



Axillary Lymph Node Burden in Invasive Breast Cancer: A Comparison of the Predictive Value of Ultrasound-Guided Needle Biopsy and Sentinel Lymph Node Biopsy

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Abstract

In this study we demonstrate that breast cancer patients with a positive node on ultrasound-guided biopsy have a higher stage of axillary disease than patients with a positive sentinel lymph node. Based on these results, further study is required before exempting this subset of patients from axillary dissection.

Background: Recent studies suggest that axillary lymph node dissection (ALND) may be omitted in select breast cancer patients with a positive sentinel lymph node biopsy (SLNB). As we trend away from ALND, we must understand the burden of axillary disease among various patient subgroups. For patients with positive nodes determined using ultrasound-guided needle biopsy (USNB), there are no data regarding the extent of axillary disease. **Patients and Methods:** An institutional breast cancer registry was retrospectively reviewed to identify women with invasive cancer and a positive USNB/SLNB who had completion ALND. For statistical analysis, we used χ^2 and 1-way analysis of variance. **Results:** One hundred ninety-nine USNB-positive (USNB⁺) patients and 434 SLNB⁺ patients were eligible for the study. Positive USNB patients were significantly older, had larger tumors, and were more likely to be estrogen receptor-negative/progesterone receptor-negative and HER2/*neu*⁺ than SLNB⁺ patients. USNB⁺ patients had much higher rates of N2 (33.2% vs. 12.4%; $P < .05$) and N3 (17.1% vs. 3.9%; $P < .05$) disease compared with SLNB⁺ patients. Higher axillary disease burden was demonstrated in USNB patients who were clinically node negative and those who met Z11 criteria. **Conclusion:** Patients with invasive breast cancer with a positive node on USNB have a significantly greater burden of axillary disease compared with patients with a positive SLNB. USNB⁺ patients represent a distinct patient population and further research is required to determine if these patients can be safely exempted from axillary dissection.

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Introduction

The presence of axillary lymph node metastases is an important prognostic predictor in patients with breast cancer, second only to the presence of distant metastases.¹ Unfortunately, nodal involvement cannot be reliably determined using clinical examination,

because up to 45% of patients with clinically negative axilla have nodal metastases.² Initially, widespread use of complete axillary lymph node dissection (ALND) was the standard of care for axillary staging, however, sentinel lymph node biopsy (SLNB) is now routinely used in patients with a clinically negative axilla.^{3,4} Ultrasound (US) staging of the axilla is increasingly used^{5,6} to identify suspicious axillary nodes based on morphologic features including size, shape, cortical thickness, and echogenicity.⁷⁻⁹ When abnormal nodes are identified, US-guided fine or core needle biopsy (USNB) can histologically confirm axillary metastases and improve the specificity of the procedure.^{10,11} Axillary lymph node metastases identified using this technique spare a significant number of patients from undergoing unnecessary SLNB by allowing them to proceed directly to ALND.^{12,13}

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Axillary Disease Burden After Ultrasound-Guided Biopsy

Currently, ALND is the gold standard for patients with clinically positive nodes or with biopsy proven nodal disease, either using sentinel node or US-guided biopsy. However, ALND is associated with significant morbidity including seromas, infection, paresthesias, pain, and lymphedema, which affects breast cancer survivors' quality of life.¹⁴ As a result, there has been a clear trend away from axillary dissection in selected breast cancer patients.¹⁵⁻¹⁷ The number of women with positive sentinel lymph nodes who do not undergo complete axillary dissection is increasing.¹⁸ Results of the American College of Surgeons Oncology Group (ACOSOG) Z0011 randomized trial demonstrated no difference in locoregional breast cancer recurrence or overall survival in women with T1/T2 tumors and 1 to 2 positive sentinel node(s) who underwent breast-conserving surgery with whole breast irradiation and who did not undergo completion ALND compared with control patients who received completion ALND.¹⁹ These findings suggest that additional nodal metastases might be adequately managed with adjuvant therapy and calls into question the role of routine ALND in these patients.

Identification of patients for whom ALND can safely be omitted without adversely affecting breast cancer outcomes is an important goal. Although Z0011 data suggest that ALND can be avoided in patients with a positive sentinel node, it is unclear if these findings can be expanded to include patients with a positive USNB. Only 20% to 50% of patients with a positive sentinel lymph node have further axillary disease on ALND,²⁰ but for patients with a positive USNB, there are no data on the percentage who will be found to have further node involvement on axillary dissection. Furthermore, Z0011 did not require axillary US before SLNB to determine eligibility. For invasive breast cancer patients who do not have palpable adenopathy, it is tempting to omit preoperative axillary US as a positive USNB would mandate ALND. But omitting axillary US and performing a SLNB could potentially render the patient a Z0011 candidate. Before extrapolating the findings of Z0011 to patients with abnormal nodes identified using axillary US, it is essential to determine if USNB-positive (USNB⁺) patients are comparable with Z0011 SLNB⁺ patients.

Studies of US-guided needle biopsy have focused mainly on the ability of the test to detect axillary disease, reporting the sensitivity, specificity, and predictive value of the technique.^{10,11,13,21-26} Although these studies provide useful information, to date, no study has evaluated the rate and extent of additional axillary disease after an US-guided needle biopsy. This information is essential for counseling patients who have a positive USNB, which determines the prognostic value of the test and allows the development of a comprehensive management strategy for their axillary disease.

Rather than focusing on the diagnostic attributes of USNB, this study will determine if patients with positive axillary nodes identified using US are comparable with patients with a positive sentinel node with respect to tumor characteristics and axillary nodal disease burden. With recent trends toward a more conservative approach to axillary disease, this information is necessary to determine how to manage the axilla in these patients.

Methods

Patient Selection and Data Collection

After the study was approved by the institutional review board, an institutional breast cancer tumor registry was searched to identify

women with histologically confirmed invasive breast cancer and a positive US-guided needle biopsy or SLNB from 2005 through 2010. Patients were included only if they had a completion ALND during that time period. Patients who received neoadjuvant chemotherapy were excluded. Electronic health records including office consultations, operative reports, and pathology reports were retrospectively reviewed to collect relevant clinical and pathologic staging data.

Patient Management

Our institutional protocol during the study period was for patients with histologically confirmed invasive breast cancer to undergo an axillary staging US examination. If lymph nodes suspected to have disease were discovered they were routinely biopsied with either fine needle aspiration or core needle biopsy. Patients with clinically positive or biopsy proven axillary lymph nodes, either using USNB or SLNB, were recommended to undergo completion axillary dissection. All patients who underwent segmental mastectomy were recommended to undergo radiation therapy. Systemic adjuvant therapy decisions were made by a multidisciplinary team.

Statistical Analysis

Continuous data are presented as the mean, median, and the range. Categorical variables are expressed as numbers and percentages for the group from which they were derived. χ^2 test was used to evaluate data from categorical variables. One-way analysis of variance was used to evaluate continuous data. Results were considered statistically significant for P values < .05.

Results

Our institutional breast cancer registry contained records for 5030 women with invasive breast cancer from 2005 to 2010. A review of these patient records revealed 199 patients with a positive USNB and 434 patients with a positive SLNB who were eligible for the study. Clinical characteristics are presented and compared between groups in Table 1. Patients with a positive US-guided needle biopsy were more likely to be older (58.7 vs. 56.3 years of age; P < .05), and to present with a palpable breast tumor (133 patients [71.1%] vs. 182 patients [43.8%]; P < .05). There was no difference in menopausal status between the groups, with most women presenting with postmenopausal breast cancer. USNB patients were more likely to undergo total mastectomy (122 patients [62%] vs. 181 patients [42%]; P < .05) than SLNB patients. USNB patients were less likely to be treated with hormonal therapy (112 patients [56%] vs. 331 patients [76%]; P < .05) and/or radiation therapy (85 patients [43%] vs. 260 patients [59%]; P < .05) and more likely to receive chemotherapy (164 patients [82%] vs. 341 patients [79%]; P < .05).

Pathologic data from the primary breast tumors were evaluated for all patients and compared between experimental groups in Table 2. Patients with an US-guided needle biopsy had higher T stage and were more likely to have estrogen receptor-/progesterone receptor-negative and HER2/*neu*-positive cancers (P < .05). They were also more likely to have extracapsular extension, lymphovascular invasion, and higher Nottingham grade and score (P < .05) than patients with a positive SLNB.

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