CONTINUOUS GLUCOSE MONITORING AND TYPE 1 DIABETES MELLITUS CONTROL IN CHILD, ADOLESCENT AND YOUNG ADULT POPULATION − ARGUMENTS FOR ITS USE AND EFFECTS

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SUMMARY – Sensors for continuous glucose monitoring (CGM) in intercellular fluid are used as a contemporary method to achieve better control in type 1 diabetes mellitus (DM), which is best shown through lower glycated hemoglobin (HbA1c) levels. The aim of this study was to assess how many of our patients used CGM (parents were solely financing all the cost of the device) and what was the effect of CGM on the control of DM. Data were retrospectively collected from medical records of patients actively treated at the Division of Endocrinology, Diabetology, Pulmonology and Allergology, Department of Pediatrics, Sestre milosrdnice University Hospital Center. The t-test was used for independent samples to compare the mean levels of HbA1c before and after the inclusion of CGM. CGM was used by 81 (32.1%) of our patients with type 1 DM, of which 43 met the inclusion criteria. The mean HbA1c level 6 months before the introduction of CGM was 8.2%±1.9 and after 12 months of CGM use it was 7.4%±1.2, which was a statistically significant improvement (p=0.026). Furthermore, our results demonstrated that the greatest improvement in HbA1c level was recorded in the groups of young adults (18-25 years) and youngest children (<12 years). We confirmed the efficacy of CGM in achieving better control of type 1 DM by significantly improving HbA1c levels in a population of highly motivated patients.

Key words: *Type 1 diabetes mellitus; Continuous glucose monitoring; Children; Adolescents*

Introduction

The main goal of diabetes mellitus (DM) treatment is to reduce complications by achieving the best possible metabolic control using complex treatment measures. Until recently, the only method available to most patients was measurement of glycemia in capillary blood by glucometers, which had to be conducted 6-8 times a day to get complete information. Many hyperglycemia and hypoglycemia episodes, especially during the night, remained unrecognized, thus aggravating adjustment of insulin therapy. Twenty years ago, the advent of sensor usage for continuous glucose monitoring (CGM) in intercellular fluid brought a real breakthrough. Nowadays, it is a validated method to achieve better control in type 1 DM[1]. Results of randomized, controlled studies show the use of CGM to be safe and effective in the population of children and adolescents[2]. Better control of the disease leads to lower glycated hemoglobin (HbA1c) level, as well as less variable glycemia and longer time spent in range (usually glucose range of 3.9-10 mmol/L)[3-8].

At the beginning of CGM utilization, errors in the measurements ranged up to 20%, whereas today all sensors are more accurate, more precise, and more acceptable for the population of children because of its size and comfort. The possibility of data transfer to the computer and insight into data by more people *via*

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smartphones contributes to further improvement of system functionality. CGM is suitable for use with all forms of insulin therapy, while indications for its use are unsatisfactory disease control or frequent, severe or nocturnal hypoglycemia, especially when the child is unaware of hypoglycemia. Many studies have shown clinical benefit in different subpopulations of children, adolescents and adults with type 1 and 2 DM and with different initial disease control[2,9]. Of course, the benefit is directly proportional to the number of readings or insight in the results, i.e. duration of CGM usage[2,9].

Currently, two methods of CGM are available to patients, i.e. real-time CGM (rtCGM) and intermittently scanned/viewed CGM (isCGM). The rtCGM sensor transmits signals in regular intervals (1-5 minutes), which enables viewing glucose level in different ways, using the screen of the device or insulin pump, or even smartphones or tablets. These devices show information on current glucose in interstitial fluid and on the course of changes, i.e. whether glucose is rising, falling, or stable. The benefit of this method is the possibility of using an alarm in case of hypoglycemia or hyperglycemia, and the warning threshold is set by the patient or the parents. These devices need to be calibrated using data on capillary glycemia. Flash method, isCGM, is simpler and less expensive; glucose concentration and the pattern of changes is read on the screen of the device only when the patient crosses over the sensor with the device. This type of device does not have an alarm, the sensors are factory calibrated, and last for 14 days[6,8,10,11].

There are established benefits of CGM in comparison with self-control using a glucometer, but clinical use is still quite modest. CGM is used by 20%-30% of children with type 1 DM[12,13]. At the time of conducting this study, the cost of CGM was not covered by mandatory health insurance of our patients, so the high cost was one of the limiting factors. The use of CGM depended on the awareness and financial capability of the patient's family.

The aim of the study was to assess how many of our patients used the aforementioned method (parents were solely financing all the cost of the device), what were the motives for its use, what was the effect of CGM on disease control manifested as changes in HbA1c level, and whether patient and/or parent expectations from CGM were met.

Patients and Methods

Data were retrospectively collected from medical records of type 1 DM patients actively treated at the Division of Endocrinology, Diabetology, Pulmonology and Allergology, Department of Pediatrics, Sestre milosrdnice University Hospital Center. The study included 43 patients who met the criteria of having type 1 DM for more than one year and using CGM for more than one year. The mean values of HbA1c 6 months before the introduction of CGM and the mean values of HbA1c between 7 and 12 months of CGM use were analyzed. The t-test for independent samples was used to test differences in arithmetic means of the two groups (before and after the introduction of CGM). The aforementioned test is known to be robust and resistant to failing to satisfy the normality requirements if the samples are of the same size, which was the case in our study.

Furthermore, all respondents completed a questionnaire on the use of CGM in children and young people with type 1 DM by themselves or with assistance of their parents (mostly in children under 10 years of age). The questionnaire contained 15 questions related to the reasons for using CGM, consistency in CGM use, and satisfaction with the CGM device.

Results

Out of 252 patients with type 1 DM that were actively treated at our department, 81 (32.1%) patients used CGM. The inclusion criteria were met by 43 patients, mean age 11.6±4.9 (range 2-20) years. The mean duration of type 1 DM was 4.2±3.7 years. Considering the use of CGM, there was a male predominance (n=26; 60%).

The mean HbA1c level 6 months before the introduction of CGM was 8.2%±1.9 (66 mmol/mol)and after 12 months of CGM use it was 7.4%±1.2 (57 mmol/mol), which was a statistically significant improvement at 5% significance level (p=0.026) (Table 1). Furthermore, we divided patients by age into three groups, as follows: <12 years, 12-18 years (adolescents), and >18 to <25 years (young adults). Gender distribution looking through groups showed male predominance in patients aged <12 years (71% male *vs.* 29% female) and in the population of young adults (66% male *vs.* 34% female) but female predominance in the

Table 1. Mean HbA1c level before and after one year of using continuous glucose monitoring

	n	Mean value	SD	Min	Max	t-test for independent samples (HbA1c before-after)		
						t-test	df	sig. (2-tailed)
HbA$_{1c}$ before	43	8.2% (66 mmol/mol)	1.94	5.8% (40 mmol/mol)	14% (129 mmol/mol)			
HbA$_{1c}$ after	43	7.4% (57 mmol/mol)	1.24	5.6% (38 mmol/mol)	12% (108 mmol/mol)	2.314	43	0.026*

HbA1c = glycated hemoglobin; *statistically significant

Table 2. Difference in HbA1c before and after one year of using continuous glucose monitoring according to age groups

Age (years)	<12	12-18	>18
n	23	14	6
HbA1c before	8.7%±2.4 (72 mmol/mol)	7.4%±0.9 (57 mmol/mol)	8.4%±1.9 (68 mmol/mol)
HbaA1c after	7.7%±1.5 (61 mmol/mol)	7.2%±0.8 (55 mmol/mol)	6.9%±0.4 (52 mmol/mol)
Improvement	10%	2%	15%

HbA1c= glycated hemoglobin

group of adolescents (43% male *vs.* 57% female). Study results showed that the greatest improvement in HbA1c level was recorded in the groups of young adults and youngest children (<12 years), whereas least positive results were found in adolescents (Table 2).

Before using CGM, satisfactory metabolic control according to the International Society for Pediatric and Adolescent Diabetes (ISPAD; HbA1c <7%) had only 26% of our patients, whereas after using CGM 42% of them were fulfilling that goal. If we look at satisfactory metabolic control according to the American Diabetes Association (ADA; HbA1c <7.5%), 47% and 65% of our patients were in that goal group before and after implementation of CGM, respectively.

Most patients using CGM were on intensive insulin therapy with multiple daily injections (76%) or insulin pump (15%), and 9% of patients used conventional insulin therapy. Results were quite similar compared with overall population of patients at the center, where 73% of patients used intensive insulin therapy with multiple daily injections, 22% used insulin pump, and 5% used conventional insulin therapy. The isCGM flash method was used by 88% of patients and the rest

used rtCGM. Most of them (65%) used CGM permanently (≥6 days a week). The motives for using CGM were similar in most patients, e.g., they wanted to improve HbA1c (88%), reduce glucose variability (50%), achieve better glycemic control at night (74%), and prevent hypoglycemia (74%). Most patients with CGM measured capillary glucose two to four times a day (35%), and 26% less frequently than once a day; 71% of patients were completely satisfied with CGM and the result achieved, 29% were partly satisfied, whereas none of them said they were unsatisfied. In 53% of families that decided to use and bear the cost of CGM, one or both parents had a university degree (Table 3).

Discussion

Although families themselves covered the costs of CGM, 32.1% of patients with type 1 DM treated at our department used CGM. This is a slightly higher rate than the average reported in the studies conducted in pediatric population, where 21.7% of patients were CGM users[13]. In our group of highly motivated pa-

Table 3. Results of the questionnaire on the use of continuous glucose monitoring in children and young people with type 1 diabetes mellitus

Sex:	
Male	60%
Female	40%
Route of insulin administration:	
Conventional insulin therapy	9%
Intensive insulin therapy	76%
Insulin pump	15%
Type of sensor:	
isCGM, 'flash' method	88%
rtCGM	12%
Duration of sensor use:	
Permanently	64%
75% of time	15%
50% of time	9%
Periodically, when glycemia worsens	12%
Satisfaction with result achieved:	
Entirely	71%
Partially	29%
Dissatisfaction	0%
Reasons for using sensor:	
Improvement of disease control (HbA1c)	88%
Reduction of glucose variability	54%
Achieving better glycemic control	74%
Preventing hypoglycemia	74%
Detection of dawn phenomenon	24%
Encouraging independence	38%
Increased supervision of the child	38%

CGM = continuous glucose monitoring; isCGM = intermittently scanned/viewed CGM; rtCGM = real-time CGM; HbA1c = glycated hemoglobin

tients aged 2-20 years, after one year of using CGM, control of the disease improved significantly, as demonstrated by a statistically significant improvement in HbA1c level, which was reduced by 9.6% from the initial value (drop 0.8%; HbA1c was 8.2% before *vs.* 7.4% after CGM introduction). This result is crucial because the Diabetes Control and Complications Trial (DCCT) demonstrated that a 10% relative reduction in HbA1c was associated with a 40% decrease in the rate of development and progression of early diabetic retinopathy[14]. According to other authors, even a slight decrease in HbA1c is beneficial[15]. In our study, the greatest improvement in HbA1c level was observed in the group of young adults, i.e. those over 18 years of age, in whom HbA1c was reduced by 15%. At the same time, adolescents and the group of 12- to 18-year-olds had the worst results, with HbA1c having improved by only 2%. However, it should be noted that in the group of adolescents, the HbA1c level prior to the introduction of CGM was the best of all age groups, which is not accordant with other adolescent groups. This well controlled group was motivated for even better control and that is why they decided to use CGM. Thus, a well-controlled disease (in our group, mean HbA1c was 7.4%) is hard to further improve.

Other studies show that the greatest benefit of CGM is recorded in those over 25 years of age and in children up to 14 years of age, whereas the smallest benefit manifested through improvement in disease control has been reported in young people aged 15 to 24 years. The reason is that young adults are more committed to wearing sensors properly and constantly, whereas in children up to 14 years of age, parents play a major role in achieving results[16]. According to various studies, adolescents are currently most exposed to poor disease control among all age groups, as a result of transition from parental managing their disease to themselves being solely responsible for it, along with psychological and hormonal changes that accompany adolescence[13,17]. DCCT studies have shown that elevated HbA1c levels persisting for 5-7 years (the duration of puberty) have a prolonged effect on the development of chronic complications of diabetes[1,18].

According to the ISPAD recommendations, an individual approach is needed to achieve optimal disease control, with the idea of achieving HbA1c levels as close to normal as possible but without the risk of severe hypoglycemia. HbA1c levels <7.0% (53 mmol/mol) should be aspired to, while higher HbA1c levels (up to 7.5%, 58 mmol/mol) are acceptable in the states of failed recognition of hypoglycemia and with a lack of technology in the treatment process[8]. According to the ADA guidelines, the HbA1c target value is <7.5% (<58 mmol/mol), which is achieved by only 22%-23% of children younger than 12 years and 17% of children aged 13-17 years in the US[2,3,20]. In our population of patients, initially 26% had HbA1c <7% and 47% had

HbA1c <7.5% in the period before using CGM. Using CGM we see improvement, so now 42% have HbA1c <7% and 65% have HbA1c <7.5%. A recent study in Norway showed a mean HbA1c value of 9.3% (78 mmol/mol) in girls aged 17 and 9.1% in boys aged 19[21].

In our study, 64% of patients used CGM permanently (≥6 days a week), indicating high commitment to using CGM that leads to good results, i.e. significant improvement in disease control. Improvement in HbA1c has been shown to be proportional to the time and frequency of CGM use (hours or days *per* week)[5,8,16,22], especially in patients with initially high HbA1c levels[3]. Non-adherence to the CGM was mostly seen in the older age group, which could be associated with poor compliance. Also, 12% of patients used CGM only periodically, when their glycemia worsened, because of the cost of device; one (3%) patient reported he had to stop using CGM because of skin allergy, similar to 1% of patients having discontinued using isCGM because of skin reactions in a recent adult study[23].

Some studies did not find statistically significant difference between the groups using CGM and glucometer, the reason being only occasional use of the device[24]. One study showed that isCGM alone was not inferior to self-monitoring of blood glucose[25]. Some studies found the use of CGM to decline over time, so that only 38% of users used CGM permanently (more than 75% of the time) throughout 12 months, affecting final outcome[2]. It was also demonstrated that only 30% of young people aged 15-24 and 50% of those younger than 14 used CGM permanently for at least 6 days *per* week for a period of 6 months, compared with 86% of those older than 25 years[12].

In our study, 88% of patients were isCGM users, and isCGM is associated with reduced time in hyperglycemia (>10 mmol/L) and also with improvement of time in range in patients with suboptimal glycemic control (population with HbA1c >7%)[25].

Of our patients using CGM, 15% were pump users. Within pump users, 67% of them used CGM permanently, which is in correlation with other patients and did not show to be a much better adherent group. Other studies showed pump users to have a trend of a longer period of wearing CGM during the week compared to patients on multiple daily injections of insulin with the injector[4,26].

Most (35%) of our patients used finger-stick glucose monitoring along with CGM 2-4 times a day and 26% of them did it less than once daily, as opposed to the standard 6-8 measurements as recommended when using a glucose meter. Recent studies have undoubtedly shown that the use of CGM is associated with better HbA1c levels and thus better disease control compared to the use of glucometer[27]. However, it is still necessary to check for capillary glycemia in situations such as rapid glucose change in CGM readings, with symptoms of hypoglycemia or low glucose levels in CGM, with symptoms not corresponding to CGM readings, and certainly before driving[28].

It is worth noting that none of our patients was unsatisfied with CGM; quite the contrary, 71% were very satisfied, which is in line with other studies[29]. However, some studies state that the users are not satisfied with the method of setting the sensor, that is, with gluing the sensor to the skin, which can irritate the skin. One of the problems is the need for calibration of rtCGM, which increases the cost of the method and the number of devices required, and contributes to the complexity of its use[14,15,30]. As our patients mostly used isCGM which does not require calibration, maybe that was one of the reasons for greater satisfaction than in other studies. An equally important goal of using CGM, along with positive change in HbA1c, is to reduce the risk of hypoglycemia, which is a less common subject of research. Randomized controlled studies have confirmed a 40% reduction of time spent in hypoglycemia and reduction in the number of mild hypoglycemia episodes during the day in subjects using CGM[31,32]. The occurrence of severe hypoglycemia in CGM users is associated with a statistically significantly shorter period of wearing the device. Of the 10% of patients who had an episode of severe hypoglycemia within 6 months of starting CGM, only 14% used the device permanently or more than 6 days a week[4]. CGM has also been shown to be a useful and important diagnostic tool in detecting nocturnal hypoglycemia after exercise[33,34]. Certainly, studies showing that the use of CGM decreases glucose variability should be mentioned, which also reduces the risk of complications, independently of HbA1c level[35,36].

Conclusion

In this study, we confirmed that CGM is effective in achieving better control of type 1 DM by significantly improving HbA1c levels in a population of

highly motivated families, diseased children, adolescents and young adults. Meanwhile, inclusion of CGM in the mandatory form of health insurance will most certainly be an incentive to evaluate the impact of this technology on a broader population of patients.

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Sažetak

KONTINUIRANO MJERENJE GLUKOZE I KONTROLA ŠEĆERNE BOLESTI TIP 1 U POPULACIJI DJECE, ADOLESCENATA I MLADIH ODRASLIH – RAZLOZI ZA PRIMJENU I UČINAK

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Senzori za kontinuirano mjerenje glukoze (*continuous glucose monitoring*, CGM) u međustaničnoj tekućini danas se rabe za postizanje bolje kontrole šećerne bolesti tip 1 (ŠB tip 1), što je najbolje vidljivo smanjivanjem vrijednosti glikiranog hemoglobina (HbA1c). Cilj ovog istraživanja provedenog u razdoblju kada su roditelji sami snosili troškove CGM-a bio je utvrditi koliko naših bolesnika primjenjuje navedenu metodu te kakav je učinak CGM-a na kontrolu bolesti. Restrospektivno su prikupljeni podaci iz medicinske dokumentacije bolesnika koji se aktivno liječe na Zavodu za endokrinologiju, dijabetologiju, pulmologiju i alergologiju Klinike za pedijatriju KBC Sestre milosrdnice. Za usporedbu srednjih vrijednosti HbA1c prije i poslije uvođenja CGM-a primijenjen je t-test za nezavisne uzorke. CGM je rabio 81 (32,1%) oboljeli od ŠB tip 1, od kojih su 43 bolesnika ispunili kriterije za uključivanje u ispitivanje. Prosječni HbA1c šest mjeseci prije uvođenja CGM-a bio je 8,2%±1,9, a nakon 12 mjeseci primjene CGM-a bio je 7,4%±1,2, što je statistički značajno poboljšanje (p=0,026). Nadalje, iz rezultata je vidljivo da je najveće poboljšanje u vrijednosti HbA1c imala skupina mladih odraslih (18-25 godina) te skupina najmlađe djece (<12 godina). Ovim ispitivanjem potvrdili smo učinkovitost CGM-a u postizanju bolje kontrole ŠB tip 1 kroz značajno poboljšanje razine HbA1c u populaciji visoko motiviranih bolesnika.

Ključne riječi: *Šećerna bolest tip 1; Kontinuirano mjerenje glukoze; Djeca; Adolescenti*