ADA 2019 - a good start for Beta Bionics

The iLet system showed decent blood sugar control in its first trial, but the highly automated system is far from proven.

Data from the first human trial of Beta Bionics’ so-called bionic pancreas suggest that the device, which aims to be even more hands-off than other artificial pancreas-type systems, can improve blood sugar control compared with insulin injections or other insulin pumps.

The device worked well when used with glucose monitors from either Dexcom or Senseonics. But Medtronic’s status as the only company with a marketed artificial pancreas is safe for a little while yet: Beta Bionics intends to start a pivotal US trial of a newer version of the iLet next year.

The trial assessed the third-generation form of the iLet. The device’s USP is that patients only need to enter their weight and the machine calculates insulin doses from there, with no need to enter the other information, such as meal sizes and times, that is required by other closed-loop systems (Beta Bionics brings machine learning to insulin delivery, June 21, 2018).

The iLet system can administer insulin, glucagon or both to modulate blood sugar levels. In this trial, data from which were presented at the meeting of the American Diabetes Association on Saturday, the device was used to deliver insulin only.

Time in range

The trial enrolled 12 type 1 patients who usually treated their condition with multiple daily injections of insulin and 22 who used insulin pumps. It had a crossover design in which patients used their usual treatment method for seven days and iLet for seven days. 17 of the enrollees used Dexcom’s G5 continuous glucose monitor as the data input for the iLet, and the other 17 used the Eversense CGM from Senseonics.

Use of the iLet significantly increased the percentage of time patients had glucose levels in the target range of 70-180mg/dl compared with their usual care, and there was no statistically significant difference in time spent in hypoglycaemia between the two groups.
The amount of time spent in hypoglycaemia when on the iLet was lower when it was used with Dexcom’s G5 glucose monitor than with Senseonics’ Eversense; however, the researchers noted that it is unclear whether this represents an actual difference in hypoglycaemia or a difference in the detection of hypoglycaemia between the two sensors.

According to the abstract, “several device issues” occurred, prompting Beta Bionics to make changes to the design of the fourth-generation iLet to improve safety and usability. It is this version that will enter pivotal studies.

### Bihormonal

The ADA data add to results from a different study assessing the use of the iLet to deliver both insulin and glucagon which reported last week. This dual-hormone configuration is one of the key stages in the development of a more advanced artificial pancreas, since it enables more sensitive control of blood sugar levels than an insulin-only system.

Also a crossover trial, this study compared the iLet in its insulin-only configuration for one week versus the bihormonal configuration, using Zealand Pharma’s dasiglucagon, for one week in 10 adults with type 1 disease.

When delivering both hormones the system allowed a mean glucose level of 139mg/dl, versus 149mg/dl during the insulin-only period. During the bihormonal period, participants spent 79% of the time with their glucose level in range, vs 71% during the insulin-only period. Both differences were statistically significant, which the company said was particularly impressive given the cohort size of only 10 subjects.

These results are encouraging, though of course both trials are small. The dual-hormone configuration is behind the insulin-only form, not least because dasiglucagon is not yet approved. If the pivotal trial of the fourth-gen insulin-only version succeeds, iLet could hit the market in 2021, though 2022 might be more likely. The bihormonal version could arrive a year or two after that.

### Beta vs alpha

The device would go up against Medtronic’s MiniMed 670G, the only approved closed-loop system in which a blood glucose sensor is linked to an insulin pump. It might also go up against Medtronic’s next-generation version, the 780G.

The 780G is designed to automate the delivery of insulin boluses when the user experiences, or is predicted to experience, prolonged high blood sugar. The pivotal study will enrol 250-350 adults and children with type 1 diabetes and is expected to conclude in January.

Beta Bionics’ single-hormone system stands little chance of knocking Medtronic’s tech into second place on the
market. Medtronic, though, does not have a means of delivering glucagon as well as insulin, so if and when Beta Bions can bring its dual-hormone system to market it will have an advantage. But that interesting situation will take some years to come about, if indeed it ever does.