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ORIGINAL ARTICLE

Design of the Health Monitoring System for the Artificial Pancreas: Low Glucose Prediction Module

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Abstract

Background:

The purpose of this study was to design and evaluate a safety system for the artificial pancreas device system (APDS). Safe operation of the APDS is a critical task, where the safety system is engaged only as needed to ensure reliable operation without positive feedback to the controller.

Methods:

The Health Monitoring System (HMS) was designed as a modular system to ensure the safety of the APDS and the user. It was designed using a large set of ambulatory data and evaluated *in silico* by inducing hypoglycemia with a missed meal [bolus for a 65 g carbohydrate (CHO) meal] and administering rescue CHOs per HMS alerting. The HMS was validated in-clinic with a real-life challenge of a subject who overdosed insulin prior to admission.

Results:

The HMS was evaluated for clinical use with a 15 min prediction horizon. Retrospectively, 93.5% of episodes were detected with 2.9 false alarms per day. During *in silico* evaluation, the HMS reduced the time spent <70 mg/dl from 15% to 3%. When the HMS was first tested in-clinic, the subject overdosed ~3 U of insulin prior to her arrival to a closed-loop session (against protocol). The controller reduced insulin delivery, and the HMS gave four alerts that were successfully received via clinical software and text and multimedia messages. Even with insulin reduction and CHO supplements, hypoglycemia was unavoidable but manageable due to the HMS, confirming that a safety system to detect adverse events is an essential part of the APDS.

Conclusions:

The ability of the HMS to be an effective alert system that provides a safety layer to the APDS controller has been demonstrated in a clinical setting.

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Abbreviations: (ADA) American Diabetes Association, (APDS) artificial pancreas device system, (APS) artificial pancreas system, (CGM) continuous glucose monitor, (CHO) carbohydrate, (CRC) clinical research center, (FDA) Food and Drug Administration, (FPR) false positive ratio, (HMS) Health Monitoring System, (IOB) insulin on board, (LGP) low glucose predictor, (MMS) multimedia message service, (MPC) model predictive control, (*PH*) prediction horizon, (*SAR*) successive alarms required, (SMS) short message service, (SSM) safety supervision module, (TPR) true positive ratio

Keywords: artificial pancreas, hypoglycemia, safety, telemedicine

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