Benefits and Drawbacks of Continuous Glucose Monitoring (CGM) Use in Young Children With Type 1 Diabetes: A Qualitative Study From a Country Where the CGM Is Not Reimbursed

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Abstract
Investigating the daily life experiences of patients using Continuous Glucose Monitoring (CGM) can highlight the benefits and barriers in using this system for people with type 1 diabetes (T1D). Semi-structured qualitative interviews were conducted with the caregivers of 10 children aged <9 years, all of whom had been treated for T1D and had used CGM >6 months. These interviews were analyzed using the content analysis approach and from these interviews, four meta themes emerged: metabolic control, barriers to CGM use, CGM use in daily life, and comparison with fingersticks. Families reported the following as benefits of CGM: pain relief, better hypoglycemia and hyperglycemia management, increased control over diet and social life, reduced worries at school and during the night, and convenience in entrusting the child to the care of others. Cost, concerns related to accuracy and reliability of measurements, insertion, adhesion and removal issues all emerged as barriers to CGM use. The most prominent issue was the economic burden of CGM. Families accept this burden, even though it is challenging, as their experiences in using CGM are positive and they feel that CGM is necessary for T1D management.

Keywords
Type 1 diabetes, continuous glucose monitoring, qualitative methods, family experiences, young children

Introduction
Comparative studies have shown that continuous glucose monitoring (CGM) systems can provide better glycemic control in type 1 diabetes (T1D) management than self-monitoring of blood glucose (SMBG), regardless of multiple daily injections or insulin pump therapy (1,2). The T1D Exchange study showed that the use of CGM in the US increased from 7% to 30% between 2010–2012 and 2016–2018. This increase was even more dramatic in younger age groups with <6 and 6–12 age groups increasing from 4% to 51% and from 3% to 37%, respectively (3). The Diabetes Prospective Follow-up Registry (DPV) study in Germany reported CGM use as being 44% in 2017 (4). Although CGM provides better quantitative data on glycemic and metabolic control, the prevalence of use is below 50%. To explain this situation, it is necessary to understand the experience, psychosocial and economic factors related to the use of CGM. Qualitative studies can report experiences through ‘patient-reported outcomes’ which provide a wider perspective of CGM use (5). In recent years, qualitative CGM studies have been conducted to determine the benefits and insufficiencies of CGM use in countries with a partial or

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full state reimbursement, and some have focused on specific age groups (6–11).

CGM experiences and its effect on users’ lives differ among age groups. T1D management in young children sees difficulties such as variable glucose fluctuations, resistance to painful fingerstick tests and the inability to recognize symptoms of hypo/hyperglycemia, all of which cause distress to parents cumulatively (7). Therefore, CGM’s place in T1D management is different for young children. Moreover, since children are not able to undertake their T1D management themselves, all the effort and responsibility lies with their caregivers. The fact that the social environment, school life and daily activities of children are different from those of adolescents and adults, also contributes to CGM interactions being different for children.

No CGM experience has been reported from countries where the cost of CGM was not reimbursed. Additionally, only a few studies have investigated the CGM experiences and specific needs of young children and their parents (7,11).

This study aims to analyze the experiences of children with T1D and their caregivers as well as their perceived benefits, barriers, and specific needs regarding use of CGM in Turkey. The results of the study can provide guidance for countries where CGM is not reimbursed and patient-reported data on CGM use are limited.

### Methods

The inclusion criteria of this qualitative study were that the child was under the age of 9, had been treated for T1D for at least 6 months and had used CGM for at least 6 months, HbA1c <10.5% in the past 90 days, and they had been followed up in the same department.

The study was conducted in the Pediatric Endocrinology Department of a University Hospital. The research team contacted the parents via routine follow-up visits, appointments were made, and verbal consents were obtained. All contacted caregivers agreed to participate in the study. The study was explained to the interviewees and consent was obtained for audio recording. The interviews were conducted in the clinic by two researchers: a fourth-year medical student with T1D and a researcher experienced in conducting in-depth interviews. A semi-structured interview guide was developed based on literature reviews and contributions from clinical-researcher members. Through the interview guide, participants were asked about their CGM experiences in terms of ease of use, benefits, barriers to use, hypoglycemia & hyperglycemia experiences, impacts on daily T1D management including evenings and school times. The interviews lasted 42 minutes on average. After 10 interviews, the research team decided to stop interviewing due to data saturation.

| Table 1. Sample Questions of Semi-Structured in-Depth Interviews. |
|---------------------------------------------------------------|
| **Opening questions**                                         |
| • How did you feel when the diagnosis was made? What did you do? |
| **Main topics**                                               |
| Glucose measurements experiences                              |
| Can you tell us about your experiences with glucose measurement? |
| Who is doing it, how was this decision made?                   |
| Have you ever experienced severe Hypo or hyperglycemia?       |
| When did it happen; tell us a bit how did you manage, how did you feel? |
| **Management at night**                                       |
| How do you measure glucose at night? What are the problems, have things changed in night management over time? (as a feeling, as a measurement frequency, etc.) can you tell? |
| **Daytime/School management**                                  |
| Can we talk about your T1D experience at school?              |
| **Opinions on the use of CGM**                                |
| Can you tell us about your positive and negative opinions/ experiences about CGM? |
| **Closing question(s)**                                       |
| • Is there anything else you want to say about the use of CGM? |
List of the questions that guided the semi-structured interviews is shown in Table 1.

The audio records of the interviews were transcribed by four researchers, mostly on the same day the interview was held. The transcripts were double-checked against the audio records by one researcher to prevent data loss. The transcripts were analyzed using MAXQDA 2020 software based on content analysis. The interviews were coded by two researchers and the agreement between the two coders was checked. In case of a disagreement, researchers further discussed code differences to reach a consensus. Both deductive and inductive coding were used (6–8). After completing the coding, codes were categorized, and themes were formed.

After the code list was created, we used the main topics in the semi-structured interview form as a guide to classify codes and create themes.

Results
A total of 15 caregivers of 10 children were interviewed, including 3 mothers, 1 father, 1 aunt and 5 sets of parents (both mother and father). The children’s characteristics are given in Table 2. Seven were female, the mean age at interview was 68 months with a mean T1D duration of 23 months (9–49 months). Mean CGM duration was 19 months (9–34 months) and mean HbA1c measurement was 6.81% (5.9%–8.2%). Five children had started using CGM in the same month of diagnosis. Two children were under IIP (insulin infusion pump) and the other eight were under (MDI) Multiple Daily Injections. The brands of CGMs used by the participants varied.

Based on content analysis, four meta-themes emerged from the interviews: metabolic control, barriers to CGM use, CGM use in daily life, and comparison with fingersticks.

Metabolic Control
Most caregivers reported that the alarm function of the CGM system provided significant support in the management of hypo and hyperglycemia through early intervention, thus reducing the duration and severity of these events. Caregivers also noted that arrows help parents detect trends, determine the correct time and dosage when intervening, thus preventing under/over treatment. The trend arrows show postprandial course and the effects of insulin and food on glucose levels. Therefore, interpreting trends is an essential element of making decisions and interventions.

“It (CGM) affects my management a lot, because at least it shows what this (glucose level) will be. For example, if you are driving in a car, if there is no arrow or sign in front of you, how do you know where to go? But, thanks to these arrows, I know where to go. They guide me.” – Interview#7

I’m a little calm in hypo, but that’s also thanks to technology. I wait 15 min after hypo treatment. If it does not rise, I give more carbs and see how it is going. I have to react a little faster if it is down 20 mg. If it is down 5 mg, it may fall or turn, I keep an eye on the CGM a little more.” – Interview#10

Families reported that the trending function increased overall control over glucose and therefore reduced parents’ anxiety. However, some families reported pressure and anxiety as the arrows showed them the risk of hyperglycemia.

Barriers to CGM Use
Caregivers reported three main drawbacks regarding CGM use: cost, concerns with accuracy & reliability, and insertion, adhesion, and removal difficulties.

Cost
Families reported that CGM was a significant financial burden and they made sacrifices to cover its cost as they saw CGM as a must. All families emphasized the importance of including CGM in the state reimbursement system. Moreover, they stated they felt sorry for other families who could not afford the system.

“...At that time, I thought, there are families that cannot afford (CGM), it's very difficult. There are children who cannot use CGMs, what are these mothers doing? How does a mother understand? How long have children been suffering from hypoglycemia? I felt the pain of this ... Besides, what if there are 2 children with diabetes in the same family. Economic income is limited in Turkey and I wondered what these kids are doing.” – Interview#7

Concerns With Accuracy and Reliability
All participants reported they experienced differences between CGM and SMBG measurements. However, most of them did not perceive this as a major problem. Initially, families were more skeptical about CGM’s results reliability, but over time this suspicion subsided.

Multiple families reported that CGM was less reliable out of the target range. CGM showed lower measurements compared to SMBG during hypoglycemia, which worried families.

“...For example, CGM shows a low measurement, when I check the blood, it measures 100 or so. If I do not check the finger, I will make the child eat or drink carbs for nothing. ... those differences scare us.” – Interview#3

The important benefits of CGM, such as early recognition and early intervention of hypo- and hyperglycemia, make the less accurate results of CGM compared to SMBG acceptable to families.
CGM is not perfect or 100%, but these little mistakes are no bigger than the ones you would encounter without CGM.

Interview #10

**Insertion, Adhesion and Removal Difficulties**

Families noted that children worried about insertion and did not want to use CGM at first. However, almost all children got used to wearing the CGM, and over time their anxiety subsided. Families reported that the placement experience differs by brand.

Parents stated their worries about reduced stickiness of the sensor tapes and peeling of adhesives due to increased sweating and swimming in summer. Since CGMs are expensive and their adhesives are not strong enough, most of the participants noted that they use extra adhesives to protect the CGM from water, impacts, and becoming dislodged. Half of them reported skin irritations, itching, and sweating because of using extra adhesives.

“I manage somehow while taking a bath. But it changes a lot when there is a pool or the sea. We need to use waterproof, hospital-used transparent tapes. However, removing it irritates her skin…but it is not possible to fix CGM without the tape, otherwise it does not measure correctly. I never believe what they say about water not entering.”

-Interview #1

Families reported no major problems during removal. However, extra adhesives increased the depilation area and caused pain during removal. Families reported using baby oil, creams, and sprays for a more comfortable removal.

**CGM Use in Daily Life**

The effects of CGM use in daily life focused on diet, social life, management at school, management at night, convenience in entrusting the child, and increased flexibility in daily life in general.

Families reported that they allow their children to eat more freely with CGM, while their control over foods and their effects increased. Parents also noted that they can observe and understand the effects of foods separately, and how they increase glucose levels.

“Just 15 min after meals, you can see the course of the food if it is something that increases rapidly. You can instantly observe the results of feeding.”

-Interview #8

Families noted that children did not want to talk about their diabetes and CGM at first and hid them. However, children usually received positive and supportive reactions about diabetes and CGM from their friends.

“Her neighbor friend asked, ‘what is this, what is on your arm?’ She answered, ‘It’s my sensor, we are together all the time.’ Then, they moved on. When she went to nursery, her friends asked her too, she answered ‘this is my shell of power’. There is nothing negative.”

-Interview #9

Parents also noted that CGM with remote monitoring helps a child to stay with her/his friends during playtime without any interruption. Remote monitoring together with an alarm system also help teachers to reduce their worries about diabetes care at school.

“CGM provides tremendous comfort in active lessons such as physical education, dancing, and ice skating. It is a great advantage to be able to measure without separating the child from the environment.”

-Interview #3

The families reported that they suffered a seriously degraded quality of sleep before using CGM. Families reported that they still woke up often, but measuring

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**Table 2. Characteristics of Children (n = 10).**

| Interview # | Age at Diagnosis (Months) | Duration of T1D (Months) | Age at Interview (Months) | CGM Use (Months) | HbA1c(%) | CGM brands and models |
|-------------|---------------------------|--------------------------|--------------------------|-----------------|----------|----------------------|
| Interview 1 | 21                        | 14                       | 35                       | 14              | 7.8      | Dexcom G4            |
| Interview 2 | 52                        | 26                       | 78                       | 14              | 6.8      | Freestyle Libre 1    |
| Interview 3 | 46                        | 34                       | 81                       | 29              | 6.5      | Freestyle Libre 1    |
| Interview 4 | 39                        | 23                       | 63                       | 20              | 6.9      | 6 months Libre 1, 1 Year Medtronic |
| Interview 5 | 47                        | 49                       | 97                       | 34              | 8.2      | 3 months Libre 1, 2.5 years Medtronic |
| Interview 6 | 33                        | 26                       | 59                       | 26              | 6.6      | Freestyle Libre 1, 1-year Libre, 1-year Dexcom G4 |
| Interview 7 | 46                        | 23                       | 70                       | 23              | 6.8      | 1-year Libre, 1-year Dexcom G4 |
| Interview 8 | 49                        | 11                       | 61                       | 11              | 6.4      | Freestyle Libre 1, Medtronic |
| Interview 9 | 27                        | 11                       | 39                       | 11              | 6.3      | Medtronic            |
| Interview 10| 90                        | 9                        | 100                      | 9               | 5.8      | Dexcom G4 and G6     |
| Average     | 45                        | 23                       | 68                       | 18              | 6.81     |                      |
became easier. Those using CGM with an alarm feature stated CGM reduces the loss of control at night and gives confidence and comfort.

“I was checking his blood glucose before he went to bed. I was checking again at 12 am. At 3 am I was sure to set an alarm and check again. I was sleepless for 1 year. We were checking (SMBG) 6–7 times at night or every 2 h or so. Nothing like that since we switched to the CGM, it gives warnings of ups and downs once or twice a night. Our sleep patterns are now back to normal. -Interview#4

The families also spoke about entrusting their children to grandparents and teachers. With the use of CGM, Grandparents’ anxiety regarding management of the disease was reduced. Families reported that while CGM liberates children, flexibility also reduces the anxiety of families.

**Comparison With Fingersticks**

When comparing the two systems, the most prominent factor was the drop in fingerstick usage of children with CGM. Most families stated that CGM reduced the number of fingersticks used to 2–4 per day compared to SMBG, and some days none were used at all. Families emphasized that the sensor was not a luxury, but a necessity and they could not imagine a life without a sensor. They said that although it was expensive, they would try to get a CGM because they could not bear continuing to pierce their children’s fingers.

“Even if you measure it from the finger, you want to measure it again after 15 min… This time, her fingertips were hurt so much that she could not hold her toys… She was trying to hold it with her elbows. But I couldn’t stop taking measurements, I was afraid that I was going to lose her.” -Interview 7

This was so difficult for families that some said they wanted to experience the pain by piercing their own fingers.

**Discussion**

In this study, the families of 10 young children diagnosed with T1D were interviewed and their CGM experience was evaluated from their perspective. The results showed that families generally found CGM use more advantageous than SMBG. The main advantages were a decrease in the number of fingersticks used and in pain, a decreased anxiety in daily life -especially in terms of diet, school times and sleep at night - and when entrusting the child to someone else’s care.

The most frequently reported obstacle to using CGM was its high cost due to lack of state reimbursement coverage. The issues concerning insertion and removal, and the reliability of the measurements were among the other negatives mentioned.

Although families try to feel in control by increasing the frequency of measurements thanks to CGM, they cannot fully relax due to fear of hypoglycemia and the responsibility of managing their child’s T1D. Without CGM, their concerns are increased, and children suffer from frequent fingerstick use. Our results show that parents appreciate the benefits of CGM more at night and during school hours when they cannot actively control their children. These results are in line with previous studies showing that CGM reduces nighttime hypoglycemia fear (12), improves sleep quality (13), and relaxes parents while the child is at school (9,14).

In our study, it was seen that families grasp the features of CGM technology, the trend arrows and the alarm function, and use them to improve their children’s daily lives and have a safe and comfortable night. Accordingly, CGM use can help many families remove the fear of hypoglycemia at night, as well as prevent attitudes that negatively affect metabolic control, such as trying to begin the night with a high glucose above the target.

Families’ experiences show that the data and functions provided by CGM enable them to understand the effects of food on their children’s glucose patterns. This can increase families’ participation and adherence to personalized treatment - a recommended approach to diabetes management (15).

In our study, unlike previous studies, families did not mention the bulkiness of CGM (11), negative perception of visibility (11), altered body image (8), or the emotional burden of wearing one. The reason for this may be the young age of the children participating in our study - the results reflect the views of the parents and they prioritize glycemic control over body perception. Reported problems with insertion and removal are similar to those in the literature (6). However, the families participating in the study seem to put a lot of effort into taking good care of the CGM. The families’ efforts to keep the CGM in good condition with additional adhesives, even if it causes mild skin reactions and irritations, is likely due to the high cost of the system and the lack of state reimbursement.

One of the most important observations of this study is the economic burden of CGM, which all families emphasized strongly. Considering that this study was conducted in a private hospital and that participated families can afford the service cost, it can be predicted that the problem is much greater for the families who have lower socioeconomic status.

CGM utilization rate in Turkey is unknown. However, as in many countries, low socio-economic groups are known to have difficulties in accessing such technologies that facilitate diabetes care and improve glycemic control (16). Qualitative studies such as this one reveal the burning nature of the problem much more strongly, as it conveys the experience of people directly experiencing the problem (17). In addition, CGM is becoming a standard of care for T1D since it provides better T1D management both quantitatively and qualitatively. Therefore, just as insulin is in the reimbursement
system, the need for CGM to be reimbursed receives more support from families and professionals (17).

Emerged themes in our study are similar to previously published studies on this subject and cover almost all subjects in quantitative research on CGM (6–8,11). However, it is seen that the families are not aware of “time in range centered diabetes care” approach that has been on the T1D agenda in recent years (18,19). In other words, families have neither mentioned nor focused on the increasing time in range. It is necessary to focus on the interpretation of the data obtained from CGM and set new targets accordingly. For this to occur, there is a need for structured training programs for children and adolescents with diabetes for themselves and their families.

Our study has some limitations. It can be assumed that the experience of patients is positive for CGM use since the study was conducted in a private hospital and the patients were followed by a multidisciplinary team with sufficient time available. Repeating a similar study with patients using CGM who are followed up in a public hospital may increase the generalizability of the results. In addition, there are variations in T1D duration, CGM use, and age distribution among our study participants. However, due to the limited number of participants, we could not analyze the effects of these factors in detail.

Conclusion
This is the first qualitative study that investigated the CGM experiences of young children’s families from a country where CGM is not reimbursed. Increased glycemic control, increased control at night and school, overall relief of pain, and decreased worries in daily life have emerged as prominent benefits. The cost of CGM appears to be the primary barrier. Families undertake the economic burden since CGM is indispensable in T1D management.

Similar conclusions that the cost is a burden for families in other countries where CGM is not reimbursed may provide advocacy for state reimbursement of the cost of CGM.

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Ethical Approval
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Statement of Human and Animal Rights
All procedures in this study were conducted in accordance with the Koç University (2020.008.IRB3.007) approved protocols.

Statement of Informed Consent
Verbal informed consent was obtained from a legally authorized representative(s) for anonymized patient information to be published in this article.

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