

Hemoglobin A1C as an Indicator of the Accuracy of Blood Glucose Measurement: Comparative Study of Three Technologies Used for Blood Glucose Measurements

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Abstract

In previous studies, the accuracy of glucose measurements were found with significant variations in different self-monitoring devices. This study suggests Hemoglobin a1c (Hba1c) to be used as an indicator for the accuracy of blood-glucose monitoring devices. In this study, the association between the readings of glycohematoglobin HbA1C and the hyperglycemic readings of thirty hyperglycemic patients is used as an indicator of the accuracy of three types of glucometer devices. The association between hyperglycemic readings and the percentage of HbA1C for the same patients was investigated. The results showed significant association between levels of blood glucose and the percentage of HbA1C in three devices with statistically significant ($p < 0.05$). Such relationship is suggested to be used as a relative accuracy of various types of blood glucose self-monitoring devices.

Keywords

Hemoglobin HbA1C, Blood Glucose Measurement, Accuracy, Diabetes Technology, Precision Medicine

1. INTRODUCTION

Hundreds of millions of diabetics in the world measure blood glucose concentration several times a day requiring more focus towards accuracy evaluation [1],[2],& [3]. The most common endocrine disorder of carbohydrate metabolism is Diabetes Mellitus (DM). DM is a primary reason of morbidity and mortality and main health problems for most communities. The prevalence of hyperglycemia continues to increase. As per our local collected data in Aljouf region, Saudi Arabia, it reaches 40% as shown in Figure 1. Cowie et al estimated prevalence of DM in the USA has been reported to be over 20 million (9.6%) between year 2003 and 2006 [4] & [5]. Shaw et al in a recent study estimated that the world prevalence of diabetes among adults affecting 285 million, would be 6.4% in year 2010 [6]. Furthermore, World Health Organization (WHO) predicted that 366 million people in the world will have diabetes by 2030 [7].

For diagnosing and managing patients with diabetes, there are many lab tests are used. The levels of blood glucose concentration and glycohematoglobin HbA1C are the main diagnostic criteria for diabetes [8]. They are valuable tool for blood glucose monitoring. Self-monitoring of blood glucose (SMBG) has been proven as a useful tool for diabetic patients to manage diabetes [9–15].

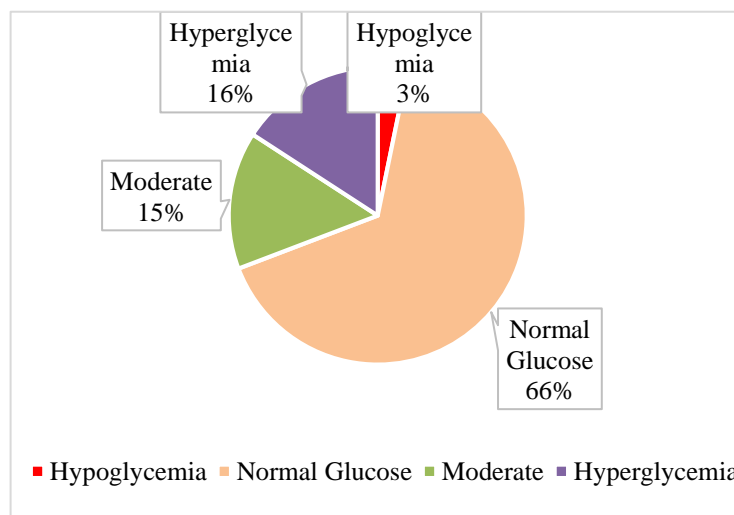


Figure 1. Prevalence of high glucose levels in local population

Diabetic and no-diabetic individuals use blood glucose self-monitoring systems. The accuracy of glucose measurement is important for reliable therapeutic decision. Instrumentally, it is dependent on used methodology for glucose measurement. Conducting periodic and standardized assessment of self-testing blood glucometers is important to ensure adherence to quality standards. Two main reasons affect the clinical practice, research, and development made the accuracy issue more important; first reason, due to an inaccurate glucose measurement which cause risk of false therapeutic decisions, Secondly, advancement of new technology in this field require us to perform regular evaluation for such technologies. Although Hemoglobin A1c (HbA1c) is used as a standard of clinical management for maintaining glycemic control [2] & [3], Hba1c is suggested to be used as an indicator for the accuracy of self-monitoring of blood-glucose monitoring (SMBG) at hyperglycemic readings. Previous stud-ies [16],[17] & [18] indicated that the accuracy variations of glucose measurements



were found with significant in different self-monitoring devices. Therefore, the reliability of therapeutic decisions is thought to be affected accordingly.

In this study , the association between the readings of glycohematoglobin HbA1C and the levels of blood glucose of thirty hyperglycemic patients is used as an indicator of the accuracy of various types of glucometer devices used for blood glucose self-monitoring. We investigated the association between levels of blood glucose in three glucometers and the percentage of HbA1C for the same patients.

Thirty hyperglycemic patients participated in this study and another twenty healthy adults participated as a control group. The results showed significant association between levels of blood glucose and the percentage of HbA1C . Comparison between Accu-Check® Performa-nano with Accu-Check® Active -in relation to Hba1c readings- was statistically significant (p<0.05). Such association between Hba1c and glucose readings of the same samples was suggested to be used as a relative accuracy of various types of blood glucose self-monitoring devices.

2. MATERIALS AND METHODS

Thirty hyperglycemic patients were invited to participate in the study. Each participant was given informed consent for his participation in the study according to according to principles of Hel-sinki Declaration and bioethics guidelines of Al Jouf University (JU) bioethics committee , based on the bylaw of the National Committee of Bioethics at King Abdulaziz City for Science and Technology (NCBE/KACST), Kingdom of Saudi Arabia. The fifty samples were collected from patients at the Diabetes Centre at King AbdulAziz Specialist Hospitals. Three enzyme-based systems for blood glucose measurement were investigated for their performance and ac-curacy. The Accuracy of blood glucose levels of three systems in association with HbA1C per-centages is investigated.

The used gulcometer systems for blood glucose self-monitoring utilize different methods of enzyme-based sensors for blood glucose measurement. Accuracy of the three glucose monitoring systems which use enzyme-based method [Glucose Oxidase (GOx) and Glucose Dehydrogenase (GDH)] were compared. A total of 100 (standard) tests were performed. MINDRAY chemistry- glucose analyzer served as a reference. To evaluate the minimally invasive glucometers, the meters were compared with reference auto-analyzer (Chemistry Analyzer) to assess the accuracy of the devices, glucose standard was used.

The used device for HbA1C is DCA Vantage ® Analyzer, Siemens while the three blood glu-cose monitoring systems were Performa-nano-Accucheck, performa-Accucheck, and Active-Accucheck. All of the blood glucometer enzyme-based method based on Glucose Oxidase (GOx) and (Glucose Dehydrogenase (GDH). A total of 20 (standard) tests were performed to compare variations among the three glucometers.

To evaluate the three glucometers, they were compared with reference auto-analyzer (MIN-DRAY BS-300 Chemistry Analyzer) to assess the accuracy of the devices, glucose standard (94.1 mg/dL) was used. Accuracy was evaluated by calculating the standard deviation (SD) of the means for twenty readings for each system. P value was considered (p<0.05) for statistical significance.

3. RESULTS

The results revealed significant association between the percentage of HbA1C and the accuracy of different types of systems used GLU measurement. Mean and Standard deviation (sd) of the three devices compared to reference chemistry analyzer BS-300 mindry ® is illustrated in table 2 and as a measure of accuracy in figure 1.

The comparison between the three used devices of minimally invasive blood glucometers in relation into HbA1C % are illustrated in table 1 & table 2. As well as in figure 3.

Table 1. The comparison between the three used devices of minimally invasive blood glucometers in relation into HbA1C % were illustrated.

NANO	PERFORMA	ACTIVE	HBA1C	AGE
148	144	158	6.20%	46
197	193	206	8.80%	45
145	139	150	6.80%	59
347	367	378	12.00%	38
132	133	151	5.70%	76
137	130	140	10.00%	40
174	170	177	8.20%	76
261	264	282	8.80%	52
294	321	325	9.50%	48

237	239	240	8.00%	70
169	170	178	6.60%	33
169	170	178	7.60%	54
142	139	156	6.70%	58
212	213	222	8.80%	60
113	114	129	4.00%	66
196	194	206	7.40%	64
267	266	289	9.70%	52
253	252	283	9.40%	46
216	223	232	9.30%	48
215	218	231	8.60%	50
269	271	276	8.30%	50
204.42	206.19	218.42	8.11%	54
51.97	55.99	56.46		

Table 2. Comparison between three minimally invasive devices used blood glucometers in relation into HbA1C %.

Device	Mean	Standard Deviation
ACUU-CHECK Performa Nano	204*	52
ACUU-CHECK Performa	206*	55
ACUU-CHECK Active	218*	56.5
hba1c %	8.1%	0.02

(N= 30 hyperglycemic patients. *Mean in mg/dL)

Table 3. Three blood glucometers compared with BS-300 mindry® chemistry analyzer as a reference.

Nano	Performa	Active	BS 300
242*	226*	279*	257*
8.5‡	5.2‡	6.6‡	4.3‡

*Mean in mg/dL, ‡ Standard deviation

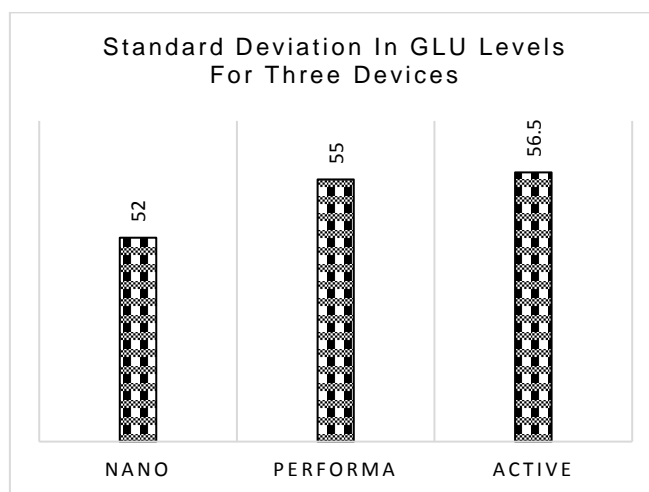


Figure. 2. Standard deviation in GLU levels for three devices indicated that the less sd in the readings of measured samples is more accurate.

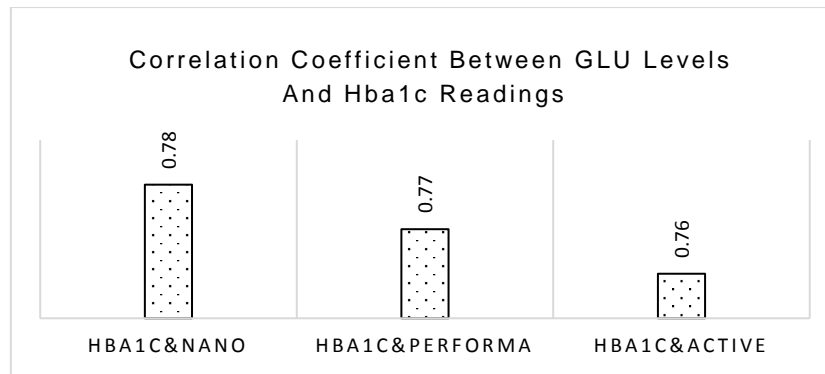


Figure 3. Comparison of each monitoring system with Hba1C in term of correlation coefficient indicated that the Hba1c test is more correlated (0.78) with nano devices, which revealed better accuracy.

The relation between the age of the participant and the results of GLU for nano device showed no significant correlation (correlation coefficient = - 0.025) as in figure 4.:

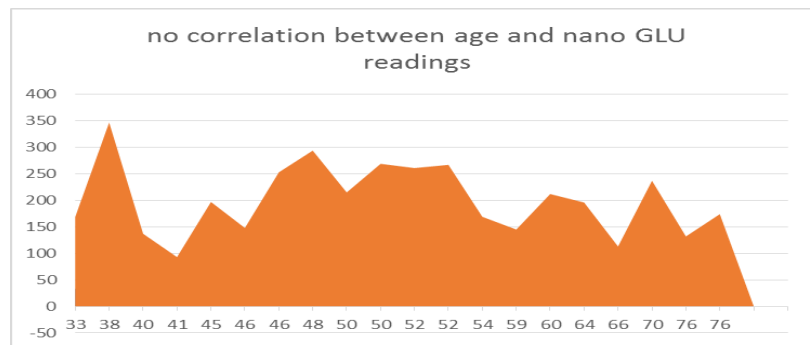


Figure 4. Correlation between patient's age and GLU readings of nano device

4. DISCUSSION

Precision medicine is a new concept that has been used to describe tailored accurate medical treatments selected according to individual characteristics of each patient [19]. The findings of this study, indicated that there is an association between the levels of blood glucose and the percentage of HbA1C. The age didn't show any significant factor in hypoglycemia

The accuracy of blood glucose reading is connected with this relation. The found correlation coefficient between various devices and the Hba1c % of indicated that the Hba1c percentage can be used as an indicator of the accuracy of Blood Glucose Measurement for the same samples.

The technology of accu-check nano-performa one of the latest products of accu-check company which is more accurate than the other used technologies from the same company.

5. CONCLUSION

Further studies with higher sample size is recommended to be conducted. The thirty hyperglycemic patients participated in this study couldn't be considered as enough sample size.

However, the found association between hyperglycemic readings and the percentage of HbA1C for the same patients is concluded to be a suitable accuracy parameter to be investigated.

Such association between levels of blood glucose and the percentage of HbA1C in three de-vices with statistical significance is importance when studying relative accuracy on various types of blood glucose self-monitoring devices.

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REFERENCES

1. E. H. Yoo, and S. Y. Lee , Glucose Biosensors: An Overview of Use in Clinical Practice , Sensors, 2010, 10, 4558-4576
2. American Diabetes Association. Standards of medical care in diabetes—2006 [published correction ap-pears in Diabetes Care. 2006;29:1192], (Mayo Clin Proc. 2007;82(2):229-236



3. George Dailey, Assessing Glycemic Control With Self-monitoring of Blood Glucose and Hemoglobin A1c Measurements (GEORGE DAILEY, MD). *Diabetes Care*. 2006;29(suppl 1):S4-S42.8.
4. Cowie, C.C.; Rust, K.F.; Byrd-Holt, D.D.; Gregg, E.W.; Ford, E.S.; Geiss, L.S.; Bainbridge, K.E.; Fradkin, J.E. Prevalence of diabetes and high risk for diabetes using hemoglobin A1c criteria in the U.S. population in 1988–2006. *Diabetes Care* 2010, 33, 562–568.
5. Narayan, K.M.; Boyle, J.P.; Geiss, L.S.; Saaddine, J.B.; Thompson, T.J. Impact of recent increase in incidence on future diabetes burden: U.S., 2005–2050. *Diabetes Care* 2006, 29, 2114–2116. Wild, S.; Roglic, G.; Green, A.; Sicree, R.; King, H. Global prevalence of diabetes: estimates for the year 2000 and projections for 2030. *Diabetes Care* 2004, 27, 1047–1053.
6. Shaw, J.E.; Sicree, R.A.; Zimmet, P.Z. Global estimates of the prevalence of diabetes for 2010 and 2030. *Diabetes Res. Clin. Pract* 2010, 87, 4–14.
7. Wild, S.; Roglic, G.; Green, A.; Sicree, R.; King, H. Global prevalence of diabetes: estimates for the year 2000 and projections for 2030. *Diabetes Care* 2004, 27, 1047–1053.
8. American Diabetes Association. Diagnosis and classification of diabetes mellitus. *Diabetes Care* 2010, 33, S62–69
9. Poolsup, N.; Suksomboon, N.; Rattanasookchit, S. Meta-analysis of the benefits of self-monitoring of blood glucose on glycemic control in type 2 diabetes patients: an update. *Diabetes Technol. Ther* 2009, 11, 775–784.
10. Murata, G.H.; Shah, J.H.; Hoffman, R.M.; Wendel, C.S.; Adam, K.D.; Solvas, P.A.; Bokhari, S.U.; Duckworth, W.C. Intensified blood glucose monitoring improves glycemic control in stable, insulin-treated veterans with type 2 diabetes: the Diabetes Outcomes in Veterans Study (DOVES). *Diabetes Care* 2003, 26, 1759–1763.
11. Skeie, S.; Kristensen, G.B.; Carlsen, S.; Sandberg, S. Self-Monitoring of Blood Glucose in Type 1 Diabetes Patients with Insufficient Metabolic Control: Focused Self-Monitoring of Blood Glucose Intervention Can Lower Glycated Hemoglobin A1C. *J. Diabetes Sci. Technol* 2009, 3, 83–88.
12. Tunis, S.L.; Minshall, M.E. Self-monitoring of blood glucose (SMBG) for type 2 diabetes patients treated with oral anti-diabetes drugs and with a recent history of monitoring: cost-effectiveness in the US. *Curr. Med. Res. Opin* 2010, 26, 151–162.
13. Boutati, E.I.; Raptis, S.A. Self-monitoring of blood glucose as part of the integral care of type 2 diabetes. *Diabetes Care* 2009, 32(Suppl. 2), S205–210.
14. Jovanovic, L.G. Using meal-based self-monitoring of blood glucose as a tool to improve outcomes in pregnancy complicated by diabetes. *Endocr. Pract* 2008, 14, 239–247.
15. O'Kane, M.J.; Pickup, J. Self-monitoring of blood glucose in diabetes: is it worth it? *Ann. Clin. Biochem* 2009, 46, 273–282.
16. W. L. Clarke, "Evaluating clinical accuracy of systems for self-monitoring of blood glucose." *Diabetes care* 10.5 (1987): 622-628.
17. G. Freckmann, et al. "System accuracy evaluation of 43 blood glucose monitoring systems for self-monitoring of blood glucose according to DIN EN ISO 15197." *J Diabetes Sci Technol*. 6.5 (2012): 1060-1075.
18. Hassan Almarshad, "Evaluation of Five Systems and Two Methods for Invasive and Minimally Invasive Blood Glucose Measurements", Proceedings of the 36th International Conference of the IEEE Engineering in Medicine and Biology Society. (2014).
19. Klonoff, David C. "Precision Medicine for Managing Diabetes." *Journal of diabetes science and technology* 9.1 (2015): 3-7.

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