

Updated Abstract

Artificial pancreas (AP) systems improve glucose control while reducing the daily burden of living with type 1 diabetes (T1D). People with T1D often avoid physical activity due to a fear of hypoglycemia and thus daily energy expenditure (EE) is often suboptimal. While emerging AP systems may improve glucose control, it is unclear whether activity levels are impacted.

This pilot study aims to determine the feasibility in measuring physical activity in adults with T1D during an AP study. Twenty-three participants (17 females) with T1D (age 38±14 yrs, mean±SD) participated in each of the following treatment arms for 2-weeks during a 6-week random-order crossover study: usual care, insulin-only AP, and dual-hormone (insulin and glucagon) AP; each with and without monitoring of glycemia. Participants wore an activity monitor (ActiGraph) on their wrist and were instructed to exercise freely. Data were analyzed using a two-factor ANOVA on subjects with complete datasets for active calories as measured by ActiGraph (n=14). Participants were reasonably active throughout the study period, expending 2,289±785 kcals/day. No differences were observed between any of the conditions over the duration of this short-term study. Factors that contributed to the incomplete datasets (n=9) included battery/equipment failure, water damage, and/or possible user non-compliance.

Wrist-worn accelerometers also have a tendency to over-report step count and therefore, the location of wear may need to be modified in future studies (i.e. worn at the hip). Future studies will need to implement longer interventions with aims to improve overall compliance and feasibility.

Background

Physical activity is known to be beneficial for people living with T1D, but a fear of hypoglycemia often inhibits patient engagement in regular activity (1). It is hoped that the AP not only reduces hypo and hyperglycemia risk, but also allows patients to more comfortably engage in regular physical activity.

This was an outpatient study testing two configurations of the Bionic Pancreas (BP insulin-only, dual-hormone (2,3)) in 23 adults (≥ 18 years of age) with T1D in a random-order crossover study vs. usual care (usual insulin pump with blinded CGM). Physical activity was measured by accelerometry.

Methods

Subjects with T1D (see table 1) wore an accelerometer on their non-dominant wrist (usual care – patients own pump and CGM if usually used plus blinded CGM; insulin-only BP; dual-hormone BP) and were asked to only remove the activity monitor during showering and water-based activities.

In our analysis of activity levels, vector magnitude counts and step counts were corrected for non-dominant wrist wear, based on Kamada et al. (4). Complete datasets across all conditions could only be retrieved from 14 of 23 subjects because of technical issues with the activity monitors. ActiGraph GT3X+ was used to assess physical activity levels (see inset photo).



Initialization for ActiGraph GT3X+ was set to:

- 60s epochs
- Deselected for inclinometer and low-frequency extension

Subject	Sex (M/F)	Age (Years)	Diabetes Duration (Years)	Weight (kg)	Height (cm)	BMI (kg/m ²)	Baseline HbA1c (%)
1	F	32	25	102	173	34.1	6.9
2	M	24	17	68	173	22.5	8.7
3	F	61	28	80	154	34.1	8.4
4	F	32	20	83	160	32.3	6.6
5	M	26	22	95	173	32.0	8.7
6	F	31	16	73	162	28.0	6.3
7	F	36	15	90	174	29.6	7.8
8	F	47	46	73	156	30.1	7.3
9	M	35	20	73	182	21.9	6.6
10	M	79	31	76	183	22.8	6.4
11	M	49	29	69	175	22.7	7.9
12	F	35	31	64	161	25.0	7.4
13	M	37	25	110	188	31.2	6.9
14	F	23	11	86	170	29.7	8.7
Mean ± SD	8 F / 6 M	39 ± 16	24 ± 9	82 ± 14	170 ± 10	28.3 ± 4.5	7.5 ± 1.0

Table 1: Demographic information

Results: Physical Activity Levels with Usual Care vs. Single and Dual Hormone BP

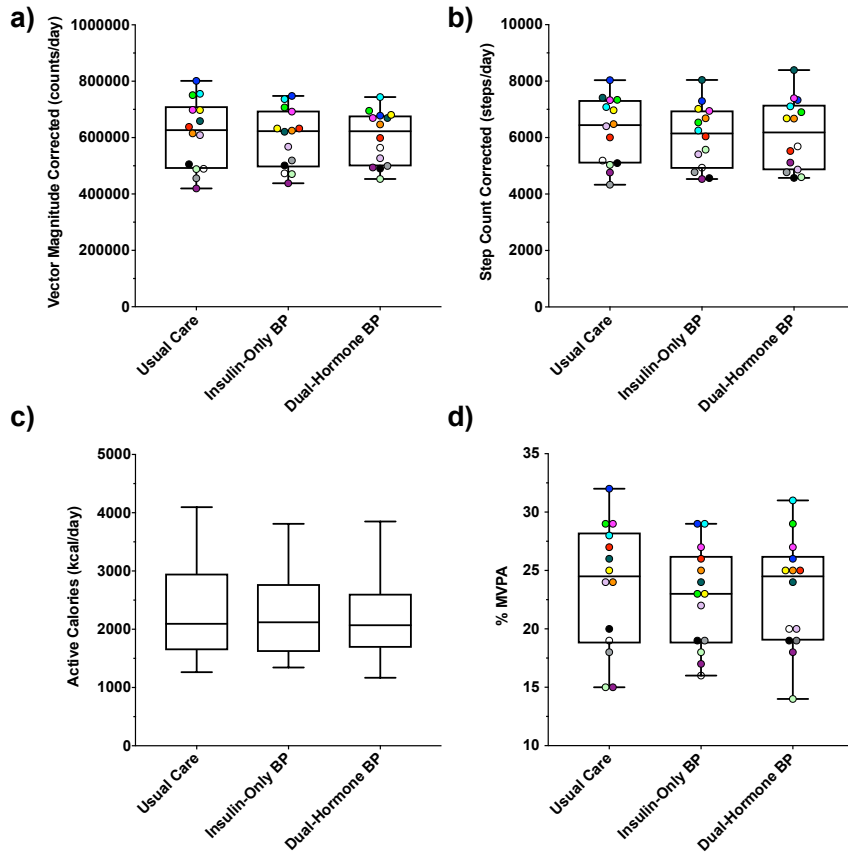


Figure 1: Box & whisker plots of (a) vector magnitude corrected (counts per day), (b) step count corrected (steps per day), (c) active calorie expenditure (kcal per day) and (d) time in moderate-to-vigorous physical activity (% time) for data collapsed across the week of wear-time in usual care, insulin-only BP, and dual-hormone BP. No differences were observed across the three treatment arms in any of these variables.

Conclusions and Future Directions

- There was no detectable impact of treatment modality (usual care vs. insulin-only BP vs. dual-hormone BP) on physical activity levels, at least in the short time frame of this study.
- Use of remote telemetric monitoring for hypoglycemia did not appear to facilitate regular PA (data not shown).
- In future studies, longer interventions need to be implemented with aims to improve overall compliance and feasibility.

Notes on using ActiGraph GT3X+

If using the ActiGraph GT3X+ activity monitor, we suggest the following:

1. During initialization, set collection mode between 1-10s epochs in order to use Crouter Adult (2010) equation for improved METs calculation (5)
2. Expect to retrieve ~1-week of activity data on a single usage (60s epochs), as long as heart rate mode with chest strap is not selected
3. For accuracy, ActiGraph should ideally be worn on the hip rather than wrist
4. ActiGraph reports active calories and not total daily energy expenditure (does not take into account Basal Metabolic Rate) and estimates of energy expenditure may be markedly exaggerated with wrist-wear
5. Make sure to select appropriate equations for analyses (i.e. default equations may not be suitable to specific study parameters such as analyses on youth, sleep, active calories, etc.)

References

1. Brazeau et al. Barriers to physical activity among patients with type 1 diabetes. *Diabetes Care*. 31: 2108-09, 2008.
2. Russell et al. Outpatient glycemic control with a bionic pancreas in type 1 diabetes. *N Engl J Med*. 371: 313-325, 2014.
3. El-Khatib et al. Home use of a bi-hormonal bionic pancreas versus insulin pump therapy in adults with type 1 diabetes: A multicentre randomised crossover trial. *Lancet*. 389:369-380, 2017.
4. Kamada et al. Comparison of physical activity using hip- and wrist-worn accelerometers. *Gait Posture*. 44: 23-28, 2016.
5. Crouter et al. A refined 2-regression model for the actigraph accelerometer. *Med Sci Sports Exerc*. 42: 1029-1037, 2010.