

Therapy for Small, HER2-Positive Breast Tumors Is Highly Effective After 10 Years

Dana-Farber breast cancer researchers performed genomic testing, yielding findings may help personalize treatment in the future.

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Follow-up results of a clinical trial that defined the standard treatment for patients with small, HER2-positive breast cancer that hasn't spread to the lymph nodes reinforce the long-term effectiveness of the therapy.

In a paper posted online February 28 by the journal *Lancet Oncology*, researchers report that 10 years after being treated with the regimen — a combination of the drugs paclitaxel and trastuzumab following breast surgery — 96.3% of participants in the trial were alive without a recurrence of their cancer. A genomic analysis of tumor tissue from some of the participants provided clues to which patients were less likely to have a cancer recurrence — information that may help further personalize treatment in the future.

“Previous large clinical trials that showed the benefit of adjuvant [post-surgical] trastuzumab and chemotherapy for patients with early-stage HER2-positive breast cancer included few patients with stage I cancer,” says Sara Tolaney, MD, MPH, of Dana-Farber Cancer Institute, lead author of the new study and principal investigator of the trial. “The 10-year results of our trial, which was open to patients with small, HER2-positive breast tumors, confirm that the drug combination produces excellent long-term outcomes for this group.”

HER2-positive breast cancer is marked by higher-than-normal levels of the HER2 protein, which promotes the growth of cancer cells. It accounts for about 20% of breast cancers and, if left untreated, has a worse prognosis than breast cancers that test negative for HER2.

The trial, dubbed APT (for Adjuvant Paclitaxel and Trastuzumab), included 406 patients with HER2-positive breast tumors smaller than 3 cm that hadn't spread to the lymph nodes or had spread to just one. After undergoing breast surgery, patients received weekly doses of paclitaxel, a chemotherapy agent, and trastuzumab, a drug targeting the HER2 protein, for 12 weeks. Patients then received trastuzumab either weekly or every three weeks over a 40-week period.

The follow-up analysis found that an average of 10.8 years after treatment, 94% of participants were alive and 96.3% had no recurrence of the disease. Breast cancer-specific survival — a measure of how many hadn't died of breast cancer — was 99.1%.

In conjunction with the trial, researchers performed genomic testing on tumor tissue samples from 284 participants. They found that tumors from patients with low HER2DX risk scores — a tool that utilizes gene expression — were considerably less likely to have a cancer recurrence than those with higher scores. The finding, if confirmed by additional research, may be a step toward more personalized treatment of this form of breast cancer, potentially enabling doctors to identify patients who will benefit from less intense treatment or don't require systemic treatment at all, the study authors say.

The senior author of the study is Eric Winer, MD, formerly of Dana-Farber and now director of the Yale Cancer Center. Co-authors are Michelle DeMeo, Molly DiLullo, Ann Partridge, MD, MPH, Adrienne Waks, MD, Harold J. Burstein, MD, PhD, Noah Graham, MB, and Nabihah Tayob, PhD, of Dana-Farber; Paolo Tarantino, MD, of Dana-Farber, the University of Milan, Milan, Italy, and the European Institute of Oncology, IRCCS; Jorge Gomez Tejeda Zanutto, PhD, and Nikhil Wagle, MD, of Dana-Farber and the Broad Institute of MIT and Harvard; Ian E. Krop, MD, PhD, formerly of Dana-Farber and now of the Yale Cancer Center; Laia Parè, PhD, Guillermo Villacampa, MSc, Patricia Villagrasa, PhD, and Aleix Prat, MD, PhD, of Reveal Genomics, Barcelona, Spain; Chau T. Dang, MD, of Memorial Sloan Kettering Cancer Center; Clifford A. Hudis, formerly of Sloan Kettering and now of the American Society of Clinical Oncology; Denise A. Yardley, MD, of Sarah Cannon Cancer Center, Nashville, Tenn.; Beverly Moy, MD, MPH, of Massachusetts General Hospital; P. Kelly Marcom, MD, of Duke Cancer Institute; Kathy S. Albain, MD, of Loyola University Medical Center; Hope S. Rugo, MD, of the University of California, San Francisco; Matthew J. Ellis, MB, PhD, of Baylor Clinic Lester and Sue Smith Breast Center, Houston, Tex.; Iuliana Shapira, MD, of Regional Cancer Care Associates, New Hyde Park, New York, N.Y.; Antonio C. Wolff, MD, of Johns Hopkins Sidney Kimmel Comprehensive Cancer Center; Lisa A. Carey, MD, of Lineberger Comprehensive Cancer Center, University of North Carolina School of Medicine; Romualdo Barroso-Sousa, MD, of Brasilia Hospital, Brasília, Brazil; and Jakob Weiss of the Broad Institute of MIT and Harvard.

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