including tumor heterogeneity, fixation techniques, and preanalytical variables, were evaluated.

Results: ER showed high concordance (90.6%), sensitivity (83.3%), specificity (100%), PPV (100%), and NPV (82.4%). PR demonstrated moderate concordance (78.1%), sensitivity (73.3%), specificity (82.4%), PPV (78.6%), and NPV (77.8%). HER2/neu showed moderate to low concordance (51.6%), sensitivity (64.7%), specificity (86.7%), PPV (84.6%), and NPV (68.4%). HER2/neu discordance was linked to intratumoral heterogeneity, staining variability, equivocal results requiring fluorescence in situ hybridization.

Conclusions: Trucut biopsy is highly reliable for ER and PR assessment but shows moderate reliability for HER2/neu, warranting confirmatory testing in borderline cases. Awareness of potential discrepancies and supplementary diagnostics can enhance preoperative accuracy and guide personalized breast cancer management.

Keywords: Diagnostic concordance, Fluorescence in situ hybridization, Hormone receptor status, Immunohistochemical analysis, Invasive ductal carcinoma, Oncologic pathology, Preoperative biopsy, Tumor grading

INTRODUCTION

Breast cancer is the most prevalent malignancy affecting women worldwide, significantly contributing to cancer-related morbidity and mortality. According to the World Health Organization (WHO), breast cancer is a heterogeneous group of diseases originating from the ducts and lobules of the breast tissue, characterized by uncontrolled cell division leading to tumor formation.[1] The burden of breast cancer is disproportionately high in low- and middle-income countries (LMICs), where over 70% of breast cancer-related deaths occur in individuals under the

age of 70. The economic and social impact of breast cancer is profound, affecting not only patients but also their families and communities. Children who lose their mothers to cancer often face long-term disadvantages in health and education, exacerbating generational social and financial disruptions.[2]

Breast cancer develops through multiple pathways involving genetic mutations, hormonal influence, and environmental factors. While some cases arise due to inherited mutations in tumor suppressor genes like BRCA1 and BRCA2, the majority of cases are sporadic, driven by hormonal and molecular changes that facilitate tumor progression.[3] Immunohistochemical (IHC) assessment of ER, PR and HER2/neu is critical in classifying breast cancer subtypes, determining prognosis, and guiding treatment decisions.[4] ER and PR status are particularly important in predicting response to endocrine therapy, while HER2/neu overexpression is associated with aggressive tumor behaviour and targeted therapy eligibility.[5]

Core needle biopsy (CNB), commonly known as trucut biopsy, is a well-established, minimally invasive method for preoperative diagnosis and biomarker evaluation in breast cancer. While surgical specimen (SS) analysis remains the gold standard, CNB offers the advantage of early diagnosis and treatment planning.[6] However, due to tumor heterogeneity and sampling limitations, discrepancies between trucut biopsy and surgical specimens may occur, particularly in HER2/neu assessment. A recent meta-analysis suggests that CNB can be a reliable alternative for determining ER, PR, and HER2/neu status, but its concordance with surgical specimens requires further evaluation.[7]

The present study aims to determine the concordance rate, sensitivity, specificity, positive predictive value (PPV), and negative predictive value (NPV) of trucut biopsy in comparison to surgical specimens for assessing ER, PR, and HER2/neu status in breast carcinoma patients.

METHODS

This cross-sectional study was conducted in the department of pathology, Gandhi Medical College and associated Hamidia Hospital, Bhopal, over a period of 1.5 years (August 2022 to January 2024). A total of 32 female patients diagnosed with Invasive ductal carcinoma (IDC) breast were included in the study. The age of participants ranged from 30 to 81 years. This study was approved by the Institutional Ethics Committee of Gandhi Medical College, Bhopal (MP), and all procedures were conducted following ethical guidelines. All histopathologically diagnosed cases of invasive ductal carcinoma breast with availability of both trucut biopsy and subsequent surgical specimen for comparative analysis were included in the study. Cases with inadequate tissue samples, histologically undiagnosed cases, histologically diagnosed other than breast carcinomas, male patients with breast carcinoma and patients who had received neoadjuvant therapy/ radiotherapy/hormonal therapy prior to biopsy were excluded. The clinical details like age, sex, laterality, duration of symptoms, size of the tumour, axillary lymph node status and imaging findings like ultrasound (USG) were recorded in each case.

Trucut biopsy samples were processed with fixation in 10% neutral buffered formalin for 6-24 hours, followed by standard hematoxylin and eosin (H and E) staining. Surgical specimens from modified radical mastectomy were serially sectioned at 5-10 mm intervals, fixed for 24-48 hours, and assessed for tumor size, histologic grade, and axillary lymph node status. Immunohistochemistry (IHC) was performed using primary antibodies for ER, PR, and HER2/neu, with scoring based on the Allred system for ER/PR and ASCO/CAP guidelines for HER2/neu. Equivocal HER2/neu (2+) cases were recommended for confirmatory fluorescence in situ hybridization (FISH) testing.

Statistical analysis

Statistical analysis was performed using IBM SPSS version 20, with sensitivity, specificity, positive predictive value (PPV), and negative predictive value (NPV) calculated. Chi-square test and Cohen's Kappa coefficient were applied to assess concordance between trucut biopsy and surgical specimens, with a p value <0.05 considered statistically significant.

The chi-square test statistic was calculated using the following formula: $\chi^2=\sum(Oi-Ei)^2/Ei$, where Oi is the observed frequency and Ei is the expected frequency. The chi square test was applied using the following tests namely Pearson Chi-Square, continuity correction, likelihood ratio, Fisher's exact test, and linear-by-linear association.

The formula for Cohen's kappa (κ) is: $\kappa=Po-Pe/1-Pe$, where, Po is the observed agreement among raters, i.e., the proportion of times the raters agree and Pe is the expected agreement, i.e., the proportion of times raters are expected to agree by chance.

RESULTS

A total of 32 cases of invasive ductal carcinoma breast were analyzed to evaluate the concordance between trucut biopsy and surgical specimen findings in determining ER, PR and HER2/neu status. Patients had a mean age of 52.3 years, with ages ranging from 30 to 81 years. 17 (53%) out of 32 patients had tumor size less than or equal to 5 cm while 15 (47%) had tumor size >5 cm. 20 (62%) patients presented with lymph node metastasis, 8 (25%) had absent metastasis while no lymph node was isolated in 4 (13%) patients. Demographic, clinical, and histopathologic characteristics of patients are shown in Table 1. Histopathological grading according to Scarff-Bloom-Richardson grading system revealed that 4 (12%) cases

were classified as grade I, 13 (41%) cases as grade II, and 15 (47%) cases as grade III, as shown in Figure 1.

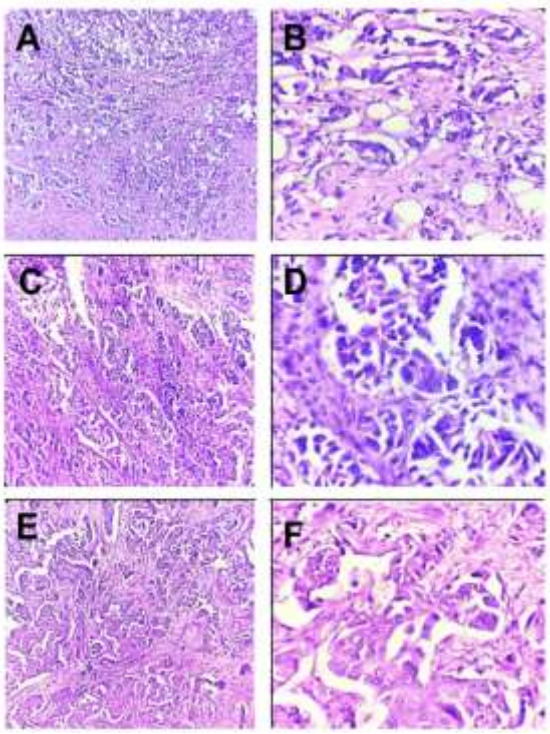

Figure 1: Grading of invasive ductal carcinoma on light microscopy (H and E staining)- grade I (A, B)- low and high power, grade II (C, D)- low and high power, grade III (E, F)- low and high power.

H and E (hematoxylin and eosin).

Table 1: Demographic, clinical, and histopathologic characteristics of patients (n=32).

Variables	N (%)
Age group (years)	
30-39	6 (18.8)
40-49	7 (21.9)
50-59	4 (12.5)
≥60	15 (46.8)
Mean±SD	52.3 years
Menopausal status	
Premenopausal	12 (38)
Postmenopausal	20 (62)
Tumor size	
≤5 cm	17 (53)
>5 cm	15 (47)
Axillary lymph node status	
Positive	20 (62)
Negative	8 (25)
Not isolated	4 (13)
Histologic grade (as per Scarff-Bloom-Richardson grading system)	
Grade I (well differentiated)	4 (12)
Grade II (moderately differentiated)	13 (41)
Grade III (poorly differentiated)	15 (47)

In our study, the high proportion of ER-negative (47%) and PR-negative (56%) cases among patients with invasive ductal carcinoma breast suggests that a substantial subset of tumors exhibit low estrogen and progesterone receptor expression. These patients may not respond well to hormone therapy. The positive scores represent cases with varying levels of ER expression and they might show good response to hormonal therapy. Table 2 and Figure 2 illustrate the Allred scoring distribution (intensity score + proportion score) for estrogen receptor (ER) and progesterone receptor (PR) respectively.

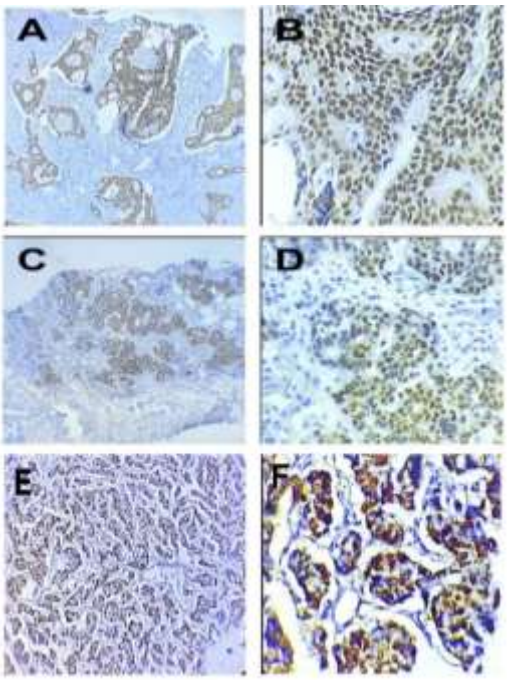

Figure 2: Allred scoring for estrogen receptor-nuclear positivity on IHC staining- (A, B)-2+4, low and high power; (C, D)-3+5, low and high power and progesterone receptor; (E, F)-3+5, low and high power.

IHC- Immunohistochemical.

Table 2: Allred scoring (intensity + proportion scores) distribution for estrogen receptor (ER) and progesterone receptor (PR) status.

Score category	ER- frequency (%)	PR- frequency (%)
Negative	15 (47)	18 (56)
Positive (3+5)	7 (22)	5 (16)
Positive (2+4)	4 (13)	-
Positive (3+4)	3 (9)	-
Positive (2+3)	2 (6)	4 (13)
Positive (2+5)	1 (3)	1 (3)
Positive (3+3)	-	2 (6)
Positive (1+3)	-	1 (3)
Positive (2+2)	-	1 (3)
Total	32 (100)	32 (100)

ER=estrogen receptor, PR = progesterone receptor; N=32 cases.

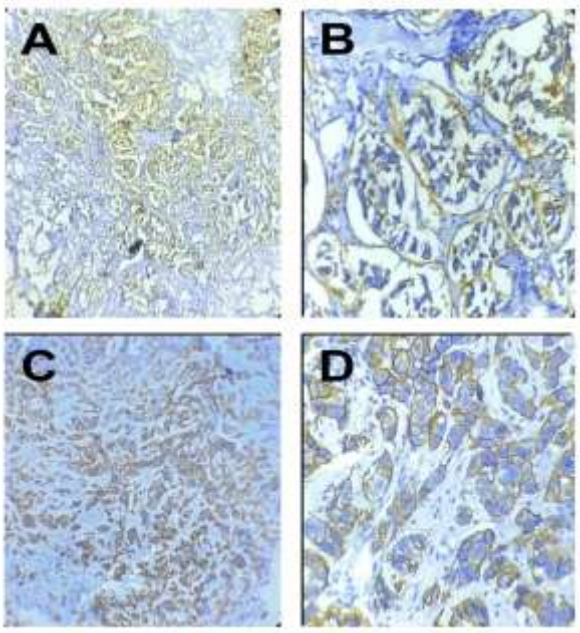

Figure 3: ASCO/CAP scoring for Her2neu receptor-cytoplasmic membrane positivity on IHC staining (A, B - score 2+, low and high power) (C, D- score 3+, low and high power).

ASCO- American Society of Clinical Oncology, CAP- College of American Pathologists, IHC- Immunohistochemical.

For HER2/neu, result was reported as HER2/neu positive and given score 3+ if >10% of tumor cells showed strong complete membrane staining, result reported as HER2/neu negative and given score 0 (no staining or <10% of tumor cells with any staining) or 1+ (faint/barely perceptible incomplete membrane staining in >10% of tumor cells). Result reported as HER2/neu equivocal if weak/moderate complete membrane staining in >10% of tumor cells indicating that further testing is required. ASCO/CAP scoring for Her2/neu receptor is shown in Figure 3.

Out of 18 cases with ER positive status on surgical specimen, trucut biopsy correctly identified 15 cases (83.3%) as ER positive. Out of 14 cases with ER negative status on surgical specimen, trucut biopsy correctly identified all the cases (100%) as ER negative. A p value of 0.001 suggested that the agreement between the trucut biopsy and surgical specimen ER status was statistically significant. The high kappa value (0.814) and significant p value (0.001) indicate that the trucut biopsy is a reliable method for determining ER status compared to the surgical specimen, with almost perfect agreement between the two methods (Table 3).

Out of 15 cases with PR positive status on surgical specimen, trucut biopsy correctly identified 11 cases (73.3%) as PR positive. Out of 17 cases with ER negative status on surgical specimen, trucut biopsy correctly identified 14 cases (82.4%) as PR negative. A p value of 0.002 suggested that the agreement between the trucut biopsy and surgical specimen PR status was statistically significant. The moderate kappa value (0.559) and significant p value (0.002) indicate that the trucut biopsy is a reasonably reliable method for determining PR status compared to the surgical specimen, with moderate agreement between the two methods. Although the agreement was not as strong as with the ER status, it was still statistically significant and suggests that trucut biopsy is a useful tool for assessing PR status in breast cancer patients (Table 4).

Table 3: Concordance between CNB and SS for ER status.

Trucut biopsy	Surgical specimen		Total	k	χ^2	P value
	ER+	ER-				
ER+	15 (100.0%)	0 (0.0%)	15			
ER-	3 (17.6%)	14 (82.4%)	17	0.814	21.9	0.001
Total	18	14	32			

Statistical test used for calculating p value: Chi-square test and Cohen's Kappa (κ) test used for agreement, df (degree of freedom) =1, values for Pearson Chi-Square =21.961[a], continuity correction[b] =18.742, likelihood ratio =28.016, linear-by-linear association =21.275, no. of valid cases =32. The percentages in brackets next to each cell count in the table are row percentages showing the proportion of the trucut biopsy result which falls into each surgical specimen category.

Table 4: Concordance between CNB and SS for PR status.

Trucut biopsy	Surgical specimen		Total	k	χ^2	P value
	PR+	PR-				
PR+	11 (78.6%)	3 (21.4%)	14			
PR-	4 (22.2%)	14 (77.8%)	18	0.559	10.04	0.002
Total	15	17	32			

Statistical test used for calculating p value: Chi-square test and Cohen's Kappa (κ) test used for agreement, df (degree of freedom) =1, Values for Pearson Chi-Square =10.041[a], continuity correction[b] =7.906, likelihood ratio =10.619, linear-by-linear association =9.727, no. of valid cases =32. The percentages in brackets next to each cell count in the table are row percentages showing the proportion of the Trucut biopsy result which falls into each Surgical specimen category.

Table 5: Concordance between CNB and SS for human epidermal growth factor receptor 2 (Her2/neu) status.

	Her2neu+	Her2neu-	Total	k	χ^2	P value
Trucut biopsy	11 (84.6%)	2 (15.4%)	13			
Surgical specimen	6 (31.6%)	13 (68.4%)	19	0.506	8.72	0.003
Total	17	15				

Statistical test used for calculating p value: Chi-square test and Cohen's Kappa (κ) test used for agreement, df (degree of freedom) =1, values for Pearson Chi-Square =8.719[a], continuity correction[b] =6.719, likelihood ratio =9.375, linear-by-linear association =8.446, no. of valid cases =32. The percentages in brackets next to each cell count in the table are row percentages showing the proportion of the Trucut biopsy result which falls into each Surgical specimen category.

Out of 17 cases with HER2/neu positive status on surgical specimen, trucut biopsy correctly identified 11 cases (64.7%) as HER2/neu positive. Out of 15 cases with HER2/neu negative status on surgical specimen, trucut biopsy correctly identified 13 cases (86.7%) as HER2/neu negative. A p value of 0.003 suggested that the agreement between the trucut biopsy and surgical specimen HER2/neu status was statistically significant. The moderate kappa value (0.506) and significant p value (0.003) indicate that the trucut biopsy is a reasonably reliable method for determining HER2/neu status compared to the surgical specimen, with moderate agreement between the two methods. Although the agreement was not as strong as with ER and PR status, it was still statistically significant and suggests that trucut biopsy is a useful tool for assessing HER2/neu status in breast cancer patients (Table 5).

Statistical analysis using the Chi-square test and Kappa statistics demonstrated substantial agreement for ER (κ=0.81) and moderate agreement for PR (κ=0.59). However, HER2/neu exhibited only fair agreement (κ=0.38), indicating a higher discordance rate compared to ER and PR. The lower concordance in HER2/neu was attributed to factors such as intratumoral heterogeneity, staining variability, and equivocal cases requiring FISH confirmation. Additionally, cases with high tumor grades (grade III) exhibited greater biomarker discordance, suggesting that more aggressive tumors have heterogeneous receptor expression patterns.

Table 6: Diagnostic statistics of the patients' ER, PR and human epidermal growth factor receptor 2 (Her2/neu) status.

	ER	PR	Her2neu
Sensitivity	83.3%	73.3%	64.7%
Specificity	100%	82.4%	86.7%
PPV	100%	78.6%	84.6%
NPV	82.4%	77.8%	68.4%
Diagnostic accuracy	90.6%	78.1%	51.6%

Concordance between trucut biopsy and surgical specimens for ER status was 90.6%, with a sensitivity of 83.3%, specificity of 100%, PPV of 100%, and NPV of 82.4%. PR expression demonstrated a 78.1% concordance rate, with sensitivity at 73.3%, specificity at 82.4%, PPV at 78.6%, and NPV at 77.8%. HER2/neu positivity was 44% in trucut biopsy and 50% in surgical specimens, with an overall concordance rate of 51.6%, sensitivity of 64.7%, specificity of 86.7%, PPV of 84.6%, and NPV of 68.4% (Table 6).

DISCUSSION

The current study was conducted to analyze the concordance rate of trucut biopsy and subsequent surgical specimen in assessing levels of ER, PR and HER2/neu in breast cancer patients. Additionally, we aimed to calculate the sensitivity, specificity, positive predictive value (PPV), and negative predictive value (NPV) of the outcome.

A total of 32 cases of trucut biopsy and subsequent modified radical mastectomy specimens received in our department for breast cancer were evaluated by light microscopy to determine the histological type. Immunohistochemistry (IHC) was performed to assess the ER, PR, and HER2/neu status of the tumor. Breast cancer is a heterogeneous group of tumors and is the most common malignant tumor among female malignancies. Ovarian steroid hormones are necessary for normal breast development, and an imbalance can initiate a neoplastic process.[8] Endocrine therapies work by antagonizing ER effects, which are essential for tumor growth.[9] The presence of hormone receptors in tumor tissue correlates well with the response to hormone therapy and chemotherapy.[10]

The existence of hormone receptors ER and PR, as well as the overexpression of HER2/neu, are crucial factors in determining the best treatment course for breast cancer patients.[11] These variables not only predict treatment response but also influence the risk of disease relapse.[12] Unlike triple-negative breast cancers (TNBCs), which lack ER, PR, and HER2 expression and have a poor prognosis due to the absence of targeted therapy, hormone receptor-positive breast cancers tend to have better outcomes.[13]

In our study, we observed considerable variability in hormone receptor and HER2/neu status across different age groups. The highest proportion of ER, PR, and HER2-positive cases was found in the 50-59-year age group (60%), while the 40-49-year age group had the highest number of triple-negative cases (50%). Studies by Dutta et al and Asogan et al reported similar findings, with breast

cancer being most prevalent in the 41-60 years age group.[7,14] De Waard et al suggested that after 60 years, the risk of breast cancer increases due to postmenopausal hormonal stimuli.[15]

Regarding menopausal status, most patients in our study were postmenopausal (62%). Among premenopausal patients (38%), the majority (34%) had triple-negative breast cancer. Postmenopausal patients showed a more even distribution across different receptor statuses. These findings align with Mudduwa et al, who reported 85.7% postmenopausal and 14.3% premenopausal women in their study.[16]

Lymph node involvement plays a critical role in breast cancer prognosis. In our study, patients with absent lymph node metastasis had a higher prevalence of ER, PR, and HER2-positive tumors (52%). Among patients with metastases, ER- and PR-positive, HER2-negative cases, as well as triple-negative cases, were equally distributed, each accounting for 25% of the cases. Similar findings were reported by Karaman et al, Dutta et al, and Mudduwa et al who observed significant lymph node involvement in breast cancer patients but found no statistically significant correlation between lymph node status and ER/PR scoring.[14,16,17]

ER and PR expression play a crucial role in predicting treatment response. In our study, 44% of trucut biopsy specimens were positive for both ER and PR, while 50% were negative. The corresponding surgical specimens revealed 41% ER/PR positivity and 44% negativity. These findings are consistent with previous studies by Von Minckwitz et al and Spyratos et al who reported ER/PR positivity rates between 33% and 42%.[18,19] Other studies by Onitilo et al and Lui Z et al showed higher ER/PR positivity rates (55-73%).[20,21] Harvey et al found that 71% of all tumors were ER positive by IHC.[22]

PR is an essential molecular marker predicting breast cancer prognosis and response to endocrine therapy. Studies suggest that PR expression can inhibit estrogen-mediated proliferation and ER transcriptional activity in ER-positive breast cancer cells. High PR levels in early-stage disease may suppress tumor metastasis, and administering progesterone injections before surgery has shown clinical benefits.[23]

HER2/neu expression is another crucial prognostic factor in breast cancer. In our study, HER2/neu was positive in 44% of trucut biopsy samples and 50% of surgical specimens. This finding is in concordance with studies by Bloom and Richardson, who found 35% HER2/neu positivity, and Almasari, who reported 25% HER2/neu positivity.[24,25] A study by Mouttet et al showed lower HER2/neu positivity rates (6-12.6%).[26]

Allred scoring provides a semi-quantitative assessment of ER and PR expression, classifying patients based on receptor levels. Our study found that 47% of patients having Invasive Ductal Carcinoma Breast had low ER expression, which may indicate poor response to hormone therapy. Conversely, HER2/neu overexpression in cases with score 3+ suggested a potential benefit from anti-HER2 therapies such as trastuzumab (Herceptin).[27]

The overall concordance rates between trucut biopsy and surgical specimens in our study were 90.6% for ER, 78.1% for PR, and 51.6% for HER2/neu. Sensitivity values were 83.3% for ER, 73.3% for PR, and 64.7% for HER2/neu, while specificity values were 100%, 78.6%, and 84.6%, respectively. Similar findings were reported by Barathi et al, Karaman et al and Franco et al, as shown in Table 7.[7,17,28]

These results suggest that trucut biopsy is a highly reliable diagnostic tool for determining ER and PR status but requires confirmatory FISH testing for HER2/neu assessment. The study underscores the importance of quality control in IHC processing and standardization of scoring methods to minimize interobserver variability. Future studies should incorporate molecular profiling techniques such as digital PCR or next-generation sequencing (NGS) to improve HER2/neu assessment. AI-based histopathological analysis may further enhance diagnostic accuracy and reduce interobserver variability.

This study has some limitations that could potentially impact the interpretation of the findings. Firstly, the sample size of 32 cases is relatively small, which limits the generalizability of the results to a broader population. For instance, Lui et al (n=85) reported 55% ER and PR positivity, while Ricci et al (n=69) evaluated molecular profiling and reported a high ER concordance (κ=0.89), despite their smaller cohort.[21,29] A larger sample size would enhance statistical power and allow for better representation of variability in biomarker expression. Additionally, the lack of FISH testing in HER2/neu equivocal (2+) cases is a notable limitation, as confirmatory testing could improve diagnostic accuracy in these borderline assessments.

CONCLUSION

Trucut biopsy has been found reliable and consistent with tissue from surgical specimens in preoperative evaluation of estrogen and progesterone receptor status in breast cancer patients. There was lower agreement in HER2/neu evaluation, possibly due to biological variation and limitations of the technique, but it provided some preliminary knowledge. This shows the value of early diagnosis and treatment planning made possible by the use of trucut biopsy in those situations where surgery or sophisticated diagnostics may not be easily accessed right now. Understanding that there can be variance, especially for HER2/neu variation, clinicians should evaluate biopsy findings with surgical considerations and additional confirmatory tests where appropriate. In general, this study affirms the role of trucut biopsy as an efficient and minimally invasive tool in the management of breast

cancer and its continued use with improved diagnostic protocols to provide comprehensive management.

ACKNOWLEDGEMENTS

The authors thank the department of pathology, Gandhi Medical College and Hamidia Hospital, Bhopal for the institutional support provided during the conduct of this study.

Funding: No funding sources
Conflict of interest: None declared
Ethical approval: The study was approved by the Institutional Ethics Committee of Gandhi Medical College, Bhopal under IEC Protocol No. 51/EC/2022 following a full board review dated 25-07-2022

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Cite this article as: Sakalle S, Tandon P, Balani S, Malik R, Pal S, Choudhary R, et al. Concordance between trucut needle biopsy and surgical specimen for estrogen receptor, progesterone receptor and human epidermal growth factor receptor status in breast cancer. Int J Res Med Sci 2025;13:4183-90.