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Acceptability of Implantable Continuous Glucose Monitoring Sensor

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Abstract

Background: Real-time continuous glucose monitoring is associated with significant benefits for diabetes management. Implantable sensors could overcome some challenges reportedly associated with device visibility, psychosocial functioning and sensor durability.

Methods: A psychosocial assessment was conducted to determine acceptability and impact of an implantable continuous glucose monitoring (CGM) sensor as part of the PRECISE trial. Questionnaires were administered to participants comprising the Diabetes Distress Scale, the CGM impact scale, and bespoke device satisfaction.

Results: Fifty-one participants across the United Kingdom (n = 10) and Germany (n = 41) completed the questionnaires. Of these, 90% had T1D, 50% followed an insulin pump therapy regimen, and 45% of the participants were previous CGM users. CGM Impact Scale results show 86% (n = 44) of participants reported feeling better (14% neutral) about their diabetes control with 90% CGM naïve participants and 81% previous CGM users reporting increased confidence about their diabetes management. Furthermore, 73% (n = 37) felt more safe (27% neutral) while sleeping and 78% (n = 39) more confident (22% neutral) about avoiding serious hypoglycemia. Responses correspond with an average improvement in HbA1c from 7.51 to 7.05 ($P < .0001$) over the 90 days use of the CGM. Overall, the system was rated highly on ease of use, convenience and comfort. 84% would choose to be inserted again with 93% of CGM naïve participants (86% previous CGM users) reporting minimized burden of diabetes.

Conclusions: Implantable CGM devices are acceptable to users and are evaluated favorably. The considerable majority of participants (93% of first time users and 77% previous CGM users) would like to continue using the system to help manage their diabetes more effectively.

Keywords

implantable, type 1 diabetes, psychosocial, continuous glucose monitoring

An important technical innovation for type 1 diabetes has been the introduction of real time systems providing information on glucose trajectories and trends for users to improve their diabetes self-management decisions. CGM has been shown to be clinically effective and to enhance psychosocial outcomes such as increased confidence in diabetes self-management.[1] Interindividual variability is substantial however with some users not realizing such benefits.[2] In particular, benefits seem to depend on duration of use, and in some groups with low usage, there have been limited benefits.[3]

Downsides to the technology have focused on poor reliability, alarm fatigue, frequent changes of sensors (typically every 6-7 days), increased burden associated with diabetes self-management and visibility of disease state with the need for additional sensors/transmitter and receiving device.[4,5] A

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Table 1. Frequency of BG Checking on iPod.

	Therapy		CGM Use	
Frequency	CSII (n = 25)	MDI (n = 25)	First (28)	Repeat (n = 22)
Every hour or less	18	18	21	15
Every 2 hours	4	5	5	4
Approx 6 times daily	3	2	2	3

recently introduced implantable sensor with a duration of three to 6 months with connectivity through smartphone technology addresses issues of regular usage, longevity and to some extent visibility of disease state.

The aim of the current study was to explore the psychosocial outcomes associated with wearing an implantable CGM for six months. Key issues include impact of device on perceptions of diabetes self-management and diabetes control, usability, safety, social relationships, and fear of hypoglycemia.

Methods

A psychosocial substudy was conducted as part of the PRECISE trial, a 180-day prospective multicenter pivotal trial.[6] Participants aged 18 years or older with type 1 or type 2 diabetes were implanted with the implantable Eversense (Senseonics Inc) CGM sensor. The sensor was placed in participants' upper arm with the removable transmitter positioned on the skin over the sensor. Quantitative psychosocial assessments were administered at 90 days to participants to explore patient-reported outcomes associated with an implantable CGM sensor. The questionnaire comprised three instruments: First was the Diabetes Distress Scale (DDS),[7] a 28-item scale that assesses worries and concerns specifically related to diabetes and its management; it has been shown to be a good marker of factors important to diabetes-related quality of life (QoL). Responses are rated on a 6-point scale from "not a problem" to "a very serious problem." The second instrument was the CGM Impact Scale,[8] which is a 16-item scale assessing experiences with CGM and designed to measure the impact of CGM on diabetes management and family relationships, plus on satisfaction with emotional, behavioral, and cognitive effects of CGM use. Responses are rated on a 5-point scale from "much better" to "much worse." The final instrument included 33 bespoke device satisfaction questions, which were developed by a multidisciplinary team to assess acceptability of the device. The questionnaire bank was piloted with potential participants prior to use and minor revisions made.

Quantitative analysis was conducted using SPSS v.21, and free-text responses were analyzed using content and thematic methodology. Two researchers independently reviewed all free-text responses, and consensus of key themes was reached.

Results

Fifty-one participants took part in the study across the United Kingdom (n = 10) and Germany (n = 41). Of these, 46 had T1D, 5 had T2D. Participants were similarly split between multiple daily injections (MDI) (n = 25) and insulin pump therapy regimen (n = 26). Similarly, 55% of participants were first time users of CGM (n = 28), 45% were current or previous CGM users

Table 1 shows the frequency at which participants looked at the glucose display on their iPod, subdivided by mode of therapy and first versus previous CGM users. Recommended daily testing frequency of blood glucose is around four times a day, however the ability to easily see the reading without having to perform a finger prick test is commonly associated with greater frequency of checking. This was reflected in the current study where all participants viewed their CGM data more frequently.

CGM impact scale data show that participants reported improvements in terms of confidence over their diabetes control (85%), blood glucose levels (60%), and optimism about avoiding long-term complications (78%). Furthermore, participants reported feeling safer when sleeping (72%), more confident about avoiding severe hypoglycemia (76%), and more motivated to keep up with their diabetes management (80%) (see Table 2).

Overall, the system was rated highly on ease of use, convenience, and comfort, as 92% indicated that they did not experience pain or discomfort when using the sensor; 84% would choose to be inserted again, with 93% of CGM naïve participants (86% previous users) reporting minimized burden of diabetes. Previous CGM users reported better sensor comfort (82% vs 71%) and were more likely to use the sensor for every day management than naïve users (93% vs 77%).

Participants reported improvements on all domains of the DDS, that is, emotional burden, physician-related distress, regime-related distress, and interpersonal distress (see Table 3). Furthermore, 72% (n = 36) judged the CGM to be very helpful in managing their diabetes more easily (score 8-10) on a scale of 1 to 10, 18% (n = 9) scored 4-7, and 8% scored 1-3 (not very helpful).

Free-text responses identified key themes in terms of what participants particularly liked about the device, what they particularly disliked, experiences with CGM alarms, challenges using the device, and overall impressions. The main benefit reported was visibility of trends and data (n = 33) with key dislike reported as technical difficulties such as alarms,

Table 2. CGM Impact Scale at 3-Month Follow-up.

		Mean response (SD)			
		Therapy		CGM use	
Item	All users	CSII (n = 25)	MDI (n = 25)	First (n = 28)	Repeat (n = 22)
Do you now feel more confident or less confident that you can control your diabetes?	1.51 (0.74)	1.56 (0.77)	1.36 (0.64)	1.39 (0.69)	1.61 (0.78)
Do you now feel more or less in control or less in control of your life and your diabetes?	1.86 (0.87)	2.04 (0.98)	1.56 (0.65)	1.79 (0.96)	1.87 (0.76)
Do you now feel more hopeful or less hopeful that you can avoid long-term complications?	1.87 (0.76)	2.12 (0.73)	1.56 (0.71)	1.75 (0.75)	1.96 (0.77)
Do you now feel more motivated or less motivated to keep up with your diabetes management?	1.80 (0.82)	1.84 (0.75)	1.72 (0.89)	1.79 (0.83)	1.78 (0.80)
Is it now harder or is it easier to adjust your insulin doses correctly?	1.96 (0.82)	1.88 (0.78)	1.92 (0.86)	1.89 (0.83)	1.96 (0.82)
Have your blood glucoses become more or become less of a "roller coaster"?	2.16 (0.85)	2.36 (0.81)	1.92 (0.81)	2.14 (0.71)	2.17 (0.98)
Has your A1C improved or has it worsened?	2.25 (0.75)	2.42 (0.58)	2.00 (0.86)	2.13 (0.80)	2.38 (0.67)
Do you now feel more free or less free to do the things in your life you really want to do?	2.24 (0.92)	2.48 (0.77)	1.92 (1.00)	2.14 (0.97)	2.30 (0.88)
Do you now feel more safe or less safe when exercising?	2.04 (0.91)	2.04 (0.79)	2.00 (1.04)	2.04 (1.00)	2.04 (0.82)
Do you now feel more safe or less safe about sleeping?	1.84 (0.85)	1.96 (0.84)	1.64 (0.86)	1.68 (0.86)	1.96 (0.82)
Do you now feel more fearful or less fearful about hypoglycemia?	2.08 (0.98)	2.12 (0.97)	1.92 (1.00)	2.00 (1.09)	2.09 (0.85)
Do you now feel more confident or less confident that you can avoid serious hypoglycemia?	1.73 (0.84)	1.68 (0.80)	1.68 (0.85)	1.57 (0.74)	1.87 (0.92)
Do you now feel more safe or less safe while driving?	2.08 (0.93)	2.04 (0.93)	2.04 (0.93)	1.93 (0.94)	2.22 (0.90)
Are your relationships with your family and friends now better or worse?	2.78 (0.59)	2.92 (0.40)	2.64 (0.70)	2.79 (0.57)	2.78 (0.60)
Is your partner now worrying less or worrying more about sleeping at night?	2.33 (0.85)	2.52 (0.77)	2.12 (0.88)	2.32 (0.86)	2.35 (0.83)
Are your friends and family now bothering you less or bothering you more about your diabetes?	2.53 (0.77)	2.72 (0.61)	2.36 (0.86)	2.61 (0.74)	2.48 (0.79)

Scale: 1 = much better, 2 = slightly better, 3 = neutral, 4 = slightly worse, 5 = much worse.

connectivity, and frequency of charging (n = 23). Specifically relating to alarms, there were mixed responses with 56% (n = 28) of participants reporting positive experience; however 20% (n = 10) preferred the ability to customize the alarms, with 22% (n = 11) finding them too sensitive or too quiet at night. The most common occasions when participants chose not to wear the transmitter were when bathing/showering/swimming (98%, n = 49), followed by recharging (20%, n = 10). Participants were informed that the transmitter was not watertight. Furthermore, it had to be charged once daily, which could be done within 15 minutes, such as during bathing. Overall, the majority of participants were impressed with the system stating ease of use of making life easier (n = 41).

Discussion

Here we report that 51 participants who took part in the PRECISE study across the United Kingdom and Germany reported positive psychosocial outcomes while using an implantable continuous glucose monitor.

Most studies show that users receive verifiable benefit when they use CGM intensively, that is, every day.[2,6] In practice, however, up to 40% of those who use sensors discontinue use over the course of a year.[9] Even in clinical studies, sensor usage has often been below 60% in some groups.[2] There are a number of reasons for this: the cost of sensors is unaffordable for many; inaccurate measurement and interpretation of glucose information occurs; alarm fatigue; pain, irritation at the site of the sensor;[9] negative reactions from the social environment, such as needing to justify why a technical device is being constantly worn or to explain an alarm; the overload of data; and feelings of being overwhelmed by information. An implantable sensor addresses some of these issues. Participants specifically cite the longevity of the device as a benefit, removing the need for frequent sensor replacements. The low visibility of the sensor

Table 3. Diabetes Distress Scale—All Items at 3-Month Follow-up.

	Mean response (SD)				
		Therapy		CGM use	
Item	All users	CSII (n = 25)	MDI (n = 25)	First (n = 28)	Repeat (n = 22)
Feeling overwhelmed by the demands of living with diabetes.	1.88 (0.85)	1.96 (0.84)	1.76 (0.83)	1.75 (0.70)	2.04 (0.98)
Feeling that I am often failing with my diabetes routine.	2.00 (1.11)	2.2 (1.15)	1.68 (0.80)	1.61 (0.69)	2.48 (1.31)
Feeling that diabetes is taking up too much of my mental and physical energy every day.	1.54 (0.71)	1.56 (0.65)	1.52 (0.77)	1.39 (0.63)	1.78 (0.80)
Feeling that my doctor doesn't know enough about diabetes and diabetes care.	1.20 (0.57)	1.12 (0.33)	1.36 (0.81)	1.32 (0.72)	1.13 (0.46)
Feeling angry, scared, and/or depressed when I think about living with diabetes.	1.46 (0.68)	1.48 (0.65)	1.44 (0.71)	1.39 (0.57)	1.57 (0.79)
Feeling that my doctor doesn't give me clear enough directions on how to manage my diabetes.	1.20 (0.49)	1.2 (0.41)	1.20 (0.58)	1.14 (0.52)	1.26 (0.45)
Feeling that I am not testing my blood sugars frequently enough.	1.58 (0.99)	1.8 (1.26)	1.36 (0.57)	1.36 (0.56)	1.83 (1.30)
Feeling that I am often failing with my diabetes routine.	1.96 (1.01)	2.12 (1.09)	1.68 (0.63)	1.64 (0.68)	2.35 (1.19)
Feeling that friends or family are not supportive enough of self-care efforts (eg, planning activities that conflict with my schedule, encouraging me to eat the "wrong" foods).	1.42 (0.76)	1.64 (0.95)	1.20 (0.41)	1.32 (0.55)	1.52 (0.95)
Feeling that diabetes controls my life.	1.94 (1.04)	1.84 (0.75)	1.92 (1.12)	1.79 (0.88)	2.13 (1.18)
Feeling that my doctor doesn't take my concerns seriously enough.	1.14 (0.35)	1.17 (0.38)	1.12 (0.33)	1.11 (0.32)	1.17 (0.39)
Not feeling confident in my day-to-day ability to manage diabetes.	1.43 (0.71)	1.38 (0.49)	1.40 (0.71)	1.22 (0.42)	1.70 (0.88)
Feeling that I will end up with serious long-term complications, no matter what I do.	2.24 (1.30)	2.54 (1.53)	1.96 (0.98)	2.00 (1.21)	2.52 (1.34)
Feeling that I am not sticking closely enough to a good meal plan.	2.12 (1.25)	2.25 (1.39)	1.92 (0.95)	1.85 (0.91)	2.48 (1.50)
Feeling that friends or family don't appreciate how difficult living with diabetes can be.	2.02 (1.18)	2.25 (1.33)	1.76 (0.93)	1.67 (0.88)	2.48 (1.34)
Feeling overwhelmed by the demands of living with diabetes.	1.57 (0.79)	1.63 (0.65)	1.44 (0.77)	1.37 (0.63)	1.83 (0.89)
Feeling that I don't have a doctor who I can see regularly enough about my diabetes.	1.14 (0.46)	1.08 (0.28)	1.2 (0.58)	1.19 (0.56)	1.09 (0.29)
Not feeling motivated to keep up my diabetes self management.	1.49 (0.77)	1.58 (0.65)	1.36 (0.86)	1.22 (0.42)	1.78 (0.95)
Feeling that friends or family don't give me the emotional support that I would like.	1.43 (0.84)	1.58 (1.06)	1.32 (0.56)	1.19 (0.40)	1.74 (1.10)

device removes the visible appearance of the technology and the use of a mobile device is commonplace so avoids drawing attention to a piece of "medical" equipment lowering the visibility of disease state.

Often, participants feel frustrated that their expectations of CGM technology are not met. Exploring expectations prior to use and revisiting these periodically may help to address this. Helping people to learn how to process the additional data provided by CGM and managing expectations around the amount of time and effort required to master the system to best meet individual needs is important to support optimal use. Furthermore, user-friendliness of CGM devices has been reported as an area requiring improvement.[10]

Patient-reported outcome data reported here are comparable for CGM users and non-CGM users with T1D in the literature,[11] something that is reinforced in the current study with no deterioration associated with implantable CGM use. Interestingly, Pickup et al [10] report significantly greater benefit for convenience, acceptability of BG monitoring requirements, BG control efficacy, diabetes worries, and interpersonal hassles associated with CGM and CSII use; however participants were naïve to pump therapy as well as

CGM and it is not possible to separate the impact in terms of device. All of the benefits are commonly reported as associated with insulin pump therapy, so it could be argued that the benefit in insulin therapy overshadowed CGM impact on these psychosocial outcomes.

Engagement with CGM usage is positively associated with improvements in glycemic control[11] and results from the current study show that the majority participants were routinely checking the screen to see their BG values frequently (Table 1) during the trial. The ability to easily see the number and trend direction of BG travel has been widely positively reported as reassuring in closed loop research[5] and this was cited by 66% of participants as a particular benefit in the current study. The reduced burden of technology in terms of ease of use, ease to learn, ability to wear in everyday settings, convenience, and comfort reported by participants addresses the needs of people with diabetes reported in the literature.[12]

Strengths of the study include rigorous psychosocial assessment alongside medical outcomes in the main PRECISE trial including both quantitative and free-text response options to explore potential facilitators and barriers to sustained use of the device. Limitations of the current study include the lack of baseline psychosocial data; however the consistency across 3- and 6-month follow-up reflects durable impact on such factors important to QoL of participants.

In conclusion, an implantable CGM sensor was acceptable to participants and use of the system was associated with minimized burden of diabetes. Psychosocial functioning and factors important to QoL were positively associated with the device for users.

Abbreviations

CGM, continuous glucose monitoring; CSII, continuous subcutaneous insulin infusion; DDS, Diabetes Distress Scale; MDI, multiple daily injections; QoL, quality of life.

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Declaration of Conflicting Interests

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