

## CASE REPORT

The effect of intentional underestimation of the food carbohydrate content and other diet-related negligence on glycaemic patterns in patient utilizing the loop-based do-it-yourself artificial pancreas systems

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# ABSTRACT

Artificial pancreas systems (APS) are supposed to minimize the workload of managing type I diabetes mellitus for patients, but even APS users are still supposed to count carbohydrates and announce meals to achieve the best control. Here, we present the effect of intentional underestimation of food carbohydrate content and other diet-related negligence on glycaemic patterns in patients utilizing a loop-based APS. Since the patient started using the "Loop", his glycaemic control has been satisfactory (glycated haemoglobin: 6.7% (50 mmol/mol) to 6.4% (46 mmol/mol). The problems with glycaemic control occurred when the patient went on holiday. During this period, the patient deliberately underestimated his carbohydrate meal content announced to the APS. He also used the "override" function (set to 70–80% of normal insulin requirements), which reduced the amount of insulin delivered. The patient tended to consume more alcohol and routinely consumed high glycaemic index products during this period of time. The food bolus was delivered either just before or even during meals. No loop system settings were modified. An intentional underestimation of food carbohydrate content led to the deterioration of glycaemic control in the user of the loop-based APS; however, one can speculate that with some dietary modifications (e.g. limiting carbohydrate intake) the patient could achieve better glycaemic patterns.

**KEY WORDS:** type 1 diabetes mellitus, do-it-yourself artificial pancreas systems, time in the range, carbohydrate meal.

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#### Introduction

Daily self-management of type I diabetes mellitus (TIDM) is a difficult challenge demanding precise planning and strict implementation of tasks for patients, which have a profoundly negative effect on their quality of life. Therefore, the major goal of diabetes technology is to reduce the burden of TIDM patients. Artificial pancreas systems (APS), also referred to as closed-loop systems are supposed to minimize the workload of managing TIDM for patients [1–3]. Currently the hybrid closed-loop devices that are commercially available are able to offer partially automatic insulin delivery (e.g. basal insulin, correction boluses); however, to achieve the best control, moderate patient intervention is required to manually adjust dosages, including carbohydrate counting and meal announcement [1-3]. This applies also to "doit-yourself artificial pancreas systems (DIY APS)", which connect existing insulin pumps and glucose monitoring system sensors and close the loop between these devices through automated insulin dosing controlled by an open-source algorithm. The 3 most popular DIY APSs include OpenAPS, AndroidAPS, and Loop [4].

#### **Case description**

Here, we present the effect of intentional underestimation of food carbohydrate content and other diet-related negligence on glycaemic patterns in a patient utilizing a do-it-yourself APS based on the "Loop" open-source project. Patient signed informed consent to use his data in this case report.

The clinical characteristics of the patient are as follows: male, 34 years old, duration of diabetes – 22 years, daily insulin dose – 47 U (daily basal insulin – 20.3 U). Late complications of diabetes: proliferative retinopathy treated by laser photocoagulation therapy, albuminuria (35–70 mg/24 h). Last available haemoglobin  $A_{lc}$  (Hb $A_{lc}$ ) level before DIY implementation – 7.7% (60.7 mmol/mol). The patient has been using "Loop" since September 2018.

The components of the loop-based APS utilized by the patient include the following:

- personal insulin pump: Medtronic 722 (Medtronic, Northridge, CA),
- continuous glucose monitoring system: Dexcom G6 (Dexcom Inc. San Diego, CA),
- phone: iPhone X,
- RileyLink, a device that enables wireless communication between the personal insulin

pump and the phone (https://loopkit.github. io/loopdocs/faqs/rileylink-faqs/).

The patient used the "automatic bolus" option, which, instead of increasing the basal dosage, gave 40% of the calculated demand in the form of a bolus. The patient utilized the Nightscout website (http://nightscout.pl/) to synchronize all the APS data together and make it available to health care providers.

Since the patient started using "Loop", his glycaemic control has been satisfactory (HbA<sub>1c</sub> levels from 6.7% [50 mmol/mol] in October 2018 to 6.4% [46 mmol/mol] in February 2020). The problems with glycaemic control occurred when the patient went on holiday (29 September -5 October 2020). During this period, the patient deliberately underestimated carbohydrate meal content announced to the APS. He also used the "override" function (set to 70-80% of normal insulin requirements), which reduced the amount of insulin delivered. That was attributed both to his fear of a hypoglycaemic episode due to increased physical activity and the patient's wish to have a "mental vacation" from precise carbohydrate counting.

In addition, the patient's typical routine was to have programmed alerts including food announcement and bolus delivery approximately 15 minutes before meal onset (the patient used Fiasp insulin), but during this holiday period the food bolus was delivered either just before or even during meals. The patient also tended to consume more alcohol and routinely consumed high glycaemic index products during this period (his breakfast, most likely a buffet, had a clear postprandial excursion). Because the participant might increase his physical activity load, there was a risk of late hypoglycaemia episodes at night, but this risk was potentially avoided. No loop system settings were modified.

Those changes in the patient's behaviour resulted in a rapid deterioration of glycaemic control – time in range (TIR): 62%; time below range (TBR): 0% (Figure 1 A). When the patient returned from his vacation, his glucose patterns improved and were comparable to baseline levels once he resumed his typical routine – TIR: 84%, TBR: 0% (Figure 1 B).

### Conclusions

An intentional underestimation of food carbohydrate content and other diet-related negligence led to the deterioration of glycaemic control in The effect of intentional underestimation of the food carbohydrate content and other diet-related negligence on glycaemic patterns in patient utilizing the loop-based do-it-yourself artificial pancreas systems



Figure 1. Changes in the patient's behaviour resulted in a rapid deterioration of glycaemic control

the user of the loop-based DIY APS; however, his TIR was close to goals indicated by the TIR consensus for patients with TIDM [5]. One could speculate that with some dietary modifications (e.g. limiting carbohydrate intake, avoiding high glycaemic index products) the patient could achieve somewhat better glycaemic patterns even without exact carbohydrate counting.

On the basis of this described case, we can conclude that for the loop-based DIY APS, reaching optimal glycaemic control requires accurate carbohydrate counting and pre-meal food announcement. Novel approaches to meal detection allowing the removing of meal announcements in the APS will be a key step to fully closing the loop in APSs [6–9].

Healthcare providers need to be aware of the advantages and disadvantages of the system and that the user must undertake responsibility for the risk of building and running the system [10].

### Acknowledgements

All procedures followed were in accordance with the ethical standards of the responsible committee on human experimentation (institutional and national) and/or with the Helsinki Declaration of 1964 and later versions. Informed consent or a substitute for it was obtained from all patients included in the study.

## **Conflict of interest**

The authors declare no conflict of interest.

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