

Sentinel Node Biopsy Confirmed Effective in Detecting Spread of Breast Cancer

<http://www.cancer.gov/clinicaltrials/results/summary/2003/sentinel-node-biopsy0803>

Key words

breast cancer, [lymph node](#), [sentinel lymph node biopsy](#). (Definitions of many terms related to cancer can be found in the [Cancer.gov Dictionary](#).)

Summary

Researchers in Italy report that a less-invasive experimental procedure was as effective as [standard care](#) at detecting whether early breast cancer had spread to the lymph nodes. Although this finding confirms previous studies, it does not resolve the question of whether patients who undergo the experimental procedure, known as sentinel node biopsy, survive as long as patients who receive standard treatment.

Source

New England Journal of Medicine, August 7, 2003 ([see the journal abstract](#)).

Background

Standard treatment for breast cancer usually involves removing a breast tumor (by either [lumpectomy](#) or [mastectomy](#)) and most of the lymph nodes in the underarm closest to the cancerous breast. Removal of the lymph nodes causes [side effects](#) in some patients, such as swelling in the arm and numbness.

When breast cancer spreads to the lymph nodes, it can appear in some nodes (known as sentinel nodes) before others. A sentinel node biopsy is an experimental procedure in which only the sentinel nodes are removed and tested for the presence of cancer cells. To identify the sentinel nodes, the surgeon injects a [radioactive](#) substance or dye near the tumor. The surgeon can then look for nodes that contain the dye or use a scanner to look for radioactive nodes; the nodes that collect the radioactive substance or dye first are called the sentinel nodes. Preliminary studies suggest that, if these nodes are cancer-free, [pathologists](#) are unlikely to find cancer in other nodes.

The sentinel node biopsy could save many patients whose cancer has not spread to the lymph nodes from the undesirable side effects associated with lymph-node removal. However, studies have not yet established whether there is any [overall survival](#) difference between patients treated with sentinel node biopsy and patients treated with conventional lymph-node removal.

The Study

The current study involved 516 patients with early breast cancer (tumors less than 2 centimeters in [diameter](#)). All patients had a sentinel node biopsy after surgery to remove their breast tumors. Then they were [randomly assigned](#) to one of two groups. In the first group, all patients' underarm lymph nodes were removed immediately after the sentinel node biopsy. In the second group, patients' underarm lymph nodes were removed only if the sentinel nodes contained cancer cells.

The study's primary purpose was to test the accuracy of the sentinel node biopsy in predicting the presence of cancer cells in the underarm lymph nodes. The study was conducted at the European Institute of Oncology in Milan, Italy. The lead investigator was Umberto Veronesi, M.D.

Results

Of the 259 patients in the sentinel-node-only group, 92 (35.5 percent) had a positive sentinel node (that is, a node that contained cancer cells). These patients had surgery to remove their underarm lymph nodes.

In the group in which all patients had their underarm lymph nodes removed, 83 of 257 patients (32.3 percent) had a positive sentinel node. Of the 174 patients in this group whose sentinel nodes showed no sign of cancer, 8 (or 4.6 percent) were subsequently found to have cancer in their lymph nodes.

This rate of so-called “false negatives” (when a test fails to detect disease that's present) was comparable to what has been seen in previous studies of the sentinel node biopsy technique. The overall accuracy of sentinel node biopsy in the group whose underarm lymph nodes were immediately removed for testing was 96.9 percent.

After a [median](#) follow-up period of nearly four years, breast cancer had recurred in 15 patients in the total-lymph-node-removal group and in 10 patients in the sentinel-node-only group. Two patients in the total-lymph-node-removal group and one in the sentinel-node-only group died of breast cancer.

Patients who underwent sentinel node biopsy alone had less pain, numbness, and arm swelling and better arm mobility than patients in the group in which everyone's underarm lymph nodes were initially removed – a significant quality-of-life improvement.

Comments Jeffrey Abrams, M.D., of the National Cancer Institute's Cancer Therapy Evaluation Program, “these findings confirm earlier studies showing that the sentinel node biopsy is accurate in predicting the presence or absence of cancer cells in underarm lymph nodes.”

Note: Longer follow-up data from this trial were subsequently published in the December 2006 issue of the *Lancet Oncology* ([see the journal abstract](#)).

Limitations

The number of patient deaths in this study (eight, five of which were due to something other than breast cancer) “is too small to allow meaningful conclusions to be drawn about survival differences between the two randomized groups,” write David Krag, M.D., and Takamaru Ashikaga, Ph.D., of the Vermont Cancer Center in Burlington, in an [accompanying editorial](#).

The question of whether sentinel node biopsy is as safe as total lymph node removal in terms of overall survival must await the completion of larger clinical trials, the editorial writers add.