

Voglibose Reduces Occurrence of Type 2 Diabetes in High Risk People



The increased prevalence of type 2 diabetes mellitus is a major concern for health providers. A study published in the journal *The Lancet* reports that together with lifestyle changes, the drug voglibose an α -glucosidase inhibitor, reduces the progress of type 2 diabetes in high-risk Japanese people. The study investigated the effectiveness of voglibose that reduces diurnal insulin secretion, for prevention of the development of type 2 diabetes in Japanese patients with impaired glucose tolerance. Voglibose lowers the amount of glucose absorbed into the bloodstream. The randomized trial included 1,780 eligible participants who showed signs of impaired glucose tolerance, but not full-blown diabetes. Eight hundred and ninety seven were assigned daily three oral doses of 0.2mg of voglibose, and the remaining 883 received a placebo. All participants maintained a regular diet and performed routine exercise. Treatment was continuous for a minimum of three

years or until participants developed either type 2 diabetes or normal blood sugar control. The study shows that after one year of treatment, participants consuming voglibose had more effective results than those on the placebo, having a 40 percent lower risk of developing type 2 diabetes and 54% more likely to reach normoglycemia. Probably associated with the treatment, there were adverse effects on 48 percent of the participants with voglibose compared to only 29% in the placebo group. However, in both groups there were reports of some serious adverse events. In the voglibose group, there was a gall bladder inflammation, a colonic polyp, a rectal tumor, an inguinal hernia, a liver dysfunction and a brain hemorrhage. In the placebo group there was a report of a blockage of brain blood-flow and a swelling of a gall-bladder. The authors write in conclusion: "Voglibose significantly improved glucose tolerance, in terms of delayed disease progression and in the number of patients who achieved normoglycemia. Thus, long-term prophylaxis with this α -glucosidase inhibitor in high-risk individuals with impaired glucose tolerance could provide a pharmacological option, along with lifestyle modification, to help reduce the burden of type 2 diabetes in Japan." In a supplementary note, the researcher remarks: "This study showed that, if best efforts to educate individuals do not work, treatment with voglibose could be an important way forward." He also suggests that the same results could be obtained for other populations since they match documented results of comparable trials in Europe and Canada.

World Diabetes Day 2016



EYES ON DIABETES

One in two adults with diabetes is undiagnosed. Screening for type 2 diabetes is important to ensure early diagnosis and treatment to reduce the risk of serious complications.

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Cardiovascular Disease Mortality Declining among U.S. Adults with Diabetes

From 2000 to 2011, adults with diabetes experienced greater reductions in cardiovascular disease (CVD) mortality than adults without diabetes, with the steepest declines observed in black and older adults, according to data presented at the American Diabetes Association Scientific Sessions. "In the United States, all-cause and CVD mortality have declined for decades. However, we don't know whether the decline in CVD mortality among adults with diabetes has been continuing in recent years," Yiling J. Cheng said during a presentation. The study aimed to examine recent trends in CVD mortality among adults with diabetes to determine whether there have been improvements in disparities by age, sex and education levels. Cheng and colleagues analyzed data from the ongoing annual National Health Interview Survey (NHIS) from 1985 to 2009, linked to the National Death Index to track death outcomes through the end of 2011 (n = 366,067). The main outcome was CVD death (heart disease, heart failure, stroke and arrhythmias). During a mean follow-up of 8 years, 5,704 adults with diabetes died. Of those, 1,596 deaths were attributed to CVD. Among adults with diabetes, death rates per 1000 person-years were 7.5 for CVD, 5.9 for heart disease and 1.6 for stroke, according to researchers. After adjusting for age, sex and race, the mortality risk for adults with diabetes vs. adults without diabetes was 110% for



CVD (95% CI, 95-124), 116% for heart disease (95% CI, 101-134) and 86% for stroke (95% CI, 63-113). From 2000 to 2011, annual relative decreases of death rates paralleled those of adults without diabetes, Cheng said, with decreases of 5.3% for CVD death (95% CI, 3-7.5), 5.5% for heart disease (95% CI, 2.9-8.1) and 4.1% for stroke (95% CI, 0.1-7.8). The researchers also found that annual absolute decreases of death rates per 1,000 person-years were greater for adults with diabetes — 0.29 for CVD (95% CI, 0.17-0.42), 0.25 for heart disease (95% CI, 0.13-0.36) and 0.05 for stroke (95% CI, 0.01-0.09) — compared with adults without diabetes, who had rates of 0.11 for CVD (95% CI, 0.09-0.14), 0.08 for heart disease (95% CI, 0.06-0.11) and 0.03 for stroke (95% CI, 0.02-0.04). Researchers did not observe any between-sex differences for the adjusted CVD death rate. However, black adults experienced a greater decrease in CVD death vs. white adults, dropping from 0.34 in 2000 to -0.04 in 2011. Adults aged at least 65 years also experienced a decline in CVD death, whereas adults aged 55 to 64 years experienced no decline in CVD death, according to the results. "These findings suggest that adults with [diabetes] have experienced large reductions in CVD mortality over the past decade that have also reduced the race-related disparity," the researchers wrote.

Study Sees No Evidence Linking Diabetes Drugs with Pancreatic Cancer

There's no firm evidence that the type 2 diabetes medications known as incretin-based drugs cause pancreatitis or pancreatic cancer, U.S. and European health officials say. But it's too early to say there's definitely no link between the injectable drugs and pancreatitis or pancreatic cancer, according to the safety assessment by the U.S. Food and Drug Administration (FDA) and its counterpart overseas, the European Medicines Agency (EMA). "Both agencies agree that assertions concerning a causal association between incretin-based drugs and pancreatitis or pancreatic cancer, as expressed recently in the scientific literature, and in the media, are inconsistent with the current data," states the report in *The New England Journal of Medicine*. "The FDA and the EMA have not reached a final conclusion at this time regarding such a causal relationship." Incretin-based drugs are among the newest medications available to treat type 2 diabetes. Nearly 26 million people in the United States and 33 million in the European Union have diabetes, and type 2 is by far the most common type. There are two types of incretin-based medications: Glucagon like peptide-1 (GLP-1) agonists and DPP-4 inhibitors. Examples of DPP-4 inhibitors include sitagliptin and saxagliptin. Sitagliptin was the first DPP-4 inhibitor approved by the FDA, receiving consent in 2006. Glucagon like peptide-1 agonists slow stomach emptying and increase insulin secretion, which help keep blood sugar lower. They also suppress secretion of a hormone that raises blood sugar levels. DPP-4 inhibitors slow the absorption of carbohydrates through the stomach, help increase insulin levels and suppress the blood-sugar elevating hormone. One of the challenges in diabetes control is keeping blood sugar levels low while avoiding hypoglycemia, or dangerously low blood sugar. "The clinical data suggests these are very effective drugs that don't cause hypoglycemia," said the researcher. Also, unlike some diabetes drugs that promote harmful weight gain, GLP-1 agonists cause weight loss, while DPP-4 inhibitors are weight neutral.



Weight loss often improves diabetes. After the drugs received approval, the FDA and EMA received reports of pancreatitis and pancreatic cancer in people taking the drugs. "There was a disproportionate reporting of these adverse events detected," said the lead author. However, the risks of pancreatitis and pancreatic cancer are already elevated in people with type 2 diabetes, said Egan. In addition, because they can aid weight loss, GLP-1 agonists are often prescribed to heavier people. Because these and other factors can confound findings of an association in people taking the drugs, the FDA and EMA conducted extensive reviews of the available data from animals. The FDA reviewed 250 toxicology studies conducted in nearly 18,000 healthy animals. The EMA conducted a similar review. Neither agency found an increased risk of pancreatitis related to incretin-based drugs. And neither agency found any drug-induced pancreatic tumors in rats and mice treated for two years (their adult life span) with the drugs. Both agencies also reviewed data from hundreds of trials in humans and found no convincing link. Two large clinical trials are currently underway, and experts hope they will provide a more definitive answer. So what's a person taking these medications supposed to do in the meantime? "The American Diabetes Association, the European Association for the Study of Diabetes and the International Diabetes Federation released a statement recommending that no patient should discontinue their medication without consulting their doctor first. And patients taking these medications should be informed of all the possible risks and benefits so they can make the best decision for themselves," said the researcher. The FDA and EMA have further validated that position, the researcher said. "We need to continue to be vigilant, but as of now, there doesn't seem to be any reason to change our approach," he noted. The FDA concluded that the current labeling for these drugs contains the necessary information and isn't recommending any labeling changes at this point.

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Older Drug May Help Type 1 Diabetics' Heart Health

An inexpensive medication metformin, normally given to people with type 2 diabetes may help preserve heart health in people with the less common form of diabetes -- type 1, a new study finds. Metformin previously carried a "black box" warning from the U.S. Food and Drug Administration advising against its use in treating diabetes in heart failure patients. Many medications commonly used to lower serum glucose levels have theoretic or demonstrated adverse effects on heart failure. As a result, many physicians have been reluctant to use metformin and other similar medications to treat this patient group. A recent study shows that using metformin to treat diabetes in patients with advanced, systolic heart failure is not only safe, but may also play a role in improving outcomes compared to conventional diabetes care. According to this study metformin is safe for diabetes patients with advanced heart failure, say U.S. researchers. The study was published in the *Journal of Cardiac Failure*. The study included 401 patients, average age 56, with type 2 diabetes and advanced systolic heart failure who were followed for 14 years in a heart-failure management program. The results suggest that metformin is safe in patients with both advanced heart failure and diabetes, and may be associated with better heart failure survival. There may be over 2 million individuals with heart failure and type 2 diabetes mellitus in the U.S. alone, so this important finding will have fairly broad impact.



help control blood sugar levels. It also appears to help repair damaged blood cells by increasing the number of blood vessel vascular stem cells. "We have shown - both in test tube and in patients - the mechanism behind the cardio protective effects of metformin," said the study's senior author. "This is likely to lead to the development of new drugs for heart disease in diabetes," the researcher added. This well-designed study have shown which cardiovascular biomarkers go up and down with metformin. But these are markers only. For a drug to be approved or widely accepted, researchers have to demonstrate hard outcomes," explained the researcher. Type 1 diabetes is an autoimmune disease. Heart disease is the leading cause

of premature death in people with type 1 diabetes. Even with good blood sugar control, the risk of heart attack or stroke is twice as high for people with type 1 diabetes compared to people without it, the researchers said. The new study included 23 adults with type 1 diabetes who were treated with metformin for eight weeks. None had overt signs of heart disease. Their average age was 46 years. The starting dose was 500 mg a day, which was increased to 2,000 mg a day if tolerated. These people were compared to 23 healthy age- and sex-matched volunteers without type 1 diabetes. They were also compared to nine people with type 1 diabetes who weren't given metformin. Their average age was 47 years. The people with diabetes were asked to keep their blood sugar control similar to what it was before the metformin. The researchers didn't want an improvement in blood sugar levels to affect the findings. The researchers saw a number of markers indicating blood vessel repair go up in patients taking metformin. And on the flip side, cells associated with blood vessel damage were reduced in people taking metformin.

Another study shows that metformin may help preserve heart health in people with type 1 diabetes. Findings from the study were published in *Cardiovascular Diabetology*. Metformin is the standard first-line treatment for type 2 diabetes to

Metformin may Help Kids With Autism Fight Unwanted Pounds



The diabetes drug metformin may help overweight children and teens with autism slim down, a new study suggests. The study was published in the journal *JAMA Psychiatry*. The study included 60 people with autism, aged 6 to 17. The patients were overweight due to the side

effects of taking antipsychotic medications for irritability and agitation. For the study, participants were given either metformin or an inactive placebo for 16 weeks. Those given metformin had much greater reductions in body mass index (BMI) than those who took the placebo, the findings showed. "Our results showed that [gastrointestinal] side effects occurred for more days in the metformin group compared to placebo group, but the large majority of children taking metformin were able to maintain their treatment. Importantly, the metformin didn't cause behavioral changes, such as increased irritability," said lead investigator. Teens with autism are more likely to be overweight than those without developmental disorders. But there has been little study of ways to counteract their weight gains, the researchers said. In addition, the food preferences of children and teens with autism add to the challenge of managing their weight, the study authors noted. "It's not the amount that's eaten, rather the food choices that are a byproduct of the cravings and linked to weight gain," the researcher said in a university news release.



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Some is Good, More is Better: Regular Exercise can Cut Diabetes Risk

Walking briskly or cycling for the recommended 150 minutes a week can reduce a person's risk of developing type 2 diabetes by up to 26%, according to new research by University College London (UCL) and the University of Cambridge. People who carry out an hour of moderate to vigorous exercise every day can reduce their risk of getting type 2 diabetes by 40%. The study also revealed that any amount of physical activity can reduce the risk of developing the disease. The research, published in the journal *Diabetologia*, is the most comprehensive study to look at the impact of exercise, independent of other behavioral factors such as diet, on a person's risk of developing type 2 diabetes. The UK Department of Health recommends 150 minutes of moderate to vigorous exercise a week, which includes brisk walking, gentle cycling or sports such as doubles tennis. According to the Health Survey for England (2012), as many as a third of adults are not meeting this target. The study, which analyzed summarized data from over a million people, demonstrated that while any amount of physical activity is good for a person, the benefits of exercise are greater for people who exceed this recommended level. The study analyzed data from 23 studies carried out in the USA, Asia, Australia and Europe. By combining



observations from these studies, the researchers were able to separate out the effect of leisure time physical activity from other behavioral factors, and obtain better estimates of the effects of different physical activity levels. Previous studies have often included changes to both diet and physical activity, making it difficult to isolate the impact of physical activity alone. "Our results suggest a major potential for physical activity to slow down or reverse the global increase in type 2 diabetes and should prove useful for health impact modeling, which frequently forms part of the evidence base for

policy decisions.," said Andrea Smith (UCL Health Behavior Research Centre and Institute of Public Health, University of Cambridge), who led the study. The prevalence of type 2 diabetes is growing rapidly due to rising obesity levels and is estimated to reach nearly 600 million cases worldwide by 2035. "This research shows that some physical activity is good, but more is better," said Dr Soren Brage, co-author of the study. "We already know that physical activity has a major role to play in tackling the growing worldwide epidemic of type 2 diabetes. These new results add more detail to our understanding of how changes in the levels of physical activity across populations could impact the incidence of disease"- he concluded.

Diabetes in Children is a Chronic, but Treatable Disease

For those people living with diabetes, every day requires around-the-clock monitoring and management. "In order to successfully manage blood sugar levels, those living with diabetes must perform fingerstick checks, keep records, monitor food intake, keep up their physical activity, and calculate medication doses based on past trends. Needless to say, day to day monitoring can become tedious and at times exhausting for patients, and so it is important that they stay motivated," says the researcher. This daily monitoring can be a particular challenge for young people who also have to be attentive to when and what they eat and drink, as well as their activities at home, in school or while hanging out with friends. Even a minor ailment like a cold may require changes in the medical regimen because of the effect inflammation has on the blood sugar. But diabetes is not the "death sentence" that the researcher says many of his patients and their families seem to believe. "Although there is no cure at this time, treatment options have significantly improved over the years," assures the researcher. "With insulin pens, pumps, and modern devices that allow more precise and continuous day and night monitoring of blood sugar levels, we can make small adjustments in the dosage of insulin to prevent sugar levels from rising or dropping too fast. Excellent glucose control gives patients and their families peace of mind. There are many misperceptions of diabetes. One of the most common misunderstandings is that people get diabetes solely from eating too much and gaining excessive weight. While type 2 diabetes -- most common in adults but certainly present in children and adolescents -- does develop due to weight gain, it is also genetically based. But the much more common diabetes in the pediatric age range -- type 1 diabetes -- does



not develop secondary to poor eating habits; it is an autoimmune disease that prevents the body's normal production of insulin. "Regardless of the type of diabetes a patient may have, education of the patient and the family is extremely important. We treat the whole family not just the person who has the diagnosis of diabetes because it affects everyone in the family" --says the researcher. Kidney problems, blindness, amputations and cardiovascular disease are among the most serious and most widely known long-term complications of diabetes. And given the prevalence of the condition, he says that when patients are given a diagnosis of diabetes, many families can only picture unfortunate outcomes for their kids. "We begin with

listening to what the families and patients know about diabetes, since many of their fears are based in old or incorrect information," the researcher says. "With good blood sugar control and use of modern treatments and technologies, patients today do not have to have overly rigid lifestyles in order to life long, healthy lives free of complications." He makes clear to patients and their families about the need for a healthy diet, avoidance of sugary drinks, and a good amount of physical activity or exercise. Moderation is key. Some signs that a child may have high blood sugar include increased thirst and frequent urination. For patients who already have diabetes, directs kids to get involved in their treatment and continues to motivate them when they become adolescents. He focuses on engaging patients in their own diabetes management, developing good habits and awareness in order to prevent complications.

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