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25-Year Study: Radiation to Breast Does Not Cause Long-Term Cardiac Toxicity

BY CHARLENE LAINO

"Any potential cardiac morbidity had been attenuated with modern treatment planning, CT simulation, and 3D planning."

BOSTON—Women with early-stage breast cancer who undergo radiotherapy to the whole breast are not at increased long-term risk for cardiac toxicity compared with patients who have modified radical mastectomy, according to a 25-year study reported here at the American Society for Radiation Oncology Annual Meeting (*Abstract 87*).

While the survival curves for the two groups began to separate after 25 years, "cardiac toxicity does not seem to be responsible for the slight decrease in survival time in the BCT [breast-conserving treatment] arm," said the study's principal investigator, Charles B. Simone II, MD, Assistant Professor of Radiation Oncology at the Abramson Cancer Center at the University of Pennsylvania.

"Over the past two decades, radiation therapy has become more precise and safer with modern techniques. We are pleased to find that early-stage breast cancer patients treated with modern radiation therapy treatment planning techniques do not have an increased risk of long-term cardiac toxicity and that BCT with radiation should remain a standard treatment option."

CHARLES B. SIMONE II, MD: "Over the past two decades, radiation therapy has become more precise and safer with modern techniques."

The analysis involved 50 of 102 surviving patients who were treated from 1979 to 1987 in the landmark NCI Breast Conservation Trial and returned for cardiac testing 25 years later.

During the 25 years of follow-up, the mortality curves for the two groups were superimposed. A total of 63 of the 116 women in the mastectomy group died, as did 76 of the 121 in the breast-conservation therapy group—a nonsignificant difference. But after that point, the curves started to separate, leading the researchers to question whether

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→DEMONSTRATION

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Practices that participate will be evaluated on oncology-specific standards—most likely based on ASCO's QOPI, as well as outcome measures being developed by the Community Oncology Alliance.

the Committee decided to reserve the designation solely for primary care practices. Thus, that imprimatur is no longer available to other oncology or other specialty practices.

But NCQA has received so many inquiries from specialty and subspecialty practices wanting to jump on the medical-home bandwagon that it decided to develop a new specialty practice recognition program. Medical practices believe that, by earning official recognition for meeting the NCQA's quality and efficiency standards, they will convince payers of their increased value and that they should be paid more than their peers who have not done so.

Earlier this year, Sprandio approached NCQA about developing oncology-specific standards to advance the oncology medical home model. "We convinced them in the spring to make oncology a first priority because of the crisis in community oncology," he said.

This fall NCQA convened an expert panel that included oncologists, payers, and representatives from COA and ASCO to discuss the demonstration project. Barrett said the Committee did not originally envision the use of specialty-specific standards to evaluate practices, but the oncology demonstration project will examine whether they add value.

Trademarked Term

NCQA does not use the term "medical home" for specialty practices, but Sprandio does. Indeed, he trademarked the term "Oncology Patient-Centered Medical Home®" in response to the proliferation of definitions as to what constitutes an oncology medical home. And he formed a consulting firm to help other practices adopt the model CMOH uses.

The demonstration is considered important because it may usher in a new way for oncology practices to be paid.

"We really needed the NCQA to step up and develop a standard to protect the concept and to define what this is so that payers could have a standard model to build a methodology for changing the payment system."

Demonstration Details

NCQA is applying for grant funding that would help practices participating in the demonstration to re-engineer their practices and pay for an evaluation of the project. If that funding is obtained, Barrett expects the demonstration to launch in January. About 10 to 15 delivery sites in southeastern Pennsylvania will convert to the medical home model and their outcomes will be compared with those of a control group of similar size.

She said she expects it to be a three-year project, but preliminary data will be analyzed and put to use before the demonstration is completed. "Within a year of implementing the model, we think we will be able to get some data that will show us whether or not it's promising, whether it's looking somewhat like the Sprandio results," she said.

If it is, the findings will be used to help develop the final standards of the NCQA's formal recognition program for patient-centered oncology practices.

How to Earn Recognition

Separate from the demonstration project, NCQA expects to introduce its recognition program for all specialty medical practices in March. In developing its specialty recognition standards, NCQA is building off the standards it uses for the primary care patient-centered medical home.

The draft standards, which were made available for public comment last summer, include some 150 practice elements that fall into six buckets:

- Provide Access and Communication
- Identify and Coordinate Patient Populations
- Track and Coordinate Referrals
- Plan and Manage Care
- Track and Coordinate Care
- Measure and Improve Performance

The NCQA scores practices based on the number of elements they have attained. In its primary care patient-centered medical home program, certain elements—for example, active support of patient self-management and measurement of clinical and/or service performance—are "must-haves" for practices that want the top recognition level, regardless of their overall score.

→CARDIOTOXICITY

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treatment toxicity could account for the separation.

Several small, single-center studies have linked breast radiation to cardiac toxicity, Simone noted. In the original NCI trial, 247 women with Stage I-II breast cancer were randomized to BCT or modified radical mastectomy, both with Level I/II axillary dissection. Patients in the BCT arm received lumpectomy plus radiation with 45.0 to 50.4 Gy to the whole breast with or without regional nodes as needed, and a 15.0 to 20.0 Gy boost to the tumor bed.

"The trial was unique in that patients were treated with modern CT planning—specifically CT simulation with dose inhomogeneity correction—and modern radiation techniques," he said.

The 40 percent of patients with node-positive disease received axillary dissection plus six to 11 cycles of chemotherapy with doxorubicin and cyclophosphamide. After 1985, postmenopausal node-positive patients also received tamoxifen.

Sister-Brother

At last year's ASTRO meeting, Simone's sister, Nicole Simone, MD, Assistant Professor of Radiation Oncology at the Kimmel Cancer Center at Thomas Jefferson University, reported that long-term pulmonary toxicity was basically equivalent in the two treatment group.

This year, Charles Simone reported on the long-term cardiac toxicity.

> "The trial was unique in that patients were treated with modern CT planning and modern radiation techniques."

Of the 50 patients in the analysis, 26 were in the BCT group and 24 in the modified radical mastectomy arm. All the patients had a detailed cardiac history and exam and cardiac labs as well as extensive imaging with 3T cardiac magnetic resonance imaging (MRI) to evaluate anatomy and function and computed tomography angiography to look for any coronary artery disease and determine the coronary arterial calcium score. A high score is a sign of atherosclerosis and increased risk of cardiac morbidity, Simone said.

The groups were similar with regard to patient characteristics and exam and lab results. "There were very few coronary events such as myocardial infarction or heart failure and they did not differ between the groups," he said.

CT angiograms showed that there was no significant difference in the extent of atherosclerosis between the two arms. And in the breast-conserving treatment group, there was no difference in the extent of atherosclerosis "in any segment of any vessel" between the breast that was irradiated and the breast that was not.

There was a trend for patients from either group who received chemotherapy to have visible atherosclerosis.

Diastolic function, including peak filling rate and diastolic volume recovery, as well as peak midwall strain, chamber mass, volume, and function were similar between the two treatment groups. Among BCT patients, cardiac structure and function were similar for right- or left-breast tumors.

The median coronary arterial calcium score was also similar in both groups.

The Bottom Line

"There was absolutely no difference in cardiac toxicity between the two groups," Simone concluded, adding that he believes that any potential cardiac morbidity had been attenuated with modern treatment planning, CT simulation, and 3D planning.

Patients treated today would have even less of a risk of cardiac toxicity because newer radiotherapy techniques are even safer for the heart, he said.

The moderator of an ASTRO news briefing about interesting breast cancer research reported at the meeting, Bruce G. Haffty, MD, Chair of Radiation Oncology at Robert Wood Johnson Medical School of the University of Medicine and Dentistry of New Jersey, said the findings "should give some reassurance to our patients that with modern techniques, radiation does not compromise cardiac function or cause cardiac toxicity." OT