

Evaluation of Different Disinfectants on the Performance of an On-Meter Dosed Amperometric Glucose-Oxidase-Based Glucose Meter

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Abstract

Background:

Off-meter dosed photometric glucose-oxidase-based glucose meters have been reported to be susceptible to interference by hydrogen-peroxide-based disinfecting agents. The objective of this study was to determine if a single application of hydrogen-peroxide-containing Accel[®] wipe to disinfect an on-meter dosed amperometric glucose-oxidase-based glucose meter will influence its performance.

Method:

The performance of five on-meter dosed amperometric glucose-oxidase-based glucose meters was determined before and after disinfecting the devices with a single application of either CaviWipes[®] (14.3% isopropanol and 0.23% diisobutyl-phenoxy-ethoxyethyl dimethyl benzyl ammonium chloride) or Accel (0.5% hydrogen peroxide) wipes. Replicate glucose measurements were conducted before disinfecting the devices, immediately after disinfecting, and then 1 and 2 min postdisinfecting, with measurements in triplicate. Analysis was sequentially completed for five different meters. Results were analyzed by a two-way analysis of variance (Analyze-it software).

Results:

No clinical (<0.3 mmol/liter) or statistical differences ($p > .05$) in glucose concentration were detected when the on-meter dosed amperometric glucose-oxidase-based glucose meters were disinfected with either CaviWipes or Accel wipes and measured immediately or 1 or 2 min postdisinfecting. No clinically significant difference in glucose concentration was detected between meters (<0.3 mmol/liter).

Conclusion:

The on-meter dosed glucose oxidase amperometric-based glucose meters are not analytically susceptible to interference by a single application of hydrogen-peroxide-containing Accel disinfectant wipes.

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Introduction

The Food and Drug Administration sent a letter to manufacturers of blood glucose monitoring systems regarding mitigation of the risk of disease transmission through the provision of validated cleaning and disinfection procedures.¹ In this communication, it was outlined that disinfection procedures need to demonstrate efficacy against human immunodeficiency, hepatitis C, and hepatitis B viruses. Since disinfectant efficacy for hepatitis B is particularly problematic, a list of Environmental Protection Agency Office of Pesticide Programs registered disinfectants effective against hepatitis B and human immunodeficiency virus-1 was also provided (http://www.epa.gov/oppad001/list_d_hepatitisbhiv.pdf). Several of these approved products contain hydrogen peroxide as a component active ingredient (i.e., Accel[®] TB, 0.5% hydrogen peroxide; Oxivir[®] TB, 0.5% hydrogen peroxide; and H2Orange2 Concentrate 117[®], 3.95% hydrogen peroxide). To date, two case reports have been published documenting the effect of hydrogen-peroxide-containing disinfectants (i.e., Accel wipe) on the performance of an off-meter dosed photometric glucose-oxidase-based glucose meter.^{2,3} The objective of this technical report was to determine if a single application of hydrogen-peroxide-containing Accel wipes to disinfect an on-meter dosed amperometric glucose-oxidase-based glucose meter will influence its performance.

Methods

Instrumentation and Materials

Disinfectant Wipes

Accel (0.5% hydrogen peroxide) wipes were purchased from HANSA Med Ltd., Mississauga, Canada, and CaviWipes XL[®] (14.3% isopropanol and 0.23% diisobutyl-phenoxo-ethoxyethyl dimethyl benzyl ammonium chloride) were obtained from Metrex, Orange, CA.

Glucose Meter

The Nova StatStrip Xpress[®] meter is a nonconnectivity hospital meter that utilizes a modified glucose-oxidase-based amperometric detection system and a hematocrit correction test strip. This meter is calibrated to report plasma equivalence of glucose concentration (mmol/liter).

Disinfection and Experimental Protocol

External disinfection of the on-meter dosed glucose meter was accomplished by thoroughly wiping all external areas, including the test strip port, with the prescribed disinfectant wipe.

The performance of five glucose meters was determined before and after disinfecting the devices with either CaviWipes or Accel wipes. The glucose concentration in a whole blood specimen was measured ($n = 3$) before disinfecting the devices, immediately after disinfecting, and then 1 and 2 min postdisinfecting. Analysis was sequentially completed for five different meters. The same five meters were used to evaluate both disinfectant wipes. These meters were removed from clinical service to be used in this study. A nonfasting whole blood specimen collected from a healthy volunteer was maintained on ice to minimize glycolysis during the period of experimentation.

Statistical Analysis

Results were analyzed by a two-way analysis of variance (Analyze-it software). Power analysis of this experimental design to detect 0.3 mmol/liter change in blood glucose was > 0.90 .

Results

Table 1 outlines the effect of CaviWipes on the measurement of whole blood glucose using the on-meter dosed

Table 1.
Effect of CaviWipes on the Performance of the On-Meter Dosed Amperometric Glucose Oxidase Glucose Meter^a

	Meter 1	Meter 2	Meter 3	Meter 4	Meter 5
Before disinfection	4.87 ± 0.15	4.87 ± 0.21	4.83 ± 0.15	4.80 ± 0.10	4.70 ± 0.17
Immediately after disinfection	4.77 ± 0.06	4.57 ± 0.15	4.83 ± 0.06	4.70 ± 0.10	4.80 ± 0.17
1 min postdisinfection	4.80 ± 0.10	4.67 ± 0.15	4.90 ± 0.00	4.57 ± 0.23	4.67 ± 0.06
2 min postdisinfection	4.60 ± 0.17	4.77 ± 0.06	4.93 ± 0.12	4.70 ± 0.00	4.60 ± 0.00

^a Glucose concentrations are expressed as mean (mmol/liter) ± standard deviation (mmol/liter) for three determinations.

amperometric glucose-oxidase-based glucose meter. Cavi-Wipes served as a control in that it does not contain hydrogen peroxide. The active ingredients are reported to be 14.3% isopropanol and 0.23% diisobutyl-phenoxy-ethoxyethyl dimethyl benzyl ammonium chloride.⁴

A two-way analysis of variance was conducted to determine if statistically significant differences were related to meter differences or meter disinfecting and time postdisinfecting. The source of variation attributed to disinfection and times postdisinfection were not statistically significantly different ($p = .24$). The variation detected between meters was statistically significant ($p < .01$) and was thought to be due to glycolysis.

Table 2 outlines the effect of Accel wipes on the performance of the glucose meter under investigation.

Contrary to results obtained with the off-meter dosed photometric glucose oxidase meter, Accel wipes did not influence the performance of the on-meter dosed amperometric glucose-oxidase-based meter ($p = .31$).

Discussion

Concern about potential disease transmission through the use of a single glucose meter for multiple patients has been supported with a study that documented glucose meter use for 1 month in a 214-bed hospital. It was reported that 61% and 80% of glucose measurements were sequentially performed within 1 and 24 h, respectively, with glucose meters that were used on more than one patient.⁵ In 2005, an audit for blood-contaminated glucose meters in 12 academic and nonacademic hospitals revealed that, overall, 30.2% of glucose meters were contaminated with blood and that intensive care unit meters were 2.2 times more likely to be contaminated with blood than meters used in general medicine areas.⁶ To reduce disease transmission, off-meter dosing of the

glucose meter test strips was developed. However, in the 2005 audit, the percentage of glucose meters found to be contaminated with blood with off-meter (26.6%) versus on-meter (31.4%) dosing was not statistically significant.⁶ These studies emphasize the need for disinfection and cleaning protocols regardless of meter dosing format.

Susceptibility of an off-meter dosed photometric glucose-oxidase-based meter to hydrogen peroxide interference following a single use of Accel wipes for meter disinfection has been previously reported.^{2,3} In the first publication, it was speculated that hydrogen peroxide in the Accel wipes was the cause of increased frequency of error 2b codes, which, according to the manufacturer, indicate the "meter detected a problem with the test strips."² This speculation was extended in the second citation, where a significant overestimation of glucose concentration was detected for hours after disinfecting the meter with Virox® (0.5% hydrogen peroxide) wipes. Results of the current study indicated that the on-meter dosed amperometric glucose-oxidase-based meter under investigation was not susceptible to interference after a single application of a hydrogen-peroxide-containing Accel disinfecting wipe. Because both the on-meter and the off-meter dosed glucose-oxidase-based meters require hydrogen peroxide formation to measure glucose, the apparent discrepancy with respect to susceptibility to hydrogen peroxide could be related to the different disinfection protocols used for these meters. On-meter dosed glucose meters are designed such that only external meter disinfection is required, whereas insertion of blood-saturated test strips into the interior of off-meter dosed glucose meters dictates regular disinfection of the optical read/test strip holder in addition to the external surface of the meter. If the hydrogen peroxide solution in the disinfectant was not adequately rinsed or removed from the off-meter dosed test strip holder, then the residual hydrogen peroxide would enhance the reaction mechanism for glucose detection.

Table 2.
Effect of Accel Wipes on the Performance of the On-Meter Dosed Amperometric Glucose Oxidase Glucose Meter^a

	Meter 1	Meter 2	Meter 3	Meter 4	Meter 5
Before disinfection	4.60 ± 0.20	4.60 ± 0.26	4.50 ± 0.17	4.50 ± 0.00	4.50 ± 0.26
Immediately after disinfection	4.83 ± 0.06	4.53 ± 0.31	4.43 ± 0.15	4.47 ± 0.25	4.50 ± 0.10
1 min postdisinfection	4.67 ± 0.23	4.47 ± 0.15	4.40 ± 0.20	4.27 ± 0.15	4.40 ± 0.10
2 min postdisinfection	4.70 ± 0.26	4.57 ± 0.15	4.47 ± 0.15	4.33 ± 0.23	4.27 ± 0.15

^a Glucose concentrations are expressed as mean (mmol/liter) ± standard deviation (mmol/liter) for three determinations.

Conclusion

The on-meter dosed amperometric glucose-oxidase-based glucose meter under investigation was not analytically affected by the single application of hydrogen-peroxide-containing Accel wipes used for meter disinfection.

Study Limitations/Future Studies

- This study evaluated the impact of a single application of hydrogen-peroxide-containing Accel disinfectant wipes.
- The susceptibility of the on-meter dosed amperometric glucose-oxidase-based meter to hydrogen peroxide was evaluated with one hydrogen peroxide concentration.
- Investigation of clinically realistic repeated use of hydrogen peroxide disinfectants on the performance of on- and off-meter dosed glucose-oxidase-based meters should be examined in future studies.
- Investigation of hydrogen-peroxide-containing agents used for disinfection of patient rooms on the performance of on- and off-meter dosed glucose-oxidase-based meters should also be examined in future studies.

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