Early Real-World Hypoglycemia Outcomes with Use of the Tandem Basal-IQ Technology System

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Introduction

The t:slim X2™ insulin pump with Basal-IQ® technology from Tandem Diabetes Care predicts glucose levels 30 minutes ahead based on the last 4 consecutive CGM readings (Figure 1). Insulin delivery is suspended if the predicted sensor glucose is <80 mg/dL or if the observed sensor glucose is <70 mg/dL. Insulin delivery resumes as soon as sensor glucose begins to rise, if glucose is no longer predicted to drop below 80 mg/dL, if no CGM data are available for 10 minutes, or if insulin suspension exceeds 120 minutes in any 150-minute period.[1]

The PROLOG (PLGS for Reduction Of LOw Glucose) trial was a multicenter, randomized controlled crossover outpatient pivotal trial assessing the efficacy and safety of the Basal-IQ PLGS algorithm to reduce hypoglycemia compared with sensor-augmented pump therapy. PROLOG showed 3 weeks of Basal-IQ technology use reduced sensor glucose time <70 mg/dL by 31% compared to sensor-augmented pump use, with no change in mean glucose and an improvement in percent time 70-180 mg/dL.[2]

FIGURE 1: The t:slim X2 insulin pump with Basal-IQ technology. The system is integrated with the Dexcom G6 CGM.

Methods

We sought to determine real-world effects of Basal-IQ technology on hypoglycemia outcomes as compared to the results from the PROLOG pivotal trial. De-identified data voluntarily uploaded to the Tandem t:connect® diabetes management application between August 30, 2018, and February 7, 2019, from individuals with diabetes who had used Basal-IQ technology for 3, 6, and 9 weeks (N=4,082, 2,370, and 1,307 respectively) were retrospectively analyzed. Real-world Basal-IQ technology hypoglycemia outcomes were compared to the PROLOG results.

Results

After 3 weeks of real-world use, median time sensor glucose <70 mg/dL was 1.0% overall (1.0% daytime and 0.9% nighttime) vs. 2.6% (2.4% daytime and 2.7% nighttime) in PROLOG. Median time with sensor glucose <60 was 0.3% and time <50 mg/dL was 0.1%, vs. 0.9% and 0.2% in PROLOG. After 6 and 9 weeks, median time sensor glucose <70 mg/dL was 1.1%. The number of insulin suspensions and suspension duration were similar to PROLOG with the same number of mean insulin suspensions per 24 hour period (5.7/day). Mean sensor glucose at suspension was also the same (104 mg/dL) (Table 1).

TABLE 1: Mean Insulin Suspension Metrics. Real-world use of Basal-IQ technology for the full 24-hour day, daytime and overnight after 3 weeks of real-world use and during the pivotal PROLOG clinical trial.

	24 Hours		Day		Night	
Metrics	Real-World	PROLOG	Real-World	PROLOG	Real-World	PROLOG
Number of Suspensions	5.7	5.7	4.1	4.0	1.6	1.8
Cumulative Duration (mins)	93.9	104	69.3	72	24.7	32
Duration/Suspension (mins)	16.1	18	16.3	18	15.4	18
Sensor Glucose at Suspend (mg/dL)	104	104	106	105	101	102
Sensor Glucose at Resume (mg/dL)	96	92	96	92	96	93

Discussion

System performance in preventing hypoglycemia is best in class, with only 1.0% overall hypoglycemia rates after 3 weeks of use, and 1.1% median time sensor glucose <70 mg/dL after 6 and 9 weeks. One working hypothesis for why hypoglycemia outcomes are so positive while not increasing hyperglycemia is due to the design of the algorithm, which quickly resumes insulin delivery on the first glucose reading past the sensor nadir. Other systems are distinctly different. They do not resume insulin delivery until the sensor glucose has increased above a higher specific threshold and/or a future predicted glucose value has increased above a specified threshold, in some cases requiring a fixed minimum suspension time.

Usability of the system is critical for continued long-term use, and the system was rated very highly both in the pivotal trial[3] and the real world.[4] A limitation of this data is that these outcomes represent a cohort of users who upload their data to the t:connect application, therefore these individuals may be more engaged in their care than users who never upload data.

Conclusions

Basal-IQ technology was found to be safe and effective in a real-world setting, with similar PLGS activation metrics as observed in PROLOG. Overall system performance was excellent, with only 1.0% overall hypoglycemia rate at 3 weeks of use.

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