ORIGINAL ARTICLE

Impact of the Hybrid Closed-Loop System on Sleep and Quality of Life in Youth with Type 1 Diabetes and Their Parents

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Abstract

Background: Insufficient sleep is common in youth with type 1 diabetes (T1D) and parents, likely secondary to diabetes-related disturbances, including fear of hypoglycemia, nocturnal glucose monitoring, hypoglycemia, and device alarms. Hybrid closed-loop (HCL) systems improve glycemic variability and potentially reduce nocturnal awakenings.

Methods: Adolescents with T1D ($N=37$, mean age 13.9 years, 62% female, mean HbA1c 8.3%) and their parents were enrolled in this observational study when starting the Medtronic 670G HCL system. Participants completed study measures (sleep and psychosocial surveys and actigraphy with sleep diaries) before starting auto mode and ~ 3 months later.

Results: Based on actigraphy data, neither adolescents' nor parents' sleep characteristics changed significantly pre–post device initiation. Adolescents' mean total sleep time decreased from 7 h 16 min (IQR: [6:43–7:47]) to 7 h 9 min (IQR: [6:44–7:52]), while parents' total sleep time decreased from 6 h 47 min (IQR: [6:16–7:10]) to 6 h 38 min (IQR: [5:57–6:57]). Although there were no significant differences in most of the survey measures, there was a moderate effect for improved sleep quality in parents and fear of hypoglycemia in adolescents. In addition, adolescents reported a significant increase in self-reported glucose monitoring satisfaction. Adolescents averaged 44.7% use of auto mode at 3 months.

Conclusions: Our data support previous research showing youth with T1D and their parents are not achieving the recommended duration of sleep. Lack of improvement in sleep may be due to steep learning curves involved with new technology. We observed moderate improvements in parental subjective report of sleep quality despite no change in objective measures of sleep duration. Further evaluation of sleep with long-term HCL use and larger sample size is needed.

Keywords: Type 1 diabetes, Adolescents, Sleep, Hybrid closed-loop systems, Parents.

Introduction

QUALITY SLEEP IS essential for maintaining good physical and mental health.¹ In the general population, children and adolescents often do not get the recommended amount of sleep^{1,2} and this is especially true for those with chronic diseases.³ Sleep disruptions and nocturnal caregiving behaviors are common occurrences in type 1 diabetes (T1D) and can greatly impact sleep quality.^{4–6} Disrupted sleep in

T1D often occurs due to swings in glucose levels, in particular, hypoglycemic events or rapid drops in glucose levels that mimic hypoglycemic symptoms and cause awakenings.⁷ In addition, fear of hypoglycemia, especially in parents of youth with T1D, results in general diabetes-related distress, difficulty sleeping or falling asleep, and frequent nighttime glucose testing. In a recent large, multicenter study completed by the Type 1 Diabetes Exchange Registry,⁸ children with T1D and their parents reported overall sleep duration

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well below the amount recommended for the general population (8–10 h/night for adolescents and 7–9 h/night for adults) and shorter sleep duration significantly correlated with greater fear of hypoglycemia. In fact, a meta-analysis found that adolescents with T1D averaged ~26 min less sleep than healthy peers,⁹ representing a significant amount of time that could impact both mental and physical health. Furthermore, Perfect et al.¹⁰ found that adolescents with T1D spent less time in slow wave sleep than matched controls and this finding was associated with worse glycemic control and worse quality of life. These reports highlight the impact of diabetes on sleep duration for those affected by T1D, including family members, but do not address the effects of sleep disturbances or a means of intervening to promote healthy sleep habits.

While sufficient sleep is beneficial for everyone, poor quality sleep has unique implications in patients with T1D. Sleep restriction and sleep disturbances have been linked to increased insulin counter regulatory hormones such as cortisol, resulting in increased insulin resistance.¹¹ Short sleep duration also results in poor food choices (i.e., energy-rich foods),¹² making maintaining a healthy diet and matching insulin doses with carbohydrate intake challenging. Sleep problems, including difficulty falling asleep and frequent nighttime awakenings, are also known to contribute to behavioral and psychological problems, including Attention-Deficit Hyperactivity Disorder (ADHD) and depression,^{13,14} which have the potential to interfere with diabetes management.^{6,15} As an indication of this, increased sleep duration is significantly correlated with increased self-management of T1D.¹⁶ Youth with T1D already have a particularly difficult time achieving optimal hemoglobin A1c (HbA1c) values, making the impact of sleep disturbances even more substantial in this population. Despite the accumulating evidence that sleep has physiological and behavioral impacts on diabetes management, sleep habits are not routinely addressed in the standard of care for youth with T1D and are therefore a prime target for intervention.

Addressing methods to improve glycemic variability at night may prove beneficial in reducing both hypoglycemic events causing nighttime awakenings and parental fear of hypoglycemia leading to decreased distress and less frequent nighttime blood glucose monitoring. New technologies for diabetes management, including the advancements toward a “closed-loop system” or an “artificial pancreas,” have been demonstrated to significantly improve glycemic variability and reduce the number of hypoglycemic events.^{17–23} These devices pair an insulin pump with a continuous glucose monitor (CGM) and use algorithms to adjust insulin delivery based on CGM data. The current devices are often referred to as “hybrid closed-loop” (HCL) systems since they are not fully automated and require human input to account for variable activity levels, prolonged hyperglycemia and food intake. Safety and efficacy studies indicate significantly decreased glycemic variability and improved time in range during the nighttime,^{20–22,24} making it a particularly successful period of time for HCL systems. The current HCL systems have been studied in both inpatient and outpatient settings; however, minimal data on the impact of the devices on sleep duration and sleep quality have been collected outside of study settings.

The current study was a natural experiment that sought to determine the impact of real-world use of HCL systems on sleep quality and duration in adolescents with T1D and their parents. In addition, we assessed the psychosocial impact of

the HCL system, including evaluation of fear of hypoglycemia, diabetes-related distress, and glucose monitoring satisfaction, in both adolescents with T1D and their parents. We hypothesized that the use of an HCL system would improve sleep quality and duration, as well as psychosocial measures in both adolescents with T1D and their parents.

Methods

Participant population

Pediatric patients were recruited from the Vanderbilt Es-kind Diabetes Clinic. Patients were eligible if they were between the ages of 10 and 17 years, diagnosed with T1D for 12 months or more, had no episodes of diabetic ketoacidosis or severe hypoglycemia (requiring glucagon or medical assistance) in the previous 3 months, had no diagnosed sleep disorders (i.e., narcolepsy, insomnia), and lived with a parent who was willing to participate in the study. Parents who participated in the study identified themselves as a primary caregiver for the adolescent patient. All patients were scheduled by the clinic to start using the Medtronic 670G HCL System as part of routine diabetes care. Chart review was completed by study personnel to verify that inclusion and exclusion criteria were met, and only patients who met these were approached during their clinic visit and asked to enroll in the study. A goal of 40 dyads was set based on statistical power calculations, demonstrating that a sample size of 40 would provide power of 0.87 to detect a clinically meaningful change in sleep duration (30 min). For the measure of sleep quality (Pittsburgh Sleep Quality Index [PSQI]), a sample size of 40 would give a power of 0.94 to detect a medium-sized effect (mean difference of 1.25 points) pre–post device. Recruitment was completed at the end of the project period.

Procedures

The Institutional Review Board at Vanderbilt University Medical Center approved this study. All parents gave informed consent and all adolescents completed an assent form before participation. Families were approached for enrollment during a regularly scheduled clinic visit at the time of initiation of the Medtronic 670G insulin pump and follow-up data collection was timed to coincide with a clinic appointment with their primary endocrinologist ~3 months later. Baseline data were collected at the time of enrollment while on the 670G insulin pump in the manual mode setting. Study measures obtained at both time points are described below. Of the 39 patients approached, 37 (95%) agreed to participate in the study. The two families that did not participate reported excess stress related to starting a new diabetes technology device as the reason for declining.

Measures

Demographics and medical data. Demographic data were obtained from the parent during the initial study visit from a questionnaire with information on ethnicity, marital status, parental education, child diabetes medical history (which was confirmed by electronic chart review), child sleep environment, and frequency of nocturnal glucose testing.

Additional medical information was extracted from the child’s electronic medical record. This included date of T1D diagnosis, technology use history, HbA1c levels, and pump, glucose meter, and sensor downloads at the time of study visits.

Actigraphy (objective sleep data). Sleep was assessed in adolescents and parents over a period of seven nights with a wrist-worn accelerometer, the Actiwatch Spectrum (Philips Respironics), which measures activity and light levels. The Philips software algorithms were used to score the data and included information on sleep characteristics, including total sleep time (duration), sleep efficiency, and wake after sleep onset. A minimum of four nights of usable data were necessary for analysis. Based on previous work,^{25–27} we scored actigraph data in Philips Actiware software using a 1 min epoch, with a sleep interval of 10 epochs for onset of sleep, and an awake threshold setting of 40 (medium).

Actigraphy data have demonstrated correlations with polysomnographic measures ranging from 0.90 to 0.97 (sleep duration) in normal subjects^{26,28} and the use of actigraph watches is considered a valid method of obtaining objective measures of sleep in the natural environment.²⁹

Sleep diary (subjective sleep data). Parents and adolescents each completed a sleep diary while wearing the actigraphy watch. The diary included information on bedtime, wake time, and nighttime awakenings (reason and duration). We used this information to corroborate and score the actigraphy watch data. Diaries enhance the accuracy of actigraphy watches when used as a source of objective sleep data.²⁶

Pittsburgh Sleep Quality Index. Both parents and adolescents completed the PSQI to evaluate subjective quality and patterns of sleep. Questions cover seven aspects of sleep, including subjective sleep quality, sleep latency, sleep duration, habitual sleep efficiency, sleep disturbances, use of sleeping medications, and daytime dysfunction over a period of 1 month. The PSQI is used to differentiate “poor” versus “good” sleep quality; a score of >5 indicates clinically significant sleep disturbances.³⁰ This instrument has demonstrated good internal consistency in parents (0.86)³¹ as well as in adolescents (0.90).³²

Hypoglycemia Fear Survey, Worry subscale. Both parents and adolescents completed the Hypoglycemia Fear Survey (HFS)-Worry to evaluate parental and adolescent fear of hypoglycemia. The 13 items are scored on a 5-point Likert scale, with higher scores indicating more fear. The HFS-Worry scale has demonstrated good reliability for adolescent self-report (0.88)³³ and for parent self-report (0.88–0.91).³³

Problem Area in Diabetes Scale–Teen and Parent Report. The Problem Area in Diabetes (PAID) surveys is used to assess emotional distress in people with diabetes and their caregivers. The questions in this survey measure emotional problems that are commonly reported in patients with diabetes. The Problem Area in Diabetes–Parent Report (PAID-PR) consists of 18 questions, while the Problem Area in Diabetes–Teen (PAID-T) consists of 26 questions. Each question in the PAID-PR is scored on a 5-point Likert scale, where the PAID-T is a 6-point scale, with higher scores indicating a more serious problem. The PAID surveys have shown good internal consistency in adolescents (0.96)³⁴ and good internal consistency in parents of children (0.87).³⁵

Glucose monitoring satisfaction survey. Parents and adolescents completed this survey, which was developed to

TABLE 1. ADOLESCENT BASELINE DEMOGRAPHICS

	<i>All adolescents (n = 37)</i>
Age, years, mean $\pm$ SD	13.9 $\pm$ 2.3
Diabetes duration, years, mean $\pm$ SD	6.5 $\pm$ 3.3
Gender, female, %	62.1
Baseline HbA1c (%), mean $\pm$ SD	8.3 $\pm$ 1.0
Previous pump users, n (%)	29 (78.4)
Previous CGM users, n (%)	23 (62.1)
Race, Caucasian, n (%)	35 (94.6)
Number of nocturnal glucose checks per week (parent report)	2.9 $\pm$ 2.5

CGM, continuous glucose monitor; HbA1c, hemoglobin A1c; SD, standard deviation.

evaluate satisfaction with the glucose monitoring system that is used as the primary meter/sensor at the time of the survey. The survey includes 15 questions, and a higher total score indicates greater satisfaction. This measure has demonstrated good internal consistency for T1D (0.86).³⁶

Data analyses

Descriptive analyses were conducted for sleep characteristics (based on actigraphy data) and questionnaire measures of sleep quality and psychosocial outcomes. To assess differences before and after initiation of the HCL system, we conducted paired *t*-tests. Only participants with both pre- and postdata for the measure were included in each data analysis. In addition, we examined the percent time each participant spent in auto mode on the HCL system.

Results

Thirty-seven patient–parent dyads enrolled in the study (Table 1). Three participants never completed training for auto mode on the device and therefore follow-up data were not collected. During the study, one patient withdrew due to other health concerns and two patients were lost to follow-up. Follow-up data collection occurred at an average of 14.6 weeks, or $\sim$ 3.4 months after initiation of auto mode. At the time of follow-up data collection, participants averaged 44.7% of the time in auto mode; 16.7% (5/31) of participants were not in auto mode at the time of follow-up or for 2 weeks prior, and 20% (6/31) were in auto mode <10% of the time (Table 2).

TABLE 2. ADOLESCENT DIABETES OUTCOMES AT 3-MONTH FOLLOW-UP

	<i>Adolescents (n = 31)</i>
Time from auto mode to follow-up, weeks, mean $\pm$ SD	14.6 $\pm$ 5.1
HbA1c, %, mean $\pm$ SD	8.1 $\pm$ 1.0
Time in auto mode, %	
All participants	44.7
Participants with >0% auto mode	51.3
Pts who discontinued HCL, %	
0% auto mode use at follow-up	5 (16.7)
<10% auto mode use at follow-up	6 (20.0)

HCL, hybrid closed-loop.

TABLE 3. ACTIGRAPHY DATA BEFORE AND AFTER HYBRID CLOSED-LOOP INITIATION

	<i>Before HCL initiation (baseline)</i>	<i>After HCL initiation (follow-up)</i>	<i>T value</i>	<i>Effect size (d)</i>
Adolescents (<i>n</i> = 17)				
Total sleep time (H:M), mean $\pm$ SD	7:16 $\pm$ 0:51	7:09 $\pm$ 0:39	0.47	0.11
Sleep efficiency (%), mean $\pm$ SD	79.9 $\pm$ 8.0	82.1 $\pm$ 5.0	-1.26	0.31
Wake after sleep onset, mean $\pm$ SD	57.3 $\pm$ 17.2	54.2 $\pm$ 18.1	0.56	0.14
Parents (<i>n</i> = 19)				
Total sleep time (H:M), mean $\pm$ SD	6:47 $\pm$ 0:57	6:38 $\pm$ 0:54	0.81	0.18
Sleep efficiency (%), mean $\pm$ SD	84.8 $\pm$ 7.6	84.4 $\pm$ 8.2	0.43	0.10
Wake after sleep onset, mean $\pm$ SD	40.6 $\pm$ 15.4	37.8 $\pm$ 13.4	0.93	0.22

Sleep characteristics

Actigraphy watch data were obtained over a seven-night period before initiation of the HCL system and again $\sim$ 3 months after starting automatic mode of the system. Sleep characteristics evaluated using actigraphy data included total sleep time (duration), sleep efficiency, and number of awakenings after sleep onset (Table 3).

There was no significant change in any of the sleep characteristics for either the adolescent or the parent. At baseline, adolescents averaged 7 h, 16 min of sleep. Parents averaged 6 h, 47 min of sleep. Adolescents exhibited a moderate improvement in sleep efficiency (improved from 79.9% to 82.1%, $d=0.31$), but this was not statistically significant. Based on self-report (PSQI), we observed a moderate effect ($d=0.42$) for improved sleep quality among parents; however, it did not reach statistical significance ($t=2.01$, $P=0.057$), and there was no change in adolescents' self-reported sleep quality (Table 4). Table 5 indicates correlations between auto mode use and sleep outcomes after device initiation.

Psychosocial measures

Among adolescents, glucose monitoring satisfaction significantly increased after initiating the HCL system ($t=-7.15$, $P<0.001$) (Table 4). In addition, we observed a moderate effect size on fear of hypoglycemia ($d=0.35$), but this was not statistically significant. Diabetes distress did not change. In the parents, there were no significant changes in any of the survey measures.

Discussion

The current study was the first to use objective measures to examine changes in sleep among adolescents with T1D and their parents after initiating HCL systems. In line with previous research,⁸ we found that both youth with T1D and their parents were not achieving the recommended amount of sleep (8–10 h for adolescents, 7–9 h for adults).³⁷ However, data from this exploratory study did not support the hypothesis that use of HCL systems in a T1D pediatric population would improve sleep over a 3-month period. In addition, psychosocial outcomes did not change following initiation of the device, other than a significant improvement in glucose monitoring satisfaction among adolescents after 3 months of HCL use. Further, while not statistically significant, we observed moderate effect sizes for improvements in adolescents' sleep efficiency and fear of hypoglycemia and in parents' self-reported sleep quality.

Although we did not observe the predicted improvements in sleep or psychosocial outcomes, it is important to note that we did not detect negative outcomes after initiation of the HCL system. It has previously been reported that, while the use of devices for diabetes management may improve glycemic control, they frequently cause increased general disruptions resulting in decreased device use, in part, due to frequent alarms.^{38,39} Our findings suggest that the initiation of the HCL system did not result in more frequent nocturnal awakenings, decreased sleep duration or poorer, self-report of sleep quality. In fact, parents reported better sleep quality after initiating the system, although this improvement did not

TABLE 4. SELF-REPORTED OUTCOMES BEFORE AND AFTER HYBRID CLOSED-LOOP INITIATION

	<i>Before HCL initiation (baseline), mean $\pm$ SD</i>	<i>After HCL initiation (follow-up), mean $\pm$ SD</i>	<i>T value</i>	<i>Effect size (d)</i>
Adolescent outcomes (<i>n</i> = 23)				
HFS-Worry Scale	16.14 $\pm$ 9.69	13.33 $\pm$ 7.90	1.62	0.35
PAID-T	22.39 $\pm$ 15.16	23.04 $\pm$ 17.57	-0.23	0.05
PSQI	5.57 $\pm$ 2.04	5.38 $\pm$ 2.77	0.33	0.01
GMS	2.38 $\pm$ 0.49	3.60 $\pm$ 0.56	-7.15*	1.4
Parent outcomes (<i>n</i> = 24)				
HFS-Worry Scale	16.35 $\pm$ 8.12	16.26 $\pm$ 8.77	0.07	0.01
PAID-PR	6.79 $\pm$ 4.09	6.21 $\pm$ 6.61	0.86	0.18
PSQI	7.41 $\pm$ 3.72	6.18 $\pm$ 2.1	2.01	0.42
GMS	2.64 $\pm$ 0.50	2.59 $\pm$ 0.53	0.41	0.08

* $P<0.001$.

GMS, glucose monitoring satisfaction; HFS, Hypoglycemia Fear Survey; PAID-PR, Problem Areas in Diabetes-Parent Report; PAID-T, Problem Areas in Diabetes-Teen; PSQI, Pittsburgh Sleep Quality Index.

TABLE 5. CORRELATIONS BETWEEN AUTO MODE AND SLEEP OUTCOMES AFTER DEVICE INITIATION

	1	2	3	4	5	6	7	8	9	10
1. Auto mode	—									
2. Adolescent PSQI	−0.18	—								
3. Adolescent TST	−0.23	−0.23	—							
4. Adolescent Eff	−0.33	−0.04	0.62**	—						
5. Adolescent WASO	0.26	−0.24	−0.13	−0.60**	—					
6. Parent PSQI	0.10	0.26	−0.35	−0.44	0.53*	—				
7. Parent TST	−0.15	0.19	0.20	0.20	−0.02	0.37	—			
8. Parent Eff	−0.04	−0.11	0.37	0.53*	−0.41	−0.23	0.43*	—		
9. Parent WASO	0.11	−0.02	−0.24	−0.39	0.37	0.49*	−0.03	−0.78***	—	
10. HbA1c	−0.56***	0.28	−0.25	−0.20	0.04	0.24	0.28	−0.24	0.35	—

* $P < 0.01$. ** $P < 0.01$. *** $P < 0.001$.

HbA1c, hemoglobin A1c; Eff, sleep efficiency; PSQI, Pittsburgh Sleep Quality Index, higher scores indicate poorer sleep quality; TST, total sleep time; WASO, Awakenings After Sleep Onset.

reach significance. Although we hypothesized that improved glycemic variability with HCL systems during the nighttime hours would result in improved sleep, the current study was not powered to assess this. Data were analyzed for the participants who were able to complete both the pre- and post-HCL study measures, including participants who discontinued the device (~17% of adolescents by 3 months, Table 2) (similar to an intention-to-treat analysis). Based on anecdotal report from study participants, discontinuation of the device was due to device discomfort, requirement of an extra site, sensor failure, and skin reactions. These are very similar reasons to previously published data on device discontinuation and barriers to device use.⁴⁰

It is important to consider other reasons why there was minimal change in sleep and psychosocial outcomes after 3 months of HCL use. The sample size for this exploratory study was potentially too small to detect small effects and this may have affected our ability to detect statistically significant changes. Follow-up data collection occurred after ~3 months of HCL use, a period where there is a significant learning curve when initiating a new diabetes device. For HCL systems, many families may need an extended amount of time to optimize the device settings and to gain a sense of comfort and trust with the system. It is possible that long-term use will result in improvements in sleep and psychosocial outcomes once the learning curve and device adjustments have been completed. Furthermore, the adolescents in our sample only spent about 47% of the time in auto mode with around 20% discontinuing use at 3 months (similar to other recent reports³⁹), which may have limited their improvements in glycemic variability. As the HCL system used at the time of this study was newly available on the market, we are only now learning more about the long-term use of this system.^{39,41–43} Additional longitudinal studies on the use of HCL systems in the general T1D population are needed to assess effects on sleep and psychological measures. In addition, new advanced systems are undergoing clinical trials and include additional features not currently available in the HCL system used during this study. These advances include reduced requirements for calibrations with a glucometer (or no calibrations), improved sensor accuracy, automated administration of correction and meal boluses, tighter glucose targets, and dual hormone systems. The impact on sleep may differ depending on the features of each system and would require further evaluation.

The current study has several limitations that must be noted. First, given that adolescents have different sleep patterns during school and summer breaks, we attempted to limit the number of study visits that occurred during two different sleep settings (summer and holiday breaks vs. school). Despite our efforts, it was not possible to perform all study visits during the same time of year, which could have an impact on both sleep quality and duration and psychosocial measures. Second, the age range was limited to 10 to 17 years old; therefore, further research is needed on both younger patients with T1D and their parents (as parents are more directly involved in diabetes management during this age), as well as adult patients with T1D. Third, as mentioned previously, participants in this study were in auto mode 47% of the time at follow-up, likely limiting the effect that the HCL system would have on glycemic variability and sleep outcomes.

The small sample size of this exploratory study limited our ability to detect smaller effects related to initiating HCL systems. Our sample was primarily white, non-Hispanic, which may limit generalizability to other populations. It is likely that patients starting on HCL systems are a unique group of patients and therefore these data cannot be generalizable to the entire pediatric T1D population. However, our high recruitment rate (95%) suggests that the current sample was reflective of the adolescents in our clinic who were initiating HCL systems. Finally, this study utilized actigraphy watches to obtain objective sleep data. While actigraphy watches have been used frequently in the research setting, they can underestimate sleep duration in patients who move frequently during the night or overestimate sleep duration in people who lay still despite remaining awake. In this setting, the gold standard polysomnography would not have been an appropriate tool for sleep data due to its inherent invasiveness and inability to measure routine sleep behaviors.

Future studies are needed to further assess sleep outcomes in patients with T1D and their family members. These studies would likely need larger sample sizes to be able to detect smaller, yet, clinically meaningful changes. In addition, for patients starting on new diabetes technology, monitoring patients over a longer period of time would be beneficial to avoid the potential early adjustment period related to initiation of a new system or changing the medical management of a patient. It is not clear at this time how long that adjustment time is, but likely this would include monitoring up to a year or more. It will be important to include multiple means to

measure sleep outcomes due to the inherent issues with reliability in their use. If actigraphy watches are used, sleep diaries should also be used to verify the data. As polysomnography is not ideal for real-world sleep information, further advancements in devices to measure sleep should be explored for accuracy and validity in the pediatric population. Additional analysis of overnight data would be useful to fully understand sleep in the T1D population.⁴⁴ In the diabetes technology realm, this would include frequency of alarms, overnight auto mode use, and glycemic outcomes as these can have an impact on sleep quality and duration.

Given the increased recognition of sleep as an important component of diabetes management,⁴⁵ it will be critical to not just evaluate sleep in people with T1D, but to have options available to treat sleep disturbances. These treatments will likely need to include a combination of behavioral and medical management to improve sleep in patients with T1D, especially in the pediatric population. Since this is a relatively new field within T1D care, limited data exist to provide strong, evidence-based recommendations on how to address sleep in this population.

Author Disclosure Statement

No competing financial interests exist.

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