Two years of extended anastrozole therapy proved as effective as five years in clinical trial

December 7 2017

Postmenopausal women with hormone-receptor positive (HR-positive) breast cancer who took the aromatase inhibitor anastrozole for two years after an initial five years of adjuvant endocrine therapy received an equal benefit to those who took the drug for five additional years. The trial results suggest that a shorter duration of treatment may provide sufficient benefits while protecting women from harmful side effects, according to data from the ABCSG-16 phase III trial presented at the 2017 San Antonio Breast Cancer Symposium, held Dec. 5–9.

"In early-stage HR-positive breast cancer, the risk of relapse persists despite many advances in treatment," said Michael Gnant, MD, FACS, director and chairman of the Department of Surgery, Comprehensive Cancer Center, at the Medical University of Vienna. "Adjuvant treatment with aromatase inhibitors has been demonstrated to improve disease-free survival of postmenopausal women with this subtype of breast cancer. However, the optimal duration of extended AI has previously been unknown. Because this treatment leads to prolonged side effects and impacts quality of life, it is important to establish how long the treatment should be given."

In this trial, between February 2004 and June 2010, 3,484 postmenopausal women with HR-positive early-stage breast cancer were randomized in 71 centers in Austria to receive either two years or five years of extended adjuvant therapy. All had undergone an initial five

years of adjuvant endocrine treatment, either tamoxifen or other regimens containing aromatase inhibitors.

The trial's primary endpoint was disease-free survival. Secondary endpoints included overall survival, contralateral breast cancer (cancer in the opposite breast), fractures, and toxicity.

As of June 30, 2016, 78 percent of women in both trial arms were alive without recurrence; 757 women experienced recurrence, relapse, or other disease-free survival events: 377, or 22 percent, of women in the two-year group and 380, or 22 percent, of women in the five-year group.

There was also no significant difference in overall survival or time to contralateral breast cancer. Bone fractures were more likely in years three to five after randomization, suggesting that a longer duration of anastrozole treatment may be a risk factor for fractures.

Gnant said the trial results suggest that clinicians should consider a two-year course of anastrozole sufficient for most patients.

"I believe that these trial results should be implemented into daily practice at once," Gnant said. "There is simply no rationale to keep most patients on extended AI for longer than two years. This result can help save a lot of unnecessary side effects for many women around the world."

In addition to bone fractures, other side effects of prolonged AI therapy include bone fractures, hot flashes, arthralgia, sexual dysfunction, and hair loss.

Gnant cautioned that researchers cannot rule out benefits for some patients who take anastrozole for longer periods. He said future translational research using data and biomaterial from the patients in the

ABCSG-16 trial could be useful to characterize potential molecular factors that influence patients' response to anastrozole.

Provided by American Association for Cancer Research