

Use of a biohormonal, bionic pancreas in the home setting can safely and effectively lower mean blood glucose levels and hypoglycemia (low blood glucose), compared to the use of an insulin pump, in adults with type 1 diabetes performing normal daily activities, according to a study presented at the Association's 76th Scientific Sessions®, June 11, 2016, at the Ernest N. Morial Convention Center in New Orleans.

This is the first study to test the efficacy and safety of a fully automated, dual hormone (glucagon and insulin) bionic pancreas for adults with type 1 diabetes over multiple days in a home setting, with no restrictions on diet and exercise. The findings are consistent with those of three previous outpatient studies of children and adults with type 1 diabetes by the same researchers in more supervised settings. In a pair of random-order, crossover studies in Boston, published in 2014¹, the team compared use of a bionic pancreas with that of an insulin pump over five days by 32 adolescents and camp counselors (ages 12-20) with type 1 diabetes in a summer camp setting and 20 adults (ages 21 years and older) who were shadowed by study staff during the day and restricted to a hotel at night. In a separate study published earlier this year², they compared the safety and effectiveness of the bionic pancreas to that of conventional insulin pump therapy when used by 19 pre-adolescent children (ages 6-11 years) with type 1 diabetes in a summer camp setting.

"These results, in addition to the results from our previous studies, suggest that the bionic pancreas, as an autonomous system, could profoundly reduce patient burden and provider involvement in type 1 diabetes management. At the same time, it could also offer significantly improved clinical outcomes in terms of reductions in both average blood sugar levels and hypoglycemia," said one of the lead investigators Edward R. Damiano, PhD, Professor of Biomedical Engineering, Boston University. In this random order, crossover study, 39 adults (age 33 and older) with type 1 diabetes (of a mean duration 7 ± 10 years) used the bionic pancreas for 11 consecutive days (intervention arm) and their own insulin pump (control arm) for the same amount of time to manage their diabetes while continuing their normal daily activities at home.

Patients had a mean A1C of 7.7 ± 1.2 percent at baseline. During bionic pancreas use, a continuous glucose monitor provided data to an autonomously adaptive algorithm, which determined how much glucagon and insulin to deliver subcutaneously to the patient and when to deliver it. When using the insulin pump, patients managed insulin delivery on their own, following their normal insulin regimens. During the entire course of the study, patients were allowed to perform all normal daily activities, including driving and exercise, and were allowed to eat meals without caloric or carbohydrate restrictions. Use of the bionic pancreas was associated with a 20 mg/dl decrease in average blood glucose levels (141 ± 10 vs. 162 ± 29

mg/dl, p "The cumulative results of our four studies suggest the bionic pancreas could potentially solve the four greatest concerns of type 1 diabetes management," continued Damiano.

"First, the bionic pancreas reduces mean glycemia in nearly everyone to levels that would meet or exceed the American Diabetes Association's goal for therapy and could potentially nearly eradicate long-term microvascular and neurological complications, if implemented at the time of diagnosis. Second, it profoundly curtails mild hypoglycemia and could potentially eliminate the risk of severe hypoglycemia." "Third, it automates glycemic management, thus unburdening people with type 1 diabetes of the active management needed to comply with therapy, as the bionic pancreas itself is the first technology we aware of that is entirely compliant with the patient's needs rather than the other way around. And finally, it relieves people with type 1 diabetes and their families of the emotional hardship of daily management, of the constant fear of hypoglycemia, and of the worry and dread of hyperglycemia." "A device that solves any one of these concerns would be groundbreaking," Damiano concluded.

"A device that simultaneously solves all four of these concerns is without precedent and represents a paradigm shift in clinical outcomes and type 1 diabetes management."

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