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Clinical trial finds concurrent therapy not necessary to achieve high pathological in breast cancer

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Giving trastuzumab and anthracyclines at the same time is effective at treating HER-2-positive breast cancer, but there is concern that this combination can be associated with an increased risk of cardiac toxicity. New research from Aman Buzdar M.D., professor and vice president of clinical research at The University of Texas MD Anderson Cancer Center, and colleagues in the Alliance for Clinical Trials in Oncology, shows these agents do not need to be given concurrently to achieve a high rate of complete pathological remission.

The findings, published in the journal *Lancet Oncology*, investigated the timing of trastuzumab administration with anthracycline and taxane chemotherapy.

"In a previous MD Anderson study concurrent administration of trastuzumab with chemotherapy, including anthracyclines, demonstrated high pathologic complete response rates in breast cancer patients with HER-2-positive disease," Buzdar said. "In the current trial, we examined whether concurrent administration of anthracyclines with trastuzumab was necessary to achieve the high pathologic response rates or whether these drugs could be given sequentially. Findings show that high pathologic response rates were observed in both treatment groups with similar cardiac safety profiles in both arms of the trial."

The randomized phase III trial enrolled 280 women with operable

HER-2 positive invasive breast cancer at 36 centers across the United States from September 2007 through December 2011.

Patients were randomly assigned to two treatment regimens, 138 in the sequential group who received fluorouracil, epirubicin and cyclophosphamide on day one of a 21-day cycle for four cycles followed by paclitaxel plus trastuzumab weekly for 12 weeks.

The 142 patients in the concurrent group were treated with paclitaxel and trastuzumab weekly for 12 weeks. This was followed by fluorouracil, epirubicin and cyclophosphamide on day one of a 21-day cycle with trastuzumab on days one, eight and 15 of the 21-day cycle for four cycles.

Each patient in both arms of the trial received a total of one year of trastuzumab therapy. The primary endpoint of the trial was the proportion of patients who had pathological complete remission in the breast, defined as the percentage of women who started the neoadjuvant treatment with no histological evidence of disease in the breast at surgery.

"If a patient achieves complete pathological remission, we know from previous experience that more than 90 percent continue to remain free of their disease at longer follow-up," Buzdar said, who also served as the principal investigator of the trial.

Similar responses seen in both treatment groups

The findings showed that 56.5 percent of patients in the sequential group had a complete pathological remission versus 54.2 percent of the patients who received the concurrent regimen, a difference that was not significant.

Next Steps

Researchers are now in the process of analyzing the genomic profiles of the breast tumors that were obtained during the trial to better understand patient responses. The purpose is to evaluate the specific characteristics of a tumor that is sensitive to these therapies, as well as identify the profiles that are resistant.

Kelly Hunt, M.D., professor in MD Anderson's Department of Surgical Oncology and co-principle investigator of the trial, said if we can identify the patients most likely to have pathologic complete response with therapy, we can reduce or potentially eliminate surgery for these patients in the future.

Provided by University of Texas M. D. Anderson Cancer Center

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