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THE ROLE OF PREOPERATIVE PET-CT SCAN IN NON-INVASIVE STAGING OF AXILLARY LYMPH NODES IN BREAST CANCER: A DIAGNOSTIC ACCURACY STUDY

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Abstract

Background: Metastases from axillary lymph nodes are a crucial prognostic indicator that affects the course of treatment methods for individuals suffering from breast cancer. Post-surgery, lymphedema has been shown to have a detrimental effect on prognosis and to affect upper body function and quality of life adversely. **Materials and Methods:** A total of 100 patients with operable breast carcinoma were enrolled with the primary objective being to assess the axillary lymph node status using PET-CT imaging. The secondary objective was to correlate the PET-CT findings with the histopathological results. **Result:** This study evaluated the diagnostic accuracy of preoperative PET-CT scans in detecting axillary lymph node involvement, with postoperative histopathological examination serving as the gold standard. The results showed a sensitivity of 64.71% (95% CI: 50.07-77.57), specificity of 48.98% (95% CI: 34.42-63.66), positive predictive value of 56.90% (95% CI: 48.41-64.99), negative predictive value of 57.14% (95% CI: 45.48-68.06), and overall accuracy of 57.00% (95% CI: 46.71-66.86). **Conclusion:** Our findings demonstrate that PET scans have low sensitivity, low specificity, high false-negative rates, and low accuracy. As a result, PET scans cannot be relied upon to replace sentinel lymph node biopsy (SLNB) as a standard method for evaluating axillary lymph node status in breast cancer patients.

INTRODUCTION

Survival rates for breast cancer vary significantly, ranging from 99% to 27%, and are influenced by factors such as disease stage, histological and molecular subtypes, and genomic profiles. Contemporary breast cancer diagnosis relies on clinical examination and radiological and histopathological examinations.[1] Accurate initial staging is essential for determining prognosis and informing optimal treatment decisions for breast cancer patients. To diagnose and stage breast carcinoma, various imaging modalities are used which include mammography, ultrasound, computed tomography (CT), magnetic resonance imaging, and positron emission tomography/computed tomography (PET-CT).

Metastases from axillary lymph nodes serve as a critical prognostic indicator, influencing the treatment approach for breast cancer patients. Surgical options available for treating breast cancer are modified radical mastectomy with axillary lymph node dissection and breast-conserving surgery, both yielding comparable outcomes. For axillary lymph node staging, patients with clinically node-negative axilla are recommended to undergo sentinel lymph node biopsy (SLNB), whereas those with lymph node metastases should undergo axillary lymph node dissection (ALND).[2] When the sentinel lymph node finding is negative, patients undergoing SLNB and those undergoing ALND exhibit similar prognoses. However, SLNB has a false-negative rate of approximately 10%.[3] Compared to SLNB, ALND is associated with a higher incidence of surgical complications, such as lymphedema and axillary paraesthesia.[4,5] Notably, lymphedema has been shown to adversely impact prognosis and negatively affect upper body function and quality of life following breast cancer therapy.[6-8]

Given the need for a non-invasive axillary staging method, Positron Emission Tomography/Computed Tomography (PET-CT) has emerged as a valuable diagnostic tool. With its ability to provide anatomical information by combining PET images with CT scans, PET-CT has largely supplanted PET alone in clinical practice.[9-11] FDG PET-CT leverages the increased glycolysis in rapidly proliferating malignant cells to visualize potential problem areas within the body using the radioactive tracer 18-fluoro-2-deoxy -2- glucose (FDG). PET-CT has demonstrated a sensitivity of up to 96% and is a valuable modality for detecting distant metastases in breast cancer patients, outperforming conventional imaging modalities

In individuals who exhibit no lymph node involvement, PET CT aids in assessing axillary and Internal mammary node (IMN) involvement, perhaps minimizing the need for axillary lymph node dissection and its associated risks. Compared to other imaging modalities, PET has a higher accuracy in detecting local or distant illnesses, making it a valuable test for staging or restaging breast cancer.[12,13] FDG-PET, has been used to diagnose, stage, and track treatment response, and restaging patients, and evaluate response to chemotherapy.[14] Since changes in metabolic activity typically take place before changes in tumor size, functional and morphological imaging modalities, including PET-CT, can be utilized to assess treatment response before morphologic imaging techniques.[15]

The primary objective of this study was to assess the role of FDG PET-CT scans in evaluating the locoregional nodal status in breast cancer, specifically to determine the axillary lymph node status preoperatively, while the secondary objective was to compare the PET-CT evaluation results with post-operative histopathological reports of axillary lymph nodes.

MATERIALS AND METHODS

A prospective study was conducted in the Department of Surgery Pt. B.D. Sharma PGIMS, Rohtak, a tertiary care hospital, after getting approval from the review board and ethical committee. The primary objective was to evaluate the axillary lymph node status in patients with carcinoma breast by using PET-CT. The secondary objective was to compare the observed results of PET-CT evaluation with postoperative histopathological reports.

Sample Size and Sampling Technique: A total of 100 patients were enrolled in the study group, following approval from the review board and ethical committee, until the desired sample size was attained.

Inclusion and Exclusion Criteria

All patients diagnosed with breast carcinoma were admitted to the General Surgery Department. The study included patients with clinically detected breast carcinoma and those scheduled for surgical intervention. However, patients with stage IV breast cancer, non-operable breast carcinoma, male breast cancer patients, and those who declined to provide informed consent were excluded from the study.

Formula Used

Sample size (N)		=	$(Z1{-}\alpha/2)\ pq$ ———— $L2$
$Z1{-}\alpha/2$		=	1.96 (at 95% confidence level)
P		=	64.6% [0.646] prevalence
q		=	1-P
L		=	5% relative error (15% of prevalence)
N		=	94
Total Sample size		=	100

Following informed consent, a comprehensive history was obtained, and a thorough Clinical examination was performed. Patients underwent bilateral breast and axillary ultrasound imaging, followed by mammography. A definitive diagnosis of breast cancer was established via core needle biopsy. Based on this, patients were classified into operable breast cancer and advanced breast cancer. The operable breast cancer patients were selected based on the inclusion criteria. Next, patients were referred for PET-CT scans at government institutions or empanelled centres to evaluate axillary status in breast carcinoma. The level of lymph node involvement in the axilla was carefully documented. After counselling, patients willing to undergo surgery were scheduled for Modified Radical Mastectomy. Modified radical mastectomy was performed under general anaesthesia. The axillary lymph node dissection was done up to the level III lymph node by removing all the lymphatic tissue and fascia anterior and inferior to the axillary vein. The specimen of breast and axilla removed en-bloc were sent for histopathological reporting. The histopathological status of the axilla was taken as the gold standard. Axillary lymph node status as reported in the PET-CT scan was compared to that reported in the histopathological report.

Statistical Analysis: The data was recorded in a Microsoft Excel spreadsheet and statistically analyzed using the Statistical Package for Social Sciences (SPSS). Descriptive statistics were presented as mean, standard deviation, and frequencies for continuous variables, and as numbers and percentages for categorical variables. Inferential statistics, including correlation coefficients, Fisher's exact test, and Chi-square tests, were employed to analyze the data. Categorical data was analyzed using the Chi-square test, with a P-value of <0.05 considered statistically significant. Inferences were drawn based on the results, with appropriate tests used to determine significance.

RESULTS

This prospective study examined 100 patients with breast carcinoma, aged 35-76 years, with a mean age of 55.75 years. The majority of patients (56%) were between 45-65 years old. The mean body mass index (BMI) was 23.65 ± 2.05, with a range of 20.13-28.32. Tumor staging revealed that 39 patients had T1 lesions, 31 had T2 lesions, 28 had T3 lesions, and 2 had T4 lesions. Clinically, 32 patients were node-negative, while 68 were node-positive, comprising 44 patients with N1 axillary status and 24 patients with N2 axillary status. PET-CT scans detected axillary nodes in 58 patients (58%) and negative nodes in 42 patients (42%). Disease staging showed that 17 patients had stage I disease, 24 had stage IIa, 24 had stage IIb, 33 had stage IIIa, and 2 had stage IIIb. Breast carcinoma was more common on the right side (54%) than the left side (46%), and modified radical mastectomy (MRM) was performed accordingly. Histopathological reports indicated that 51 patients (51%) were axillary node-positive, while 49 patients (49%) were axillary lymph node-negative. A summary of patient and tumor characteristics is presented in [Table 1].

The axillary lymph node status as detected by PET-CT scan pre-operatively in patients with carcinoma breast at various stages of the disease is presented in [Table 2]. PET scans detected positive axillary lymph nodes in 24 patients (41.4%) and negative nodes in 15 patients (35.7%) with T1 disease, 18 patients (31.0%) with positive nodes and 13 patients (31%) with negative nodes had T2 disease, 15 patients (25.9%) with positive nodes and 13 patients (31.0%) with negative nodes had T3 disease, 1 patient (1.7%) with positive nodes and no patients with negative nodes had T4a disease, and no patients with positive nodes and 1 patient (2.4%) with negative nodes had T4b disease.

[Table 3] presents the axillary lymph node status as detected by histopathological examination (HPE) post-operatively in patients with carcinoma breast at various stages of the disease. In T1 disease, HPE revealed positive axillary lymph nodes in 25 patients (49%) and negative nodes in 14 patients (28.6%). For T2 disease, 11 patients (21.6%) had positive axillary lymph nodes, while 19 patients (38.8%) had negative nodes. In T3 disease, HPE detected positive axillary lymph nodes in 12 patients (23.5%) and negative nodes in 16 patients (32.7%). Additionally, in T4a disease, only 1 patient (2%) had positive axillary lymph nodes, with no patients having negative nodes, whereas in T4b disease, no patients had positive axillary lymph nodes, while 1 patient (2%) had negative nodes.

A comparative analysis of axillary lymph node status was conducted in 100 patients with carcinoma breast using PET scan and histopathological reports. The results, presented in [Table 4 and Figure 1], revealed a concordance between PET scan and histopathological reports in 57 patients (33 node-positive and 24 node-negative). However, discrepancies were observed in 43 patients, where 25 patients were falsely labeled as node-negative by histopathological reports despite being node-positive on PET scan, and 18 patients were falsely labeled as node-positive by histopathological reports despite being node-negative on PET scan.

[Table 5] Presents a comparison of axillary lymph node detection by PET scan pre-operatively and histopathological reporting post-operatively at different stages of the disease. PET scan accurately detected axillary lymph nodes negative in 6 patients with T1 disease (falsely detecting 8 positive), 10 patients with T2 disease (falsely detecting 9 positive), and 8 patients with T3 disease (falsely detecting 8 positive). Conversely, PET scan accurately detected axillary lymph nodes positive in 16 patients with T1 disease (falsely detecting 9 negatives), 9 patients with T2 disease (falsely detecting 3 negatives), 7 patients with T3 disease (falsely detecting 5 negatives), 1 patient with T4a disease (no false detections), and falsely detected 1 patient with T4b disease as negative (no true positives).

The statistical analysis of PET-CT scans for detecting metastatic axillary lymph nodes in breast carcinoma revealed a sensitivity of 64.71% (95% CI: 50.07-77.57%), specificity of 48.98% (95% CI: 34.42-63.66%), positive predictive value of 56.90% (95% CI: 48.41-64.99%), negative predictive value of 57.14% (95% CI: 45.48-68.06%), and accuracy of 57.00% (95% CI: 46.71-66.86%), as presented in [Table 6].

Table 1: Demographics and tumor characteristics.

Characteristic (N=100)	Value	Percentage (%)
Mean age (years) (range)	55.75 (35-76)	
Mean BMI (kg/m2) (range)	23.65 (20.13-28.32)	
Diagnosis		
Left CA Breast	46	46
Right CA Breast	54	54
Tumor stage		
T1	39	39.0
T2	31	31.0
T3	28	28.0
T4a	1	1.0
T4b	1	1.0
Nodal stage		
N0	32	32.0
N1	44	44.0
N2	24	24.0
Clinical stage at presentation		
I	17	17.0
IIA	24	24.0
IIB	24	24.0

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IIIA	33	33.0
IIIB	2	2.0
Axillary Lymph node on PET-CT		
Node -	42	42.0
Node +	58	58.0
Axillary lymph node on HPER		
Node -	49	49.0
Node +	51	51.0

Table 2: Axillary lymph node status by PET-CT preoperatively in patients with carcinoma breast at different stages of the disease

								Total	P Value
			T1	T2	T3	T4a	T4b		
PET	NODE -	N	15	13	13	0	1	42	
		%	35.7%	31%	31.0%	0.0%	2.4%	100.0%	
	NODE +	N	24	18	15	1	0	58	0.55
		%	41.4%	31.0%	25.9%	1.7%	0.0%	100.0%	
Total		N	39	31	28	1	1	100	
		%	39.0%	30.0%	28.0%	1.0%	1.0%	100.0%	

Table 3: Axillary lymph node status by post-operative histopathological report at different stages of the disease

								Total	P value
			T1	T2	T3	T4a	T4b		
HPER	NODE -	N	14	19	16	0	0	49	
		%	28.6%	38.8%	32.7%	0.0%	0.0%	100.0%	
	NODE +	N	25	12	12	1	1	51	0.11
		%	49.0%	23.5%	23.5%	2.0%	2.0%	100.0%	
Total		N	39	31	28	1	1	100	
		%	39.0%	31.0%	28.0%	1.0%	1.0%	100.0%	

Table 4: Comparison of axillary lymph nodes detected by PET-CT scan pre-operatively to those detected by histopathological reporting post-operatively

		HPER-AXILLA STATUS		Total	P value
		NODE -	NODE +		
PET-CT SCAN LYMPH NODE DETECTED	NODE -	24	18	42	0.16
	NODE +	25	33	58	
Total		49	51	100	

Table 5: A comparison of axillary lymph node detection by PET scan pre-operatively and histopathological reporting post-operatively at different stages of disease

HPER					T Stage			Total
			T1	T2	T3	T4a	T4b	
NODE -	PET	NODE -	6	10	8	0	0	24
		NODE +	8	9	8	0	0	25
	Total		14	19	16	0	0	49
NODE +	PET	NODE -	9	3	5	0	1	18
		NODE +	16	9	7	1	0	33
	Total		25	12	12	1	1	51

Table 6: The statistical analysis of PET-CT scans in the evaluation of Metastatic Axillary Lymph nodes

Statistic	Value	95% CI
Sensitivity	64.71%	50.07% to 77.57%
Specificity	48.98%	34.42% to 63.66%
Positive Predictive Value	56.90%	48.41% to 64.99%
Negative Predictive Value	57.14%	45.48% to 68.06%
Accuracy	57.00%	46.71% to 66.86%

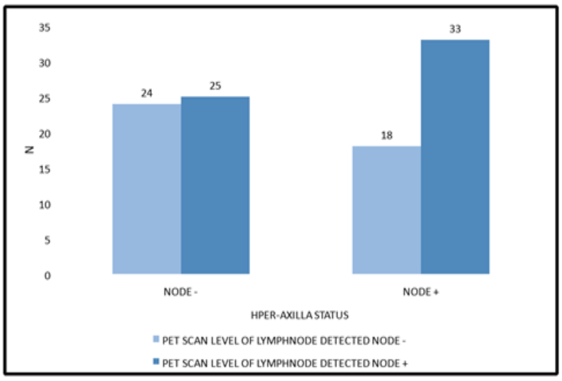

Figure 1: Comparison of axillary lymph nodes detected by PET-CT scan pre-operatively to those detected by histopathological reporting post-operatively

DISCUSSION

Breast cancer is a leading cause of cancer-related mortality worldwide, affecting women of all ages. Accurate tumor staging is crucial before initiating therapy. According to the ACS, the five-year survival rate for localized breast cancer is 99%, while for regional breast cancer, this rate decreases to 86%.[16] Despite being highly curable when detected early, about one-third of women with breast cancer ultimately succumb to the disease. Therefore, precise prediction of prognosis and selection of optimal treatment are important.[17,18] In India, increased awareness has led to more patients being diagnosed at an early stage, making breast conservation a viable option. Sentinel lymph node biopsy (SLNB) is essential for determining axillary status, but this facility is not widely available in government hospitals or private institutions. PET-CT scans have become widely used and accessible over the past decade, enabling evaluation of metastatic cancer status. Notably, metastatic axillary lymph nodes in breast cancer patients take up 18FDG, making PET-CT a potential alternative to Sentinel Lymph Node Biopsy. The present study aimed to compare the preoperative PET-CT scan results with the postoperative histopathological staging of axillary lymph nodes.

In our study statistical analysis of PET-CT scans for detecting metastatic axillary lymph nodes in breast carcinoma revealed a sensitivity of 64.71% (95% CI: 50.07-77.57%), specificity of 48.98% (95% CI: 34.42-63.66%), positive predictive value of 56.90% (95% CI: 48.41-64.99%), negative predictive value of 57.14% (95% CI: 45.48-68.06%), and accuracy of 57.00% (95% CI: 46.71-66.86%).

According to a meta-analysis conducted by Zhang et al., the sensitivity of PET-CT was found to be 56% (95% confidence interval: 47%-63%).[19] A study by Jeong et al. reported a sensitivity of 20.8% for PET-CT in detecting ALN metastases, which may be attributed to the early stage of tumors and the presence of micrometastatic nodes in the study population.[20] In two systematic reviews, FDG PET-CT had a sensitivity of 56–64%.[19,21] The relatively low sensitivity is a disadvantage of FDG PET-CT. The low sensitivity of PET-CT in detecting axillary lymph nodes (ALN) may be attributed to primary tumors with low 18FDG uptake.[22]

Notably, this study revealed a substantial false-negative rate of 42.8% for axillary lymph nodes, highlighting a significant limitation in the accuracy of axillary lymph node assessment. Wazir et al. reported a significantly higher false-negative rate of 48% for PET-CT, corresponding to a sensitivity of 52%, in contrast to a notably lower false-negative rate of 10% for sentinel lymph node biopsy.[23] The likelihood of false negatives (FNs) can be significantly influenced by various factors, including advanced age, specific primary tumor characteristics, and the extent of axillary disease.[24] The limited spatial resolution of PET-CT can lead to undetected small ALN metastases, resulting in increased false-negative rates and decreased sensitivity.[20,24,25-29] This issue is particularly pronounced for micrometastases, as observed by Kutlutürk et al., who found that these accounted for 32% of false negatives.[24] Furthermore, the detection of metastases by PET-CT is influenced by the nature of the tumor, as 18FDG uptake varies depending on tumor characteristics.[29]

Wahl RL et al. found high specificity of PET-CT which makes it a valuable tool for potentially avoiding sentinel node biopsy (SNB) and axillary lymph node dissection (ALND) in patients with negative results.[27] Furthermore, a positive axillary finding on PET-CT is a reliable indicator of axillary lymph node (ALN) involvement, owing to its high specificity.[31] A systematic meta-analysis conducted by Zhang X et al and Robertson IJ et al revealed that PET-CT exhibits high specificity, ranging from 93% to 96%.[19,21] A systematic review and meta-analysis by Rebecca Peare et al reported a high specificity of 94% for PET-CT in lymph node assessment.[32] Our study yielded a significantly lower specificity of 49% and an accuracy of 57 % for PET-CT in detecting axillary lymph nodes, contrasting with previous findings.

Overall, our study demonstrated that PET-CT has limited diagnostic utility for detecting axillary lymph nodes, characterized by low sensitivity, low specificity, low accuracy, and a high false-negative rate.

CONCLUSION

This study's findings indicate that PET-CT is not a suitable replacement for sentinel lymph node biopsy (SLNB) in staging axillary lymph node disease. The conclusion is based on PET-CT's low sensitivity and specificity, as well as its high false-negative rate, which hinders its ability to detect early axillary lymph node disease and micrometastases. Consequently, due to its limited sensitivity compared to SLNB, sentinel lymph node biopsy remains the preferred method for diagnosing axillary lymph node

(ALN) involvement. However, it is essential to note that the results of this study should be interpreted with caution due to the limited sample size. Generalizability and validation of our findings would necessitate a larger sample size, which would provide more robust and reliable results.

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