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Closing the loop overnight at home setting: psychosocial impact for adolescents with type 1 diabetes and their parents

Katharine D Barnard,[1] Tim Wysocki,[2] Janet M Allen,[3,4] Daniela Elleri,[3,4] Hood Thabit,[4] Lalantha Leelarathna,[4] Arti Gulati,[4] Marianna Nodale,[4] David B Dunger,[3] Tannaze Tinati,[5] Roman Hovorka[3,4]

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[1]Human Development and Health Academic Unit, Faculty of Medicine, University of Southampton, Southampton, Southampton, UK
[2]Center for Healthcare Delivery Science, Nemours Children's Health System, Jacksonville, Florida, USA
[3]Department of Paediatrics, University of Cambridge, Cambridge, UK
[4]Wellcome Trust-MRC Institute of Metabolic Science, University of Cambridge, Cambridge, UK
[5]MRC Lifecourse Epidemiology Unit, University of Southampton, Southampton, UK

Correspondence to
Dr Katharine Barnard; k.barnard@southampton.ac.uk

ABSTRACT

Objective: To explore the experiences of adolescents with type 1 diabetes mellitus (T1DM) and their parents taking part in an overnight closed loop study at home, using qualitative and quantitative research methods.

Research design and methods: Adolescents aged 12–18 years on insulin pump therapy were recruited to a pilot closed loop study in the home setting. Following training on the use of a study insulin pump and continuous glucose monitoring (CGM), participants were randomized to receive either real-time CGM combined with overnight closed loop or real-time CGM alone followed by the alternative treatment for an additional 21 days with a 2–3-week washout period in between study arms. Semistructured interviews were performed to explore participants' perceptions of the impact of the closed loop technology. At study entry and again at the end of each 21-day crossover arm of the trial, participants completed the Diabetes Technology Questionnaire (DTQ) and Hypoglycemia Fear Survey (HFS; also completed by parents).

Results: 15 adolescents and 13 parents were interviewed. Key positive themes included reassurance/ peace of mind, confidence, 'time off' from diabetes demands, safety, and improved diabetes control. Key negative themes included difficulties with calibration, alarms, and size of the devices. DTQ results reflected these findings. HFS scores were mixed.

Conclusions: Closed loop insulin delivery represents cutting-edge technology in the treatment of T1DM. Results indicate that the psychological and physical benefits of the closed loop system outweighed the practical challenges reported. Further research from longitudinal studies is required to determine the long-term psychosocial benefit of the closed loop technology.

Key messages

- Closed loop insulin delivery represents cutting-edge technology in the treatment of type 1 diabetes.
- The psychosocial aspects of a closed loop require investigation to ensure minimal burden on participants and support with managing expectations.
- The psychological benefits of closed loop technology show promising benefits in terms of important patient-centered and family-centered outcomes.

Fear of hypoglycemia, particularly nocturnal, is common[1 2] and a serious complication of insulin treatment in people with type 1 diabetes mellitus (T1DM). It represents a critical problem in the management of the disease and causes psychological distress for many parents of children with T1DM.[3] Severe hypoglycemia can potentially lead to seizures and coma and may play a role as a precipitating factor in cardiac arrhythmias resulting in the 'dead in bed' syndrome.[4]

Nocturnal hypoglycemia is a special concern in the pediatric population, where a high incidence has been reported.[5 6] Intensification of insulin treatment and strict glycemic control have been shown to cause further increases in rates of hypoglycemia in this population.[7 8] Risk of hypoglycemia represents a major obstacle to the achievement of optimal blood glucose levels.[9]

The development of the artificial pancreas (AP), a system that combines glucose monitoring with computer-based algorithm dictated insulin delivery, may provide a solution and represent an additional realistic treatment option for people with T1DM. The vital component of a closed loop system is a computer-based algorithm. Other components include a real-time continuous glucose monitor and an infusion pump to titrate and deliver insulin.[10] The role of the control algorithm is to translate, in real time, the information it receives from the glucose monitor and to compute the amount of insulin to be delivered by the pump.

There has been no previous prolonged evaluation of a closed loop under free-living conditions. The purpose of this study, alongside the assessment of the safety and efficacy of an overnight closed loop at home setting, was to explore the experiences of adolescents and their parents taking part in the study, using qualitative and quantitative research methods.

PARTICIPANTS AND METHODS

Sixteen adolescents with T1DM aged 12–18 years were recruited to an open-label, single-center, randomized two-period crossover study.[11] This assessed the efficacy, safety, and utility of real-time continuous subcutaneous glucose monitoring (FreeStyle Navigator, Abbott Diabetes Care, Alameda, California, USA) combined with an overnight closed loop glucose control in the home setting in comparison with real-time continuous subcutaneous glucose monitoring alone in adolescents with T1DM on subcutaneous insulin infusion pump therapy (Dana R Diabecare, Sooil, Seoul, South Korea). Participants connected to the system in the evening and disconnected on waking in the morning. Closed loop technology was not used during the day or for meals. Every 12 min, the treat-to-target algorithm calculated a new insulin infusion rate, which was automatically set on the study pump.[11]

A mixed methods psychosocial evaluation was conducted to determine the utility of the device in terms of participants' perceptions of lifestyle change, diabetes management, and fear of hypoglycemia. Participants aged 16 years and older and parents or guardians of participants aged younger than 16 years signed informed consent; assent was received from minors.

As part of the study, participants received prestudy training on the use of a study insulin pump and study real-time continuous glucose monitoring (CGM), and then a minimum of 7 days of masked CGM data was recorded over a training period and used to optimize insulin therapy. Participants underwent two interventions: overnight closed loop combined with real-time CGM for 21 nights and the real-time CGM alone for 21 days with a 2–3 week washout period. The order of the two interventions was random.

Qualitative methods

Semistructured interviews to explore participants' perceptions of the impact of the closed loop technology on their lived experience were designed in collaboration with the clinical research team. The interview schedule was then piloted on four potential participants for usability, relevance, and acceptability. These participants were not included in the study. The feedback was positive with minor revisions suggested, and the interview schedule was revised in line with this. All adolescents taking part in the closed loop study were invited to participate in the qualitative interview study as well as one/both of their parents, and 15 of the 16 participants elected to do so.

On completion of the study, participants/parents were invited to partake in an audio-recorded telephone interview conducted by KDB. All interviews were conducted within 2 weeks of the end of the trial. Audiotapes were transcribed with all identifying details removed.

A thematic approach was used to analyze the data, informed by the method of constant comparison, and involved concurrent data collection and analysis.[12] Following transcription, KDB and TT performed independent analyses, reading each participant's interview in full before performing cross-comparisons to identify continuities and differences between accounts. A joint thematic analysis was used to compare interpretations and resolve any differences in interpretation to reach agreement on recurrent themes and findings.[12] This analysis was used to develop a coding framework which captured original research questions and emerging findings.

Content analysis focused on the number/frequency of 'instances', their context, meaning, and whether they were common across participants. Thematic analysis concentrated on identifying key themes arising with a view to understanding the experiences of adolescents and their parents, exploring connections between themes, and identifying how closed loop technology affects everyday living and factors important to quality of life in ways that are important to adolescents and their parents.

Quantitative methods

At study entry and again at the end of two interventions, each adolescent completed the Diabetes Technology Questionnaire (DTQ). This is a 30-item measure of the impact of, and satisfaction with, technological tools that may be used in the management of T1DM.[13] Participants were asked to rate their agreement or disagreement with statements regarding the specific complement of diabetes technologies (ie, meter, pump, continuous glucose monitor, closed loop AP). Items related to 'current' satisfaction and impact as well as 'change' in satisfaction and impact since the new technology was added to the participant's regimen and administered at the end of the two 21-day crossover periods.

The DTQ yields separate scores for 'current' (How much is this a problem now?) and 'change' (How has it changed compared to before the study?) subscales. After reverse scoring of some items, higher scores are indicative of more favorable satisfaction and impact ratings of the technology. Unpublished psychometric data based on a sample of 115 youths enrolled in a CGM trial indicate that the internal consistency (Cronbach's α) was 0.96 for parents and 0.94 for adolescents, split half reliability was 0.87 for parents and adolescents, 3-month test–retest reliability was 0.68 for parents and 0.59 for adolescents, and parent–adolescent agreement was 0.61.

Parents and adolescents also completed the Hypoglycemia Fear Survey (HFS),[14] a 23-item measure that assesses the frequencies of certain behaviors that are designed to avoid hypoglycemia (10 items) and of sources of worry or anxiety about hypoglycemia (13 items). Numerous studies have supported the instrument's psychometric properties.[15 16]

RESULTS

Qualitative interviews

Fifteen adolescent participants agreed to be interviewed along with 13 parents (12 mothers; 1 father). The two eldest participants did not wish for their parent to be interviewed. Interview duration ranged from 14 to 28 min for adolescents (mean 22 min) and from 25 to 65 min for parents (mean 36 min). Parent interviews always lasted longer than those of their child; boys' interviews were shorter than girls' interviews. Only one parent from each family chose to be interviewed. Participants included nine males and six females, age 15.6 (2.1) years; diabetes duration 7.2 (4.3) years; glycated hemoglobin 8.0 (0.9) % (63.9 (9.3) mmol/mol); body mass index (BMI) 22.4 (3.7) kg/m^2; BMI z-score 0.8 (0.8); insulin pump therapy duration of 3.0 (2.3) years.

Twelve adolescents directly commented on having perceived improved blood glucose levels as a result of using the closed loop system, which was mirrored by seven of the parents. Twelve parents and adolescents reported feeling safe using the closed loop system; a negative incidence for one parent–adolescent pair resulted in a loss of this confidence in the system. On one occasion, the closed loop was connected when the participant had a very high blood glucose level. The participant assumed that it would regulate to within the target; however, it did not do so and no alarm sounded, so no manual correction insulin dose was given, resulting in high blood glucose until the next morning (the high overnight glucose was retrospectively explained by the missed evening meal bolus and possibly incorrect pump priming). This did not deter the family from continuing participation in the trial.

Six adolescents spoke directly about their improved sleep and how it led to 'waking up normal' and facilitated improved diabetes control during the day. Six parents also commented on sleep, but focused on reduced anxiety and increased confidence that their child would wake up with 'normal' blood glucose levels. Seven parents commented that the closed loop system enabled them to feel less anxious about their child's diabetes.

Difficulties with calibration, alarms, and size of the device were key concerns. Key aspects of closed loop technology are included in table 1.

Table 1 Key aspects of a closed loop

Issue	Positive Parent	Positive Adolescent	Negative Parent	Negative Adolescent
Improved sleep	7	9		
Reduced anxiety	9	–		
Stable blood glucose levels	9	15		
Felt safe	14	15		
Alarms/beeping			3	6
Uncomfortable			–	3
Too big			4	6
Calibration issues			5	4

There was 100% agreement between parents and adolescents on the key benefits of the closed loop system. Agreement focused on safety, improved blood glucose control, trust in the device, and reassurance without having to get up in the night to do a blood test. Tables 2 and 3 present the details of key positive and negative themes.

Deeper exploration showed additional benefits and downsides; for example, one parent reported on the alarms being a downside (004). Additional downsides were reported by participant 004 who explained that "it [*the CGM transmitter*] was uncomfortable to lie on…, it was inconvenient to plug in…" and that when the device went off [*alarm*] he believed his dad felt powerless "as he had to leave it up to the system." Participant 002 and their parent commented on the 'constant blood sugar level' and 'numbers were perfect' and the parent of participant 002 added that they 'didn't want to give it back and would definitely keep it'.

The concept of feeling 'normal' as opposed to 'diabetic' was raised by two adolescent participants, perhaps reflecting the stigma associated with diabetes and the challenges of living with it.[1] No parent commented on this. Hope for the future was expressed by several participants, for example, 'I liked the idea of how good it could be' (003) as well as satisfaction that they were taking part in an important clinical research trial that would ultimately benefit other people with diabetes.

Ten parents and 15 adolescents would recommend the closed loop technology. There was agreement between the 10 parent–adolescent pairs in their recommendation.

Diabetes Technology Questionnaire

The DTQ measure completed by adolescents covers similar content as the qualitative interviews, albeit with a forced choice questionnaire format. Results for the 'current' subscale showed that, at baseline, 21% of answers indicated either 'very much' or 'some' in response to the question "Is this a problem now?" compared with 14.7% following the closed loop treatment. Corresponding proportions of answers indicative of 'Not much at all' were 57.7% and 59.1%, respectively. Results for the 'change' subscale indicated that 8.7% of responses were indicative of 'Worse or Much Worse' following the closed loop treatment with 20.5% responses for 'Better or Much Better'. The small number of

Table 2 Key positive themes

Theme and participant examples	ID
Reassurance/peace of mind	
"The reassurance really…It was perfect because whatever happened it seemed to take control of it"	(009a)
"Knowing that I was going to wake up on a good number"	(004)
"My parents didn't have to worry so much about what was happening"	(002)
"I felt I could completely trust it at night and I felt completely relaxed about it being there"	(004a)
Confidence and 'time off' from diabetes demands	
"I could rely on it and know that I would be alright in the morning"	(006)
"That you could just hook it up and it does it all for you"	(011)
"If you always wake up on a good number then it kind of sets you up for the rest of the day"	(004)
Safety	
"Knowing that they're going to be OK in the night…that's a safety thing"	(004a)
"At night I didn't have to worry about being diabetic, I just thought, leave it"	(006)
"It was good really because it was like having someone taking care of you"	(010)
"It always seemed to work and once I'd had it a couple of nights I knew it worked and it was good"	(012)
Improved diabetes control	
"The perfect sugar control overnight…"	(015)
"My improved HbA1c was probably best for me…"	(001)
"It really did keep my blood sugar within a very tight range all through the night …"	(008)
"…cos I was lower I could do more, I could concentrate better…"	(013)
Being able to get a good night's sleep	
"For the first time in 10 years I didn't have to do a blood test at 11 o'clock at night"	(013a)
"Not having the worry…not having to drag yourself out of bed testing at 2 or 3 o'clock in the morning…It was reliable"	(002a)
"I had better sleep, you don't worry about what you have to do"	(001)
"Every night we could sleep"	(005a)

Table 3 Key negative themes

Theme and participant examples	ID
Calibration difficulties/frustration when equipment 'fails'	
"Sometimes it would stop working for a few minutes…every 5th day"	(013)
"It would sometimes turn off during the night, it sometimes wouldn't connect which took quite a long time to sort out…once or twice a week"	(013)
"The battery life…It wasn't very good"	(007)
"Do it [calibrate] where you won't be seen or it won't be about midnight when you have to calibrate"	(007)
Size and alarms	
"Just having this little brick on my arm really…Just the size of it"	(002)
"Probably the alarm because they were just really loud"	(010)
"It was quite big and I'd quite like to have a slightly littler one"	(012)
"Once we had a problem with the pump, it was alarming all the time"	(005a)
Accuracy/trust	
"Maybe it won't recognise that I have taken quite a lot of insulin before and it would give me more insulin and then I'll end up having a crashing hypo"	(008)
"It wasn't the most reliable system…Your bloods weren't always what they said it was"	(001)
"It was a bit hit and miss…you couldn't rely on it completely"	(003)
"I didn't really trust it because I think for a whole day I was using it, it didn't give any insulin"	(006)
Discomfort/painful	
"I wasn't allowed to roll on my side or lie on my front because…the thing in my tummy was like, kept beeping and it set off alarms and stuff"	(006)
"The implants for the pump, they were annoying…the needle was sore"	(008)
"There was one time when I did actually rip the sensor out of my arm after a rowing session, I was just like 'oh…I just can't'…"	(008)

participants precluded inferential statistical analyses of these results.

As an alternative method of exploring the DTQ results in greater detail, table 4 summarizes the five DTQ 'change' subscale items that reflected the most improvement and the five items reflecting the most worsening relative to the participants' circumstances prior to the study. As table 4 shows, the top four items reflecting improvement clustered around reduced anxiety related to hyperglycemia and hypoglycemia (both with 66.7% of responses of 'Much Better' or a 'Little Better') and around effort to prevent these glycemic excursions (60% and 53.3%, respectively). The remaining item reflecting the patient-reported benefit of the closed loop system concerned ensuring that the right insulin dose is given when meals are skipped or delayed (40% positive responses). No other DTQ item received more than 33.3% of responses in these positive categories and, for 12 of the 30 items, fewer than 10% of respondents indicated that their closed loop experience had been 'Much Better' or 'A Little Better' when compared with their prestudy experiences on those same dimensions.

Conversely, table 4 also shows that a sizable minority of participants reported worsened outcomes relative to their past experience regarding certain aspects of the closed loop experience. The items that were most likely to engender responses of 'Much Worse' or 'A Little Worse' were concerned with carrying and using several devices (40%), trouble sleeping (33.3%), perhaps

Table 4 Diabetes Technology Questionnaire (DTQ), the five DTQ items on which the largest percentage of closed loop participants responded 'Much Better' or 'A Little Better' compared to their experiences prior to the study and the five DTQ items on which the largest percentages of closed loop participants who responded 'Much Worse' or 'A Little Worse'

	Percentage of responding 'Much Better' or 'A Little Better'
Worry or fear about high blood sugar	66.7
Worry or fear about low blood sugar during sleep	66.7
Effort to keep high blood sugar from happening	60.0
Effort to keep low blood sugar from happening	53.3
Getting the right amount of insulin when meals are skipped or delayed	40.0
	Percentage of responding 'Much Worse' or 'A Little Worse'
Coping with carrying and using several devices	40.0
Trouble sleeping well	33.3
Reacting to all of the alarms from diabetes devices	33.3
Pain or discomfort from insulin injections or pump sets	21.4
Feeling that diabetes devices run my life	20.0

associated with the alarms; however, in the interviews, many participants and parents reported better sleep, reacting to alarms (33.3%), pain or discomfort (21.4%), and feeling that devices run one's life (20%). Negative outcomes of closed loop use were reported somewhat less often by participants than were the benefits, and all had to do with various forms of intrusion into daily life.

Hypoglycemia Fear Survey

Mean±SD HFS total scores obtained from adolescents declined very slightly from the baseline level of 60.1±1.2 to 58.0±0.9 after the closed loop phase and 54.8±1.1 after the open loop phase. For parents, mean HFS total scores increased from 65.7±1.4 at baseline to 68.2±1.5 after the closed loop phase and 70.4±1.6 after the open loop phase. Time spent in hypoglycemia below 70 mg/dL was low in both periods. The number of nights when the glucose was below 63 mg/dL for at least 20 min was lower during closed loop (10% vs 17% nights; p=0.01).

DISCUSSION AND CONCLUSIONS

Closed loop technology represents cutting-edge technological research in the treatment of T1DM. Restricted to hospital-based trials until recently, technological advancements have facilitated a progression to home-based trials, where it is possible to determine, alongside clinical and cost-effectiveness, the impact on everyday living and experiences of participants in terms of impact, trust, and safety.

Participation in the study was reported as a positive experience for all participants, with several expressing hope for the future of diabetes management associated with the closed loop technology. A key benefit reported in the interviews by many participants was the positive impact on their sleep, which somewhat contradicts the questionnaire responses. This may reflect the reduced anxiety at the same time as sometimes being disturbed in the night by the alarms of the technology. Furthermore, the disparity may reflect the forced choice on the questionnaire compared with the reflective nature of the interviews.

Parental fear of hypoglycemia is common, with nocturnal hypoglycemia being a particular problem. Many parents wake up in the night to check their child's blood glucose level, with a subsequent impact on sleep patterns. This affects anxiety levels and daily functioning.[2] The visual affirmation of stable blood glucose levels throughout the night was reassuring for participants. Many commented that waking up on a 'good number' set them up for the rest of the day and the improved glucose control lasted well into the next morning, thus aiding concentration and enhancing well-being at school. Poorer educational attainment for children with diabetes is reported and poor sleep may be a contributing factor to this.

The downsides reported by families were practical difficulties with calibrating the device, insulin infusion set canula insertions, and inconvenience of the size of the device. These issues are not related to the closed loop system but to sensor augmented insulin pump therapy per se. This perhaps reflects the technological world that we live in and general lack of mechanical sympathy but, more interestingly, it reflects the underlying belief by all participants that the algorithm would work and that they had faith in it to do so. One participant and their family found participation challenging and frightening at times; however, they were still pleased that they had taken part.

It is noteworthy that so many adolescent participants commented on the improved blood glucose control as a key benefit of the closed loop technology and the potentially reduced risk of long-term complications. A common misconception suggests that social life is prioritized over diabetes at this age; however, the results of this study do not support this. It may be a consequence of greater focus on diabetes management when participating in a clinical trial; however, the spontaneity with which adolescents talked about diabetes control and concern for future complications suggests otherwise and may in fact reflect challenges with communication in clinic outpatient settings rather than a lack of interest in diabetes self-management.

A key success of the closed loop system until now is that it has enabled parents to feel less anxious and more in control of their child's diabetes. This reflects the underlying, widely reported generalized increased anxiety associated with living with diabetes and the specific impact on the parents' own health and quality of life status.[2] The closed loop system provided reassurance, and for some parents, it was the first time they felt confident that their child would sleep safely throughout the night since their diagnosis with T1DM, often many years earlier.

Although the DTQ covers content similar to that discussed in the qualitative interviews, the differential effects obtained following open loop versus closed loop treatment were somewhat less striking than might have been anticipated given the qualitative findings. However, the overall pattern of DTQ 'change' subscale scores shown in table 4 suggests similar findings regarding the aspects of closed loop use that were perceived by participants as beneficial (anxiety about glycemic fluctuations and the effort required to prevent them) and as intrusive (burden of using several devices, sleep disturbance, excessive alarms, pain or discomfort, and feeling that the devices control one's life). The DTQ results therefore provide a quantitative complement to the findings obtained during the qualitative interviews.

Similar to other pediatric studies using the HFS, parents reported greater fear of hypoglycemia than did adolescents at each measurement point.[14] The HFS results also affirmed some findings of the qualitative analyses that were performed, showing that adolescents reported modest decreases in total scores for fear of hypoglycemia. However, in contrast to the qualitative results, compared with their baseline HFS scores, parents reported a slight increase in HFS scores after the closed loop phase and a marked increase in HFS scores after the open loop phase. Perhaps formative experience with CGM and recognition that glycemic fluctuations are more common and more labile among adolescents than they had expected caused some parents to experience heightened anxiety about the threat of hypoglycemia.

The strengths of the current research are that it explores participants' subjective experiences of taking part in the trial and the impact of overnight closed loop technology on their everyday lives. Furthermore, it provided an opportunity for parents to explore their fears and hopes regarding their child's T1DM, its impact, and the potential of the closed loop technology. The limitations of the study included the small number of participants and the telephone, rather than face-to-face, methodology for interviews. It was considered to be less intrusive for families and facilitated separate and private interviews for adolescents and parents. Similarly, the sample was based on the availability of participants from the clinical trial, and so it is not possible to know whether saturation of views was reached.

The qualitative and quantitative methods converged in supporting the observation that closed loop treatment carries with it promising benefits in terms of important patient-centered and family-centered outcomes, but that integration of closed loop use in daily life will require advances that reduce the intrusiveness of this technology.

In conclusion, closed loop insulin delivery represents cutting-edge technology in the treatment of T1DM. Results indicate that the psychological and physical benefits of the closed loop system outweighed the practical challenges reported. These qualitative results were largely confirmed using a quantitative measure, the DTQ. Further research from longitudinal studies is required to determine the long-term benefit of the closed loop technology.

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Competing interests RH reports having received speaker honoraria from Minimed Medtronic, Lifescan, Eli Lilly, BBraun, and Novo Nordisk; serving on the advisory panel for Animas, Minimed Medtronic, and Eli Lilly; receiving license fees from BBraun and Beckton Dickinson; and having served as a consultant to Beckton Dickinson, BBraun, Sanofi, and Profil. RH and DBD report patent applications.

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