

Satisfaction with continuous glucose monitoring is positively correlated with time in range in children with type 1 diabetes

Marco Marigliano^{a,1}, Riccardo Pertile^{b,1}, Enza Mozzillo^{c,1}, Alda Troncone^d, Claudio Maffei^a, Elisa Morotti^a, Francesca Di Candia^c, Ludovica Fedi^c, Dario Iafusco^e, Angela Zanfardino^e, Vittoria Cauvin^f, Giulio Maltoni^g, Stefano Zucchini^g, Valentino Cherubini^h, Valentina Tiberi^h, Nicola Minutoⁱ, Marta Bassiⁱ, Ivana Rabbone^l, Silvia Savastio^l, Davide Tinti^m, Gianluca Torneseⁿ, Riccardo Schiaffini^o, Stefano Passanisi^p, Fortunato Lombardo^p, Riccardo Bonfanti^q, Andrea Scaramuzza^{r,*}, Roberto Franceschi^f

^a Department of Surgery, Dentistry, Pediatrics and Gynecology, Section of Pediatric Diabetes and Metabolism, University and Azienda Ospedaliera Universitaria Integrata of Verona, Verona, Italy

^b Clinical and Evaluative Epidemiology Unit, Department of Governance, APSS, Trento, Italy

^c Department of Translational Medical Science, Section of Pediatrics, Università degli Studi di Napoli Federico II, Naples, Italy

^d Department of Psychology, University of Campania "L. Vanvitelli", Caserta, Italy

^e Department of Woman, Child and General and Specialistic Surgery, Regional Center of Pediatric Diabetes, University of Campania "L. Vanvitelli", Naples, Italy

^f Department of Pediatrics, S. Chiara Hospital of Trento, APSS, Trento, Trentino-Alto Adige, Italy

^g Pediatric Unit, IRCCS Azienda Ospedaliero-Universitaria di Bologna, Bologna, Italy

^h Department of Women's and Children's Health, Azienda Ospedaliero-Universitaria, Ospedali Riuniti di Ancona, "G. Salesi Hospital", Ancona, Italy

ⁱ Pediatric Clinic, IRCCS Giannina Gaslini, Department of Neuroscience Rehabilitation Ophthalmology Genetics, Maternal and Child Health, University of Genoa, Genoa, Italy

^l Division of Pediatrics, Department of Health Sciences, University of Piemonte Orientale, Novara, Italy

^m Center of Pediatric Diabetology—A.O.U. Città della Salute e della Scienza di Torino, Torino, Italy

ⁿ Institute for Maternal and Child Health IRCCS "Burlo Garofolo", Trieste, Italy

^o Pediatric Diabetology Department, Bambino Gesù Pediatric Hospital Roma, Lazio, Italy

^p Department of Human Pathology of Adulthood and Childhood G. Barresi, University of Messina, Messina, Italy

^q Department of Pediatrics, Diabetes Research Institute, IRCCS San Raffaele, Milano, Italy

^r Pediatric Diabetes, Endocrinology and Nutrition, Pediatric Unit, ASST Cremona, Ospedale Maggiore, Cremona, Italy

ARTICLE INFO

Keywords:

Adolescent
Child
Continuous glucose monitoring
Satisfaction
Time in range
Young people

ABSTRACT

Aims: Continuous glucose monitoring (CGM) can improve glucometrics in children with type 1 diabetes (T1D), and its efficacy is positively related to glucose sensor use for at least 60% of the time. We therefore investigated the relationship between CGM satisfaction as assessed by a robust questionnaire and glucose control in pediatric T1D patients.

Methods: This was a cross-sectional study of children and adolescents with T1D using CGM. The CGM Satisfaction (CGM-SAT) questionnaire was administered to patients and demographic, clinical, and glucometrics data were recorded.

Results: Two hundred and ten consecutively enrolled patients attending 14 Italian pediatric diabetes clinics completed the CGM-SAT questionnaire. CGM-SAT scores were not associated with age, gender, annual HbA1c, % of time with an active sensor, time above range (TAR), time below range (TBR), and coefficient of variation (CV). However, CGM satisfaction was positively correlated with time in range (TIR, $p < 0.05$) and negatively correlated with glycemia risk index (GRI, $p < 0.05$).

Abbreviations: T1D, type 1 diabetes; CGM, continuous glucose monitoring; rtCGM, real time CGM; isCGM, intermittent scanned CGM; CGM-SAT, CGM Satisfaction; PROs, patient reported outcomes; MDI, multiple daily injection; IQR, interquartile range; JDRF, Juvenile Diabetes Research Foundation.

* Corresponding author at: Pediatric Diabetes and Endocrinology & Nutrition, ASST Cremona, Viale Trento e Trieste 15, 26100 Cremona, Italy.

E-mail addresses: a.scaramuzza@gmail.com, andrea.scaramuzza@asst-cremona.it (A. Scaramuzza).

¹ Contributed equally to this work.

<https://doi.org/10.1016/j.diabres.2023.110895>

Received 30 March 2023; Received in revised form 28 August 2023; Accepted 4 September 2023

Available online 6 September 2023

0168-8227/© 2023 Elsevier B.V. All rights reserved.

Conclusions: CGM seems to have a positive effect on glucose control in patients with T1D. CGM satisfaction is therefore an important patient-reported outcome to assess and it is associated with increased TIR and reduced GRI.

1. Introduction

Continuous glucose monitoring (CGM) has had a positive impact on blood glucose control, improving HbA1c levels and time in range (TIR, 70–180 mg/dl) and limiting glucose variability and number of hypoglycemic episodes [1]. This positive effect is strictly associated with glucose sensor use for at least 60% of the time [2]. Similarly, combining CGM systems with continuous subcutaneous insulin infusion (CSII) reduces HbA1c and increases TIR without detrimental effects on the number of hypoglycemic events when compared with multiple daily injections (MDI) with self-monitoring of blood glucose (SMBG) or the use of CSII alone [3–6].

With the first systems, CGM satisfaction in the pediatric population was lower than neutral [7,8], although satisfaction and quality of life of young people and parents increased with subsequent improvements in sensor accuracy, convenience, and ease of use [9–11]. This has led to the rapid uptake of these devices over the last few years [12]. These results have now been replicated in parents of children aged 4–9 years [13] and even those younger than 4 years [14]. Similarly, children using sensor augmented pumps (SAPs) reported increased treatment satisfaction compared with using MDI or CSII alone [3–5].

However, even with the best technology such as automatic insulin delivery (AID) systems, overall patient satisfaction is often unaltered and only in some cases improved [15]. In particular, there have been reported issues with satisfaction impacting the long-term use of these devices, with lower satisfaction scores related to the CGM device [16,17]. Barriers identified by children and caregivers were: (1) difficulty calibrating; (2) too many alarms; (3) too much time needed to make the system work; (4) too many error alerts; and (5) the hassle of wearing devices [17].

Here we aimed to explore the influence of CGM satisfaction on glucose control in pediatric patients using different treatment modalities including AID systems such as hybrid closed loop (HCL) and advanced hybrid closed loop (AHCL) systems.

2. Subjects, materials and methods

2.1. Participants and procedure

This was a cross-sectional study of children and adolescents with T1D using CGM. The pediatric diabetes centers participating in the study belonged to the Italian Society for Pediatric Endocrinology and Diabetes and included centers in Ancona, Bologna, Cremona, Genova, Messina, Milan S. Raffaele Hospital, Napoli Federico II University, Napoli G. Stoppoloni, Novara, Roma, Trento, Trieste, and Verona. The inclusion and exclusion criteria of the study cohort are detailed elsewhere [18]. In Italy CGM systems are covered by the National Healthcare System.

The Clinical Research Ethics Committee (A787) of the coordinating center of Trento reviewed and approved the study, which was conducted in accordance with the Helsinki Declaration. Written informed assents and consents were obtained by minors aged ≥ 12 years and all parents prior to study entry.

In this study, the Italian version of the CGM-SAT questionnaire was used [18], which was completed by 210 out of the 232 consecutively enrolled patients (at least 8, but not yet 18, years old), and parents of youth <18 years old, attending the 14 pediatric diabetes clinics for three-monthly scheduled visits.

2.2. Outcomes

Demographic and clinical data: Data on age, gender, diabetes duration, sensor experience, type of CGM, insulin treatment modality, total daily insulin dose, BMI SDS, pubertal stage, number of visits per year (in person or in telemedicine), and number of severe hypoglycemia and DKA events in the last 12 months were recorded.

Glucose control parameters: Mean annual HbA1c, last HbA1c, and the sensor metrics based on the last 14 days prior to enrollment were collected: time below range (TBR < 70 mg/dl), TIR, time above range (TAR, >180 mg/dl), % of time with active sensor, mean blood glucose, coefficient of variation (%CV), glucose management indicator (GMI), and glycemia risk index (GRI).

2.3. Statistical analysis

Analyses were conducted using SAS v9.1.4. (SAS Institute Inc., Cary, NC). All variables are presented as frequencies, percentages, mean \pm SD, and medians with interquartile ranges (IQR). The Kolmogorov-Smirnov test was used to verify normality of distributions.

Mean and SD values of item scores on the CGM-SAT were calculated. One-way analysis of variance (ANOVA) or the non-parametric Kruskal-Wallis test was used to assess for significant differences between CGM-SAT scores by categorical independent variables (TIR, TAR, GRI, etc.). Associations between categorical variables were tested with Fisher's exact test. Correlations between CGM-SAT scores and other continuous variables were calculated using Pearson's correlations. The significance level was set to a p-value ≤ 0.05 .

3. Results

Descriptive statistics of the 232 participants are displayed in Table 1. The mean age was 13.7 ± 2.9 years and patients had a normal BMI z-score of 0.23 ± 1.33 . CGM had been used for 2.3 ± 1.9 years, and the annual HbA1c level was $7.0 \pm 0.8\%$. Most patients (66.8%) wore a Dexcom G6 sensor, and the treatment modality was MDI in 36.2%, SAP in 27.6%, and AID (HCL and AHCL) in 36.2% of cases. The percentage time with an active sensor was >70% for most patients (89.7 ± 13.2), and TIR was $64.2 \pm 17.3\%$.

Clinical characteristics and glucometrics according to the three main treatment modalities (MDI, SAP, AID) are reported in Table 2. BMI z-scores were similar between the three groups, while daily insulin requirements were slightly higher in patients with MDI and AID compared with patients with SAP ($p = 0.046$).

AID systems were associated with a higher TIR ($p < 0.0001$) and lower TAR ($p < 0.0007$) and GRI ($p < 0.0001$) compared with SAP and MDI (Table 2). SAP and AID were associated with a higher frequency of annual telemedicine visits compared with patients on MDI (SAP and AID 0.70 ± 1.17 vs MDI 0.44 ± 0.95 , $p = 0.049$).

Mean overall CGM-SAT scores in young people, calculated after reverse scoring for each benefit item, were greater than neutral (3.0) for all three treatment modalities without significant differences between classes. Patients with AIDs reported higher CGM benefits ($p = 0.038$) but similar hassles compared with other treatment modalities. In the whole group, CGM benefits were perceived as higher (higher values in reverse benefits items) among patients with TIR $\geq 70\%$ and GRI < 40 ($p < 0.05$ and $p < 0.001$ respectively; see Fig. 1 and Table 3). GRI was also weakly negatively correlated with CGM-SAT score hassles ($r = -0.19$, $p < 0.02$). Patients with longer diabetes duration reported higher scores, while experience with CGM (in years) did not impact CGM satisfaction scores,

Table 1

Descriptive statistics of the participants. Data are reported as mean \pm SD (median) unless otherwise indicated.

Sample size	232
Female n (%)	104 (44.8)
Age at study enrollment (years) [mean \pm SD (median)]	13.7 \pm 2.9 (13.9)
Age at diabetes onset (years) [mean \pm SD (median)]	7.0 \pm 3.7 (7.0)
Age at CGM start [mean \pm SD (median)]	10.4 \pm 3.3 (11.0)
CGM experience (years) [mean \pm SD (median)]	2.3 \pm 1.9 (2.0)
CGM type n (%)	155
Dexcom G6	(66.8)21
Guardian 3	(9.1)21
Guardian 4Free Style Libre 2	(9.1)35
	(15.0)
Insulin treatment n (%)	84
MDI	(36.2)
SAP	64 (27.6)13
HCLAHCL	(5.6)71
	(30.6)
Weight (kg) [mean \pm SD (median)]	53.1 \pm 15.4 (52.7)
Height (m) [mean \pm SD (median)]	158.4 \pm 13.8
	(159.9)
BMI	20.67 \pm 3.81
	(20.13)
BMI z-score	0.23 \pm 1.33 (0.25)
Stage of Puberty n (%)	43
Prepubertal	(18.5)75
Pubertal	(32.3)114
Postpubertal	(49.1)
% HbA1c annual [mean \pm SD (median)]	7.0 \pm 0.8 (7.0)
% HbA1c last value [mean \pm SD (median)]	6.9 \pm 0.8 (6.9)
Number of visits in clinic [mean \pm SD (median)]	3.5 \pm 1.2 (3.0)
Number of telemedicine visits [mean \pm SD (median)]	0.6 \pm 1.1 (0.0)
Total daily insulin dose (U/Kg) [mean \pm SD (median)]	0.76 \pm 0.26 (0.74)
Number of severe hypoglycemia (last year) n (%)	230
0	(99.1)2
1	(0.9)
Number of severe DKA episodes (last year) n (%)	231
0	(99.6)1
1	(0.4)
% of time with active sensor [mean \pm SD (median)]	89.7 \pm 13.2 (93.3)
% of time in range (70–180 mg/dL) [mean \pm SD (median)]	64.2 \pm 17.3 (68.0)
% of time below range < 70 mg/dL [mean \pm SD (median)]	2.3 \pm 2.4 (1.0)
% of time below range < 54 mg/dL [mean \pm SD (median)]	0.7 \pm 1.3 (0.0)
% of time above range > 180 mg/dL [mean \pm SD (median)]	24.1 \pm 11.6 (23.0)
% of time above range > 250 mg/dL [mean \pm SD (median)]	11.4 \pm 11.6 (7.0)
Mean glucose (mg/dL) [mean \pm SD (median)]	162.3 \pm 29.7
	(156.0)
% Coefficient of variation (CV) [mean \pm SD (median)]	36.1 \pm 5.8 (35.8)
% Glucose management indicator (GMI) [mean \pm SD (median)]	7.26 \pm 0.90 (7.1)

nor did patients' age, gender, or treatment modality (Table 3). Patients using flash CGM reported fewer hassles (higher score in hassles) compared with other systems (4.22 \pm 0.50 vs 3.94 \pm 0.53, $p = 0.0067$). CGM-SAT score benefits and hassles were not associated to categories of % time of active CGM (Table 4). A multiple regression analysis was conducted keeping the variable score benefits continuous, in order to obtain the estimates for each parameter entered in the model adjusted for the others. We did not find any correlation and we reported the data in the Results (Table S1). We also stratified the results between score benefits and TIR 70–180 mg/dL, GRI and HbA1c, by treatment modality and sensor type (Table S2, S3), with no relevant results.

After reverse scoring for each benefit item, the items that obtained the lowest overall mean scores (lower satisfaction) in patients were item 32 (3.44 \pm 1.04, "Shows more glitches and bugs that it should"), item 29 (3.67 \pm 1.08, "Causes our family to talk about blood sugars too much"), item 33 (3.69 \pm 1.17, "Interferes a lot with sports, playing outside etc."). The items obtaining the highest overall mean scores, indicating aspects of CGM that led greater satisfaction, were item 2 (4.29 \pm 0.70, "Makes adjusting insulin easier"), item 6 (4.29 \pm 0.77, "Helps to keep low blood sugars from happening"), and item 44 (4.27 \pm 0.72, "Makes me feel safer knowing that I will be warned about low blood sugar before it

Table 2

Patient characteristics, sensor metrics, and CGM-SAT scores subdivided into the three main treatment modalities: MDI, SAP, and AID (HCL and AHLC). For benefit items, a lower mean score indicates higher satisfaction, and for hassles items a higher mean score refers to higher satisfaction. Overall CGM score was calculated after reverse scoring for each benefit item. CGM metrics refers to the last 14 days.

	MDI (n = 84)	SAP (n = 64)	AID (n = 84)	p-value*
Age [mean (SD), median (IQR)]	13.0 (2.9), 13.0 (4.0)	12.9 (2.8), 13.0 (5.0)	13.8 (2.8), 14.0 (4.0)	$p = 0.114$
Gender [% female]	42.9%	47.2%	44.9%	$p = 0.892$
BMI z-score [mean (SD), median (IQR)]	0.37 (1.12), 0.42 (1.09)	0.21 (1.09), 0.23 (1.40)	0.20 (1.18), 0.12 (1.38)	$p = 0.537$
Annual HbA1c [mean (SD), median (IQR)]	7.15 (0.86), 7.15 (1.35)	6.88 (0.74), 6.70 (1.05)	7.07 (0.80), 7.00 (0.95)	$p = 0.163$
Total daily insulin/kg	0.79 (0.28), 0.76 (0.41)	0.68 (0.25), 0.69 (0.37)	0.78 (0.24), 0.78 (0.31)	$p = 0.046$
TIR	57.89 (19.13), 58.40 (29.00)	58.94 (18.52), 63.00 (23.45)	72.99 (10.59), 73.00 (13.00)	$p < 0.0001$
TBR < 70 mg/dL	2.41 (2.40), 1.40 (2.00)	2.75 (2.87), 2.00 (3.00)	1.73 (1.59), 1.00 (2.00)	$p = 0.222$
TAR > 180 mg/dL	27.21 (13.21), 24.90 (14.00)	25.49 (11.39), 24.00 (14.00)	20.40 (9.38), 19.50 (12.00)	$p = 0.0007$
CV	37.27 (10.52), 36.33 (7.11)	37.70 (8.72), 36.28 (9.70)	35.85 (9.96), 34.79 (6.55)	$p = 0.268$
GRI	49.13 (23.90), 46.50 (26.00)	48.44 (22.00), 43.00 (29.00)	31.30 (12.20), 33.00 (18.00)	$p < 0.0001$
Annual no. face-to-face visits	3.5 (1.1), 4.0 (1.0)	3.3 (1.1), 3.0 (2.0)	3.7 (1.4), 4.0 (1.0)	$p = 0.111$
Annual no. telemedicine visits	0.4 (1.0), 0.0 (0.0)	0.7 (1.2), 0.0 (1.0)	0.7 (1.2), 0.0 (1.0)	$p = 0.137$
Overall CGM score	3.94 (0.45), 4.02 (0.63)	4.03 (0.38), 3.98 (0.49)	4.04 (0.40), 4.01 (0.54)	$p = 0.653$
CGM benefits score	2.1 (0.5), 2.0 (0.6)	2.0 (0.5), 2.0 (0.5)	1.9 (0.4), 2.0 (0.6)	$p = 0.038$
CGM hassles score	4.0 (0.6), 4.0 (0.8)	4.1 (0.5), 4.1 (0.7)	3.9 (0.5), 4.0 (0.7)	$p = 0.317$

*For gender, the Fisher's exact test was used, while other associations were tested by ANOVA or the Kruskal-Wallis test.

happens").

4. Discussion

Our study reporting daily life use of CGM showed, for the first time, that children and adolescents with T1D reporting higher CGM benefit scores have better glycemic control (higher TIR) and reduced glycemic risk index (lower GRI), regardless of the technology used.

In our patients, CGM benefit scores associated with TIR over the last 14 days but not with mean annual HbA1c or the most recent HbA1c value. Similar findings were recently reported in adults [19], and probably CGM satisfaction was associated with TIR and not with HbA1c because TIR represents overall glycemic control better than HbA1c alone, which lacks detailed information on short-term glycemic control. While TIR has high correlation with other CGM metrics for hyperglycemia, only moderate correlation with HbA1c has been reported [1].

It has also been reported that using more complex technology (SAP versus MDI, for instance) is associated with better TIR and lower HbA1c values [6]. Here we confirmed this finding, also finding lower GRI when using AIDs compared with SAP or MDI.

Our study goes further, because satisfaction with the CGM system in terms of perceived benefits was associated with TIR > 70%, regardless of the insulin delivery system used, as the CGM-SAT questionnaire measures only the effect of CGM use (including sensors that require calibration), differently from “diabetes technology questionnaires” (DTQ) which assesses the impact and satisfaction of all technological tools that may be used in the management of T1DM [20]. To our knowledge, this is the first report of such data and the correlation between high satisfaction with CGM (more benefits and fewer hassles) and reduced GRI.

Surprisingly, CGM-SAT scores were not related to percentage time with an active sensor, probably because the mean usage was high in all three subgroups ($89.7 \pm 13.2\%$). While it has been observed that the frequency of use decreases over time in young people with T1D, we registered high levels of use even after 2.3 ± 1.9 years. This positive outcome may be due in part to improved CGM technology and the use of education programs on CGM for children and their caregivers in pediatric centers with extensive experience using this technology for diabetes care [6]. Interestingly, diabetes duration, rather than years of CGM experience, was a determinant of reduced hassles related to CGM, probably because patients who had experienced previous less accurate CGM models are now more satisfied with the newer technologies. Indeed, the first studies on CGM satisfaction reported a mean item score of approximately 2.7 for parents and young people [7], and real-time CGM compared with retrospective analysis did not lead to a negative or positive effect on satisfaction [8]. In the JDRF CGM trial, CGM-SAT scores in young people and parents were 3.6 ± 0.5 and 3.8 ± 0.5 , respectively, and were higher for those who used CGM ≥ 6 days/week [9]. Frequent CGM use was associated with higher satisfaction in young people and parents in both the benefits and hassles sub-scales of the CGM-SAT [21].

In our population, the overall mean CGM-SAT score was greater than neutral but not as high as expected, even in patients using the most advanced technologies and, *vice versa*, patients using CGM systems in combination with MDI treatment showed the same level of satisfaction. These data confirm the reliability of the CGM-SAT scale in evaluating patients using sensors with different treatment modalities independent of the influence of insulin pump or algorithm used, while patients on AIDs probably have higher expectations of technology, with the weak link in the system still being CGM. Even in the case of CGMs that do not require calibration, the mean overall CGM-SAT scores were not high.

We tried to explore the barriers contributing to incomplete satisfaction with their CGMs. Skipped readings, wearability while playing sports and outdoor activities (items 32 and 33), and the challenge of managing a large amount of data (item 29) were still issues raised by

primarily teenagers today. Interestingly, technical problems, such as insertion pain, skin irritation, false alarms, and inaccuracy were not major problems, unlike previously reported [7,17,21]. Common benefits include opportunities to self-correct out-of-range glucose levels and to prevent or detect hypoglycemia, as previously reported [17,21]. No significant differences related to wearability were observed among CGM models, even in the latest generations of devices. New technologies will overcome some of the technical barriers and in the meanwhile continuing therapeutic education has probably to focus more on skin preparation, adhesive products to use before and after inserting the sensor in subjects playing sports, inaccuracy in the hours after sensor insertion; when to perform a fingerstick and how to set appropriate alarm thresholds.

The CGM systems used by enrolled patients are linked to web-based software that helps structured telemedicine diabetes care through video consultations. This new option was widely used to care for children with T1D during the COVID pandemic [22–24]. Our study, conducted in 2022, suggests that patients using SAP or AHCL are more prone to be followed up with telemedicine visits compared with patients treated by MDI, but the mean of only 0.7 visits per year suggests that multi-professional consultation at clinic is still the most common modality of care.

This study has the limitations of: i) its cross-sectional design: we have planned a longitudinal study that could provide a more accurate analysis of patient satisfaction with the sensor, including data on exercise, diet, socioeconomic status and on drop-out from system use, as previously reported [25]; ii) enrolment of patients using different CGM systems with different accuracies could bias CGM-based glucose metrics analysis; iii) we did not use the DTQ questionnaire in addition to CGM-SAT, as this study was performed after only the Italian version of the CGM-SAT was validated [18]; iv) Italian participants may not represent the global population of pediatric diabetes patients in terms of cultural, socioeconomic and healthcare system differences. In particular in Italy CGM systems are provided for free to all the children-adolescents with T1D, and we can speculate that over the time our patients get used to the most recent CGM devices and they want to get more, they are less satisfied regard CGM accuracy and wearability than subjects of other countries; v) The rapid evolution of CGM technology might make the results of this study less applicable in the future.

Nevertheless, the study has the strengths of: i) a large sample enrolled in different centers distributed in different areas of Italy, so the results are likely transferable to the general population; ii) enrolled patients used different treatment modalities associated with CGMs; iii) we analyzed the most recent glucose variability indices.

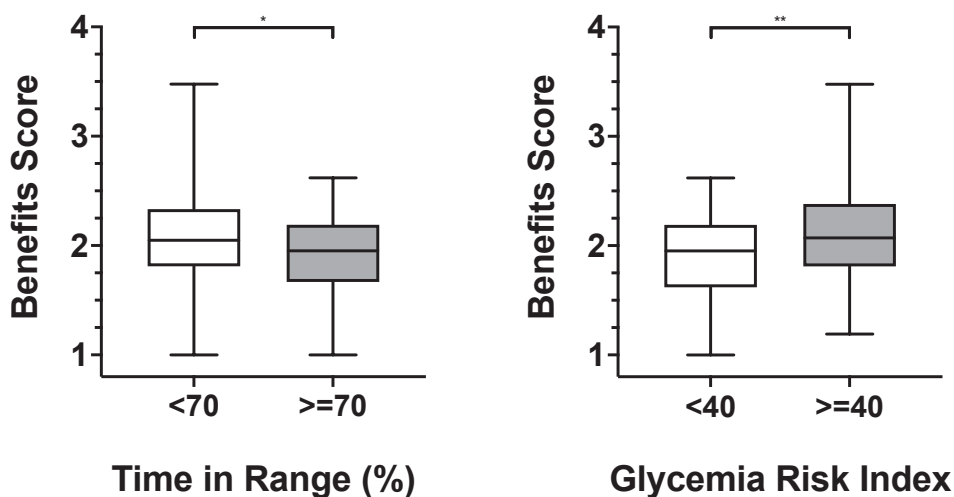


Fig. 1. In the entire cohort ($n = 210$), CGM benefits were perceived as higher (higher values in reverse benefits items) in patients with TIR $\geq 70\%$ and GRI < 40 ($p < 0.05$ and $p < 0.001$, respectively).

In conclusion, our study confirms that CGM systems have a positive effect on glucose control in pediatric patients with T1D, and CGM satisfaction is an important patient-reported outcome to evaluate and the perceived benefits of CGM are associated with increased TIR and reduced GRI. There are still a few barriers to real-world CGM use for all the different treatment modalities, and new technologies - along with continuing therapeutic education - could improve satisfaction and glucose control.

5. Authors' contributions

All persons who meet authorship criteria are listed as authors, and all authors certify that they have participated sufficiently in the work. RF, EM, AT, and MM designed the study. All authors except RP enrolled patients in this study. RP performed statistical analyses. RF, EM, and MM wrote the manuscript. All authors discussed, critically edited, and approved the manuscript.

Informed consent

Written informed consent was obtained from each participant and parent/legal guardian.

Ethics approval

The current study was approved by the local Institutional Review

Table 3

Correlation analysis between CGM-SAT scores and patient characteristics and glucose metrics. For benefit items, a lower mean score indicates higher satisfaction, and for hassles items, a higher mean score refers to higher satisfaction.

	N	Patient benefits score	Kruskal-Wallis test p-value	Pearson correlation coefficient (p-value)	Patient hassles score	Kruskal-Wallis test p-value	Pearson correlation coefficient (p-value)
Age at the study	42	2.01 ± 0.43	0.811	-0.029 (0.675)	3.90 ± 0.51	0.690	0.078 (0.263)
< 10 yrs	46	2.01 ± 0.45			3.97 ± 0.56		
11-12	41	2.02 ± 0.53			3.99 ± 0.57		
13-14	46	1.94 ± 0.36			4.07 ± 0.52		
15-16	33	1.98 ± 0.42			4.00 ± 0.54		
17-18							
Gender Male	115	1.96 ± 0.42	0.412		3.99 ± 0.53	0.987	
Female	93	2.02 ± 0.47			3.98 ± 0.55		
Diabetes duration				0.023 (0.740)			0.143 (0.039)
≤2 yrs	52	1.98 ± 0.46	0.960		3.85 ± 0.56	0.032	
3-5 yrs	51	2.01 ± 0.49			3.98 ± 0.55		
6-10 yrs	74	1.97 ± 0.43			4.03 ± 0.52		
>10 yrs	31	2.00 ± 0.34			4.12 ± 0.50		
CGM experience duration							
<1 year	36	1.90 ± 0.53	0.337	0.078 (0.265)	4.02 ± 0.47	0.624	0.089 (0.199)
1 year	41	1.98 ± 0.48			3.90 ± 0.67		
2 years	55	2.01 ± 0.37			4.00 ± 0.51		
3 years	38	1.93 ± 0.40			3.92 ± 0.55		
>3 years	38	2.11 ± 0.44			4.10 ± 0.45		
Annual HbA1c < 7%							
≥7%		1.96 ± 0.432.02 ± 0.46	0.331	0.079 (0.265)	4.01 ± 0.553.96 ± 0.54	0.545	-0.090 (0.120)
Sensor type G6	137	2.02 ± 0.451.84 ± 0.40	0.247		3.92 ± 0.52	0.017	
Guardian 3	20				3.94 ± 0.50		
Guardian 4	2031	1.82 ± 0.44			4.13 ± 0.654.23 ± 0.50		
FSL2		2.05 ± 0.36					
Treatment modality							
MDI	77	2.09 ± 0.46	0.106		3.97 ± 0.57	0.270	
SAP	53	2.03 ± 0.47			4.06 ± 0.47		
AHCL	66	1.89 ± 0.37			3.94 ± 0.53		
% Time active CGM				0.018 (0.801)			0.051 (0.470)
<70	18	1.93 ± 0.41	0.28		3.96 ± 0.58	0.794	
≥70	185	1.99 ± 0.44			3.99 ± 0.54		
TIR 70-180 mg/dL < 70	11,592	2.06 ± 0.481.90 ± 0.37	0.0388	-0.212 (0.002)	3.96 ± 0.564.02 ± 0.51	0.444	0.098 (0.159)
≥ 70							
TBR < 70 mg/dL < 4%	164	1.99 ± 0.44	0.892	0.009 (0.892)	4.00 ± 0.553.94 ± 0.50	0.480	-0.006 (0.933)
>4%	44	2.00 ± 0.45					
CV < 36%	84	1.95 ± 0.45	0.65	-0.044 (0.580)	3.97 ± 0.563.93 ± 0.51	0.66	0.012 (0.879)
≥36%	78	2.00 ± 0.48					
GRI < 40	86	1.86 ± 0.402.11 ± 0.50	0.007	0.192 (0.0142)	4.04 ± 0.50	0.0295	-0.194 (0.0133)
≥40	76				3.86 ± 0.55		

Table 4

Score benefits and hassles according to categories of % time active CGM.

% time active CGM	No.	Score benefits	Score hassles
<70	18	1.99 ± 0.39	3.96 ± 0.58
70-80	13	2.27 ± 0.40	3.82 ± 0.47
81-90	38	1.98 ± 0.37	4.05 ± 0.49
>90	134	2.02 ± 0.45	3.99 ± 0.56
p-value		0.2555*	0.5901#

Board (A787). The study was performed in accordance with the ethical standards as laid down in the 1964 Declaration of Helsinki and its later amendments.

Funding

The authors received no specific funding for this work.

Declaration of Competing Interest

The authors declare that they have no known competing financial interests or personal relationships that could have appeared to influence the work reported in this paper.

Data availability statement

All data generated for this study are included in the article.

Acknowledgments

We would like to thank all children and adolescents with type 1 diabetes and their families who took part in the study.

Appendix A. Supplementary data

Supplementary data to this article can be found online at <https://doi.org/10.1016/j.diabres.2023.110895>.

References

- [1] de Bock M, Codner E, Craig ME, Huynh T, Maahs DM, Mahmud FH, et al. ISPAD Clinical Practice Consensus Guidelines 2022: Glycemic targets and glucose monitoring for children, adolescents, and young people with diabetes. *Pediatr Diabetes* 2022;23(8):1270–6. <https://doi.org/10.1111/medi.13455>.
- [2] Sherr JL, Schoelwer M, Dos Santos TJ, Reddy L, Biester T, Galderisi A, et al. ISPAD Clinical Practice Consensus Guidelines 2022: Diabetes technologies: Insulin delivery. *Pediatr Diabetes* 2022;23(8):1406–31. <https://doi.org/10.1111/medi.13421>.
- [3] Norgaard K, Scaramuzza A, Bratina N, Lalic NM, Jarosz-Chobot P, Kocsis G, et al. Interpret Study Group. Routine sensor-augmented pump therapy in type 1 diabetes: the INTERPRET study. *Diabetes Technol Ther* 2013;15(4):273–80. <https://doi.org/10.1089/dia.2012.0288>.
- [4] Barnard KD, Bromba M, de Lange M, Halbron M, Levy BL, Lévy M, et al. High reported treatment satisfaction in people with type 1 diabetes switching to latest generation insulin pump regardless of previous therapy. *J Diabetes Sci Technol* 2015 Mar;9(2):231–6. <https://doi.org/10.1177/1932296814567893>.
- [5] Picard S, Hanaire H, Baillot-Rudoni S, Gilbert-Bonnemaison E, Not D, Reznik Y, et al. Evaluation of the Adherence to Continuous Glucose Monitoring in the Management of Type 1 Diabetes Patients on Sensor-Augmented Pump Therapy: The SENLOCOR Study. *Diabetes Technol Ther* 2016;18(3):127–35. <https://doi.org/10.1089/dia.2015.0240>.
- [6] Cherubini V, Bonfanti R, Casertano A, De Nitto E, Iannilli A, Lombardo F, et al. Time In Range in Children with Type 1 Diabetes Using Treatment Strategies Based on Nonautomated Insulin Delivery Systems in the Real World. *Diabetes Technol Ther* 2020;22(7):509–15. <https://doi.org/10.1089/dia.2020.0031>.
- [7] Diabetes Research in Children Network (DirecNet) Study Group. Youth and parent satisfaction with clinical use of the GlucoWatch G2 Biographer in the management of pediatric type 1 diabetes. *Diabetes Care* 2005;28(8):1929–35. 10.2337/diacare.28.8.1929.
- [8] Hermans N, Kulzer B, Gulde C, Eberle H, Pradler E, Patzelt-Bath A, et al. Short-term effects on patient satisfaction of continuous glucose monitoring with the GlucoDay with real-time and retrospective access to glucose values: a crossover study. *Diabetes Technol Ther* 2009;11(5):275–81. <https://doi.org/10.1089/dia.2008.0078>.
- [9] Beck RW, Lawrence JM, Laffel L, Wysocki T, Xing D et al. Juvenile Diabetes Research Foundation Continuous Glucose Monitoring Study Group; Quality-of-life measures in children and adults with type 1 diabetes: Juvenile Diabetes Research Foundation Continuous Glucose Monitoring randomized trial. *Diabetes Care* 2010; 33(10):2175–7. 10.2337/dc10-0331.
- [10] Franceschi R, Micheli F, Mozzillo E, Cauvin V, Liguori A, Soffiati M, et al. Intermittently Scanned and Continuous Glucose Monitor Systems: A Systematic Review on Psychological Outcomes in Pediatric Patients. *Front Pediatr* 2021;9: 660173. <https://doi.org/10.3389/fped.2021.660173>.
- [11] Rusak E, Ogarek N, Wolicka K, Mrówka A, Seget S, Kuźnik M, et al. The Quality of Life and Satisfaction with Continuous Glucose Monitoring Therapy in Children under 7 Years of Age with T1D Using the rtCGM System Integrated with Insulin Pump-A Caregivers Point of View. *Sensors (Basel)* 2021;21(11):3683. <https://doi.org/10.3390/s21113683>.
- [12] Battelino T, Alexander CM, Amiel SA, Arreaza-Rubin G, Beck RW, Bergenstal RM, et al. Continuous glucose monitoring and metrics for clinical trials: an international consensus statement. *Lancet Diabetes Endocrinol* 2023;11(1):42–57. [https://doi.org/10.1016/S2213-8587\(22\)00319-9](https://doi.org/10.1016/S2213-8587(22)00319-9).
- [13] Mauras N, Beck R, Xing D, Ruedy K, Buckingham B, Tansey M, et al. A randomized clinical trial to assess the efficacy and safety of real-time continuous glucose monitoring in the management of type 1 diabetes in young children aged 4 to <10 years. *Diabetes Care* 2012;35(2):204–10. <https://doi.org/10.2337/dc11-1746>.
- [14] Tsalikian E, Fox L, Weinzimer S, Buckingham B, White NH, Beck R, et al. Feasibility of prolonged continuous glucose monitoring in toddlers with type 1 diabetes. *Pediatr Diabetes* 2012;13(4):301–7. <https://doi.org/10.1111/j.1399-5448.2011.00837.x>.
- [15] Farrington C. Psychosocial impacts of hybrid closed-loop systems in the management of diabetes: a review. *Diabet Med* 2018;35(4):436–49. <https://doi.org/10.1111/dme.13567>.
- [16] Von dem Berge T, Remus K, Biester S, Reschke F, Klusmeier B, Adolph K, et al. In-home use of a hybrid closed loop achieves time-in-range targets in preschoolers and school children: Results from a randomized, controlled, crossover trial. *Diabetes Obes Metab* 2022;24(7):1319–27. <https://doi.org/10.1111/dom.14706>.
- [17] Messer LH, Campbell K, Pyle L, Forlenza GP. Basal-IQ technology in the real world: satisfaction and reduction of diabetes burden in individuals with type 1 diabetes. *Diabet Med* 2021;38(6):e14381.
- [18] Mozzillo E, Marigliano M, Troncone A, Maffei C, Morotti E, Di Candia F, et al. Italian translation and validation of the CGM satisfaction scale questionnaire. *Acta Diabetol* 2023 Feb 20. <https://doi.org/10.1007/s00592-023-02043-w>.
- [19] Lukács A, Szerencsi LB, Barkai L. Continuous glucose monitoring (CGM) satisfaction and its effect on mental health and glycemic control in adults with type 1 diabetes. *Physiol Int* 2022;109(4):501–10. <https://doi.org/10.1556/2060.2022.00125>.
- [20] Wysocki T, Reeves G, Kummer M, Ross J, Yu M. Psychometric validation of the Diabetes technology questionnaire. *Diabetes* 2015;64:A633–A.
- [21] Tansey M, Laffel L, Cheng J, Beck R, Coffey J, Huang E, et al. Satisfaction with continuous glucose monitoring in adults and youths with Type 1 diabetes. *Diabet Med* 2011;28(9):1118–22. <https://doi.org/10.1111/j.1464-5491.2011.03368.x>.
- [22] Frielitz FS, Müller-Godeffroy E, Hübner J, Eisemann N, Dördelmann J, Menrath I, et al. Monthly Video-Consultation for Children With Type 1 Diabetes Using a Continuous Glucose Monitoring System: Design of ViDiKi, a Multimethod Intervention Study to Evaluate the Benefit of Telemedicine. *J Diabetes Sci Technol* 2020;14(1):105–11. <https://doi.org/10.1177/1932296819861991>.
- [23] Tornese G, Schiaffini R, Mozzillo E, Franceschi R, Frongia AP, Scaramuzza A. The effect of the COVID-19 pandemic on telemedicine in pediatric diabetes centers in Italy: Results from a longitudinal survey. *Diabetes Res Clin Pract* 2021;179: 109030. <https://doi.org/10.1016/j.diabres.2021.109030>.
- [24] Tornese G, Schiaffini R, Mozzillo E, Franceschi R, Frongia AP, Scaramuzza A. Telemedicine in the Time of the COVID-19 Pandemic: Results from the First Survey among Italian Pediatric Diabetes Centers. *Healthcare (Basel)* 2021;9(7):815. <https://doi.org/10.3390/healthcare9070815>.
- [25] Rabbone I, Minuto N, Bonfanti R, Marigliano M, Cerutti F, Cherubini V, et al. Insulin pump failures in Italian children with Type 1 diabetes: retrospective 1-year cohort study. *Diabet Med* 2017;34(5):621–4. <https://doi.org/10.1111/dme.13294>.