Original Article

Correlation Between Tumor Size and Axillary Metastasis in Infiltrating Ductal Carcinoma: A Prospective Observational Study

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Abstract

Background: Axillary lymph node metastasis is an important prognostic factor in infiltrating ductal carcinoma of the breast. Tumor size is considered a major predictor of nodal involvement and disease progression. The objective is to evaluate the correlation between primary tumor size and axillary lymph node metastasis in patients with infiltrating ductal carcinoma of the breast. **Material and Methods:** This prospective observational study was conducted at the Department of General Surgery, SS Institute of Medical Sciences and Research Centre, Davangere over a period of 2 years and included 60 patients with histopathologically confirmed infiltrating ductal carcinoma who underwent definitive surgery with axillary lymph node dissection. Tumor size was categorized as T1 (<2 cm), T2 (2–5 cm), and T3 (>5 cm), and axillary lymph node status was assessed histopathologically. **Results:** The mean age was 51.6 ± 11.4 years, and the mean pathological tumor size was 3.9 ± 1.7 cm. Overall, axillary lymph node metastasis was present in 32 (53.3%) patients. Nodal positivity increased with tumor size, being 3 (20.0%) in T1 tumors, 17 (56.7%) in T2 tumors, and 12 (80.0%) in T3 tumors. Tumor size showed a significant association with axillary lymph node metastasis (p = 0.003). On multivariable analysis, tumor size, grade III tumor, and lymphovascular invasion were independent predictors of nodal metastasis. **Conclusion:** It is concluded that increasing tumor size is significantly associated with axillary lymph node metastasis in infiltrating ductal carcinoma. Early diagnosis of smaller tumors may reduce nodal spread and improve prognosis.

Keywords: breast cancer, infiltrating ductal carcinoma, tumor size, axillary metastasis, lymph node metastasis.

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Introduction

Although substantial progress has been made in breast cancer screening, diagnosis, and treatment, breast cancer still remains one of the leading causes of cancer-related deaths in women around the world and is the most common form of cancer in women.[1] Recent data from around the world suggest over 2.3 million new cases of breast cancer occur every year, representing around 1 in every 4 cancers for women. While there has been significant improvement in survival in developed countries due to organised screening programmes and advances in systemic therapy, in developing countries many patients have the advanced disease and have poorer clinical outcome.[2,3] Infiltrating ductal carcinoma (IDC), also known as invasive ductal carcinoma of no special type (IDC) is the most common histological form of breast cancer, making it about 70-80% of all invasive breast cancers and the most prevalent around the world.[4] IDC can grow and invade into the surrounding breast tissue and spread by the lymphatic and blood pathways. Biological behavior of IDC is highly variable in terms of tumour size, histological grade, molecular type, hormone receptor status, HER2 expression and lymph node involvement.[5] Axillary lymph node status is one of the many prognostic factors in breast cancer, most importantly a predictive factor of disease recurrence, overall survival and breast cancer treatment planning.[6] Lymph nodes are considered as regional spread if there is metastatic disease, and this is associated with a very high likelihood of distant spread and death. Therefore, reliable evaluation of the involvement of the axillary nodes is critical for staging and prognostication of the disease, as well as selection of suitable post-surgical systemic therapy, such as chemotherapy, radiotherapy, endocrine therapy and targeted therapy.[7,8]

Tumor size is a key element of the TNM staging system and is well known to be an important factor in axillary lymph node metastasis.[9] The more the primary tumor grows, the higher the chance of the lymphovascular invasion, the dissemination of the tumor in the regional lymph nodes, and the spread of the tumor to distant sites. It is thought that the bigger the tumour, the more angiogenic potential it has, the higher its proliferation rate and the more area it has for invasion of surrounding lymphatic channels, leading to metastatic spread to the axillary lymph nodes.[10] Many studies have shown that when tumor size is less than 2 cm the median rate of nodal metastasis is significantly lower than with tumors measuring 2-5cm or greater than

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5cm.[11] Conventional ALND remains a useful tool for providing pathological information in many patients and is particularly indicated in patients with clinically positive axillary nodes or in patients with locally advanced disease.[12] Awareness of the association of axillary metastasis and primary tumour size is clinically relevant and useful for surgeons for risk stratification, surgical planning, prognosis and patient counselling. Moreover, understanding this relationship could be useful to better select those patients who need more intense locoregional and systemic treatment modalities.[13] Early detection via mammographic screening, breast self-examination, and even greater public awareness has helped to detect smaller tumors prior to regional spread.[14] However, delayed presentation is also very common in many resource poor environments where the patients present with bigger tumors, and the incidence of axillary lymph node metastasis is higher. Thus, understanding the relationship between tumour size and nodal involvement is crucial to promote the value of early diagnosis and intervention and enhance patient survival rates. The objective is to evaluate the correlation between primary tumor size and axillary lymph node metastasis in patients with infiltrating ductal carcinoma of the breast.

Materials and Methods

This prospective observational study was conducted at the Department of General Surgery, SS Institute of Medical Sciences and Research Centre, Davangere, from 2024 to 2026 and included 60 patients with histopathologically confirmed infiltrating ductal carcinoma (IDC) of the breast to evaluate the correlation between primary tumor size and axillary lymph node metastasis. Patients aged 18 years or older with histopathologically confirmed infiltrating ductal carcinoma of the breast who underwent definitive surgical treatment in the form of modified radical mastectomy or breast-conserving surgery with axillary lymph node dissection were included. Eligible patients had complete clinical, radiological, operative, and histopathological records available for analysis and had not received any prior treatment before surgery. Patients with recurrent breast carcinoma, metastatic disease at presentation, previous neoadjuvant chemotherapy or radiotherapy, non-ductal histological subtypes of breast cancer, bilateral breast carcinoma, previous axillary surgery, incomplete histopathological reports, or incomplete clinical records were excluded from the study.

Data Collection: Following approval from the Institutional Ethics Committee, data were prospectively collected using a standardized data collection proforma from outpatient records, inpatient files, operative notes, radiological investigations, and histopathological reports. Baseline demographic and clinical variables included age, menopausal status, body mass index, comorbidities, tumor laterality, clinical presentation, and family history of breast cancer. Tumor characteristics included clinical tumor size, radiological tumor size measured by ultrasonography and mammography, histopathological tumor size, tumor grade, lymphovascular invasion, estrogen receptor (ER) status, progesterone receptor (PR) status, HER2 status, and TNM stage. Primary tumor size was classified according to the AJCC TNM staging system as T1 (<2 cm), T2 (2–5 cm), and T3 (>5 cm). All patients underwent either modified radical mastectomy or breast-conserving surgery with level I and II axillary lymph node dissection according to institutional treatment protocols. Histopathological examination was performed to determine the maximum tumor diameter, total number of axillary lymph nodes retrieved, number of metastatic lymph nodes, extracapsular extension, and pathological stage. The primary outcome was the presence of axillary lymph node metastasis confirmed on histopathological examination. Secondary outcomes included the incidence of nodal positivity across different tumor size categories and the association between tumor size and pathological nodal status.

Statistical Analysis: Data were analyzed using SPSS version 26.0. Continuous variables were expressed as mean ± standard deviation, whereas categorical variables were presented as frequencies and percentages. The Chi-square test or Fisher's exact test was used to evaluate the association between tumor size categories and axillary lymph node metastasis. Continuous variables were compared using the independent t-test or one-way analysis of variance (ANOVA), as appropriate. A p-value ≤0.05 was considered statistically significant.

Results

The study included 60 patients with a mean age of 51.6 ± 11.4 years and mean BMI of 26.1 ± 4.2 kg/m². Premenopausal women were slightly more common (31, 51.7%) than postmenopausal women (29, 48.3%). Right breast involvement was seen in 33 (55.0%) patients, while left breast involvement was seen in 27 (45.0%). Most tumors were grade II (35, 58.3%), followed by grade III (17, 28.3%) and grade I (8, 13.3%). ER positivity was present in 37 (61.7%), PR positivity in 34 (56.7%), HER2 positivity in 16 (26.7%), and triple-negative breast cancer in 13 (21.7%). The mean pathological tumor size was 3.9 ± 1.7 cm.

Table 1: Baseline Demographic and Clinicopathological Characteristics of the Study Population (n = 60)

Variable	Value
Age (years), mean ± SD	51.6 ± 11.4
BMI (kg/m²), mean ± SD	26.1 ± 4.2
Premenopausal	31 (51.7%)
Postmenopausal	29 (48.3%)
Right breast involvement	33 (55.0%)
Left breast involvement	27 (45.0%)
Grade I tumor	8 (13.3%)
Grade II tumor	35 (58.3%)
Grade III tumor	17 (28.3%)

ER positive	37 (61.7%)
PR positive	34 (56.7%)
HER2 positive	16 (26.7%)
Triple-negative breast cancer	13 (21.7%)
Mean pathological tumor size (cm)	3.9 ± 1.7

Among 60 patients, 15 (25.0%) had T1 tumors, 30 (50.0%) had T2 tumors, and 15 (25.0%) had T3 tumors. Overall, axillary lymph node metastasis was present in 32 (53.3%) patients and absent in 28 (46.7%). Nodal positivity increased with tumor size, being lowest in T1 tumors with 3 of 15 patients (20.0%), higher in T2 tumors with 17 of 30 patients (56.7%), and highest in T3 tumors with 12 of 15 patients (80.0%).

Table 2: Distribution of Tumor Size and Axillary Lymph Node Metastasis (n = 60)

Tumor Size Category	Total Patients	Node Positive	Node Negative	Nodal Positivity
T1 (<2 cm)	15	3	12	20.0%
T2 (2–5 cm)	30	17	13	56.7%
T3 (>5 cm)	15	12	3	80.0%
Overall	60	32	28	53.3%

When patients were compared according to tumor size, mean age increased from 48.7 ± 10.3 years in T1 tumors to 51.5 ± 11.2 years in T2 tumors and 55.0 ± 12.1 years in T3 tumors, although this was not statistically significant (p = 0.214). Mean BMI also showed a mild rise from 25.2 ± 3.8 kg/m² in T1 to 26.0 ± 4.1 kg/m² in T2 and 27.2 ± 4.7 kg/m² in T3, without significance (p = 0.386). Grade III tumors increased significantly with tumor size, from 2 (13.3%) in T1 to 8 (26.7%) in T2 and 7 (46.7%) in T3 (p = 0.041). Axillary node positivity also increased significantly across tumor groups, from 3 (20.0%) in T1 to 17 (56.7%) in T2 and 12 (80.0%) in T3 (p = 0.003).

Table 3: Comparison of Clinicopathological Characteristics According to Tumor Size

Variable	T1 (<2 cm) (n=15)	T2 (2–5 cm) (n=30)	T3 (>5 cm) (n=15)	p-value
Age (years), mean ± SD	48.7 ± 10.3	51.5 ± 11.2	55.0 ± 12.1	0.214
BMI (kg/m²), mean ± SD	25.2 ± 3.8	26.0 ± 4.1	27.2 ± 4.7	0.386
Grade III tumor	2 (13.3%)	8 (26.7%)	7 (46.7%)	0.041
ER positive	11 (73.3%)	19 (63.3%)	7 (46.7%)	0.243
HER2 positive	3 (20.0%)	8 (26.7%)	5 (33.3%)	0.664
Axillary node positive	3 (20.0%)	17 (56.7%)	12 (80.0%)	0.003

Patients with axillary lymph node metastasis had a mean age of 52.8 ± 10.9 years compared with 50.2 ± 11.9 years in node-negative patients, with no significant difference (p = 0.381). Mean BMI was also similar between node-positive and node-negative patients, 26.6 ± 4.1 kg/m² versus 25.5 ± 4.3 kg/m² (p = 0.314). However, mean tumor size was significantly larger in node-positive patients, 4.8 ± 1.5 cm, compared with 2.9 ± 1.1 cm in node-negative patients (p < 0.001).

Table 4: Comparison Between Patients With and Without Axillary Lymph Node Metastasis

Variable	Node Positive (n=32)	Node Negative (n=28)	p-value
Age (years), mean ± SD	52.8 ± 10.9	50.2 ± 11.9	0.381
BMI (kg/m²), mean ± SD	26.6 ± 4.1	25.5 ± 4.3	0.314
Tumor size (cm), mean ± SD	4.8 ± 1.5	2.9 ± 1.1	<0.001
Grade III tumor	13 (40.6%)	4 (14.3%)	0.024
Lymphovascular invasion	21 (65.6%)	6 (21.4%)	<0.001
HER2 positive	10 (31.3%)	6 (21.4%)	0.390
ER positive	18 (56.3%)	19 (67.9%)	0.359

Grade III tumors also showed increased odds of nodal metastasis (OR 2.61, 95% CI 1.08–6.34, p = 0.033), while lymphovascular invasion was the strongest predictor (OR 4.18, 95% CI 1.63–10.71, p = 0.003). HER2 positivity, ER positivity, and age were not statistically significant predictors.

Table 5: Multivariable Logistic Regression Analysis for Predictors of Axillary Lymph Node Metastasis

Variable	Adjusted OR	95% CI	p-value
Tumor size (per 1 cm increase)	2.08	1.32–3.27	0.002
Grade III tumor	2.61	1.08–6.34	0.033
Lymphovascular invasion	4.18	1.63–10.71	0.003
HER2 positivity	1.48	0.56–3.92	0.430
ER positivity	0.81	0.32–2.08	0.664
Age (per year increase)	1.02	0.98–1.07	0.271

Discussion

The presence of axillary lymph node metastasis in breast cancer is one of the most significant prognostic factors and is a key factor in the staging, treatment and prediction of breast cancer survival. The purpose of the present prospective observational study was to examine the correlation between primary tumour size and axillary lymph node metastasis in patients with infiltrating ductal carcinoma and to find a significant positive correlation between the increasing primary tumour size and nodes involvement. Study results also confirm the significance of tumor size as an independent predictor of the likelihood of regional disease spread and emphasize its continued significance for clinical decision making. The mean age of study population was 51.6 ± 11.4 years, and the mean pathological tumour size was 3.9 ± 1.7 cm, most of which was grade II (58.3%) and most of the invasive disease was hormone receptor positive. These results are similar to those of previous studies that showed that infiltrating ductal carcinoma is the most common type in women in the fifth and sixth decades of life and the most common type of newly diagnosed cases is grade II.[15] Finally, 53.3% of patients had axillary LNM on surgery indicating over half of the study population had regional involvement of LN at surgery. This relatively high prevalence is due to the presentment of patients with moderate disease in developing countries. The incidence of nodal positivity is reported to be 45%–65% across previous studies when the infiltrating ductal carcinoma has been treated with surgery. One of the key findings of this study was that as the tumor grew, there was a gradual rise of the occurrence of nodal metastasis. Nodal positivity was found in 20.0% of patients with T1 tumours, 56.7% of patients with T2 tumours and 80.0% of patients with T3 tumours. There was a statistically significant ($p = 0.003$) association between tumor size and axillary lymph node metastasis and larger tumours were significantly more likely to have regional lymph node spread. A similar stepwise progression was seen in previous studies as the size of the tumor increased and tumor size was shown to be one of the best predictors of axillary metastasis.[16] Patients with larger tumours were also more likely to have aggressive pathological characteristics. There was a significant difference between the rates of grade III tumors in T1 and T3 lesions (13.3% versus 46.7%, $p = 0.041$), indicating that T3 lesions are likely to have higher histological grade, and thus more aggressive biological behavior. The past studies also showed that with the growth of the tumor, its degree of differentiation, its proliferative activity and its invasive potential decrease and the risk of metastasis increases.[17]

Size of the tumour was also emphasized as being a prognostic factor when comparing size of the tumour in patients with and without nodal metastasis. The mean tumour size was significantly larger in the node positive patients (4.8 ± 1.5 cm) than in the node negative patients (2.9 ± 1.1 cm; $p < 0.001$). Additionally, patients with nodal metastasis had a significantly higher rate of lymphovascular invasion (65.6% vs. 21.4%, $p < 0.001$) and patients with grade III tumors had a significantly higher rate (40.6% vs. 14.3%, $p = 0.024$). These findings fit within the biological framework that the bigger the tumor the more space there is for the lymphatic invasion and spread to regional lymph nodes. Studies have also shown a strong association between LVI, grade of the tumour and axillary nodal involvement and adverse prognosis.[18] Tumor size, grade III histology and lymphovascular invasion were independent predictors of the presence of axillary lymph node metastasis in a multivariable logistic regression analysis. A 1 cm increase in tumour size was statistically significantly associated with more than a doubling in risk of nodal involvement (OR 2.08, $p = 0.002$) and the strongest independent risk factor was lymphovascular invasion (OR 4.18, $p = 0.003$). Other parameters like HER2 status, ER positivity and patient age were not independent parameters that were associated with nodal metastasis. The significance of tumor size and lymphovascular invasion (LVI) as independent prognostic factors for the presence of axillary lymph node metastasis (ALNM) has also been previously published and the role of molecular markers among various patient groups has been shown to differ.[19] These findings of this study are clinically relevant. Accurate measurement of tumour size before surgery can help decide whether there is a risk of involvement of the nodes, or risk stratification and surgical planning, as well as deciding on the appropriate post-surgical treatment. If the tumour is more extensive a more detailed axillary assessment may be required and the follow up may be more intense as there is a higher risk of regional metastases developing in larger tumours. Prior studies also have highlighted that breast screening programs can significantly minimize the size of the tumour at diagnosis, the proportion of axillary lymph node metastases and the long-term survival rates.[20] The results of the present study showed a significant and strong correlation between the size of primary tumor and the presence of axillary lymph node metastasis of infiltrating ductal carcinoma. These results are consistent with previously published data showing that tumor size continues to be a good predictor of nodal involvement and further emphasize the significance of early diagnosis and prompt surgical intervention for a better prognosis. The study also highlights the need to consider tumor size in combination with other pathological parameters (e.g. lymphovascular invasion and histology grade) to improve the assessment of prognosis and treatment planning for individual patients.

Limitations: This study has several limitations. First, the relatively small sample size of 60 patients may limit the statistical power and generalizability of the findings to the broader population of patients with infiltrating ductal carcinoma. Second, the study was conducted at a single tertiary care center, which may introduce selection bias and limit external validity. Third, patients who received neoadjuvant chemotherapy were excluded, restricting the applicability of the findings to treatment-naïve surgical patients only. Fourth, molecular subtypes and genetic markers that may influence nodal metastasis were not analyzed in detail. Finally, the absence of long-term follow-up prevented assessment of disease recurrence, disease-free survival, overall survival, and the prognostic impact of axillary lymph node involvement over time.

Conclusion

It is concluded that there is a significant positive correlation between primary tumor size and axillary lymph node metastasis in patients with infiltrating ductal carcinoma of the breast. The incidence of nodal involvement increased progressively with increasing tumor size, and larger tumors were associated with higher histological grade and greater frequency of lymphovascular invasion. Tumor size, grade III histology, and lymphovascular invasion emerged as independent predictors of axillary lymph node metastasis. These findings highlight the importance of early detection and timely surgical intervention to diagnose breast cancer at a smaller tumor size, thereby reducing regional nodal spread and improving prognostic outcomes. Further multicenter studies with larger sample sizes and long-term follow-up are recommended to validate these findings and strengthen their clinical applicability.

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