Control-IQ Technology in the Real World: The First 30 Days

Lars Mueller PhD,* Alexandra Constantin PhD,† Harsimran Singh PhD,† Steph Habif EdD MS†

Introduction

Recent data from the type 1 diabetes (T1D) exchange suggests that there has been no significant improvement in glycemic outcomes in individuals with T1D in the last decade. This indicates the need for improved systems and technologies to support diabetes management efforts.

The t:slim X2™ insulin pump with Control-IQ™ technology (Tandem Diabetes Care) is an advanced hybrid closed-loop system designed to help improve time in range‡ (TIR) (70-180 mg/dL) using continuous glucose monitoring (CGM) values to predict glucose levels 30 minutes ahead and adjust insulin delivery accordingly. The International Diabetes Closed-Loop trial confirmed the efficacy and safety of Control-IQ technology as compared with a sensor-augmented pump.

The t:slim X2 pump with Control-IQ technology was cleared by the Food and Drug Administration in December 2019.

Aim

To examine real-world glycemic outcomes in a sample of early adopters of Control-IQ technology.

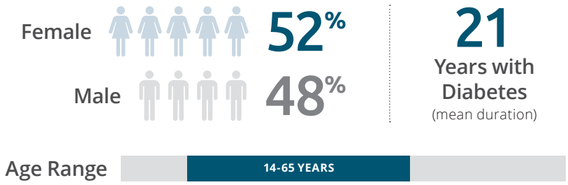
Method

This retrospective study included individuals with type 1 and type 2 diabetes (T2D) who had recently started using Control-IQ technology and had uploaded at least 30 days of pre- and post-Control-IQ software usage data to the t:connect® web application from Tandem Diabetes Care as of March 11, 2020. Only individuals who had ≥75% CGM data were included in the analysis.

Outcomes evaluated included total daily insulin and sensor glucose values during open and closed-loop use of Control-IQ technology. Changes in glycemic outcomes were analyzed using the Wilcoxon signed-rank test.

Percent time in closed-loop automation was calculated as the percent of the total basal rates delivered by the pump that were decided by the Control-IQ algorithm. If CGM was unavailable for 20 or more minutes, the system switched from algorithm-commanded basal rates to using a user's personal profile rate.

FIGURE 1: Demographics. Study participants included people with TID and T2D.



Results

The sample included 1,659 participants, of which 52% were female and 90% had T1D. The mean age of patients was 43 years, and mean diabetes duration was 21 years (Figure 1).

During the 30-day period of Control-IQ technology use, participants showed a 96% median time in closed-loop automation (IQR=93%-98%). Mean sensor glucose decreased from 161 mg/dL to 148 mg/dL while the median total daily insulin increased from 48u to 49u.

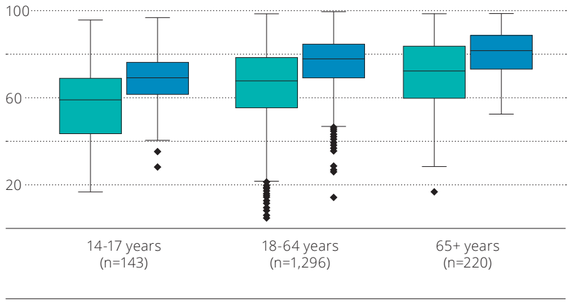
Overall, after 30 days of using Control-IQ technology, participants showed a 10% increase in median sensor TIR (from 68% to 78%; p<0.001) (IQR=69%-85%) (Table 1, Figure 2). Improvements in sensor TIR were consistent across age groups (Figure 2). Sensor time >180mg/dL showed a 9.5% decrease after 30 days of using Control-IQ technology (30% to 21%; p<0.001) (IQR=13%-30%) and a 0.1% decrease of sensor time <70 mg/dL to 1.1% from 1.2% (IQR=0.5%-2.2%).

TABLE 1: Participant Glycemic Outcomes. Pre- and Post-Control-IQ technology use.

Outcomes	Pre-Control-IQ	Post-Control-IQ
Mean Glucose (mg/dL)§	161.4 (± 54.9)	148.2 (±47.3)
Glucose Management Indicator§	7.2 (±0.7)	6.9 (±0.5)
Sensor Time in Range (%)§	68.0 (55.5-78.7)	77.8 (69.3-84.8)
Sensor Time <70 mg/dL (%)§	1.2 (0.5-2.6)	1.1 (0.5-2.2)
Sensor Time >180 mg/dL (%)§	30.1 (18.6-43.3)	20.6 (13.2-29.4)
Total Daily Insulin§	47.6 (35.0-67.0)	48.7 (35.4-68.3)
% Closed-Loop Automation	N/A	96.0 (92.9-97.5)

§ p<0.001

FIGURE 2: Sensor Time in Range. Percentage of time participants (by age group) spent in range pre-Control-IQ (■) and post-Control-IQ (■) technology use.



Conclusions

These real-world data from early adopters of Control-IQ technology demonstrate significantly improved sensor TIR and other glycemic outcomes after 30 days of using this technology without increasing hypoglycemia (sensor time <70 mg/dL).

Improvements in sensor TIR based on reduced time in hypoglycemia and hyperglycemia, if maintained long-term, can help reduce the risk of diabetes-related complications.

Longitudinal studies involving the use of Control-IQ technology are encouraged to evaluate clinical and psychosocial outcomes related to the use of this system in diverse groups of people with diabetes.

KEY MESSAGE

Data from early adopters of Control-IQ technology demonstrate **significantly improved glycemic outcomes including sensor time in range after 30 days.**

* UC San Diego Design Lab Center for Health † Tandem Diabetes Care ‡ As measured by CGM

References: 1. Foster NC, et al. State of Type 1 Diabetes Management and Outcomes from the T1D Exchange in 2016–2018. *Diab Tech & Therap.* 2019; 21(2). **2.** Brown SA, et al. Six-month randomized, multicenter trial of closed-loop control in type 1 diabetes. *N Eng J Med.* 2019;381(18):1701-1717. **3.** Brown SA, et al. Clinical acceptance of the artificial pancreas: Glycemia outcomes from a 6-month multicenter RCT. 2019 ADA 79th Scientific Sessions, San Francisco, CA. **4.** Beck RW, et al. Validation of time in range as an outcome measure for diabetes clinical trials. *Diabetes Care.* 2018; 42(3): 400-405.