

## Recommendation to omit radiation therapy after lumpectomy is not frequently implemented

January 27 2016

Nearly two thirds of U.S. women age 70 or older with stage I breast cancer<sup>1</sup> who undergo lumpectomy and are eligible to safely omit subsequent radiation therapy (RT) according to national cancer guidelines still receive this treatment, according to new study results. The researchers looked at more than 205,000 cases of breast cancer nationwide, and their study is published as an "article in press" on the *Journal of the American College of Surgeons* website in advance of print publication.

After a lumpectomy, also called a breast-sparing or breast-conserving operation, radiation usually is given to the breast to reduce the chance of the cancer returning. However, treatment recommendations changed in 2004 for a select group of elderly breast cancer patients after research found that postoperative RT did not significantly prolong their survival over five years compared with women who received no RT.<sup>2</sup>

In the new study, the researchers compared post-lumpectomy RT utilization before and after 2004 and found that RT use decreased only 3 percent among women for whom the value of this treatment is questionable.

This finding demonstrates a lack of compliance with or poor awareness of the recommended treatment for what probably is a large number of breast cancer patients, said lead author Quyen D. Chu, MD, MBA,



FACS, professor of surgery at Louisiana State University (LSU) Health Sciences Center, Shreveport.

"Why are we as a nation mostly not following a national guideline on breast cancer treatment?" Dr. Chu asked. "This guideline applies to a significant proportion of patients. About 30 percent of new diagnoses of invasive breast cancer<sup>3</sup> are in women 70 and older."

In 2004 researchers of a multicenter clinical trial, known as the Cancer and Leukemia Group B (CALGB) 9343 trial,<sup>2</sup> advised that it is reasonable to omit RT in women with certain characteristics that put them at low risk of dying of cancer. Those characteristics were as follows:

- age 70 or older
- stage I breast cancer measuring 2 cm or less (roughly threefourths of an inch or smaller) that has not spread to the lymph nodes on clinical examination
- estrogen-receptor-positive tumor status (the most common type of breast cancer)
- surgical removal of the tumor with lumpectomy and negative surgical margins, meaning no more cancer is observed at the edge of the removed tumor
- subsequent long-term anti-hormone therapy such as tamoxifen

They based this recommendation on their study finding that no difference existed in the length of overall survival of these elderly lumpectomy patients between those treated with and without postoperative RT plus tamoxifen.

Subsequently, organizations including the National Comprehensive Cancer Network and the American Cancer Society updated their stage I breast cancer treatment guidelines to include when to consider omitting



## RT.4

To find out whether clinical practice changed after the CALGB 9343 trial, Dr. Chu and his co-investigators evaluated RT use using the National Cancer Data Base (NCDB), a joint project of the American College of Surgeons Commission on Cancer (CoC) and the American Cancer Society. NCDB captures an estimated 70 percent of newly diagnosed cancer cases in the United States from approximately 1,500 cancer programs accredited by the CoC.

From 2.8 million breast cancer cases diagnosed between 1998 and 2012 and listed in the database, the researchers identified 205,860 women at least 70 years old who underwent lumpectomy for treatment of hormone-receptor-positive stage I breast cancer. Approximately 50 percent of the women received their cancer diagnosis before publication of the CALGB criteria (1998 to 2004), and the other half, after publication (2005 to 2012).

In the pre-CALGB group 31.2 percent of patients did not undergo RT versus 34.2 percent in the post-CALGB group, a decrease in RT use of 3 percent, the investigators reported. Patients ages 80 and older had the greatest decrease in RT use among the different age groups according to the article. However, Dr. Chu said after the CALGB 9343 trial, 30 percent of patients ages 85 years and older still received RT.

Possible side effects of breast RT include breast swelling, pain, skin discoloration or firmness, and shrinkage in the size of the breast.

The researchers reported a large variation in RT use depending on demographic, tumor, and other characteristics.

Poorer access to cancer care, rather than better adherence to the guideline, may explain some differences observed in RT use, Dr. Chu



said. For instance, significant predictors of lowest RT use included residence in the central southeastern states (Kentucky, Tennessee, Mississippi, and Alabama) or in a small rural population not near a metropolitan area, or an increased distance between the patient's home and the hospital that reported the cancer. However, insurance status did not influence RT use, he noted.

Alternatively, Dr. Chu suggested that some women might have chosen to receive RT to reduce their worries about a recurrence. In the initial CALGB 9343 trial, women who did not receive RT had a 3 percent higher breast cancer recurrence rate over five years compared with those who did undergo RT.<sup>2</sup>

Another possible explanation given by Dr. Chu for the apparently low adoption of the guideline is the increasing popularity in the past decade of faster forms of RT, such as brachytherapy. A course of brachytherapy typically takes only five days versus up to six weeks with conventional external beam RT according to Dr. Chu. The newer technique involves implanting radioactive materials (seeds or in catheters) into the breast cavity.

Several other predictors of not receiving RT surprised the researchers, Dr. Chu said. Patients were less likely to undergo RT if they did not adhere to long-term anti-hormone therapy and if they had "residual," or remaining, tumor after lumpectomy. Although Dr. Chu said they could only speculate on the possible reasons why these patients tended to not receive RT as experts recommend, further analysis of the study data showed a correlation between advanced age and residual tumor.

"Surgeons should try to achieve negative lumpectomy margins for patients who are 85 and older because they are less likely to receive radiation treatment," Dr. Chu suggested.



The CALGB 9343 trial results have been confirmed in a 10-year update of that trial and in other recent studies.<sup>5</sup>

Dr. Chu said he hopes the message of when to withhold this breast cancer treatment receives better awareness in the community.

"Patients often ask a surgeon, do I need this operation? Maybe it's time to ask your doctor, do I need radiation treatment for my <u>breast cancer</u>?" Dr. Chu said.

More information: Quyen D. Chu et al. Impact of Cooperative Trial and Sociodemographic Variation on Adjuvant Radiation Therapy Usage in Elderly Women (≥70 years) with Stage I, Estrogen Receptor-Positive Breast Cancer: Analysis of the National Cancer Data Base, *Journal of the American College of Surgeons* (2016). DOI: 10.1016/j.jamcollsurg.2015.12.018

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## Provided by American College of Surgeons

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