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ORIGINAL ARTICLE

The Effect of an Instant Hand Sanitizer on Blood Glucose Monitoring Results

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Abstract

Background:

People with diabetes mellitus are instructed to clean their skin prior to self-monitoring of blood glucose to remove any dirt or food residue that might affect the reading. Alcohol-based hand sanitizers have become popular when soap and water are not available. The aim of this study was to determine whether a hand sanitizer is compatible with glucose meter testing and effective for the removal of exogenous glucose.

Methods:

We enrolled 34 nonfasting subjects [14 male/20 female, mean ages 45 (standard deviation, 9.4)] years, 2 with diagnosed diabetes/32 without known diabetes]. Laboratory personnel prepared four separate fingers on one hand of each subject by (1) cleaning the second finger with soap and water and towel drying (i.e., control finger), (2) cleaning the third finger with an alcohol-based hand sanitizer, (3) coating the fourth finger with cola and allowing it to air dry, and (4) coating the fifth finger with cola and then cleaning it with the instant hand sanitizer after the cola had dried. Finger sticks were performed on each prepared finger and blood glucose was measured. Several *in vitro* studies were also performed to investigate the effectiveness of the hand sanitizer for removal of exogenous glucose.z

Results:

Mean blood glucose values from fingers cleaned with instant hand sanitizer did not differ significantly from the control finger (p = .07 and .08, respectively) and resulted in 100% accurate results. Blood glucose data from the fourth (cola-coated) finger were substantially higher on average compared with the other finger conditions, but glucose data from the fifth finger (cola-coated then cleaned with hand sanitizer) was similar to the control finger. The data from *in vitro* experiments showed that the hand sanitizer did not adversely affect glucose meter results, but when an exogenous glucose interference was present, the effectiveness of the hand sanitizer on glucose bias (range: 6% to 212%) depended on the surface area and degree of dilution.

Conclusions:

In our study, use of an instant hand sanitizer was compatible with the results of a blood glucose monitor and did not affect finger stick blood glucose results. However, depending on surface area, hand sanitizers may not be adequate for cleaning the skin prior to glucose meter testing.

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Abbreviations: (CV) coefficient of variation, (SD) standard deviation, (SMBG) self-monitoring of blood glucose, (YSI) Yellow Springs Instrument

Keywords: blood glucose monitoring, hand sanitizer, pre-analytical error, self-monitoring of blood glucose

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Introduction

Self-monitoring of blood glucose (SMBG) involves laypersons in the performance of an *in vitro* diagnostic test. One of pre-analytical factors to consider is that the skin of the puncture site must be clean prior to blood sampling.[1,2] When skin is contaminated with an exogenous glucose-containing substance, blood glucose readings can show markedly high biases.[3,4] Soap and water are typically used to clean the skin prior to skin puncture in home settings, but 70% isopropyl alcohol wipes are commonly used in clinical settings.[5] It is not known if alcohol-based hand sanitizers will adversely affect blood glucose meter results and/or if they are capable of minimizing interference from exogenous glucose.

The purpose of this report is to describe the data, from clinical and laboratory studies, regarding an alcohol-based hand sanitizer and its (1) compatibility with a blood glucose monitoring system and (2) its effectiveness in the removal of exogenous glucose.

Methods

Clinical Study

A clinical study protocol was approved by the LifeScan internal review board. Thirty-four subjects were enrolled and asked to wash (with warm water and soap) and dry their hands prior to the study. Then a technician prepared the four fingers of one hand of each subject as follows: second finger was the control, and the subject was asked not to touch anything with this finger; the third finger was wiped with instant hand sanitizer (Purell® Instant Hand Sanitizer with Aloe, active ingredient 65% ethyl alcohol, Johnson & Johnson Consumer Products, Skillman, NJ) by the technician until dry according to labeled instructions; and the fourth and fifth fingers were coated with cola (Coca-Cola®, Coca-Cola Company, Atlanta, GA), which contains sugars, sodium, phosphorus, and caffeine, and then dried with a fan. When all four fingers were dry, a technician performed five punctures. Blood from the second finger was used for the Yellow Springs Instrument (YSI) 2700 Biochemistry Analyzer (Yellow Springs Instrument Co., Inc., Yellow Springs, OH) and a hematocrit test (Hematastat, Separation Technology, Inc., Sanford, FL), and a second puncture was used to obtain blood for a blood glucose meter test [OneTouch® Ultra®2 Blood Glucose Monitoring System (LifeScan, Inc., Milpitas, CA)]. Fingers 3 and 4 were also punctured and the blood tested with Ultra2. Prior to the finger puncture on finger 5, the subject rubbed the instant hand sanitizer over both hands (including finger 5) until dry according to labeled instructions. Finally, finger 5 was punctured and the blood tested with Ultra2.

Hand sanitizer manufacturer instructions were carefully followed for this last (fifth) finger. The instructions state to

- Wet hands thoroughly with product and
- Briskly rub hands together until dry.

By allowing the subjects to rub their hands together (without technician intervention), we were able to follow instructions precisely, which allowed us to investigate the effectiveness of the hand sanitizer for the removal of an exogenous glucose interference.

In Vitro Studies

First, an *in vitro* laboratory test was used to confirm the compatibility of the hand sanitizer with blood glucose measurements. A 116 cm^2 surface area was used as a conservative estimate of the surface area of one side of an adult human hand. Thin plastic transparencies (HP C2934A Color LaserJet Transparency Film, Hewlett-Packard, Palo Alto, CA) were cut into strips (22.9×5.1 cm = 116 cm^2) and used to simulate the skin surface. A 0.25 ml volume of hand sanitizer, equivalent to the pump volume from the dispenser, was applied, and a squeegee was used to cover the plastic strips with a thin film. When the surface was completely dry, 1.5 μl of blood was placed in the center and a glucose reading was immediately taken with an Ultra2. Next, a second 1.5 μl blood drop was placed on a separate plastic "control" sheet (i.e., without hand sanitizer), and a glucose reading was taken immediately using a different Ultra2 meter. This testing procedure was repeated for 10 strips for each of the 3 Ultra strip lots.

Next, another *in vitro* study was performed to elucidate the interaction of hand sanitizer with sugar compounds. Increasing volumes of hand sanitizer were added to Gatorade® (The Gatorade Company, Chicago, IL) that contained high-fructose corn syrup and sucrose syrup. The Ultra2 meter was used to test the glucose of the resultant mixture.

In a final *in vitro* study, small drops of blood were applied to two sizes of plastic sheets (area = 58 and 387 cm^2) containing a topcoat of hand sanitizer over a basecoat of 8000 mg/dl glucose solution in order to ascertain the effect of surface area. Glucose results were analyzed with the Ultra2 glucose meter.

Results

Clinical Study

Demographics for the study population are shown in **Table 1**. The 34 subject hematocrit values were within the acceptable range of the Ultra2 blood glucose meter (hematocrit range: 30–55%).

Table 2 shows the averaged glucose data for each condition. The hand sanitizer results were 3% higher than the control condition but this difference was not significant. The relatively large standard deviation (SD) for the control condition is due to the fact that some of the 34 subjects were fasting while other subjects were in the post-prandial state. As expected, skin surfaces coated in cola caused a +82% average bias in blood glucose results. The large SD for the cola finger glucose was due to the fact that the effect of the cola residue was heterogeneous—some subjects showed a modest effect while others produced extremely high results. Data from the fifth finger condition (hand sanitizer after cola treatments) suggest that the hand sanitizer effectively cleaned the skin surfaces of cola because the mean meter response did not differ significantly from either the control or the hand sanitizer conditions. Compared to the concomitant YSI glucose value, 100% (34/34) of both the hand sanitizer and hand sanitizer after cola treatment Ultra meter glucose results were within ± 20% of the reference glucose, which meets the acceptance criteria stated in the International Organization for Standardization 15197.[6] Analysis by consensus error grid showed that 98.5% (67/68) of the combined results for the hand sanitizer and hand sanitizer after cola treatment were in zone A, one value was in zone B, and none were in zones C, D, or E.

In Vitro Studies

Table 3 shows the results of an *in vitro* study intended to verify the blood glucose results of the clinical study. Under controlled conditions, both control and hand sanitizer results were precise [coefficient of variation (CV) < 4%],

Table 1.
Study Demographics

Demographic	Data
Males	14 (41%)
Females	20 (59%)
Diagnosed Diabetes	2 (6%)
Age	Mean, 45 years SD, 9 years Range, 27–66 years
Hematocrit	Mean, 41.1% SD, 3.9% Range, 33–48%
Random glucose	Mean, 105 SD, 17.2 mg/dl Range, 86–153 mg/dl

Table 2.
Average Glucose Values Associated with Various Skin Surface Conditions

Finger skin condition	*N*	Glucose mean (mg/dl)	Standard deviation (mg/dl)
Control	34	100.6	16.5
Hand sanitizer	34	103.6	17.1
Cola	18[a]	285.2[b]	253.5
Hand sanitizer after cola	34	103.8	17.4

[a] Cola residue caused the Ultra meter to display 16 non-numeric error messages.
[b] Statistically different ($p < .001$) from the other conditions at 95% confidence. Three values > 600 mg/dl are included (804, 831, and 755 mg/dl). The OneTouch Ultra2 is not validated above 600 mg/dl.

Table 3.
***In Vitro* Data from a Hand Sanitizer Tested with Three Lots of Ultra Test Strips**

Lot number	*n*	Hand sanitizer mean	Control mean	Mean difference	Control CV (%)	Hand sanitizer CV (%)	*P* value
3031655	10	87.7	88.3	-0.6	1.85	3.44	0.56
3029595	10	114.6	114.7	-0.1	2.14	2.83	0.92
3029590	10	168	167.6	0.4	3.38	1.90	0.80

and the mean difference between control and the hand sanitizer (<1 mg/dl) was not significantly different.

When different volumes of hand sanitizer were added to a fixed volume of Gatorade (aqueous) fluid, the glucose meter response was reduced in proportion to the diluted volume. In one experiment, in a fixed 0.5 ml Gatorade volume, hand sanitizer was added in volumes of 0, 0.2, and 0.5 ml and the glucose levels of the resultant fluid samples were 110, 53, and 21 mg/dl, respectively. In a second experiment, in a fixed 1.0 ml Gatorade volume, hand sanitizer was added in volumes of 0, 0.5, and 1.1 ml and the glucose levels of the resultant fluid samples were 114, 57, and 20 mg/dl, respectively.

When a portion of a blood sample (native glucose = 78 mg/dl) was applied to a plastic sheet (area = 58 cm^2) containing exogenous glucose, the glucose level rose to 243 mg/dl (bias = 212%). When hand sanitizer was applied over this same surface and a portion of the native blood sample was reapplied, measured glucose was 115 mg/dl (bias = 40%). When the surface area was increased (area = 387 cm^2) and blood and hand sanitizer was applied as before, measured glucose was observed to be 83 mg/dl (bias = 6%).

Discussion

Blood glucose meter manufacturers typically recommend that the skin puncture site be both clean and dry before skin puncturing and subsequent glucose meter testing. Washing hands with warm water and soap has the advantage of increasing blood perfusion (enhancing blood flow and producing larger blood volumes), and soap is adequate to prevent infection in most circumstances. However, even the use of soap and water does not guarantee uncompromised glucose meter test results. If skin is not dry, the blood sample might become diluted with water. In addition skin-surface water can adversely affect the test strip chemical reaction if the dried chemicals in the sample chamber are prematurely solubilized. Therefore, users should ensure that their skin is both “clean” and “dry” prior to SMBG.

Hand sanitizers are recognized as effective for reducing infection rates and are recommended as a component of hand hygiene in clinical settings.[7] Frequent use of alcohol-based hand sanitizers containing emollients may be better tolerated than washing hands with soaps or detergents,[8] perhaps because alcohol removes fewer skin surface lipids and is less drying.[9] However, the frequency of use of hand sanitizers for skin cleaning prior to glucose testing is unknown.

In our clinical study, the hand sanitizer was initially observed to cause a 3% average bias compared with the control condition, which was not statistically significant. Hand sanitizer may coat the skin with nonvolatile ingredients. In a more controlled laboratory study, the bias was observed to be minimal (<±1 mg/dl), with excellent associated imprecision over three different lots of OneTouch Ultra test strips (**Table 3**). Therefore, when used according to manufacturer’s instructions, the data suggest that alcohol-based hand sanitizers are compatible with the OneTouch Ultra2 blood glucose monitoring system, and hand sanitizer does not cross react or otherwise interfere with test strip chemistry or glucose meter results.

Our clinical study data also showed that some of the glucose results, associated with the testing of the fourth finger contaminated with cola, were markedly spurious (**Table 2**). Use of hand sanitizer on the fifth finger eliminated the exogenous glucose due to cola, when used according to instructions, and returned the average glucose response to near baseline. The reason for this observation is likely because the interference was confined to a relatively small area (i.e., fifth finger of one hand), the volume of hand sanitizer was relatively larger than the volume of exogenous glucose, and the exogenous glucose was subsequently diluted over a large surface area.

In laboratory studies, increasing volumes of hand sanitizer proportionately decreased the glucose meter readings of fixed volume of an aqueous, sugar-containing athletic beverage. In addition, the amount of interference on a plastic sheet decreased with use of hand sanitizer—but this decrease was dependent on the available surface area. Therefore, the effectiveness of a hand sanitizer, with regard to potential interferences, is dependent on dilution—in both terms of relative volume and surface area. When hand sanitizer was used to spread the sugar-containing compound over a large surface area, interference was minimized. However, when skin surrogates were exposed to very high glucose concentrations over a small surface area, the hand sanitizer failed to prevent interference, and glucose meter results were adversely affected. Use of soap and warm water has the potential to remove—not merely dilute—any potential interference from the skin surface and may provide the additional benefit of increasing localized skin site perfusion.

Conclusion

Instant hand sanitizers did not adversely affect the test strip chemistry of a blood glucose monitoring system. Instant hand sanitizers perform a dilution of preexisting sugar-containing compounds and may or may not minimize interference from exogenous glucose prior to blood glucose monitoring. Therefore, depending on the surface area, instant hand sanitizers may or may not be appropriate to clean the skin surface prior to SMBG.

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Disclosure:

This study was funded by LifeScan, Inc., a Johnson & Johnson company. John Mahoney and John Ellison are employees of LifeScan, Inc., and shareholders of Johnson & Johnson. Danielle Glaeser is a former employee of LifeScan, Inc. David Price is a former employee of LifeScan, Inc., and a current employee of Dexcom, Inc.

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