Concurrent Validity of a Continuous Glucose-Monitoring System at Rest and During and Following a High-Intensity Interval Training Session

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Abstract

Purpose: To assess the concurrent validity of a continuous blood glucose monitoring system (CGM) Post-Breakfast, Pre-exercise, Exercise and Post-exercise, while assessing the impact of two different breakfasts on the observed level of validity. ***Methods:*** Eight non-diabetic recreational athletes (age: 30.8±9.5 years; height: 173.6±6.6 cm; body mass: 70.3±8.1 kg) took part in the study. Blood glucose concentration was monitored every 10 min using both a CGM (FreeStyle Libre, Abbott, France) and finger-prick blood glucose measurements (FreeStyle Optimum, Abbott, France) over 4 different periods (Post-Breakfast, Pre-Exercise, Exercise and Post-Exercise). Two different breakfasts (carbohydrates- [CHO] and protein- [PROT] oriented) over two days (2x2 days in total) were used. Statistical analyses included the Bland-Altman method, standardized mean bias (expressed in standardized unit), median absolute relative difference (MARD) and the Clarke Error Grid (EGA). ***Results:*** Overall, mean bias was trivial-to-small at Post-Breakfast (effect size ± 90% confidence limits: -0.12±0.08), Pre-Exercise (-0.08±0.08) and Post-Exercise (0.25±0.14), while moderate during Exercise (0.66±0.09). Higher MARD was observed during Exercise (13.6% vs 7 to 9.5% for the other conditions). While there was no effect of the breakfast type on the MARD results, EGA revealed higher value in Zone D (*i.e.* clinically unsafe zone) during Exercise for CHO (10.5%) compared with PROT (1.6%). ***Conclusion:*** The CGM device examined in this study can only be validly used at rest, after both a CHO and PROT-rich breakfast. Using CGM to monitor blood glucose concentration during exercise is not recommended. Moreover, the accuracy decreased when carbohydrates are consumed before exercise.

Introduction

Regulation of blood glucose has first been widely studied from a health perspective. Hyperglycemia for example, is believed to be an independent risk factor for the development of several diseases such as type II diabetes mellitus[1] and cardiovascular disease.[2] More recently, the monitoring of blood glucose concentration has also elicited great interest in sport, as hypoglycaemia influences both physical and cognitive performances.[3]

In particular, it is known that at the beginning of exercise or after half-time in team sports, athletes experience transient hypoglycemia, which may affect physical and cognitive performance.[4] Moreover, it has then been shown that a large glycemic variability exists among individuals in the general population.[5] Additionally, similar results have been shown in sub-elite athletes,[6] suggesting that providing more individualized guidelines to regulate blood glucose would be beneficial for both health and performance goals.

The emergence of new technologies such as continuous glucose monitoring (CGM) devices has allowed blood glucose concentration dynamics to be captured more frequently and less invasively than traditional measures such as finger pricks. Indeed, as CGM devices only need to be placed once (usually on the back of the arm), it can be used for several days without disturbing sport practices. So far, these devices have been mainly used by diabetic populations but as the technology becomes more accurate, less invasive, and less expensive, their use has increased in other populations and especially in healthy individuals. Therefore, the inclusion of CGM in sport nutritionists' monitoring tool box could help to optimize nutritional strategies before and during exercise, and in turn, improve athletes' performance by preventing hypoglycemia. However, to date, the validity of these new systems at rest or during exercise has been only assessed in diabetics patients and showed promising results.[7] Evidence regarding its relevance with an athletic population is still lacking. Moreover, the ability of such devices to detect potential glucose fluctuations due to different nutritional intakes need to be confirmed.

Therefore, the aim of this study was to assess the concurrent validity of a new CGM device during different periods, *i.e.* pre, during and after exercise, while assessing the potential impact of different nutritional intakes in the observed level of validity.

Methodology

Study Population

Eight non-diabetic recreational athletes (5 females, 3 males) (age: 30.8 ± 9.5 years; height: 173.6 ± 6.6 cm; body mass: 70.3 ± 8.1 kg) who regularly participate in running and resistance-based training (8±2 hours per week) were included in the study. An a priori power analysis was conducted using the package *pwr* from R software (Version 4.0.0) for t-tests for non-parametric data with a significance level alpha of 0.05 a power of 0.8 and add a non-parametric correction of 15%. Result showed a minimal sample of 310 paired observations for 8 participants were necessary. Alcohol intake was prohibited during the study period. Regarding female participants, we ensured they were all within the same menstrual phase during the study period.

Participants provided informed consent prior to starting the study. Ethics approval was granted before any data collection wwas undertaken and the recommendations of the Declaration of Helsinki were respected.

Design

A concurrent validity design was employed to assess the validity of a CGM system against finger prick measures which was considered as the reference method. Over 2 consecutive weeks, participants took part in 4 nonconsecutive standardized days. Each standardized day was broken-down into 4 distinct periods: 1) Post-Breakfast which corresponded to the first hour after the end of the Breakfast 2) Pre-Exercise which corresponded to the first hour following the Post-Breakfast, 3) Exercise, which started 2 hours after the end of the breakfast and lasted from the beginning of the warm up to the end of the workout and 4) Post-exercise, which started immediately at the end of the workout, and up to 30 min later. A detailed outline of the standardized day structure is provided in Figure 1. Nutritional intake during breakfast was manipulated in order to provide either a high carbohydrate (CHO) or protein (PROT) breakfast, to induce different levels of resting ad pre-exercise glycemia. Each typical breakfast was repeated twice. Over those standardized days, blood glucose was measured continuously with a CGM, while finger prick measures were taken every 10 minutes and. Day 1 was used for each participant to familiarize with the CGM and ensure calibration (as per manufacturer recommendations) before the experimentation could start. Between day 2 and

13, participants undertook at their convenience the 4 standardized days. They were also instructed to have at least one full day of recovery between each experimental day.

Insert Figure 1

Methodology

Continuous glucose monitoring. Each participant was provided with a CGM system (FreeStyle Libre, Abbott, France) over the full duration of the study. Each participant inserted a sensor (FreeStyle Libre, Abbott, France) in their non-dominant upper arm (*i.e.* back the triceps brachialis) one day before the beginning of the study. Glucose concentration was recorded in the interstitial fluid every minute.

Finger prick blood glucose. Finger prick (FreeStyle Optium, Abbott, France) measures were collected following the procedure described by Gomez.[8] Each sample was immediately analysed using the FreeStyle Libre reader (FreeStyle Libre Reader, Abbott, France) (The validity and reliability of this device has been previously confirmed.[9]

Breakfast. Two typical breakfasts were employed. The CHO breakfast contained a high proportion of carbohydrates (CHO) with 1 $g \cdot Kg^{-1}$ of body mass with a ceiling set at 70g of carbohydrates per breakfast (*e.g.* breakfast contained a mix of orange juice, bread and jam).The macronutrients and energy were as follow: 65±7g of carbohydrates, 9±1g of proteins and 1±0g of fat for a total of 311±31 Kcal. The protein (PROT) breakfast was isoenergetic compared with CHO (*e.g.* breakfast contained a mix of eggs, ham and cheese). The macronutrients and energy were as follow: 1±0g of carbohydrates, 30±0g of proteins and 23±0g of fat for a total of 311±31 Kcal.

Standardized exercise. Participants completed the 30-15 Intermittent Fitness Test ($30\text{-}15_{IFT}$) as described by Buchheit et al.[10] prior the beginning of the study. The speed ($km \cdot hr^{-1}$) achieved by each participant during the last successfully completed stage of the test was recorded (V_{IFT}) in order to prescribe exercise intensity. The standardized exercise started with a 10-min low-intensity run (30 to 40% of V_{IFT}) and was followed by a high-intensity intermittent training exercise performed outdoor. The trials consisted of six reps of 3-min running intervals interspersed with 2 min of passive recovery. Reps 1 and 2 were performed at

75% V_{IFT}, reps 3 and 4 at 80% V_{IFT} and reps 5 and 6 at 85% V_{IFT}. The session was ended with a 10-min walk.

Data processing. Each time point within a specific period was averaged as described above to perform the concurrent validity analysis for each method (CGM and finger prick) and per specific period (Figure 1). Each standardized day was analyzed first without (overall) and then as a function of breakfast type (CHO and PROT).

Statistical Analysis

Bland-Altmann method for repeated measures and standardized mean bias were first applied to assess the agreement between CGM and finger prick measures at each specific period.[11] The following thresholds were applied to rate the magnitude of the bias as follow: >0.2 (small), >0.6 (moderate), >1.2 (large) and >2 (very large).[12]

Additionally, analysis of the median average relative difference (MARD)[13] and the Clarke Error Grid Analysis (EGA)[14] were conducted. Regarding MARD, further comparisons between the different periods were performed using Wilcoxon test and/or Kruskal-Wallis tests. Level of statistical significance was set at $P<0.05$. Results were further analyzed while calculating standardized differences, *i.e.* Wilcoxon effect sizes. The thresholds to rate the magnitude of the effects were the same than those used for mean bias. Regarding EGA, results were divided into 5 zones (A, B, C, D, E). Each zone denotes a degree of clinical implications of blood glucose concentration measures. Zones A and B were considered clinically acceptable while zone C, D and E (erroneous treatment) were deemed possibly unsafe.[14]

Results

The Bland-Altman analysis for the 4 periods is presented in Figure 2 and reported as mean bias (standard error). Irrespectively of the breakfast content, mean biases were trivial-to-small for Post-Breakfast (-2.99 [17.75] mg/dL), Pre-Exercise (-1.67 [10.95] mg/dL), Post-Exercise (4.18 [17.88] mg/dL) and moderate during Exercise (12.25 [13.86] mg/dL). Regarding CHO breakfast, mean biases were trivial-to-small for Post-Breakfast (-1.43 [25.98] mg/dL), Pre-Exercise (-4.29 [11.66] mg/dL), Post-Exercise (3.32 [18.18] mg/dL) and moderate during Exercise (14.06 [13.81] mg/dL). For PROT Breakfast, trivial mean bias was observed for Pre-Exercise (0.91 [8.98] mg/dL), Post-Breakfast (-4.51 [8.31] mg/dL) and Post-Exercise (5.13

[15.98] mg/dL), while moderate mean biases were observed for Exercise (10.47 [13.19] mg/dL).

Insert Figure 2

Insert Figure 3

The results of the MARD analysis between the different periods are presented in Table 1 and 2.

Insert Table 1 and 2

Results regarding EGA are presented in Table 3. Irrespectively of the breakfast content, Post-Breakfast, Pre-Exercise, and Post-Exercise periods fell into Zone A (accurate) and B (benign errors) (100%). However, during Exercise, 94% of the values fell into A (70.4%) and B (23.6%), and 6% in Zone D (failure to treat errors). For CHO breakfast, 10.5% of data fell into Zone D for Exercise, while the other periods fell into Zone A and B. Similarly, for PROT breakfast, 1.6% fell into Zone D during the Exercise period.

Insert Table 3

Discussion

The aim of this study was 1) to investigate the concurrent validity of a new CGM device in recreational athletes at Post-Breakfast, Pre-exercise, Exercise and Post-exercise, and 2) to assess the potential impact of either a CHO-rich or protein-rich breakfast on the observed level of validity. The main results highlighted that, while the validity of CGM was acceptable at rest (*i.e.* Post-Breakfast, Pre-Exercise and Post-Exercise), it was lower during Exercise and especially after the CHO breakfast.

The first results demonstrated trivial-to-small mean bias during all the non-exercise periods, irrespectively of nutritional intake. Moreover, all results from EGA fell into the "clinically safe zone" (A and B), albeit during Exercise. These results are similar to those shown previously in non-athletic diabetic populations.[15] Indeed, the present results suggest that

assessing glucose dynamics at rest is feasible with this CGM device. This could open the door to a better individualization of nutritional strategies.[5]

Yet, we observed a higher bias during Exercise compared with the other periods, confirming previous studies in a non-athletic diabetic population.[16] Reasons that may contribute to the reduced validity of the CGM device in this context include microcirculation perturbations as a as a result of movements around or within the insertion area, increases in body temperature and rapid fluxes in glucose levels during exercise.[17] Regarding the likely physiological time lag of glucose transport between blood and interstitial fluid compartments (see Figure 3, finger pricks measures changed faster Post-Breakfast than that of the CGM device), it should be noted that it might not have accounted for the observed difference in accuracy as the pattern is not only delayed but it varies with time and conditions. Indeed, while a clear hypoglycemia was observed with finger prick measures immediately at the start of exercise (which was the expected physiological response), the CGM showed an increased blood glucose response (Figure 2). Nonetheless, this discrepancy indicates that the CGM device was unable to detect a potential hypoglycemia observed at the onset of exercise, and could therefore not be used to assess strategies aiming at preventing this phenomenon in practice. It is worth mentioning that a trend for a better agreement was observed toward the end of the exercise periods (Figure 2). If the duration of the exercise also affects the accuracy of CGM, it means that while the device may not be suitable for sport including short and intermittent exercise durations, its use could perhaps be considered during longer event such as cycling, trail or triathlon. This potential better accuracy toward longer exercise duration highlights the need to conduct further research involving 1) longer exercise duration, 2) nutritional intake during long endurance race 3) various exercise modalities and 4) different intensities.

To examine the potential effect of the absolute levels of glycemia on the validity of the CGM device, different breakfasts were proposed (CHO and PRO). Similar MARD and EGA results were observed, suggesting that the CGM validity was not affected by the breakfast content during non-exercise periods (*i.e.* Post-Breakfast, Pre-Exercise, Post-Exercise). Specific pre-competition nutritional strategies can have a positive influence on both the acute running performance among rugby league players[18] or endurance athletes,[19] and the chronic training adaptations to training.[20] Consequently, the use of this CGM device could be considered by practitioners willing to monitor glycemic responses before and after competition or training, to ensure the efficacy of the nutritional strategies employed.

However, during the Exercise period, the CGM accuracy was modulated by breakfast content. Indeed, a 10 times higher value in Zone D of the EGA (*i.e.* clinically unsafe) was observed post CHO (10.5%) compared with post PROT (1.6%) breakfast. In our study, zone D corresponds to the situation where finger prick measures indicate an hypoglycemic state whereas CGM measures are within the normal range[14] suggesting that CGM failed to detect the hypoglycemia occurring during exercise after the CHO-rich breakfast. It is well known there is a rapid drop of blood glucose concentration at the onset of exercise, due to an increased glucose uptake by exercising muscles.[21] This physiological mechanism could explain why the sensor lacks sensitivity to rapid changes in glucose concentration, as observed in the present study. As it stands, if practitioners want to monitor blood glucose during high-intensity intermittent exercise, they need to consider other devices than CGM (e.g. finger prick).

Practical applications

- The present CGM system provided valid measures at rest. Therefore, the use of such a system may allow for a better individualization of nutritional strategies before or after competition.

- The level of validity was lower during high-intensity intermittent training and was in addition influenced by the type of breakfast consumed (i.e. high carbohydrates or high protein). Consequently, practitioners should avoid using this device during intermittent exercise.

Conclusion

Daily monitoring of blood glucose is of importance in athletes given the likely impact of glycemia on performance and the individualized nutritional recommendations that can be made with CGM. Our results highlighted that the CGM device examined in the present study presented only trivial-to-small bias when compared with a traditional fingerpick device at rest, suggesting that it could be used confidently during this specific period. The CGM device is not valid enough to monitor glucose during intermittent exercise. Further analyses should however evaluate the validity of this device over longer exercise duration.

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Table and figure caption

Figure 1. Schematic representation of the study design.

Figure 2. Bland-Altman analysis between the continuous glucose monitoring device (CGM) and finger prick measures (FPBG). Dash lines represent the limits of agreements.

Figure 3. Continuous glucose monitoring (CGM) and finger prick measures during each standardized condition, when ingesting a carbohydrate- (upper) and protein- (lower) oriented breakfasts, with the 2 days of each breakfast condition pooled for each participant (n = 2 x 8 for each curve). Data are presented as mean (SE).

Table 1. Median Absolute Relative Difference between the continuous glucose monitoring device (CGM) and finger prick measures. Data are median (interquartile range) and expressed in percentage. *: significantly different from Post-Breakfast. $^{\#}$: significantly different from Pre-Exercise. †: significantly different from Exercise. Comparisons between period are presented as effect size with 90% confidence interval.

Table 2. Comparisons between period are presented as effect size for Wilcoxon test with 90% confidence interval.

Table 3. Clark Error Grid Analysis between the continuous glucose monitoring device (CGM) and finger prick measures. Zone A represents a clinically accurate measure. Zone B stands for benign errors. Zone C represents overcorrection errors. Zone D and E represent failure to treat errors and erroneous treatment errors respectively. For more details see Clarke et al. (1987).

Figures

Figure 1

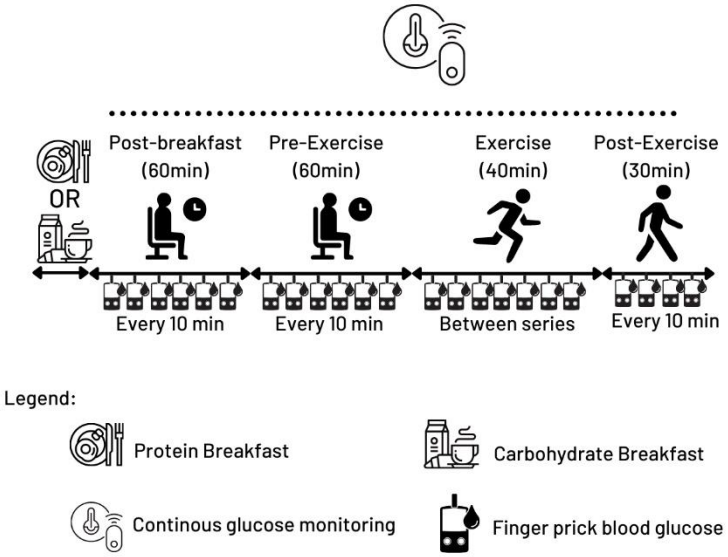


Figure 2

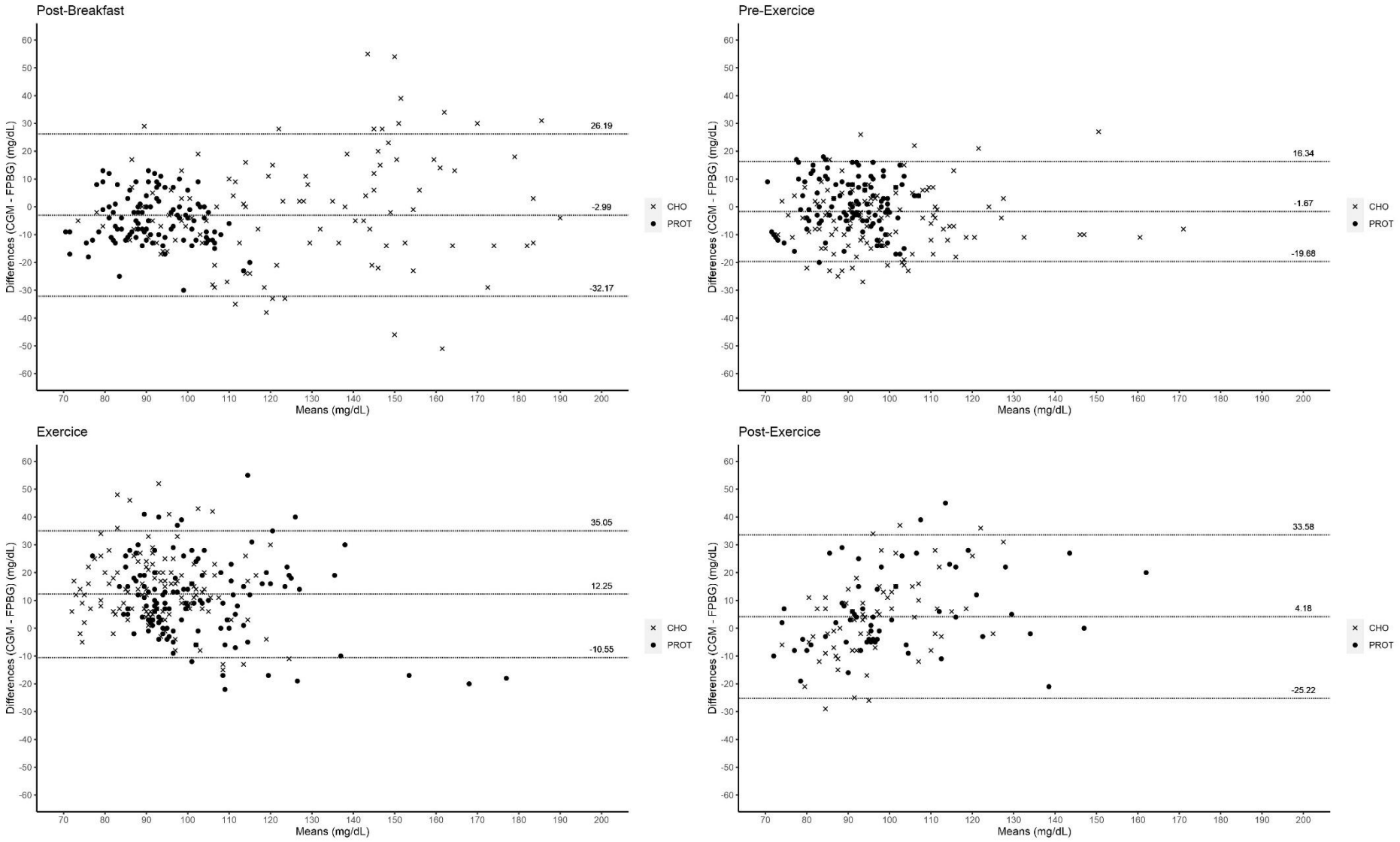
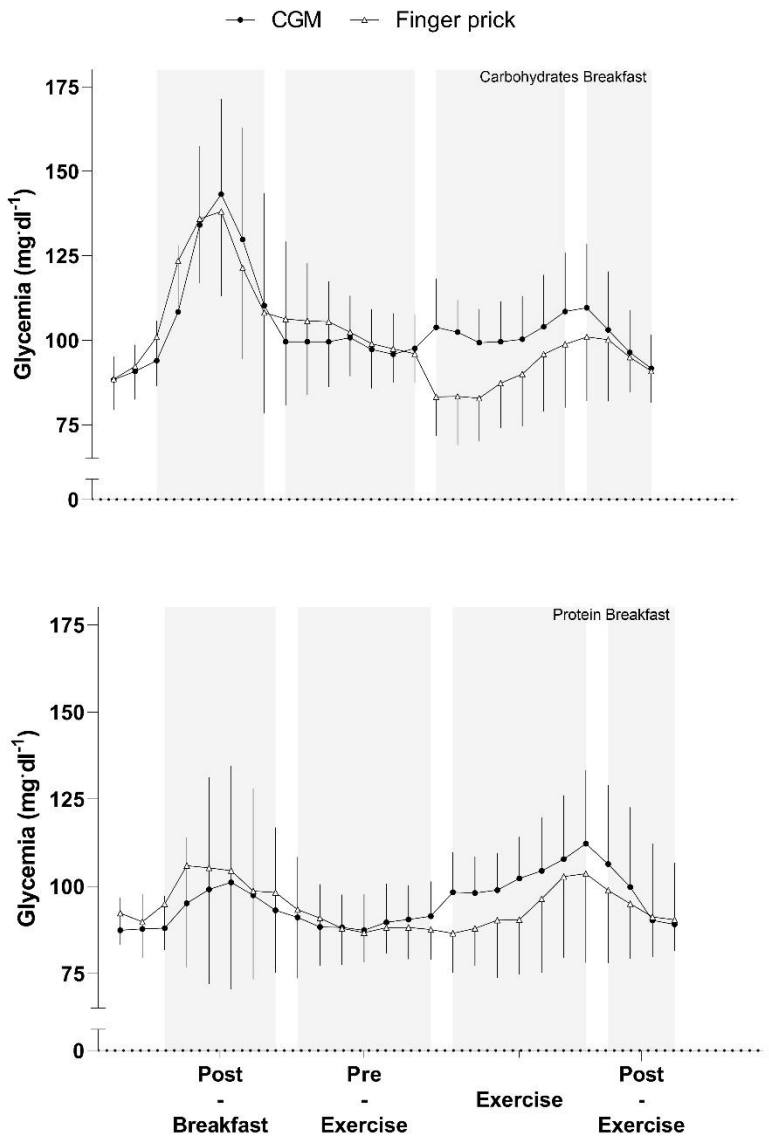

Post-Breakfast
Pre-Exercice
Exercice
Post-Exercice
Differences (CGM - FPBG) (mg/dL)
Means (mg/dL)
26.19
-2.99
-32.17
16.34
-1.67
-19.68
35.05
12.25
-10.55
33.58
4.18
-25.22
CHO
PROT

Figure 3


CGM
Finger prick
Carbohydrates Breakfast
Protein Breakfast
Glycemia (mg·dl-1)
175
150
125
100
75
0
Post - Breakfast
Pre - Exercise
Exercise
Post - Exercise

Tables

Table 1

	Post-Breakfast	Pre-Exercise	Exercise	Post-Exercise
Overall	9.1 (4.6-13.8)	7.1 (3.6-13.4) [#]	13.6 (6.8-23.2) [*]	9.4 (5.0-17.3) [#†]
CHO	9.4 (5.3-16.8)	7.1 (3.9-13.2) [*]	16.2 (7.4-25.6) [*#]	10.1 (6.1-16.9) [#†]
PROT	8.8 (4-11.9)	7.0 (3.4-13.4)	11.3 (6-19.7) [*#]	8.2 (4.1-17.3)

Table 2

	Post-Breakfast vs. Exercise	Post-Breakfast vs. Post-Exercise	Pre-Exercise vs. Exercise	Pre-Exercise vs. Post-Exercise	Exercise vs. Post Exercise
Overall	0.24 (0.17 to 0.31)	0.07 (0.01 to 0.16)	0.31 (0.24 to 0.38)	0.16 (0.07 to 0.24)	0.15 (0.06 to 0.23)
CHO	0.24 (0.13 to 0.34)	0.06 (0.01 to 0.18)	0.37 (0.27 to 0.46)	0.19 (0.07 to 0.31)	0.18 (0.07 to 0.28)
PROT	0.24 (0.14 to 0.34)	0.08 (0.01 to 0.2)	0.26 (0.16 to 0.36)	0.18 (0.01 to 0.24)	0.12 (0.02 to 0.24)

	Zone	Post-Breakfast	Pre-Exercise	Exercise	Post-Exercise

Table 3

Overall	A (Accurate)	189 (88.3%)	213 (93.4%)	176 (70.4%)	100 (76.3%)
	B (Benign errors)	25 (11.7%)	14 (6.1%)	59 (23.6%)	31 (23.7%)
	D (Failure to treat errors)	/	1 (0.5%)	15 (6.0%)	/
CHO	A (Accurate)	85 (80.2%)	104 (92.0%)	81 (65.3%)	52 (75.4%)
	B (Benign errors)	21 (19.8%)	9 (8.0%)	30 (24.2%)	17 (24.7%)
	D (Failure to treat errors)	/	/	13 (10.5%)	/
PROT	A (Accurate)	104 (96.3%)	109 (94.8%)	95 (75.4%)	48 (77.4%)
	B (Benign errors)	4 (3.7%)	5 (4.3%)	29 (23.0%)	14 (22.6%)
	D (Failure to treat errors)	/	1 (0.9%)	2 (1.6%)	/