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ORIGINAL ARTICLES

Accuracy of a New Real-Time Continuous Glucose Monitoring Algorithm

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Abstract

Background:

Through minimally invasive sensor-based continuous glucose monitoring (CGM), individuals can manage their blood glucose (BG) levels more aggressively, thereby improving their hemoglobin A1c level, while reducing the risk of hypoglycemia. Tighter glycemic control through CGM, however, requires an accurate glucose sensor and calibration algorithm with increased performance at lower BG levels.

Methods:

Sensor and BG measurements for 72 adult and adolescent subjects were obtained during the course of a 26-week multicenter study evaluating the efficacy of the Paradigm® REAL-Time (PRT) sensor-augmented pump system (Medtronic Diabetes, Northridge, CA) in an outpatient setting. Subjects in the study arm performed at least four daily finger stick measurements. A retrospective analysis of the data set was performed to evaluate a new calibration algorithm utilized in the Paradigm® Veo™ insulin pump (Medtronic Diabetes) and to compare these results to performance metrics calculated for the PRT.

Results:

A total of $N = 7193$ PRT sensor downloads for 3 days of use, as well as 90,472 temporally and nonuniformly paired data points (sensor and meter values), were evaluated, with 5841 hypoglycemic and 15,851 hyperglycemic events detected through finger stick measurements. The Veo calibration algorithm decreased the overall mean absolute relative difference by greater than 0.25 to 15.89%, with hypoglycemia sensitivity increased from 54.9% in the PRT to 82.3% in the Veo (90.5% with predictive alerts); however, hyperglycemia sensitivity was decreased only marginally from 86% in the PRT to 81.7% in the Veo.

Conclusions:

The Veo calibration algorithm, with sensor error reduced significantly in the 40- to 120-mg/dl range, improves hypoglycemia detection, while retaining accuracy at high glucose levels.

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Abbreviations: (BG) blood glucose, (CLSI) Clinical and Laboratory Standards Institute, (CGM) continuous glucose monitoring, (DCCT) Diabetes Control and Complications Trial, (FoH) fear of hypoglycemia, (HbA1c) hemoglobain A1c, (MARD) mean absolute relative difference, (PRT) Paradigm REAL-Time, (SMBG) self-monitoring of blood glucose

Keywords: continuous glucose monitoring, hypoglycemia, insulin pump, sensor

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