'Bionic Pancreas' Begins Clinical Trials

By Chuck Dinerstein — August 29, 2018

By Johann Georg Wirsung [1]

Nothing controls our blood sugar as well as the pancreas, that should be no surprise. Using a cellular sensing and communication mechanism we are just beginning to understand, the pancreas releases insulin to lower and glucagon to raise our blood glucose maintaining a narrow “homeostatic” range. We also know that staying within the homeostatic range results in fewer short and long-term complications for patients with diabetes. For Type 1 diabetes, which begins in childhood, the need for glucose control is imperative; they will have the condition far longer than the patient with Type II diabetes which appears in our late middle age.

Mimicking the pancreas’s precise control is difficult, and our human efforts are plagued by too high (hyperglycemia) and too low, and far more deadly, (hypoglycemia) blood sugar levels – continuous glucose monitors have made a difference as have insulin pumps. In July investigational device studies began with a system that is capable of dosing insulin and glucagon based on those continuous glucose monitors autonomously, without the intervention of a physician or patient. The “artificial” pancreas is now far closer to fruition and it will be a major therapeutic advance, especially for patient’s with Type I diabetes were control is difficult.

The Study

A study in the Lancet will help us understand the value of such a system – which consists of three components, an implantable pump for both insulin and glucagon, a continuous glucose monitor (CGM) and an algorithm that learns your response to insulin and glucagon and adjusts the dosing. All three components are handled by a dedicated blue-tooth smartphone app although systems with a built-in controller, eliminating the problems of wireless communication are in the works. The Lancet reports on 39 adults with Type 1 diabetes that participated in a randomized cross-over study comparing their use of an insulin pump with this “artificial pancreas.” Unlike prior studies that

were heavily supervised, these patients continued all their normal activities, eating what and when they liked, exercising as they might. Patients were asked to limit their alcohol intake.

The only information given to the algorithm was the patient's weight, there was no information regarding their current insulin regimen. Patients could but were not required to characterize their meals by type, breakfast, lunch or dinner and by size, snack, less than, normal or greater than usual and use the smartphone to give the algorithm a "heads-up" on the glucose coming down the line. There were no calorie counts.

Participants completed two eleven day study periods with a "washout" period in between to move closer to their "baseline" measurements. The order in using their insulin-pump alone or the system dispensing insulin and glucagon was randomized, and neither physician or patient was "blinded" to treatment.

- The mean continuous glucose measurement was 11% lower for the "pancreas" than the insulin pump.
- Time with too low a blood sugar was reduced (1.9% to 0.6%) as was time spent with too high a blood sugar (33.6% to 19.8%) – as a result, time in the normal range increased (61.9% to 78.4%).
- The number of symptomatic episodes of low blood sugar was reduced as was the need for patient-initiated intake of carbohydrates to correct the low sugar levels.
- Variation in blood sugar levels was reduced when using the dual drug system and was further reduced at night when exercise and eating were not a factor for the algorithm to consider.
- Patients using the insulin pump self-administered their insulin 5-6 times daily for meals or corrections in blood sugar, the "pancreas" acted autonomously.
- Providing meal feedback to the dual drug system varied among participants, but subsequent analysis found no correlation between this information and the mean glucose measurements.
- The bionic pancreas participants experienced more nausea than those using the insulin pump.

There were some wireless problems with connectivity lost about 4% of the time between the CGM and the dual pumps. Loss of CGM information was about the same for both systems, and both systems were worn and working correctly 96% of the time. Because of remote monitoring and notification of glucose values that were dangerously low, an FDA requirement for safety concerns under the unsupervised conditions of this trial, these periods might have been longer. Finally, the current formulations of glucagon require daily refilling of the pump while insulin can be stored in the system for two to three days.

This particular bionic pancreas is beginning clinical trials, first as an autonomous insulin pump and later as an autonomous bihormonal system. It holds great promise to change the course and complications of Type 1 diabetes and perhaps for those patients with Type 2 diabetes who have difficulty with blood sugar management.

Source: Home use of bihormonal bionic pancreas versus insulin pump therapy in adults with Type

1 diabetes: a multicenter randomized crossover trial Lancet DOI: 10.106/S0140-6736(16)32567-3

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