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Statistical Approach of Assessing the Reliability of Glucose Sensors: The GLYCENSIT Procedure

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Abstract

Background:

In healthcare, patients with diabetes are instructed on how to apply intensified insulin therapy in an optimal manner. Tight blood glucose control is also performed on patients treated in the intensive care unit (ICU). Different blood glucose meters and glucose monitoring systems (GMSs) are used to achieve this goal, and some may lack reliability.

Methods:

The GLYCENSIT procedure is a statistical assessment tool we are proposing for evaluating the significant difference of paired glucose measurements. The performance of the GlucoDay® system in the ICU is analyzed with GLYCENSIT.

Results:

The GLYCENSIT analysis comprises three phases: testing possible persistent measurement behavior as a function of the glycemic range, testing the number of measurement errors with respect to a standard criterion for binary assessment of glucose sensors, and computing the tolerance intervals that indicate possible test sensor deviations for new observations. The probability of the tolerance intervals directly reflects the number of samples and additionally improves current assessment techniques. The method can be tuned according to the clinician's preferences regarding significance level, tolerance level, and glycemic range cutoff values. The measurement behavior of the GlucoDay sensor is found to be persistent but inaccurate and returns wide tolerance intervals, suggesting that the GlucoDay sensor may not be sufficiently reliable for glycemia control in the ICU.

Conclusions:

The GLYCENSIT procedure aims to serve as statistical guide for clinicians in the assessment of glucose sensor devices.

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Abbreviations: (ANOVA) analysis of variance, (DETM) diabetes error test model, (EGA) error grid analysis, (GLYCENSIT) GLYCemia sENSor IT, (GMS) glucose monitoring system, (ICU) intensive care unit, (ISO) International Organization for Standardization

Keywords: glucose measurement, glucose sensor(s), glycemia monitoring, sensor validation, standardized evaluation, statistical analysis

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