Capecitabine improved outcomes for breast cancer patients with disease after presurgery chemo

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Treatment with the chemotherapy agent capecitabine increased disease-free survival for women with HER2-negative breast cancer that was not eliminated by presurgery chemotherapy, according to results from the phase III CREATE-X clinical trial presented at the 2015 San Antonio Breast Cancer Symposium, held Dec. 8-12.

Treatment given to shrink or eliminate a tumor before surgery is called neoadjuvant therapy. In some patients with breast cancer treated with neoadjuvant chemotherapy, residual invasive cancer can be detected in breast tissue samples and lymph nodes removed during surgery. These patients tend to have worse long-term outcomes compared with women who respond completely to neoadjuvant therapy.

"It has been suggested that patients with residual invasive disease after neoadjuvant chemotherapy have chemoresistant breast cancer, but there have been no large-scale clinical trials to test whether adjuvant systemic chemotherapy is beneficial for these patients," said Masakazu Toi, MD, PhD, a professor at Kyoto University Hospital in Japan, and founder and senior director of the Japan Breast Cancer Research Group (JBCRG). "CREATE-X was designed to evaluate this clinical question by testing whether capecitabine could improve disease-free survival for patients with residual invasive disease after neoadjuvant chemotherapy.

"These first efficacy results show that after two years of follow-up, disease-free survival is significantly improved by addition of capecitabine to standard therapy," continued Toi. "These data are exciting, because the side effects of the treatment were manageable and the benefit of capecitabine treatment was clear."

Toi and colleagues enrolled 910 patients in the trial all of whom had HER2-negative breast cancer and residual invasive disease after neoadjuvant therapy that included an anthracycline and/or a taxane. All patients received standard treatment and were randomly assigned to capecitabine or no additional therapy. The 455 patients randomly assigned capecitabine received eight cycles, each lasting 21 days, with 1,250 milligrams of the chemotherapeutic per meter squared twice a day for the first 14 days, followed by seven days with no treatment.

The researchers found that, two years after starting the study, patients who were assigned capecitabine had a 30 percent reduced risk of disease recurrence compared with those assigned no capecitabine. Disease-free survival was 87.2 percent for those assigned capecitabine and 80.4 percent for those assigned no capecitabine.

According to Toi, a recent analysis with updates showed that there was a significant difference in median overall survival between the two groups. Two-year median overall survival was 96.4 percent for those assigned capecitabine versus 94.2 percent for those assigned no capecitabine.

Toi also noted that the researchers are conducting subset analyses to determine whether certain groups of patients benefited more than others from capecitabine. For example, they are looking at whether hormone-receptor status affected outcomes, he said.

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