Evaluate Vantage

June 24, 2013

ADA – Medtronic brings constant blood sugar control closer to reality

Elizabeth Cairns

The much-vaunted artificial pancreas – a combined blood glucose sensor and insulin pump that can keep a diabetic patient's blood sugar levels under constant, near-perfect control – has taken a sizeable leap towards becoming a reality.

Advances reported by both Medtronic and Johnson & Johnson for their respective technologies, both showing a decrease in incidences of overnight hypoglycaemia, show how close this race for a multibillion dollar market is getting. The finish line is still some years away, but the world's biggest medtech companies have seen the future, and are sparing no effort or expense in pursuit of a win.

Both blood glucose sensors and insulin pumps already exist; the challenge lies in developing sufficiently advanced software to allow instant correction of blood sugar levels. This will ultimately involve predicting the pattern blood sugar will take and adjusting insulin delivery pre-emptively.

The target here is type 1 diabetes, which despite representing just 5% of the overall US diabetes market would still be highly lucrative for developers of this technology. Type 1 tends to strike children who are naturally less able to take control of their glucose levels, so a device that requires no input from patients would provide a real therapeutic improvement. It would also be a shoo-in for reimbursement, even if priced significantly higher than separate sensors and pumps.

Aspiration

Leading the charge at this week's meeting of the American Diabetes Association was Medtronic, with data from a trial called Aspire showing that its MiniMed 530G system can significantly decrease incidences of overnight hypoglycaemia.

The MiniMed 530G boasts a feature called Threshold Suspend, which automatically halts insulin delivery for two hours when the sensor detects that glucose levels have reached a pre-set low, and the patient does not respond to an alarm. The patient can resume insulin delivery before the two hours are up if they wish.

The 247-patient Aspire study tested the MiniMed 530G system, used at home for three months, with and without Threshold Suspend enabled. Data showed that the mean area under the curve for nocturnal hypoglycaemic events – a proxy for the severity and duration of such events – was 37.5% lower in the Threshold Suspend group than in the control group.

Nocturnal hypoglycaemic events occurred 31.8% less frequently with Threshold Suspend enabled than without, and the feature also improved combined day and night hypoglycaemic events. There was no change in HbA1C in either group, meeting the study's primary safety endpoint.

The MiniMed 530G is set for US approval by the end of this year, and is already on sale outside the US as MiniMed Veo.

A hint that this research is still at a fairly early stage is given by the fact that the system sounds an alarm when the threshold is reached. If the system were perfect, no alarm would be necessary – the patient's blood sugar would be regulated with no need to alert them.

Prediction

Johnson & Johnson's diabetes unit Animas posted clinical data on its artificial pancreas device at the ADA meeting. The company aims to take the technology, in the shape of its Hypoglycemia-Hyperglycemia Minimizer (HHM) device, from reactive to predictive.

The HHM system, which in this study uses a continuous glucose sensor provided by Dexcom, incorporates a control algorithm designed to extrapolate future glucose levels from past behaviour, predicting fluctuations. The ADA data show that it permitted over 90% of the 20 type 1 patients in the study to maintain a healthy blood glucose range between 9pm and 7am.

The trial is the second of three feasibility studies J&J is conducting to secure FDA approval of the device. The next will, like Aspire, permit patients to take the device home and therefore facilitate enrolment of more patients.

It will take some years yet to refine this technology to the point at which it is approvable, and it is too soon to tell which of these products will be first to market – if indeed it is one of these and not one of the rival technologies under development by other companies including Abbott and Becton Dickinson.

But the lure of ever-changing basal insulin therapy is strong, and with the current market for sensors and pumps placed at $2.4bn worldwide, developers will vie to create the first true artificial pancreas.

Trial name	Trial ID
Aspire	NCT01497938
Animas HHM trial	NCT01638299

To contact the writer of this story email Elizabeth Cairns in London at elizabethc@epvantage.com or follow @LizEPVantage on Twitter

© Copyright 2021 Evaluate Ltd.