Impact of Daily Physical Activity as Measured by Commonly Available Wearables on Mealtime Glucose Control in Type 1 Diabetes

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Abstract

Objective: In contrast with exercise, or structured physical activity (PA), glycemic disturbances due to daily unstructured PA in patients with type 1 diabetes (T1D) is largely underresearched, with limited information on treatment recommendations. We present results from retrospective analysis of data collected under patients' free-living conditions that illuminate the association between PA, as measured by an off-the-shelf activity tracker, and postprandial blood glucose control.

Research Design and Methods: Data from 37 patients with T1D during two clinical studies with identical data collection protocols were analyzed retrospectively: 4 weeks of continuous glucose monitoring, carbohydrate intake, insulin injections, and PA (assessed through wearable activity tracker) were collected in free-living conditions. Five-hour glucose area under curves (GAUCs) following the last-bolused meal of every day were computed to assess postprandial glucose excursions, and their relation with corresponding antecedent PA was analyzed using linear mixed-effects regression models, accounting for meal, insulin, and current glycemic state.

Results: Datasets yielded 845 days of data from 37 subjects (22.8 ± 11.6 days/subject); postmeal GAUC was negatively associated with total daily PA measured by step count ($P=0.025$), and total time spent performing higher than light-intensity PA ($P=0.042$). Patients with higher median total daily PA exhibited lower average postprandial GAUC ($P<0.01$). Additional analyses indicated that daily PA likely presents an immediate and delayed impact on glucose control.

Conclusion: Daily PA assessed by commonly available sensors is significantly associated with glycemic exposure after an evening meal, indicating that quantitative assessment of PA may be useful in mealtime treatment decisions.

Keywords: Activity tracker, Exercise, Physical activity, Postprandial glucose control, Step count, Type 1 diabetes.

Introduction

ENGAGING IN PHYSICAL ACTIVITY (PA) is associated with improved health outcomes^{1,2} and a total of 150 min of PA per week is recommended by both the Centers for Disease Control and Prevention³ and the American Diabetes Association.⁴ The benefits include improved mental health,⁵ better weight management,⁶ increased cardiovascular health,⁷ better lipid profile, and longer lifespan with a decrease in all-cause mortality.⁸ For people with type 1 diabetes (T1D), PA may be even more critical considering the prevalence of

cardiovascular disease and resulting mortality in this group compared with the general population.⁹ Despite these proven benefits and health care providers' recommendations, a majority of adults with T1D show low engagement in regular PA^{10,11} along with higher body mass indices, increased blood pressure, and dyslipidemia.¹²

While physical inactivity is a general public health problem, there are T1D-specific barriers to PA¹³ in addition to those already existing for the overall population.^{14,15} A particular challenge to PA for patients with T1D is the hurdle presented by prolonged changes in glucose uptake and insulin

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sensitivity associated with PA.^{16,17} These changes make effective insulin dosing in the hours following PA difficult. As a consequence, late-onset hypoglycemia risk remains a concern¹⁸ along with an increased risk of nocturnal hypoglycemia^{17,19} following PA performed in the afternoon.

Despite well-documented empirical strategies regarding treatment adjustment of insulin dosing and carbohydrate intake related to structured exercise bouts,²⁰ quantifying and classifying the performed exercise and choosing the corresponding guideline is both complex and burdensome for patients. Affordable off-the-shelf activity-tracking devices and smartphone applications may provide an opportunity to simplify this process and extend insulin dose modulation to daily life PA (vs. structured exercise).

Apart from structured exercise bouts, research shows that increase in unstructured daily PA also provides significant health benefits in improving fitness,^{21,22} decreasing the risk for chronic diseases,²³ and improving cardiovascular health.^{2,24} Furthermore, in a nondiabetes study, Duvivier et al. demonstrated that light-intensity PA is more effective in compensating for the negative impacts of inactivity during the day on insulin sensitivity and circulating lipids compared with a 1-h daily bout of moderate to vigorous exercise when the total energy expenditure is the same.²⁵ While people with T1D can also harness the aforementioned benefits of increased daily PA, it is important to examine the glycemic impact of such an increase in patients with T1D and provide them with effective blood glucose (BG) management strategies.

Recent studies in controlled environment have shown that even light PA may have a significant effect on reducing postprandial BG excursion in health^{26,27} and in T1D.²⁸ Since variations in daily PA are a part of everyday life for both people who engage in regular exercise and those who do not, understanding the relationship between these variations and BG control would be important in enacting T1D treatment strategies and improve glucose control. Studies that have linked light-intensity walking bouts with lower postprandial glycemia were conducted under controlled clinical conditions.^{26–28} The only study in people with T1D²⁸ explored the postprandial impact of PA performed following a meal. Herein, we provide analyses for the complementary case which is the impact of antecedent PA on postprandial BG excursion. The primary aim of this study was to determine the impact of daily PA as measured by an off-the-shelf activity tracker on postprandial BG control in patients with T1D in their free-living conditions. Because both the utility and performance of any PA-related glucose control strategy are limited without an objective measure of PA, we also aimed to indirectly evaluate the feasibility of using PA tracker data to link exercise (structured activity) to glycemic control in these patients.

Research Design and Methods

Participants

Data were retrospectively obtained from two different clinical studies (clinicaltrials.gov: NCT02558491, NCT03394352), which enrolled 54 subjects (age range 15–65 years) with T1D for more than a year, and HbA1c range 7%–10%. Each study contained a free-living data collection period of ~28 days conducted before the study intervention. During this pe-

riod, the participants followed their regular therapy while wearing continuous glucose monitors (CGMs) and a wristband PA tracker (Fitbit Charge HR and HR2; Fitbit, Inc., San Francisco, CA). Patients were provided with G4 Platinum (Dexcom, Inc., San Diego, CA) CGM. Participants using insulin pumps recorded consumed carbohydrate grams (meals, snacks, and hypoglycemia treatment) through the pump bolus wizard and multiple daily injections users recorded carbohydrates through application MySugr (MySugr, Vienna, Austria). All devices were downloaded at regular intervals during the study period. See Ref.²⁹ for more protocol details.

Data procedures

To capture the impact from total PA accumulated throughout the day, we selected the last-bolused meals consumed before 10 pm for each day. Selection of the last-bolused meals gave us the opportunity to observe the impact of a wide range of PA within a 12-h time frame. Additionally, compared with any other meal of the day, postprandial BG excursions associated with these meals are less likely to be followed, and influenced, by another big meal or exercise.

Some data-cleaning procedures were needed to perform the proposed analyses:

- (1) A meal was rejected from analysis if more than 24 CGM values (2 h) were missing between 4:30 pm and 10 pm or if no insulinized meal was present in this interval. When there was a CGM gap that did not violate this criterion, we replaced the missing values by linear interpolation of the closest available CGM data.
- (2) PA data (i.e., heart rate and step count) had to be available in the morning (6 am to noon), afternoon (noon to 5 pm), and evening (5 pm to 10 pm), as defined by no more than 2 h missing data in any of these three intervals.
- (3) When the total number of steps taken following the selected evening meal was higher than the total number of steps in the preceding 12 h, the day was eliminated to avoid the confounding impact from high amounts of PA performed after the selected meal.
- (4) Finally, the first day of the data collection period was included only if there were at least 12 h of valid CGM, PA, and pump data preceding the selected evening meal.

Statistical analyses

Data analyses were performed using RStudio 1.0.136 and statistical significance was set to $P < 0.05$.

Association of PA with postprandial glucose. We assessed postprandial BG control following the selected meals through 5-h incremental glucose area under the curve (GAUC) with respect to the CGM value at the time of the selected meal. This area is naturally associated with the CGM value at the meal time,³⁰ the amount of carbohydrates ingested, and the amount of insulin in the bloodstream. Therefore, these factors constituted the core independent variables in our regression models as follows: CGM value

at meal time ($\text{CGM}_{\text{mealtime}}$), total carbohydrate on board (COB), as calculated by adding the amount of carbohydrates consumed with the selected meal to the prevailing weighted sum of carbohydrate grams consumed within 6 h before the meal; and total insulin on board (IOB), computed by combining the bolus associated with the selected meal and insulin doses from previous injections within the past 4 h. To minimize interpatient variability, we further divided COB by patient's body weight (BW) and IOB by patient's average total daily insulin (TDI). To investigate the association between PA and GAUC, we designed linear mixed-effects (LME) regression models with different PA variables along with the core independent variables. LME models, similar to general linear models, are used to explore the relationship between the variables in the data. While general linear models explain the variation in the dependent variable in terms of the independent variables as well as error terms, LME models attribute individual variations to the error terms so that random errors are somewhat customized for each data point. Specifically, in our LME models, intercepts of the regression lines are computed for each patient capturing their individual differences to some extent. By this way, we also control for the confounding effect of repeated measures per patient.

Before running our statistical analyses, we visually inspected the distribution of the independent variables. When a variable showed a pronounced skewed distribution, we used a logarithmic transform of that variable in our analyses to prevent a potential influence from extreme values in the results. Finally, all independent variables in the LME models were centered around their mean values.

Association between higher-intensity PA and postprandial BG. In this analysis, we explored a way for leveraging PA classification of an activity tracker for use as an indicator of exercise. For this purpose, we used activity levels provided by Fitbit with the following levels and corresponding definitions: 0: sedentary, 1: lightly active, 2: fairly active, and 3: very active.³¹ We analyzed the relationship between postprandial GAUC and the time spent performing a PA labeled as fairly or very active and sustained for no <20 min. All covariates were centered around their mean values before the analysis. We consider the PA that satisfies these criteria as higher than mild-intensity PA and refer to it as higher-intensity PA in the following sections.

Timing of PA effect. As the glycemic impact of a moderate exercise bout over time has been shown to vary over the hours following the bout,^{17,32} we designed a set of LME regression models that explored the association between postprandial GAUC and total number of steps taken within each hour in the 12-h time frame before the selected meals. A total of 12 models were obtained with the response variable as postprandial GAUC and the covariates as total steps taken within each hour along with the previously described core variables. Similar to the previous analyses, we use LME regression models with covariates centered around their mean values for these analyses. Bonferroni correction is applied to account for the multiple comparisons in the dataset.

Daily PA trend and postprandial BG across patients. Although this study concentrates on the relationship

between variations in daily PA and postprandial BG control, we also tested whether having a higher median of total number of steps before mealtime was associated with a lower median value of the postprandial GAUC. The rank-based Jonckheere-Terpstra test³³ was used to test this hypothesis by ordering patients based on their daily median total number of steps before the selected evening meals.

Results

Overall impact of PA on postprandial control

Over the course of the data collection periods, 1488 days of data were collected from 37 patients. Out of these days, 201 days were eliminated according to the CGM validity criterion, 120 days were eliminated for not having a bolused carbohydrate intake between 4:30 pm and 10 pm (101 days of no reported carbohydrate intake between 4:30 and 10 pm, 6 days of no reported bolus, 13 days of no associated pairs of carbohydrate and insulin bolus). From the remaining dataset, 305 additional days were excluded due to requirements for PA data validity criteria, and 17 days for having higher total step count in the postprandial period than the 12 h prior.

The final dataset consisted of 845 days with complete glucose, insulin, meal, and PA data obtained from 37 subjects (17 males, 20 females, and 22.8 ± 11.6 days/participant) with an age range of 17–62 years (41.1 ± 12.2), and HbA1c range 5.3%–9.2% (7.1 ± 0.9). Eight patients used multiple daily injections while the rest used insulin pumps. Participants had an average TDI dose of 42.3 ± 18.7 U and an average BW of 80.5 ± 19.4 kg. Average values of the covariates were 152.4 ± 60.6 mg/dL for $\text{CGM}_{\text{mealtime}}$, 0.15 ± 0.07 for IOB/TDI, 0.7 ± 0.3 g/kg for COB/BW, 7481.5 ± 4348.3 steps for the total number of steps, and 42.4 ± 72.3 min of total time spent in higher-intensity PA before the selected mealtime.

Participants showed large individual differences in daily PA levels with average total steps ranging from 2866 to 14,532 total steps within the 12 h preceding the selected meal. Visual inspection revealed a left-skewed distribution for the step count and time spent in higher-intensity PA, therefore, we used logarithmic transform of these variables. The averages for the transformed covariates were 8.8 ± 0.6 transformed steps through LN (total number of steps) and 2 ± 2.1 transformed minutes through LN (total time spent in higher-intensity PA).

Results showed a significant relationship between postprandial GAUC and (A) total steps taken, and (B) total time spent in higher-intensity PA (Table 1). Both higher total daily PA quantified by step count and greater total time spent in higher-intensity PA were inversely associated with postprandial GAUC ($P=0.025$ for total daily PA, $P=0.043$ for higher-intensity PA). The core independent variables also showed statistically significant association with GAUC in both models presented ($P<0.01$ for $\text{CGM}_{\text{mealtime}}$, COB/BW, and IOB/TDI). Using the regression coefficients of covariates representing carbohydrates, insulin, and PA, the estimated change in the GAUC from an increase/decrease of these factors can be calculated. We calculated the estimated change in the GAUC from an additional unit of insulin for a representative participant with a BW of 80.5 kg and a TDI of 42.3 U as observed in our dataset. We then calculated the additional amounts of PA and carbohydrates that have a similar absolute contribution to the GAUC for this

TABLE 1. REGRESSION RESULTS FOR THE IMPACT OF DAILY PHYSICAL ACTIVITY ON GAUC (LEFT PANEL) AND THE IMPACT OF HIGHER-INTENSITY PHYSICAL ACTIVITY ON GAUC (RIGHT PANEL)

(A) Regression results for total PA			(B) Regression results for higher-intensity PA		
	Coefficient $\pm$ Standard error	P		Coefficient $\pm$ Standard error	P
Intercept	104.4 $\pm$ 184	0.6	Intercept	95.9 $\pm$ 181.4	0.57
CGM _{mealtime}	-34.7 $\pm$ 1.6	<0.01	CGM _{mealtime}	-34.6 $\pm$ 1.6	<0.01
COB/BW	1166.3 $\pm$ 348.6	<0.01	COB/BW	1160 $\pm$ 348.4	<0.01
IOB/TDI	-7750.6 $\pm$ 1710.1	<0.01	IOB/TDI	-7970.5 $\pm$ 1713.5	<0.01
LN (total steps)	-426.4 $\pm$ 189.4	0.025	LN (time spent at higher-intensity PA)	-103 $\pm$ 50.9	0.043

BW, body weight; CGM, continuous glucose monitor; COB, carbohydrate on board; GAUC, glucose area under curve; IOB, insulin on board; PA, physical activity; TDI, total daily insulin.

participant. This calculation showed that the GAUC diminishing effect of an additional unit of insulin was equivalent to the effect of an additional 3420 steps or 40.3 min of higher-intensity PA. The resulting corresponding amounts are depicted in the plots in Figure 1.

Timing of PA effect

After Bonferroni correction, we set $P=0.004$ as the threshold for statistical significance of covariates in these models. The effect of an increment of the log-transformed steps in each hour on GAUC is demonstrated with corresponding standard error bars in Figure 2. While statistical significance was not reached, one unanticipated finding was the similarities between the trend we observed in the impact of daily PA over time and the biphasic glycemic impact of moderate-intensity exercise demonstrated in a prior study.¹⁷

Specifically, these results suggested that PA performed in the hour right before the meal, between 4–5, and 7–10 h preceding the meal had a higher estimated GAUC-diminishing impact compared with other hours. This impact appears to vanish by 11 h. Again, the core variables showed statistically significant association with postprandial GAUC ($P<0.004$) in all of the models and the coefficients obtained for the PA variables in each model are presented in Figure 2. Diagnostic plots confirmed the compliance of all our regression models with the linear regression analysis assumptions for normality and homoscedasticity.

Finally, results of the Jonckheere-Terpstra test suggested a significant association between having a higher median of the total number of steps taken before mealtime and decreased median postprandial GAUC across patients ($P<0.01$).

Discussion

The purpose of this study was to examine the impact of daily PA, as measured by a commercially available PA tracker, on postprandial BG control, and to explore how available information from PA trackers can be leveraged to improve BG control in patients with T1D. While people with T1D have long been aware of the increased risk of hypoglycemia during and following exercise,¹⁶ little is known about the effect of unstructured daily PA on BG control. Our findings suggest that the range of PA that influences BG is broader than only structured exercise bouts. The results showed that both an increased number of cumulative daily steps and an increased amount of time spent in higher-intensity daily PA before an evening meal were associated with lower postprandial GAUC.

Since we did not test for insulin sensitivity, it is not possible to give a definite physiological explanation for how much of the observed PA effect is due to behavioral changes or changes in the insulin/glucose metabolism. Nonetheless, these findings indicate that daily PA may need to be taken into consideration in patient's everyday treatment decisions (i.e., insulin bolus dose and carbohydrate intake). Translation

FIG. 1. Example clinical translation of the results for a representative patient with body weight of 80.5 kg and TDI of 42.3 U. Correspondence between carbohydrates (CHO), insulin units, and PA with similar absolute contribution to the GAUC. Left panel: PA explored as total steps taken in the previous 12 h, right panel: PA explored as moderate- to high-intensity PA (expressed with higher-intensity PA) defined based on Fitbit activity levels. GAUC, glucose area under curve; PA, physical activity; TDI, total daily insulin.

FIG. 2. Bar plot representation of the observed magnitude of decrease in the postprandial GAUC with an increment in the LN (total number of steps taken) for each hour preceding the mealtime (e.g., [0–1]: the hour right before the meal). These results are obtained from 12 separate LME models. LME, linear mixed-effects.

of the regression analyses' results into daily treatment terms revealed an equivalency in the postprandial GAUC-diminishing effects of an additional unit of insulin, an additional 3420 steps, and an additional 40 min of higher-level PA. These results are consistent with prior studies in which 30 min of moderate-intensity walking was demonstrated to accumulate 3000 to 3100 steps on average.^{34,35} As these values are derived from average models, they are expected to vary from patient to patient.

All of our regression analyses used logarithmic transformation of PA. This implies that the greater values of PA covariates had a lower marginal impact on decreasing the postprandial GAUC. This is a result of our model design to minimize the influence of extreme values in the regression analyses. Prospective data on a wide PA range with a larger sample size is required to evaluate this design's compatibility with real-life observations.

Our results hint at the feasibility of using a PA tracker to facilitate existing exercise management strategies for patients with T1D. Research shows that most patients already take various measures to prevent exercise-related hypoglycemia surrounding an exercise bout, however, there is little consistency in the strategies used among patients.³⁶ Leveraging information from PA trackers can provide an objective (if even somewhat inaccurate) PA measurement, time, and duration, which then could be used to select the strategy that corresponds to the particular situation.

Our results suggest that step count could be a good surrogate for PA, especially considering its ubiquitous avail-

ability and simplicity of collection in day-to-day life. Additionally, conversion tables are available to translate sports and home activities into their equivalent steps per minute,^{34,37} which can be used to standardize PA quantification and facilitate the use of PA-related BG management strategies for a variety of activities. Further studies are required to systematically examine the performance and practicality of different PA quantifiers for PA-related treatment adjustment to improve BG control in patients with T1D. As it is well documented in the literature, PA may have different glycemic impacts depending on its intensity, frequency, fitness level, and metabolic state of the person.³⁸ There is also need for further studies to explore differences in the impact of daily PA based on these factors.

It is noteworthy that the pattern we observed for the glycemic impact of PA over time was in line with earlier studies,^{17,32} although statistically insignificant. The substantial variability in the total steps taken in an hour in daily life, hence in our dataset, likely contributed to this result. These preliminary results support the need for further investigation of daily PA's glycemic influence over time.

Because the participants in this study widely varied in their daily PA level, we also had the opportunity to explore whether the magnitude of postprandial glucose exposure changed with increased habitual daily PA. The significant association between higher daily PA and lower postprandial GAUC supports recommendations for higher PA engagement to reduce hyperglycemia-related complications. Promoting higher PA engagement through setting step count goals was

shown efficacious in various populations³⁹ and PA trackers may have potential use in promoting, prescribing, and monitoring PA also in patients with T1D.

It should be noted that the data used in this study was collected during patients' daily lives and BG values are likely influenced by various physiological, behavioral, and environmental factors. This introduced difficulty in analyzing the impact of isolated episodes of daily PA. On the other hand, it also provided an opportunity for observing the relationship between daily PA and BG control under real-life conditions. Use of step count is an imperfect surrogate of PA and fails to capture any PA that does not increase the measured step count. As for PA that increases step count, the accuracy of our quantification depends on the accuracy of the tracker.⁴⁰ However, walking is the most common form of daily PA and is also a highly preferred form of PA.^{41,42} While its low cost and practicality in daily use make it a good PA indicator, there is a need for further studies to compare and contrast different PA indicators' accuracy, performance, practicality, and usability for advising treatment decisions in patients with T1D.

Finally, providing our participants with PA trackers may have introduced a study effect leading to an increase in their daily PA considering that some previous studies have shown an increased total daily step count after pedometer use interventions.^{39,43}

Conclusion

In this study we have (1) demonstrated an inverse association between daily PA and postprandial glucose exposure, (2) provided a clinical translation of statistical results to link PA information from a commercially available tracker to common factors known to also affect postprandial BG, (3) demonstrated results for the overtime variation in daily PA's glycemic impact, and (4) presented evidence that an increase in total daily PA pattern is associated with better average postprandial BG control. The results of this study provide quantitative evidence that exercise-related BG management strategies should be broadened to include daily PA. With a good understanding of daily PA's glycemic impact and guidelines/decision support systems addressing necessary treatment adjustments, patients with T1D can safely increase their daily PA and harness its significant health benefits even when they do not engage in structured exercises.

Acknowledgments

B.O. thanks Linda Gonder-Frederick for her insightful comments on the article, Jonathan Hughes for reviewing the article draft and providing feedback, and Christian Wakeman for helping with the storage, access, and understanding of the a posteriori data.

Author Disclosure Statement

No competing financial interests exist.

Funding Information

Funding was received from NIH NIDDK 1DP3DK106826-01.

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