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Continuous glucose monitoring (CGM) satisfaction and its effect on mental health and glycemic control in adults with type 1 diabetes

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ABSTRACT

Background and aim: A continuous glucose monitoring (CGM) helps the user stay continuously informed about blood glucose levels and reach the right target range. This study aimed to compare glycemic control and mental health of adults with type 1 diabetes with or without CGM and to examine their experiences using it. *Methods:* Patients were included in the survey, whether or not they had used a CGM. Standardized questionnaires were used to assess mental health, problems with disease management, hypoglycemia attitudes and behavior, as well as glucose monitoring satisfaction. *Results:* 277 people participated in the study. CGM users (61.3%) had a more favorable glycemic control than those who were not. No differences were observed between the 2 groups in mental health and in response to hypoglycemic events; however, users reported more disease-related problems. CGM users reported they felt more open and free about diabetes, however, the pain and skin irritation caused by the device was disturbing and it was difficult to cope emotionally with the constant thought and worrying about diabetes. *Conclusions:* CGM did not show clear satisfaction among users, however, less fear of hypoglycemia, fewer depression symptomology and improved glycemic control indicate better clinical status, which is one of the most important goals of disease management.

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KEYWORDS

adults, continuous glucose monitoring, glycemic control, mental health, type 1 diabetes

INTRODUCTION

Controlling blood glucose levels remains a key factor to manage diabetes and prevent or delay the risk of micro- and macrovascular complications [1]. Regular self-monitoring of glycemia can be inconvenient in the long term (painful, antisocial and affected by daily life activities), however, it is inevitable for the proper insulin therapy [2, 3]. Advances in technology have provided a new alternative way to monitor blood glucose levels, the continuous glucose monitoring (CGM). The CGM detects the glucose level in the extracellular fluid between tissues. The sensor sends readings every few minutes to the device or a mobile app allowing the users to monitor their glucose levels in response to diet, exercise or insulin therapy and to calculate the percentage of time they spend with blood glucose levels in the target range [4]. Well-controlled diabetes helps to achieve near normal glycemic control, higher time in range (TIR), avoid hypoglycemic episodes and maintain good mental health [5, 6]. In Hungary, the sensor has only recently become widely available for adults with type 1 diabetes (T1D), since it has been subsidized by health insurance. Thus, there is not yet much feedback on satisfaction with the sensor and its impact on mental and clinical status.

The aim of the study is to compare glycemic control (HbA_{1c}), mental health, problems with disease management, hypoglycemia attitudes and behavior in adults with T1D with and without using CGM. This study also aimed at examining the patients' experience of using CGM device.

MATERIAL AND METHODS

Study design, participants and ethics

A prospective comparative analysis was conducted among adults with T1D between CGM users and non-users. People with T1D were contacted via social networks designed for people with diabetes within a month interval in autumn 2021 ("Medtronic diabetic community", "Diabetics and insulin pumpers club", "Enlite and Guardian 3 users", "Diabetic community", "Abbott Freestyle Libre users").

The study was reviewed and approved by the Borsod-Abaúj-Zemplén County and Regional Ethics Committee (Miskolc, Hungary) and was conducted in accordance with the Helsinki Declaration of 1975. Using survey method, a brief description of the study was provided at the beginning of the questionnaire. All responses were anonymous as no personal identifying information was requested. Participants gave their consent by clicking on the consent button before completing the online questionnaire. The inclusion criteria were: age 18 years or older and diagnosed with T1D for at least two years, and at least 6 months of CGM experience. Individuals were invited to take part in the survey regardless using CGM or not.

Outcome measures

Demographic and clinical data. Participants provided data about their age, sex, economic status, educational level, and diabetes duration, glycemic control (HbA_{1c}), use of insulin pump, presence of diabetes complications, TIR range (time in and the length of time CGMs were used).

Mental health. The Patient Health Questionnaire (PHQ-9) monitors the severity of depression, and its nine questions are based on DSM-IV (The fourth edition of the Diagnostic and Statistical Manual of Mental Disorders) criteria [7]. Responses were required on a 4-point scale as "0" (not at all) to "3" (nearly every day). It has been validated for use in primary care [8]. A higher total score indicates a less favorable mental state. The internal reliability of the questionnaire was excellent for the study sample (Cronbach's alpha = 0.877).

Diabetes-related problems. Problem Areas in Diabetes Questionnaire-5 (PAID-5) assesses negative emotions related to diabetes (fear, anger, frustration) with its 5 items as "0" (not a problem) to "4" (serious problem) [9, 10]. Higher mean scores refer to higher diabetes-related emotional distress (Cronbach's alpha = 0.855).

Hypoglycemic attitudes and behavior. The Hypoglycemia Attitudes and Behavior Scale was developed by Polonsky et al. [11] and validated for adults with type 1 diabetes in 2020 [12]. The scale assesses attitudes towards hypoglycemic events including avoidance, confidence and anxiety, and consists of 14 items, which are answered on a five-point scale from 1 (strongly disagree) to 5 (strongly agree). Higher mean score indicates greater hypoglycemic concern.

CGM satisfaction. The Glucose Monitoring Satisfaction Survey (GMSS) examines thoughts and feelings regarding the current glucose monitor [13]. The 15-item questionnaire has four subscales: Openness to seeking experience (four items) (e.g., "*Helps me be more open to new experiences in life.*"), Emotional burden (four items) (e.g., "*Makes me feel more frustrated with my diabetes.*"), Functional difficulties (four items) (e.g., "*Takes too much time to use.*"), and Confidence (three items) (e.g., "*Often gives me results that don't make sense.*"). Responses are given on a five-point scale from 1 (strongly disagree) to 5 (strongly agree) and a higher mean scores indicate greater satisfaction.

Statistical analysis

Data were analyzed using SPSS 26.0 statistical software (IBM Corp., Armonk, NY, USA). Significance level was set at $P \leq 0.05$. All variables were presented in frequencies, percentage, mean ± standard deviation. Cronbach's alphas were calculated to determine internal consistency of scales/questionnaires used in the study [14]. An independent samples *t*-test was used to compare those who used the sensor and those who did not. Pearson bivariate correlation was applied to find associations among variables. General linear model (GLM) with Bonferroni correction was used to find differences in glycemic control between CGM users and non-users adjusted for demographics and clinical variables.

RESULTS

Patients with T1D

A total of 294 people completed the questionnaire. Due to incomplete completion, data of two persons could not be used, two persons were under 18, two persons had type 2 diabetes, seven persons had diabetes duration shorter than two years and five persons had less than half a year of CGM experience, subsequently their data were deleted. In total, 274 persons' data were processed, 62.3% of them used CGM. Descriptive statistics of the participants are displayed in Table 1.

Glycemic control

Considering that there were differences in demographic and clinical variables between the groups, we investigated which parameters affect glycemic control. Univariate GLM indicated two significant explanatory variables, education and CGM use. The estimated HbA_{1c} remained significantly favorable for CGM users (=7.07, 95% CI: 6.89–7.25 vs 7.59 95% CI: 7.35–7,83; $P = 0.002$) (Table 2).

Table 1. Comparative descriptive statistics for people with T1D with and without using CGM

	CGM users	Non-users	Sig
Sample size	172	102	
Female (%)	82	70	0.025
Mean age (years)	38.10 (±12.10)	41.71 (±12.39)	0.009
Financial situation (%) under aver, average, above aver	8.7, 70.9, 20.3	16.8:70.3:12.9	0.061
Education (%) lower than SC:SC: higher than SC	1.2:37.8:61.0:	4.9:51.0:44.1	0.009
Diabetes duration (years)	18.95 (±11.73)	22.53 (±14.74)	0.024
Mean HbA1c-value	7.03 (±0.90) ($n = 168$)	7.73 (±1.54) ($n = 94$)	<0.001
Insulin pump use (%)	45.3	23.0	<0.001
Presence of complication (%)	18.0	30.4	0.025
Time in range (TIR) ($n = 59$) (%)	75.68 (±12.1)		

SC – secondary school.

Table 2. Univariate analysis of variance for glycemic control

Parameters	Type III sum of squares	df	F	Sig.	η_p^2
Sex	3.005	1	2.271	0.133	0.009
Age	0.090	1	0.068	0.794	0.000
Education	13.650	1	10.314	**0.001**	0.039
Disease duration	0.670	1	0.506	0.477	0.002
Presence of consequences	2.398	1	1.811	0.180	0.007
Insulin pump	0.008	1	0.006	0.939	0.000
CGM use	14.760	1	11.152	**0.001**	0.042

HbA_{1c} significantly correlated with PHQ score (measuring depression) ($r_{(265)} = 0.206$; $P < 0.001$) and HABS score (measuring hypoglycemic attitude) ($r_{(265)} = 0.253$; $P < 0.001$). TIR significantly associated with HbA_{1c} ($r_{(n\ =\ 59)} = -0.523$; $P < 0.001$), depression ($r_{(n\ =\ 59)} = -0.444$; $P < 0.001$), and CGM satisfaction score ($r_{(n\ =\ 59)} = 0.383$; $P = 0.003$).

Mental health, diabetes-related problems, and attitudes to hypoglycemic events between groups of CGM users and non-users

There was no significant difference in mental health and in attitudes to hypoglycemic events between groups. Regarding the disease-related problems, users (4.97 ± 4.72) faced more problems than those not using the sensor (3.95 ± 3.64; $P = 0.027$).

CGM satisfaction

Patients had positive experience regarding openness to seeking experience and they trusted in the devices, however, experienced operational difficulties when using the instrument and felt a greater emotional burden associated with the disease (Table 3).

Qualitative analysis

The last question of the questionnaire provided an opportunity to express individual opinions on the use of CGM. This question was answered by 94 respondents. These qualitative data were processed using content analysis [15].

Analyzed the answers, four main categories were identified:

1. CGM gives more freedom to the users in managing disease and gives a feeling of safety from hyper and hypoglycemia, reducing the fear of hypoglycemia.

   "Until I had a sensor, I always cut my insulin for meals slightly because I was terrified of hypoglycemia. The sensor has helped me a lot with my anxiety and mental health." (woman, 32)

   "I feel safer when driving, with a few clicks I can check my blood glucose while driving. I'm a car mechanic by profession and it's easier to control while at work." (man, 46)

   "Panic attacks due to fear of hypos have almost completely disappeared." (woman, 24)

   "A great help in correcting high blood sugar and managing hypo." (man, 52)

   "This is a super thing, I wish I would have known it sooner. I can live my life with complete peace of mind because there's no hypo, no high sugar, I can correct it in a minute." (women, 59)

Table 3. CGM usage satisfaction

GMSS total scale and subscales	Min	Max	Mean (±)
GMSS mean total score	2.00	3.73	2.87 (±0.29)
Openness	1.50	5.00	4.18 (±0.82)
Emotional burden	1.00	4.75	1.91 (±0.87)
Behavior burden	1.00	3.75	1.81 (±0.67)
Trust	1.00	5.00	3.79 (±0.98)

GMSS: Glucose Monitoring Satisfaction Survey.

2. Help to calculate the insulin bolus for meals and help with regular exercise.

   "It enables sport without limits." (woman, 33)

   "The sensor helped me dare to start running; because I can keep myself under control." (man, 35).

   "I like using it, it helps me in my daily life, in sports and in university studies." (man, 21)

   "Until I had a sensor, I always adjusted my insulin for meals a little less because I was afraid of hypo. The sensor helped my anxiety and mental health a lot." (woman, 32)

3. Technical problems and operational inaccuracies when using CGM.

   "I feel safer because of the alarm; however, sometimes it triggers an alarm unnecessarily." (man, 45)

   "In the summer, adhesive doesn't last long, so I need to take care of extra fixing, especially if I'm going to the beach." (woman, 41)

   "Sometimes I have technical problems with it, e.g. *it wouldn't start or shuts down early, but most of the time it gives me very accurate values and I can protect a lot of hippos."* (man, 29)

   "I don't have a problem with the sensor but the compatible phone application, that's what the company should work on." (woman, 49)

   "Stops before time or does not detect glucose." (man, 26)

   "It's often inaccurate, only a couple of them can last 7 days, I had to replace a whole box because it gave me a fault after 5 days." (woman, 41)

   "Unfortunately, the device is quite sensitive, it's almost unusable in the summer, neither the heat nor the sweat, so it is a torture to use during this period. (man, 33)

   "In case of non-calibration, the sugar values are no longer displayed." (woman, 42)

   "We often receive sensors that are defective from the start, or sensors that fail quickly." (man, 28)

   "The fitting itself is not always reliable, and there is not much room for correction, but this is a manufacturer problem. Basically, it is useful and a great help if the sensor itself is good." (woman, 29)

4. Incorrect data transmission, the need for continuous calibration, painful use or poor aesthetic appearance.

   "It's cool, but for me it takes more time to treat than traditional measurement." (woman, 24)

   "Providing data about me is a disturbing feeling." (woman, 49)

   "Finger pricks cannot be omitted, and even with these, blood must be taken at least 3-4 times a day and the device must be calibrated." (man, 22)

   "Sometimes it gives you a false sense of security that you only realize when you've been disappointed a few times." (woman, 32)

   "Sometimes they can be painful to put on, and aesthetically unpleasing." (woman, 40)

   "Sometimes it gives unrealistic data…" (woman, 38)

   "I don't use a sensor, but I don't have a big problem with hypo. I can detect it immediately and fix it, but I understand that for someone who has a serious problem, it gives them a greater sense of security." (woman, 34)

DISCUSSION

This study investigated the popularity of CGM use among adults with T1D and whether the use of sensor had any positive mental and clinical effects compared to group self-monitoring of blood glucose. We did not aim to test the type of sensor or make any other comparison regarding the manufacture. In our study, CGM users had significantly better HbA_{1c} than the group of non-users and lower HbA_{1c} was related to favorable mental state (PHQ score). No significant differences in mental health and in attitudes to hypoglycemic events were found between groups. However, in CGM users better TIR was associated with lower HbA_{1c}, less depressive features and higher CGM satisfaction score. CGM use was related to positive openness and trust in the devices, on the other hand, CGM users faced more disease-related problems than those not using the sensor and operational difficulties and greater emotional disease burden were also associated with the use of the device.

Previous studies have suggested people with diabetes have higher rates of depression than normal population [16]. The presence of depression affects patient compliance to management of diabetes and consistently leads to worse glycemic values. Our result suggests that CGM use does not necessarily reduce depressive symptoms. Although some previous studies indicate this, our present findings do not confirm it. Depression may be attributed to deeper emotional distress and burdensome chronic disease management, which is only insignificantly affected by sensor use [17]. However, there was difference in glycemic control. Those using the sensor were better able to monitor their actual blood glucose levels and to respond immediately and appropriately [18–20]. The primary goal of diabetes management is to achieve glycemic targets and to maintain the disease properly. The long-term goal is to achieve and maintain good mental health and quality of life. CGM provides people with diabetes with a real-time blood glucose level and plays important role in regulating metabolic control. In addition it helps patients in reducing time spent in hypo- and hyperglycemia. Although we have limited data about TIR, it seems, information provided by the sensor is very important for patients and physicians for the proper treatment and care. It is worth to emphasize that in our study higher TIR was associated with better metabolic control and less depressive symptomology. All these point out that this parameter is useful to characterize the quality of metabolic control and confers impact on mental health in patients with T1D.

No significant group differences were observed in attitude and behavior towards hypoglycemic events. This is probably because people with diabetes pay the greatest attention to avoiding hypoglycemia, as it is the greatest concern and barrier to achieving optimal glycemic control. People using a sensor get real-time information on blood glucose level. This helps with management, but also puts an emotional burden on them because they are constantly dealing with the disease; add to that the discomfort and skin irritation of wearing the sensor [21].

Patient opinion was mixed on the use of the sensor, but the final outcome was still positive, with a detectable improvement in glycemic control. *"The use of a sensor does not give a sense of safety per se, but rather through the fact that blood glucose levels are much more controllable."* (woman, 34)

This study is not without limitations. We did not look at what kind of sensor was used, which could have provided an answer to whether there is a difference between different CGM companies. However, in this study, we did not want to evaluate brands. This study was

cross-sectional in design, so a longitudinal examination would provide a more accurate picture of patient satisfaction with the sensor. Another limitation of our study is that we chose non-probability sample selection as patients were recruited through social network, which may limit the generalizability of the results.

Future perspective

There is no doubt that CGM use has a positive effect on diabetes management and patient outcome. Our study confirms this observation. Findings of patient experiences having more disease-related problems, operational difficulties and emotional burden in those who use the sensor for glucose monitoring reflect that there are still barriers in clinical application and not all patients are appropriate subjects for extensive use of this device. This study stresses the need for further research and development to overcome these barriers.

CONCLUSION

In conclusion, CGM use has a beneficial effect on glycemic control. Its use is related to positive openness and trust in device but no clear effect on mental health and attitudes to hypoglycemic events is explored. TIR proved to be indicator of glycemic control and smaller blood glucose fluctuation (e.g. better TIR) is related to less depressive features and higher CGM satisfaction score. Disease-related problems, operational difficulties and emotional disease burden are still barriers of CGM use in T1D patients. Further research and development is needed to eliminate these barriers in CGM users in the clinical practice.

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ABBREVIATIONS

CGM continuous glucose monitoring
GLM general linear model
GMSS Glucose Monitoring Satisfaction Survey

HbA_{1c}	hemoglobin A1c
T1D	type 1 diabetes
TIR	time in range

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