Bionic pancreas outperforms insulin pump in adults, youth

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People with type 1 diabetes who used a bionic pancreas instead of manually monitoring glucose using fingerstick tests and delivering insulin using a pump were more likely to have blood glucose levels consistently within the normal range, with fewer dangerous lows or highs. The full report of the findings, funded by the National Institutes of Health, can be found online June 15 in the *New England Journal of Medicine*.

The researchers – at Boston University and Massachusetts General Hospital – say the process of blood glucose control could improve dramatically with the bionic pancreas. Currently, people with type 1 diabetes walk an endless tightrope. Because their pancreas doesn't make the hormone insulin, their blood glucose levels can veer dangerously high and low. Several times a day they must use fingerstick tests to monitor their blood glucose levels and manually take insulin by injection or from a pump.

In two scenarios, the researchers tested a bihormonal bionic pancreas, which uses a removable tiny sensor located in a thin needle inserted under the skin that automatically monitors real time glucose levels in tissue fluid and provides insulin and its counteracting hormone, glucagon, via two automatic pumps. In one scenario, 20 adults wore this device combination and carried a cell phone-sized wireless monitor around Boston for five days, unrestricted in their activities. In the other, 32 youth wore the device combination for five days at a camp for children with type 1 diabetes. Both groups were also monitored for five

days wearing their own conventional pumps that deliver insulin.

"The bionic pancreas system reduced the average blood glucose to levels that have been shown to dramatically reduce the risk of diabetic complications," said co-first author Steven Russell, M.D., Ph.D., assistant professor of medicine at Massachusetts General Hospital. "This is tremendously difficult with currently available technology, and so most people with diabetes are unable to achieve these levels."

The researchers found about 37 percent fewer interventions for low blood glucose (hypoglycemia) and a more than twofold reduction in the time in hypoglycemia in adults using the bionic pancreas than with the manual pump. For adolescents using the bionic pancreas, results showed more than a twofold reduction in the need for interventions for hypoglycemia. As well, both groups had significant improvements in glucose levels with the bionic pancreas, particularly during the night.

"The performance of our system in both adults and adolescents exceeded our expectations under very challenging real-world conditions," said Ed Damiano, Ph.D., the paper's senior author, an associate professor of biomedical engineering at Boston University and the parent of a son with type 1 diabetes.

"A cure is always the end goal," he said. "As that goal remains elusive, a truly automated technology, which can consistently and relentlessly keep people healthy and safe from harm of hypoglycemia, would lift an enormous emotional and practical burden from the shoulders of people with type 1 diabetes, including my child and so many others."

Just as a thermostat helps control a home's temperature, the normal pancreas senses blood glucose levels and adjusts the hormones that control it. People with type 1 diabetes, whose pancreas produces little or no insulin, have been using the equivalent of a manual thermostat,

needing constant checking and adjustment. A bionic pancreas – like the one used in these studies – would function more like an automated thermostat, automatically monitoring blood glucose and delivering insulin or glucagon when needed to keep glucose within the normal range. As well, these bionic pancreas devices could be monitored remotely by the patient's medical provider or parent.

"With promising results such as these, we plan to support larger multicenter trials of the artificial pancreas in the near future," said Guillermo Arreaza-Rubín, M.D., the project officer for artificial pancreas studies funded by the NIH's National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK). "Within the next few years, we hope these technologies will go beyond experimental trials and be available to benefit more people with type 1 diabetes."

"The landmark Diabetes Control and Complications study – also funded by NIDDK – has long shown that maintaining as normal a blood glucose level as possible early on can stave off complications, including heart, kidney and eye diseases, decades later," said NIDDK Director Griffin P. Rodgers, M.D. "By funding research on the artificial pancreas, we aim to help people with type 1 diabetes maintain healthy blood glucose levels, prevent painful and costly complications, and lead freer, healthier lives."

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