Closed-Loop Artificial Pancreas Using Subcutaneous Glucose Sensing and Insulin Delivery and a Model Predictive Control Algorithm: Preliminary Studies in Padova and Montpellier

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Abstract

New effort has been made to develop closed-loop glucose control, using subcutaneous (SC) glucose sensing and continuous subcutaneous insulin infusion (CSII) from a pump, and a control algorithm. An approach based on a model predictive control (MPC) algorithm has been utilized during closed-loop control in type 1 diabetes patients. Here we describe the preliminary clinical experience with this approach.

Six type 1 diabetes patients (three in each of two clinical investigation centers in Padova and Montpellier), using CSII, aged 36 ± 8 and 48 ± 6 years, duration of diabetes 12 ± 8 and 29 ± 4 years, hemoglobin A1c 7.4% ± 0.1% and 7.3% ± 0.3%, body mass index 23.2 ± 0.3 and 28.4 ± 2.2 kg/m², respectively, were studied on two occasions during 22 h overnight hospital admissions 2–4 weeks apart. A Freestyle Navigator® continuous glucose monitor and an OmniPod® insulin pump were applied in each trial. Admission 1 used open-loop control, while admission 2 employed closed-loop control using our MPC algorithm.

In Padova, two out of three subjects showed better performance with the closed-loop system compared to open loop. Altogether, mean overnight plasma glucose (PG) levels were 134 versus 111 mg/dl during open loop versus closed loop, respectively. The percentage of time spent at PG > 140 mg/dl was 45% versus 12%, while postbreakfast mean PG was 165 versus 156 mg/dl during open loop versus closed loop, respectively. Also, in Montpellier, two patients out of three showed a better glucose control during closed-loop trials. Avoidance of nocturnal hypoglycemic excursions was a clear benefit during algorithm-guided insulin delivery in all cases.

This preliminary set of studies demonstrates that closed-loop control based entirely on SC glucose sensing and insulin delivery is feasible and can be applied to improve glucose control in patients with type 1 diabetes, although the algorithm needs to be further improved to achieve better glycemic control.