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ORIGINAL ARTICLES

Hypoglycemia Prevention via Pump Attenuation and Red-Yellow-Green "Traffic" Lights Using Continuous Glucose Monitoring and Insulin Pump Data

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Abstract

Background:

Hypoglycemia has been identified as a primary barrier to optimal management of diabetes. This observation, in conjunction with the introduction of continuous glucose monitoring (CGM) devices, has set the stage for achieving tight glycemic control with systems that adjust the insulin pump settings based on measured glucose concentrations. Because system safety and system reliability are key considerations, there is a need for algorithms that reduce the risk of hypoglycemia in closed-loop, open-loop, and advisory-mode systems. More specifically, the algorithm presented here is formulated as a component of the independent *safety system module* proposed in the modular *control-to-range* architecture.

Methods:

We developed two algorithms for attenuating insulin pump injections, which we refer to as *Brakes* and *Power Brakes*: Brakes is a pump attenuation function computed using CGM information only, while Power Brakes is an attenuation function in which a metabolic state observer with insulin input is used *in addition to* CGM information to inform the level of pump attenuation. These algorithms modulate the insulin pump delivery so that the insulin injection rate is dramatically reduced when the risk of hypoglycemia is high. Additionally, we combined these algorithms with an alert system that indicates a *level* of hypoglycemic risk to the user.

Results:

We demonstrated the effectiveness of Brakes and Power Brakes in reducing the incidence of hypoglycemia in two simulated scenarios: an elevated basal rate scenario and a scenario in which a bolus is delivered for a meal that is skipped. For these scenarios, the incidence of hypoglycemia using Power Brakes was reduced by 88 and 94%, respectively, where we defined hypoglycemia based on the American Diabetes Association guidelines for defining and reporting as 70 mg/dl. In the elevated basal rate scenario, no rebounds above 180 mg/dl (the desired upper limit of the control-to-range protocol) following hypoglycemia were shown to occur. We demonstrated the way the hypoglycemia alert system can trigger the intake of carbohydrates to reduce the incidence of hypoglycemia by 98%.

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Abbreviations: (BG) blood glucose, (CGM) continuous glucose monitoring, (T1DM) type 1 diabetes mellitus

Keywords: hypoglycemia, Kalman filter, modeling, risk of hypoglycemia, simulation

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Abstract cont.

Conclusions:

This article offers, for the first time, a method for smoothly reducing insulin delivery rate to prevent hypoglycemia in individuals with type 1 diabetes mellitus based on a mathematically formal assessment of hypoglycemic risk. *In silico*, we demonstrate the way this method can prevent hypoglycemia while avoiding hyperglycemia rebounds that exceed 180 mg/dl. In conjunction with the pump attenuation algorithms, this article also proposes a system for alerting an individual of their hypoglycemic risk that contains three "levels" of alerts in the form of a traffic light. This alert system can be used in an advisory mode setting to alert the user to take action when hypoglycemia is imminent ("red" light) or in a closed-loop setting where initiation of rescue action begins when the red light alert is triggered.

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