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Breast

Cosmetic Results and Side Effects of Accelerated Partial-Breast Irradiation Versus Whole-Breast Irradiation for Low-Risk Invasive Carcinoma of the Breast: The Randomized Phase III IRMA Trial

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Clinical Trial

J Clin Oncol. 2023 Apr 20;41(12):2201-2210.

doi: 10.1200/JCO.22.01485.

Abstract

PURPOSE

The results in terms of side effects vary among the published accelerated partial-breast irradiation (APBI) studies. Here, we report the 5-year results for cosmetic outcomes and toxicity of the IRMA trial.

METHODS

We ran this randomized phase III trial in 35 centers. Women with stage I-IIA breast cancer treated with breast-conserving surgery, age ≥ 49 years, were randomly assigned 1:1 to receive either whole-breast irradiation (WBI) or external beam radiation therapy APBI (38.5 Gy/10 fraction twice daily). Patients and investigators were not masked to treatment allocation. The primary end point was ipsilateral breast tumor recurrence. We hereby present the analysis of the secondary outcomes, cosmesis, and normal tissue toxicity. All side effects were graded with the Radiation Therapy Oncology Group/European Organisation for Research and Treatment of Cancer Radiation Morbidity Scoring Schema. Analysis was performed with both intention-to-treat and as-treated approaches.

RESULTS

Between March 2007 and March 2019, 3,309 patients were randomly assigned to 1,657 WBI and 1,652 APBI; 3,225 patients comprised the intention-to-treat population (1,623 WBI and 1,602 APBI). At a median follow-up of 5.6 (interquartile range, 4.0-8.4) years, adverse cosmesis in the APBI patients was higher than that in the WBI patients at 3 years (12.7% v 9.2%; $P = .009$) and at 5 years (14% v 9.8%; $P = .012$). Late soft tissue toxicity (grade ≥ 3 : 2.8% APBI v 1% WBI, $P < .0001$) and late bone toxicity (grade ≥ 3 : 1.1% APBI v 0% WBI, $P < .0001$) were significantly higher in the APBI arm. There were no significant differences in late skin and lung toxicities.

CONCLUSION

External beam radiation therapy-APBI with a twice-daily IRMA schedule was associated with increased rates of late moderate soft tissue and bone toxicities, with a slight decrease in patient-reported cosmetic outcomes at 5 years when compared with WBI, although overall toxicity was in an acceptable range.

