Patient-reported outcomes predict aromatase inhibitor adherence

December 13 2019

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If you want to predict which breast cancer patients will most likely stop taking aromatase inhibitors, check out their own responses to the health questions patients commonly answer in cancer clinical trials, according to research findings to be presented Friday, Dec. 13 at the San Antonio Breast Cancer Symposium.

Known as patient-reported outcomes, these surveys are used in trials to provide a patient perspective on a treatment and its impact on quality of life. Was the drug easy to take? What are your symptoms? Are you in pain? Are you able to work? Are you getting family support?

Answers can predict who is likely to stop taking aromatase inhibitors (AIs), pills taken by tens of thousands of postmenopausal women each year to treat their hormone-sensitive breast cancers, according to new research led by SWOG Cancer Research Network Vice Chair Dawn Hershman, MD. Women taking AIs who reported a poorer quality of life than their peers on the trial, and higher levels of both pain and endocrine symptoms, Hershman found, are more likely to stop taking their medication. So are women with negative beliefs about whether medication works—and whether they need it to keep their cancer from returning.

"We found a clear association between women who started the trial who were struggling with pain, poor quality of life, and endocrine symptoms—as well as beliefs that the medicine isn't helping—and those not taking the medication 36 months later," said Hershman, director of the Breast Cancer Program at NewYork-Presbyterian and Columbia University Irving Medical Center's Herbert Irving Comprehensive Cancer Center. "In this way, patient-reported outcomes can act like biomarkers. They can predict an outcome—and be used to personalize treatments."

The work will be presented the morning of Friday, Dec. 13 in a Spotlight Session highlighting notable poster presentations at the San Antonio Breast Cancer Symposium, the world's largest breast cancer research conference, with 7,500 attendees from more than 90 countries expected this year. The study was supported by SWOG, an international cancer clinical trials network funded by the National Cancer Institute (NCI) through the National Institutes of Health.

AIs are one of the most common treatments for breast cancer. The pills stop the production of estrogen in postmenopausal women, essentially starving hormone receptor-positive breast cancer cells. Many women must take AIs for a long as five years. About half report bone pain, and many have side effects that include headaches, nausea, and hot flashes. Quitting treatment can be dangerous. Women who do are at increased risk for their breast cancer returning.

Hershman and colleagues at SWOG have studied AIs intensely, searching for better ways for patients to manage AI associated pain, like acupuncture and depression drugs, and otherwise improve quality of life for women taking the pills. At the annual meeting of the American Society of Clinical Oncology (ASCO) in June, Hershman presented results of S1105, a SWOG randomized trial testing the effectiveness of text message reminders to improve AI adherence. Women on S1105 were taking AI pills for at least 30 days. The team found no difference in adherence rates between women who did and did not receive the texts. S1105 was the first long-term, prospective study to evaluate an intervention to improve cancer drug adherence.

To conduct this current study, Hershman and her team analyzed data from S1105. They reviewed information about 702 patients randomized into two groups—one that received a text twice a week for 36 months and one that did not. To see if they could find factors connected to non-adherence, researchers noted which patients quit taking the drugs, based on negative urine tests. They also studied patient-reported outcome (PRO) responses at baseline, or the start of the trial, and also at the end of the trial.

PROs included questions about:

- Joint pain levels on a 1-10 scale
- Endocrine symptoms, such as hot flashes, hot or cold sweats, and

weight gain
- Quality of life, such as mood, sleep, and walking ability
- Beliefs about medications, such as confidence in effectiveness

The team divided patient responses into two groups—those with low scores on each PRO measure (0-50 percent) and those with high scores on each PRO measure (50-100 percent). The association was clear. Those who were less satisfied with medications, and didn't see their usefulness, and those who had higher reports of pain, side effects, and poor quality of life, were more likely to stop taking AIs in the long-term.

"This means we can look at baseline PRO data and identify—early on—which patients are at risk of non-adherence," Hershman said. "Consistently taking a medication over time isn't as simple as being given a reminder. There are a host of factors that affect why patients may stop. We can use PROs data to tailor interventions so they're more likely to continue taking these potentially life-saving medications. That's good to know."

Provided by SWOG