

Women experiencing menopausal symptoms less likely to adhere to medication in breast cancer prevention trial

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Among women enrolled in the International Breast Cancer Intervention Study I (IBIS-I), those who had certain symptoms of menopause—nausea/vomiting and headaches—were significantly less likely to be adherent to the assigned medication 4.5 years after starting the treatment, according to data presented at the 2016 San Antonio Breast Cancer Symposium, held Dec. 6–10.

The placebo-controlled, randomized IBIS-I was designed to investigate whether five years of [tamoxifen](#) could prevent breast cancer in [women](#) at increased risk of developing the disease.

"Data from the IBIS-1 and other trials indicate that five years of tamoxifen treatment reduces risk of breast cancer by at least 30 percent for women at [increased risk](#) for the disease, and that this effect seems to last for at least 20 years," said Samuel G. Smith, PhD, Cancer Research UK postdoctoral fellow and university academic fellow at the University of Leeds in the United Kingdom. "However, the effectiveness of tamoxifen is dependent on its appropriate use for the duration of therapy.

"We were surprised to find that while [menopausal symptoms](#) do play a role in adherence to medication, the strength of the association between menopausal symptoms and adherence was similar among those women assigned placebo and those assigned tamoxifen," Smith continued. "This

suggests that women may be attributing menopausal symptoms that occur naturally as being caused by the medication that they are taking. Therefore, we need to find new and innovative ways of supporting women who experience these symptoms."

IBIS-I was carried out at the Wolfson Institute of Preventive Medicine, Queen Mary University of London, United Kingdom, with Jack Cuzick, PhD, John Snow professor of epidemiology, as its principal investigator.

Smith and colleagues investigated the effect of menopausal symptoms on adherence to treatment among 3,987 U.K. women enrolled in the IBIS-I. Of these, 2,000 were assigned to placebo and 1,987 were assigned to tamoxifen. Significantly more women assigned to placebo remained adherent for at least 4.5 years compared with women assigned to tamoxifen, 71.5 percent versus 62.1 percent.

Among all the women, 5 percent reported nausea/vomiting, 7 percent reported headaches, 31.5 percent reported [hot flashes](#), and 13.8 percent reported gynecological symptoms such as irregular bleeding and vaginal dryness.

According to Smith, the researchers included nausea/vomiting and headaches as menopausal symptoms because the prevalence of these is increased among peri- and postmenopausal women and they have been reported as adverse effects among women receiving tamoxifen treatment after a breast cancer diagnosis.

Women reporting nausea/vomiting were 82 percent and 84 percent more likely to be nonadherent to placebo and tamoxifen, respectively, compared with women who did not report these symptoms. Headaches were significantly associated with adherence only among those assigned placebo, with those reporting this symptom 70 percent more likely to be nonadherent. Gynecological symptoms were significantly associated with

adherence only in the tamoxifen arm, with those reporting this symptom 30 percent more likely to be nonadherent. Hot flashes were not associated with adherence in either treatment group.

"Our findings have implications for how clinicians communicate with women who are considering initiating [breast cancer](#) preventive therapy," said Smith. "Managing expectations, and providing realistic and accurate information about the likelihood of experiencing a side effect, as opposed to a naturally occurring symptom, is needed."

According to Smith, the main limitation of the study was that medication adherence was measured during a routine clinic visit and the researchers cannot be certain that each woman attending the clinic was still taking their medication. "This is a problem in all medication adherence studies, and a gold standard assessment needs to be developed," said Smith. He also noted that because assessment of menopausal symptoms was recorded using single item measures, the researchers may not have captured the full impact of those symptoms on overall quality of life.

Provided by American Association for Cancer Research

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