Glycaemia around exercise in adults with type 1 diabetes using automated and non-automated insulin delivery pumps: A switch pilot trial.

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Abstract

In an in-patient switch study, 10 adults with type 1 diabetes (T1D) performed 45-minutes of moderate intensity exercise on two occasions : 1) when using their usual insulin pump (UP) and 2) after transitioning to automated insulin delivery (AID) treatment (MiniMed^{TM} 780G). Consensus glucose management guidelines for performing exercise were applied. Plasma glucose (PG) concentrations measured over a 3-hour monitoring period were stratified into time spent below (TBR [<3.9 mmol/L]) within (TIR [3.9-10.0 mmol/L]) and above (TAR [>10.0 mmol/L]) target range.

Overall, TBR (UP: 11±21 vs. AID: 3±10 %, p=0.413), TIR (UP: 53±27 vs. AID: 66±39 %, p=0.320) and TAR (UP: 37±34 vs. AID: 31±41 %, p=0.604) were similar between arms. A proportionately low number of people experienced exercise-induced hypoglycaemia (UP: n=2 vs. AID: n=1, p=1.00).

In conclusion, switching to AID therapy did not alter patterns of glycaemia around sustained moderate intensity exercise in adults with T1D.

Introduction

In the past decade, the treatment landscape of type 1 diabetes (T1D) has changed considerably with new pharmacological and technological therapies penetrating the market. In the case of the latter, recent advances have led to the development of automated insulin delivery (AID) systems which combine an infusion pump with a control algorithm that regulates subcutaneous insulin delivery based on continuous glucose monitoring (CGM) data.

The safety, efficacy, and feasibility of transitioning to AID therapy in T1D has been documented in various inpatient and real-world studies with associated improvements in glycaemic control (1–5). The increased automaticity of AID therapy lessens the constraints of constant self-management, thereby liberating users to focus on other life factors (6). Nevertheless, some user involvement is still needed in circumstances where an adjustment in insulin infusion rate may be required to temper anticipated glycaemic excursions (i.e., meals and exercise).

However, there is limited knowledge about the integration of AID use around exercise which can cause considerable and sometimes clinically concerning glycaemic disturbance in those with T1D. This is particularly evident when exercise is performed post-prandially (7–9), at a time when circulating insulin levels are raised due to the pharmacokinetics of the concomitant bolus insulin dose (10). Though consensus glucose management guidelines for exercise exist (11), it is unclear whether they are applicable to the newest generation of diabetes technologies. Hence, as it stands, exercise advice for AID use is largely based on expert opinion and/or experience (12).

With the commercial introduction of AID systems for the glycaemic management of people with T1D, there is a pressing need to test their safety and efficacy around exercise. As such, we sought to detail the glycaemic responses to a controlled bout of moderate intensity exercise in adults with T1D using automated and non-automated insulin delivery pumps.

Methods and Materials

Study design and ethical approval

This was a two-period, in-patient, switch study involving adults with T1D. The study was carried out in accordance with the Helsinki Declaration, EU Directive on good clinical practice and ICH-GCP guidelines after approval by the Regional Scientific Ethical Committee and the Capital Region's Videnscenter for Dataanmeldelser (P-2021-169). All participants were provided with a full written and verbal description of the study and gave informed consent prior to taking part. The study was registered as a clinical trial (Clinical Trials Register; NCT05133765).

Screening procedures

Participants in the present study were recruited from a separate, but simultaneously conducted and ongoing randomised, crossover trial exploring the efficacy of the MiniMed 780G in people with elevated HbA_{1c} during which the following inclusion and exclusion criteria applied:

Main inclusion criteria were: aged 18-75 years; T1D ≥2 years; HbA_{1c}; ≥7,5% (58 mmol/mol); use of insulin pump treatment for ≥12 months; use of a continuous, or an intermittently scanned, glucose monitoring system for ≥6 months; use of insulin Aspart (Novo Nordisk A/S, Bagsværd, Denmark) for ≥1 week. Main exclusion criteria were: females who were pregnant or breastfeeding; use of glucose-lowering medications (other than insulin), corticosteroids and/or other drugs affecting glucose metabolism during the study period or within 30 days prior to study start; use of an AID system; daily use of acetaminophen; alcohol or drug abuse; conditions contraindicating HbA_{1c} <7% (53 mmol/mol).

After confirmation of suitability for the main study, participants were asked whether they would be interested in participating in the present exercise sub-study. Interested individuals then performed a graded exercise test to volitional exhaustion on a workload-controlled cycle ergometer (Corival, Lode©, Groningen, The Netherlands). The results were used to determine the individualised workload (watts) required to complete the moderate intensity (~60% $\dot{V}O_{2peak}$) exercise bout incorporated in each of the exercise trial experimental visits.

Insulin pump therapy switch

Participants were switched from their usual insulin pump to the MiniMed™ 780G system (Medtronic, Northridge, CA, USA). The technology automatically adjusts basal insulin every 5 minutes based on CGM input, houses adjustable glucose targets of: 100 (5.5), 110 (6.1), and 120 (6.7) mg/dL (mmol/L), and includes an automatic correction bolus feature. A raised temporary glucose target of 150 (8.3) mg/dL (mmol/L) can be set for scenarios such as exercise. By doing so, the auto-correction feature is suspended, and the automatic basal insulin delivery rate is adjusted in an attempt to attain the temporary target glucose. User-initiated meal announcements are required for optimal glycaemic results (12,13). In the present study, each participant had been using the MiniMed™ 780G system >4 weeks before the AID trial day. Participants used Guardian 3 link or Guardian 4 transmitters connected to the MiniMed™ 780G system and were advised to change their sensor 24 hours before the trial visit.

Experimental trial day procedures

In a switch fashion, participants attended the laboratory and performed a 45-minute bout of exercise 90 minutes after consuming a carbohydrate-based drink on two separate occasions: Firstly, when using their usual insulin pump (UP) and secondly, after transitioning to the AID system (AID). Participants arrived at the research facility following an overnight fast (≥10 hours) from food with water *ad libitum*. Upon arrival, participants adopted a bed-rest position and were fitted with an indwelling cannula ahead of the interventional period. Following the first sample draw (baseline i.e., t=-90 min), participants consumed a standardised low-glycaemic index, carbohydrate-based drink ([Isomaltulose, BENEO GmbH, Mannhein, Germany] equating to 0.75 grams of carbohydrates per kg body mass) with a 25% bolus insulin dose reduction (11). At the same time, participants reduced their basal insulin rate by 20% in the UP arm or applied the temporary target in the AID system arm (12) as per consensus guidelines. In both arms, these settings were maintained until 15 minutes after exercise (t=+60 minutes).

Fifteen minutes before the anticipated exercise start time, plasma glucose (PG) concentrations were checked to ensure safe starting concentrations (11). If PG was <5.0 mmol/L (<100 mg/dL), participants were given 15 grams of oral glucose (Dextro Energy GmbH & Co. KG, Krefeld, Germany). If PG was ≥15.0 mmol/L (≥270 mg/dL) and blood ketones levels were <0.6 mmol/L, exercise went ahead but only at the discretion of the participant with frequent

monitoring for ketone body formation. If ketone levels were ≥1.5 mmol/L, the visit was cancelled and rescheduled (11).

After 90 minutes of bed-rest (t=0 min), participants commenced a bout of moderate intensity (~60% $V\dot{O}_{2peak}$) exercise on a workload-controlled cycle ergometer (Corival, Lode©, Groningen, The Netherlands). The exercise session lasted for 45 minutes (t=+45 min), or until hypoglycaemia (PG <3.9 mmol/L [<70 mg/dL]). In the case of the latter, exercise was stopped immediately, and a standardised hypoglycaemia treatment protocol was initiated i.e., provided 15 grams of oral carbohydrates (Dextro Energy GmbH & Co. KG, Krefeld, Germany), waited 15 minutes, repeated if necessary (14–16). Following exercise, participants remained within the laboratory for a further 60 minutes of observational bed-rest.

Blood sampling procedures

Venous-derived whole blood samples were obtained in 15-minute intervals from -90 to -15 minutes, 5-minute intervals from -15 to +60 minutes and 15-minute intervals from +60 to +105 minutes (Figure 1) for PG determination (YSI Inc. Ohio, USA).

Statistics and computation of glycaemic parameters

All statistical analyses were performed via SPSS (IBM®, SPSS Inc. Chicago, USA). Unless otherwise stated, data are presented as mean±SD. Time spent within a specific glucose zone was calculated as the number of PG readings that fell within that zone divided by the total number of glucose readings from the participant represented as a percentage i.e., time below range ([TBR] <3.9 mmol/L [<70 mg/dL]), time in range ([TIR] 3.9–10.0 mmol/L [70-180 mg/dL]), time above range ([TAR] >10.0 mmol/L [>180 mg/dL]) (17). To account for the confounding effect of rescue carbohydrate provision on subsequent PG concentrations, the first point at which a hypoglycaemic event occurred was carried forward for the remainder of the experimental trial day. Differences in glycaemic parameters between experimental arms were assessed via the paired samples t-test or, failing the assumption of normality, the non-parametric equivalent (Wilcoxon Signed Ranks test). The McNemar test was used to identify differences in the prevalence of hypoglycaemia between arms. Alpha was set at 0.05 and significance was accepted when p values were ≤ alpha.

Results

Participant characteristics

Data from 10 adults with T1D (7 females, age: 49±15 years, HbA_{1c}: 67±8 mmol/mol [8.3±0.8%], diabetes duration: 28±15 years, BMI: 27.5±3.5 kg/m^2, $\dot{V}O_{2peak}$: 24.0±7.7 mL/min/kg) were included in this study. Before switching to AID, participants used the following insulin pumps; MiniMed 640G, Medtronic, USA (n=7), Veo Paradigm, Medtronic, USA (n=2), Accu-Chek Insight, Roche diagnostics, Germany (n=1); whereof 6 used CGM and 4 used intermittently scanned CGM. Following transition to the AID system, participants were provided with adequate time for therapy familiarisation before conducting the second experimental visit (130±30 days).

Plasma glucose responses

Pre-exercise period

Fasted PG levels were comparable between arms (UP: 8.3±2.5 vs AID: 7.9±2.2 mmol/L, p=0.634) and remained as such at each timepoint throughout the 90-minute pre-exercise period (figure 1). The meal-induced rise in PG was similar between arms (UP: Δ+1.6±2.4 vs AID: +1.9±1.4 mmol/L, p=0.787) as was the individualised dose of meal-time bolus insulin (UP: 5.3±2.7 vs AID: 5.2±3.1 IU, p=0.834). All glycaemic parameters were similar between pumps (Table 1 and Figure 1).

Exercise period

PG immediately prior to exercise onset were similar between arms (UP: 10.0±3.5 vs. AID: 9.8±2.9 mmol/L, p=0.850). Both the magnitude (UP: Δ-3.0±1.9 vs AID: Δ-3.1±1.2 mmol/L, p=0.818) and rate (UP: -0.07 ±0.04 vs. AID: -0.07±0.03 mmol/L/min, p=0.893) of change in PG over exercise was comparable between conditions as was the duration (UP: 40.0±10.6 vs. AID: 45±0.0 minutes, p=0.195) and intensity (UP: 65±11 vs. AID: 60±14 %$\dot{V}O_{2peak}$, p=0.194) of the exercise bout. Two people experienced hypoglycaemia during cycling in UP whereas one person did so in AID (p=1.00). All in-exercise glycaemic parameters were similar between arms (Table 1 and Figure 1).

Post-exercise period

Point concentrations of PG throughout the 1-hour post-exercise period were similar between arms (Figure 1) as were all other glycaemic parameters (Table 1). There was one episode of hypoglycaemia during the post-exercise period in UP and none in AID (p=1.00). Participants completed the trial with equivalent PG concentrations on both occasions (UP: 7.2±3.5 vs. AID: 7.2±3.0 mmol/L, p=0.970).

Overall period

Overall, two people experienced hypoglycaemia during UP, whereas one person did so during AID (p=1.00). The time to hypoglycaemia onset was similar between arms (UP: 130±31.2 vs. AID: 135±0.0 minutes, p=0.902) Overall TBR (UP: 11±21 vs. AID: 3±10 %, p=0.285), TIR (UP: 53±27 vs. AID: 66±39 %, p=0.320) and TAR (UP: 37±34 vs. AID: 31±41 %, p=0.735) were similar between arms as were all other glycaemic parameters (Table 1 and Figure 1).

Discussion

This study assessed the glycaemic responses to a bout of aerobic exercise in adults with T1D before and after therapy switch to an AID system. We found similarities in all glycaemic parameters between the automated and non-automated insulin delivery pumps before, during and acutely after a sustained bout of moderate intensity cycling when consensus guidelines for glucose management were applied (11,12).

Our findings indicate that for 45-minutes of aerobic exercise undertaken 1.5 hours after a meal, a strategy involving both a 25% reduction in the concomitant bolus insulin dose and an increase in the individualised sensor glucose target (to 8.3 mmol/L) is associated with minimal risk of exercise-induced hypoglycaemia in adults with T1D using AID therapy. Indeed, during cycling the AID system achieved 1% TBR, which although not statistically significant, was proportionately less than the 12% observed in the usual pump arm, a theme that continued into the post-exercise period, where one individual experienced a recurrent event whilst using their predecessor pump. It is interesting to consider whether the prevalence of hypoglycaemia would have been more prominent had our exercise stimulus or indeed observational window been of longer duration. Even so, given that hypoglycaemia represents a major clinical concern that

dissuades regular exercise engagement in those with T1D, the poignance of the present findings should perhaps not be easily overlooked.

In light of the synergistic glucose lowering effects of exercising muscle tissue and active on-board insulin, the need to consider exercise announcement and bolus dose reductions ahead of activities performed soon after a meal in those using closed-loop systems has been highlighted (9). Our data provide extension of findings by those of Paldus and colleagues (18), who highlighted glycaemic superiority when using a hybrid-closed loop system (MiniMed 670G system) relative to standard therapy during moderate- and high-intensity exercise in adults with T1D. Our results align with recent work by Myette-Cote et al., (19) who in their investigation of AID use around exercise in adults with T1D, documented the complete avoidance of hypoglycaemia during 60-minutes of moderate intensity continuous exercise performed 1 and 2-hours after a meal when combining a 33% reduction in the meal-time insulin dose with an increased glucose target (6.0 to 9.0 mmol/L). Hence, though caution must be erred when considering the pilot nature of both our studies, these data provide empirical evidence to support the suitability and safety of current consensus guidelines for AID use around post-prandially performed exercise (12). Nevertheless, how best to utilise the newest generation of insulin pumps in an exercise setting is yet to be established, and more research is needed to identify strategies that mitigate risk under different exercise scenarios.

With the ongoing technological evolution of diabetes care, access to information that represents the latest management tools is critical in providing the greatest scope for maximising safety. As we continue to design, develop, and disseminate new diabetes technologies, it is important we consider their integration around exercise. .

Study strengths limitations and future research directives

This study is amongst the first to characterise the efficacy of an AID system around physical exercise in adults with T1D. Though inherent limitations of this study include the provision of a carbohydrate-only drink and the small sample size with homogeneity in diabetes and physical fitness characteristics, the novelty of this work provides a foundational basis from which others can start to formulate prudent management strategies using AID therapy in different exercising scenarios. Expansion of this work to a larger and more heterogenous population should be considered for further research.

Conclusion

In this study, switching to AID therapy did not alter patterns of glycaemia around sustained moderate intensity exercise in adults with T1D. These data provide evidence-based information that may help govern decision making for exercise management using the newest generation automated insulin pumps.

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Authorship contributions

OMM, MBC, SS, RMB, SCB and KN contributed to the conception and design of the study. OMM, KBK, MBC, SS, KN, and AGR contributed to the acquisition of data. OMM was responsible for data analyses. All authors were responsible for data interpretation. OMM wrote the original draft of the manuscript. All authors contributed to revising the article. All authors provided final approval of the version to be published.

Authors disclosures

SS is an employee of Novo Nordisk A/S as of May 1st, 2022. SS has received speaker's fee from Novo Nordisk. KN received funding to her institution for participating in advisory boards from Medtronic, Novo Nordisk, and Convatec and for lecturing from Sanofi, Novo Nordisk, Medtronic, and Dexcom. Her institution received funding for studies she performed from Zealand Pharma, RSP Systems, Novo Nordisk, Medtronic, and Dexcom. The remaining authors report having no relevant conflicts of interest to disclose.

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Tables

Table 1. Glycaemic parameters during each designated time-period.

Glycaemic parameter	UP	AID	p-value
Pre-exercise period(-90min to -5min)			
Mean (mmol/L)	9.7±3.0 (11.1 [4.7])	9.2±2.3 (8.3 [3.9])	0.476
Minimum (mmol/L)	8.1±2.6 (8.8 [4.0])	7.8±2.2 (7.9 [3.4])	0.705
Maximum (mmol/L)	11.0±3.4 (12.5 [5.3])	10.3±2.5 (8.8 [4.3])	0.509
TBR (%)	0.0±0.0 (0.0 [0.0])	0.0±0.0 (0.0 [0.0])	1.00
TIR (%)	47.2±40.4 (25.0 [75.0])	62.5±45.9 (100.0 [87.5])	0.388
TAR (%)	52.8±40.4 (75.0 [75.0])	37.5±45.9 (0.0 [87.5])	0.388
CV (%)	10.4±4.4 (9.6 [6.4])	10.6±5.4 (8.6 [9.6])	0.943
Exercise period(0min to +45min)			
Mean (mmol/L)	8.6±3.0 (9.6 [4.3])	8.4±2.7 (7.4 [4.2])	0.801
Minimum (mmol/L)	7.0±2.5 (7.4 [4.7])	6.7±2.7 (5.9 [3.8])	0.705
Maximum (mmol/L)	10.1±3.5 (11.0 [5.1])	9.8±2.8 (8.6 [4.7])	0.756
TBR (%)	12.2±25.4 (0.0 [20.0])	1.2±3.7 (0.0 [0.0])	0.285
TIR (%)	52.2±38.0 (50.0 [75.0])	67.7±41.7 (88.9 [70.0])	0.325
TAR (%)	35.6±42.2 (10.0 [80.0])	31.1±42.6 (0.0 [70.0])	0.588
CV (%)	13.5±7.2 (11.8 [10.4])	14.6±5.2 (16.3 [9.7])	0.729
Post-exercise period(+50min to +105min)			
Mean (mmol/L)	7.1±2.7 (7.7 [4.9])	7.1±3.2 (6.7 [4.4])	0.992
Minimum (mmol/L)	6.6±2.4 (7.4 [4.6])	6.5±2.8 (6.0 [4.1])	0.942
Maximum (mmol/L)	7.6±3.0 (8.2 [5.6])	7.6±3.5 (7.2 [4.8])	1.00
TBR (%)	22.2±44.1 (0.0 [50.0])	11.1±33.3 (0.0 [0.0])	0.564
TIR (%)	61.1±44.9 (83.3 [91.7])	66.7±50.0 (100.0 [100.0])	0.796
TAR (%)	16.7±30.0 (0.0 [33.4])	22.2±44.1 (0.0 [50.0])	0.854
CV (%)	5.0±4.0 (3.6 [6.6])	5.6±3.3 (5.1 [4.8])	0.741
Exercise + Post-exercise period(0min to +105min)			
Mean (mmol/L)	8.1±2.8 (8.5 [4.6])	7.9±2.9 (7.1 [4.2])	0.852
Minimum (mmol/L)	6.5±2.4 (7.0 [4.6])	6.5±2.8 (5.9 [4.0])	0.967
Maximum (mmol/L)	10.3±3.4 (11.1 [4.4])	9.8±2.8 (8.6 [4.7])	0.620
TBR (%)	16.0±32.1 (0.0 [31.3])	5.2±15.6 (0.0 [0.0])	0.285
TIR (%)	55.6±35.6 (56.3 [71.9])	67.0±41.3 (75.0 [73.4])	0.594
TAR (%)	28.5±35.5 (6.3 [59.4])	27.8±42.3 (0.0 [62.5])	0.917
CV (%)	16.4±9.2 (13.1 [8.6])	16.5±6.2 (20.0 [11.0])	0.985
Overall period(-90min to +105min)			
Mean (mmol/L)	8.6±2.8 (9.3 [3.6])	8.3±2.6 (7.2 [4.1])	0.682
Minimum (mmol/L)	6.2±2.0 (6.7 [3.7])	6.3±2.5 (5.9 [3.0])	0.904
Maximum (mmol/L)	11.2±3.3 (12.6 [4.0])	10.4±2.4 (8.8 [4.1])	0.383
TBR (%)	10.7±21.4 (0.0 [20.9])	3.4±10.1 (0.0 [0.0])	0.285
TIR (%)	52.6±27.1 (54.2 [37.0])	65.6±39.0 (69.6 [68.8])	0.320
TAR (%)	36.7±34.0 (29.2 [62.5])	31.0±40.7 (0.0 [68.8])	0.735
CV (%)	18.6±8.3 (15.4 [10.8])	17.9±6.7 (20.4 [11.6])	0.844

Table 1.Glycaemic parameters during each pre-defined time-period on experimental trial days. Data are presented as mean±SD (median [IQR]))UP: The visit on which participants were using their usual insulin pump. AID: the visit in which participants had been switched to an automated insulin delivery system. TBR: Time spent with plasma glucose below the target range (<3.9 mmol/L). TIR: time spent with plasma glucose levels within the target range (3.9 – 10.0 mmol/L). TAR: time spent with plasma glucose above the target range (>10.0 mmol/L). CV: Coefficient of variation.

Figures

Figure 1. Plasma glucose responses before, during, and after a 45-minute bout of sustained moderate intensity exercise when participants were using their usual insulin pump and after transitioning over to an automated insulin delivery system.

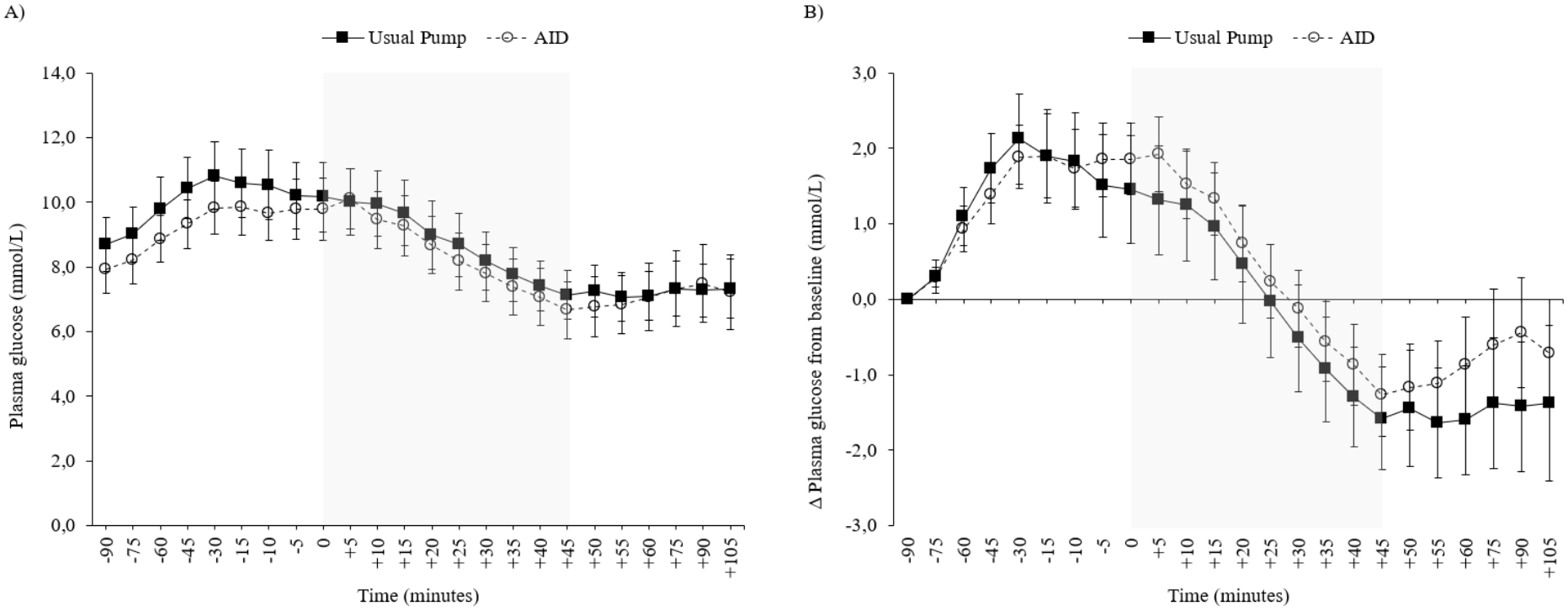

Figure 1. Plasma glucose concentrations on experimental visits when data are expressed as A) the absolute concentrations at each timepoint and B) the change from fasted starting values at each timepoint. Unfilled markers indicate no change in the point concentration of plasma glucose from fasted levels. AID: Automated insulin delivery system. Shaded grey rectangle represents the designated moderate intensity continuous exercise period. Data are presented as mean±SEM.