International Journal of Biomedicine 13(1) (2023) 41-46
http://dx.doi.org/10.21103/Article13(1)_OA3

ORIGINAL ARTICLE

Diabetes Mellitus

INTERNATIONAL JOURNAL OF BIOMEDICINE

Therapy Goal Achievement in Children and Adolescents with Type 1 Diabetes Mellitus in Insulin Pump Therapy Depending on the Glucose Monitoring and Educational Programs

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Abstract

Background: Education and treatment programs can help children and adolescents with type 1 diabetes (T1D), and their parents, to independently carry out the necessary measures to achieve the treatment goals. In this regard, it seems extremely relevant to develop and evaluate the effectiveness of a training-modified program, considering national characteristics for children and adolescents with T1D who are devoted to using insulin pumps for insulin administration. The purpose of this work was to evaluate the effectiveness of a modified training program in achieving target levels of glycemia in children and adolescents with T1D on insulin pump therapy in Almaty.

Methods and Results: Our study included 125 children and adolescents with T1D who were divided into 2 groups. The main group (MG), with a modified educational program, consisted of 68 children and adolescents with T1D who studied quarterly at the "School of T1D." The comparison group (CG) consisted of 57 children and adolescents with T1D who were on outpatient and inpatient treatment in different clinics and were trained in the "School of T1D" by the traditional method. All surveyed children and adolescents took a training course 2-3 times a year (each session 5 days long) from 2018 to 2021.

The patients of MG and CG were divided into 2 subgroups depending on the method of assessing glycemia: self-monitoring blood glucose (SMBG) using an individual glucometer and FreeStyle Libre Glucose Sensor (FSLGS) for continuous glucose monitoring (CGM). The modified program included the installation of Flash monitoring and a strategy to increase time in the target range, as well as calculating the insulin bolus dose in bread units, calculated in national dishes, then monitoring treatment correction.

After a year of training, the frequency of achieving target levels of HbA1c (≤7.0%) increased to 60.5% compared to 30.6% at the initial stage in the main subgroup with SMBG and 66.4% versus 28.7% in the main subgroup with the FSLGS for CGM; it was significant in both cases (P=0.01). In the comparison subgroups, achieving target levels of HbA1c was less pronounced and not significant (46.2% compared to 29.5% at the initial stage in the subgroup with SMBG and 51.1% compared to 29.1% at the initial stage in the subgroup with the FSLGS for CGM, P>0.05 in both cases).

Conclusion: CGM and modified learning significantly contribute to the management of T1D, are associated with lower HbA1c levels and longer stay in the time-in-range, and increase the commitment of patients and their parents to the self-control of glucose.(**International Journal of Biomedicine. 2023;13(1):41-46.**)

Keywords: type 1 diabetes • pediatrics • continuous glucose monitoring • glycated hemoglobin

For citation: Tashmanova AB, Rakhimova GN, Berkinbaev SF, Mansurova ME, Srailova KB. Therapy Goal Achievement in Children and Adolescents with Type 1 Diabetes Mellitus in Insulin Pump Therapy Depending on the Glucose Monitoring and Educational Programs. International Journal of Biomedicine. 2023;13(1):41-46. doi:10.21103/Article13(1)_OA3

Abbreviations

ADA, American Diabetes Association; **BC**, bolus calculator; **CSII**, continuous subcutaneous insulin infusion; **CGM,** continuous glucose monitoring; **FSLGS**, FreeStyle Libre Glucose Sensor; **HbA1c,** glycated hemoglobin; **SMBG,** self-monitoring blood glucose; **TIR,** time-in-range; **TBR,** time below range; **T1D**, type 1 diabetes.

Introduction

Continuous subcutaneous insulin infusion (CSII) is gradually being introduced into traditional clinical practice, facilitated by the availability of modern, reliable insulin pumps, increased clinical experience with pump therapy, a strong evidence base for the effectiveness of pump therapy, and the development of national guidelines on diabetes management.[1,2]

In the world, insulin pump therapy is used quite widely: up to 34% of patients with type 1 diabetes (T1D) in the USA and up to 25% in Europe use insulin pumps to administer insulin.[3]

The incidence and prevalence of T1D vary significantly in different countries. In Almaty, Kazakhstan, the prevalence of T1D was 1.2 and the incidence 13.2 per 100,000 child population. Among the children of Almaty, the number of pump users has been progressively increasing and, by 2020, amounted to 281 children and adolescents.[4]

Education and treatment programs can help children and adolescents with T1D, and their parents, to independently carry out the necessary measures to achieve the treatment goals, thereby sharing responsibility for the effectiveness of therapy between the doctor and the patient. Most studies on the application of this method state a significant positive trend in 1-2 years after training.[5,6]

The ADA Standards of Care in Diabetes recommend that all children and adolescents with T1D perform self-monitoring of glucose levels 6–10/day using self-monitoring blood glucose (SMBG) or continuous glucose monitoring (CGM), including the periods before meals, before going to bed, and as needed in certain situations (exercise, symptoms of hypoglycemia).[3,7,8]

In 2017, the CGM Consensus for Patient Education was published,[9] requiring all patients to receive training on how to interpret and respond to their glucose data.

Today in the world, there are several programs for patients with CGM. The first was the SPECTRUM (Structured Patient Education and Treatment Program for Self-Reliant Continuous Glucose Monitoring) patient education and treatment program for CGM users. The SPECTRUM program included 110 patients. As a result of training, knowledge about the CGM system improved by 43%, study participants mastered almost all practical skills in working with the system, and patients showed a decrease in HbA1c levels.[10,11]

The Dynamic GM training program for children and adolescents with T1D who are CGM users was based on a review of international guidelines for structured learning for CGM users.[12] The program included children and adolescents with T1D (n=50) (mean age of 10.2 years, mean disease duration of 5.2 years). The training was conducted by a nurse or trainer. The total time of classes was 10 hours, lasting 6 months.

The results of the Flash program, a self-management-based treatment and education program developed in Germany aimed at educating patients using the FreeStyle Libre system, is built on a different principle. The Flash program lasts 6 weeks and includes 4 sessions. This program was evaluated in a randomized, open-label study with a control group to study the impact of education on patients with diabetes on glycemic control parameters. The results of the Flash program showed a more pronounced decrease in HbA1c in patients from the Flash training program than in the control group (69.6% and 54.6%, respectively, P=0.003).[13,14]

Currently, in some countries, when transferring patients to CSII, appropriate selection and training are often not carried out, which leads to many errors in handling devices and decompensation of diabetes, even in those patients who were compensated using syringe pens. Monitoring patients receiving this expensive type of treatment is also chaotic, without considering the characteristics of these patients and the opportunities that an insulin pump gives an endocrinologist.[15,16]

In this regard, it seems extremely relevant to develop and evaluate the effectiveness of a training-modified program, considering national characteristics for children and adolescents with T1D who are devoted to using insulin pumps for insulin administration. The learning process should consider the individual psychological characteristics of patients, traditional-national nutritional characteristics, and modern methods of intensive care and monitoring of blood glucose concentration with a glucometer or FreeStyle Libre glucose sensor (FSLGS).

The purpose of this work was to evaluate the effectiveness of a modified training program in achieving target levels of glycemia in children and adolescents with T1D on insulin pump therapy in Almaty.

Materials and Methods

Our study included 125 children and adolescents with T1D who were divided into 2 groups. The main group (MG), with a modified educational program, consisted of 68 children and adolescents with T1D who studied quarterly at the "School of T1D." The comparison group (CG) consisted of 57 children and adolescents with T1D who were on outpatient and inpatient treatment in different clinics and were trained in the "School of T1D" by the traditional method. The groups did not differ in age or duration of the disease (Table 1).

Table 1.

General characteristics of patients on CSII

Variable	Modified educational program	Traditional educational program	*P*-value
Age, yrs.	12.0 [8;16]	13.0 [7;16]	0.209
Experience of diabetes, yrs.	6.7 [4;14]	7.2 [5;16]	0.181
HbA_{1c}, % before training	8.7 [7.0;9.8]	9.0 [8.1;10.0]	>0.05

The patients of MG and CG were divided into 2 subgroups depending on the method of assessing glycemia:

MG1(n=35) and CG1 (n=30): Patients performed SMBG using an individual glucometer.

MG2 (n=33) and CG2 (n=27): Patients used FSLGS for CGM.

The training was conducted in the "School for T1D" (the Children's Clinical Hospital #2) on an outpatient basis. All surveyed children and adolescents took a training course 2-3 times a year (each session 5 days long) from 2018 to 2021. The modified program included the following steps: 1- familiarization lesson and setting individual goals, 2- prevention of hypo-hyperglycemia, 3- installation of Flash monitoring and a strategy to increase time in the target range, 4 and 5 lessons included calculating the insulin bolus dose in bread units (BU), calculated in national dishes, then monitoring treatment correction.[17-19]

All subjects were tested based on a modified questionnaire, including 30 key questions on self-monitoring glucose during insulin pump therapy, on sensors, and on counting BU before and after training.[18-20]

Compensation was assessed based on the determination of the level of HbA1c by the immunochemical method using DCA Vantage Analyzer (Siemens Healthcare Diagnostics). The method for determining HbA1c corresponds to the NGSP certificate (The National Glycohemoglobin Standardization Program).

Statistical analysis was performed using STATISTICA version 8 (StatSoft Inc., USA). For descriptive analysis, results are presented as median (Me), first quartile (Q1), and third quartile (Q3). Differences of continuous variables were tested by the Mann-Whitney *U*-test. Group comparisons with respect to categorical variables are performed using the chi-square test. A probability value of $P<0.05$ was considered statistically significant.

This study was approved by the Ethics Committee of the Kazakh National University named after Al-Farabi (Almaty, Kazakhstan). Written informed consent was obtained from the parent/guardian/relative of each patient.

Results and Discussion

When evaluating the training effectiveness using a questionnaire, it was found that patients in the MG (an average T1D duration of 6.7[4;14] years), before training, could correctly answer questions only in 16%-20% of cases. After 6 months and after one year after training, correct answers were obtained in 80%-90% of cases. During the observation period, CG patients (an average T1D duration of 7.2[5;16] years) had a low level of correct answers, from 20% to 37%. Patients of the CG were more likely to be admitted to the intensive care unit both before and after traditional training.

At the time of transfer from the regimen of multiple insulin injections to CSII, MG and CG did not significantly differ from each other in the degree of compensation of carbohydrate metabolism (Table 2).

Six months after training and switching from multiple insulin injections to CSII, the HbA1 level showed a greater decrease in the MG1 and MG2 than in the dynamics in the CG1 and CG2. At the same time, a more pronounced reduction in the HbA1 level was noted in CG2 than in CG1 (8.0% [6.2;8.3] vs. 8.8% [8.2;9.5], $P<0.01$). After one year, the HbA1c level was significantly lower in MG subgroups, especially in MG2, compared to CG1 and CG2. At the same time, a more pronounced decrease in the HbA1c level was found in CG2 compared to CG1 (7.6% [7.4;8.0] vs. 7.8% [7.5;8.5], $P<0.05$) (Table 3).

Table 2.

Clinical characteristics of patients on CSII depending on the method of assessing glycemia and the type of training at the initial stage

Variable	Modified educational program		*P*	Traditional educational program		*P*
	MG1	MG2		CG1	CG2	
Age, yrs.	10.0 [6;15]	12.0 [8;16]	0.56	9.7 [6;16]	13.0 [9,5;17]	
Experience of T1D, yrs.	6.6 [7;14]	8.4 [6;14]	0.21	7.1 [5;15]	9.2 [7,5;15]	0.12
HbA_{1c}, %	8.1 [7.4;9.6]	7.7 [8.0;9.2]	0.69	9.3 [8.4;10.3]	8.9 [7.7;9.0]	>0.05

Table 3.

Dynamics of HbA1c (%) in the study subgroups.

Training phase	Modified educational program			Traditional educational program		
	MG1	*P*	MG2	CG1	*P*	CG2
At the time of transfer to CSII (I)	8.1 [7.4;9.6]	>0.05	7.7 [8.0;9.2]	9.3 [8.4;10.3]	<0.05	8.9 [7.7;9.0]
6 months after	7.6 [6.7;8.0]	>0.05	7.3 [6.1;7.6]	8.8 [8.2;9.5]	<0.01	8.0 [6.2;8.3]
12 months after (II)	7.4 [6.3;8.2]	>0.05	7.1 [6.0;7.4]	7.8 [7.5;8.5]	<0.05	7.6 [7.4;8.0]
$P_{I\text{-}II}$	<0.05		<0.05	<0.05		<0.05

Before switching to CSII, the frequency of achieving target levels of HbA1c (≤7.0%) in MG1 and MG2 was 30.6% and 28.7%, respectively, versus 29.5% and 29.1% in CG1 and CG2, respectively (Table 4). After a year of training, the frequency of achieving target levels of HbA1c in MG1 increased to 60.5%, compared to 30.6% at the initial stage ($P=0.01$). In MG2, similar dynamics were also seen, and the target values were achieved in 66.4% of patients versus 28.7% at the initial stage ($P<0.01$). In subgroups CG1 and CG2, a similar trend was observed, but without significant dynamics (Table 4).

Glycemia was evaluated according to reports obtained by downloading data from insulin pumps to a personal computer using CareLink Personal software ver. 7.0 (Medtronic BV,

USA). Additionally, glycemia indicators were evaluated according to the data of reports obtained by downloading data from the FSLGS using the software (Figure 1).

Table 4.

The frequency of achieving target levels of HbA1c in study subgroups

Variable	Modified educational program			Traditional educational program			*P* MG1-CG1	*P* MG2-CG2
	MG1 (n=35)	*P*	MG2 (n=33)	CG1 (n=30)	*P*	CG2 (n=27)		
Before switching to CSII	30.6%	>0.05	28.7%	29.5%	>0.05	29.1%	>0.05	>0.05
6 months after	42.7%	>0.05	47.5%	34.6%	>0.05	38.4%	>0.05	>0.05
12 months after	60.5%	>0.05	66.4%	46.2%	>0.05	51.1%	>0.05	>0.05
P	0.01		<0.01	>0.05		>0.05		

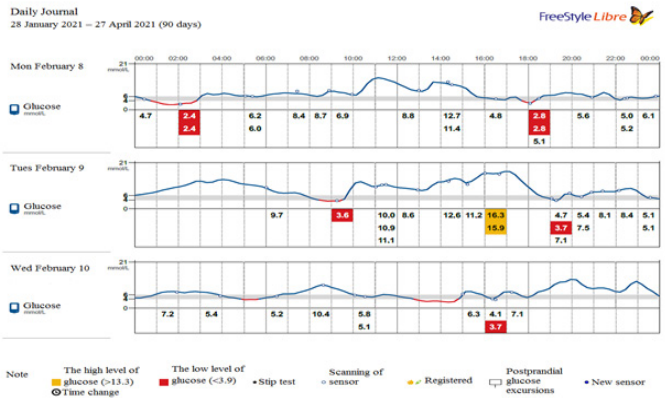

Fig. 1. *Glycemic values according to the FreeStyle Libre sensor report.*

The introduction of training-modified programs for patients with T1D in the MG contributed to a more significant improvement in glycemic control than in the CG. Thus, there was an increase in the time-in-range (TIR) from 47.4% to 57.8% in the MG and from 46.9% to 51.5% in CG (P<0.001). Time below range (TBR) decreased from 10.6% to 2.8% in the MG and from 10.8% to 6.3% in the CG (P<0.001) (Fig. 2). The modified training program has contributed to more regular use of CGM data by patients, a reduced need for routine glucometry, and improved use of continuous subcutaneous insulin infusion.

Based on the reports obtained when loading data from insulin pumps into a computer, we analyzed the frequency of bolus calculator use as one of the factors affecting the compensation of carbohydrate metabolism (Table 5). It was found that patients in the CG used a bolus calculator less frequently than in the MG (5.9±3.0 vs. 7.1±3.4, P=0.040) and administered self-calculated bolus ("in mind") more often or calculated using different Internet sites.

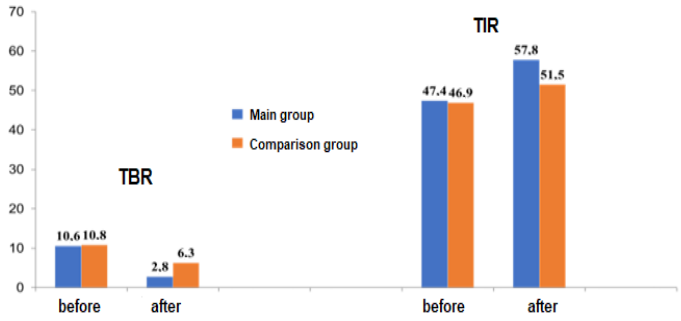

Fig. 2. *Dynamics of TBR (%) and TIR (%) before and after the training programs.*

Table 5.

The frequency of bolus calculator use in the study groups and subgroups.

Group	Number of the bolus calculator use per day			*P*-value
	Total	SMBG	FSLGS	
MG (n=68)	7.1±3.4	6.2±3.1 (n=35)	7.9±3.7 (n=33)	0.044
CG (n=57)	5.9±3.0	5.3±2.9 (n=30)	6.7±3.2 (n=27)	0.089
P-value	0.040	0.234	0.190	

Conclusions

1. In children and adolescents with T1D of the main group with modified learning, after one year of observation, the average level of HbA1c achieved 7.4% [6.3;8.2] in the subgroup with self-monitoring blood glucose and 7.1% [6.0;7.4] in the subgroup with the FreeStyle Libre Glucose Sensor for continuous glucose monitoring. Children and adolescents with T1D of the comparison group with standard learning achieved compensation after one year of observation by a lesser degree (HbA1c of 7.8% [7.5.;8.5] in the subgroup with self-monitoring blood glucose and 7.6% [7.4;8.0] in the subgroup with the FreeStyle Libre Glucose Sensor for continuous glucose monitoring). The FreeStyle Libre Glucose Sensor for continuous glucose monitoring was more effective in both groups.

2. After a year of training, the frequency of achieving target levels of HbA1c (≤7.0%) increased to 60.5% compared

to 30.6% at the initial stage in the main subgroup with self-monitoring blood glucose and 66.4% versus 28.7% in the main subgroup with the FreeStyle Libre Glucose Sensor for continuous glucose monitoring; it was significant in both cases (P=0.01). In the comparison subgroups, achieving target levels of HbA1c was less pronounced and not significant (46.2% compared to 29.5% at the initial stage in the subgroup with self-monitoring blood glucose and 51.1% compared to 29.1% at the initial stage in the subgroup with the FreeStyle Libre Glucose Sensor for continuous glucose monitoring, P>0.05 in both cases).

3. Continuous glucose monitoring and modified learning significantly contribute to the management of T1D, are associated with lower HbA1c levels and longer stay in the time-in-range, and increase the commitment of patients and their parents to the self-control of glucose.

Sources of Funding

This work was funded by Committee of Science of Republic of Kazakhstan AP09260767 "Development of intellectual information-analytical system for assessing the health of students in Kazakhstan" (2021-2022).

Competing Interests

The authors declare that they have no competing interests.

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