

# Mismatch in breast cancer trial results and real-world outcomes based on treatment discontinuation

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New research in the June 2022 issue of the *Journal of the National Comprehensive Cancer Network* raises issues with clinical trial findings

that show adjuvant hormone therapy (AHT)-related hot flashes predict better outcomes for estrogen receptor-positive (ER+) breast cancer. The population-based study looked at 7,152 chemotherapy-free patients with breast cancer in Sweden between 2006 and 2019 and found patients who were treated for hot flashes after beginning AHT were actually more likely to have *worse* outcomes. Patients who were subsequently treated for hot flashes had a 14.2% higher early discontinuation rate, which may account for the significantly shorter length of disease-free survival (DSF).

"Results from clinical trials might not translate to the [real world](#) because the therapy discontinuation rates differ between these two settings," said corresponding author Wei He, Ph.D., School of Public Health, Zhejiang University, China; and Department of Medical Epidemiology and Biostatistics, Karolinska Institutet, Stockholm, Sweden. "Cancer care providers need to be aware that prescribing symptom-relieving drugs to patients with treatment-related side effects may not be enough to prevent treatment discontinuation."

Lead author Erwei Zeng, MSc, also with Karolinska Institutet, added that "the link between using drugs for hot flashes and discontinuing AHT was weaker among patients with a family history of cancer. This may be because patients with family members who had cancer or died of cancer had a stronger motivation to complete AHT, even if they experienced treatment-related adverse effects."

According to research cited in the article, AHT for ER+ [breast cancer](#)—including tamoxifen and aromatase inhibitors—reduces breast cancer mortality by 30% and 40% respectively in randomized [clinical trials](#). Hot flashes were one of the most common side effects, but only led to an 8%-28% rate of treatment discontinuation. In real-world settings, the rate of patients ending treatment earlier than initially prescribed ranged from 31% to 73%.

"Precision medicine based on the patient's genetic background may help to reduce treatment discontinuation," said senior author Kamila Czene, Ph.D., Karolinska Institutet. "Another potential intervention could be lowering the dose of AHT for some patients to reduce treatment-related side effects."

"Approximately 20% of patients with breast [cancer](#) discontinue anti-estrogen therapy prematurely," commented Jame Abraham, MD, FACP, Chairman, Department of Hematology and Medical Oncology, Cleveland Clinic Taussig Cancer Institute, Member of the NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines) Panel for Breast Cancer.

Dr. Abraham, who was not involved in this research, continued: "There can be multiple reasons for this, including side effects. It is interesting to see that this real-world data shows worse outcomes in patients with hot flashes, likely leading to more early discontinuation of endocrine therapy. It is important for the clinicians to continue to pay attention to the management of side effects and adherence to therapy."

The study authors did caution that this research took place in a country with a unified healthcare system, potentially complicating generalizations that can be made to the United States.

**More information:** Erwei Zeng et al, Adjuvant Hormone Therapy–Related Hot Flashes Predict Treatment Discontinuation and Worse Breast Cancer Prognosis, *Journal of the National Comprehensive Cancer Network* (2022). [DOI: 10.6004/jnccn.2021.7116](https://doi.org/10.6004/jnccn.2021.7116)

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