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Most women with early-stage breast cancer avoid extensive lymph node removal

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A new study of women with early-stage breast cancer finds that surgeons no longer universally remove most of the lymph nodes in the underarm area when a biopsy of the nearby lymph nodes shows cancer—a major change in breast cancer management. The study, which evaluated data from 2.7 million U.S. breast cancer patients, is published as an "article in press" on the *Journal of the American College of Surgeons* website in advance of print publication later this year.

Until now, it was unclear to what extent surgeons were following the recommendations of a landmark clinical trial published more than four years ago, known as the American College of Surgeons Oncology Group Z0011, or ACOSOG Z-11, trial. Those researchers reported that most early-stage breast cancer patients with tumor in their sentinel lymph node (the first draining node) who undergo lumpectomy do not benefit from surgical removal of the remaining lymph nodes in the underarm area, called completion axillary lymph node dissection (ALND). That study found no difference in cancer recurrence and five-year survival between patients who underwent ALND and those who did not but were monitored for recurrences.

The new study found a dramatic increase in the proportion of lumpectomy patients who underwent only a sentinel lymph node biopsy (SNB)—removal of the "gatekeeper" lymph nodes that the cancer is most likely to spread to first—without an ALND after discovery of cancerous sentinel nodes. According to the study authors, the SNB-alone rate more than doubled, from 23 percent in 2009, before publication of

the first results of the ACOSOG Z-11 trial in September 2010, to 56 percent in 2011, the first year after publication.

"As far as I know, our study is the first to show that the findings from the ACOSOG Z-11 trial have changed clinical practice for breast cancer patients nationwide," said lead author Katharine Yao, MD, FACS, director of the Breast Surgical Program at NorthShore University HealthSystem, Evanston, Ill., and clinical associate professor of surgery at the University of Chicago Pritzker School of Medicine. "The Z-11 trial has had a huge impact because of the lower risks for patients who undergo SNB alone."

Removal of small numbers of lymph nodes in SNB alone, according to Dr. Yao, greatly lowers the lifetime risk of developing the often disabling complication of lymphedema. This buildup of lymph fluid under the skin results in swelling and sometimes pain.

For the new study, Dr. Yao and colleagues used the National Cancer Data Base (NCDB), a joint project of the American College of Surgeons Commission on Cancer (CoC) and the American Cancer Society. NCDB captures an estimated 70 percent of newly diagnosed cancer cases in the United States from approximately 1,500 cancer programs accredited by the CoC.

Although NCDB does not identify the type of lymph node dissection (SNB or SNB plus ALND) performed, the researchers used the number of lymph nodes removed as surrogates for these procedures. They categorized the removal of four or fewer lymph nodes as SNB only and removal of 10 or more nodes as ALND.

From the 2.72 million breast cancer cases diagnosed between 1998 and 2011 and listed in the database, the investigators found that 74,309 patients met the Z-11 trial's eligibility criteria for having SNB alone.

These patients underwent lumpectomy and radiation therapy to the whole breast; had tumors 5 centimeters or smaller (less than 2 inches) that appeared clinically node negative; had negative surgical margins (no cancer cells seen at the outer edge of the breast tissue removed); and had two or fewer tumor-positive sentinel lymph nodes.

The rate of SNB alone reportedly increased from 6.1 percent in 1998 to 56 percent in 2011, the most recent data at the time of the study. Because the Z-11 trial results were new in 2011, Dr. Yao said she expects the rate will have increased further in 2012.

Statistical analyses revealed that lumpectomy patients were more likely to undergo ALND if they had any of the following characteristics considered high risk: age younger than 50; black race; triple negative tumors (absence of the three most common types of receptors known to fuel most breast cancer growth); and larger tumors (3 cm or less). In addition, patients with two positive sentinel lymph nodes were twice as likely to have an ALND as patients with one tumor-positive sentinel node. Patients whose tumor metastases measured 2 mm (the width of two grains of rice) or larger were more than three times likelier to undergo ALND compared with patients who had a smaller spread of the cancer, called micrometastases.

Dr. Yao said their findings suggest that some practitioners may feel uncomfortable not performing ALND in high-risk patients, although the Z-11 trial included them. She called for more education for surgeons regarding the applicability of the Z-11 trial findings to these high-risk subgroups and for longer follow-up of these high-risk patients.

The researchers also analyzed 400,052 breast cancer cases that did not meet one of the Z-11 trial's eligibility criteria. Dr. Yao said these results were "somewhat surprising."

They reported that more than 22 percent of patients who underwent a mastectomy in 2011 had only SNB despite mastectomy patients not being included in the Z-11 trial. In addition, SNB without ALNB

occurred in more than 50 percent of patients who had tumors larger than the recommended 5 cm or those who received no or partial radiation therapy, rather than whole-breast irradiation.

"It is a little concerning that patients who fall outside the Z-11 eligibility criteria are getting SNB alone," Dr. Yao said. "It's controversial to perform SNB alone in mastectomy patients because we don't know if it affects overall outcomes."

More information: Impact of the ACOSOG Z0011 Randomized Trial on the Number of Axillary Nodes Removed for Patients with Early Stage Breast Cancer, *Journal of the American College of Surgeons*. DOI: dx.doi.org/10.1016/j.jamcollsurg.2015.02.035

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