

Most Patients With Intermediate-Risk Breast Cancer May Safely Avoid Chest Wall Irradiation After Mastectomy

There was no significant difference in 10-year overall survival between women who received radiation after surgery and those who did not.

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Patients with intermediate-risk breast cancer had similar rates of 10-year overall survival whether or not they underwent chest wall irradiation (CWI) after mastectomy, according to results from the [BIG 2-04 MRC SUPREMO](#) clinical trial presented at the [San Antonio Breast Cancer Symposium \(SABCS\)](#), held December 10-13, 2024.

“While post-mastectomy CWI is the standard of care for most patients with early-stage breast cancer who have four or more positive axillary lymph nodes, its role in patients with fewer positive lymph nodes or node-negative disease remains controversial,” said [Ian Kunkler, MA, MB BChir](#), a professor at the University of Edinburgh and the presenter of the study.

He explained that while guidelines vary, CWI is commonly used to treat patients with intermediate-risk breast cancers, defined as patients with one to three positive lymph nodes or patients who have no positive lymph nodes but whose cancers exhibit other factors that increase the risk of recurrence, such as grade 3 histology and/or lymphovascular invasion.

To evaluate the impact of post-mastectomy CWI in patients with intermediate-risk breast cancer, Kunkler and colleagues conducted the BIG 2-04 MRC SUPREMO phase III clinical trial. The international trial enrolled patients from several countries with:

- breast tumors 50 mm or less across (pT1-2) and one to three positive axillary lymph nodes (N1);
- breast tumors larger than 50 mm across (pT3) and node-negative disease (N0); or
- breast tumors larger than 20 mm but no larger than 50 mm across (pT2), N0 disease, and grade 3 histology and/or lymphovascular invasion.

Of the 1,607 patients available for analysis after exclusions for ineligibility and withdrawals, 808 were randomly assigned to receive CWI after mastectomy (CWI arm), and 799 patients were randomly assigned to omit CWI after mastectomy (no CWI arm); patients also received guideline-concordant axillary node clearance and systemic treatments.

There were no significant differences in overall survival between those who received CWI and those who did not, with 81.4% and 82.0% of patients in the CWI and no CWI arms, respectively, alive after a median follow-up of 9.6 years. Although CWI reduced the risk of chest wall recurrence by over half, the absolute rate of chest wall recurrence was reduced by less than 2%, which Kunkler explained was a clinically insignificant difference.

When the researchers analyzed CWI's impact in specific patient subgroups, they found that neither patients with N0 disease nor those with N1 disease experienced survival benefits with CWI, suggesting that omission of post-mastectomy CWI may be safe even for patients with lymph node-positive disease.

"This study demonstrates that CWI after a mastectomy has no influence on 10-year overall survival for patients with intermediate-risk breast cancer," said Kunkler. "The results are important considerations for shared decision-making conversations between patients and clinicians, as many patients eligible for post- mastectomy CWI may not require the treatment."

Limitations of the study were the low accrual of patients with pT3, N0 disease and better overall survival than anticipated.

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