Cancer Research

General Session Abstracts

Abstract GS4-03: RAPID: A randomized trial of accelerated partial breast irradiation using 3-dimensional conformal radiotherapy (3D-CRT)

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Abstract

Background

Whole breast irradiation (WBI) after lumpectomy reduces the risk of local recurrence, thereby avoiding subsequent mastectomy. It is a key component of breast conserving therapy. WBI is usually given in daily fractions over 3-6 weeks. With accelerated partial breast irradiation (APBI), radiation is delivered over a week or less to the surgical cavity with a margin of normal tissue. It was introduced to provide treatment in a shorter more convenient form. 3D-CRT is an attractive approach as it is non-invasive and uses standard techniques for external beam RT that are widely available. The objective of the RAPID trial was to determine if APBI using 3D-CRT was not inferior to WBI following breast conserving surgery (BCS).

Methods

Women ≥40 years of age with axillary node-negative invasive ductal carcinoma, or ductal carcinoma in situ (DCIS) ≤3cm treated by BCS with clear margins of excision were eligible. Randomization was stratified for age (< or ≥50y), histology (DCIS alone or invasive breast cancer), tumor size (< or ≥1.5cm), ER status (+/-) if invasive disease, and treatment center. Patients were allocated to APBI using 3D-CRT (38.5Gy in 10 fractions delivered twice daily) or WBI (42.5Gy in 16 daily fractions or 50Gy in 25 daily fractions; boost radiation was permitted). The primary outcome

assessed adverse cosmesis (fair or poor on global assessment). The trial was designed to show that the 5-year IBTR rate in the APBI arm was not inferior to the WBI arm by more than 1.5% (hazard ratio [HR] ≤ 2.02) with 85% power and a one-sided alpha of 5%.

Results

From February 2006 to July 2011, 2135 patients from sites in Canada, Australia, and New Zealand were randomly assigned: 1070 to APBI and 1065 to WBI. The median follow-up was 8.6 years. The mean age of the study population was 61 years; 82% of patients had invasive breast cancer and 18% had DCIS only. For invasive cancers: 60% were < 1.5cm and 90% were ER positive. For DCIS tumors: 68% were < 1.5cm. A total of 65 IBTRs were observed. For the APBI patients, the 5-year and 8-year cumulative rates of IBTR were 2.3% and 3.0%, respectively. The corresponding data for the WBI patients were 1.7% and 2.8%. The HR for APBI versus WBI was 1.27, 90% confidence interval, 0.84 to 1.91. Acute radiation toxicity (occurring within 3 months of treatment start) e.g. radiation dermatitis and breast swelling was less in patients treated with APBI compared with WBI (≥ Grade 2, 28% vs 45%, p<0.001). Late radiation toxicity (beyond 3 months) e.g. breast induration and telangiectasia was greater in patients treated with APBI (≥ Grade 2, 32% vs 13%, p<0.001 and Grade 3, 4.5% vs 1.0%, p<0.001). Adverse cosmesis was higher in patients treated with APBI compared with WBI at 3 years (29% vs 17%, p<0.001) and at 5 years (32% vs 16%, p<0.001).

Conclusions

The APBI regimen used in our trial was non-inferior to WBI in preventing local recurrence. Although it was associated with less acute toxicity, an increase in late normal tissue toxicity and adverse cosmesis was observed with APBI.

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