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To interview Frank Vicini, contact Julia Gunther at julia.gunther@aacr.org or 770-403-7690. For a photo of Vicini, click [here](#).

Accelerated Partial Breast Irradiation, Although Close, was Not Equivalent to Whole Breast Irradiation To Control Ipsilateral Breast Tumor Recurrence

SAN ANTONIO — Data from the NRG (NSABP B-39/RTOG 0413) trial indicated that ipsilateral breast tumor recurrence (IBTR) rates 10 years after treatment could not reject the hypothesis that accelerated partial breast irradiation (PBI) after lumpectomy was inferior to whole breast irradiation (WBI), according to a presentation at the 2018 [San Antonio Breast Cancer Symposium](#), held Dec. 4–8.

Moreover, the 10-year estimates for relapse-free interval (RFI) disclosed a statistically significant inferiority for PBI compared to WBI. Because the differences relative to both IBTR and RFI were small, PBI may be an acceptable alternative to WBI for a proportion of women who undergo breast-conserving surgery.

“Because of advancements in screening and public awareness, the majority of breast cancer patients in the U.S. are diagnosed in early stages, and over 100,000 women each year face treatment decisions about breast-conserving therapy,” said [Frank Vicini, MD](#), principal investigator at the MHP Radiation Oncology Institute/21st Century Oncology in Pontiac, Michigan. “It is important that breast cancer patients and the health care system have modern information about breast-conservation treatment and options that can improve access to care, combat overtreatment, reduce the burden of treatment and health care costs, and improve quality of life.”

WBI following lumpectomy has comparable ipsilateral recurrence rates compared to mastectomy, Vicini explained. Accelerated PBI treats the tumor bed area instead of the entire breast and reduces radiation treatment time from 3-6 weeks to 5-8 days, he noted. “The main purpose of our study was to determine if accelerated PBI is equivalent to WBI in controlling for ipsilateral breast cancer recurrence in women who desire breast-conservation surgery,” he said.

Vicini, Julia White, MD, co-principal investigator at The Ohio State University, and colleagues randomized breast cancer patients who had recently received a lumpectomy with 0-3 positive axillary nodes to treatment with WBI or PBI. Of these breast cancer patients, 25 percent had ductal carcinoma in situ (DCIS), 65 percent had stage I breast cancer, and 10 percent had stage II

breast cancer. Eighty-one percent of patients had hormone receptor-positive cancer, and 61 percent of patients were postmenopausal.

Of the 4,216 breast cancer patients, 2,109 received WBI and 2,107 received PBI. Treatment with WBI was defined as daily treatment with 2 grays (Gy) of radiation totaling 50 Gy with a sequential boost to the surgical site; treatment with PBI was defined as twice daily treatment with 3.4-3.85 Gy totaling 10 treatments delivered via 3D external beam radiation or brachytherapy.

The primary endpoint of the trial was evidence of IBTR. Secondary endpoints included RFI, distant disease-free interval (DDFI), and overall survival (OS). The median follow-up time was 10.2 years. Disease-free survival (DFS) was also analyzed.

IBTR as a first event was observed in 161 women; of these patients, 90 had received PBI, while 71 had received WBI. While the risk of recurrence was not statistically different between the two treatment arms, the hazard ratio did not meet the statistical criteria for treatment equivalence, Vicini explained.

The proportion of patients IBTR-free 10 years after treatment was 95.2 percent among those who received PBI and 95.9 percent among those who received WBI. The difference in the 10-year RFI between the two treatment arms was statistically significant (91.9 percent for patients treated with PBI versus 93.4 percent for patients treated with WBI).

“Despite only small differences in IBTR (<1 percent) and RFI (1.5 percent) between the two treatment arms at 10 years, we could not declare that WBI and PBI were equivalent in controlling local in-breast tumor recurrence because the hazard ratio between arms fell short of meeting statistical equivalence,” said Vicini. “On the other hand, we also could not claim that it is inferior.”

Importantly, statistically significant differences between the two treatment arms were not observed for DDFI, DFS, or OS, noted Vicini. “These findings suggest that the less burdensome radiation method of accelerated PBI may be an acceptable choice for many women,” said Vicini. “Additional analyses are underway to determine if specific cohorts may have advantages in local and regional relapse control between the two treatment arms.”

Grade 3 toxicity was modestly higher in patients who received PBI compared to those who received WBI (9.6 percent and 7.1 percent, respectively). Likewise, grade 4-5 toxicity was slightly higher in patients who received PBI compared to those who received WBI (0.5 percent and 0.3 percent, respectively).

“The delivery of radiation is operator-dependent and it will be important to complete future analyses to determine the influence on radiation quality and technical treatment delivery on toxicity outcomes,” Vicini said.

While multiple methods of PBI were utilized in the trial, a limitation of the study was a lack of statistical power to determine which PBI technique is optimal in individual clinical scenarios, noted Vicini.

The study was sponsored by the National Cancer Institute. Vicini is a research advisor for ImpediMed.

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