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Home Glucose Meters: How Accurate Should They Be to Avoid Dysglycemia in Patients Using Carbohydrate Counting?

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Abstract. Accurate self-monitoring of blood glucose is the key to an effective and safe intensive insulin therapy. Indeed, most insulin dosing decisions are made based on the blood glucose values obtained from home glucose meters, in particular for those using diet planning and carbohydrate counting. Patients on that therapeutic regimen depend not only on their ability to accurately estimate the carbohydrate content of each meal but also on the accuracy of the glucose meter being used. Therefore, in order to avoid postprandial hypoglycemia and hyperglycemia, it is of great importance to realize how important is the accuracy of blood glucose meters according to the particular characteristics of each patient. In this regard, we propose an analytic method to find the limits of the blood glucose meters accuracy according to the insulin-to-carb ratio, the insulin sensitivity factor and the ability of each patient to estimate the carbohydrate content of each meal.

INTRODUCTION

Self-Monitoring of Blood Glucose (SMBG) is the mainstay of proper diabetes management, supporting tight blood glucose control in patients on intensive insulin regimens, e.g., patients using diet planning and carbohydrate counting. However, to be useful and safe SMBG needs to be accurate. The accuracy of SMBG systems relies on several factors, being the accuracy of the blood glucose meters one of the most important [1]. As reported by Ekhlaspour *et al* in [2], the accuracy of commercially available blood glucose meters varies significantly. Regarding this study, 17 glucose meters were tested and it was found that their mean absolute relative difference (MARD) range from 5.6% to 20.8%.

Inaccurate blood glucose measurements may lead to incorrect dosing calculations which may result in dangerous variations of insulin doses and negatively influence glycemic control [1, 3]. Indeed, Campos-Náñez *et al* conducted a 30-day in-silico study and found that blood meters accuracy clearly affect the glycemic control in type 1 diabetes patients. Moreover, the study shows that the meters' accuracy has a significant impact not only on the occurrence of severe hypoglycemic events but also on long-term average glycemia (HbA1c) [4].

In this context, it is of great importance to choose the correct blood glucose meter taking into account the particular characteristics and glycemic goals of each patient. Therefore, we propose an analytic method to find the limits of the blood glucose meters accuracy that considers the ability of each patient to estimate the carbohydrate content of each meal¹ along with its' insulin-to-carb ratio and insulin sensitivity factor.

¹The ability of each patient to accurately estimate the carbohydrate content of each meal could be quantified considering the average absolute error committed by the patient while evaluating a set of N meals, by: $\overline{\Delta CHO} = \sum_{i=1}^N |CHO_{correct}^i - CHO_{estimate}^i| / N$, where the $CHO_{correct}^i$ and the $CHO_{estimate}^i$ are, respectively, the correct and estimate values of the carbohydrate content of i -meal, $i = 1, \dots, N$.

MATHEMATICAL METHODS

The equation

$$B = \left(\frac{CHO}{ICR} + \frac{G - G_T}{ISF} \right) K - IOB \quad (1)$$

allows patients using carbohydrate counting to calculate the insulin bolus (i.e., prandial and correctional insulin) for each meal, according to the carbohydrates planned to be consumed in that meal (CHO), the insulin-to-carb ratio (ICR), the preprandial blood glucose target (G_T), the preprandial blood glucose value (G), the insulin sensitivity factor (ISF), the physiologic status of the patient represented by K , and the insulin remaining active from the last bolus (IOB , Insulin-on-Board) [5, 6]. In the subsequent analysis, we will consider $K = 1$ (i.e., the impact of illness, physical activity or medication on insulin and glucose metabolism of patients will not be addressed in this study) and $IOB = 0$ (i.e., it will be considered that the time between meals is larger than the duration of the insulin action, and there is no insulin stacking). Moreover, we also assume that patient's ICR and ISF are physiologically appropriate.

Let's consider $CHO = \hat{C}HO \pm \Delta CHO$ and $G = \hat{G} \pm \Delta G$ to be variables of Equation 1, where $\hat{C}HO$ is an estimate of CHO with an absolute error $\Delta CHO > 0$, and \hat{G} is an estimate of G with an absolute error $\Delta G > 0$. The remaining variables of Equation 1 are considered to be exact values. In such conditions, the absolute error of B is $\Delta B = |B - \hat{B}|$, where: $B = CHO/ICR + (G - G_T)/ISF$ and $\hat{B} = \hat{C}HO/ICR + (\hat{G} - G_T)/ISF$ (n.b., ICR and ISF are positive values). Therefore, we have:

$$\Delta B = \left| \frac{CHO - \hat{C}HO}{ICR} + \frac{G - \hat{G}}{ISF} \right| \leq \frac{\Delta CHO}{ICR} + \frac{\Delta G}{ISF}.$$

The bolus' absolute error, ΔB , will perform as an unplanned and inappropriate correction bolus, with the consequent undesired effect on the patient's postprandial glycemia ($G_{postprandial}$) given by:

$$\Delta G_{postprandial} = \Delta B \cdot ISF \leq \frac{ISF}{ICR} \Delta CHO + \Delta G,$$

where $\Delta G_{postprandial}$ is the variation on the patient postprandial blood glucose.

By denoting the hyperglycemia and hypoglycemia limits as G_{Hyper} and G_{Hypo} , respectively, it is possible to conclude that the maximum value of $\Delta G_{postprandial}$ allowed, in order to avoid hyperglycemia and hypoglycemia episodes, is given by $\min\{G_{Hyper} - G_T, G_T - G_{Hypo}\}$ (n.b., the function $\min\{\cdot\}$ returns the minimum value of a set of elements) and, therefore, it is sufficient to satisfy the following condition to avoid them:

$$\Delta CHO \leq \frac{ICR}{ISF} \left(\min\{G_{Hyper} - G_T, G_T - G_{Hypo}\} - \Delta G \right). \quad (2)$$

Equation 2 shows that the sufficient limits of accurate carbohydrate counting, in order to avoid dysglycemia, depend not only on each patient data but also on the accuracy of the blood glucose meter being used. Therefore, taking into account the ability of each patient to correctly estimate the carbohydrate content of each meal, along with its ISF , ICR , and glycemic targets, the blood glucose meter absolute error, ΔG , should satisfy the following conditions:

$$\Delta G \leq \min\{G_{Hyper} - G_T, G_T - G_{Hypo}\} - \frac{ISF}{ICR} \overline{\Delta CHO}$$

and

$$\overline{\Delta CHO} \leq \frac{ICR}{ISF} \left(\min\{G_{Hyper} - G_T, G_T - G_{Hypo}\} - \Delta G \right).$$

DISCUSSION

To assess and discuss the implications of the proposed method let's consider a hypothetical patient of 75 kg body weight, consuming a total of 50 U of insulin each day, having a preprandial glucose target of $G_T = 110$ mg/dL, and the following glycemic thresholds for hyperglycemia and hypoglycemia, respectively: $G_{Hyper} = 150$ mg/dL, $G_{Hypo} = 70$ mg/dL. Suppose, without loss of generality, that the ICR and ISF for this patient are calculated according to the recommendations of the American Association of Clinical Endocrinologists/American College of Endocrinology

(AACE/ACE) [7], using the following rules: $ICR = 450/TDD$ and $ISF = 1700/TDD$, where TDD is the Total Daily Dose of insulin that, in this case, is equal to 50 U. Therefore, under these assumptions, the patient's ICR and ISF are 9 g/U and 34 mg/dL/U, respectively. Finally, this patient is able to estimate the carbohydrate content of each meal with an average absolute error of 10 g (i.e., $\overline{\Delta CHO} = 10$ g).

According to Equation 2, the maximum absolute error allowed while estimating the carbohydrate content of each meal depends on the meter accuracy and on the patient data, as shown Figure 1. Let us consider first the use of an ideal blood glucose meter, i.e., having no error. In that case, the maximum admissible absolute error while estimating the carbohydrates is given by $\Delta CHO_{max} = 9 \times 40/34 \approx 10.59$ g. Hence, since $\overline{\Delta CHO} \leq \Delta CHO_{max}$, the risk of the patient facing dysglycemic events is reduced. However, such an ideal meter does not exist. Moreover, the accuracy of the blood glucose meters available on the market varies significantly, as can be seen in Table 1.

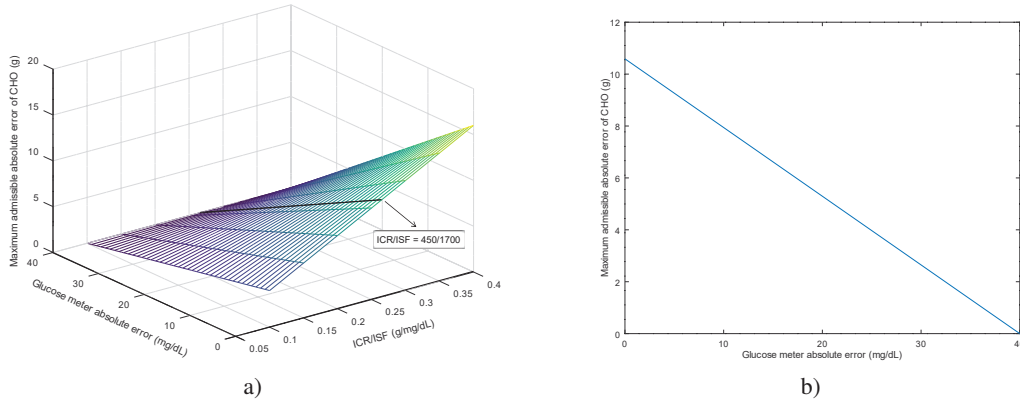


FIGURE 1. a) The maximum admissible absolute error of CHO as a function of the glucose meter accuracy and the ICR/ISF ratio; b) The maximum admissible absolute error of CHO as a function of the glucose meter accuracy for $ICR/ISF=450/1700$.

Taking into account the accuracy of the blood glucose meters, the value of ΔCHO_{max} could be significantly smaller. Table 1 shows the value of ΔCHO_{max} for several blood glucose meters and, makes clear that none of them fits into the diabetes management strategy of this patient. Therefore, this patient must improve their carbohydrates counting skills or change their glycemic targets. As an example, if the patient glycemic goals change to $G_T = 120$ mg/dL, $G_{Hyper} = 170$ mg/dL, and $G_{Hypo} = 70$ mg/dL, it will be safe to use any of the first four blood glucose meters listed in Table 1, under the range $20 \leq BS < 180$.

Therefore, the accuracy of the blood glucose meters is a determinant factor for a proper glycemic control and must be taken into account while fitting the diabetes management strategy of each patient.

CONCLUSION

Patients with diabetes make their insulin dosing decisions based on the glycemic values obtained from home glucose meters. Indeed, patients on intensive insulin regimens, particularly those using meal planning and carbohydrate counting, heavily depend not only on their ability to accurately estimate the carbohydrate content of each meal but also on the accuracy of the blood glucose meters to achieve a rigorous glycemic control. Therefore, to avoid dysglycemic events, it is fundamental to understand the impact of the blood glucose meters accuracy on the insulin bolus. To that end, we propose an analytic method to find the limits of the blood glucose meters accuracy according to the insulin-to-carb ratio, the insulin sensitivity factor and the ability of each patient to estimate the carbohydrate content of each meal. By using the proposed method, healthcare professionals are able to make informed decisions about the best blood glucose meter for each patient according to their particular characteristics. Moreover, this method allows healthcare professionals to optimize the glycemic goals of each patient according to their characteristics and meter accuracy in order to lessen the risk of hypoglycemic and hyperglycemic episodes.

TABLE 1. The maximum of the glucose meter absolute error (ΔG_{max}), and the maximum admissible absolute error of carbohydrate counting (ΔCHO_{max}) for each glucose meter. The value of ΔG_{max} was estimated according to the data reported in Table 2 of [2], for different glucose ranges as: $\Delta G_{max} \approx MARD \times \max\{BS \text{ in the range}\} / 100$ (n.b., BS stands for Blood Sugar). On its turn, ΔCHO_{max} was calculated according to Equation 2, taking into account the ΔG_{max} of each glucose meter, and the specific characteristics of the patient being considered.

Blood Glucose Meter	Blood Sugar Ranges (mg/dL)					
	$20 \leq BS < 70$		$70 \leq BS < 180$		$180 \leq BS < 440$	
	ΔG_{max}	ΔCHO_{max}	ΔG_{max}	ΔCHO_{max}	ΔG_{max}	ΔCHO_{max}
# 1 Contour Next	6.23	8.94	8.64	8.30	23.76	4.30
# 2 StatStrip Xpress	7.77	8.53	8.82	8.25	26.40	3.60
# 3 OneTouch VerioIQ	6.93	8.75	11.34	7.59	29.92	2.67
# 4 Accu-Chek Nano	8.12	8.44	12.06	7.40	29.92	2.67
# 5 FreeStyle Freedom Lite	10.78	7.73	13.14	7.11	27.28	3.37
# 6 Accu-Chek Aviva Plus	8.47	8.35	13.14	7.11	30.36	2.55
# 7 FreeStyle Lite	11.62	7.51	14.22	6.82	29.92	2.67
# 8 Nova Max	18.90	5.59	16.02	6.35	30.36	2.55
# 9 TRUEresult	9.24	8.14	23.04	4.49	57.64	*
# 10 HemoCue Glucose 201	13.93	6.90	20.88	5.06	55.44	*
# 11 OneTouch Ultra2	21.21	4.97	28.26	3.11	42.68	*
# 12 ReliOn Prime	11.34	7.59	20.52	5.16	66.44	*
# 13 BREEZE @2	17.99	5.83	23.94	4.25	65.56	*
# 14 ReliOn Micro	20.93	5.05	25.56	3.82	62.04	*
# 15 AgaMatrix PRESTO	27.44	3.32	38.16	0.49	43.12	*
# 16 AgaMatrix JAZZ	26.60	3.55	40.14	*	46.20	*
# 17 SideKick	22.19	4.71	30.06	2.63	89.76	*

* As $\Delta G_{max} > \min\{G_{Hyper} - G_T, G_T - G_{Hypo}\}$, Equation 2 does not apply. In this case, even with $\Delta CHO = 0$, the patient may have dysglycemic episodes.

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