Is Preoperative Axillary Imaging Beneficial in Identifying Clinically Node-Negative Patients Requiring Axillary Lymph Node Dissection?



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BACKGROUND: American College of Surgeons Oncology Group (ACOSOG) Z0011 results support the

omission of axillary lymph node dissection (ALND) in women with less than 3 positive sentinel lymph nodes (SLNs) undergoing breast-conserving surgery (BCS) and radiation therapy. We sought to determine if abnormal axillary imaging is predictive of the need for

ALND in this population.

STUDY DESIGN: Patients with cT1-2N0 breast cancer by physical examination undergoing BCS were managed

according to Z0011 criteria independent of axillary imaging. Patient characteristics and rates of ALND were compared among those with and without abnormal lymph nodes (LNs) detected by mammogram, ultrasound (US), or MRI. All available axillary imaging was

reviewed by 1 breast radiologist.

RESULTS: Between August 2010 and December 2013, 3,253 breast cancer patients were treated with BCS

and SLN biopsy; 425 patients met Z0011 criteria (cT1-2N0) and had nodal metastasis on SLN biopsy. Clinicopathologic features were median patient age, 58 years; median tumor size, 1.8 cm; 85% ductal histology; and 89% estrogen receptor positive. All women had a mammogram, 242 had axillary US, 172 had MRI. Abnormal LNs were seen on 7%, 25%, and 30% of mammograms, US, and MRIs, respectively. Although abnormal LNs on mammogram or US were associated with a significant increase in ALND and a non-significant trend was

seen with MRI, 68% to 73% of women with abnormal axillary imaging did not require ALND.

CONCLUSIONS: Among clinically node-negative patients with abnormal axillary imaging, 71% did not meet

criteria for ALND and were spared further surgical morbidity. Abnormal nodes on US, MRI, or mammogram in clinically node-negative patients are not reliable indicators of the need for ALND. (J Am Coll Surg 2016;222:138–145. © 2016 by the American College of

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Sentinel lymph node biopsy (SLNB) alone is the standard axillary management of clinically and pathologically node-negative breast cancer patients, ¹⁻³ and has subsequently evolved into the primary surgical management for select patients with low-volume axillary disease. ⁴⁻⁶ The American College of Surgeons Oncology Group (ACOSOG) Z0011 study was practice changing, and it established the safety of SLNB alone for axillary management in women with clinical T1-2N0 invasive breast carcinoma, with 1 to 2 positive sentinel lymph nodes (SLNs), undergoing breast-conserving surgery (BCS) with whole breast radiation. This randomized controlled trial of SLNB alone vs completion axillary lymph node dissection (ALND) reported no difference in overall survival, disease-free survival, or locoregional

Abbreviations and Acronyms

ACOSOG = American College of Surgeons Oncology

ALND = axillary lymph node dissection **BCS** = breast-conserving surgery

= lymph node LN

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MSKCC = Memorial Sloan Kettering Cancer Center

OR = odds ratio

= sentinel lymph node biopsy SLNB = sentinel lymph nodes

SLNs US = ultrasound

recurrence between arms, with rates of axillary recurrence <1% in both surgical arms.^{6,7} A subsequent single-institution experience of prospectively accrued patients meeting ACOSOG Z011 criteria found that among SLN-positive patients, 84% were able to avoid an ALND and the associated morbidity.8

Although the ACOSOG Z0011 trial identified clinically node-negative patients by physical exam alone, some have suggested that axillary imaging with or without needle biopsy may be beneficial to allocate high-risk, node-positive patients directly to ALND, 9-13 omitting SLNB and the possible need for 2-step axillary surgery. However, when managing patients according to ACO-SOG Z0011, preoperative axillary imaging is beneficial only if it accurately discriminates between patients with metastases in 1 or 2 axillary nodes and those with involvement of 3 or more nodes or gross extracapsular extension (matted nodes) who require ALND. In this study, we sought to determine if abnormal preoperative axillary imaging is associated with the need for ALND in women managed according to ACOSOG Z0011 criteria.

METHODS

After Memorial Sloan Kettering Cancer Center (MSKCC) institutional review board approval, consecutive, prospectively accrued patients meeting ACOSOG Z0011 criteria, defined as clinical T1-2N0 invasive breast carcinoma, undergoing BCS and SLNB with a positive SLN, between August 2010 and December 2013 were identified. During this time period at our institution, women staged as clinically node-negative by physical examination alone were managed according to ACOSOG Z0011 criteria without the routine use of preoperative axillary imaging. Although some patients had axillary ultrasound before presentation at MSKCC, and others underwent breast MRI at the surgeons' discretion, regardless of the axillary imaging results, this cohort of clinically node-negative patients was managed with an SLNB and completion ALND based on SLN pathology. Patients

not meeting clinical criteria for ACOSOG Z11 (T3-4 tumors, palpable adenopathy, undergoing mastectomy) and patients undergoing neoadjuvant chemotherapy were excluded. Patient and breast tumor characteristics were recorded. All preoperative axillary imaging by mammogram, ultrasound, or MRI was identified by chart review. Although mammography and MRI are not performed for dedicated axillary evaluation, these studies were included because when abnormal axillary nodes are visualized, this information is included in the radiology report. All available images were reviewed by 1 breast radiologist with 32 years of experience, who was blinded to the need for ALND at the time of review, but who was aware that the study population consisted of nodepositive patients. Results for images not available for review were abstracted from the radiology report. For each imaging modality, the presence of abnormal axillary lymph nodes and the number of abnormal axillary lymph nodes were documented. Axillary lymph nodes were considered abnormal on ultrasound (US) or MRI when there was abnormal nodal morphology including loss of fatty hilum and/or cortical thickening, or irregularity regardless of nodal size. Enhancement of normal nodes is routinely identified on MRI and was therefore not considered in nodal evaluation. Lymph nodes seen on mammogram were called abnormal when enlarged, dense, or with loss of the fatty hilum. Preoperative axillary lymph node needle biopsy results were collected. Axillary surgical management and final pathology were recorded, including the total number of SLNs removed, SLN metastasis size, whether completion ALND was performed, and the total number of positive axillary lymph nodes. Indication for ALND was either more than 2 positive SLNs or gross extracapsular extension/matted nodes. Associations were assessed using a 2-sample t-test for continuous variables and the chi-square test for categorical variables. A multivariable logistic regression model was fit to assess the effect of abnormal axillary imaging on subsequent ALND after adjusting for age, tumor size on imaging, and the number of lymph nodes removed at SLNB. These covariates were chosen based on univariate findings and our knowledge of clinical factors. Similar models were built for all imaging modalities alone as well as for any abnormal axillary imaging by US or MRI combined. Tests with p values < 0.05 were considered statistically significant.

RESULTS

Between August 2010 and December 2013, 3,253 breast cancer patients were treated with BCS and SLNB; 424 patients (1 bilateral cancer) met ACOSOG Z0011 criteria and had axillary nodal metastasis on SLNB, for a total

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