Breast-Conserving Surgery with or without Irradiation in Early Breast Cancer

Ian H. Kunkler, M.B., B.Chir., Linda J. Williams, Ph.D., Wilma J.L. Jack, M.B., Ch.B., David A. Cameron, M.D., and J. Michael Dixon, M.D.

February 16, 2023
N Engl J Med 2023; 388:585-594
DOI: 10.1056/NEJMoa2207586

Abstract

BACKGROUND

Limited level 1 evidence is available on the omission of radiotherapy after breast-conserving surgery in older women with hormone receptor–positive early breast cancer receiving adjuvant endocrine therapy.

METHODS

We performed a phase 3 randomized trial of the omission of irradiation; the trial population included women 65 years of age or older who had hormone receptor–positive, node-negative, T1 or T2 primary breast cancer (with tumors ≤3 cm in the largest dimension) treated with breast-conserving surgery with clear excision margins and adjuvant endocrine therapy. Patients were randomly assigned to receive whole-breast irradiation (40 to 50 Gy) or no irradiation. The primary end point was local breast cancer recurrence. Regional recurrence, breast cancer–specific survival, distant recurrence as the first event, and overall survival were also assessed.

RESULTS

A total of 1326 women were enrolled; 658 were randomly assigned to receive whole-breast irradiation and 668 to receive no irradiation. The median follow-up was 9.1 years. The cumulative incidence of local breast cancer recurrence within 10 years was 9.5% (95% confidence interval [CI], 6.8 to 12.3) in the no-radiotherapy group and 0.9% (95% CI, 0.1 to 1.7) in the radiotherapy group (hazard ratio, 10.4; 95% CI, 4.1 to 26.1; P<0.001). Although local recurrence was more common in the group that did not receive radiotherapy, the 10-year incidence of distant recurrence as the first event was not higher in the no-radiotherapy group than in the radiotherapy group, at 1.6% (95% CI, 0.4 to 2.8) and 3.0% (95% CI, 1.4 to 4.5), respectively. Overall survival at 10 years was almost identical in the two groups, at 80.8% (95% CI, 77.2 to 84.3) with no radiotherapy and 80.7% (95% CI, 76.9 to 84.3) with radiotherapy. The incidence of regional recurrence and breast cancer–specific survival also did not differ substantially between the two groups.

CONCLUSIONS

Omission of radiotherapy was associated with an increased incidence of local recurrence but had no detrimental effect on distant recurrence as the first event or overall survival among women 65 years of age or older with low-risk, hormone receptor–positive early breast cancer. (Funded by the Chief Scientist Office of the Scottish Government and the Breast Cancer Institute, Western General Hospital, Edinburgh; ISRCTN number, ISRCTN95889329.)