

Avoiding radiotherapy is an option for some older patients with breast cancer

December 11 2013

Omission of radiotherapy is a reasonable option for women age 65 or older who receive hormone therapy after breast-conserving surgery for hormone receptor-positive, axillary node-negative breast cancer, according to results of the PRIME 2 trial presented here at the 2013 San Antonio Breast Cancer Symposium, held Dec. 10-14.

"Radiotherapy has been known to reduce the risk of breast cancer [recurrence](#) three- to fourfold. However, what our trial has shown is that although this is still the case, the proportion of women who will actually have a recurrence without [radiotherapy](#) is very small (less than 5 percent), five years after treatment," said Ian Kunkler, F.R.C.R., professor of clinical oncology at the Edinburgh Cancer Research Center in the University of Edinburgh. "We have identified a subgroup of older patients at sufficiently low risk of recurrence for whom omission of postoperative radiotherapy after breast-conserving surgery and adjuvant endocrine therapy is a reasonable option.

"What this study shows is that for every 100 women (from our selected population) treated with radiotherapy, one will have a recurrence anyway, four will have a recurrence prevented, but 95 will have had unnecessary treatment," said Kunkler. "Once a patient has had radiotherapy, they are unable to have it again on the same breast. Had these women not had radiotherapy, they would have been able to have minor surgery and radiotherapy following a recurrence," he explained. "Besides, radiotherapy carries its own health risks, particularly in the elderly, as well as the inconvenience of travel for daily treatment for

three or four weeks.

"Allowing us to defer radiotherapy in this group of patients until a recurrence occurs will be of benefit to the patient and to the health service," said Kunkler.

PRIME 2 is an international, phase III, randomized, controlled trial that set out to address the question of whether whole-breast radiotherapy can be omitted in carefully defined groups of older patients receiving appropriate therapy. The primary endpoint of this trial is recurrence of breast cancer in the same breast, known as ipsilateral breast tumor recurrence (IBTR).

The investigators found that at five years, 1.3 percent of patients who received radiotherapy had IBTR, and 4.1 percent of patients who did not receive radiotherapy had IBTR.

Between 2003 and 2009, 1,326 patients were enrolled in the trial; 658 patients were randomly assigned to receive radiotherapy and 668 did not receive radiotherapy. All participants were age 65 or older; had hormone-positive, low-grade breast cancer; did not have the disease in lymph nodes adjacent to the breast (axillary node-negative); did not have metastasis; had cancer-free breast tissue margins where tumor was surgically removed; and received [hormone therapy](#).

The investigators found that at five years, between patients who received radiotherapy and those who did not, there was no significant difference in overall survival (97 percent vs. 96.4 percent); regional recurrence (0.5 percent vs. 0.8 percent); or breast cancer in the opposite breast (0.5 percent vs. 0.7 percent). The difference in [breast cancer](#)-free survival between those receiving and not receiving radiotherapy (98.5 percent vs. 96.4 percent), however, was statistically significant.

"Our results are likely to lead to the consideration of omission of postoperative radiotherapy in [patients](#) meeting the eligibility criteria for the trial," Kunkler said.

Provided by American Association for Cancer Research

Citation: Avoiding radiotherapy is an option for some older patients with breast cancer (2013, December 11) retrieved 25 January 2023 from <https://medicalxpress.com/news/2013-12-radiotherapy-option-older-patients-breast.html>

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