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## Outcomes with and without axillary node dissection for node-positive lumpectomy and mastectomy patients

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## Abstract

**BACKGROUND:** American College of Surgeons Oncology Group Z0011 trial of select node-positive breast cancer patients demonstrated no survival or recurrence differences between SLN/axillary lymph node dissection (ALND) vs SLN. Our comparable node-positive lumpectomy and mastectomy populations should have similar outcomes.

**METHODS:** An Institutional Review Board approved, retrospective review of pathologic SLN (N1) cases was performed. Treatment, recurrence, and survival were collected. Statistics was analyzed via exact chi-square test with Monte Carlo estimation, Kaplan–Meier curves, and log-rank tests.

**RESULTS:** Of 528 node-positive patients, 318 patients met criteria: 28 (21.7%) lumpectomy, 32 (16.9%) mastectomy had SLN; 101 (78.2%) lumpectomy, 157 (83.0%) mastectomy had SLN + ALND. Median age was 57.5 years for SLN and 53 years for SLN + ALND (P = .003). Mean positive nodes were 1.1 for SLN and 1.47 for SLN + ALND (P = .0018). Chemotherapy use differed (SLN = 73.5%, SLN + ALND = 89.7%, P = .0032). Stage and recurrence were higher for SLN + ALND (P = .0001, P = .007). No difference in comorbidities, nodes retrieved, extracapsular extension, radiation, hormone therapy, or overall survival was observed.

**CONCLUSION:** In clinically node-negative breast cancer patients, ALND for N1 disease has no impact on short-term recurrence or survival.

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Rachael Snow and Chantal Reyna contributed equally to this study.

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Nodal status, in terms of the presence or absence of metastasis and the number of lymph nodes involved, remains the most important prognostic factor in breast cancer. Historically, breast cancer was treated with Halstead radical mastectomy, requiring the removal of the breast, overlying skin, the pectoralis major and minor muscles, and all the regional lymph nodes, including the axillary contents (levels I to III).<sup>1</sup> Despite large studies demonstrating no survival advantage of radical mastectomy over less invasive approaches for the breast primary, axillary lymph node dissection (ALND) remained the routine operation for axillary staging and local–regional control.<sup>2,3</sup> Unfortunately, ALND

advantage of radical mastectomy over less invasive approaches for the breast primary, axillary lymph node dissection (ALND) remained the routine operation for axillary staging and local–regional control.<sup>2,3</sup> Unfortunately, ALND confers a significant risk of lymphedema, nerve damage, and decreased range of motion, and the current focus is on less invasive approaches to axillary staging. In the mid-1990s, Giuliano et al<sup>4</sup> introduced the sentinel lymph node biopsy into the breast cancer arena. Several international studies, including the National Surgical Adjuvant Breast and Bowel Project B-32 and studies from the European Institute of Oncology, demonstrated the accuracy and feasibility of sentinel lymph node biopsy with no impact on overall survival in clinically node-negative patients.<sup>5–7</sup> In addition, the randomized multicenter trial of sentinel node biopsy vs standard axillary treatment in operable breast cancer(Almanac), sentinel lymph node biopsy vs axillary clearance in operable breast cancer (a multicenter randomized trial of the Royal Australian College of Surgeons section of breast surgery, in collaboration with the Australian national health and medical research council clinical trials center-Sentinel-lymph-nodebased management or routine axillary trial), and other trials demonstrated significantly less morbidity after sentinel lymph node biopsy, setting this as the new standard for axillary staging.<sup>5,8–10</sup>

With the adoption of sentinel lymph node biopsy for axillary staging, the role of ALND is being re-examined, especially in light of the National Surgical Adjuvant Breast and Bowel Project B-04 trial findings suggesting that not all nodal disease is clinically relevant.<sup>11</sup> As a result, several trials have attempted to evaluate whether ALND may be omitted in a select population. A Spanish multicentered, randomized trial of 233 clinically node-negative patients with less than or equal to 3.5 cm tumors and micrometastatic disease were randomized to sentinel lymph node biopsy alone or sentinel lymph node biopsy with completion ALND, regardless of primary cancer surgery, with no difference seen in overall diseasefree survival.<sup>12</sup> The American College of Surgeons Oncology Group (ACOSOG) Z0011 trial enrolled 891 women having breast conserving surgery with SLN biopsy for clinically node-negative invasive breast cancer. In the face of a positive lymph node biopsy, patients were randomized to observation (after sentinel node only) or completion node dissection. No significant difference in overall survival was found after 6.3 years of follow-up.<sup>13</sup> These studies suggest that axillary dissection may be omitted in patients undergoing breast conserving therapy and whole breast irradiation. However, it is still unclear if the omission of ALND can be extended to other populations, such as patients undergoing mastectomy. Therefore, the primary objective of this study was to quantify the outcomes of sentinel node-positive breast cancer patients with and without lymph node dissection at our institution.

An IRB approved, single institution, retrospective review of women with sentinel lymph node-positive breast cancer from January 1, 1995 to November 1, 2012 was performed. Female patients who underwent sentinel lymph node biopsy with and without completion axillary dissection were identified at our National Comprehensive Center Networkdesignated comprehensive cancer center. From this population, patients over 18 years of age with a sentinel lymph node biopsy for an invasive cancer with or without an axillary dissection were selected for further evaluation.

Inclusion was limited to patients with 1 to 3 positive sentinel lymph nodes, similar to the enrollment criteria for the ACOSOG Z0011 trial. Both breast conservation surgery and mastectomy patients were included. Exclusion criteria included neoadjuvant chemotherapy, noninvasive cancer as the most significant lesion in the ipsilateral breast as the positive sentinel lymph node, or stage IV disease identified on staging studies performed shortly after definitive surgery. At the time of data collection, these patients were staged as  $N_1$  by the American Joint Commission on Cancer 7th edition staging manual (metastasis >.2 mm).<sup>14</sup>

Clinical data were obtained from electronic medical records and included demographics, presence of comorbidities, histology, invasive tumor size, receptor status, surgery type (lumpectomy, mastectomy), performance of an axillary node dissection, final pathology results with stage, adjuvant treatment recommended/received, development of a local/regional/distant recurrence, and overall survival. In both mastectomy and breast conserving surgery groups, administration of nodal field radiation was at the discretion of the treating radiation oncologist based on nodal burden and/or nodal ratio. Delivery of postmastectomy radiotherapy over the study time period was based on 4 or more positive lymph nodes. If an axillary dissection was not performed, then use of radiation was based on physician discretion at the time of a weekly multidisciplinary tumor board consensus conference. Of note, all patients treated at our institution undergo multiple presentations at a weekly multidisciplinary tumor board conference, including recommendations for adjuvant regional and systemic therapy.

Endpoints of the study included overall survival and local/regional/distant recurrences for sentinel node-positive patients with and without ALND. A subset analysis was conducted stratifying patients based on surgery type (lumpectomy vs mastectomy). Overall survival was calculated as the time from definitive surgery date to the date of death or last follow-up. Local/regional/distant recurrence time was calculated from completion of definitive surgery and documentation of recurrence. A disease-free clinical status was established by medical record documentation stating no Download English Version:

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