## 10-Year Follow-up of Axillary Dissection vs No Dissection in Breast Cancer With Sentinel Node Micrometastases

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In the 10-year follow-up of the phase III International Breast Cancer Study Group (IBCSG) 23-01 trial reported in *The Lancet Oncology*, Galimberti et al found no significant difference in disease-free survival with axillary dissection vs no axillary dissection in patients with breast cancer and sentinel-node micrometastases, confirming findings from the 5-year follow-up.

In the trial, 934 patients from 27 sites in 9 countries were randomly assigned between April 2001 and February 2010 to surgery (mastectomy or breast-conserving) with no axillary dissection (n = 469) or axillary dissection (n = 465). Patients had a largest lesion diameter of  $\leq$  5 cm and 1 or more metastatic sentinel nodes  $\leq$  2 mm with no extracapsular extension. The current 10-year analysis was not prespecified in the trial protocol and was not adjusted for multiple sequential testing.

## **Treatment Outcomes**

Median follow-up was 9.7 years (interquartile range = 7.8–12.7 years). Disease-free survival at 10 years was 76.8% in the no axillary dissection group vs 74.9% in the axillary dissection group (hazard ratio [HR] = 0.85, P = .24; P = .0024 for noninferiority). The 10-year cumulative incidence of breast cancer events was 17.6% vs 17.3% (HR = 0.98, P = .92). Overall survival at 10 years was 90.8% vs 88.2% (HR = 0.78, P = .20).

Long-term surgical complications included lymphedema of any grade in 4% of the no axillary dissection group vs 13% of the axillary dissection group, sensory neuropathy of any grade in 13% vs 19%, and motor neuropathy of any grade in 3% vs 9%. A serious adverse event, consisting of postoperative infection and inflamed axilla requiring hospital admission that resolved without sequelae, was considered related to axillary dissection.

The investigators concluded: "The findings of the IBCSG 23-01 trial after a median follow-up of 9.7 years ... corroborate those obtained at 5 years and are consistent with those of the 10-year follow-up analysis of the Z0011 trial [no significant differences in locoregional recurrence, disease-free survival, or overall survival]. Together, these findings support the current practice of not doing an axillary dissection when the tumour burden in the sentinel nodes is minimal or moderate in patients with early breast cancer."

The study was funded by the International Breast Cancer Study Group. **Viviana Galimberti, MD**, of the Department of Surgery, <u>European Institute of Oncology, Milan</u>, is the corresponding author for *The Lancet Oncology* article.

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