

ИСПОЛЬЗОВАНИЕ ТЕЛЕМЕДИЦИНЫ ДЛЯ УЛУЧШЕНИЯ ГЛИКЕМИЧЕСКОГО КОНТРОЛЯ И КАЧЕСТВА ЖИЗНИ У ДЕТЕЙ С САХАРНЫМ ДИАБЕТОМ 1 ТИПА НА ПОМПОВОЙ ИНСУЛИНОТЕРАПИИ



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АКТУАЛЬНОСТЬ. Доступность медицинской помощи играет значительную роль в улучшении и поддержании удовлетворительного гликемического контроля у пациентов с сахарным диабетом 1 типа (СД1).

ЦЕЛЬ исследования состояла в оценке возможности удаленной поддержки детей и подростков с СД1 и ее влияния на гликемический контроль и качество жизни.

МАТЕРИАЛЫ И МЕТОДЫ. У 40 детей и подростков ($13 \pm 2,7$ лет, 18/22 м/ж) на помповой инсулинотерапии с неудовлетворительной компенсацией СД1 ($HbA_{1c} \geq 7,5\%$) была оценена эффективность телемедицинской поддержки путем дистанционного консультирования (ДК) по сравнению с традиционным контролем (ТК). На очных визитах производились оценка и регистрация показателей гликемического контроля (HbA_{1c} , средняя гликемия, SD гликемии и др.) и качества жизни. Пациенты или их родители, распределенные в группу ДК, 2 раза в месяц в домашних условиях отправляли данные с инсулиновой помпы специалисту в центр помповой инсулинотерапии, а в ответ получали от него рекомендации по лечению и самоконтролю. Первичной конечной точкой исследования были изменение HbA_{1c} к концу исследования по сравнению с исходным уровнем и доля пациентов, достигнувших HbA_{1c} менее 7,5%.

РЕЗУЛЬТАТЫ. Через 24 нед исследования исходный HbA_{1c} (8,7% в двух исследуемых группах) в группе ДК снизился до 7,7% по сравнению с 8,5% в группе ТК ($p < 0,05$). Изменение уровня HbA_{1c} к концу исследования относительно исходного составило 0,97% в группе ДК по сравнению с 0,26% в группе ТК (общая разница между группами 0,71%, $p < 0,05$). Доля пациентов, которые достигли целевого уровня HbA_{1c} ($< 7,5\%$), была выше в группе ДК (50%) по сравнению с группой ТК (20%, $p < 0,05$). Ряд показателей качества жизни как у родителей, так и детей с СД1 к концу исследования по сравнению с исходным уровнем статистически значимо увеличился в группе ДК по сравнению с группой ТК ($p < 0,05$). За время исследования частота эпизодов диабетического кетоацидоза (ДКА) и тяжелой гипогликемии статистически значимо не различались между группами.

ЗАКЛЮЧЕНИЕ. У детей с неудовлетворительным метаболическим контролем СД1 дистанционная поддержка оказалась осуществимой и привела к значительному улучшению гликемического контроля (HbA_{1c} , вариабельность гликемии) и качества жизни, не сопровождаясь при этом учащением эпизодов ДКА и тяжелой гипогликемии.

КЛЮЧЕВЫЕ СЛОВА: сахарный диабет 1 типа; телемедицина; дети; качество жизни; гликемический контроль

USE OF TELEMEDICINE IMPROVES GLYCEMIC CONTROL AND QUALITY OF LIFE IN TYPE 1 DIABETES CHILDREN ON INSULIN PUMP THERAPY

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RATIONALE: Healthcare access plays a significant role in the improvement and maintaining of glycemic control and quality of life in type 1 diabetes mellitus (T1DM) patients on continuous subcutaneous insulin infusion (CSII).

AIMS: The aim of the study was to evaluate the feasibility of remote support in children and adolescents with type 1 diabetes mellitus (T1DM) and its effect on glycemic control and quality of life.

MATERIALS AND METHODS: In 40 children and adolescents ($13 \pm 2,7$ years, 18/22 m/f) on CSII with inadequately controlled T1DM ($HbA_{1c} \geq 7,5\%$) we evaluated the effectiveness of telemedical support (TS), as compared with conventional support (CS). Parameters of glycemic control (HbA_{1c} , average glycemia, SD, etc.) and quality of a life were obtained on follow-up visits. Patients and their parents in TM group twice a month sent their insulin pump data using to CSII center and diabetologists sent back their advice via e-mail, phone or Skype. The primary end point was the change from the baseline HbA_{1c} level and the proportion of patients achieving HbA_{1c} of less than 7.5%.

RESULTS: At 24 weeks, the baseline mean HbA_{1c} (8.7% in the two study groups) had decreased to 7.7% in the TS group, as compared with 8.4% in the CS group ($P < 0,05$). The proportion of patients who reached the HbA_{1c} target ($< 7,5\%$) was greater in the TS group (50%) than in the CS group (20%, $p < 0,05$). A number of quality of life indicators for both parents and children



with T1DM at the end of the study compared to baseline significantly increased in the TS group compared with the TC group ($p < 0.05$). During the study period rate of severe hypoglycemia and DKA in TS group (0 and 10 cases per 100 person-years) did not differ significantly from that in CS group (0 and 20 cases per 100 person-years, $P > 0.05$).

CONCLUSION: In children with inadequately controlled T1DM, telemedical support proved to be feasible and resulted in significant improvement in glucose control (HbA_{1c} , glucose variability) and quality of life without the increase in the incidence of DKA and severe glycaemia.

KEYWORDS: type 1 diabetes mellitus; telemedicine; children; quality of life; glycaemic control

INTRODUCTION

Prolonged subcutaneous insulin infusion (PSII), or insulin pump therapy, is an effective method for improving and maintaining glycaemic control in children with type 1 diabetes mellitus (DM1) [1–7]. However, the use of PSII requires the expertise of an endocrinologist, direct involvement and contact of the treating physician with the patient and may not always result in satisfactory glycaemic control. Thus, according to the international study TEENS which included >500 children and adolescents with DM1 (20% of whom received PSII) in the Russian Federation, only 16.9% of children and 14.6% of adolescents achieved glycated haemoglobin (HbA_{1c}) target levels [8]. Unsatisfactory control of DM1 may be associated with a number of factors, including the availability of medical care from qualified personnel (absence of paediatric endocrinologists, lack of skills and experience with insulin pumps, etc.). Given the geographic and demographic characteristics of the Russian Federation, the use of telemedicine may be one of the methods to improve the effectiveness of the treatment.

The use of telemedicine in the context of DM1 is very relevant because of the therapeutic aspects of this disease. Diabetes mellitus is a chronic disease requiring the observation of a patient by an endocrinologist. Patients with DM1 should constantly monitor glycaemic parameters, and the treating physician must adjust the ongoing regimen of insulin therapy in accordance with these data. Absence of appropriate correction of ongoing therapy by the treating physician and suboptimal self-control by the patient as a result of inadequate training may lead to unsatisfactory control of DM1. Consequently, this contributes to the development and progression of acute and chronic complications that worsen the patient's quality of life, further disease prognosis, and therefore, significantly increase the cost of treatment.

According to international studies, the use of telemedicine in children with DM1 contributes to reducing the HbA_{1c} level, improving quality of life and reducing emergency treatment and hospitalisation [9]. In addition, the use of telemedicine may reduce the costs associated with inter-hospital patient transfer, provide additional medical services, and evenly distribute the duties of medical personnel. Currently, no published systematised results on the effectiveness of telemedicine for the control of DM1 in children are available in Russia.

STUDY AIM

This study aimed to assess the possibility of remote counselling for children and adolescents with DM1 and its effect on glycaemic control, quality of life and frequency of acute complications.

MATERIALS AND METHODS

This study presents the data obtained from the children's department of diabetes mellitus of the Federal State Budgetary Institution National Medical Research Centre of Endocrinology of the Ministry of Health of Russia.

Study design

A 24-week, prospective, open-label, controlled clinical study was conducted, including children and adolescents who met the following basic criteria: 1) age ≥ 8 and 18 years; 2) diagnosis of DM1 with disease duration ≥ 1 year; 3) insulin therapy by PSII pump of Medtronic Paradigm (Medtronic MiniMed, USA) with duration ≥ 6 months; 4) according to the instructions of CareLink Professional, self-control of glycaemia for the previous 3 months was conducted on average ≥ 4 times a day and replacement of the infusion system of the insulin pump was performed at least once every 4 days; 5) inadequate glycaemic control (HbA_{1c} level $\geq 7.5\%$); 6) the presence of a personal computer at the patient's residence with access to the Internet; 7) signed informed consent.

The main exclusion criteria were as follows: 1) not type 1 diabetes mellitus; 2) insulin therapy by multiple insulin injections or a pump other than Medtronic Paradigm®; 3) clinically significant acute diseases of the cardiovascular, nervous, genitourinary and gastrointestinal systems and blood diseases; 4) violation of the study protocol such as irregular self-control of blood glucose <4 times a day, irregular replacement of the insulin pump infusion system less than once in 4 days, failure to attend visits, failure in sending the data from an insulin pump every 2 weeks (for a group of remote counselling); and 5) refusal to participate in the study.

Study procedures and registration of indicators

Patients enrolled in the study were randomly distributed to a remote counselling (RC) group or traditional control (TC) group at their first visit to the clinic. For comparing both groups, a basic training programme on DM1 and PSII was conducted for all patients included in the study at the first visit.

All patients underwent standard examination and anthropometry at baseline, as well as 12 and 24 months after enrolment in the study. During these visits, the level of HbA_{1c} was determined (DCA Vantage® Analyzer, Siemens, Germany); glycaemia and daily doses of insulin were recorded and analysed; treatment was assessed and adjusted; and recommendations for self-control and follow-up were provided. In addition, the quality of life of children and parents was assessed at baseline and the end of study.

Registration and analysis of glycaemic parameters (mean level of glycaemia, glucose variability [DM], blood glucose

Table 1. Baseline characteristics of groups

	RC group	TC group	P level
Age (years)	13±0,6	13±0,7	н/д
Male/Female	10/10	8/12	н/д
Duration of DM1 (years)	6±0,7	6,1±0,6	н/д
Duration of PSII (years)	2,6±0,4	3,1±0,5	н/д
HbA1c (%)	8,7±0,3	8,7±0,2	н/д

Note: Data are represented as mean ± standard error of the mean (M±SEM) or number.

RC, remote counselling; TC, traditional control; DM1, type 1 diabetes mellitus; PSII, prolonged subcutaneous insulin infusion; HbA1c glycated haemoglobin

measurements in the range <4 and >10 mmol/l) and calculation of average daily doses of insulin were performed using the software CareLink Professional (Medtronic MiniMed, USA) for the two-week period preceding the day of the visit. This software enables the user to generate reports containing information regarding the main indicators of glycaemia, insulin therapy, frequency of self-control, replacement of the infusion set and other data for a selected period.

All patients were provided with a Contour TS glucometer (Bayer, Switzerland) and test strips for the duration of the study. Patients in the RC group were also provided with technical equipment [CareLink USB (Medtronic MiniMed, USA)] for transferring data from the insulin pump to their personal computer.

Remote consulting

Patients or their parents randomised to the RC group submitted data stored in the memory of the insulin pump to a specialist in the insulin pump therapy centre twice every month and, in response, received advice on treatment and self-control. Data were transmitted via the Internet using the software CareLink Personal (Medtronic MiniMed, USA) and technical support CareLink USB (Medtronic MiniMed, USA). Interpretation and analysis of the data obtained in the insulin pump therapy centre was performed using the software CareLink Professional (Medtronic MiniMed, USA). Based on the reports received, the specialist adjusted the therapy or provided recommendations on self-control. Depending on the volume or the requirement for additional information from the patient, the specialist provided these recommendations via e-mail, telephone, or video call.

Assessment of quality of life of children and parents

The quality of life of children and their parents was assessed using the questionnaire PedsQLTM 3.0 Diabetes Module. The questionnaire comprised 28 elements (situations) composing 5 modules, namely Diabetes, Treatment I, Treatment II, Anxiety, and Communication. In the questionnaire, children or parents were asked to assess the difficulty of different situations during the previous month. Each element is estimated on a 5-point scale from 0 (never) to 4 (almost always). The scores for each element were transformed in the reverse order on a scale from 0 to 100 as follows: 0 = 100, 1 = 75, 2 = 50, 3 = 25, 4 = 0. Subsequently, the average score was calculated for all elements in general

and for each section separately. High scores indicated a better quality of life for the patient or parent.

Primary study outcome

Change in the level of HbA1c at the end of study compared with baseline and the proportion of patients who achieved a level of HbA1c of <7.5% at the end of study.

Additional study outcomes:

1) Change at the end of study compared with the baseline level of the following indicators: the average level of glycaemia, DM, blood glucose measurements in the range <4 and >10 mmol/l, quality of life indicators; 2) frequency of episodes of diabetic ketoacidosis (DKA) and severe hypoglycaemia during the study.

Ethical review

The study protocol was approved by the local Ethics Committee of the Federal State Budgetary Institution Endocrinology Research Center of the Ministry of Health of Russia (extract from protocol No. 11 of 04.10.2015).

Statistical analysis

Statistical processing of the results was performed using the statistical package STATISTICA 8.0 (StatSoft, USA). The quantitative characteristics are presented as the mean ± standard error of the mean (M ± SEM), unless otherwise indicated. The difference between the quantitative characteristics was estimated using the Mann-Whitney test. The difference between the qualitative characteristics was estimated using the two-tailed Fisher's test. The difference between the incidences of acute complications was assessed using a two-tailed Z-test. A value of $p < 0.05$ was considered significant.

RESULTS

The study included 41 children, one of whom withdrew his participation in the study at a second visit in accordance with the exclusion criteria. The baseline characteristics of patients in the RC and TC groups are presented in Table 1. Patients in both groups did not differ in age, sex, duration of DM1 and PSII, as well as in the level of HbA1c.

At baseline, the level of HbA1c was 8.7% in both study groups. After 24 weeks, the level of HbA1c in the RC and TC groups decreased to 7.7% and 8.5%, respectively (Figure 1).

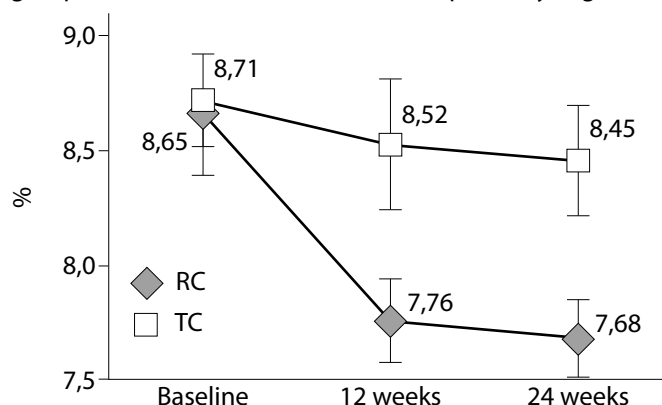


Fig. 1. Dynamics of the level of HbA1c during the study in the RC group (red diamond and line) and TC group (blue square and line). The data are presented as the mean ± standard error of the mean (M±SEM)
RC, remote counselling; TC, traditional control

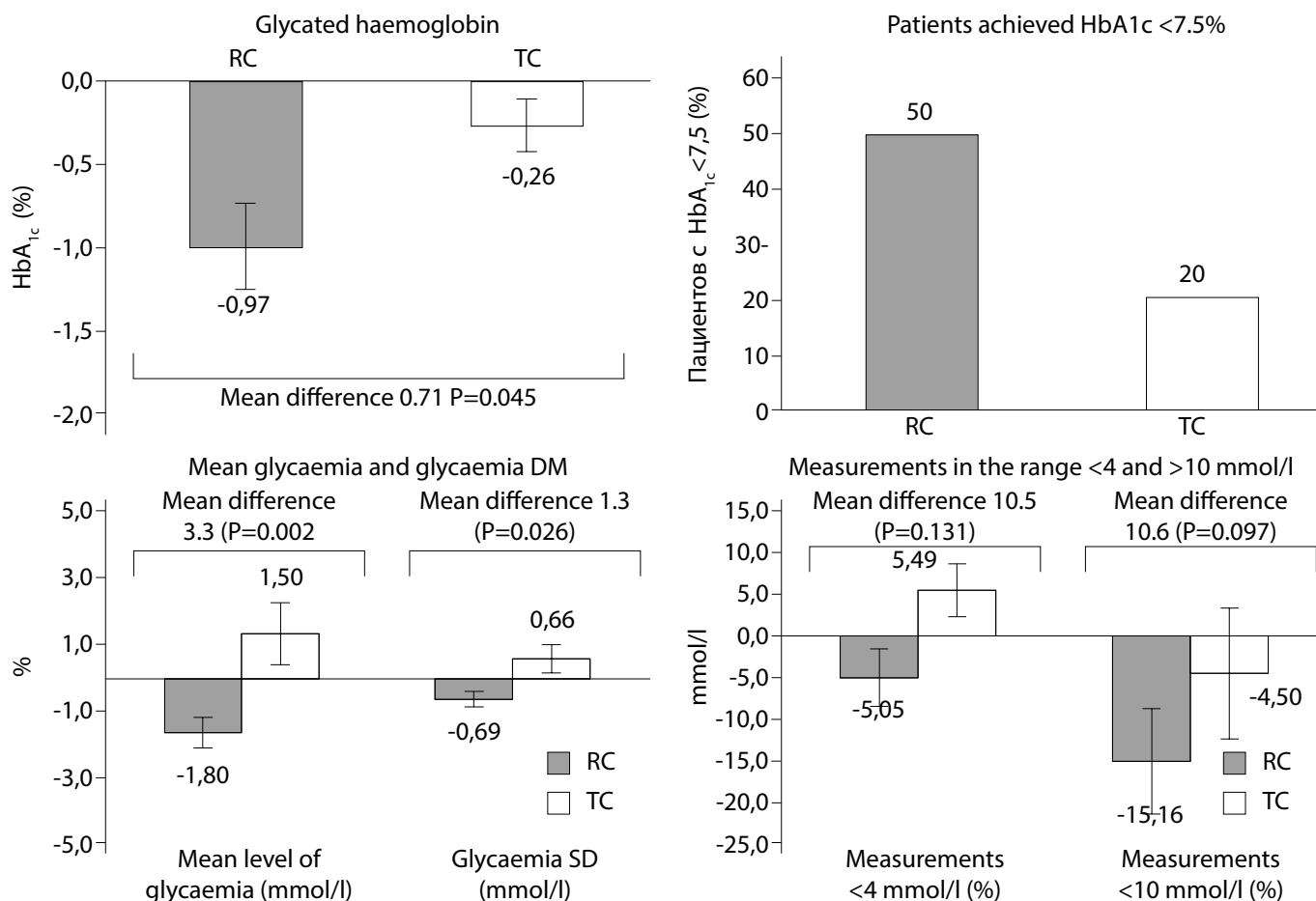


Fig. 2. Change in indicators at the end of the study relative to baseline levels in the RC group (red columns) and TC group (blue columns). Data are presented as mean \pm standard error of the mean ($M \pm SEM$)

RC, remote counselling; TC, traditional control; HbA_{1c} glycated haemoglobin

Table 2. Average daily doses of insulin at the baseline and at the end of the study in the RC and TC groups

Indicator name	Baseline		After 24 weeks	
	RC group	TC group	RC group	TC group
Insulin therapy				
Average daily dose of insulin, U	42,3 \pm 5,2	43,8 \pm 3,9	43,8 \pm 4,6	45,4 \pm 3,7
Average daily basal dose of insulin, U	17,1 \pm 2	19,8 \pm 2,1	20,2 \pm 2,1	19,1 \pm 1,7
Average daily bolus dose of insulin, U	25,2 \pm 3,4	24 \pm 2,6	23,7 \pm 2,8	26,2 \pm 2,6

Note: Data are presented as the mean \pm standard error of the mean ($M \pm SEM$). All p values were >0.05 when comparing the indicators of the RC and TC groups. RC, remote counselling; TC, traditional control

Table 3. Changes in the indicators of quality of life in parents of children with DM1, relative to baseline levels, at the end of study

Indicator name	Baseline		After 24 weeks	
	RC group	TC group	RC group	TC group
Adherence to treatment				
Frequency of glycaemia determination, per day	5 \pm 0,6	4,4 \pm 0,6	5,8 \pm 0,6	4,3 \pm 0,5
Frequency of use of the bolus calculator, per day	4,7 \pm 0,5	4,9 \pm 0,5	5,8 \pm 0,5	5,2 \pm 0,6
Frequency of replacement of the infusion system, quantity/2 weeks	4,2 \pm 0,3	4,9 \pm 0,6	5 \pm 0,4	5 \pm 0,6

Note: Data are presented as the mean \pm standard error of the mean ($M \pm SEM$). All p values were >0.05 when comparing the indicators of the RC and TC groups. RC, remote counselling; TC, traditional control

At the end of the study, the decrease in the level of HbA_{1c} relative to the baseline was significantly greater in the RC group than in the TC group (0.97% vs. 0.26%, respectively; $p < 0.05$) (Figure 2). The difference in change in the level of HbA_{1c} at the end of the study relative to the baseline between the groups was 0.71%. The proportion of patients who achieved

the target level of HbA_{1c} (defined as $<7.5\%$) was significantly higher in the RC group than in the TC group (50% vs. 20%, respectively; $p < 0.05$) (Figure 2). In the RC group, by the end of the study, there was a decrease in the mean level and DM of glycaemia relative to the baseline compared to the TC group, which showed a slight increase in the levels of these

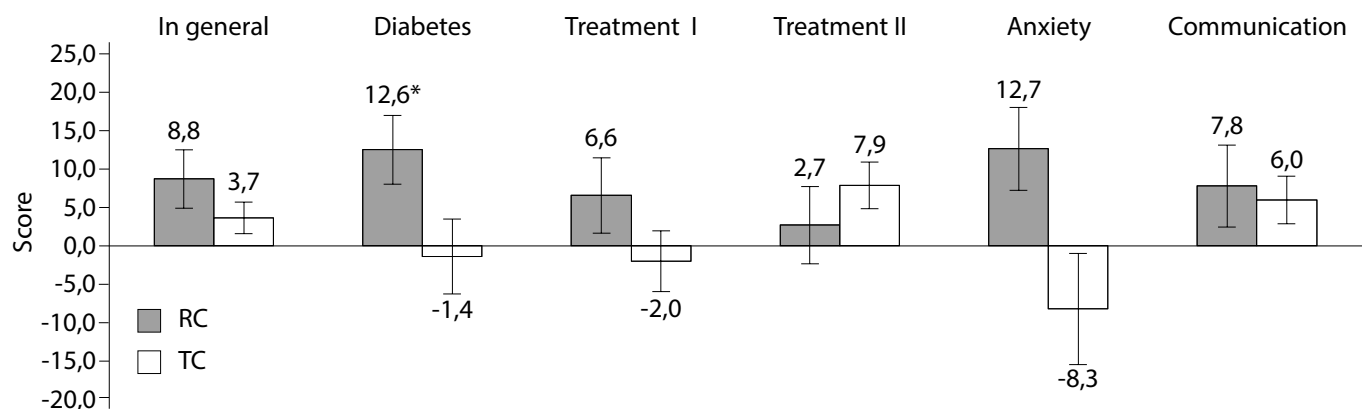


Fig. 3. Changes in the indicators of quality of life in parents of children with DM1, relative to baseline levels, at the end of study
The data are presented as mean \pm standard error of the mean ($M \pm SEM$). * $P < 0.05$ when comparing the indicators of the RC and TC groups.
RC, remote counselling; TC, traditional control

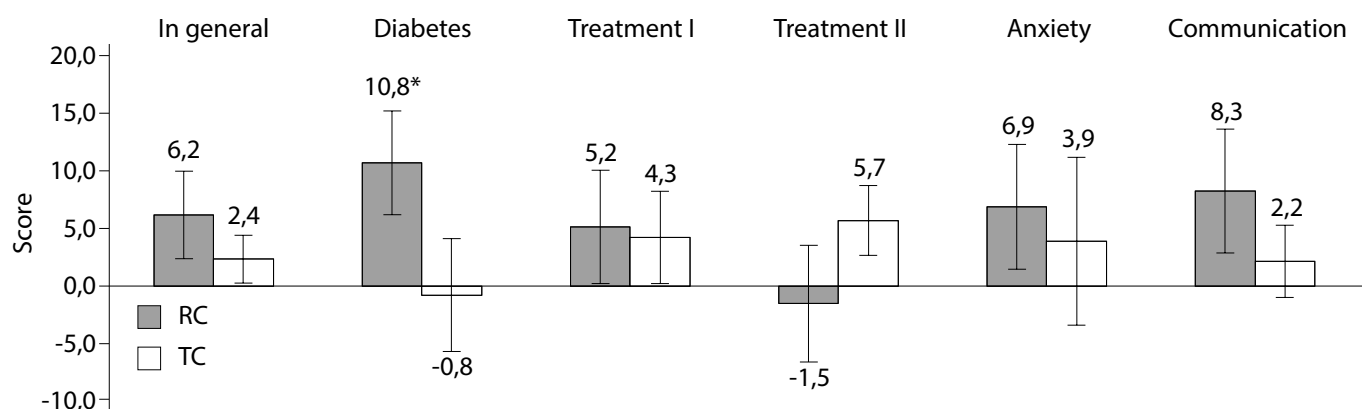


Fig. 4. Changes in the indicator of quality of life in children with DM1, relative to baseline levels, at the end of study
The data are presented as the mean \pm standard error of the mean ($M \pm SEM$). * $p < 0.05$ when comparing the indicators of the RC and TC groups.
DM1, type 1 diabetes mellitus; RC, remote counselling; TC, traditional control

indices (Figure 2). Also, in the RC group, the percentage (%) of the measurements decreased lower than 4 mmol/l and more than 10 mmol/l by the end of the study relative to the baseline, however the dynamics did not reach a statistically significant level compared to the TC group (Figure 2).

Insulin therapy, determined by the level of daily average doses of basal and bolus insulin, did not differ between groups at baseline and at the end of the study (Table 2).

At the end of the study, patients in the RC group had non-statistically significant higher adherence rates compared with those in the TC group (Table 3).

Assessment of the quality of life at the end of the study showed a similar trend between the RC and TC groups for all indicators. However, only two indices of the parents and one index of children in the RC group compared with that of the TC group showed changes relevant to the baseline that reached statistical significance (Fig. 3, 4).

During the study, the frequency of DKA episodes and severe hypoglycaemia in the RC group did not significantly differ in comparison with that observed in the TC group (Figure 3).

DISCUSSION

Lower levels of HbA1c in patients with DM1 is associated with a reduction in the risk of late complications of DM1 [10]. In the present study, after 24 weeks, a significant improvement in the level of HbA1c was observed in the patients who received RC compared with those with traditional observation. These findings are in agreement with previous data from a number of studies showing

a statistically significant decrease in the level of HbA1c achieved as a result of a telemedicine intervention in patients with DM1 [11, 12]. The present analysis established that this decrease was caused by a decrease in the average level of glycaemia and the variability of glycaemia determined by the level of DM. Decrease in variability of glycaemia resulted in, albeit not reliable, a decrease in the measurement frequency in the range of less than 4 mmol/l and more than 10 mmol/l by the end of the study relative to the baseline in the RC group compared to the TC group. Thus, the decrease in the level of glycaemia was achieved not at the expense of more frequent episodes of hypoglycaemia. On the contrary,

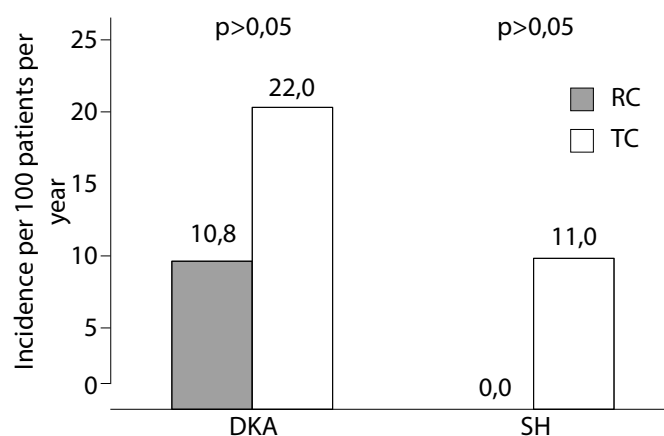


Fig. 5. The incidence of episodes of severe hypoglycaemia and diabetic ketoacidosis for the entire study period in the RC group (red columns) and TC group (blue columns).
SH, severe hypoglycaemia; DKA, diabetic ketoacidosis; RC, remote counselling; TC, traditional control

it was accompanied by a reduction in episodes of hypo- and hyperglycaemia. Considering the potential contribution of high variability of glycaemia to the development of vascular complications of DM1 [13], the results shown in the present and other studies [14] indicate the potential of telemedicine in improving glycaemic control.

The improved effectiveness of the treatment may be attributed to an increase in the level of awareness of patients and their parents, better adherence to treatment and improvement in the quality of life, as a result of the RC. Although not statistically significant, in the RC group, there was a tendency for better adherence rates (more frequent self-control, replacement of the infusion system and use of the bolus calculator). In addition, we noted a tendency towards better quality of life indicators for both parents and children with DM1 in the RC group. However, only a few indicators reached statistical significance.

The average daily requirement for insulin did not differ between the groups. This indicates that the effect observed and the change in daily doses of insulin may not be associated.

In the RC group, there was no increase in the frequency of episodes of acute DM1 complications, such as severe hypoglycaemia and DKA, in comparison with the TC group. Of note, none of the studies conducted so far on the use of telemedicine for the counselling of patients with DM1 have shown an increase in the frequency of acute complications of the disease, highlighting the safety of this type of medical aid [15].

At present, there are no sufficient legal grounds for the use of telemedicine for the counselling of children with DM1 in the Russian Federation. As a consequence, there is no possibility for government financing of this type of medical aid. The accumulation of evidence on the feasibility and effectiveness of the use of telemedicine for the control of diabetes mellitus may contribute to the introduction of this approach into practical health care.

Study limitations

A limitation of this pilot study is the small sample size which complicates the statistical analysis. However, most indicators reached statistical significance between groups, and the results are likely to be more convincing when analysing a larger sample. In addition, these findings are limited by the period of intervention investigated in this study; hence further investigations are required to assess the effect of telemedicine on glycaemic control.

CONCLUSION

In children with unsatisfactory glycaemic control of DM1, RC was feasible and led to a significant improvement in glycaemic control (HbA1c, glycaemic variability), in the absence of more frequent episodes of DKA and severe hypoglycaemia. Further evaluation of the effectiveness of telemedicine in such children with DM1 through studies with larger sample size is warranted. Moreover, additional studies are required to assess the duration and long-term effect of the use of telemedicine for counselling patients on glycaemic control.

ADDITIONAL INFORMATION

Funding. The work was performed within the framework of the national charity programme for helping children with endocrine diseases Alpha Endo with the financial support of the KAF foundation. The company Medtronic LLC provided CareLink USB for the research. The stock company Bayer provided the glucometers Contour TS and test strips to them for the study.

Conflict of interest. The authors have no conflicts of interest to declare.

Participation of authors. Laptev D.N. participated in the clinical study, registration, analysis and statistical processing of the data obtained and writing the text. Peterkova V.A. participated in the scientific management, design and study planning.

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