'Bionic Pancreas' Improves Blood Sugar Control for People With Type 1 Diabetes

By Serena Gordon
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MONDAY, June 16, 2014 (HealthDay News) -- The "bionic pancreas" -- a device that uses a sophisticated computer program working in concert with several diabetes management devices -- successfully managed blood sugar levels in its first real-world trials on adults and children with type 1 diabetes.

What may be even more important is that the device took away the constant monitoring that's required with type 1 diabetes.

"It's difficult for people who don't live with type 1 diabetes to understand how much work it is. It's such a burden. But, everyone in the trial said that burden was all lifted. The device is inherently automated -- it's diabetes without the numbers," said study senior author Edward Damiano, an associate professor in the department of biomedical engineering at Boston University. Damiano understands the issue more keenly than most, as he is the father of a 15-year-old son with type 1 diabetes.

Damiano said the device "exceeded our expectations, reducing average [blood-sugar levels] to what's well below standard-care therapy, while at the same time reducing [low blood-sugar levels]."

Type 1 diabetes is an autoimmune disease caused by a mistaken attack on healthy insulin-producing cells in the body, destroying them. Insulin is a hormone necessary for ushering sugar into cells to provide fuel for those cells. People with type 1 must replace the insulin their bodies no longer produce through injections or through a tiny catheter attached to an insulin pump.

However, figuring out exactly how much insulin to give is no easy task. Both too much insulin and too little insulin can have dangerous, even deadly, consequences.

Here's how the bionic pancreas can help. It contains two hormones -- insulin and glucagon. Insulin lowers blood sugar and glucagon can raise blood sugar quickly. The current version of the bionic pancreas had two insulin pumps -- one that delivered small doses of insulin and the second for glucagon. The device also included a smartphone with an app that contained the computer program to control the pumps. The phone also wirelessly communicated with a continuous glucose monitor that constantly reported blood sugar levels.

Damiano said that, within 18 months, he hopes to have one integrated machine containing an insulin reservoir, a glucagon reservoir, a continuous glucose monitor receiver and the computer program. The device would also require the insertion of a continuous glucose monitor sensor, and two tiny tubes inserted under the skin every three days to deliver the hormones.

In the current study, the researchers tested the device in outpatient trials for 20 adults and 32 teenagers with type 1 diabetes. The teens were at a diabetes summer camp. Both trials included five days on the bionic pancreas and five days on usual management with an insulin pump.
In the adults, average daily blood sugar levels were 159 milligrams per deciliter (mg/dL) on their usual management. On the bionic pancreas, that dropped to 133 mg/dL. The amount of time spent with low blood sugar levels was nearly halved -- from just over 7 percent on usual care to about 4 percent on the bionic pancreas, according to the study.

For the campers, aged 12 to 20, their usual care routines gave them an average blood sugar reading of 157 mg/dL, while they had an average of 138 mg/dL on the bionic pancreas. Time spent with low blood sugar levels were slightly reduced in the campers. The trials were funded by the U.S. National Institute of Diabetes and Digestive and Kidney Diseases.

Both Damiano and his co-author, Dr. Steven Russell from the Massachusetts General Hospital Diabetes Unit in Boston, were especially pleased that the device worked on everyone.

"No one was left behind. That was really encouraging," said Russell.

"A cure is what we hope for, but this is a bridge until that happens. Although we're not totally normalizing blood sugar levels, everybody gets below what's predicted to be an A1C of 7. We could keep people safe and dramatically reduce the risk of complications," said Russell.

A1C is a long-term measure of blood sugar levels -- about two to three months. The American Diabetes Association A1C goal for most people is under 7 to avoid diabetes complications. However, because of the many variables involved in diabetes care, that's often difficult to consistently achieve.

"These results are promising," said Aaron Kowalski, vice president of artificial pancreas research for JDRF (formerly the Juvenile Diabetes Research Foundation).

"And, from the patient experience, it's hard to underestimate the reduction of burden -- not having to make as many decisions, not being awakened in the middle of the night," said Kowalski, who has type 1 diabetes.

He noted that he does have concerns about artificial pancreas systems that rely on glucagon, because if the tubing delivering glucagon were to become blocked, potentially dangerous low blood sugar levels could result.

Russell said there are alarms that will sound if the tubing becomes blocked. And, in the new design for the fully integrated device, both the insulin tube and the glucagon tube will be on the same adhesive patch, so if one comes out, the other will, too.

There were no serious low blood sugar events in either the adults or the teens during the trials.

The next step begins Monday, with expanded outpatient trials. In the meantime, the researchers will continue to work on the fully integrated device, and hope to start clinical trials on that in 18 months or so, according to Damiano.

Both Damiano and Russell believe they'll have their device ready to market in fewer than five years. Damiano is hoping for no longer than 39 months -- that's when his son will head off to college.

Kowalski said: "For many years with the artificial pancreas, people have been saying will this happen? It's not a matter of if anymore, but when. I think we're going to see this moving quickly."

He added that other research teams have also had successes, and are in -- or planning for -- clinical trials.

The findings were presented Sunday at the American Diabetes Association's meeting in San Francisco, and were published online simultaneously in the New England Journal of Medicine.
More information

To read about one adult's experience as she participated during the "bionic pancreas" trial, go to DiaTribe.org.

SOURCES: Edward Damiano, Ph.D., associate professor, biomedical engineering, Boston University; Steven Russell, M.D., Ph.D., assistant professor, medicine, Massachusetts General Hospital, Boston; Aaron Kowalski, vice president of artificial pancreas research for JDRF (formerly the Juvenile Diabetes Research Foundation); June 15, 2014, *New England Journal of Medicine*, online; June 15, 2014, presentation, American Diabetes Association annual meeting, San Francisco

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