

Triple drug combination is promising option to treat metastatic HER2+ breast cancer

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Combining two chemotherapy drugs with trastuzumab (Herceptin) to treat women who have metastatic HER2+ breast cancer may offer physicians another choice in their treatment options.

At the 45th Annual Meeting of the American Society of Clinical Oncology (ASCO), researchers from the Mayo Clinic campus in Florida report that using a combination of capecitabine, vinorelbine, and trastuzumab offers a treatment option that is at least as beneficial as other current options - and doesn't cause hair loss in <u>patients</u>.

"This is a very well tolerated regimen. The combination is a good example of an excellent therapeutic ratio: good activity and low toxicity," says the study's senior investigator, Edith Perez, M.D., director of Mayo Clinic's Breast Center in Jacksonville.

The clinical trial is the first in the United States to study this particular combination of therapies in patients with HER2+ metastatic breast cancer, researchers say. The chemotherapy regimen was previously tested in Europe and demonstrated good anti-tumor activity and low toxicity, so Mayo researchers combined it with Herceptin, says the study's lead author, Winston Tan, M.D., a medical oncologist at Mayo Clinic.

Sixty-seven percent of the 45 patients in this trial responded to treatment, with their tumors decreasing in size by at least 30 percent. Historic response to conventional drug regimens (one chemotherapy



drug with Herceptin) that are currently used to treat metastatic HER2+ breast cancer is about 50 percent, Dr. Tan noted.

"The results are encouraging, and would support a larger, randomized Phase III study," he says. "This is a Phase II study of this triple combination, so we would need to study this treatment against the standard best two-drug treatment in a randomized Phase III study to know if this triplet is more effective."

"This regimen seems to be a very reasonable choice, and it offers the added advantage that women who use it do not lose their hair," he says. The <u>drug combination</u> used most commonly for patients with HER2+ breast cancer that has spread - paclitaxel or docetaxel with trastuzumab - always causes hair loss, Dr. Tan says.

All of the agents are approved for use by the U.S. Food and Drug Administration for cancer, although vinorelbine has not been approved for this particular treatment regimen in the U.S., the researchers say.

Capecitabine chemotherapy is not usually paired with trastuzumab because some studies had suggested it does not offer a synergistic, or additive, benefit. However, Dr. Tan says that newer research has shown the combination is in fact promising.

Among the patients studied, 28 (58 percent) had a partial response, a reduction in the size of the metastatic tumor of more than 30 percent by computed tomography. Four patients had a complete response with no more evidence of metastasized tumors on diagnostic scans, the researchers say.

Average survival was improved when compared historically to traditional treatment, Dr. Tan says. "Normally, survival for metastatic <u>breast cancer</u> is two years," he says. "In this study, average survival was 27 months."



He cautioned that these results should be validated in a Phase III study.

"The toxicity was tolerable, no more than is seen with a two-drug regimen," he says. The majority of patients (61 percent) experienced a low white blood count, but only about ten percent of patients had fatigue or other common side effects.

Tan stressed that this regimen does not offer curative treatment, but it offers patients an improved quality of life compared to other commonly used regimens.

"It is very difficult to treat cancer that has spread, but we believe that combining treatments together is important to help shrink tumors that are rapidly growing," he says.

He adds that 80 percent of the patients who showed benefit had been treated with other chemotherapy drugs - mostly anthracyclines and paclitaxel - and at least half of the patients had used trastuzumab in the adjuvant or metastatic setting as well. "They still got a response to these combination of two chemotherapies plus the biological agent, and that is encouraging," he says.

Source: Mayo Clinic (<u>news</u> : <u>web</u>)

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