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MD's Dispute Study on Breast Cancer Brachytherapy

Top Experts Say APBI Radiation Treatment Is Safe and Effective

A recent study on a sophisticated form of radiation treatment for breast cancer is inaccurate and has caused unnecessary concern among many patients, according to four top physician researchers.

Their target is a controversial study on breast brachytherapy, which is also known as accelerated partial breast irradiation (APBI). The data by some MD Anderson (MDA) Cancer Center researchers was presented at the recent San Antonio Breast Cancer Symposium.

The doctors challenged the data – and reassured APBI patients – during a press teleconference they organized to express their concerns about the study. The participating physicians included:

- ***Robert Kuske, MD, (Scottsdale, AZ)*** *Co-Principal Investigator, NSABP B-39 study comparing five-day APBI to six-week whole breast irradiation*
- ***Peter D. Beitsch, MD, FACS, (Dallas, TX)*** *Co-Principal Investigator of the American Society of Breast Surgeons' MammoSite Registry*
- ***Jayant Vaidya, MD, (London, U.K.),*** *pioneer of targeted intraoperative radiotherapy (IORT)*
- ***Rakesh Patel, MD, (Pleasanton, CA),*** *Chairman, American Brachytherapy Society*

The San Antonio abstract claimed an older form of APBI was associated with increased toxicity and higher rates of subsequent mastectomy in Medicare patients, compared with standard whole breast irradiation (WBI).

Disputing those conclusions, Rakesh Patel, MD said: "APBI remains a safe and effective form of treatment for appropriate patients, improves quality of life, and is now less expensive than customary forms of whole breast irradiation." Dr. Patel, moderator of the teleconference, is chairman of the American Brachytherapy Society.

The physicians said the flawed MD Anderson study could lead women to mistakenly conclude APBI is inferior to WBI and stressed several points:

1. The study is flawed in that:

    a) The data did not report cancer-recurrence rates.
    b) The study states that mastectomy rates equate to recurrence rates, which is not true.
    c) The reported complication rates are unrealistically high and differ dramatically from better-done studies in scientific literature.

2. Patients now have access to newer and better forms of APBI that have been developed since the Medicare data was created.

The physicians are internationally known as leading researchers in breast cancer radiotherapy. While the doctors convened the teleconference to talk about APBI, they also provide patients with whole breast irradiation. Among them they have pioneered research in three different forms of breast brachytherapy: Interstitial, MammoSite, IORT and SAVI.

The MDA study was based on Medicare billing claims for more than 130,000 patients over the age of 66 who were diagnosed with early-stage breast cancer between 2000 and 2007 and received a lumpectomy and radiation.

Researchers observed an increase of 1.8 percent in the rate of mastectomies among women who received breast brachytherapy. The older, “balloon” form of brachytherapy covered by the data was also associated with somewhat higher toxicity and complication rates.

“These data have serious limitations, and should not influence current treatment recommendations for women with early-stage breast cancer who fit eligibility criteria for APBI,” said Robert Kuske, MD, a radiation oncologist. Dr. Kuske pioneered APBI 20 years ago.

Among several shortcomings of the San Antonio study data, said Dr. Kuske, is the fact that it covers “an antiquated balloon catheter with a single channel. Since that time, technology has dramatically improved to encompass the use of newer, multichannel applicators. The side effects and toxicity seen with these modern technological advances are far less than the results presented in the study.”

Also critical of the data was Peter Beitsch, MD, FACS, a Dallas surgeon, co-principal investigator of the American Society of Breast Surgeons MammoSite Registry and co-author on 12 APBI papers.

“This retrospective study of an inherently inaccurate database, which has questionable outcomes and unvalidated ‘surrogate endpoints,’ should be looked at with appropriate skepticism, in the face of 20 years of retrospective studies and two prospective randomized trials to the contrary,” said Dr. Beitsch.

Jayant Vaidya, MD, a leading British researcher of a form of APBI called intraoperative radiotherapy (IORT), noted that along with other APBI modalities, IORT studies have so far shown the therapy to be equivalent to whole breast irradiation.

Among APBI patients troubled by reports of the MD Anderson study was Southern California resident Marion Brown, 80.

When she saw a TV news report on the study, she said, “My first thought was, ‘My God, am I going to have to go through five weeks of daily radiation?’ I had a bad couple of hours until I was able to speak to my surgeon.”

Brown was told by Dr. Deanna Attai, her surgeon, that APBI is supported by strong clinical evidence: “She assured me that the news I saw did not reflect the results of the published clinical research.”

The three major medical societies involved in the research and use of APBI have also issued statements of concern about the study conclusions. The organizations are the American Society of Breast Surgeons , the American Brachytherapy Society, and the American Society for Radiation Oncology.