Meta-analyses of global trials finds in favor of aromatase inhibitors

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Two separate meta-analyses of clinical trials from around the world that tested tamoxifen against aromatase inhibitor drugs in postmenopausal women with early breast cancer have each reached the same conclusion: aromatase inhibitors are more effective in preventing breast cancer from coming back. Patients using aromatase inhibitors had more than a 3 percent lower cancer recurrence 6-8 years after diagnosis, compared to women using tamoxifen alone.

One of these studies also found a significant survival benefit (1.6 percent) for users of aromatase inhibitors, but researchers say not enough time has passed since treatment to judge with confidence whether one drug is superior to another in saving lives. The joint analyses are being presented at the Cancer Therapy & Research Center-American Association for Cancer Research (CTRC-AACR) 31st annual San Antonio Breast Cancer Symposium. "Tamoxifen is a good drug, but it looks like aromatase inhibitors may be somewhat better," says James Ingle, M.D., a professor of oncology at Mayo Clinic, who is presenting the results on behalf of the Aromatase Inhibitors Overview Group (AIOG).

"The importance of these findings can be seen from the fact that 80,000 to 90,000 women in the United States alone are using endocrine therapy this year," he says. "While a three percent difference in cancer recurrence may not seem like much, it can mean that several thousand women could be spared from a breast cancer recurrence."

This international group includes leaders of all the major clinical trials that tested aromatase inhibitors against use of tamoxifen. AIOG is a subset of the Early Breast Cancer Trials Collaborative Group (EBCTCG), a global organization of researchers that studies all randomized evidence of therapies used to treat breast cancer to find insights not apparent from examining individual trials – a technique known as a meta-analysis. The AIOG collaboration is led by Professor Mitch Dowsett of the Royal Marsden Hospital, London, UK.

Tamoxifen and aromatase inhibitors are widely used to prevent recurrence of, or to treat, tumors that are estrogen-receptor positive (ER+), which comprise 70 to 80 percent of all breast cancers.

While individual studies of tamoxifen and aromatase inhibitor drugs (including anastrozole, exemestane and letrozole) have found benefit for aromatase inhibitors, it was critically important that data from all of these studies be pooled and examined, Professor Dowsett says. "This kind of analysis provides knowledge on such end points as survival and allows us to have confidence that the improvement in preventing the return of breast cancer applies to all subgroups of patients but that those at greatest risk of recurrence have most to gain. That is not possible even with a large individual trial," he says. "The global community has come together to do this."

The researchers divided the major studies into two different cohorts, or groupings. Cohort 1 consists of clinical trials in which patients were randomized to treatment with either tamoxifen or aromatase inhibitors for five years. Two trials were examined (ATAC and BIG 1-98) that included 9,856 patients. Cohort 2 included studies in which breast cancer patients received tamoxifen for two to three years and then were randomized to complete their five years of adjuvant endocrine therapy with tamoxifen or to receive an aromatase inhibitor for the remainder of their five years of therapy. These studies (ABCSG 8, ARNO 95,

IES/BIG 2-97, ITA) enrolled 9,015 patients.

The AIOG researchers found that in cohort 1, five years after beginning treatment, women using aromatase inhibitors had a 2.9 percent lower recurrence rate than those women who received tamoxifen; that decrease in recurrence rate increased to 3.9 percent at eight years after diagnosis. There were no statistically significant gains in survival between the two groups, Dr. Ingle says. "We need to follow these patients longer, for 10 to 15 years, to be sure of the effect on survival," he says.

In cohort 2, six years after the randomization, there was a 3.5 percent reduced risk of breast cancer recurrence in women who switched to aromatase inhibitors, compared to women who continued using tamoxifen. There was also a 1.6 percent reduced risk that patients using aromatase inhibitors would die from their disease – a statistically significant difference, Dr. Ingle says.

Professor Dowsett added, "These data should give clinicians and their patients greater confidence in understanding the relative effectiveness of these treatments in early breast cancer, but it is important to note that each drug is associated with its own set of side effects, and these also need to be considered in treatment decisions."

The researchers will continue mining the data in the future and specific projects are in the planning stages by the AIOG investigators. Dr. Ingle says, "The meta-analysis process provides the potential for learning more about cancer treatments than can be learned from individual clinical trials. The more we know, the better doctors can treat their patients."

Source: Mayo Clinic

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