

Ad-Lib Abstract

The purpose of these trials was to improve the robustness of the Dose Safety Controller (DSC) in an ad lib 9 hr daytime living study.

Participants were asked to perform their usual daily routine as much as possible. They were allowed to eat & exercise as they wished.

Ad-Lib Living Protocol

Conducted 15 9-hour daytime ad lib living studies on five participants in the Benaroya Research Institute.

Participants performed usual daily routine including eating & exercise.

Participants had repeated studies.

No pre meal boluses, meal or exercise notifications were given.

Ad-Lib Demographics

Avg (SD), Age = 28.9 yr (5.4), A1c = 7.0 (0.3), Length of T1D = 9.0 yr (1.5), BMI 25.7 (2.3), 3 female, 2 male

Ad-Lib Results

At CRC Ad-lib & At home (9a to 5p)	At CRC	At Home	p-value
%time < 60 (mg/dL)	0.2%	1.7%	0.0529
%time < 70 (mg/dL)	0.6%	3.1%	0.0418
%time in 70-180 (mg/dL)	35.1%	45.5%	0.1330
%time in 70-250 (mg/dL)	72.6%	78.8%	0.1855
%time > 180 (mg/dL)	64.3%	51.4%	0.0894
%time > 250 (mg/dL)	26.9%	18.1%	0.1011
%time > 300 (mg/dL)	7.7%	3.6%	0.0702
Average BG (mg/dL)	207.2	184.4	0.0462

Exercise Abstract

This eighteen-hour study evaluated the acute and late effectiveness of our fully automated closed loop (FACL) DSC with adult patients during and post exercise followed overnight.

Exercise Protocol

Seven 15 hour studies were conducted using V2.1 of the FLC. Subjects were required to have HbA1c < 8.5%. 100% of the insulin used was commanded by the FACL controller. The DSC was initialized using total daily basal insulin and the physician-set personalization factor (PF), which was 5 for all but one trial. It operated autonomously from 5p until 8a; with no announcements for exercise or meals.

Exercise Demographics

Avg (SD), Age = 29.0 yr (6.4), BMI = 26.2 (2.0), 4 female, 3 male

Exercise Results (5p-8a)

Exercise V2.1 17:00 to 8:00	Global Avg	201EV1	201EV2	203EV1	204EV2	206EV3	208EV1	210EV2
Average BG	142.8	173.4	133.5	152.4	114.4	155.7	131.2	139.2
Absolute Min BG (mg/dL)	63.9	83.8	74.6	101.0	63.9	93.0	85.3	85.5
Absolute Max BG (mg/dL)	282.5	281.5	218.0	227.5	269.0	282.5	177.0	245.5
% Time < 60 (mg/dL)	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%
% Time < 70 (mg/dL)	1.0%	0.0%	0.0%	0.0%	6.7%	0.0%	0.0%	0.0%
% Time 70-180 (mg/dL)	79.5%	63.3%	86.7%	80.0%	76.7%	73.3%	100.0%	76.7%
% Time >180 (mg/dL)	19.5%	36.7%	13.3%	20.0%	16.7%	26.7%	0.0%	23.3%
% Time >250 (mg/dL)	5.2%	16.7%	0.0%	0.0%	6.7%	13.3%	0.0%	0.0%
% Time >300 (mg/dL)	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%

Combined Results

Combined DL & Exercise	Daily Living	Exercise	Combined
Length of trial (hrs)	9	15	24
%time < 60 (mg/dL)	0.2%	0.0%	0.1%
%time < 70 (mg/dL)	0.6%	1.0%	0.8%
%time in 70-180 (mg/dL)	35.1%	79.5%	62.9%
%time in 70-250 (mg/dL)	72.6%	84.7%	80.1%
%time > 180 (mg/dL)	64.3%	19.5%	36.3%
%time > 250 (mg/dL)	26.9%	5.2%	13.3%
%time > 300 (mg/dL)	7.7%	0.0%	2.9%
Average BG (mg/dL)	207.2	142.8	167.0
SD BG	49.6	32.6	39.0

Ad-Lib (AL) and Exercise (EX) data were combined as follows:

$$\frac{Data_{AL} * Hrs_{AL} + Data_{EX} * Hrs_{EX}}{Hrs_{AL} + Hrs_{EX}}$$

Ad-Lib Limitations

Limitations of our study:

- 1) Blood glucose levels at the onset varied from 100-271 mg/dL at onset.
- 2) Carbohydrate intake varied greatly from 33-182 grams (average 113 grams) per study session.
- 3) The exercise time varied from 0-84 minutes (average of 23.7 minutes).

Conclusion

A FACL artificial pancreas is feasible and may benefit groups having difficulty obtaining adequate diabetes control. Longer duration studies in a hotel or home setting are needed to better assess DSC algorithm efficacy.

For further information:
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