

# Successful Initiation of Hybrid Closed-Loop System Using Virtual Pump Training Program in a Teenager With Type 1 Diabetes Previously Treated with Multiple Daily Injections

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## Abstract

Due to the coronavirus disease 2019 restrictions in providing diabetes services, we have developed an innovative pump training program, which consisted of technical session, pump training, one in-person practical session, and four consecutive online sessions (Skype Meet Now).

A 13-year-old female patient with a 4-year history of type 1 diabetes (T1D) on multiple daily injections (MDI) with glycated hemoglobin 8.9%; 74 mmol/mol) initiated Minimed 670G system using the program. Time in range (70–180 mg/dL) of 39% and sensor glucose (SG) of  $214 \pm 91$  mg/dL (MDI with continuous glucose monitoring) increased to 69% in the first 2 weeks and reached 86% and SG of  $140 \pm 40$  mg/dL in the first month of auto mode initiation, without severe hypoglycemia or hyperglycemia. Virtual pump training program can be an effective tool to initiate a hybrid closed-loop system and to improve glycemic control in people with T1D on MDI.

## Keywords

closed-loop systems, COVID-19, diabetes education, type 1 diabetes, virtual training

## Introduction

Training, education, and support are the most important factors<sup>1</sup> in achieving success with continuous subcutaneous insulin delivery (CSII) in people with type 1 diabetes (T1D), where CSII training is traditionally delivered in person by either individual or group sessions.

The ongoing coronavirus disease 2019 (COVID-19) pandemic has prompted many diabetes health providers to search for and implement alternative approaches to deliver diabetes services.

T1D is uniquely suited to a telemedicine approach, as many diabetes devices (CSII, continuous glucose monitoring [CGM], Bluetooth insulin pens, and glucometers) can be uploaded via the internet to a cloud-specific database. Different software applications exist which enable health providers to review the aggregated device data. Telemedicine as an innovative approach in T1D management appeared to have comparable efficacy on glycemic control with standard (in person) clinic visits.<sup>2</sup> Telemedicine can be also used safely and effectively for new-onset T1D training and education for both pediatric and adult patients and their families.<sup>3</sup>

Due to the COVID-19 restrictions in providing regular diabetes services at Sidra Medicine in Qatar, the traditional training and education, a 10-day initiation protocol<sup>4</sup> for hybrid closed-loop (HCL) system in patients previously treated with multiple daily injections (MDI) was postponed, as the service was not considered critical in the current situation. In an attempt to continue to support CSII initiation, the diabetes team developed an innovative “virtual pump training program,” based on the previous initiation protocol for the HCL system,<sup>4</sup> using video conferencing Skype “Meet Now” (Skype Communications S.a.r.l., Palo Alto, CA, USA).

HCL training, insulin start in manual mode, the transition to auto mode, and follow-up visits were performed online, using Skype.

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## Methods

A 13-year-old female patient with a 4-year history of T1D on MDI (insulin to carbohydrate ratio [ICR] 10 g, insulin sensitivity factor 60 mg/dL, and target glucose 120 mg/dL) with glycated hemoglobin 8.9% (74 mmol/mol) was commenced on the HCL system, Minimed 670G insulin pump (Medtronic, Northridge, CA, USA) using the virtual program. The pump introduction, prepump, and carbohydrate counting assessment were performed at a clinic visit, once successfully completed the patient was scheduled for regular pump training, which was subsequently postponed due to COVID-19. Virtual pump training program was then offered to the patient and her family following a positive technical assessment, which they accepted.

The program consisted of the following sessions (detailed program available as Supplemental material).

**The prerequisite technical session** (60 minutes) evaluates the patient's criteria for the virtual program, where a laptop, high-speed internet connection, email account, and skype account were set for the program. Basic computer skills (working with computer and internet) were also practically assessed. A Skype "Meet Now" session was initiated to test video and audio settings, an account on Carelink Personal software (Medtronic, Northridge, CA, USA) and uploader was set up. Precourse reading and theory requirements were explained.

**Warm-up session** (90 minutes) was performed using Skype. This session assessed the family's knowledge and understanding based on the precourse requirements which had been set. Time in range (TIR) parameters, the importance of accurate sensor calibration, and revision of basic operation modes of the HCL system were discussed in this session.

**Pump training** included one face to face practical session for pump collection and sensor insertion (90 minutes) and four consecutive online sessions (90-120 minutes per day) with the following content:

Day 1: pump menus, manual mode, basal rates, temp basal, bolus wizard, cannula insertion/reservoir, prime, connect/disconnect tubing, pump suspend and resume, operational modes of the pump (manual mode, auto mode, safe basal).

Day 2: auto mode feature, auto basal/safe basal, alarms/alerts, auto mode readiness and exits, troubleshooting and pump failure, temporary disconnection, and converting back to MDI.

Day 3: special situation management (hypoglycemia, hyperglycemia, sick day management, diabetic ketoacidosis, exit to manual mode, and temp basal), exercise and temp target (exercise types and effect on glycemia, strategies to reduce hypoglycemia in exercise), diet, and exercise.

Day 4: evaluation to initiate the HCL system, pump download, and sensor change.

Each session involved three sections: (1) evaluation of the pump training from the previous day, where educator assessed and reviewed specific topics and tasks with the patient in addition to confirmation that the patient and family had completed the previous days' homework (reading the user manual, watching videos, and/or recording videos); (2) education/pump training on specific topics (operational modes of the pump, manual mode, basal rates, bolus wizard use, infusion and reservoir change, auto mode feature, readiness, and special situation management; and (3) preparation/homework (practical skills and theoretical acquisition). Practical skills consisted of the cannula and sensor insertions, changing the insulin reservoir, and tubing. Parents and children were expected to demonstrate their competence in these skills by recording videos and sending them to us for assessment. Theoretical acquisition involved watching videos and reading training information which was relevant to the following days' pump school program.

Patient's pump knowledge and competency evaluation were assessed as satisfactory to initiate the HCL system.

## Results

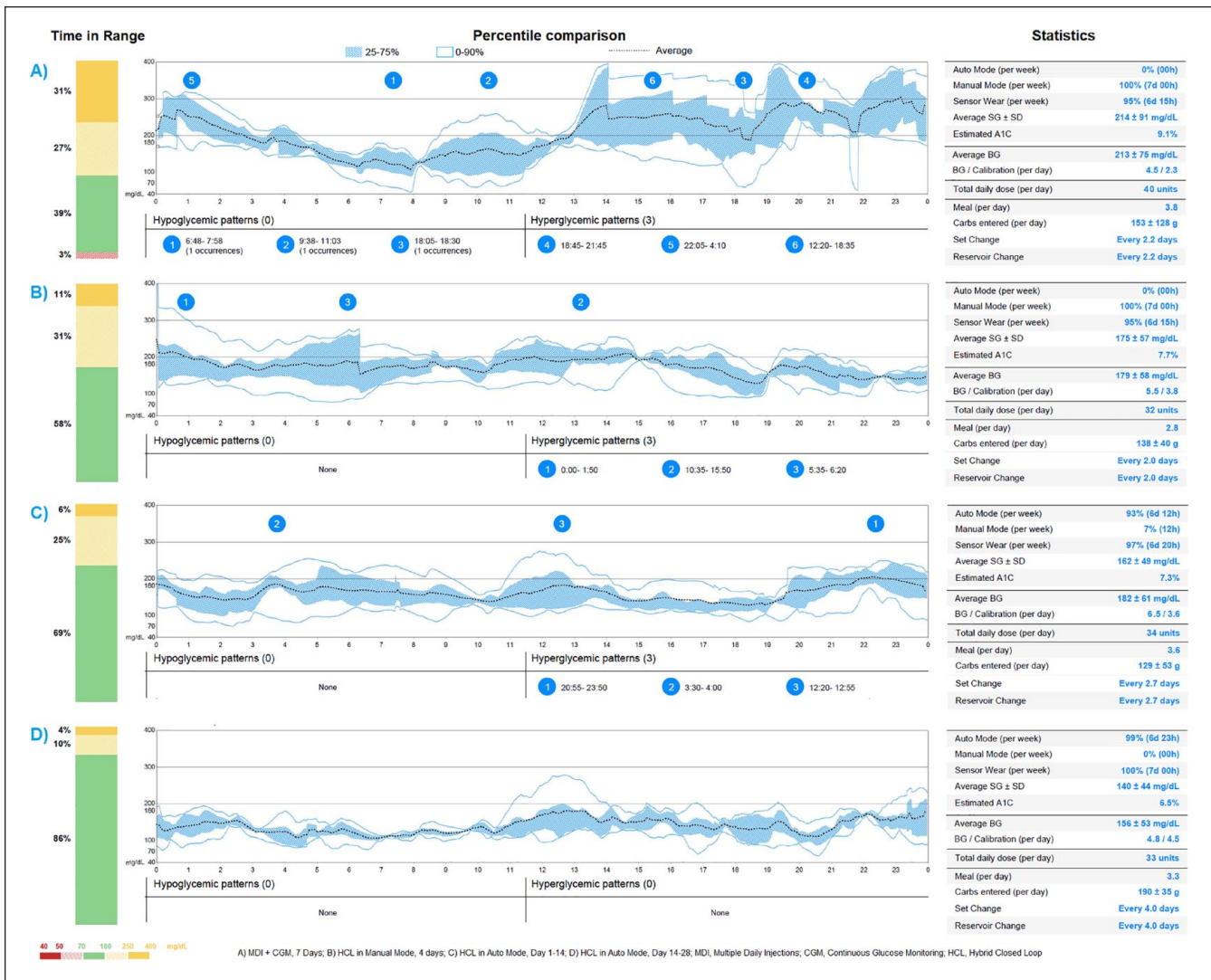
TIR (70-180 mg/dL) of 39% and sensor glucose (SG) average of  $214 \pm 91$  mg/dL (as shown in Figure 1) was noted during training sessions (MDI with CGM).

Initiation of the HCL system in manual mode was also performed online. This was the most challenging part of the program, where the patient started the insulin in the pump. HCL in manual mode was initiated with a reduction of total daily insulin by 10%, five basal rates, ICR of 10 g, a correction factor of 50 mg/dL, active insulin time of 4 hours, and glucose target range from 90 to 130 mg/dL.

Patient used the HCL in manual mode with suspend before low feature (60 mg/dL) for 4 days to allow the algorithm to establish personalized auto mode initiation parameters. TIR (70-180 mg/dL) increased to 58%, and SG average decreased to  $175 \pm 57$  mg/dL (as shown in Figure 1).

HCL system in auto mode was initiated after 4 days in manual mode (as shown in Figure 2). Our previous experience on the HCL system<sup>4</sup> shows that 4 days in manual mode are enough to initiate the auto mode feature (97% of patients enabled auto mode after 4 days). Follow-up visits were scheduled on the weekly basis using Skype Meet Now: the patient downloaded the pump into the Carelink Personal Software; physician and diabetes educator reviewed the data to evaluate patient engagement and make system changes if needed.

TIR (70-180 mg/dL) continued to increase to 69% in the first 2 weeks of auto mode initiation (as shown in Figure 1), where post-meals hyperglycemia was noted, and ICR was decreased to 8 g for more bolus insulin. TIR (70-180 mg/dL) improved above 70% after the first week, reaching 86% and SG average of  $140 \pm 40$  mg/dL in the first month of auto mode initiation (as shown in Figure 1).



**Figure 1.** Glycemic control in teenagers with T1D initiating HCL system on different treatment: MDI with CGM, HCL system in manual mode and auto mode. CGM, continuous glucose monitoring; HCL, hybrid closed-loop; MDI, multiple daily injections; T1D, type 1 diabetes.

Hypoglycemic patterns, noted during MDI with CGM were diminished using HCL in auto mode, which was also noted with hyperglycemic patterns (as shown in Figure 1).

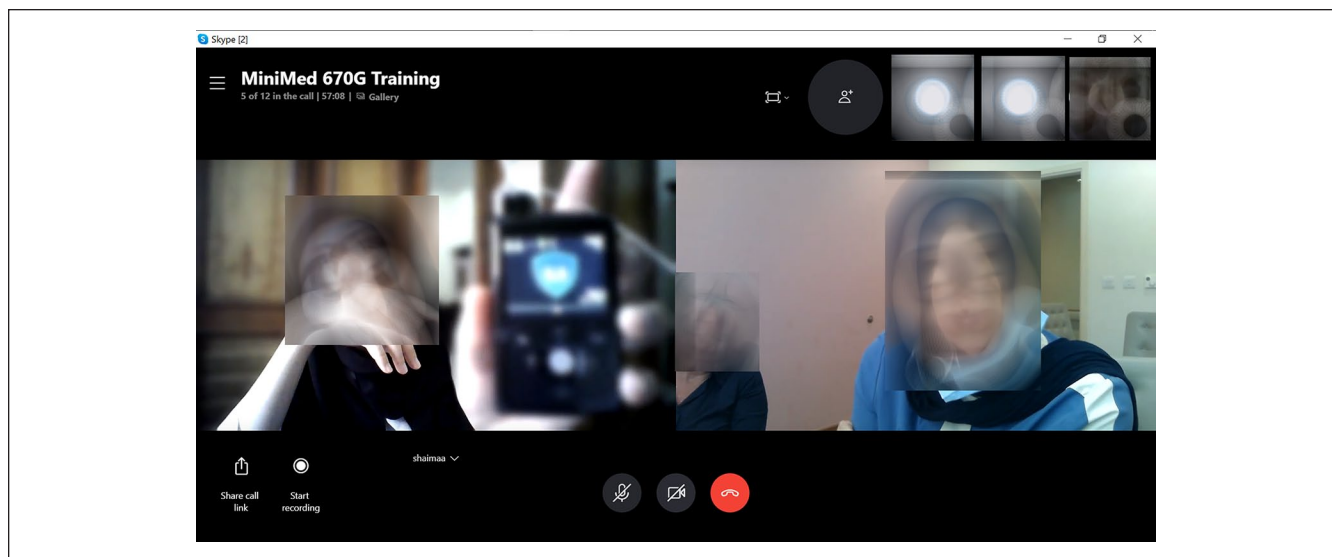
We did not find a significant difference in sensor wear, calibrations, set/reservoir change, meals, and carbohydrates per day during the study period. Auto mode exits were less than two events per week during the study.

### Discussion and Conclusion

Despite certain limitations, we have provided a general overview of the successful initiation of the HCL system using the virtual pump training program in a teenager with T1D, previously treated with MDI.

Pump training program<sup>1</sup> is an intensive two-part training: diabetes self-management (carbohydrate counting, infusion

site management, hypoglycemia, and hyperglycemia prevention and management) and technical training of the insulin pump (navigating pump menus, button pressing, infusion set and reservoir change, bolusing for food, and correction). The technical training can be performed using different solutions such as online resources, applications, phone call support, in-person training, and 24/7 technical support. Many diabetes services use medical device (insulin pump) companies to support technical training, which is required during pump initiation; this was not the case in our program. Technical training was based on the official Medtronic user guide manual and available videos on the Minimed 670G pump (detailed program available as Supplemental material). Our pump training program combines both diabetes self-management and technical skills training, which makes the program more convenient for people with T1D. Our study showed



**Figure 2.** Virtual pump training program via Skype Meet Now. Patient enabled auto mode on hybrid closed-loop system, under online supervision by a diabetes educator.

that online pump training can be successfully used in CSII initiation in people with T1D on MDI, which confirms similar findings that remote communication technology may be an effective tool to provide technical training to adults who are familiar with insulin pump therapy.<sup>5</sup>

Our case presented improved glycemic control over the one-month use of HCL in auto mode without severe hypoglycemia or diabetic ketoacidosis, which confirms that a virtual pump training program can be used for HCL initiation. TIR, time below range, and time above range over time periods on MDI with CGM (7 days), HCL in manual mode (4 days), HCL in auto mode (14 and 28 days) followed the trends of improvements compared with the same time period in a 10-day initiation protocol,<sup>4</sup> where the training was performed in person. TIR (70-180 mg/dL) of 88% was significantly higher compared with 72% in the previous study<sup>4</sup> of HCL in auto mode after one-month use.

Modifying ICR by increasing insulin for meal bolus by almost 20% during the first week of auto mode was also confirmed in our study. HCL system characteristics (auto mode usage, sensor wear, calibrations, set and reservoir change, and auto mode exits) were similar to previously published results.<sup>4</sup>

Implementing the virtual pump program was a challenge for both patients and health providers. Initially, the patient and her family were concerned with how the training could be performed remotely without clinic visits and how the pump would be initiated from home. In addition, the diabetes educators had reservations in regard to deliver effective technical skills and to assess patients' competencies remotely. By the end of the study, both patients and health providers reported high satisfaction with the program, which gave us a positive motivation to continue the program as a regular clinical service.

Limitations in our study include a short follow-up period, evaluation of TIR and SG average as parameters for glycaemic control, and single patient experience. This program is already offered to other patients as a regular service at Sidra Medicine in Qatar. However, the objective of this study was to present the innovative approach in pump training using telemedicine, which we believe can motivate other health providers to consider implementing such a program in their diabetes services.

Virtual pump training program in people with T1D on MDI can be an effective tool to initiate an HCL system and to improve glycemic control in a safe manner without severe hypoglycemia and hyperglycemia. Health care providers will need to develop additional skills and adopt current educational recommendations on virtual teaching and assessment practices to optimize training success and patient health outcomes. Further clinical trials should be performed to confirm our findings.

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### Author Contributions

GP researched the data and wrote the manuscript. FA, JC, and K.H contributed to the discussion and reviewed and edited the manuscript. JC and DA contributed to the patients' education and follow-up. GP is the guarantor of this work and, as such, had full access to all the data in the study and takes responsibility for the integrity of the data and the accuracy of the data analysis.

### Declaration of Conflicting Interests

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### Ethical Approval

All procedures performed in studies involving human participants were in accordance with the ethical standards of the institutional and/or national research committee and with the 1964 Helsinki declaration and its later amendments or comparable ethical standards.

### Informed Consent

Informed consent was obtained from the patient.

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### Supplemental Material

Supplemental material for this article is available online.

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