Significant Reduction in Time Below Range (Hypoglycemia) in People with Type 1 Diabetes Using an Advanced Hybrid Closed-Loop System
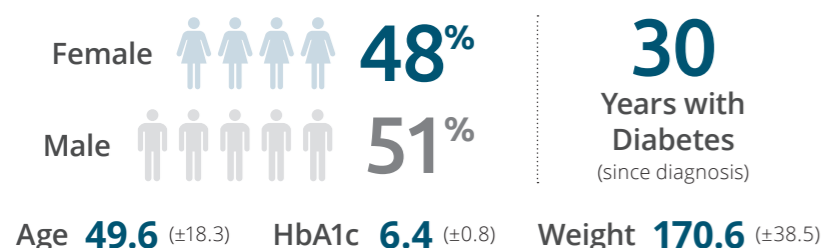
Lars Mueller PhD,* Harsimran Singh PhD,† Molly McElwee Malloy RN CDCES,† Steph Habif EdD MS†

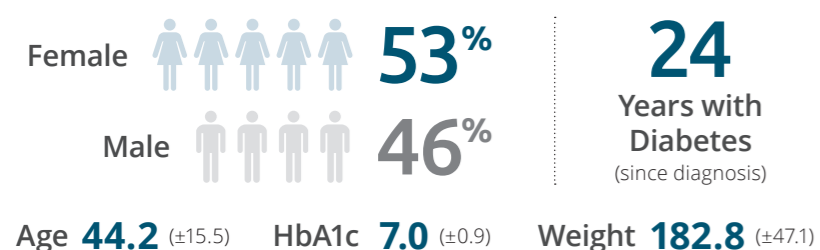**TANDEM** DIABETES CARE™

Introduction

Hypoglycemia is the most frequent complication of insulin therapy. Associations between severe hypoglycemia and mortality are well supported in the literature. Experience of hypoglycemic episodes and fear of hypoglycemia can be significant barriers to optimizing glycemic control in people with type 1 diabetes (T1D).

Internationally recognized consensus guidelines for safe glucose control recommend increasing time in range‡ (TIR) (70-180 mg/dL) while reducing time below range (TBR) for people with diabetes. While individualized blood glucose targets are recommended for patients, in general, continuous glucose monitoring (CGM)-based TBR guidelines suggest <4% time/day with sensor reading <70 mg/dL (Level 1) and <1% time/day with sensor reading <54 mg/dL (Level 2).

Advanced hybrid closed-loop systems like Control-IQ™ technology on the t:slim X2™ insulin pump from Tandem Diabetes Care can assist people with diabetes to better manage their TBR targets while optimizing glycemic control.

Methods

This study was part of a larger project evaluating real-world outcomes in early adopters of Control-IQ technology. We examined sensor TBR metrics for people with T1D, 30 days prior to starting Control-IQ technology (T1) and after 7 weeks of using Control-IQ technology (T2). Details in this presentation specifically focus on glycemic outcomes of participants who were not meeting the TBR recommendations at T1.

Glycemic data was captured from the t:connect™ web application. Wilcoxon-signed rank tests were performed to analyze change in median (IQR) TBR and TIR from T1 to T2.

Results

Of all participants at T1 (N = 1,127), 232 missed the TBR targets (Group 1) (Figure 1). Group 1 had higher TIR at T1 (median = 76.9 [IQR 69.4-83.9]) compared to those who met the TBR targets (Group 2) (median = 66.9 [IQR 53.7-77.9]).
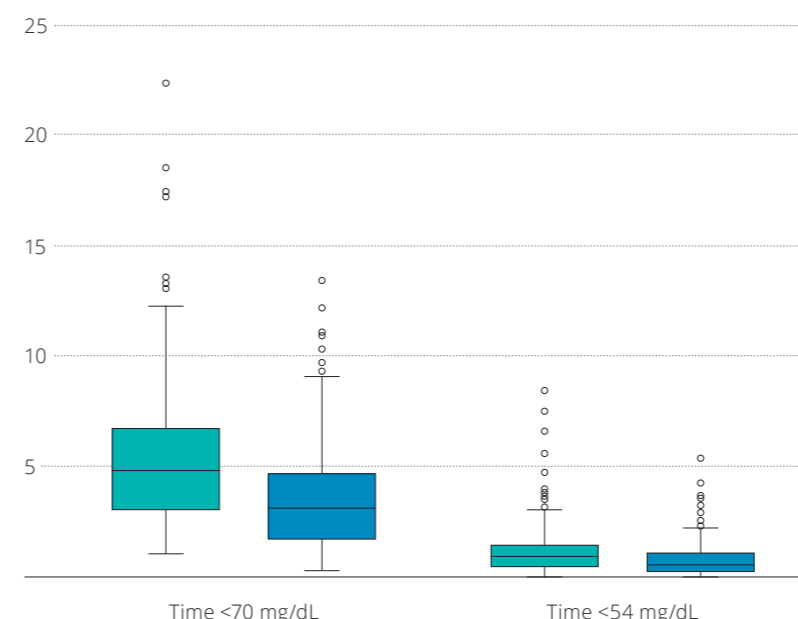
Using Control-IQ technology, Group 1 participants demonstrated significant reduction in TBR at T2 for both Level 1 and Level 2 hypoglycemia (Table 1, Figure 3) while showing significant improvement in TIR (Table 1). Overall, Group 1 participants spent 24.6 minutes less/day in Level 1 hypoglycemia and 4.6 minutes less/day in Level 2 hypoglycemia at T2 (Table 1).

Conclusions

The t:slim X2 pump with Control-IQ Technology demonstrated clinically relevant reduction in hypoglycemia (TBR) with improved TIR in people with T1D within a few weeks. We encourage future studies evaluating the long-term economic impact of safely reducing TBR while improving TIR in people with T1D.

FIGURE 1: Group 1 Characteristics. 232 participants who missed TBR targets at T1.

Female **48**%
Male **51**%
30 Years with Diabetes (since diagnosis)
Age **49.6** (±18.3)   HbA1c **6.4** (±0.8)   Weight **170.6** (±38.5)

FIGURE 2: Group 2 Characteristics. 895 participants who met TBR targets at T1.

Female **53**%
Male **46**%
24 Years with Diabetes (since diagnosis)
Age **44.2** (±15.5)   HbA1c **7.0** (±0.9)   Weight **182.8** (±47.1)

TABLE 1: Glycemic Improvements for Group 1. Glycemic improvement between T1 and T2 for participants who missed TBR targets at T1.

Measured Data	T1	T2	Effect
Days of Data	28.1 (±1.5)	32.0 (±3.5)	––
Time <70 mg/dL (median)	4.8 (2.9-6.7)	3.0 (1.6-4.6)	-24.6 minutes/day
Time <54 mg/dL (median)	0.9 (0.40-1.43)	0.5 (0.21-1.01)	-4.6 minutes/day
Time 70-180 mg/dL (median)	77.0 (69.4-83.9)	83.7 (77.2-88.7)	97.8 minutes/day

p<0.001

FIGURE 3: Percentage of Time Below Range for Group 1. Reduction in TBR between T1 ( ) and T2 ( ) for participants who missed TBR targets at T1.

KEY MESSAGE

The t:slim X2 pump with Control-IQ Technology demonstrated clinically relevant reduction in hypoglycemia with improved time in range.‡

* Design Lab, University of California San Diego. † Tandem Diabetes Care. ‡ As measured by CGM. **References: 1.** de Galan BE, et al. Reducing the burden of hypoglycemia in people with diabetes through increased understanding: design of the Hypoglycaemia REdefining SOLutions for better liVEs (Hypo-RESOLVE) project. *Diabet. Med.* 2020;37(6):1066-1073. **2.** Cryer PE. Severe Hypoglycemia Predicts Mortality in Diabetes. *Diabetes Care.* 2012;35(9):1814-1816. **3.** Gagnum V, et al. Causes of death in childhood-onset Type 1 diabetes: long-term follow-up. *Diabet Med.* 2017;34(1):56–63. **4.** Cryer PE. Hypoglycemia: the limiting factor in the glycaemic management of Type I and Type II Diabetes. *Diabetologia.* 2002;45:937–948. **5.** Speight J, et al. Cognitive, behavioral, and psychological barriers to the prevention of severe hypoglycemia: A qualitative study of adults with type 1 diabetes. *SAGE Open Med.* 2014;2:2050312114527443. **6.** Battelino T, Danne T, Bergenstal RM, et al. Clinical targets for continuous glucose monitoring data interpretation: Recommendations from the international consensus on time in range. *Diabetes Care.* 2019;42(8):1593-1603.