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Mayo Clinic

## Mayo Clinic researchers say breast cancer survival improves Herceptin used with chemotherapy

SAN ANTONIO — Using Herceptin with chemotherapy, instead of after, clearly improves treatment of women with HER2+ breast cancer, and should be the new standard of care, says a Mayo Clinic researcher who led what is regarded to be a key clinical trial determining the best use of Herceptin.

Patients using Herceptin and chemotherapy at the same time had a relative 25 percent reduction in the risk of recurrence of cancer or death, compared with women who used Herceptin after chemotherapy, says Edith Perez, M.D., chair, North Central Cancer Treatment Group (NCCTG) Breast Committee and a breast cancer researcher at the Mayo Clinic campus in Jacksonville, Fla. She presented the findings of the study at the Cancer Therapy & Research Center-American Association for Cancer Research (CTRC-AACR) 2009 San Antonio Breast Cancer Symposium.

These findings may have global implications for women being treated for HER2+ breast cancer, which makes up 20 percent to 25 percent of all cases, Dr. Perez says.

In the United States, for example, Herceptin is approved for use on either a sequential or concurrent treatment schedule with adjuvant chemotherapy (that is, chemotherapy following surgery). In much of the rest of the world, Herceptin is used sequentially, she says.

"The results of this trial have been eagerly awaited in the U.S. and in many nations as this is the only trial developed to define the optimal way to incorporate Herceptin in the context of adjuvant chemotherapy," Dr. Perez says. "The goal was to decrease the risk of cancer recurrence, and we have shown that concurrent use is the best way to achieve that."

"This could mean that up to 10,000 women around the world each year may have a better outcome if Herceptin is used along with chemotherapy. Given that, I believe this study will lead to a global re-evaluation of how Herceptin is used," she says.

Every year, approximately 250,000 women worldwide are eligible to be treated with Herceptin for invasive HER2+ breast cancer, says Dr. Perez.

Some data on part of the study, the (NCCTG) clinical trial N9831, have been released before, such as in 2005 in the New England Journal of Medicine. But this is the first time that mature outcome information on patients given sequential vs. concurrent treatment is available. The trial enrolled women who had surgery to treat Stage I-III invasive HER2+ breast cancer.

The study is the only phase III randomized clinical trial to assess chemotherapy alone (Arm A) versus either sequential (Arm B) or concurrent (Arm C) incorporation of Herceptin in patients. Chemotherapy used in the study was doxorubicin and cyclophosphamide then paclitaxel, and was administered for approximately six months. Herceptin was given for 52 weeks.

Two different comparisons were made in the study. The first looked at outcomes in Arm A (1,087 women) compared to Arm B (1,097 women) and found that five-year disease-free survival (defined as no cancer recurrence) was increased from 72 percent (Arm A) to 80 percent (Arm B). Researchers also tabulated 222 events (cancer recurrence or death) in Arm A compared to 164 events in Arm B.

The second comparison looked at 954 women enrolled in Arm B with 949 women enrolled in Arm C. Researchers found that patients in Arm C fared the best overall. Their five-year disease-free-survival increased to 84 percent, compared to 80 percent in Arm B.

"The study demonstrated that adding Herceptin clearly improves disease-free survival, with improvement if given after chemotherapy, but even more improvement if started concurrent with taxane-based chemotherapy," Dr. Perez says. "So, our recommendation for practice and regulatory agencies around the world is that Herceptin be given concurrent with adjuvant chemotherapy."

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This study was conducted as a collaborative effort, with researchers participating via the National Cancer Institute (NCI)-funded NCCTG, the Eastern Cooperative Oncology Group (ECOG), the Cancer and Leukemia Group B group (CALGB), and the Southwest Oncology Group (SWOG). In addition to NCI support, funding was also provided by Genentech.

## **About NCCTG**



NCCTG is a national clinical research group sponsored by the National Cancer Institute. Its research and administration are based at Mayo Clinic. NCCTG consists of cancer specialists at community clinics, hospitals and medical centers in the United States and Canada. The group is dedicated to bringing clinical trials with promising new cancer therapies to communities where patients live.

## **About Mayo Clinic**

Mayo Clinic is the first and largest integrated, not-for-profit group practice in the world. Doctors from every medical specialty work together to care for patients, joined by common systems and a philosophy of "the needs of the patient come first." More than 3,700 physicians, scientists and researchers, and 50,100 allied health staff work at Mayo Clinic, which has campuses in Rochester, Minn; Jacksonville, Fla; and Scottsdale/Phoenix, Ariz.; and community-based providers in more than 70 locations in southern Minnesota., western Wisconsin and northeast Iowa. These locations treat more than half a million people each year. To obtain the latest news releases from Mayo Clinic, go to www.mayoclinic.org/news. For information about research and education, visit www.mayo.edu. MayoClinic.com (www.mayoclinic.com) is available as a resource for your health stories.

VIDEO ALERT: Additional audio and video resources, including comments by Dr. Perez describing the research, are available on the Mayo Clinic News Blog. These materials also are subject to embargo but may be accessed in advance by journalists for incorporation into stories. The password for this post is perezsabcs.