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SYMPOSIUM

Analytical and Clinical Performance of Blood Glucose Monitors

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Abstract

Background:
The objective of this study was to understand the level of performance of blood glucose monitors as assessed in the published literature.

Methods:
Medline from January 2000 to October 2009 and reference lists of included articles were searched to identify eligible studies. Key information was abstracted from eligible studies: blood glucose meters tested, blood sample, meter operators, setting, sample of people (number, diabetes type, age, sex, and race), duration of diabetes, years using a glucose meter, insulin use, recommendations followed, performance evaluation measures, and specific factors affecting the accuracy evaluation of blood glucose monitors.

Results:
Thirty-one articles were included in this review. Articles were categorized as review articles of blood glucose accuracy (6 articles), original studies that reported the performance of blood glucose meters in laboratory settings (14 articles) or clinical settings (9 articles), and simulation studies (2 articles). A variety of performance evaluation measures were used in the studies. The authors did not identify any studies that demonstrated a difference in clinical outcomes. Examples of analytical tools used in the description of accuracy (e.g., correlation coefficient, linear regression equations, and International Organization for Standardization standards) and how these traditional measures can complicate the achievement of target blood glucose levels for the patient were presented. The benefits of using error grid analysis to quantify the clinical accuracy of patient-determined blood glucose values were discussed.

Conclusions:
When examining blood glucose monitor performance in the real world, it is important to consider if an improvement in analytical accuracy would lead to improved clinical outcomes for patients. There are several examples of how analytical tools used in the description of self-monitoring of blood glucose accuracy could be irrelevant to treatment decisions.

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Abbreviations: (BG) blood glucose, (CEG) consensus error grid, (DCCT) Diabetes Control and Complications Trial, (EGA) error grid analysis, (FDA) Food and Drug Administration, (HbA1c) hemoglobin A1c, (ISO) International Organization for Standardization, (SBGM) self-blood glucose monitor, (SMBG) self-monitoring of blood glucose

Keywords: diabetes mellitus, glucose, glycemic control, laboratory techniques and procedures, point of care

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