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A Comparative Assessment of the Glucose Monitor (SD Check GOLD) and Semi-auto Analyzer (Biosystems BTS350) in Measuring Blood Glucose Concentration Among Diabetics, Prediabetics, and Non-diabetics

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Abstract

Many chronic diabetics are strongly recommended to do self-monitoring to control glucose metabolism and prevent complications. A practical way to do this is using a glucometer, a device developed to measure glucose concentration from capillary samples in the comfort of the home. It is crucial to test if these glucometers are comparable to the standard laboratory method for glucose analysis. The objective of this study was to determine how well measurements from a glucometer using the SD Check GOLD are correlated with the measurements from a standard semi- auto analyzer such as the Biosystems BTS-350 using samples from a clinical laboratory in Mauban, Quezon. A cross-sectional study was conducted with a total of 45 randomly selected subjects; 16 diabetics, 14 prediabetics, and 15 non-diabetics. Venipuncture and finger prick samples were obtained, and glucose levels were measured. The mean concentration for the diabetics (n=16) using the glucometer was *significantly different* from that of the analyzer (174.910 ± 50.75 vs. 192.563 ± 61.49, p= 0.017), and over-estimated the glucose concentration. Similar readings for prediabetics (117.600 ± 13.10 vs 117.600 ± 13.10, p=0.001) and non-diabetics (85.614 ± 7.20 vs 88.930 ± 7.21, p=0.001) were observed. The correlation between the two methods was *good* and *strongly significant* (r=0.963, p=0.000). The glucometer used in this study has the tendency to overestimate glucose levels as compared to standard laboratory procedures and, therefore, must be anticipated by diabetic patients, especially those under anti-diabetic medications. The author recommends that further studies be done using multiple glucometer brands and add another group of subjects, Type 1 diabetics.

Keywords: Glucometer, self-monitoring blood glucose, diabetes, hyperglycemia, hypoglycemia.

INTRODUCTION

Diabetes mellitus (DM) is a serious disease caused by the body's failure to produce enough insulin, improper use of inulin, or both. It is characterized by hyperglycemia, the elevated blood glucose concentration, because of the lack of insulin regulation (ADA, 2014; Hromadnikova et al., 2020). Type 1-DM, which mostly occurs in individuals 18 years and below, accounts for only 5-10% of diabetics, while type-2 DM, mostly observed in people 40 years above, accounts for 90-95% of all diabetics (ADA, 2014; ADA 2020; NDEP, 2014). DM, the most common of all endocrine disorders, is one of the biggest public health concerns confronting the world today (Baptista, 2020; Nelms and Sucher, 2020; Vicente et al., 2020). It causes morbidity, disability, and

mortality worldwide. Symptoms of DM are often marked by polyuria, polydipsia, weight loss, and sometimes polyphagia and blurred vision (ADA, 2014; de Arruda, 2020). It has been estimated that 8.3% or 387 million of the population worldwide are living with diabetes and is expected to increase by 205 million by the year 2035, with more than 85% of them living in low- and middle-income countries (IDF, 2011; Rathman & Giani, 2004). Hypoglycemia, on the other hand, is low blood glucose and occurs most commonly in people with diabetes as a result of overmedication with insulin or other anti-diabetic medications. It is not as common as hyperglycemia and characterized by sweating, irritability, confusion, fast heartbeat, feeling shaky, coordination problems, and seizures (Bishop et al., 2017; Wild et al., 2004).

Glycemic control has been recognized as a priority treatment to significantly reduce mortality and morbidity in critically ill diabetic patients (Becker et al., 2017; Derde, Vanhorebeek, & Van den Berghe, 2009; Van den Berghe,2004). Getting the accurate blood glucose concentration is an essential parameter for establishing the diagnosis as well as therapy (ADA, 2007). The COVID-19 pandemic has added challenges to diabetic patients as it has limited their access to hospitals for regular check-ups and blood work. While current clinical management during the pandemic is still a work in progress, diabetic patients can still self-monitor their glucose levels using a glucometer (Caballero et al., 2020; Polonsky & Fisher, 2013).

Glucometers are devices developed to measure levels of glucose of capillary blood obtained through finger or heel puncture using a lancet. Since the device is automatic, it is fast and easy to use, mostly using photometric or electrochemical reactions technology (Louie et al., 2000; Polonsky, 2013; Topping et al., 2019). Currently, diabetics achieve self-monitoring blood glucose (SMBG) in two general methods, the glucometer and the laboratory-based testing using chemistry analyzers (Court et al., 2002). Although the use of glucometers is preferred because of it's portable and practical, auto analyzers are perceived as more reliable and accurate (Agarwal et al., 2008; Cameron et al., 2010; Clark & Foster, 2012; Miguel, 2016). However, it is essential to have correct and meaningful glucose measurements to have effective SMBG. In recent years, conflicting results have been reported about the reliability of these devices. Studies by Patel and Patel (2016) and Shete et al. (2016) concluded that capillary blood is the best sample for glucose estimation than venous blood. Another finding suggests that glucometer has acceptable sensitivity and specificity compared to auto analyzers; therefore, it can be used for screening and even early diagnosis (Chlup et al., 2011; Nayeri et al., 2014). However, Nunnelley et al. (2018) detailed that glucose estimation is not different from glucometer and auto analyzer if fluorinated plasma is used. Other studies emphasized that SMBG using glucometer regardless of samples is better in controlling diabetic complications than not monitoring at all (Baig et al., 2007; Cameron et al., 2010; Court et al., 2002; Janapala et al., 2019; Kenya et al., 2014; Miguel, 2016; Polonsky & Fisher, 2013). Currently, in the Philippines, however, little to no literature is available on the accuracy of these devices. Meanwhile, SD Check GOLD glucometer is one of the main glucometers used in Mauban, Quezon, a town in the Philippines, including the JYKEL Clinical Laboratory. This calls to question the need to determine the accuracy and reliability of the glucometer in comparison with the standard laboratory method. This study attempted to explore the accuracy of one of the many brands of glucometers available in the Philippine market. The following specific research questions were addressed:

Research Question 1: What is the level of accuracy of the SD check GOLD glucometer as compared to the standard laboratory method?

Research Question 2: Is there a significant difference between the glucose concentration of diabetic subjects using the glucometer and the standard laboratory method?

Research Question 3: Is there a significant difference between the glucose concentration of prediabetic subjects using the glucometer and the standard laboratory method?

Research Question 4: Is there a significant difference between the glucose concentration of non-diabetic subjects using the glucometer and the standard laboratory method?

Research Question 5: Is there a significant difference between the glucose concentration of using the glucometer and the standard laboratory method when assessed according to the age of diabetic, prediabetic, and non-diabetic subjects?

Research Question 6: Is there a significant difference between the glucose concentration of using the glucometer and the standard laboratory method when assessed according to the gender of diabetic, prediabetic, and non-diabetic subjects?

Research Question 7: Is there a correlation of diabetic, prediabetic, and non-diabetic subjects when measured using glucometer and standard laboratory method?

Theoretical Framework

SMBG is important to prevent diabetic complications. There are two general ways to do this, a lab test and a glucometer. However, conflicting results have been identified in some studies claiming that the use of glucometer is sensitive and specific enough to be used for diagnosis and monitoring (Chlup et al., 2011; Nayeri et al., 2014). Another study stated that its accuracy is dependent on the sample, with fluorinated plasma being the best sample to be used (Nunnelley, 2018).

This study aimed to explore the accuracy and reliability of glucometer compared to the standard laboratory procedure in determining glucose concentration. To achieve this goal, samples from diabetic, prediabetic, and non-diabetic subjects were collected and tested for glucose using the SD check GOLD and the semi-auto analyzer Biosystems BTS-350. It is hypothesized that there is no significant difference between the performance of the two methods. Age and gender of all the groups of subjects were also considered and checked whether they influenced the performance of the two methods. It is hypothesized that these factors would not affect the performance of the two methods. Moreover, the correlation was also checked to see if there was a strong correlation between the two methods.

METHODOLOGY

Research Design

The study design was cross-section comprising of a total of 45 randomly selected patients; 16 diabetics, 14 prediabetics, and 15 non-diabetics.

Population and Sampling Technique

The study was carried out in Mauban, a town in southern Quezon. Diabetic, prediabetic, and non-diabetic subjects were patients of JYKEL Clinical Laboratory and were randomly selected for this study. The study and its significance were explained to all subjects. Inclusions for the subjects were 18-60 years old and must have prior records in the laboratory. Those with other known metabolic disorders were excluded from the study

Sample collection

Consent was obtained from the subjects, and information including socio-demographic information, including sex, age, and type of DM, was collected by the author during the interview. Blood samples were collected by a registered medical technologist from the antecubital vein and capillary of the fingers for the reference glucose oxidase method and glucometer measurements, respectively, after an overnight fast (8-14 hours). Blood cells can rapidly lower the specimen's glucose concentration causing false low glucose levels. Therefore, serum was separated from blood cells as soon as it was clotted and centrifuged (ADA,2014; Bishop et al.., 2017; Louie, 2000). All samples were tested in JYKEL Clinical Laboratory, a laboratory licensed by the Philippine Department of Health. The procedures followed were all based on the laboratory manual and manufacturer's instructions.

Procedure

a. Measurement of glucose level using the glucometer

The glucose level in capillary blood was measured with the SD Check GOLD using standard procedures described by the manufacturer.

b. Measurement of glucose level using the glucometer

The glucose level in venous blood was also measured with the semi-auto analyzer (BTS-350) following standard procedures described by the manufacturer and the standard operating procedures manual in the JYKEL Clinical Laboratory.

Statistical Analysis

The data collected from the study were analyzed using SPSS version 23, and results were presented as mean ± standard deviation. The comparison of the mean values from the two methods was made using an independent t-test at a 95% confidence interval, and the differences were considered statistically significant if $p < 0.05$. To address the first to sixth research questions paired t-test was used, and Pearson Correlations was used for the seventh research question.

Ethical Considerations

Ethical considerations were observed to ensure confidentiality in handling the data. A waiver was signed by the subjects, and they were made aware of the extent of the use of the blood samples collected.

RESULTS

The blood glucose level of the diabetic, prediabetic, and non-diabetic subjects who are part of this study was determined simultaneously with the glucometer (SD Check GOLD) and semi-auto analyzer (Biosystems BTS-350) in the laboratory of the JYKEL Clinical Laboratory located in Mauban, Quezon. All the groups showed significant statistical differences between blood glucose determinations using the two different methods. When looking at the means, glucometer tends to overestimate the measurement in all cases, averagely by 17.653 mg/dL in diabetics, 10.190 mg/dL in prediabetic, and 3.316 mg/dL in non-diabetics.

Table 1: Mean Glucose Concentration of Diabetic Patients

MEAN GLUCOSE CONCENTRATION (mg/dL) ± SD				
	Semi-auto Analyzer (n=16)	**Glucometer** (n=16)	**P value**	
Mean (FBS)	174.910 ± 50.75	192.563 ± 61.49	0.017*	
Age			BS 350	SD
30-50	176.943 ± 54.98	184.714 ± 56.21	0.443	0.653
51-75	173.333 ± 50.60	198.667 ± 68.00		
Gender				
Female	184.750 ± 57.73	205.600 ± 72.57	0.101	0.011*
Male	158.517 ± 34.83	170.833 ± 30.93		

*significant at p 0.05

Among the diabetic group shown in Table 1, the result showed a statistically significant difference (p= 0.017) between glucose levels obtained with the semi-auto analyzer (174.910 ± 50.75) and glucometer (192.563 ± 61.49). When the glucose concentrations were assessed based on age and gender, results showed no statistically significant difference, although the glucometer showed a higher result. This shows that age and gender differences do not affect the methods' performances. Data shows glucometer tends to overestimate the glucose concentration compared to the semi-automated analyzer. This can be a problem for patients undergoing insulin therapy due to the overestimation of the glucose concentration. If a patient is doing SMBG at home using SD Check GOLD, there can be an overestimation of glucose level, and the patient may opt to inject insulin even if it is not needed.

Table 2: Mean Glucose Concentration of Prediabetic Patients

MEAN GLUCOSE CONCENTRATION (mg/dL) ± SD				
	Semi-auto Analyzer (n=14)	**Glucometer** (n=14)	**P value**	
Mean FBS	117.600 ± 13.10	127.790 ± 15.21	0.001*	
Age			BS 350	SD
30-50	117.937 ± 15.94	124.440 ± 18.174	0.366	0.352
51-60	116.99 ± 6.92	122.600 ± 9.40		
Gender				
Female	117.628 ± 15.08	123.600 ± 17.02	0.428	0.669
Male	117.525 ± 7.73	124.250 ± 11.53		

*significant at p 0.05

In the prediabetic group, a mean glucose level of 117.600 ± 13.10 was obtained using the semi-auto analyzer, while the glucometer yielded a mean glucose concentration of 127.790 ± 15.21. When comparing the two means using a t-test, the result was 0.001. This means that there was a significant difference between the methods used in testing for FBS. In the same group, when blood glucose level was assessed according to age and gender of patients, no significant difference was observed between the glucose levels regardless of patients' age and gender. Prediabetics are not yet categorized as having diabetes and usually have a glucose level of 100-125 mg/dL, and if these

patients test FBS using a glucometer, the patient may be misdiagnosed as diabetic (ADA,2014; Bishop et al.., 2017).

Table 3: Mean Glucose Concentration of Non-diabetic Patients

MEAN GLUCOSE CONCENTRATION (mg/dL) ± SD				
	Semi-auto Analyzer (n=15)	**Glucometer** (n=15)	**P value**	
Mean FBS	85.614 ± 7.20	88.930 ± 7.21	0.001*	
Age			BS 350	SD
20-40	86.427 ± 7.63	90.080 ± 7.38	0.171	0.475
41-60	82.367 ± 4.81	84.330 ± 5.03		
Gender				
Female	84.538 ± 6.49	87.500 ± 6.07	0.500	0.632
Male	88.846 ± 8.28	90.570 ± 8.52		

*significant at p 0.05

Among the non-diabetic group, a similar pattern was observed. There was a statistically significant difference between the two methods have a p-value of 0.001. The mean glucose level of 85.614 ± 7.20 was obtained using the semi-auto analyzer, while 88.930 ± 7.21 was obtained using the glucometer having a mean difference of 3.32 mg/dL.

Age did not seem to affect the testing, as seen with the p-value of 0.171 using the Biosystems BTS-350 and 0.475 using the glucometer. In the same category, it was observed that the glucometer overestimates the glucose concentration having a mean difference of 3.65 mg/dL in the age group 20-40 and 1.96 mg/dL in the age group 41-60.

In the gender category, the observable results show no significant difference between the two methods. Comparing the means with a t-test p-value of 0.500 in Biosystems BTS-350 and 0.632 in SD Check GOLD were computed. This means that gender does not influence the glucose testing of the two methods.

Table 4: Glucose Correlation of Diabetic, Prediabetic, and Non-diabetic Patients

	Diabetic	Prediabetic	Non-Diabetic	ALL
Pearson Correlation (r)	0.907*	0.946*	0.917*	0.963*
P-value	0.000	0.000	0.000	0.000

*significant at p 0.05

All the results indicated a strong and significant correlation between the glucometer and the semi-auto analyzer (Pearson correlation = 0.963, p-value= 0.000), as illustrated in Figure 1.

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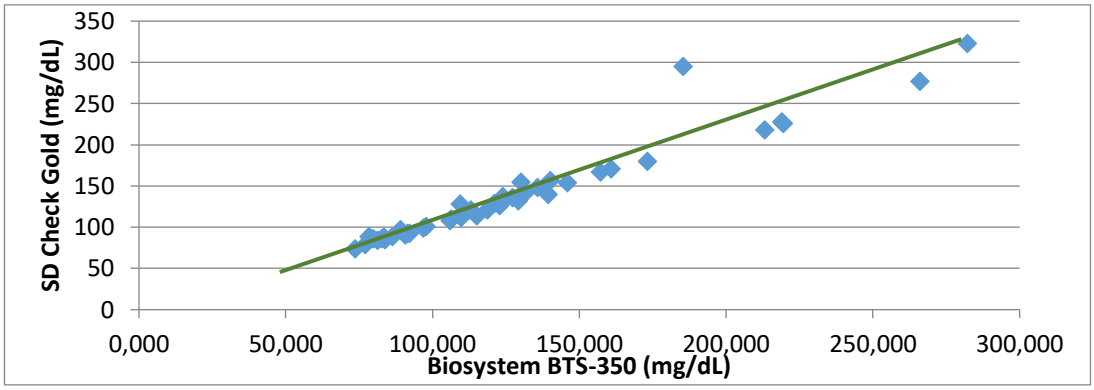
Figure 1: Correlation between glucose levels measured using Biosystems BTS-350 semi-auto analyzer and SD Check GOLD glucometer.



DISCUSSION

Self-monitoring blood glucose is an essential component of diabetic care. Levels of blood glucose provide important information about how the body is controlling blood glucose metabolism, whether glucose-lowering medications work, and the effect of illness and stress on it (Cameron et al., 2010; Court et al., 2002; Janapala et al., 2019; Kenya et al., 2014; Miguel, 2016; Polonsky & Fisher, 2013). Among the SMBG, glucometer has become the most prominent method because of its practicality and cost-effectiveness (ADA, 2007). However, conflicting results regarding the glucometer's accuracy and reliability have been observed (Ginsberg, 2009; Rajendran & Rayman, 2014; Salacinski, 2014). Hence, the aim of this study is to assess the efficiency of the glucometer in comparison with the standard glucose/peroxidase colorimetric technique used in assaying glucose in the laboratory.

The results between the two methods were significantly significant in the three groups as the glucometer tended to over-estimate the measurements. These results corroborate observations made in other studies (Gohlke, 2017; Nunneley, 2018; Tauk, 2015). However, other studies conducted by Patel and Patel (2016) and Shete et al. (2016) reported that although glucometers tend to overestimate glucose concentration, there is no statistical difference. Results shown above indicate that capillary blood glucose may be reproducible as venous blood glucose concentration, which is the standard sample used in laboratory analysis. While the brand and the standards for comparison in these studies are varying, the underlining working principles are the same and, therefore, make the results of this current study compared to other studies (Bimenya et al., 2003). It is also interesting to note that most glucometers in the market, which use capillary blood as samples, have 83% sensitivity and 97.5% specificity compared to the laboratory standard. Despite having a good specificity, it is not as sensitive as the auto analyzers in the lab; therefore, it must be used with caution (Nayeri et al., 2014). This can also explain why the performance of SD check GOLD is not comparable to the Biosystems BTS-350. Another explanation is the difference in the level of glucose levels in the capillary and the veins. Venous plasma glucose level is influenced after using glucose by tissues and effects of insulin, glucagon, other hyperglycemic hormones (Bishop et al.., 2017; Osman et al., 2017). These factors account partly for the variation of results of the glucometer and the semi-automated analyzer, as well as changes in the temperature and humidity (Ginsberg, 2009). The results of the study also show that age and gender have no influence on the levels of glucose analysis by both methods.

One of the threats of having overestimated glucose results for medicating or diet portion controlling diabetics is hypoglycemia (Bimenya et al., 2003; Nayeri et al., 2014; Sudan, 2014). It is a condition needing medical emergency, and symptoms usually occur between 45 to 50.4 mg/dL. However, there is no exact cut-off value for this, and symptoms vary from patient to patient. That's why patients with this tendency are strongly suggested to self-monitor their glucose concentration (Kumar & Kumar, 2004).

Even though there is a significant difference in the two methods in the t-test, the results still show a strong correlation in the results generated by both methods. In this aspect, the glucometer used in this study is relatively accurate at measuring patients with diabetes. This observation is aligned with the studies conducted by Louie et al., 2000 and Corstjens et al., 2006 when they used glucometers to assess critically ill patients. But other studies suggest that a weak correlation was observed, and only selected glucometer brands showed a strong correlation (Bimenya et al., 2003; MostafaGharehbaghi & Ghergherehchi, 2016). With all the contrasting findings, it is not good to generalize that all brands of glucometers are accurate and consistent in their measurements until it has been standardized. Truly, there is a need for standardization of glucometer brands against trusted methods. This will be beneficial, especially for diabetic patients who do not have access to nearby hospitals.

Overall, the results of this study showed that SD check gold is not comparable to the results of the standard laboratory method. It is imperative that attention is given to making policies standardizing the use of glucometer in the Philippines as many diabetics are dependent on it for SMBG (ADA, 2017).

Limitations

This study only used the brand and model SD check GOLD glucometer; hence results cannot be generalized for all brands of glucometers found in the Philippine market. Also, subjects used in this study are only Type 2 diabetics.

CONCLUSION

It is concluded in this study that there is a significant difference in the accuracy of the glucometer (SD check GOLD) and the semi-auto analyzer (Biosystems BTS 350) and, therefore, overestimation on the part of the glucometer must be anticipated. The author recommends that further studies be done using multiple glucometer brands and add another group of subjects – Type 1 diabetics.

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