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To interview Icro Meattini, contact Julia Gunther at julia.gunther@aacr.org or 215-446-6896. For a photo of Meattini, click here.

**Partial Breast Irradiation May be as Effective as Whole Breast Irradiation in Preventing Recurrence in Patients with Early Breast Cancer**

10-year follow-up data supports earlier findings on recurrence and survival

SAN ANTONIO — A 10-year follow-up study of breast cancer patients who had been treated with accelerated partial breast irradiation (APBI) after surgery showed that their rates of recurrence were similar to those of patients who had received whole breast irradiation (WBI), according to data presented at the 2019 San Antonio Breast Cancer Symposium (SABCS), held Dec. 10–14. The study suggests that the less invasive partial breast procedure may be an acceptable choice for patients with early breast cancer.

Many patients diagnosed with early breast cancer undergo surgery known as a lumpectomy, followed by a course of radiation. “Postoperative radiation still represents a mainstay of adjuvant treatment for breast cancer, able to significantly reduce the local relapse occurrence rate,” explained the study’s lead author, Icro Meattini, MD, of the University of Florence in Italy.

In recent years, researchers have sought to determine whether APBI might be as effective as WBI in preventing recurrence. Meattini’s study examined 10-year follow-up data for women enrolled in the **APBI IMRT trial**, a randomized phase III trial. The five-year follow-up from the trial showed no significant difference in tumor recurrence or survival rates.

The APBI IMRT trial enrolled 520 women over age 40 who had either stage 1 or stage 2 breast cancer. Between 2005 and 2013, the patients were randomly assigned in a 1:1 ratio to receive either APBI or WBI. The patients in the APBI arm received a total of 30 Gray (Gy) of radiation to the tumor bed in five daily fractions, while those in the WBI arm received a total of 50 Gy in 25 daily fractions to the whole breast, plus a boost of 10 Gy to the tumor bed in five daily fractions.

Both treatment arms were comparable in terms of age, tumor size, tumor type, and adjuvant endocrine treatment, and both achieved a median 10-year follow-up. The majority of the patients had hormone receptor-positive, HER2-negative breast cancer, and most were over age 50.

The study showed that after 10 years, 3.3 percent of patients in the APBI group had experienced a recurrence of breast cancer, compared to 2.6 percent in the group that received WBI. These results were comparable to the **five-year results**, in which the group that received APBI had a 2.4 percent recurrence rate, and the group that received WBI had a 1.2 percent recurrence rate. Both differences were not statistically significant.

Overall survival at the 10-year mark was also very similar between the two groups: 92.7 percent for the women who had received APBI and 93.3 percent for the women who received WBI.
Breast-cancer specific survival was 97.6 percent for those who received APBI and 97.5 percent for those who received WBI.

The distant metastasis-free survival rate was 96.9 percent both for the women who received APBI and for those who received WBI.

“These results reinforce the initial promising results from the previous study,” Meattini said. “Accelerated partial breast irradiation can produce excellent disease control.”

Partial breast vs. whole breast radiation has been a topic of multiple clinical trials. A study presented at SABCS in 2018 showed that while the results were close, WBI proved slightly more effective in reducing recurrence rates.

Meattini said this growing body of research may help clinicians recommend that patients at lower risk of recurrence choose to receive APBI, while those at a higher risk of recurrence may be recommended for WBI.

“In well-selected cases, there is no difference in patients’ outcomes whether they are treated with APBI or WBI,” he said. “A once-daily regimen of external APBI might also produce an improved quality of life, with less toxicity, and can potentially reduce the overall treatment time.” He added that APBI may also be less likely to cause cosmetic changes and is less expensive to administer than WBI.

“Partial breast irradiation is one of the primary examples of effective de-escalation of treatment in breast oncology,” Meattini said. “For many patients, partial breast irradiation may be an optimal choice that is cost-effective, safe, and efficacious.”

Meattini said the study’s chief limitation is its relatively small size.

This study was supported by the Radiation Oncology Unit of the Florence University Hospital. Meattini declares no conflicts of interest.

**ABSTRACT**

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Accelerated partial breast or whole breast irradiation after breast conservation surgery for patients with early breast cancer: 10-year follow up results of the APBI IMRT Florence randomized phase 3 trial

Icvo Meattini1, Calogero Saieva2, Sara Lucidi1, Monica Lo Russo1, Vieri Scotti1, Isacco Desideri1, Livia Marrazzo1, Gabriele Simontacchi1, Monica Mangoni1, Carlotta Becherini1, Luca Visani1, Lisa Paololetti3, Erica Moretti4, Luca Triggiani5, Marco Bernini1, Lorenzo Orzalesi1, Jacopo Nori1, Stefania Pallotta1, Simonetta Bianchi1 and Lorenzo Livi1.

1University of Florence, Florence, Italy2Istituto per lo Studio, la Prevenzione e la Rete Oncologica (ISPRO), Florence, Italy3Ospedale Santa Maria Annunziata - Azienda Usl Toscana Centro, Florence, Italy4Ospedale S. Stefano - Azienda Usl Toscana Centro, Prato, Italy5University of Brescia, Brescia, Italy

**Background.** Partial breast irradiation (PBI) is a reasonable alternative for a whole breast irradiation (WBI) in selected early stage breast cancer patients. The 5-year analysis of the APBI IMRT Florence phase 3 trial showed no significant difference in terms of ipsilateral tumor recurrence (IBTR) and survival rates between the two arms. We present the 10-
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year follow up data. **Methods.** From March 2005 to June 2013, women aged more than 40 years affected by early BC, with a maximum pathological tumor size of 25 mm, were randomly assigned in a 1:1 ratio to receive either WBI using three-dimensional conformal radiotherapy (3DCRT) or accelerated PBI (APBI) using intensity-modulated radiotherapy (IMRT) technique. Patients in the APBI arm received a total dose of 30 Gy to the tumor bed in five daily fractions. The WBI arm received 50 Gy in 25 fractions, followed by a boost on the tumor bed of 10 Gy in five fractions. The primary end-point, IBTR rate is now assessed at 10 years in the ITT population, as well as secondary endpoints: overall survival (OS), breast cancer specific survival (BCSS), distant metastasis free survival (DMFS), contralateral breast cancer (CBC), and locoregional recurrences (LRR). This trial is registered with ClinicalTrials.gov, number NCT02104895. **Results.** Of the 520 patients, 260 were enrolled in the APBI-arm and 260 in the WBI-arm; median age was 62.8 years (63.6 in the APBI and 61.6 in the WBI arm, p=0.20). Both treatment-arms achieved a median 10-year follow-up (10.1 in APBI-arm and 10.4 in WBI-arm, p=0.39) and were comparable regarding age, tumor size, grade, tumor type, and adjuvant endocrine treatment. No significant difference in terms of IBTR rates between treatment arms was shown (log rank test p=0.58). In the group who received APBI, the 5-year IBTR was 1.96% (5 events; 95% CI: 0.3;3.7) and the 10-year IBTR was 3.74% (9 events; 95% CI: 1.5;6.3). In the group who received WBI, the 5-year IBTR rate was 1.2% (3 events; 95% CI: 0;2.5) and the 10-year IBTR was 2.5% (6 events; 95% CI: 0.7;4.5). HR for APBI patients compared with WBI patients was 1.33 (p=0.58; 95% CI: 0.49;3.56). There were no significant differences between treatment arms regarding survival outcomes. OS (log rank test p=0.33): APBI 95.4% (95% CI: 93.6;97.2) versus WBI 94.3% (95% CI: 92.3;96.3); HR for APBI patients 0.66 (p=0.33; 95% CI: 0.29;1.53). BCSS (log rank test p=0.55): APBI 98% (95% CI: 96.8;99.2) versus WBI 97.5% (95% CI: 96.2;98.8); HR for APBI patients 0.68 (p=0.55; 95% CI: 0.19;2.42). DMFS (log rank test p=0.45): APBI 97.4% (95% CI: 96.0;98.8) versus WBI 96.1% (95% CI: 94.4;97.8); HR for APBI patients 0.67 (p=0.45; 95% CI: 0.24;1.89). Cumulative incidence estimates of 10-year LRR were 3.9% (95% CI: 2.24;5.56) for APBI versus 3.0% (95% CI: 1.53;4.47) for WBI (log rank test p=0.59). CBC observed after APBI were 5 (1.9%) as compared to 9 (3.5%) after WBI (p=0.42). **Conclusion.** IBTR rate after 10 years in patients with early breast cancer who were treated with APBI using IMRT technique in 5 fractions is rare and not significantly different from patients treated with WBI. OS, BCSS, DMFS, and LRR control are also comparable. Thus, APBI should be considered a reasonable alternative for a WBI in early breast cancer patients.

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