

Researchers: agent provides treatment option for women with hot flashes

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A pill used for nerve pain offers women relief from hot flashes, Mayo Clinic researchers report at the 45th Annual Meeting of the American Society of Clinical Oncology (ASCO).

They say the agent, pregabalin, decreased hot flash severity and frequency about 20 percent more than did a placebo agent. Thus, pregabalin appears to offer about the same benefit as gabapentin, an older, related drug, as well as newer classes of antidepressants.

"[Hot flashes](#) are a major problem in many women, and for those who opt not to take hormonal therapies or antidepressants, pregabalin appears to be another treatment option," says the study's lead author, Charles Loprinzi, M.D., a medical oncologist at the Mayo Clinic in Minnesota.

While pregabalin offers about the same benefit as gabapentin, women who use it only need to take two pills a day, versus three for gabapentin, he says. Side effects can occur with the use of either drug. However, in this study, they were not severe enough that participants stopped using the active study drug any more often than did patients who were taking placebos, researchers say.

Dr. Loprinzi has pioneered the field of nonhormonal hot flash therapy, which he began researching decades ago to help breast cancer patients using tamoxifen, an anti-estrogen treatment that creates symptoms of menopause. He is the first researcher to test the use of antidepressants, compared to [placebo treatment](#), for hot flashes.

Gabapentin, an agent that has long been on the market to treat pain caused from injury to nerves, has been shown to decrease hot flashes more than do placebos. This drug is approved by the Food and Drug Administration (FDA) to treat diabetic peripheral neuropathy and for shingles; anecdotal evidence suggested that [menopausal women](#) who used it had a reduction in hot flashes, Dr. Loprinzi says. Multiple placebo-controlled studies have since demonstrated that this drug decreases hot flashes.

Gabapentin and a variety of antidepressants are now commonly prescribed for treatment of hot flashes, although these agents are not specifically approved by the FDA for such use.

Pregabalin is a newer version of gabapentin. "We thought it might also relieve hot flashes and thus was worth testing," Dr. Loprinzi says.

So, using funds from the National Cancer Institute, Dr. Loprinzi and colleagues set up a 207-participant study conducted by the North Central Cancer Treatment Group (NCCTG). The study was a Phase III double-blinded, placebo-controlled randomized trial, testing three different treatment arms: a placebo versus daily doses of 150 milligrams (mg) of pregabalin (75 mg twice a day) and 300 milligrams (150 mg twice a day). Patients getting pregabalin started off with lower doses which were increased weekly to the eventual full dose.

Participants, who reported having at least 28 hot flashes a week, kept a "hot flash diary" in which they recorded the number and severity of hot flashes they had each day while taking their study drug — the content of which was unknown to them.

In the study group, 34 percent were using anti-estrogen therapy — either an aromatase inhibitor, raloxifene, or tamoxifen — to help prevent the recurrence of estrogen-sensitive [breast cancer](#).

The researchers found that for the 163 [patients](#) for whom information was available, both doses of pregabalin reduced hot flashes to about the same degree, but that toxicities, such as cognitive dysfunction, were increased at the higher dose. Other reported side effects included weight gain, sleepiness, dizziness, coordination troubles, concentration troubles, and concerns regarding vision changes.

They found that, after six weeks of treatment, women using a placebo agent reported about a 50 percent decrease in their hot flash score (severity), but the change was greater for those who used a 75-milligram twice daily dose of pregabalin (65 percent decrease) and a 150-milligram twice daily dose (71 percent decrease). The declines in hot flash frequency were 36 percent for placebo users, 58 percent in women who used lower-dose pregabalin, and 61 percent in women given the higher dose.

"All in all, this study demonstrates that we have another agent to add to the list of medications that offer benefit against hot flashes, even in women using anti-estrogen therapies," Dr. Loprinzi says.

Source: Mayo Clinic ([news](#) : [web](#))

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