

EMBARGOED: October 24, 12:01 a.m.

Sentinel lymph node biopsy provides no benefit for stage zero breast cancer, Yale School of Public Health study finds

Older women with a very early, non-invasive breast cancer known as ductal carcinoma in situ (DCIS), gain no long-term benefit from undergoing a sentinel lymph node biopsy to see if the cancer has spread, new research by the Yale School of Public Health has found.

The study, believed to be the first to examine the long-term impact of sentinel lymph node biopsies on thousands of older women, found that the procedure:

- Did not reduce the likelihood of dying from breast cancer
- Did not decrease the chances of developing invasive breast cancer
- Did not decrease the number of additional mastectomy

However, the researchers found that the procedure increased the patient's risk for side effects associated with the biopsy, which include pain, wound infection and lymphedema, a painful condition that can restrict a woman's arm movements.

The findings are important because between 17 percent and 40 percent of women with DCIS currently undergo sentinel lymph node biopsies, even though experts do not recommend the procedure for DCIS patients, explains Shi-Yi Wang, M.D., Ph.D., a Yale School of Public Health associate professor and the study's lead author.

Approximately 25 percent of all breast cancer patients have DCIS, the earliest form of breast cancer, in which cancer cells invade the milk duct in the breast. Known as a "stage zero" breast cancer, DCIS is not life-threatening because it is non-invasive, meaning the cancer cells do not spread beyond the milk duct. If untreated, however, DCIS can develop into an invasive type of breast cancer.

Women diagnosed with DCIS almost always have surgery (usually a lumpectomy) to remove the DCIS and not the entire breast. Many also have the sentinel node biopsy, which involves removing a few lymph nodes under the arm to determine if the cancer has spread. Since DCIS is not invasive, experts do not recommend these biopsies for DCIS patients.

So why do so many women undergo sentinel lymph node biopsies?

“Proponents of sentinel lymph node biopsy cite concerns that occult microinvasive disease within the DCIS may not be detected histologically. Also, the sentinel lymph node biopsy is included in the Centers for Medicare & Medicaid merit-based incentive payment system for invasive breast cancer,” Wang said. “This might create a financial incentive for providers to perform these biopsies even for non-invasive conditions.”

Wang’s study compared the health outcomes of 5,957 women who had undergone a lumpectomy to remove DCIS, including 1,992 who had undergone a sentinel lymph node biopsy with 3,965 women who did not have the biopsy procedure. The women, all between the ages of 67 and 94, were followed for a median of 5.75 years after their initial lumpectomy. Wang cautioned that the findings may not be generalizable to young women and that more research is also needed to determine if sentinel lymph node biopsies benefit patients with a high-risk type of DCIS.

Laura Esserman, MD professor of surgery and radiology at the University of California, San Francisco, and director of their Breast Care Clinic, is a DCIS researcher and said the findings have important implications for women with breast cancer.

“Some surgeons say that sentinel node biopsies are no big deal, but I disagree. All interventions have consequences,” she said. “More is not better. More is just more, and in this case, more is worse.” Esserman was not involved in the study.

The study will be published on October 24 in the journal *JNCI Cancer Spectrum*. The research was supported through a Patient-Centered Outcomes Research Institute (PCORI) Award [CER-1507-31631; 2016].