dexcom research spotlight

Real-World Use of Control-IQ Technology is Associated with a Lower Rate of Severe Hypoglycemia and Diabetic Ketoacidosis Than Historical Data: Results of the Control-IQ Observational (CLIO) Prospective Study[1]

Background

Individuals on intensive insulin therapy (IIT) face an elevated risk of experiencing **Severe Hypoglycemia (SH)** and **Diabetic Ketoacidosis (DKA).** It is important to minimize the occurrence of these **adverse events (AE)**, when possible. Automated Insulin Delivery (AID) systems may help reduce some of these events.

Purpose of Study

To assess the safety and effectiveness of the Tandem t:slim X2 insulin pump with Control-IQ technology in the real-world outpatient setting over 12 months of use.

Participant Demographics (n=3157)

Single-arm, prospective, fully virtual, longitudinal study

T1D

≥ 6 y.o.

Control IQ & Dexcom G6 for 12 months

Virtual check-in and data uploads

Study Outcomes Measured

✓ The primary outcomes measured were incidence rates of:

- SH and DKA
- Safety of the automatic population of CGM readings into the bolus calculator when Control-IQ technology was in use.

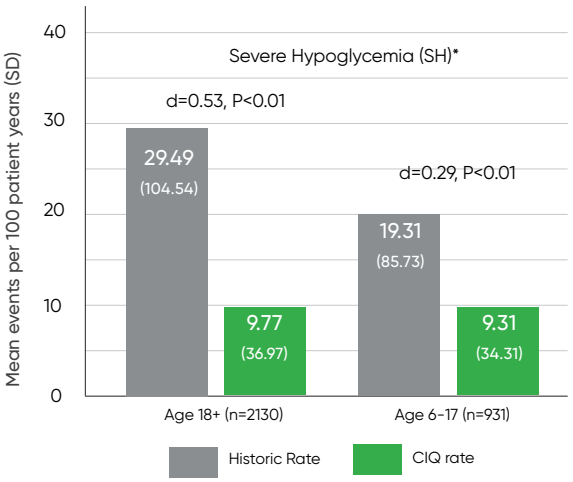
✓ Glycemic outcomes as a measure of efficacy of the system.

✓ Patient-reported satisfaction with and trust in the system, diabetes impact, and sleep quality of Control-IQ with Dexcom CGM technology users.

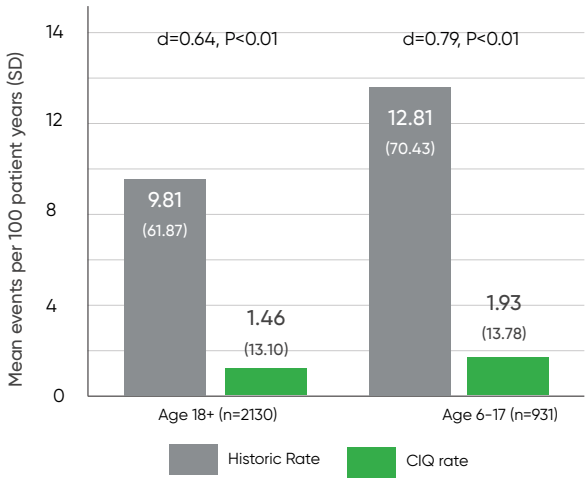
1. Graham R, et al. Diabetes Technol Ther. 2024 Jan;26(1):24-32. doi: 10.1089/dia.2023.0341.

Main Outcomes

Severe Hypoglycemia (SH)*



Diabetic Ketoacidosis (DKA)*



SH and **DKA** rates were lower for users of **t:slim X2 with Control-IQ with Dexcom CGM** compared to historical data§ for both adults and children.

Average time in range was **>70%** for adults and **>60%** for children, both groups acheiveing international consensus guidelines[1]

42% reported a decrease of **diabetes impact** on quality of life†

25% **increase in device satisfaction**‡ in both participants transitioning to Control-IQ from a different pump system and for participants transitioning from MDI therapy

Key Takeaways for t:slim X2 with Control IQ and Dexcom CGM

- **Lower observed rates of AE's** occurred independent of baseline A1C or prior insulin delivery method[2]
- Control-IQ with Dexcom CGM technology is associated with a **lower rate of severe hypoglycemia** (compared to historical data)[2]
- The study also indicates a **lower rate of diabetic ketoacidosis** in individuals using Control-IQ with Dexcom CGM technology compared to historical data[2]
- **Reduction in diabetes burden** was consistently reported[2]

*Mean (SD) AE rates per 100 patient years for study participants as self-reported on monthly surveys through 12 months of Control-IQ technology use, compared to historical rates
AE = Adverse events
† Diabetes Impact median score was 4.75 (3.25–6.0) at baseline and 2.75 (2.0–4.0) at 12 months (P < 0.01).
‡ DIDS Device Satisfaction median score increased from 7.29 (5.57–8.71) at baseline to 9.14 (8.29–9.71) at 12 months
§ Data from T1D Exchange Registry

1. 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; doi: 10.2337/dci19-0028
2. Graham R, et al. Diabetes Technol Ther. 2024 Jan;26(1):24-32. doi: 10.1089/dia.2023.0341.

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