

Modeling of Calibration Effectiveness and Blood-to-Interstitial Glucose Dynamics as Potential Confounders of the Accuracy of Continuous Glucose Sensors during Hyperinsulinemic Clamp

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Abstract

Background:

Models of the dynamics of interstitial fluid-based continuous glucose sensors imply a variable sensor deviation from reference blood glucose (BG), depending on both sensor calibration procedure and BG dynamics. These effects could have a significant effect on the cross-interpretation of nonidentical accuracy studies.

Methods:

Hyperinsulinemic euglycemic and hypoglycemic clamps were performed on 39 subjects with type 1 diabetes wearing the Medtronic Continuous Glucose Monitoring System®. Sensor calibration and interstitial glucose (IG) dynamics were modeled and analyzed as potential confounders of sensor deviation from reference BG.

Results:

The mean absolute deviation (MAD) of sensor data was 20.9 mg/dl during euglycemia and 24.5 mg/dl during descent into and recovery from hypoglycemia. Computer-generated recalibration reduced MAD to 10.6 and 14.6 mg/dl, respectively. Modeling of IG dynamics reduced the MAD further to 10.0 and 10.4 mg/dl (using idiosyncratic parameters) or to 10.6 and 11.5 mg/dl (using model parameters common for all subjects), respectively.

Conclusions:

The sensor MAD from reference is strongly influenced by the choice of calibration points. Thus, cross-experiment comparisons of sensor accuracy are likely to be heavily dependent on the employed calibration procedures. Demanding calibration points substantially differing in value was found to improve calibration effectiveness. Simulation using existing IG models and population parameters reduced the bias resulting from BG-IG dynamics.

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Abbreviations: (BG) blood glucose, (CGS) continuous glucose sensor, (IF) interstitial fluid, (IG) interstitial glucose, (MAD) mean absolute deviation, (SIG) surrogate interstitial glucose, (T1DM) type 1 diabetes

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