Partial and Whole Breast Radiation Have Similar Outcomes in Early BC

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Accelerated partial breast irradiation (APBI) using intensity-modulated radiotherapy (IMRT) is an alternative technique to whole-breast irradiation (WBI) in early stage breast cancer (BC). Lorenzo Livi, MD, Florence University Hospital, Florence, Italy, presented the 5-year survival results from the Accelerated Partial Breast Irradiation Using Intensity Modulated Radiotherapy Versus Whole Breast Irradiation trial [NCT02104895]. In this single-center phase 3 randomized equivalence trial that compared IMRT with WBI in patients with early stage BC, the hypothesis was that APBI-IMRT would be advantageous by increasing dose conformity while minimizing normal tissue exposure.

Eligible patients were women aged > 40 years, had a maximum tumor diameter of 25 mm, were considered appropriate candidates for breast-conserving surgery, and had surgical margins > 5 mm [Livi L et al. *Int J Radiat Oncol Biol Phys.* 2010; Livi L et al. *Eur J Cancer*. 2015]. Surgical clips were mandatory in all patients. The clinical target volume in patients in the APBI arm was defined as a 1-cm 3-D margin around the surgical clips. The planning target volume was a 1-cm margin added to the clinical target volume, limited to 3 mm from skin and to 4-mm intrusion in the homolateral lung.

Patients were randomized 1:1 to receive either external APBI using the IMRT technique or WBI. Patients in the APBI arm received a total dose of 30 Gy in 5 fractions (6 Gy/fr in 2 weeks) to the tumor bed and those randomized to WBI received 50 Gy plus a boost 10 Gy in 30 fractions (2 Gy/fr in 6 weeks). The primary end point was ipsilateral breast tumor recurrence (IBTR). Treatment toxicity and overall survival (OS) were secondary end points. Tolerance was evaluated using Radiation Therapy Oncology Group, the European Organization for Research and Treatment of Cancer, and the Harvard Breast Cosmesis scales.

A total of 520 patients were randomized from 2005 to 2013, with 260 in each arm [NCT02104895]. The majority of patients had a pT1b or pT1c tumor stage (about 75%) and negative axillary lymph nodes (about 86%). The most common molecular subtype was luminal A (169 patients in the APBI group and 151 in the WBI group). After a median follow-up of 5 years (range, 0.6 to 9.0), the 5-year IBTR rate was 1.5% (3 cases) compared with 1.4% (3 cases) in the WBI group ($P = .86$; Table 1). The 5-year OS rate was 99.4% in the APBI group and 96.6% in the WBI group (HR, 0.17; 95% CI, 0.02 to 1.36; $P = .057$).

Table 1. Five-Year Event Rates by Treatment (ITT Population)

	Total, n	Whole Breast, n (%) (n = 260)	Partial Breast, n (%) (n = 260)	Log-rank *P* Value
IBTR	6	3 (1.4)	3 (1.5)	.86
Local relapse	3	3 (1.4)	0	.11
New ipsilateral BC	3	0	3 (1.5)	.063
Locoregional tumor recurrence	7	4 (1.9)	3 (1.5)	.86
Contralateral breast tumor	10	7 (3.2)	3 (1.6)	.31
Distant metastasis[a]	7	4 (1.8)	3 (1.5)	.87
Total deaths	8	7 (3.4)	1 (0.6)	.057
BC	4	3 (1.6)	1 (0.6)	.40
Other cause	4	4 (1.8)	0	.065

BC, breast cancer; IBTR, ipsilateral breast tumor recurrence; ITT, intent-to-treat population.
[a]As first or secondary event.
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No grade 3 toxicity was observed in either treatment group. In terms of acute adverse events, the APBI group was significantly better considering any grade of skin toxicity ($P = .0001$). In early late side effects, 2 cases of grade 2 skin fibrosis occurred in the WBI group (0.8%). A total of 337 patients (65%) had a cosmetic evaluation with a minimum follow-up of 48 months, > 90% of patients in both groups had cosmetic results rated as excellent or good, and APBI patients were considered to have a better outcome compared with patients in the WBI arm ($P = .045$). Dr Livi was encouraged by the findings but noted that the interpretation of the study is limited by the small sample size and low IBRT event rate.