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ORIGINAL ARTICLE

Accuracy of Ultrasound-Guided Core Biopsy for Staging Axilla in Clinically Node-Negative Patients with Invasive Breast Cancer Taking Histopathology as Gold Standard

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ABSTRACT

Objective: To assess the accuracy of ultrasound-guided core biopsy in staging axillary lymph nodes in clinically node-negative invasive breast cancer patients using histopathology as the gold standard.

Methods: This cross-sectional study was conducted in the Department of Pathology at Mekran Medical College, Turbat, Pakistan, from April 2023 to September 2023. The study included breast cancer patients who were clinically negative for lymph node involvement. Ultrasound-guided core biopsies were performed on suspicious axillary lymph nodes by experienced radiologists, with histopathological analysis serving as the gold standard. Sensitivity, specificity, positive predictive value (PPV), negative predictive value (NPV), and overall accuracy were calculated to assess diagnostic performance. Patient demographics, tumor characteristics, and axillary ultrasound findings were also recorded.

Results: A total of 132 invasive breast cancer patients were included, with a mean age of 57.67 ± 13.03 years. The majority of patients were diagnosed with invasive ductal carcinoma, accounting for 113 (85.6%) cases. Hormone receptor positivity was prevalent, with estrogen receptor positivity in 119 (90.2%) and progesterone receptor positivity in 116 (87.9%) cases. The most common immunohistochemistry subtype was Luminal B, present in 66 (50%) patients, followed by Luminal A in 51 (38.6%) patients. Most tumors were of moderate grade 77 (58.4%) and early-stage (pT1) 63 (47.7%). Ultrasound-guided core biopsy exhibited a sensitivity of 87.9% and specificity of 100%, with positive and negative predictive values of 100% and 89.2% respectively, resulting in a diagnostic accuracy of 93.9%.

Conclusion: Ultrasound-guided core biopsy demonstrates strong diagnostic performance in identifying metastatic axillary lymph nodes in clinically node-negative invasive breast cancer patients.

Keywords: Axillary, Biopsy, Breast Neoplasms, Lymph Nodes.

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INTRODUCTION

Breast cancer is one of the most pervasive health challenges faced by women worldwide, accounting for over 1 in 10 new cancer diagnoses annually and ranking as the second leading cause of cancer-related deaths among women.[1,2] While breast cancer comprises a spectrum of subtypes, each with distinct characteristics, invasive breast cancer represents one of the most aggressive forms, posing significant threats to both physical health and emotional well-being.[3] Risk factors include advanced age, family history of breast cancer, inherited genetic abnormalities (such as BRCA1 and BRCA2), reproductive factors (such as early onset of menstruation, never having given birth, and late onset of menopause), hormonal influences (such as estrogen and progesterone), exposure to ionizing radiation, lifestyle habits (such as alcohol consumption and sedentary behavior), and obesity.[4] According to the World Health Organization, approximately 2.26 million new cases of breast cancer were reported globally in 2020, with an estimated 6.9% mortality rate. Between 2007 and 2017, breast cancer accounted for 23.9% of global cancer-related deaths.[5] Pakistan notably exhibits

the highest breast cancer incidence in Asia, with approximately 1 in 9 women affected during their lifetime. Projections indicate a substantial rise in breast cancer incidence, from 23.1% in 2020 to an estimated 60.7% by 2025.[6]

The transition from non-invasive to invasive breast cancer marks a critical juncture in disease progression, signifying an escalation in severity. Invasive breast cancer comprises various histological subtypes, each characterized by distinct cellular features and growth patterns.[7] Invasive ductal carcinoma is the most common form, accounting for roughly 80% of all invasive breast cancers.[8]

Axillary lymph node involvement significantly impacts breast cancer prognosis and treatment. Axillary staging in breast cancer patients often involves surgical procedures, such as sentinel lymph node biopsy (SLNB) or axillary lymph node dissection (ALND), both of which carry risks, including lymphedema and nerve damage.[9]

Ultrasound-guided core biopsy has emerged as a valuable adjunct to imaging modalities in breast cancer management, enabling targeted sampling of suspicious axillary lymph nodes with high precision and minimal morbidity. By obtaining tissue samples for histopathological analysis, ultrasound-guided core biopsy provides critical information on lymph node involvement, guiding treatment decisions and prognostic assessments.[10,11]

Evaluating the accuracy of ultrasound-guided core biopsy for axillary staging addresses a critical gap in the existing literature, particularly in the context of diverse populations and resource-limited settings. While this technique is well-established in some regions, there is limited data on its effectiveness in settings like Pakistan, where breast cancer incidence is high, and healthcare resources are often constrained. By providing robust evidence of its diagnostic utility, this study aims to help clinicians improve staging accuracy and patient management, potentially leading to better outcomes and more efficient use of available resources. Ultimately, the findings of this study could optimize axillary staging strategies and enhance the overall quality of breast cancer care in regions facing similar challenges.

METHODS

This cross-sectional study was conducted in the Department of Pathology at Mekran Medical College, Turbat, Pakistan, from April to September 2023. The study received ethical approval from the college Ethical Review Committee (Ref. No: MMC/ERC/115/ 2023). Informed consent was obtained from all participants prior to their enrolment.

A non-probability consecutive sampling method was used. The study included women aged 30 to 80 years with clinically node-negative invasive breast cancer, who underwent ultrasound-guided core biopsy for axillary staging with confirmed histological diagnoses of invasive breast cancer. Patients with prior axillary surgery or neoadjuvant therapy were excluded. Demographic data, including age, and clinical characteristics such as tumor size, histological subtype, hormone receptor status, human epidermal growth factor receptor 2 (HER2/neu) expression, tumor grade, and stage were prospectively collected from medical records. Axillary ultrasound findings indicating lymph node characteristics were also recorded.

Experienced breast radiologists performed ultrasound-guided core biopsies on suspicious axillary lymph nodes using aseptic techniques and local anesthesia. The core biopsy specimens were processed and analyzed by pathologists using standard histopathological techniques. The biopsy samples were evaluated for lymph node architecture and cytology. Immunohistochemistry was also performed to assess hormone receptor status, including estrogen receptor positivity (ER+), progesterone receptor positivity (PR+), and HER2/neu expression. Ultrasound-guided core biopsy was used to stage axillary lymph nodes by extracting tissue samples from suspicious nodes, which were examined for cancer involvement.

Histopathological analysis further evaluated the samples by assessing the lymph node's architecture, presence of cancer cells, and the extent of metastasis. Staging was determined separately for ultrasound (US) and histopathology. Histopathological staging followed the TNM system: pN0 (no nodal involvement), pN1 (1-3 positive nodes), pN2 (4-9 positive nodes), and pN3 (10 or more positive nodes). Ultrasound staging was based on the number and characteristics of suspicious lymph nodes. Patients were classified into molecular subtypes based on immunohistochemistry: Luminal A (ER+/PR+/HER2-), Luminal B (ER+/PR+/HER2+), Non-luminal HER2+ (ER-/PR-/HER2+), and Triple Negative (ER-/PR-/HER2-). These classifications helped guide treatment decisions and prognostic evaluations.

Diagnostic accuracy was measured by comparing the results of the ultrasound-guided core biopsy to the histopathological findings (gold standard). Sensitivity, specificity, positive predictive value (PPV), negative predictive value (NPV), and accuracy were calculated based on true positive, true negative, false positive, and false negative cases. Histopathologically, lymph nodes

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were classified as malignant if cancer cells were detected, including macrometastasis (cancer deposits >2 mm) or micrometastasis (0.2–2 mm). They were classified as benign if no cancer cells were present upon microscopic examination, indicating no metastatic involvement.

The Statistical Package for the Social Sciences (SPSS) version 20.0 was used for data entry and analysis. The mean & standard deviation (SD) was calculated for patient age. Age was further categorized into ≤50 years or >50 years, as this threshold marks a significant distinction between premenopausal and postmenopausal breast cancer, affecting disease behavior and treatment. Frequencies and percentages were determined for categorical variables such as tumor type, hormone receptor status, immunohistochemistry classification, tumor grade, tumor stage, and ultrasound findings. Taking histopathological analysis of sentinel lymph node biopsy or dissection specimens as the gold standard, sensitivity, specificity, PPV, NPV, and overall diagnostic accuracy of ultrasound-guided core biopsy findings were calculated. A p-value of ≤0.05 was considered statistically significant.

RESULTS

Of total 132 invasive breast cancer patients, the mean age was 57.67 ±13.03 years. The distribution of primary tumor sizes ranged widely, with a mean of 18.96 ±10.14 mm. Majority of the patients diagnosed with invasive ductal carcinoma i.e., 113 (85.6%). Hormone receptor positivity was prevalent, with ER (+) in 1119 (90.2%) and PR (+) in 116 (87.9%) of the cases. The most common immunohistochemistry subtype was Luminal B 66 (50%), followed by Luminal A 51 (38.6%). Most tumors were of moderate grade 77 (58.4%) and early-stage (pT1) 63 (47.7%). Ultrasound findings revealed 116 (87.9%) of patients had cortical thickness ≥ 3 mm, 63 (47.7%) showed eccentric cortical hypertrophy, and 44 (33.3%) had round-shaped axillary nodes, while 30 (22.7%) exhibited loss of the central hilum (Table 1).

Table 2 compares lymph node stages identified by ultrasound-guided core biopsies and histopathology of the patients. Histopathology identified pN0 in 60 (45.5%) cases, while biopsies found 66 (50.0%) cases. For pN1, histopathology reported in 48 (36.4%) cases, compared to 42 (31.8%) in biopsies. In the pN2 stage, histopathology identified 15 (11.3%) cases, whereas biopsies found 16 (12.1%) cases. For pN3, histopathology detected 9 (6.8%) cases and biopsies identified 8 (6.1%) cases.

The cross-tabulation between ultrasound-guided core needle biopsy and histopathology results showed that there were 58 (43.9%) true positive patients, 66 (50%) true negative patients with 8 (6.1%) false negative patients. However, no false positive cases were identified (Table 3).

Ultrasound-guided core biopsy exhibited a sensitivity of 87.9% and specificity of 100%, with positive and negative predictive values at 100% and 89.2%, respectively, resulting in a diagnostic accuracy of 93.9% (Table 4).

DISCUSSION

The staging of invasive breast cancer patients depends on the extent of local and regional lymph node involvement. Accurate axillary staging using ultrasound-guided core biopsy is crucial for guiding treatment decisions in clinically node-negative invasive breast cancer patients. Optimal treatment and patient outcomes are closely linked to the status of axillary lymph nodes. Ultrasound-guided core biopsy provides a less invasive method for assessing axillary involvement compared to other approaches. However, its reliability compared to histopathology, the gold standard, must be evaluated to determine its accuracy in staging axillary lymph nodes.[13] Axillary lymph node involvement is a critical factor in the staging and management of breast cancer, influencing treatment decisions and prognosis.[14,15] Ultrasound-guided core needle biopsy offers a minimally invasive approach for preoperative evaluation, providing valuable information on nodal metastasis.[16,17] This study assesses the diagnostic accuracy of ultrasound-guided core needle biopsy compared to histopathology, emphasizing its role in the precise detection of metastatic axillary lymph nodes.

In our study, invasive ductal carcinoma was the most common subtype, representing a significant majority of cases, with a mean tumor size around 19 mm. This finding is consistent with studies by Javid *et al*.[18] and Riedel *et al*.,[19] who also identified invasive ductal carcinoma as the predominant histological subtype, reflecting its high prevalence in breast cancer diagnoses. Most tumors in our study were positive for ER and PR, indicating a high prevalence of hormone receptor positivity. Similarly, Javid et al. observed a significant proportion of tumors positive for ER and PR, with a notable absence of HER2/neu positivity.[18] Riedel et al. reported a slightly lower proportion of hormone receptor-positive and HER2-negative tumors, which could be attributed to differences in patient demographics or variations in laboratory methods.[19] This study observed that many lymph nodes had increased cortical thickness and eccentric cortical

Table 1: Baseline and clinical characteristics of the patients (n= 132)

Characteristics	n (%)
Age Groups (years)	
≤ 50	41 (31.1)
> 50	91 (68.9)
Invasive Tumor Type	
Invasive-ductal	113 (85.6)
Invasive-lobular	16 (12.1)
Others	3 (2.3)
Hormone Receptor Status	
ER (+)	119 (90.2)
PR (+)	116 (87.9)
Her-2/neu (+)	11 (8.3)
Immunohistochemistry Classification	
Luminal A	51 (38.6)
Luminal B	66 (50.0)
Non-luminal HER2+	6 (4.5)
Triple Negative	9 (6.9)
Tumor Grade	
G1	18 (13.6)
G2	77 (58.4)
G3	37 (28.0)
Tumor Stage	
pT1	63 (47.7)
pT2	51 (38.6)
pT3	10 (7.6)
pT4	8 (6.1)
Axillary ultrasound Findings	
Cortical Thickness of ≥ 3 mm	116 (87.9)
Round Shape	44 (33.3)
Eccentric Cortical Hypertrophy ≥ 3 mm	63 (47.7)
Loss of the Central Hilum	30 (22.7)

- ER: Estrogen Receptor, PR: Progesterone Receptor, HER2/neu: Human Epidermal Growth Factor Receptor 2, G1: Grade 1, G2: Grade 2, G3: Grade 3, pT1: Pathological Tumor Stage 1, pT2: Pathological Tumor Stage 2, pT3: Pathological Tumor Stage 3, pT4: Pathological Tumor Stage 4

Table 2: Lymph node stages identified by ultrasound-guided core biopsies and histopathology (n = 132)

Lymph Node Stages	Ultrasound-Guided Core Biopsies	Histopathology (ALND/SLNB)
pN0	66 (50.0)	60 (45.5)
pN1	42 (31.8)	48 (36.4)
pN2	16 (12.1)	15 (11.3)
pN3	8 (6.1)	9 (6.8)

-ALND: Axillary Lymph Node Dissection; SLNB: Sentinel Lymph Node Biopsy; pN0: No regional lymph node metastasis, pN1: Micrometastasis or 1-3 Positive Nodes, pN2: 4-9 Positive Node, pN3: 10 or More Positive Nodes

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Table 3: Cross-tabulation between results of core needle biopsy and histopathology

US-guided CNB	Histopathology (ALND/SLNB)		Total
	Malignant	Benign	
Malignant	58	0	58
Benign	8	66	74
Total	66	66	132

-US: Ultrasound, CNB: Core needle biopsy; ALND: Axillary lymph node dissection; SLNB: Sentinel lymph node biopsy

Table 4: Accuracy of core needle biopsy in identifying metastatic axillary lymph nodes

	Values	95% C.I
Sensitivity	87.9%	77.5 to 94.6
Specificity	100.0%	94.6 to 100
Positive Predictive Value	100.0%	93.8 to 100
Negative Predictive Value	89.2%	81.2 to 94.1
Accuracy	93.9%	88.4 to 97.4

hypertrophy. Round-shaped nodes were present in a notable number of cases, while loss of the central hilum was found in a smaller proportion. These findings are consistent with Mwaniki's research, which also reported various lymph node shapes and a slightly higher median cortical thickness. Mwaniki's study showed a predominance of fatty hilum nodes, along with other variations such as non-hilar and focal cortical bulge nodes.[20] Additionally, Afzal *et al.* reported that a high proportion of suspicious lymph nodes had increased cortical thickness, supporting our observations.[21] In this study, ultrasound-guided core needle biopsy correctly identified fifty-eight cases as malignant and sixty-six as benign. Comparatively, Hu *et al*. found sixty percent of cases in the suspicious axillary ultrasound category were positive, aligning with our observations.[22]

The study revealed that ultrasound-guided core biopsy exhibited excellent diagnostic performance, with high sensitivity and perfect specificity. Both the positive and negative predictive values were also optimal, demonstrating strong accuracy. In contrast, Javid *et al*. reported lower sensitivity but higher specificity for axillary ultrasound, with positive and negative predictive values showing some disparity.[18] Similarly, Afzal *et al*. observed comparable sensitivity and perfect specificity for ultrasound-guided core biopsy, with both positive and negative predictive values at their highest, reflecting high diagnostic accuracy.[21]

Furthermore, Stachs *et al*. observed lower sensitivity but higher specificity for axillary ultrasound, with notable positive and negative predictive values.[23] Houssami *et al*. reported high specificity for axillary ultrasound along with substantial sensitivity.[24] Mu *et al.* demonstrated perfect sensitivity and strong specificity for core needle biopsy, with high positive and negative predictive values.[25] In contrast, Abidi *et al*. found lower sensitivity and specificity for axillary ultrasound, with moderate positive and negative predictive values and overall diagnostic accuracy in their study cohort.[26]

This study provides valuable insights into the diagnostic accuracy of ultrasound-guided core biopsy in axillary staging, specifically in a resource-limited setting where access to advanced imaging modalities may be restricted. Limitations include potential operator proficiency variability during ultrasound-guided core biopsy, impacting lymph node sampling accuracy, and variations in imaging resolution and equipment quality, affecting axillary lymph node visualization and characterization. Further research is needed to examine the incorporation of molecular biomarkers in order to improve the precision of ultrasound-guided core biopsy for determining the stage of axillary lymph nodes in patients with clinically negative invasive breast cancer. Furthermore, it is necessary to conduct longitudinal studies in order to evaluate the extended clinical results and prognostic implications of this technique for personalized treatment strategies.

CONCLUSION

In conclusion, ultrasound-guided core biopsy demonstrates strong diagnostic performance in identifying metastatic axillary lymph nodes in clinically node-negative invasive breast cancer patients. The procedure showed high sensitivity and perfect specificity and positive predictive value, with overall strong accuracy. While a small number of false-negative

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cases were observed, no false positives were detected, highlighting its reliability. These findings suggest that ultrasound-guided core biopsy is a valuable and accurate tool for axillary staging, providing crucial information for treatment planning and improving patient outcomes in early breast cancer management.

ETHICAL APPROVAL: This study received ethical approval from the Ethical Review Committee of the Makran Medical College, Turbat, Pakistan (Ref No: MMC/ERC/115/2023, dated: 13th March, 2023).

AUTHORS' CONTRIBUTIONS: SKS: Conceptualized study designed & research protocol. MWK: Collected and analyzed the data, and contributed to drafting. LH: Patient recruitment and data collection. AHS, SN & SS: Statistical analysis and interpretation of results.
All authors critically reviewed and gave final approval of the manuscript.

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