

The impact of new continuous glucose monitoring (CGM) devices versus self-management of blood glucose (SMBG) on the daily life of parents and children affected by type 1 diabetes mellitus

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Abstract

Background: Type 1 diabetes mellitus is a chronic autoimmune endocrine and metabolic disease which frequently occurs during infancy and childhood. Self-monitoring of blood glucose (SMBG) is of utmost importance to achieve good glycemic control. Common side effects of SMBG in children are pain, discomfort, skin induration, and reduced tactile sensitivity; moreover, SMBG does not allow continuous glycemic monitoring. The more recent introduction of much less invasive devices for continuous glucose monitoring (CGM) has indeed reduced procedure-related pain and discomfort, and allowed real-time glycemic monitoring.

Methods: From the beginning of May to the end of September 2019, we conducted a survey by means of a two-section (children/parents) questionnaire, aimed at assessing the impact of CGM on children affected by type 1 diabetes mellitus and their families, referring to the Pediatric Diabetes outpatient clinic at Guglielmo da Saliceto Hospital in Piacenza, Italy.

Results: The vast majority (80%) of children reported that the placement of the glycemic sensor is much less painful than fingertip multiple capillary punctures, as with traditional SMBG. Likewise, 90% of parents think that the use of CGM devices allowed a remarkable improvement of glycemic control, with regard either to the reduction of hypo- and/or hyper-glycemic episodes or to glycated hemoglobin (HbA1c) level. Moreover, 89% of parents believe that the use of glycemic sensors has led to a sharp improvement in children's quality of life. According to children, school and sport are the two areas with the most evident improvement of their quality of life; less anxiety, high comfort and better glycemic control, particularly when not at home, have been indicated as major benefits.

Conclusions: According to our data, the use of CGM devices can significantly improve the quality of life of type 1 diabetic children and their families.

Keywords

Type 1 diabetes mellitus, children, CGM, SMBG, quality of life, glycemic control.

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Introduction

Type 1 diabetes mellitus is a chronic autoimmune endocrine and metabolic disease, the incidence of which is increasing worldwide, and it is nowadays the most frequent endocrine disease within the pediatric age.

This condition significantly affects children's daily life, as it involves frequent and painful glycemia tests by means of self-monitoring of blood glucose (SMBG) devices, in order to achieve and maintain good glycemic control [1-4].

Since the early 2000s, new devices for glucose monitoring, known as continuous glucose monitoring (CGM), have become available on the market; currently, the FreeStyle Libre [5, 6], the Dexcom G5® Mobile [7], and the MiniMed™ 640G [8, 9] seem to be the most commonly utilized systems.

The use of such systems has allowed diabetic patients to obtain continuous information about their glycemic values, unlike traditional SMBG devices, which in turn provide only intermittent glycemic values. Moreover, CGM devices allow to recognize risky events, such as hypoglycemia and hyperglycemia, in real-time and to use the collected data both retrospectively to adjust the therapy and prospectively, providing a forecast of the glycemic value in the immediate future, thus giving the possibility to intervene in advance [10, 11].

The use of CGM devices has therefore greatly improved glycemic control, especially in the pediatric age; this can be, sure enough, particularly difficult during infancy and childhood due to different causes such as sports, nutrition, psychopathological conditions and hormonal alterations, typical of adolescence, that cause a considerable glycemic variability [11].

Besides improving glycemic control, these new devices have significantly improved glycated hemoglobin (HbA1c) levels and reduced pain, discomfort and disturbance during the nocturnal checks when compared to traditional fingersticks and allowed greater flexibility of the daily life [12].

The use of CGM devices appears, however, to be limited, due to some barriers that may inhibit young people from their use [13]. With regard to this issue, the main areas of dissatisfaction concern mechanical problems such as sensor alarms that interfere with the daily routine [12], the need for multiple SMBG tests for calibration every 12 hours and 2 hours after using a new sensor, the need for periodic replacement of the sensor, and emotional problems related to pain at the time of its insertion and placement [11, 13, 14]; other obstacles to their use are the size of the sensor, skin reactions related to the use of the band-aid and all those problems belonging to the psycho-social sphere, such as anxiety, the intrusiveness of third people and concern about body image [12, 13].

However, it is of interest that the concern for the body image is not so much reported by children and/or adolescents but by the parents [12], who perceive these devices as intrusive, as they may not preserve the confidentiality of the child and his illness.

Methods and subjects

From May throughout September 2019, we conducted a survey at the Pediatric Diabetes outpatient clinic of the Pediatrics & Neonatology Unit at Guglielmo da Saliceto Hospital in Piacenza, Italy.

Thirty-six children and adolescents up to 18 years (mean age: 11.05 years \pm 4.01 SD; 17 males, mean age 10.56 years \pm 4.21 SD; 19 females, mean age 11.45 years \pm 3.80 SD) suffering from type 1 diabetes mellitus, and carriers of glycemic sensors (FreeStyle Libre [n = 23], Dexcom G5® [n = 2], MiniMed™ 640G Integrated System [n = 11]), and their parents were enrolled. Of these, 25 were on a multiple daily insulin injections regimen, whereas 11 were on insulin pump therapy (**Tab. 1**).

Table 1. Characteristics of our study population.

Study population	Number	Age (years), mean \pm SD
Overall	36	11.05 \pm 4.01 (range 2-18)
Males	17	10.56 \pm 4.21 (range 2-18)
Females	19	11.45 \pm 3.80 (range 3-17)
Freestyle Libre	23	11.01
Dexcom G5®	2	6.0
MiniMed™ 640G Integrated System	11	10.18
On insulin pump therapy	11	10.18

A two-section non-validated questionnaire (one section for children/adolescents and one for their parents) was proposed and administered prior to and after medical examination, during routinely planned follow-up visits.

The patients-focused section included 13 questions (**Tab. 2**), whereas the one dedicated to their parents consisted of 8 questions (**Tab. 3**), aiming at investigating the impact of new CGM devices on the lives of diabetic children and their families, compared to traditional SMBG. Most of

the questions included were “closed”, meaning that a YES/NO answer was required.

Data analysis from the two sections was carried out separately by a skilled psychologist; comparable data from each section were then cross-matched, in order to evaluate both patients’ and parents’ perceptions about new CGM devices. The questionnaire forms were numbered and recorded on an Excel® database; each of them reported patients’ age and gender.

Information about the current Privacy Law (according to the Legislative Decree 196/2003), regulating personal data protection, was provided to patients’ parents prior to the administration of the questionnaires. Such information included the following sentence: “The questionnaire is anonymous, and data will be utilized just for statistical purposes. The consent to data utilization is considered as implicit in the agreement of filling in the questionnaire”.

According to the local Ethics Committee (EC) guidelines, the study was not submitted to EC approval as it contains anonymous data from deidentified subjects, nor the enrolled subjects may be identifiable, even by cross-matching different data, e.g., gender, age or date of birth.

Table 2. Section 1 of the questionnaire, administered to children/adolescents.

Patient's age			
Gender	Female	Male	
Questions			
1. Is subcutaneous sensor for CGM less painful than fingers' blood glucose monitoring?	Yes	No	
2. Have you noticed an improvement since using CGM in finger skin (bruise, lipodystrophies)?	Yes	No	
3. Since having used the CGM, have you found that your fingertips are more sensitive than when using the lancing device?	Yes	No	
4. Looking at yourself in the mirror, does the presence of the sensor bother you?	Yes	No	
5. Did you notice red skin around the patch that secures CGM?	Yes	No	
6. Since having used CGM, have you had difficulty showering or bathing?	Yes	No	
7. Since having used a blood glucose sensor, have you been able to do sports (swimming, football, dance)?	Yes	No	
8. Do classmates ask you questions to find out what the sensor is and how does it work?	Yes	No	
If so, does it bother you?	Yes	No	
9. When CGM's alarm sounds:	You know what to do	You get scared	You worry
10. Who told you about CGM for the first time?	Nurse	Doctor	Other: _____
11. Who taught you how to use CGM?	Nurse	Doctor	Other: _____
12. Do you feel satisfied with your CGM?	Yes		No
13. Do you think your parents are satisfied with your CGM?	Yes		No

CGM: continuous glucose monitoring.

Table 3. Section 2 of the questionnaire, administered to parents.

Parent	Mother	Father
Questions		
1. Since your child has used CGM, have you noticed an improvement in glycemic compensation (hypoglycemia, hyperglycemia, average blood glucose level)?	Yes	No
2. Is the presence of alarms (hypoglycemia/hyperglycemia) a source of anxiety and concern for you?	Yes	No
3. With the use of CGM, have you perceived an improvement in yours and your child's quality of life (e.g., sports, school, vacation, etc.)?	Yes	No
If so, which one?		
4. Does the presence of the CGM visible on your child's body bother you?	Yes	No
5. Is the management of the CGM (hygiene rules, set change) difficult and complex for you?	Yes	No
6. Have you received a complete therapeutic education in the use/management of this device?	Yes	No
If so, by whom?	Nurse	Doctor
		Other: _____
7. Are you satisfied with your CGM?	Yes	No
8. Do you think your children are satisfied with your CGM?	Yes	No

CGM: continuous glucose monitoring.

Results

Thirty-six patients took part in the survey. Patients' and parents' answers to our survey questions are summarized in **Tab. 4** and **Tab. 5**, respectively.

The vast majority (80%) of participants said that the placement of the glycemic sensor was less painful than the multiple capillary injections by means of the traditional fingerstick, while the remaining 20% did not perceive this painful symptoms reduction; it is worthy of mention that this latter group of patients had a mean age of 5 years, thus less able to assess the most appropriate level of pain intensity than those in the former 80% group (mean age of 12 years), likely more aware of pain perception and with higher pain tolerance. As for gender stratification, 18/19 females (mean age 11.6 years) reported pain reduction, compared with 12/17 males (mean age 12.6 years); the remaining female was 3 years old, whereas the mean age of the 5 remaining males was 6.5 years.

Almost all (92%) children noticed an improvement in their fingertips skin (ecchymosis, skin hardening), thanks to the use of a CGM device; among these, 15/17 males (mean age 10.3 years) and 18/19 females (mean age 11 years). The remaining 2 males had a mean age of 14.5 years, whereas the last female was 16 years old.

As for the improvement of the fingertips tactile sensitivity, 89% of children (14/17 males, mean age 9.7 years; 18/19 females, mean age 10.8 years) said they perceived a clear improvement by using CGM devices; the remaining female was 17 years old, and the 3 males had a mean age of 16 years.

The question about the perception of the body image related to the visibility of the device has been addressed to both children and their parents; 20% of children admitted to being annoyed by this visibility, while the remaining 80% were totally indifferent. In particular, among children who felt annoyed by the visibility of the device, 43% were females, with a mean age of about 14 years, while the remaining 57% of males had a mean age of about 10 years.

Asking about skin reactions related to the use of the band-aid that fixes the sensor, it emerged that exactly half (50%) of the study participants noticed a skin reddening, while the remaining 50% never reported this kind of event.

With regard to hygienic habits (shower, bathtub), only 11% of children had difficulty in taking a shower or bath using a CGM device, while the majority (89%) did not report this type of difficulty.

As for the alarms of the glycemic sensor, 46% of 13 children using Dexcom G5® and MiniMed™ 640G devices (i.e., those devices provided with alarms) were frightened by the sound activation (average age 6 years), while the remaining 54% (average age 14 years) reported knowing how to cope with the sound. When asked the same question, 54% of parents answered that the alarms of CGM devices are not a source of anxiety and concern, while the remaining 46% stated the opposite. Of those reporting anxiety, 3 had a male child (1 child < 6 years of age, 2 aged 12-18 years) and 3 a female child (2 children < 6 years of age, 1 aged 12-18 years), respectively.

Table 4. Patients’ perception about aspects and effects of the use of continuous glucose monitoring (CGM) devices.

Questions	Yes (%)	No (%)
1. Pain reduction	80	20
2. Fingertips skin improvement	92	8
3. Fingertips skin sensitivity	89	11
4. Worsening of body image self-perception	20 (43 F; 57 M)	80
5. Skin reddening around the patch	50	50
6. Difficulty in bathing or showering	11	89
7. Possibility to do sport activities	94	6
8. Queries from the classmates	89	11
Any bother? Yes/No	28/72	-
9. Ability of management of acoustic alarm	54	46
10. Information received by the doctor	72	28
11. Training by the doctor/nurse	64	36
12. Satisfaction with CGM device	97	3
13. Perception about parents’ satisfaction	97	3

CGM: continuous glucose monitoring.

Table 5. Parents’ perception about aspects and effects of the use of continuous glucose monitoring (CGM) devices.

Questions	Yes (%)	No (%)
1. Improvement of glycemic compensation	94	6
2. Concern about acoustic alarms	46	54
3. Improvement of self and children’s quality of life	89	11
4. Bother from the presence of CGM device	20	80
5. Concern about management of CGM device	6	94
6. Education about the management of CGM device	89	11
By the doctor/nurse	78	22
7. Satisfaction with CGM device	97	3
8. Perception about children’s satisfaction	94	6

CGM: continuous glucose monitoring.

Overall, 97% declared to be satisfied with the use of CGM.

When parents were asked about the improvement of their kids’ glycemic control after using the CGM device, 94% of them declared to have noticed an improvement, while 6% did not (**Fig. 1**). Among these, 16 had a male child (2 children < 6 years of age, 8 aged 6-11 years, and 6 aged 12-18 years) and 18 a female one (2 children < 6 years of age, 5 aged 6-11 years, and 11 aged 12-18 years).

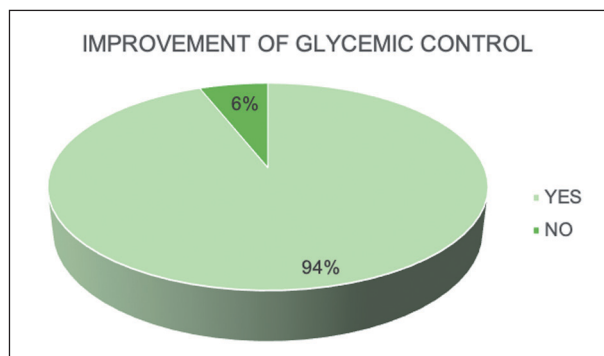


Figure 1. Percentage of parents reporting perception of glycemic control improvement in their children.

The parents’ perception of a clear improvement in both self and their kids’ quality of life was reported in 89% of cases (**Fig. 2**). Of these, 16 had a male child (2 children < 6 years of age, 9 aged 6-11 years, and 5 aged 12-18 years; mean age 10.5 years) and 16 were parents of a female child (2 children < 6 years of age, 5 aged 6-11 years, and 9 aged 12-18 years; mean age 10.5 years). Those not reporting any improvement were parents of a 16-year-old male and of 3 females with a mean age of 14.6 years.

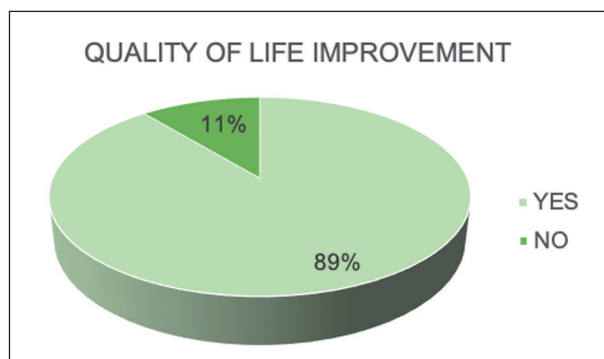


Figure 2. Percentage of parents reporting perception of improvement in their own and their children’s quality of life.

Major areas of patients’ satisfaction are shown in **Fig. 3**.

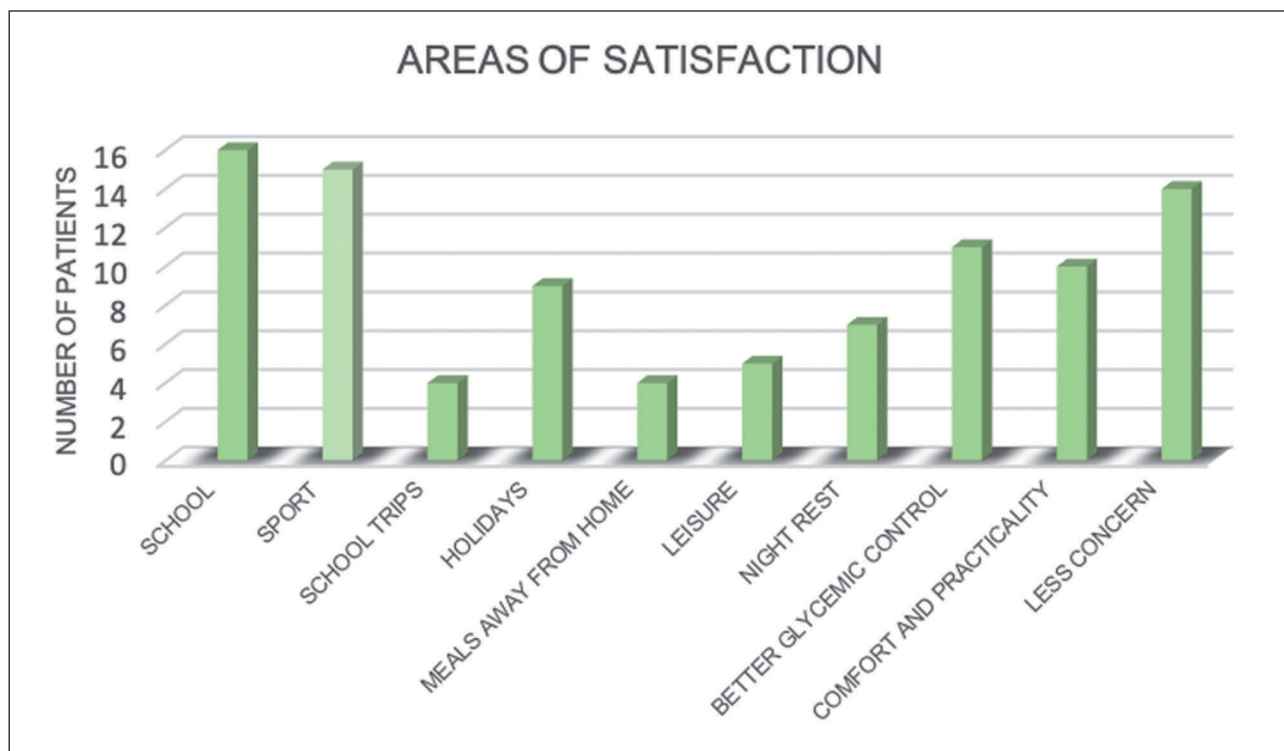


Figure 3. Number of patients reporting benefits and greater satisfaction by the use of continuous glucose monitoring (CGM) devices in different aspects of daily life.

Discussion and conclusions

On average, at the age of 11 years (the mean age of our study population), children begin to achieve greater autonomy and awareness about the use/management of the glycemic sensor, including setting and hygienic procedures.

In our survey, FreeStyle Libre was revealed to be the most used CGM device by children/teenagers up to 11 years of age; indeed, this choice, not surprisingly, may be closely related to an economic issue, as its cost is no longer covered by the National Health System from the age of 12 years onwards, thus being borne by the family.

The MiniMed™ 640G Integrated System is a more complex device than FreeStyle Libre, as it also requires the ability to manage the insulin pump for the management of insulin therapy. This device reduces the painful sensitivity, as the glycemic sensor can remain in place over 6 days, though the change set of the insulin pump takes place every 3 days. Moreover, this device may further reduce the risk of hypoglycemia as it is provided with the low glucose suspend (LGS) and predictive low glucose suspend (PLGS) integrated systems able to suspend the basal insulin in case blood glucose falls below a predefined limit.

The Dexcom System is used by younger children (mean age 6 years); this is maybe related

to the parents' desire to have a CGM device that allows to detect and report risky episodes, such as hypoglycemia and hyperglycemia via acoustic alarms, without giving the child the commitment to manage a more complex CGM system.

An interesting aspect is the perception of the child's body image related to the visibility of the glycemic sensor; among children who declared to have their body image compromised, 57% is represented by males with a mean age of 10 years, whereas female teenagers (mean age: 14 years) represent a minority.

This is particularly weird, as it is well known that the adolescence period is characterized by remarkable growth and physical change, which also includes the maturation of sexual characteristics and psycho-emotional sphere; this often leads adolescents, mostly females, to rework and not accept their own body image. Therefore, the visibility of the glycemic sensor, especially in girls, should be expected to be felt like a further body image compromise.

When we asked parents the same question concerning the device's visibility, some of them answered that they considered it as "intrusive", not so much for a purely esthetic issue, rather because it makes the disease more manifest.

With regard to the concern for skin reactions related to the use of the band-aid that fixes the

glycemic sensor, these seem to be unrelated to the patient's age; rather, they may be simply due to an individual's more sensitive skin.

Among children using CGM devices with acoustic alarm, 46% (mean age 5 years) declared to be frightened due to a lack of autonomy in the management of episodes of hypoglycemia/hyperglycemia, whereas 54% (mean age 14 years) knew how to manage the alarm, having achieved a greater awareness and autonomy.

The same percentages applied to parents; it emerged that the younger the child is (on average 9 years old), the more alarms are a source of concern, whereas the older the child is (average age 14 years), the more anxiety and concern about alarms are reduced drastically.

A recent data analysis [15-17] showed that the use of CGM devices improved well-being and alleviated the fear and concern of hypoglycemia, both for patients and parents.

According to 94% of parents, the use of the CGM devices allowed a clear improvement of the glycemic control both for the reduction of risky episodes and for the value of HbA1c. Recent studies [17-19] have shown how CGM technology can reduce the incidence of hypoglycemia, also improving the levels of HbA1c.

Interestingly, 89% of parents believe that the use of the glycemic sensor has allowed them to achieve a noticeable improvement in their quality of life.

According to children's opinion, school and sport turned out to be the areas where parents noted an obvious improvement in the quality of life; according to parents, convenience and comfort and better glycemic control, especially when away from home, turned out to be the main benefits. Indeed, these devices allow for extemporary measurements that do not imply having all the necessary tools (glucometer, finger pricks, disinfectant, cotton) always available, as for traditional SMBG detectors.

Summer holidays, school trips, and meals out of the home are further areas of quality of life improvement highlighted by the parents.

Finally, a noticeable improvement of night rest has been reported; indeed, unlike SMBG, CGM devices enable patients to detect glycemia without the need to interrupt children's sleep. With regard to this issue, a very recent study [20] demonstrated that sleep disorders can have a negative impact on diabetes management and overall well-being. Moreover, this study showed that the use of CGM devices is useful to avoid interrupting a child's night

sleep, meanwhile allowing parents to have a less disturbed night rest as they do not need to perform periodic nocturnal glycemic checks.

In conclusion, according to our survey, CGM devices clearly improved both the glycemic balance and the quality of life perceived by diabetic children, adolescents and their parents.

Though we recognize that our study has some limitations, such as the limited number of patients enrolled and the use of a non-validated questionnaire, we would like to point out some strengths as well, which may be summarized as follows:

- our study is one of the very few papers in the literature focused on CGM use in children and/or adolescents affected by type 1 diabetes;
- though non-validated, the survey was designed to have two different sections, tailored both for young patients (using simple questions and emoticons for a better understanding) and parents;
- unlike most previous studies focused on just one device, we considered the effects of three different CGM devices (FreeStyle Libre, MiniMed™ 640G, Dexcom G5® Mobile);
- several areas of possible effects were analyzed, such as: the improvement of fingertip tactile sensitivity; the reduction of HbA1c levels and of risky episodes; the self-image perception (to our knowledge, never previously reported in the literature); the patients' and parents' experience about the presence of device; the effects on daily life (e.g., sports activity, school attendance, school trips, meals away from home, nocturnal sleep); the patients' and parents' reaction to an alarm sound; and, finally, the economic aspects possibly influencing the choice of a given device.

Declaration of interest

The Authors declare no conflict of interest.

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