

Omitting Axillary Dissection in Early-Stage Breast Cancer

Martelli G, Boracchi P, De Palo M, et al. A randomized trial comparing axillary dissection to no axillary dissection in older patients with T1N0 breast cancer: results after 5 years of follow-up. *Ann Surg* 2005;242:1–6.

Study Overview

Objective. To assess whether axillary nodal dissection can be safely omitted in older women with early-stage breast cancer and no palpable axillary adenopathy.

Design. Prospective randomized trial.

Setting and participants. 219 Italian women aged 65 to 80 years with early-stage breast cancer (≤ 2 cm) and clinically negative axillary nodes were randomized to breast-conserving surgery with or without axillary dissection. All women received postoperative radiotherapy to the residual breast; axillary, supraclavicular, and internal mammary nodes were not irradiated. All women received tamoxifen after surgery for 5 consecutive years. Patients were followed every 4 months in the first 3 years, every 6 months in the 2 subsequent years, and annually thereafter. Mammography and chest radiography were performed yearly, and bone scans were performed every 2 years.

Main outcome measures. Primary endpoints were axillary events in the no axillary dissection arm. Secondary endpoints included comparisons of overall mortality, breast cancer mortality, and breast events (ie, ipsilateral breast tumor recurrence, contralateral breast cancer, and distant metastases).

Main results. Baseline characteristics between groups were similar. The median age was 70 years, and the majority of patients in each group had hormone receptor-positive tumors. 23% of patients who received axillary dissection had positive axillary lymph nodes, and of these, 24% had more than 3 positive nodes. After 5 years, there were no significant differences in overall or breast cancer-specific mortality or cumulative incidence of breast events between treatment arms. Two patients in the no axillary dissection group (8 and 40 months after surgery) developed axillary involvement. One patient in each arm developed ipsilateral breast tumor recurrence, and 5 patients in each arm developed distant metastases. Mortality from all noncancer causes was higher in the axillary dissection arm than in the no axillary dissection arm (incidence probabilities over 5 years, 3.7% and 2.1%, respectively). The probability of breast cancer death over 5 years was similar between arms

(4% in each arm). Among 27 patients with hormone receptor-negative cancers, there were 6 (22%) first events and 4 (15%) deaths from breast cancer compared with 10 (5%) first events and 4 (2%) breast cancer deaths among patients with hormone receptor-positive tumors.

Conclusion. Older patients with early-stage breast cancer can be treated with breast conservative surgery, radiation, tamoxifen, and no axillary dissection without adversely affecting breast cancer mortality or overall survival.

Commentary

Axillary dissection is a standard component of breast cancer surgery. For women with palpable axillary adenopathy or positive nodes discovered on sentinel node biopsy, complete axillary nodal dissection is routinely performed. Historically, axillary nodal clearance has reduced local recurrence and has improved overall survival, while also providing additional prognostic data to aid in adjuvant treatment planning [1,2]. However, axillary dissection can be associated with some morbidity (eg, seroma formation, lymphedema, thrombosis, neuropathy, shoulder dysfunction). Given these factors and the fact that early-stage tumors in elderly women tend to be highly responsive to oral antiestrogen therapies such as tamoxifen, axillary dissection may not be necessary in all women.

Martelli et al found no significant differences in breast cancer mortality, incidence of breast events, or overall survival between treatment arms. Importantly, only 2 patients in the no axillary dissection arm developed an axillary relapse after 5 years.

These results suggest that axillary surgery can be omitted safely in women with early-stage disease or at least can be delayed until disease becomes clinically overt. In general, this appears to be a well-conducted study with standardized treatments in each arm. Randomization resulted in a balanced distribution of early-stage tumors and comorbidities among this elderly population. However, it is important to consider that 5 years of follow-up may not be sufficient to identify enough events for valid comparisons between arms, particularly in a small sample of women. As well, it remains unclear whether radiation and/or tamoxifen compensated for

the omission of surgery by eliminating micrometastatic locoregional disease or simply delayed local and distant recurrence by several years. Early relapse could be missed with physical examination and basic radiographic studies. Thus, these data will be more convincing with longer follow-up.

Applications for Clinical Practice

Sentinel lymph node biopsy is regarded as standard practice in axillary nodal evaluation. A positive sentinel node still

warrants full axillary nodal clearance.

—Review by David R. Spigel, MD

References

1. Halsted WS. The results of radical operations for the cure of cancer of the breast. *Ann Surg* 1907;46:1–5.
2. Fisher B, Redmond C, Fisher ER, et al. Ten-year results of a randomized clinical trial comparing radical mastectomy and total mastectomy with or without radiation. *N Engl J Med* 1985;312:674–81.

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