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ORIGINAL ARTICLES

Estimates of Total Analytical Error in Consumer and Hospital Glucose Meters Contributed by Hematocrit, Maltose, and Ascorbate

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Abstract

Background:
Patients and physicians expect accurate whole blood glucose monitoring even when patients are anemic, are undergoing peritoneal dialysis, or have slightly elevated ascorbate levels. The objective of this study was to estimate analytical error in two consumer and two hospital glucose meters contributed by variations in hematocrit, maltose, ascorbate, and imprecision.

Method:
The influence of hematocrit (20–60%), maltose, and ascorbate were tested alone and in combination with each glucose meter and with a reference plasma glucose method at three concentrations of glucose. Precision was determined by consecutive analysis (n = 20) at three levels of glucose. Multivariate regression analysis was used to estimate the bias associated with the interferences, alone and in combination. Total analytical error was estimated as $|\%\ \text{bias}| + 1.96\ (\%\ \text{imprecision})$.

Results:
Three meters demonstrated hematocrit bias that was dependent upon glucose concentration. Maltose had profound concentration-dependent positive bias on the consumer meters, and the extent of maltose bias was dependent on hematocrit. Ascorbate produced small but statistically significant biases on three meters. Coincident low hematocrit, presence of maltose, and presence of ascorbate increased the observed bias and was summarized by estimation of total analytical error. Among the four glucose meter devices assessed, estimates of total analytical error in glucose measurement ranged from 6 to 68% under the conditions tested.

Conclusions:
The susceptibility of glucose meters to clinically significant analytical biases is highly device-dependent, and low hematocrit exacerbated the observed analytical error.

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Abbreviations: (CV) coefficient of variation, (IFCC) International Federation of Clinical Chemistry, (ISO) International Organization for Standardization, (PQQ) pyrroloquinoline quinone

Keywords: ascorbate, bias, glucose meters, hematocrit, imprecision, interference, maltose, total error

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