Capecitabine monotherapy does not improve survival in elderly patients with early-stage breast cancer

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In elderly breast cancer patients with moderate- to high-risk early-stage disease for whom standard chemotherapy is too toxic, the chemotherapy capecitabine, which causes fewer side effects than the standard chemotherapy agents, did not improve outcomes when tested as monotherapy, according to data from the phase III ICE trial presented at the 2014 San Antonio Breast Cancer Symposium, held Dec. 9–13.

"We tested capecitabine as single-agent chemotherapy in elderly women with early-stage breast cancer, who also took the bisphosphonate, ibandronate. After 61 months of follow-up, we found no difference in disease-free survival and overall survival between those who took capecitabine plus ibandronate and those who took ibandronate alone," said Gunter von Minckwitz, MD, chairman of the German Breast Group and a professor of gynecology at University of Frankfurt in Germany.

"Combination chemotherapy should be tried with optimal supportive care even in elderly patients," von Minckwitz added.

"We used ibandronate because many patients at this age have osteopenia/osteoporosis, especially after chemotherapy. Bisphosphonates are also potentially preventive for breast cancer metastasis ," von Minckwitz said.

Although approximately 50 percent of newly diagnosed breast cancers arise in women older than 65, they are underrepresented in clinical trials, and frail elderly patients cannot be treated with conventional chemotherapy such as anthracyclines and/or taxanes, von Minckwitz explained. Subgroup analysis of an earlier trial, CALGB 49907, with metastatic breast cancer patients, showed capecitabine to be well tolerated in elderly patients, which served as a rationale for the study discussed here.

In the ICE study, of the 1,358 breast cancer patients ages 64 to 88 recruited between 2004 and 2008, 677 were randomly assigned to six cycles of capecitabine plus ibandronate, and 681 were randomly assigned to ibandronate only. About 80 percent of the patients in both groups had hormone receptor-positive disease and received a standard-of-care endocrine therapy.

The primary endpoint of the study was disease-free survival, and secondary endpoints included overall survival, and compliance and safety.

There was no difference in disease-free survival at the end of three years (85 percent in capecitabine group versus 84 percent in control group) and five years (79 percent in capecitabine group versus 75 percent in control group). There was no difference in overall survival at the end of three years (95 percent in capecitabine group versus 94 percent in control group) and five years (90 percent in capecitabine group versus 88 percent in control group).

About 8 percent of patients discontinued capecitabine treatment due to adverse events, and another 8 percent discontinued due to other reasons.

Thirty-one percent of patients in the capecitabine plus ibandronate group had grade 3 or 4 adverse events, compared with 8.7 percent in the ibandronate group.

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