Accuracy Evaluation of a New Real-Time Continuous Glucose Monitoring Algorithm in Hypoglycemia - DTU Orbit (15/01/2019)

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**Background:** The purpose of this study was to evaluate the performance of a new continuous glucose monitoring (CGM) calibration algorithm and to compare it with the Guardian® REAL-Time (RT) (Medtronic Diabetes, Northridge, CA) calibration algorithm in hypoglycemia.

**Subjects and Methods:** CGM data were obtained from 10 type 1 diabetes patients undergoing insulin-induced hypoglycemia. Data were obtained in two separate sessions using the Guardian RT CGM device. Data from the same CGM sensor were calibrated by two different algorithms: the Guardian RT algorithm and a new calibration algorithm. The accuracy of the two algorithms was compared using four performance metrics.

**Results:** The median (mean) of absolute relative deviation in the whole range of plasma glucose was 20.2% (32.1%) for the Guardian RT calibration and 17.4% (25.9%) for the new calibration algorithm. The mean (SD) sample-based sensitivity for the hypoglycemic threshold of 70 mg/dL was 31% (33%) for the Guardian RT algorithm and 70% (33%) for the new algorithm. The mean (SD) sample-based specificity at the same hypoglycemic threshold was 95% (8%) for the Guardian RT algorithm and 90% (16%) for the new calibration algorithm. The sensitivity of the event-based hypoglycemia detection for the hypoglycemic threshold of 70 mg/dL was 61% for the Guardian RT calibration and 89% for the new calibration algorithm. Application of the new calibration caused one false-positive instance for the event-based hypoglycemia detection, whereas the Guardian RT caused no false-positive instances. The overestimation of plasma glucose by CGM was corrected from 33.2 mg/dL in the Guardian RT algorithm to 21.9 mg/dL in the new calibration algorithm.

**Conclusions:** The results suggest that the new algorithm may reduce the inaccuracy of Guardian RT CGM system within the hypoglycemic range; however, data from a larger number of patients are required to compare the clinical reliability of the two algorithms.

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Contributors: Mahmoudi, Z., Jensen, M. H., Dencker Johansen, M., Christensen, T. F., Tarnow, L., Christiansen, J. S., Hejlesen, O. K.
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