ORIGINAL ARTICLE

The effect of functional insulin therapy on glycaemic parameters in children with diabetes mellitus type 1

Diana Štimjanin-Koldžo[1], Salem Alajbegović[2], Ena Štimjanin[2], Jasmina Mehinagić[1]

[1]Department of Paediatrics, [2]Department for Endocrinology, Diabetes and Metabolic Diseases; Cantonal Hospital Zenica, Zenica, Bosnia and Herzegovina

ABSTRACT

Aim The aim of the study is to evaluate the effect of a prospectively conducted interactive 5-day education programme based on Düsseldorf model on glycated haemoglobin (A1C), and total daily dose of insulin in type 1 diabetes patients**.**

Methods A total of 67 type 1 diabetes patients was analysed; mean age of 11±0.68 years, 43 females and 24 males. The programme was led by a trained team of diabetes specialist doctors and nurses. All subjects and their parents completed a knowledge test about diabetes at beginning, and at the end of education, and after 12 months (30 questions). Subjects were evaluated for total daily insulin, and HbA1c at baseline, as well as 3, 6, 9 and 12 months after the end of the education programme.

Results Results of the knowledge test after the education have shown higher knowledge at baseline. At the end of the education programme an average of total daily insulin dose was significantly lower. There was a 3.17% reduction in HbA1c values over 9 months, and 1.8% over 12 months in the comparison to the baseline values ($p<0.001$).

Conclusions Structured education programme of functional insulin therapy was associated with improved glycaemic control in type 1 diabetes patients and their parents. It motivated patients and parents to improve glycaemic control. One year after the follow up, glycaemic control was worsening, due to lack of patients' motivation, therefore, there is a need for yearly re-education.

Key words: child, parents, education of diabetes, functional insulin therapy, glycaemic control

Corresponding author:
Diana Štimjanin-Koldžo
Department of Paediatrics,
Cantonal Hospital Zenica
Crkvice 67, 72000 Zenica,
Bosnia and Herzegovina
Phone: +387 32 447 336;
Fax: +387 32 226 576;
E-mail: dstimjanin@gmail.com
ORCID ID: http://www.orcid.org/0000-0002-7596-6630

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INTRODUCTION

Diabetes mellitus (DM) is the most common, chronic metabolic endocrine disease in children and adolescents (1). Optimal treatment for diabetes mellitus, except insulin therapy, is dietary measurement, self-control, adequate physical activity and education (2,3). Every young diabetic patient and their parents/carers have the right to accessible, planned diabetes self-management education (4). Diabetes education should be delivered by an interdisciplinary paediatric diabetes team (as a minimum a doctor, nurse and dietician), understanding of the special and changing needs of young people and their families as they grow through different stages of life; it needs to be patient-centred and thus adaptable to suit individual needs. Successful treatment of DM incorporates behavioural changes in patients and their parents/carers. Education is the keystone for diabetes care and structured diabetes self-management education (DSME) is the key to a successful outcome (5). Therapeutic education programme needs to be structured taking into account therapeutic scheme and a need to show its effectiveness. Interactive methods and materials are used taking into account patients' daily routine. In Diabetes Control and Complication Trials study (DCCT) this was one of four education programmes, as well as in DAFNE-Dose Adjustment For Normal Eating in Great Britain, Düsseldorf model of structured therapy and education, and functional intensified insulin therapy-FIT (Vienna, Ljubljana, Zagreb). Prospective studies based on carbohydrate counting evaluated a 5-days education programme in type 1 diabetic patients (6,7). Functional insulin therapy (FIT) knowledge include: functional insulin replacements, all about insulin, insulin dose adjustment, tests of basal insulin, carb factor, correction factor; functional insulin replacement under special conditions (exercise, illness). The effects are greater for children than adults, and are most effective when integrated into routine care, when education is learner-centred, parents are involved, empowerment principles are utilised, and self-management, problem-solving, goal setting and self-efficacy are promoted (2,3,6).

The aim of the study was to evaluate the effect on glycated haemoglobin (A1C) of a structured intervention in type 1 diabetes patients.

Functional insulin therapy is implemented at the Department of Paediatrics Endocrinology and Diabetes in Cantonal Hospital Zenica, Bosnia and Herzegovina (B&H) as a routine way of education and re-education of children with diabetes type 1and their parents. The purpose of monitoring the group of children is to show the importance of such access to education as well as the need for re-education after a certain period of motivation to both children and parents. Similar research was not carried out in other paediatric departments in the B&H. The results of our work should serve as a motivation for other B&H centres to organize education on this model, with the aim of improving the glycaemic control of children with diabetes type 1.

PATIENTS AND METHODS

Patients and study design

This prospective study evaluated routine and usual 5-day education programme for type 1 diabetic patients and their parents at the Department of Paediatrics Endocrinology and Diabetes, Cantonal Hospital Zenica, B&H. The study took place in the period between January 2012 to March 2013. The education programme was adapted from the Düsseldorf "Diabetes Training and Treatment Programme" (8) and based on carbohydrate counting for persons with type 1 diabetes. Intensive group education course took place over 5 consecutive days with skills based focus led by a diabetes specialist and a nurse (normally 12 participants per group, 6 children and 6 parents). Each group was followed for one year. A total of 67 type 1 diabetes patients was analysed, mean age of 11±0.68 years, 43 females and 24 males.

Methods

All subjects and their parents completed a knowledge test about diabetes at beginning and at the end of education, after five days (30 questions) and after 12 months. Total daily dose of insulin (TDD) and HbA1c were evaluated at the baseline, and 3, 6, 9 and 12 months after the education programme. Time table of education: 1st day: What is diabetes, hypoglycaemia and hyperglycaemia; 2nd day: Which food is best for me? 3rd day: Self-management of diabetes; 4th day: Therapy for me; 5th day: Chronic complications of diabetes and foot care.

Statistical analysis

Arithmetic mean value and standard deviation, Wilcoxon test for average 6-point glycaemic profile was used. For HbA1c baseline and 3, 6, 9, 12 months checks Freidman test was used.

RESULTS

In this study, 67 type 1 diabetes patients on intensive insulin therapy were analysed; mean age 11±0.68 years, 43 (64.18%) females and 24 (35.82%) males.

At the end of the education programme, the results showed significant increase of correct answers average compared to the number of correct answers before the beginning of the educational intervention (18.02:2.19; p<0.001). After 13 months the results showed a decrease of correct answers average comparing to the results at the end of the five-day education (2.19:23.85; p<0.001) (Table 1).

The percentage of pronounced results of the knowledge test before and after education as well as after 13 months was significantly increased, 60.6%, 88.17%, and 79.5%, respectively (Table 1).

Table 1. Results of knowledge test before and after education (1st day, 5th day, 12 months)

Number (%) of right answers of 30 questions							
1st day(before education)		5th day after education			12 months after education		
MV	SD	MV	SD	p	MV	SD	p
18.02 (60.06)	20.99	2.19 (88.17)	10.12	<0.001	23.85 (79.5)	12.13	<0.001

MV, middle value; SD, standard deviation

There was a statistically significant decrease in the total daily dose of insulin (TDD) at the end of education. The average decrease in insulin TDD was 2.90 IU after 5 days, but the average decrease after 12 months was 1.97 IU (Figure 1).

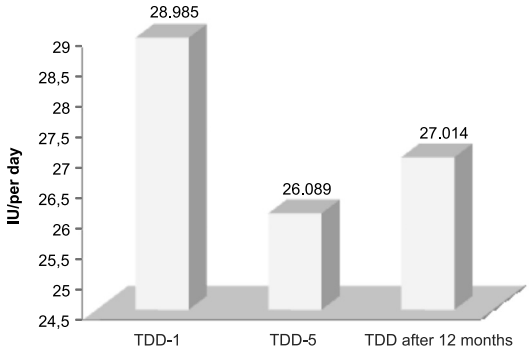

Figure 1. Average total daily insulin dosage, TDD-1, total daily dose first day; TDD-5, total 5 days daily dose

There was a 3.17% reduction in HbA1c average value over 9 months (10.60% and 7.47%, respectively; p<0.001) and 1.8% over 12 months (10.60% and 8.24%, respectively; p<0.001) in the comparison to the baseline values. HbA1C values increased by 0.77% in the period between 9 and 12 months (7.46% and 8.24%, respectively; p<0.001) (Table 2, Figure 2).

Table 2. Clinical approvement of functional intensified insulin therapy in 67 patients with type 1 diabetes mellitus

HbA1c (%)									
1st day (beginning)		6 months		Changes	p	12 months		Changes	p
MV	SD	MV	SD	MV		MV	SD	MV	
10.60	2.19	8.07	1.40	-2.53	<0.001	8.25	0.99	-2.35	<0.001

MV, middle value; SD, standard deviation

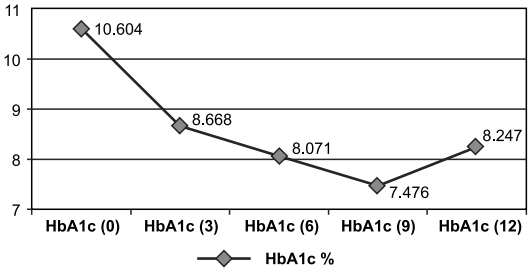

Figure 2. Results of average value of HbA1c at the beginning and the end of the study. Control checks of HbA1c at 1st day (0), after 3 days (3), 6 days (6), 9 days (9) and 12 months (12)

DISCUSSION

Structured DM education improves behavioural changes and consequently leads to better control of the disease with lower doses of insulin needed to achieve adequate glycaemia. Effects of structured DM education weaken after 13 months (18).

The rationale for pre- and post-prandial self-monitoring is to help patients understand the effects of food choices, physical activity, and medications on blood glucose concentrations, and to guide therapeutic adjustments (9) without increasing the hypoglycaemic risk. The results of this study have shown that educational intervention improved patients' knowledge of DM, e. g. results of knowledge test before and after education showed a significant increase of average correct answers to the knowledge test. Unfortunately, effects of education faded after 12 months and showed a decrease in average correct answers in relation to the test after education. Improvements in patients' knowledge resulted in improvement of their disease showing lower HbA1C values as

well as lower doses of insulin needed to achieve satisfactory glycaemic control. Observed effects weakened as time from the educational intervention passed and there was 3.17% reduction in HbA1c over 9 months, and 1.8% over 12 months compared to the baseline values; HbA1C values have increased by 0.77% between 9 months and 12 months. Effects of educational intervention were stable for 9 months and after that time effects they begun fading, but not reaching the baseline after 12 months. Average doses of insulin needed to achieve glycaemic values decreased 2.90 IU after 5 days of education, and 1.97 IU after 13 months. This finding could be explained by frequent therapeutic modifications with the intensified self-monitoring blood glucose (SMBG) and making insulin adjustments related to the additional blood glucose testing and food intake (10). The SMBG and some psychosocial factors are believed to be associated with active self-management in type 1 diabetic patients after the education programme (11). In many studies, there is evidence of an increased risk for hypoglycaemia as the HbA1c decreases (11-13), but this is not always the case (14), particularly in recent years with the increasing use of insulin analogues (15,16).

The disadvantages of the study include insubstantial analysis of newly discovered and previously discovered diabetics as well as the absence of a control group of patients who did not undergo this type of education.

The strength of this study includes selection of children with type 1 diabetes and their parents who were already on SMBG to avoid the potential impact of SMBG in ongoing and new patients and the fact that all participants had been educated and followed-up by the same diabetes team with the same education and treatment policies and clinical feedback. Educators (paediatric endocrinologist or physician trained for the care of children and adolescents with diabetes, diabetes educators, dieticians, psychologists, social workers, and other health care providers) should have access to continuing specialized training in current principles of insulin therapy, new diabetes technologies, advances in diabetes education, and educational methods (17). Diabetes education needs to be a continuous process and repeated in order to be effective (18).

In conclusion, one year after our education programme intensive management of diabetes, enabled by various and sustained changes in patient skills, was associated with improved HbA1c. Every child with type 1 diabetes with basal bolus therapy and their parents should be offered a structured functional intensive therapy (FIT) education course. Carbohydrate counting is an important skill for everyone involved, offered to all newly diagnosed patients, and to anyone who wants to improve self-management skills. Profit of FIT is a significantly better glycaemic control, raised and refreshed level of knowledge, self-satisfaction and better self-control, reduction of possible acute and chronic complications of the disease.

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TRANPARENCY DECLARATIONS

Competing interests: none to declare.

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Efekti funkcionalne inzulinske terapije na parametre glikemijske kontrole kod djece s dijabetesom tipa 1

Diana Štimjanin-Koldžo[1], Salem Alajbegović[2], Ena Štimjanin[2], Jasmina Mehinagić[1]

[1]Služba za dječije bolesti, [2]Odjeljenje za endokrinologiju, dijabetes i bolesti metabolizma; Kantonalna bolnica Zenica, Zenica, Bosna i Hercegovina

SAŽETAK

Cilj Cilj studije je evaluirati efekte interaktivnog petodnevnog edukacijskog programa po Dizeldorfskom modelu, provedenog prospektivno, na nivo HbA1c i ukupne dnevne doze inzulina kod pacijenata s dijabetesom tipa 1.

Metode Praćeno je 67 djece s dijabetesom tipa 1, prosječne dobne starosti 11±0.68, odnosno 43 djevojčice i 24 dječaka. Edukacijski program je proveo educirani tim subspecijalista (endokrinolog, dijabetolog i medicinska sestra). Svi praćeni pacijenti i njihovi roditelji pristupili su testu znanja od 30 pitanja na početku programa, na kraju petodnevne edukacije te na kraju praćenja tokom 12 mjeseci. Pacijenti i njihovi roditelji pratili su ukupnu dnevnu dozu inzulina, HbA1c na početku edukacije te nakon 3, 6, 9 i 12 mjeseci po edukativnom programu.

Rezultati Rezultati testa znanja pokazali su znatno bolje rezultate nakon edukacije i opadanje nivoa znanja nakon 12 mjeseci. Na kraju edukacijskog rada ukupna dnevna doza inzulina bila je značajno niža. HbA1c je reduciran za 3.17% tokom 9 mjeseci praćenja, a zabilježen je ukupni pad HbA1c nakon 12 mjeseci praćenja od 1.8%.

Zaključak Strukturirani edukacijski program funkcionalne inzulinske terapije ukazao je na poboljšanje kontrole dijabetesa tipa 1 kod djece. On je motivirajući i za djecu i za njihove roditelje u održavanju glikemične kontrole. S obzirom da nakon godinu dana praćenja motivacija opada, što je registrirano pogoršanjem glikoregulacije, potrebna je reedukacija.

Ključne riječi: dijete, roditelji, edukacija, funkcionalna inzulinska terapija, glikemijska kontrola.