

# Effect of Axillary Dissection vs No Axillary Dissection on 10-Year Overall Survival Among Women With Invasive Breast Cancer and Sentinel Node Metastasis

## The ACOSOG Z0011 (Alliance) Randomized Clinical Trial

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**OBJECTIVE** To determine whether the 10-year overall survival of patients with sentinel lymph node metastases treated with breast-conserving therapy and sentinel lymph node dissection (SLND) alone without axillary lymph node dissection (ALND) is non-inferior to that of women treated with axillary dissection.

**DESIGN, SETTING, AND PARTICIPANTS** The ACOSOG Z0011 phase 3 randomized clinical trial enrolled patients from May 1999 to December 2004 at 115 sites (both academic and community medical centers). The last date of follow-up was September 29, 2015, in the ACOSOG Z0011 (Alliance) trial. Eligible patients were women with clinical T1 or T2 invasive breast cancer, no palpable axillary adenopathy, and 1 or 2 sentinel lymph nodes containing metastases.

**INTERVENTIONS** All patients had planned lumpectomy, planned tangential whole-breast irradiation, and adjuvant systemic therapy. Third-field radiation was prohibited.

**MAIN OUTCOMES AND MEASURES** The primary outcome was overall survival with a non-inferiority hazard ratio (HR) margin of 1.3. The secondary outcome was disease-free survival.

**RESULTS** Among 891 women who were randomized (median age, 55 years), 856 (96%) completed the trial (446 in the SLND alone group and 445 in the ALND group). At a median follow-up of 9.3 years (interquartile range, 6.93-10.34 years), the 10-year overall survival was 86.3% in the SLND alone group and 83.6% in the ALND group (HR, 0.85 [95%CI, 0.62-1.16]; non-inferiority  $P = .02$ ). The 10-year disease-free survival was 80.2% in the SLND alone group and 78.2% in the ALND group (HR, 0.85 [95%CI, 0.62-1.17];  $P = .32$ ). Between year 5 and year 10, 1 regional recurrence was seen in the SLND alone group vs none in the ALND group. Ten-year regional recurrence did not differ significantly between the 2 groups.

**CONCLUSIONS AND RELEVANCE** Among women with T1 or T2 invasive primary breast cancer, no palpable axillary adenopathy, and 1 or 2 sentinel lymph nodes containing metastases, 10-year overall survival for patients treated with sentinel lymph node dissection alone was non-inferior to overall survival for those treated with axillary lymph node dissection. These findings do not support routine use of axillary lymph node dissection in this patient population based on 10-year outcomes.

**TRIAL REGISTRATION** [clinicaltrials.gov](https://clinicaltrials.gov/ct2/show/study/NCT00003855) Identifier: [NCT00003855](https://clinicaltrials.gov/ct2/show/study/NCT00003855)

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