MedicalXpress

DCIS patients receiving anastrozole reported symptoms different from those receiving tamoxifen

December 11 2015

Analysis of patient-reported outcomes (PRO), a secondary endpoint of the phase III, NSABP B-35 clinical trial, in which anastrazole and tamoxifen were compared in postmenopausal women with ductal carcinoma in-situ (DCIS) who underwent lumpectomy plus radiotherapy, found that there were no differences in outcomes related to quality of life (QOL) but some differences in outcomes related to symptoms in the two treatment groups, according to data presented at the 2015 San Antonio Breast Cancer Symposium, held Dec. 8-12.

The study confirmed some of the expected outcome differences in symptoms between the two drugs, which included more hot flashes with tamoxifen treatment and more vaginal problems and musculoskeletal complaints with anastrozole treatment.

"The NSABP B-35 trial enrolled 3,104 postmenopausal women with DCIS that was hormone receptor-positive, and the primary endpoint was to determine whether anastrozole was superior to tamoxifen. Anastrozole was found to be slightly but significantly better than tamoxifen in terms of breast cancer-free interval, and it was most beneficial in women younger than 60 years. There was no overall survival difference between the two treatments," said Patricia A. Ganz, MD, distinguished professor at UCLA schools of Medicine & Public Health and the Jonsson Comprehensive Cancer Center at UCLA. "The secondary endpoints of the trial were QOL and symptom outcomes, measured as PRO. Because

these two drugs have different side-effect profiles it was important to hear from women about their experiences to add that information to decision making."

PRO data is information obtained from each patient participating in the trial about her experience with the drug in terms of physical and emotional functioning (QOL) and various symptoms such as hot flashes, vaginal dryness, muscle and joint aches and pains (symptoms), Ganz explained. Since this was a double-blind trial, assessments were done without the bias of knowing what medication the women were taking, she added. "The information from this trial is important for women diagnosed with DCIS in the future who may be deciding which medication to take, along with their doctors," Ganz said.

Ganz and colleagues used data from 1,193 patients enrolled in the PRO portion of the NSABP B-35 trial. QOL and symptom data were collected at baseline prior to randomization to anastrazole or tamoxifen, every six months during the five years of treatment, and 12 months after treatment. QOL was measured using the SF-12 Physical Component Summary and Mental Component Summary. Symptoms were measured using the BCPT Symptom Checklist and other standardized methods. Patients were grouped into those younger than 60 years or those 60 years or older.

Five years after treatment, there were no differences in QOL outcomes. However, the severity of hot flashes was greater in those who received tamoxifen than those who received anastrozole, and this experience varied over time; the severity of musculoskeletal pain at 6-month to 24-month timepoints and vaginal problems was greater in those who received anastrozole than those who received tamoxifen. Sexual functioning was slightly worse for those who received anastrozole compared with those who received tamoxifen. There was no worsening of physical or emotional health and depression with either drug, and

overall, both drugs were found to be safe, according to Ganz. All symptoms were worse in women younger than 60 years than those 60 years or older, she added.

"Both of these drugs are excellent and can reduce the risk for breast cancer recurrence. Physicians and patients need to use this information along with the main trial outcomes to choose the optimal treatment for each woman. This is part of personalized or precision medicine," Ganz said.

More information: Abstract: S6-04, Title: Patient-reported outcome (PRO) results, NRG Oncology/NSABP B-35: A clinical trial of anastrozole (A) vs tamoxifen (tam) in postmenopausal patients with DCIS undergoing lumpectomy plus radiotherapy

Provided by American Association for Cancer Research