

Antibody-Drug Conjugate Shows Promise in Patients with Early Stage HER2+ Breast Cancer

The antibody-drug conjugate is highly effective in preventing recurrence in patients with early stage HER2+ breast cancer, trial finds.

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A year of treatment with a medicine made of an antibody and chemotherapy drug has proven highly effective in preventing stage 1 HER2-positive breast cancer from recurring in patients, a team led by Dana-Farber Cancer Institute researchers has found.

In a clinical trial involving 512 patients with the earliest stage of breast cancer that tested positive for the HER2 protein, 97% of those treated with trastuzumab emtansine (T-DM1) after surgery were alive and free of invasive cancer five years after treatment. The results, published online [June 27] in the *Journal of Clinical Oncology*, suggest that T-DM1 is a reasonable treatment approach for this stage 1 population, the study authors say.

In conjunction with the trial, researchers looked for biomarkers of whether the cancer was likely to recur even after treatment with T-DM1. They found that patients with high scores on the HER2DX test — which weighs clinical factors and the activity of four genes within tumor tissue — had a greater risk of recurrence.

“Patients with stage 1 HER2-positive breast cancer have recurrence rates of 5 to 30%. Post-surgical treatment with chemotherapy and the antibody trastuzumab, which binds to HER2, can significantly reduce the risk of recurrence in these patients. But the side effects can have a detrimental impact on patients’ quality of life,” says study lead author Paolo Tarantino, MD, of Dana-Farber and the University of Milan (Italy). “In this study, we evaluated T-DM1, which links trastuzumab to a powerful chemotherapy agent, for effectiveness and toxicity in this group of patients.”

T-DM1, known as an antibody-drug conjugate, is currently approved for post-surgical, or adjuvant, treatment of patients with HER2-positive breast cancer which remains after pre-surgical treatment, and is also approved for patients with metastatic HER2-positive breast cancer. The new study, a randomized phase II trial dubbed ATEMPT, involved patients with a stage 1 HER2-positive cancer, meaning it was small and without lymph node involvement.

The trial enrolled 512 patients at cancer centers across the U.S.: 384 of the participants were treated with T-DM1 and 128 were treated with chemotherapy and trastuzumab. Investigators found that, five years after treatment, 97% of patients receiving T-DM1 had no evidence of cancer recurrence. The rate of clinically relevant toxicities was similar in the T-DM1 group and the chemotherapy-and-trastuzumab group. However, patient-reported outcomes from this study show better quality of life with T-DM1, that was associated with less neuropathy, less hair loss and better work productivity than chemotherapy and trastuzumab.

Results of HER2DX testing showed that patients whose risk score was above an established threshold had a significantly higher chance of a cancer recurrence.

“The ATEMPT trial has taught us that one year of T-DM1 after surgery for patients with a stage 1 HER2-positive cancer leads to outstanding long term outcomes, making it a reasonable treatment approach for select patients,” says senior author [Sara Tolaney, MD, MPH](#), Chief, Division of Breast Oncology, Dana-Farber Cancer Institute.

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