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13 percent of women stop taking breast cancer drug because of side effects

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More than 10 percent of women with breast cancer stopped taking a commonly prescribed drug because of joint and muscle pain, according to a new study from researchers at the University of Michigan Comprehensive Cancer Center.

The women in the study were taking aromatase inhibitors, a type of drug designed to block the production of estrogen, which fuels some breast cancers. The treatment is generally given after surgery, chemotherapy or radiation therapy to prevent the cancer from returning. It's typically prescribed as one pill each day for five years. Use of these drugs has increased because they have been shown to be more effective than tamoxifen, the previous standard of care.

"We know 25 percent to 30 percent of women taking aromatase inhibitors have aches and pains. What was surprising here was the number of people who actually discontinued the drugs because of the side effects. Up to 15 percent of patients in previously reported studies stopped taking aromatase inhibitors for a variety of reasons, but in our study, we had 13 percent drop out just because of musculoskeletal problems," says N. Lynn Henry, M.D., Ph.D., lecturer in internal medicine at the U-M Medical School.

Henry will present the findings Sept. 8 in San Francisco at the 2007 Breast Cancer Symposium, a scientific meeting sponsored by five leading cancer care societies.

The study looked at the first 100 women enrolled in a trial to study how genetics play a role in the way individuals metabolize drugs and experience side effects. The women in this analysis were all post-menopausal following treatment for hormone-responsive breast cancer. They were assigned to take one of two aromatase inhibitors, exemestane or letrozole, and were followed for at least six months.

Study participants completed questionnaires about their health and side effects. If their reported joint and muscle concerns scored above a certain threshold on these questionnaires, the women were referred to a rheumatologist. Referrals were based on worsened pain or a change in function from the start of the study that resulted in more difficulty performing tasks such as rising from a chair, climbing out of a car or opening a jar.

In women who developed symptoms while taking the medication, the symptoms typically came on soon after starting treatment, at a median just under two months. The specific symptoms varied among the study participants, including tendonitis in the shoulder or wrist, inflammation in the knees or arthritis-type symptoms in the hands or hips. Some women reported joint pain while others had muscle pain.

The researchers are looking at interventions to determine how to manage the musculoskeletal side effects of these drugs. Symptoms almost always improve after stopping the drug. Researchers are trying to determine if switching to a different aromatase inhibitor will prevent the side effects in women who are affected, and they're testing interventions to manage the side effects. Another option is to switch from an aromatase inhibitor to tamoxifen, which also blocks estrogen but which is not known to cause as much joint and muscle pain.

Large randomized studies have shown aromatase inhibitors work better than tamoxifen in post-menopausal women to prevent breast cancer from

recurring. But, Henry points out, given the risks and side effects an individual woman might face, tamoxifen might be the better choice for some women.

“Tamoxifen has been around 20-30 years and has a long track record. We know about its benefits and its risks. Aromatase inhibitors are new, and we don’t have as much experience with them. We have to see in the long term which one ends up being better,” Henry says.

The goal of the larger study, which is led by the Consortium on Breast Cancer Pharmacogenomics, is to determine if breast cancer treatment can be personalized based on an individual woman’s genetic make-up. At this point, the sample size is not large enough to determine any genetic markers. Eventually, the researchers hope to enroll 500 women in the study. Finding a marker that predisposes a woman to more severe side effects could help doctors make personalized treatment decisions.

Source: University of Michigan