

New type 2 diabetes drug helps lower blood sugar: study

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Photo: U.S. National Kidney and Urologic Diseases Information Clearinghouse

But, FDA wants questions about the drug's long-term safety answered before approval

(HealthDay) -- A new type of medication for type 2 diabetes helps to lower blood sugar levels when used in concert with insulin and other diabetes drugs, new research suggests.

The medicine is called dapagliflozin, and average [blood sugar](#) levels were lower in those taking the drug compared to those taking a placebo; both groups in the trial also took [insulin](#) and other [diabetes medications](#). Daily insulin doses went down for those on the drug, and body weight dropped slightly.

"This study looked at the effects of dapagliflozin treatment in people with type 2 [diabetes](#) with high blood sugars despite [insulin treatment](#), and found it was effective at reducing blood sugar, body weight and blood pressure," said study author Dr. John Wilding, head of the department of obesity and endocrinology at the University Hospital Aintree in Liverpool, England.

"Possible disadvantages include a slightly higher risk of urine infections and genital fungal infections, although most of these responded well to standard treatment," he added.

Results of the study are published in the March 20 issue of the [Annals of Internal Medicine](#). The study was funded by AstraZeneca and Bristol-Meyers Squibb, two pharmaceutical companies who are collaborating in the development of dapagliflozin.

Type 2 diabetes affects the way your body metabolizes sugar. In type 2 diabetes, the body either doesn't use the [hormone insulin](#) effectively or it doesn't make enough insulin, according to the U.S. National Library of Medicine. Insulin allows the body's cells to convert sugar from food into fuel. If it isn't used well or there's not enough insulin, blood sugar levels will rise. [High blood sugar](#) levels can cause a number of serious [health consequences](#), including damage to the eyes, kidneys and blood vessels.

In some cases, type 2 diabetes can be controlled with [lifestyle changes](#), such as losing weight and exercising regularly. However, most people need medications to control their blood sugar levels, and many people need a combination of medications to lower their blood sugar.

Dapagliflozin is from a new class of type 2 diabetes medications that work by blocking the ability of the kidneys to hold sugar. This causes the kidneys to release sugar as waste in the urine.

Numerous clinical trials have found dapagliflozin to be effective at lowering blood sugar levels. Despite this beneficial effect, the U.S. Food and Drug Administration recently decided not to approve dapagliflozin until more information is available about its possible long-term side effects. The most significant concern cited by the FDA was a potential increase in the rates of bladder and breast cancer in people taking the drug.

Although the current trial wasn't long enough to look for longer-term outcomes, such as cancer, Wilding said that the slight increase in bladder and breast cancer was likely a chance finding. But, he said, because there is concern, it's important to continue surveillance for these cancers in future trials.

The current study was designed to see how the drug would work in combination with insulin and other type 2 diabetes medications.

The researchers enrolled just over 800 people with [type 2 diabetes](#) who were already taking insulin to control their [blood sugar levels](#). In addition, the study volunteers could be taking up to two more blood sugar-lowering medications.

Study participants were randomly assigned to one of four treatment groups. They received either a placebo, or one of three doses of dapagliflozin (2.5, 5 or 10 milligrams) daily.

After 24 weeks of treatment, people in the dapagliflozin group lowered their average hemoglobin A1C level between 0.79 percent to 0.96 percent compared with a 0.39 percent reduction in those on placebo. Hemoglobin A1C is about a three-month average blood sugar level. People with diabetes are advised to keep their levels below 7 percent.

Insulin use also dropped for people taking the medication, suggesting

more effective blood sugar control. And, body weight decreased between 2 pounds and 3.5 pounds for those taking the medication. Weight increased by almost 1 pound for those on placebo, according to the study.

In addition, the researchers found that both systolic and diastolic blood pressure levels went down more for those on the drug compared to those on placebo.

"In this study, dapagliflozin seemed to improve glucose control and lower the need for insulin, as well as cause some weight loss," said Dr. Sue Kirkman, senior vice president of medical affairs and community information of the American Diabetes Association.

"This is an interesting study on a new medication that's under development. It has a novel mechanism of action, but there have been some ongoing concerns about the safety of this class of medications, and none has been approved by the FDA yet," she noted.

More information: Learn more about type 2 diabetes and currently approved treatments from the [American Diabetes Association](#).

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