

Patient-reported data shows RT does not increase risk of lymphedema in node-negative BC patients

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A secondary analysis of the National Surgical Adjuvant Breast and Bowel Project B-32 trial (Krag 2010) indicates that radiation therapy (RT) does not increase the incidence of lymphedema in patients with node-negative breast cancer, according to research presented today at the American Society for Radiation Oncology's (ASTRO's) 56th Annual Meeting.

The original NSABP B-32 study was a randomized trial of sentinel node biopsy (SNB) versus SNB + axillary lymph node dissection (ALND) in 5,611 women with clinically node-negative breast cancer. The study was initiated to determine if SNB was as effective as ALND with fewer side effects.

Although designed to assess the impact of type of axillary surgery specifically on [lymphedema](#) risk, the NSABP B-32 trial also provided the opportunity to evaluate the impact of [radiation therapy](#) (RT) on lymphedema risk. Lymphedema, swelling of the arm commonly caused by the removal of or damage to lymph nodes, is a significant concern for women undergoing breast cancer treatment.

Measures of lymphedema were collected at baseline prior to RT and every 6 months during the 3-year follow-up period. Lymphedema was assessed both by standardized arm measurements by clinicians (objective lymphedema) and via questionnaires completed by patients (subjective

lymphedema).

Objective lymphedema (clinician measured) was defined as relative arm volume difference (RAVD) >10 percent, and was determined by a water displacement method. Subjective lymphedema was defined as patient-reported ipsilateral (occurring in the same arm) swelling that was "somewhat," "quite" or "very" bothersome. Repeated measures analyses, chi-square and Fisher's exact tests were used to evaluate the association between measures of lymphedema and RT. Kappa coefficient was used to assess agreement between objective and subjective lymphedema measures at individual time points.

Among 3,916 women in the trial with lymphedema assessments, including 1,936 randomly assigned to SNB+ALND and 1,980 randomly assigned to SNB, 82.2 percent (3,220) received RT and 17.2 percent (674) did not undergo RT. The status was unknown for 0.6 percent (22) of the patients. The original study results showed that SNB+ALND were associated with significantly greater risk of lymphedema vs. SNB alone.

Upon secondary analysis, researchers found no greater risk of lymphedema among women receiving RT vs. among women who did not receive RT. There was no significant difference in standardized arm measurements and no significant difference in patient reports of bothersome arm swelling during three years of follow up, suggesting that radiation does not contribute to lymphedema risk beyond surgery over time. Interestingly, although receipt of radiation did not impact either, there was a lack of agreement between patient reports of bothersome swelling (subjective lymphedema) and clinician measurements of arm swelling (objective lymphedema) throughout the three years of follow-up.

At 36 months follow-up of the SNB+ALND group that had received RT, 12.4 percent (147/1,183) had RAVD >10 percent (objective

lymphedema), and 7.4 percent (16/216) reported bothersome swelling (subjective lymphedema). Within the SNB+ALND group that did not receive RT, 16.7 percent (36/216) had RAVD >10 percent, and 8.8 percent (5/57) of the group reported bothersome swelling. Within the SNB-only group, 7.4 percent (90/1,218) of RT recipients had RAVD >10 percent (objective lymphedema) at 36 months of follow-up, with only 3.2 percent (8/250) of RT patients reporting bothersome arm swelling. For the SNB-only patients who did not undergo RT, 4.5 percent (10/220) had RAVD >10 percent, whereas 4.8 percent (3/63) reported bothersome swelling.

"These results provide much needed reassurance to [breast cancer](#) patients regarding the impact of radiation therapy on lymphedema risk," said lead study author Susan McCloskey, MD, MSHS, assistant professor of radiation oncology at The David Geffen School of Medicine at University of California, Los Angeles. "The study findings argue convincingly that radiation therapy to the Level 1 axilla, considered unavoidable "collateral damage" when radiating the whole breast, does not contribute to lymphedema risk beyond surgery. Several recent analyses have suggested that mastectomy rates are on the rise in the United States, and some have suggested that a desire to avoid radiation and its associated toxicities is a contributing factor. This analysis suggests that lymphedema concerns should not be an impediment to women choosing breast conservation and radiation therapy."

More information: The abstract, "The Impact of Radiation Therapy on Lymphedema Risk and the Agreement Between Subjective and Objective Lymphedema Measures: NSABP B-32 Secondary Data Analysis," will be presented in detail during a scientific session at ASTRO's 56th Annual Meeting at 3:15 p.m. Pacific time on Sunday, September 14, 2014.

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