Inaccuracy of Commercially Available Wireless Smart Glucose Monitoring Device

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Abstract **-** The purpose of the study was to determine the accuracy of a commercially available wireless smart glucose monitoring device. Blood samples were collected from fifty selected participants. Results showed that the commercially available wireless smart glucose monitoring device overestimates the laboratory test by 12.02 mg/dL [$CI_{95\%}$: 7.86 to 16.18], which did not reach an acceptable agreement with the standard laboratory testing.

Index Terms- accuracy, glucometer, glucose, wireless smart glucose monitoring device

I. INTRODUCTION

For over the past ten years, continuous glucose monitoring has served as a research tool and a device for clinical practice. It is designed to improve glucose control without requiring the addition of medications, because it provides information about glucose concentration, direction and rate of change. Continuous glucose monitoring (CGM) resembles the self-monitoring of blood glucose (SMBG), which is widely used today. The utility of blood glucometers was doubted, even though their overall accuracy was superior, due to urine glucose determination being the standard for determining dosage adjustments to hypoglycemic agents about thirty years ago (Blevins *et al*., 2010).

However, since urine tests are affected by fluid intake, glucose threshold, and inability to distinguish hypoglycemia, euglycemia, and even mild hyperglycemia, blood became the preferred sample because of its capacity to reflect “real time” concentrations of blood glucose (Clarke & Foster, 2012).

From blood glucose test strips, the ways by which determining blood glucose level has developed to a modern portable device capable of giving more accurate results, called the glucometer (Clarke & Foster, 2012). In the present, a more handy way of monitoring glucose levels is already available through wireless glucose monitoring devices. It tracks the records of glucose readings through a smartphone and having the blood sugar readings in just seconds. It comes with a downloadable application that automatically keeps track of the history of the results of the user and enables data sharing. Also, through the application, users can easily view glucose trends, set test, and medication reminders, which is distinctive to the usual glucometers. It was commercially available since 2013 and this new device is a Food and Drug Administration (FDA) and a Certification Experts (CE) approved, after meeting the standards set by the health governing bodies in the United States and Europe. Like other glucometers, it offers self-testing in managing blood glucose levels especially to people with diabetes mellitus.

II. OBJECTIVE

The goal of this study is to determine the accuracy of the commercially available wireless smart glucose monitoring device.

III. METHODS

3.1 Experiment Procedure

Blood samples were collected from a total of fifty selected participants.

For the commercially available wireless smart glucose monitoring device, 0.7 mL of whole blood was used from each participant. The specimen was then allowed to spread on the strip by capillary action. The glucometer was synced with the mobile application installed in the smartphone, on which the results were read and saved.

For the laboratory testing, 5 mL of blood was extracted from each participant. The yellow top tubes, which contain acid citrate dextrose (ACD), separated the serum from the packed cells of the blood samples. These tubes were submitted to Biocross Diagnostic Center, Inc. The aforementioned laboratory determined the blood glucose level of the participants.

The results from the laboratory, being considered as standard, were compared to those from the glucometer.

3.2 Statistical Analyses

Statistical analyses were performed using Microsoft Excel ® 2007 XLSTAT (Version 2015, Addinsoft, Brooklyn, NY, USA). Passing-Bablok regression and Bland-Altman plots were used to determine if the two methods, using wireless smart glucose monitoring device and laboratory testing, would have the same results.

IV. RESULTS AND DISCUSSION

The fifty selected participants had a mean age of 60 years (range, 18 to 85), 14 (28%) were males and 36 (72%) were females. A total of 16 (32%) participants were hyperglycemic (>100 mg/dL) and 34 (68%) were normoglycemic.

Though there was no evidence of non-linearity (p = 0.906) between the results of the commercially available wireless smart glucose monitoring device and the standard test, results from the commercially available wireless smart glucose monitoring device did not reach an acceptable agreement with the standard laboratory testing. Passing-Bablok regression estimates for the intercept and the slope are 2.13 [$CI_{95\%}$: -12.06 to 10.31] and 1.10 [$CI_{95\%}$: 1.02 to 1.26], respectively. A total of 42 (84%) observations gathered from the commercially available wireless smart glucose monitoring device are higher than the values given by the laboratory standard test. Moreover, the bias coefficient of 12.02 [$CI_{95\%}$: 7.86 to 16.18], shows evidence that the commercially available wireless smart glucose monitoring device overestimates the standard test result (Figure 1).

Based from the results above, it was found that the commercially available wireless smart glucose monitoring device had inaccurate results. In line with this, possible errors include physical factors (e.g. environment), the specimen used, physiological and pharmacological condition of the patients, the time interval of specimen collection between the tests, the calibration of the device, and various glucometer factors.

According to Ginsberg (2009), physical factors are associated with the environment where the procedure took place, which in turn influenced the altitude and temperature. Altitude and temperature could affect the accuracy of blood glucose strips, thus affecting the results from the glucometer. The user's manual clearly stated that the measuring method used is amperometric technology, using glucose oxidase. Glucose oxidase utilizing glucometers overestimate glucose at high altitudes and low temperatures. This can lead to unpredictable results because the meter technology is stressed under extreme environmental conditions.

Venous blood from the participants was used for the glucose determination of both procedures in the study. Researchers made use solely of venous blood for both tests since the glucometer user's manual requires capillary blood as specimen for the glucometer but also stated on some parts of the manual that whole blood, not particularly capillary blood, may be used as well. In addition, researchers took advantage of the accessibility of drawing blood from patients using venipuncture alone because practicality, time conservation, and convenience of the participants were taken into consideration. Due to the lack of consistency of the glucometer manual regarding the sample to be used, differences in laboratory and glucometer results might have occurred. Since random blood sugar was determined in the experiment, the researchers did not consider whether patients have undergone fasting or were in post-prandial state.

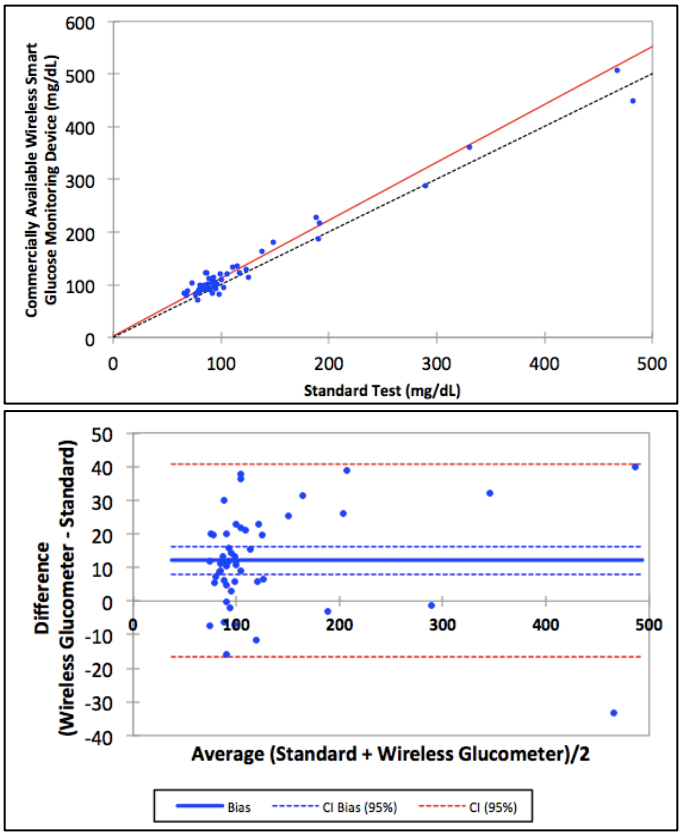

Figure 1. Passing Bablok Regression (above) and the Bland Altman plots (below) of the Commercially Available Wireless Smart Glucose Monitoring Device and the Laboratory Test (Standard)

However, glucose levels differ between fasting and post-prandial (Tonyushkina & Nichols, 2009). While capillary blood can be slightly higher than venous glucose in fasting state, it may be 20 to 25% greater than venous blood in post-prandial. This is a significant factor regarding the determination of the accuracy of the commercially available wireless smart glucose monitoring device only if it was assessed using paired capillary and venous samples from non-fasting individuals. Since the researchers only used venous blood in the experiment, this factor does not affect the overall results of the research.

Physiological and pharmacological factors could have also interfered with the results. Current condition of the patients and the medications taken prior to specimen collection may have affected the results that were obtained. Based on the US FDA (United Stated Food and Drug Administration), patient factors such as dehydration or in shock, as well as medical conditions like polycythemia and anemia may alter blood glucose measurement. Additionally, drugs, sugars, naturally occurring and exogenous substances may interfere or contribute errors to the system evaluation of blood glucose in the glucometer (Ginsberg, 2009).

Moreover, the commercially available wireless smart glucose monitoring device owner's manual suggests the testing for blood glucose using the glucometer and the laboratory be within 15 minutes of each other. Delays in transportation can lead to biases between glucometers and laboratory testing due to glycolysis (Tonyushkina & Nichols,

2009), and that the use of whole blood samples requires consideration of glycolysis effects. Also, separation of serum from cells for laboratory testing should be within 30 minutes from whole blood analysis on the commercially available wireless smart glucose monitoring device, which the researchers failed to comply. Considering the distance between the venue where the glucometer testing was conducted and the laboratory where the specimens were processed, limited resources, and practical reasons, researchers were not able to meet the 15-minute time interval as stated in the manual. This might have been one of the causes for the variations of results.

The device did not undergo calibration using the control solution due to its unavailability. This might have affected the results at some point since there are several situations that the control solution test should be performed as mentioned in the glucometer owner's manual.

Although the commercially available wireless smart glucose monitoring device is US FDA and CE approved, some blood glucose monitors, unfortunately, do not meet the required standards (Klonoff & Reyes, 2013). According to Dr. Claudio, FDA encounters difficulties on evaluating Medical Device Reportings (MDRs) because of the more than 32,000 glucose monitors submitted every year and most manufacturers lack compliance of the requirements. The incompatibility of data from the time of approval and the time of delivery in the market is also a major concern. Given the conclusions of this study, the device, being FDA and CE approved, can not be automatically considered an accurate wireless smart glucose monitoring device. Blood glucose monitors are not perfect devices, and thus are not clearly accurate as well (US FDA, 2015).

V. CONCLUSION & RECOMMENDATION

Since the proposed device was found to overestimate the standard laboratory test, the researchers recommend that users of commercially available wireless device must follow the instruction manual carefully, use the device at the recommended altitude and temperature, and proper calibration should be observed to minimize the errors caused by the device.

Future researchers of similar study should make sure that both tests were taken and tested within 15 minutes of each other. Strict use of capillary blood as specimen is advisable for testing using the wireless smart glucose monitoring device. In addition, consider the medical condition of the participants as it may affect the results.

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