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SYMPOSIUM

Continuous Glucose Sensors: Continuing Questions about Clinical Accuracy

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Abstract

Continuous glucose sensors (CGS) offer the potential to greatly change the lives of people with diabetes. Even though two of these systems (Guardian RT, Medtronic, Northridge, CA, and DexCom STS, DexCom, San Diego, CA) have been approved by the Food and Drug Administration for use as adjuncts to self-blood glucose monitoring (SBGM), questions remain concerning the accuracy of these devices. When considering accuracy, two distinct approaches should be emphasized: (1) numerical and (2) clinical. Because CGS data are a process in time, each of these two approaches includes two subtypes of accuracy: point and rate. Conventional statistics such as correlation coefficients, mean and median relative absolute differences, and International Standards Organization criteria are measures of numerical point accuracy. A new measure, the R deviation, is introduced to quantify numerical rate accuracy. Error-grid analysis (Clarke EGA) measures clinical point accuracy. The only measure of both clinical point accuracy and rate accuracy is continuous glucose error-grid analysis. This analysis is a combination of two components, P-EGA measuring point accuracy and R-EGA measuring rate accuracy, which are designed to assess the information that distinguishes continuous glucose measurements from intermittent SBGM determinations. Further, a better understanding of the source of the error associated with time lag and its effect on CGS readings may improve sensor output. Finally, the reliability of the CGS sensors, in terms of initial calibration and long-term application, needs to be assessed carefully if current CGS systems are to be used as hypoglycemia monitors or incorporated in the future design of closed loop (artificial pancreas) systems.

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Abbreviations: (ARD) absolute R deviation, (BG) blood glucose, (CG-EGA) continuous glucose error-grid analysis, (CGS) continuous glucose sensors, (EGA) error grid analysis, (FDA) Food and Drug Administration, (IG) interstitial glucose, (ISO) International Standards Organization, (MAD) mean absolute difference, (MARD) median relative absolute difference, (P-EGA) point EGA, (RD) R deviation, (R-EGA) rate EGA, (SBGM) self-blood glucose monitoring

Keywords: accuracy assessment, continuous glucose monitoring, continuous glucose error grid analysis

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