Improvement in Hypoglycemia Outcomes in a Pediatric Population Using Predictive Low-Glucose Suspend

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Introduction

Technology is changing how type 1 diabetes (T1D) is managed. Recent T1D Exchange data indicate that its overall use has increased significantly within the last 3-4 years,[1] particularly in children less than 12 years old, who showed the largest increase in insulin pump use and a 10-fold increase in continuous glucose monitoring (CGM) use. These same data indicate that even so, clinical outcomes worsened over time. Mean Hemoglobin A1c (HbA1c) increased from 8.1% at 5 years old to 9.3% between 15-18 years old, though less deterioration was evident in those who use pump and CGM. Typically, hypoglycemia has been a limiting factor for the attainment of optimal outcomes, however these data demonstrated that incidence of severe hypoglycemia was significantly lower in pump users and trended in the same direction for CGM users.[1]

The t:slim X2™ insulin pump with Basal-IQ® technology from Tandem Diabetes Care integrates these technologies and predicts glucose levels 30 minutes ahead based on the last four consecutive CGM readings (Figure 1). Insulin delivery is suspended if the predicted sensor glucose is <4.4 mmol/L or if the observed sensor glucose is <3.9 mmol/L. Insulin delivery resumes as soon as sensor glucose begins to rise, if glucose is no longer predicted to drop below 4.4 mmol/L, if no CGM data are available for 10 minutes, or if insulin suspension exceeds 120 minutes in any 150-minute period.

In a randomized controlled outpatient trial (PROLOG), use of Basal-IQ predictive low-glucose suspend (PLGS) technology reduced sensor glucose time <3.9 mmol/L by 31% compared to sensor-augmented pump use, with no change in mean glucose.[2] Real-world data of the Basal-IQ technology are presented here.

FIGURE 1: The t:slim X2 Insulin Pump With Basal-IQ Technology. The system is integrated with Dexcom G6 CGM.

Methods

De-identified real-world data uploaded to Tandem's t:connect® web application between August 31, 2018 and March 14, 2019 was retrospectively analyzed to assess hypoglycemia outcomes.§ The overall group (OG) included 2,696 pediatric users (<18 years; mean blood glucose = 188). Of these, 491 users had sensor-augmented pump data available both pre- and post-PLGS use. This subgroup (SG) included pediatric users aged 6-17 years old (mean age = 12.01; standard deviation = 2.79; 271 males [55.2%]). SG users remotely updated to Basal-IQ technology following a period of at least 21 days of using the same sensor-augmented t:slim X2 insulin pump without Basal-IQ technology.

Results

Overall Group

The overall rate of hypoglycemia (defined as percent median time spent with sensor readings <70 mg/dL or 3.9 mmol/L) for this group was 0.9%. Algorithm-enabled insulin suspensions occurred on average 4.9 times per day for an average 15.5 minutes per suspension. Users were euglycemic when insulin was suspended (mean sensor glucose = 111 mg/dL or 6.2 mmol/L) and resumed (mean sensor glucose = 100 mg/dL or 5.5 mmol/L).

Subgroup

Pre-post analysis demonstrated a significant reduction in hypoglycemia (p = <0.001). Specifically, median time <70 mg/dL or 3.9 mmol/L decreased from 1.6% to 1.1% upon introduction of Basal-IQ technology. This represents a 31% reduction in hypoglycemia.

Similar to the OG, the SG was euglycemic when insulin was suspended (mean sensor glucose = 110.4 mg/dL or 6.1 mmol/L) and resumed (mean sensor glucose = 99.5 mg/dL or 5.5 mmol/L). After algorithm-enabled insulin suspension, 95.5% resumption of basal insulin was system driven; users overrode insulin suspension only 5.1% of the time. Sensor time in range (defined as 70-180 mg/dL or 3.9-10.0 mmol/L) remained steady between pre- and post-PLGS use (53.5 vs. 53.0, p = 0.21). However, there was a significant decrease in sensor glucose values >300 mg/dL or 16.7 mmol/L (6.24% vs. 5.6%; p=.007).

FIGURE 2: Time <3.9 mmol/L (%). Rate of hypoglycemia pre- and post-PLGS use (median values).

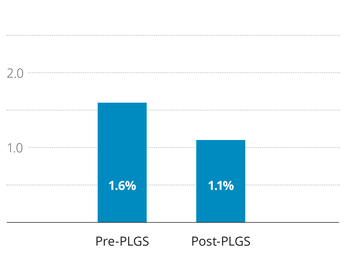

FIGURE 3: Real-World Use. Percent time Basal-IQ technology was available to users.

High System Reliability

Data from t:connect web application indicates that Basal-IQ technology was available to participants for majority of the time.

Discussion

These real-world Basal-IQ technology data extend pivotal trial results and demonstrate great promise for use in the pediatric population for whom metabolic control is the poorest. The design of the algorithm, which quickly resumes insulin delivery on the first glucose reading past the sensor nadir, is likely contributing to a significant reduction in hypoglycemia without an associated increase in hyperglycemia. Fewer episodes of hypoglycemia could reduce extra caloric intake and preserve engagement in exercise that are often factors in the problematic development of disordered eating that undermines effective metabolic control.[3] Coupled with the high time in range and few system overrides, strong system reliability may enhance trust in system, optimize product adoption and reduce micromanagement of blood sugars that can be burdensome and exacerbate diabetes-related distress. Additional benefits could include enhanced sleep quality for caregivers and children alike, which is otherwise notoriously compromised.[4] Moreover, enhanced sleep could in turn reduce risk for negative impact on executive functioning, mood, and adherence.[5]

Conclusions

These findings highlight the real-world use of Basal-IQ technology in a pediatric cohort of insulin dependent patients with diabetes. The OG revealed low rates of hypoglycemia while the SG demonstrated significant reductions in hypoglycemia over time. High system reliability and infrequent user overrides reflect high user trust and user comfort with Basal-IQ technology. Present results show great promise in improving clinical outcomes in pediatric patients with diabetes. Future longitudinal studies are needed to confirm findings in larger and diverse samples, as well as explore the impact of Basal-IQ technology on patients' psychosocial outcomes.

Real-world use of **Basal-IQ technology is associated with significant reductions in hypoglycemia** for pediatric patients.

* Tandem Diabetes Care has a consulting agreement with Jodie M. Ambrosino. † Tandem Diabetes Care. § All references to glucose values in the retrospective analysis are as measured by CGM.

References: 1. Foster NC, Beck RW, Miller KM, et al. State of type 1 diabetes management and outcomes from the T1D exchange in 2016-2018. *Diabetes Technol Ther.* 2019;21(2):66-72. **2.** Forlenza GP, Li Z, Buckingham BA, et al. Predictive low-glucose suspend reduces hypoglycemia in adults, adolescents, and children with type 1 diabetes in an at-home randomized crossover study: Results of the PROLOG trial. *Diabetes Care.* 2018;41(10):2155-2161. **3.** Goebel-Fabbri, AE. Disturbed eating behaviors and eating disorders in type 1 diabetes: clinical significance and treatment recommendations. *Curr Diab Rep.* 2009;9(2):133-139. **4.** Jaser SS, Foster NC, Nelson BA, et al. Sleep in children with type 1 diabetes and their parents in the T1D Exchange. *Sleep Med.* 2017;39:108-115. **5.** Caruso NC. Sleep, executive functioning and behaviour in children and adolescents with type 1 diabetes. *Sleep Med.* 2014;15(12):1490-1499.