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CASE REPORT

Virtual training on advanced hybrid closed-loop system MiniMed 780G in a teenager with type 1 diabetes previously treated with multiple daily injections: A case report

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1 | INTRODUCTION

A 12-year-old girl with type 1 diabetes on multiple daily injections commenced advanced hybrid closed loop (AHCL), Minimed 780G insulin pump using a virtual pump training. Training, initiation in Manual Mode of AHCL, initiation in Auto Mode of AHCL, and follow-up visits were performed using Zoom video conferencing platform. HbA1c decreased from 7.4% to 5.8%, 3 months after advanced AHCL initiation.

The current COVID-19 pandemic has rapidly moved the traditional (face to face) care delivery to new forms of consultations taking place through telehealth. The diabetes community has learned the valuable lessons about optimally supporting the most vulnerable people with diabetes, where remote technologies can ultimately improve diabetes care and outcomes for everyone.¹

Type 1 diabetes (T1D) management takes a unique place in telehealth, where personal diabetes devices provide data

Abstract

Virtual pump training program for novel devices in people with type 1 diabetes on multiple daily injections can be an effective tool to initiate an advanced HCL system (MiniMed 780G) and to improve glycemic control in a safe manner without severe hypoglycemia and hyperglycemia.

KEYWORDS

advanced hybrid closed-loop system, multiple daily injections, type 1 diabetes, virtual training

sharing, such as Bluetooth-enabled glucometers, continuous glucose monitoring (CGM), insulin pumps, and smart insulin pens. The patient's personal glucose and insulin data can be automatically uploaded via the Internet to a cloud-specific databases, and health providers can use different applications to review the aggregated device data.

The use of telehealth in diabetes management has substantially increased during the COVID-19 pandemic, and several studies on remote initiation of insulin pumps in people with T1D²⁻⁴ have shown that training and education for specific insulin pump, such as hybrid closed-loop (HCL) systems, can be virtually initiated using specific protocols.

Advanced HCL System, Minimed 780G (Medtronic) is a novel device,⁵ commercially available in Europe (CE Mark) from October 2020 and approved for children above 7 years, adolescents, and adults with T1D. The device uses an algorithm that automatically adjusts the basal insulin delivery in addition with auto-bolus correction for high glucose levels, if

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needed, every 5 min. It is a Bluetooth-enabled insulin pump with automatic data upload, which offers health providers a wider opportunity for remote follow-ups.

In an attempt to continue initiation of novel devices during COVID-19 pandemic, the previous experience for remote initiation on HCL systems² was used to develop "virtual training program for advanced HCL' using Zoom video conferencing platform (Zoom). Furthermore, this was the first advanced HCL initiated generally at our Diabetes center and Qatar, in front of regular face to face pump trainings that are traditionally offered at Sidra Medicine.

Advanced HCL training, initiation of Advanced HCL in manual mode, transition to SmartGuard Auto Mode, and follow-up visits were performed online, using Zoom platform.

2 CASE PRESENTATION

A 12-year-old girl with 5-year history of T1D on multiple daily injections (MDI) with HbA1c 7.4% (57.4 mmol/mol) and basal insulin 18 units, insulin to carb ratio (ICR) 12 g, insulin sensitivity factor (ISF) 3.2 mmol/L, and target glucose 6.1 mmol/L was commenced on the Advanced HCL system, Minimed 780G (Medtronic) using the virtual program. The expectations from the system and user's responsibilities were discussed at the regular clinic visits. Due to COVID-19 pandemic, two pump training methods were offered to the patient: face to face and virtual program, which are similar in terms of content, number, and duration of sessions. Patient and her family have chosen the virtual pump training program as more convenient method for them.

The virtual program consisted of the following sessions:

The pre-pump and technical session (60 min) evaluate the patient's criteria for the virtual program, where laptop, highspeed Internet connection, e-mail account, mobile phones compatibility for both Minimed mobile App and CareLink Mobile App, and CareLink Personal account (Medtronic) were set for the training. Basic computer skills (working with computer and Internet) were also practically assessed. Time in range (TIR) parameters, importance of accurate sensor calibration, and revision of basic operation modes of the Advanced HCL system were also discussed.

Pump training included one face-to-face practical session for pump collection and sensor insertion (90 mins) and three consecutive online sessions (90-120 mins per day) with following content: Day 1-Manual Mode, bolus wizard use, basal rates, and Carelink mobile apps; Day 2-SmardGuard Auto Mode and readiness, infusion set and reservoir change; Day 3—hypoglycemia, hyperglycemia, exercise, travel, sick day management, and evaluation to initiate Advanced HCL system.

Each session involved three sections: 1) evaluation of the pump training from previous day, (assessment and revision on specific topics and tasks, confirmation that the patient and family had completed the previous days' homework); 2) pump training session on specific topics (basal rates, bolus wizard use, infusion and reservoir change, etc.); and 3) homework (tasks to perform at home), where patient needed to read specific content for the following training day and to record videos on current session (sensor calibration, bolus for food and correction, infusion set and reservoir change, sensor insertion, both on sample [teddy bear]). Patient's pump knowledge and competency evaluation were assessed as satisfactory to initiate advanced HCL system at the end of the 3rd online session.

Initiation of advanced 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. Advanced HCL in Manual Mode was initiated with reduction of total daily insulin by 10%, four basal rates, ICR of 12 g, ISF of 2.5 mmol/L, active insulin time (AIT) of 3 h, and glucose target range from 5.6 to 6.7 mmol/L.

Patient used the advanced HCL in Manual Mode with suspend before low feature (3.5 mmol/L) for 4 days to allow the algorithm to establish personalized SmardGuard Auto Mode initiation parameters. TIR (70-180 mg/dl) of 57% and sensor glucose (SG) average of 9.1 ± 3.5 mmol/L (as shown in Figure 1) were noted during Manual Mode initiation.

Advanced HCL system in Auto Mode was initiated after 4 days in Manual Mode. Health providers evaluated Carelink reports online adjusted the settings as follows: ICR was decreased from 12 g to10 g, AIT was set on 3 h, and glucose target was set on 5.5 mmol/L for auto-corrections. Follow-up visits were scheduled on the bi-weekly basis in the first month and then monthly, using the Zoom video conferencing platform. Patient's pump and sensor data were synchronized automatically to Carelink Personal Account using Minimed Mobile App via Internet, and physician and diabetes educator reviewed the data to evaluate patient engagement and made system changes remotely, if needed.

Time in range (70–180 mg/dl) increases to 79% in the first 2 weeks of SmartGuard Auto Mode initiation (as shown in Figure 1), where post-meal hyperglycemia was noted (both morning and afternoon) and ICR was decreased to 8 g in the morning and 9 g in the afternoon for more bolus insulin. TIR (70-180 mg/dl) of 80%, GMI of 6.6%, and SG average of 7.5 ± 2.6 mmol/L were noted in the first month of SmardGuard Auto Mode initiation (as shown in Figure 1). TIR (70-180 mg/dl) over 80% and GMI below 7.0% without compromising hypoglycemia were maintained over the following 2 months, decreasing the HbA1c from 7.4% (57.4 mmol/mol) at baseline to 5.8% (39.9 mmol/mol), after 3 months of advanced HCL use.

Time below range (<3.9 mmol/L) of 5% noted during Manual Mode was decreased to 2% using advanced HCL in Auto Mode, with similar decrease of time above range



FIGURE 1 Glycemic control in teenager with T1D initiating MiniMed 780G AHCL in manual mode and smardguard auto mode. A, AHCL in Manual Mode, 4 Days; B, AHCL in SG Auto Mode, Day 1-14 C, AHCL in SG Auto Mode, Day 14-30, D, AHCL in SG Auto Mode, Day 31-90. CGM, Continuous Glucose Monitoring; AHCL, Advanced Hybrid Closed Loop; SG SmartGuard

(>10.0 mmol/L) from 41% to 16%, respectively (as shown in Figure 1).

The number and duration of virtual training sessions, and the initiation and follow-up visits did not differ from traditional (face to face) program, which is performed at our center. The virtual program has additional session for pre-pump and technical evaluation on patient's computer skills, high-speed Internet connection, and laptop setup for video conferencing.

We did not find significant difference in sensor wear, calibrations, set/reservoir change, meals and carbohydrates per day during the study period. SmardGuard Auto Mode exits were less than one event per week during the study. The main reasons for exiting SmardGuard Auto Mode were patientrelated issues, such as missed calibration and loss of sensor glucose due to sensor expiration.

DISCUSSION 3

Despite certain limitations, we have provided a general overview on successful initiation of AHCL System using virtual pump training program in a teenager with T1D, previously treated with MDI, as a first case initiating advanced HCL system in Qatar.

The pump training program that is used at our center combines both 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, bolus for food and correction), which makes the program more convenient for people with T1D. Our study showed virtual pump training for novel

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devices can be successfully used in people with T1D on MDI, which confirms similar findings that remote communication technology may be an effective tool to provide training to children, adolescents, and adults with T1D.²⁻⁴

Our case presented improved glycemic control over 3month use of advanced HCL in SmardGuard Auto Mode without severe hypoglycemia or severe hyperglycemia which confirms that virtual pump training program can be used for novel devices, such as MiniMed 780G, which was approved recently. Time in range, time below range, and time above range over time periods on advanced HCL in Manual Mode (4 Days) and advanced HCL in SmardGuard Auto Mode (2 weeks, one and 3 months) followed the trends of improvements compared to the same period of similar pump education programs either face to face ⁵ or virtual training ² for HCL systems. TIR (70–180 mg/dl) of 82% was significantly higher compared to 74% of HCL use in Auto Mode after 3month use.⁵

As there is a limited evidence in implementing advanced HCL system in clinical settings, our data show that modifying ICR by increasing insulin for meal bolus by almost 30% during the first 2 weeks of SmardGuard Auto Mode is crucial for achieving better glycemic control, compared to 20% in our previous experience on HCL systems.^{3,6} Modifying the AIT does not play a role in improving the glycemic control in HCL systems ⁶ but decreasing the AIT by almost 40% in the first month of SmardGuard AutoMode of advanced HCL system allowed the algorithm to make automatic correction of high glucose levels, if needed, which substantially improved the glycemic control. Advanced HCL system characteristics (Auto Mode usage, sensor wear, calibrations, and set and reservoir change) were similar to our previous experience on HCL.⁶ SmardGuard Auto Mode exits less than one event per week during our study were similar to recently published data on MiniMed 780G in adolescents and adults using a traditional (face to face) training program.⁷

One of the limitations in our study is a single patient experience. This virtual program for advanced HCL system is already offered to other patients as a regular service at Sidra Medicine in Qatar and ongoing study will be presented once the data are collected and analyzed. However, the objective of this study was to present that the virtual training for novel devices such MiniMed 780G advanced HCL system can be doable, even this was the first case of advanced HCL initiation at our center and Qatar. We believe that we can motivate other health providers to consider implementing such program in their diabetes services.

4 | CONCLUSION

Virtual pump training program for novel devices in people with T1D on MDI can be an effective tool to initiate an advanced HCL system and to improve glycemic control in a safe manner without severe hypoglycemia and hyperglycemia. Previous experience on remote teaching seems to play a role for smoother initiation of novel devices, which makes virtual training as an appropriate method for advanced diabetes management technology during the COVID-19 pandemic. Further clinical trials should be performed to confirm our findings.

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CONFLICTS OF INTEREST

No potential conflicts of interest relevant to this article were reported.

AUTHOR CONTRIBUTIONS

G.P. designed the study. G.P., J.C., and D.A. collected the data. G.P. and J.C. researched the data. G.P., F.A., J.C., and K.H. contributed to writing the manuscript. G.P. 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.

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.

DATA AVAILABILITY STATEMENT

The data that support the findings of this study are available from the corresponding author upon reasonable request.

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