Improvements in Parental Sleep, Fear of Hypoglycemia, and Diabetes Distress With Use of an Advanced Hybrid Closed-Loop System

Erin C. Cobry,[1] Alessandro Bisio,[2] R. Paul Wadwa,[1] and Marc D. Breton[2]

Diabetes Care 2022;45:1292–1295 | https://doi.org/10.2337/dc21-1778

OBJECTIVE

Parental sleep quality may contribute to glycemic control in youth with type 1 diabetes. In this article we present sleep analysis from a multicenter, randomized trial of children ages 6–13 years with type 1 diabetes evaluating the Tandem Control-IQ (CIQ) hybrid closed-loop (HCL) system.

RESEARCH DESIGN AND METHODS

Pittsburgh Sleep Quality Index (PSQI) scores were assessed at baseline to identify parents as "poor" sleepers (PSQI >5). Glycemic and psycho-behavioral outcomes before and after CIQ use were analyzed in poor sleepers ($n = 49$) and their children.

RESULTS

Nocturnal time in range ($P < 0.001$) and time hyperglycemic ($P < 0.001$), Hypoglycemia Fear Survey for Parents score ($P < 0.001$), Problem Areas in Diabetes scale score ($P < 0.001$), PSQI score ($P < 0.001$), and Hypoglycemia Fear Survey for Children score ($P = 0.025$) significantly improved. Of poor sleepers, 27 became good sleepers (PSQI score <5).

CONCLUSIONS

Use of CIQ in youth with type 1 diabetes ages 6–13 years significantly improved sleep and psychosocial measures in parent poor sleepers, coinciding with improvements in child nocturnal glycemia, highlighting the relationship between HCL systems and parent sleep quality.

Type 1 diabetes is complex, requiring frequent glucose monitoring and insulin administration. Quality sleep is important for physical and mental health (1), with sleep duration recommendations of 9–12 h for children 6–12 years old and 7–9 h for adults (2). In type 1 diabetes, insufficient sleep is associated with hyperglycemia, insulin resistance, elevated hemoglobin A_{1c} (HbA_{1c}), and decreased self-management (3,4). Type 1 diabetes causes unique nocturnal disruptors, and parents of children with type 1 diabetes are especially prone to sleep disruptions (5).

Novel therapeutics for diabetes management, including insulin pumps, continuous glucose monitors (CGM), and hybrid closed-loop (HCL) systems, have significantly

[1]*Barbara Davis Center for Diabetes, University of Colorado Anschutz Medical Campus, Aurora, CO*
[2]*Center for Diabetes Technology, University of Virginia, Charlottesville, VA*

Corresponding author: Erin C. Cobry, erin.cobry@cuanschutz.edu

Received 23 August 2021 and accepted 30 January 2022

Clinical trial reg. no. NCT03844789, clinicaltrials.gov

E.C.C. and A.B. contributed equally to the realization of this work.

impacted diabetes care (6,7). HCL systems improve time in range (TIR) (70–180 mg/dL), often with achievement of the recommendations (≥70%) (7). TIR improvement is most notable during the nighttime (7,8). Use of HCL systems also reduces time spent in a state of hypoglycemia (<70 mg/dL) (7) and reduces fear of hypoglycemia (8), contributors of insufficient sleep for youth with type 1 diabetes and parents (9).

The impact of HCL on sleep in youth with type 1 diabetes and their families is still being evaluated and may be system dependent, with some reporting improvement and others reporting minimal change (8,10,11). Previously published data from this study showed improving subjective sleep in parents after child HCL use compared with the control group, though statistical significance was not reached (12). This report describes the association between subjective sleep in parents of youth using the Tandem Control-IQ (CIQ) HCL system and nocturnal glycemic and psychosocial outcomes, focusing on parents with baseline poor sleep quality.

RESEARCH DESIGN AND METHODS

This multicenter, randomized trial was conducted at four U.S. pediatric diabetes centers. A central institutional review board (JAEB Center for Health Research, Tampa, FL) approved the protocol. Informed consent and assent were obtained from parents and children. Eligibility criteria included ages 6–13 years, type 1 diabetes duration ≥1 year, and total daily insulin ≥10 units/day. Parent participants were self-selected. An Investigational Device Exemption was approved for CIQ use, as the study was conducted prior to U.S. Food and Drug Administration approval.

Overall Study Design

The study design has previously been described in more detail (7). In brief, children with type 1 diabetes randomized to the CIQ group (treatment) were trained on the t:slim X2 insulin pump with CIQ (Tandem Diabetes Care, San Diego CA) and a G6 CGM (Dexcom, San Diego, CA). Control group participants used the G6 CGM with an insulin pump (sensor-augmented pump [SAP]). The study included a 16-week randomized period followed by a 12-week extension, where the SAP group transitioned to CIQ and the treatment group remained on CIQ.

Patient-Reported Outcomes

Patient-reported outcomes (PROs) were assessed at three time points (baseline and 16 and 28 weeks) with the Pittsburgh Sleep Quality Index (PSQI) (for parents) and the Hypoglycemia Fear Survey (HFS)-II and Problem Areas in Diabetes (PAID) survey (parents and children). The PSQI (validated for adults; 10 questions, with rating 0 to 3) is formulated to assess sleep quality and disturbance over the previous month. Higher scores indicate worse sleep quality and total score >5 indicates poor sleep. The HFS (validated for parent [Hypoglycemia Fear Survey for Parents (HFS-P)] and children age ≥6 years [Hypoglycemia Fear Survey for Children (HFS-C)], with 26 and 25 items, respectively) has a 0 to 4 scale (then scaled to 0 to 100) with higher scores indicating more fear. A total score and two subscales (behavior and worry) are generated. The PAID survey (validated for parent and children age ≥8 years, with 16 and 11 items) has a 0 to 6 scale (then scaled to 0 to 100) with higher scores reflecting more diabetes distress.

Outcomes

The primary safety and efficacy outcomes have previously been published (7). The current report represents a secondary analysis focused on outcomes in parents with baseline suboptimal sleep. Parents with a baseline PSQI score >5, regardless of the study arm, were identified as poor sleepers, while those with PSQI scores ≤5 were identified as good sleepers. Postintervention outcomes were obtained after 16 (treatment group) or 12 (control group) weeks. Glycemic measures reported represent nocturnal glycemic outcomes between midnight and 6:00 A.M. to ensure capture of data during sleep.

Child nocturnal glycemic data and parent and child PROs for poor sleepers were compared from pre-HCL to post-HCL with *t* test or Wilcoxon signed-rank test, according to the variable distribution. Mixed ANOVA, with HCL as a covariate, was performed for assessment of PSQI changes after use of the HCL system.

RESULTS

A total of 101 parent-child dyads were enrolled. Participants were randomly assigned in a 3:1 ratio to CIQ ($n = 78$) or SAP ($n = 23$). Child age ranged from 6.5 to 13.9 years (mean ± SD 11.2 ± 2.1 years), diabetes duration ranged from 1 to 12 years (5.2 ± 2.8 years), 50% were female, and baseline HbA_{1c} ranged from 5.5 to 11.0% (7.7 ± 1.0%). A total of 49 parents met criteria for poor sleep and 50 met criteria for good sleep; two did not complete the questionnaire and were excluded.

Parent and Child PROs

In analyses of parent poor sleeper PSQI score, changes showed improvement after CIQ use ($P < 0.001$). All parent PROs had significant improvements (Table 1). Twenty-seven of the 49 poor sleepers became good sleepers. Significant reduction in total HFS-C score occurred.

Child Glycemic Outcomes

Child nocturnal glycemic data showed significant improvements in mean sensor glucose, sensor glucose SD, TIR, and time with glucose level >180 mg/dL ($P < 0.05$). Time <70 mg/dL was not significant ($P = 0.703$). Time <54 mg/dL increased (from 0.0 to 0.1%; $P = 0.04$).

Parent Poor Sleepers Versus Good Sleepers

At baseline, median PSQI score for parents who were classified as poor sleepers was 7 (interquartile range 6–10) and for good sleepers 4 (2–4). Good sleeper scores did not significantly change over time. Poor sleepers had higher diabetes-related distress at baseline compared with good sleepers ($P = 0.002$); however, there was no longer a significant difference after use of CIQ ($P = 0.221$). Child PAID score was higher among children of parent poor sleepers compared with children of good sleepers ($P = 0.015$), a difference that continued after CIQ use ($P = 0.038$). Other glycemic outcomes and PROs scores were not

Table 1—Pre- and postintervention analysis for parents with PSQI score >5 (poor sleepers) at baseline ($n = 49$)

	Preintervention	Postintervention	*P*
Child PROs			
HFS-C total score	57 (51–67)	55 (48–67)	**0.025**
HFS-C behavior subscale score	30 (26–33)	30 (24–32)	0.144
HFS-C worry subscale score	27 (23–34)	27 (21–33)	0.096
PAID score	23 (17–32)	21 (17–31)	0.153
Parent PROs			
PSQI score	7 (6–10)	5 (3–8)	**<0.001**
HFS-P total score	73 (63–81)	65 (54–74)	**<0.001**
HFS-P behavior subscale score	33 (29–37)	29 (24–33)	**<0.001**
HFS-P worry subscale score	37 (34–47)	33 (29–40)	**0.011**
PAID score	44 (36–56)	35 (26–43)	**<0.001**
Nocturnal CGM (12:00 A.M.–6:00 A.M.)			
Mean glucose, mg/dL	182.16 ± 38.94	148.80 ± 19.11	**<0.001**
Glucose SD, mg/dL	64.00 ± 16.66	51.16 ± 14.51	**<0.001**
% time with glucose <54 mg/dL	0.00 (0.00–0.20)	0.10 (0.00–0.40)	**0.040**
% time with glucose <70 mg/dL	0.50 (0.00–2.70)	0.80 (0.40–1.60)	0.703
% TIR (70–180 mg/dL)	54.43 ± 20.85	78.53 ± 11.09	**<0.001**
% time with glucose >180 mg/dL	43.92 ± 21.08	20.35 ± 11.17	**<0.001**
HbA_{1c}, %, mmol/L	7.55 (6.9–8.3), 59 (52–67)	7.05 (6.6–7.6), 54 (49–60)	**<0.001**

Data are mean ± SD or median (interquartile range). Bold values indicate significance ($P < 0.05$).

significantly different between poor and good sleepers.

CONCLUSIONS

Poor sleep in children with type 1 diabetes and their parents is associated with hyperglycemia, increased HbA_{1c}, and decreased diabetes self-management (3,4,13), as well as depression and anxiety (14). Use of the CIQ system is associated with improved sleep after only 12–16 weeks of use in parents of children with type 1 diabetes who met criteria for inadequate sleep. Fear of hypoglycemia and diabetes distress, common sleep disruptors for parents (9), was reduced. Children of poor sleepers had significant improvement in nocturnal TIR and time hyperglycemic after using CIQ. There was a statistically significant increase in nocturnal time spent with glucose level <54 mg/dL (from 0.0 to 0.1%); however, it is not clinically relevant and the time was within the recommendations for time in a state of hypoglycemia (<4%) (15).

This study was limited to self-report of sleep measures, and further research is needed to determine whether the same findings exist with objective sleep data, including actigraphy. In addition, child sleep was not assessed. The child age was limited to 6–13 years, and therefore findings may not be generalizable to a younger or older population.

Use of HCL systems significantly improves PROs in parents of children with type 1 diabetes classified as poor sleepers while simultaneously improving glycemic control. This represents an exciting potential for HCL systems to not only manage glycemia but also improve sleep.

Acknowledgments. The authors acknowledge the iDCL Trial Research Group, JAEB Center for Health Research.

Funding. This study was funded by Tandem Diabetes Care and the National Institute of Diabetes and Digestive and Kidney Diseases (UC4DK108483). Tandem Diabetes Care provided the experimental closed-loop systems used in the trial, system-related supplies, including the Dexcom CGM and Roche glucometer, and technical expertise.

Tandem Diabetes Care was not involved in data analysis.

Duality of Interest. R.P.W. has grant support from Tandem Diabetes Care and Dexcom and honorarium from Tandem Diabetes Care. M.D.B. receives research support from Tandem Diabetes, Dexcom, Novo Nordisk, and Arecor paid to his institution; serves as a consultant for Dexcom, ADOCIA, and Air Liquide; and received speaker fees from Tandem Diabetes Care and Arecor. No other potential conflicts of interest relevant to this article were reported.

Author Contributions. E.C.C. contributed to the conduct of the study, the analysis plan, and manuscript development. A.B. contributed to the analysis plan, performed the statistical analysis, and contributed to development of the manuscript. R.P.W. and M.D.B. contributed to the study development, analysis plan, and manuscript editing. All authors approved the final manuscript and agree to be accountable for all aspects of the work. E.C.C. and A.B. are the guarantors of this work and, as such, had full access to all the data in the study and take responsibility for the integrity of the data and the accuracy of the data analysis.

Prior Presentation. Parts of this study were presented in abstract form at the 13th International Conference on Advanced Technologies & Treatments for Diabetes, Madrid, Spain, 19–22 February 2020.

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