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Diabetes & its Complications

Effects of Different Insulin Treatment Approaches on Metabolic Parameters and Quality of Life in Children with Type 1 Diabetes

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ABSTRACT

Introduction: *Type 1 diabetes mellitus (T1-DM) is a common chronic disease in childhood. This study aimed to investigate the effects of flexible insulin therapy (FIT) and insulin infusion pump therapy (IIPT) on clinical, metabolic parameters and quality of life in patients followed.*

Materials and Methods: *The study included 50 patients with type 1 diabetes who were followed in our pediatric endocrinology outpatient clinic. All patients who received detailed instruction on carbohydrate counting were receiving flexible insulin therapy. After six months of FIT, 20 willing patients were switched to IIPT. Before and after each treatment period, patients' HbA1c values, hypoglycemia frequency, basal/bolus/total insulin requirements, blood lipid levels, body mass index (BMI), glucose levels were measured by glucometer and continuous subcutaneous glucose monitoring (CSGM). In addition, quality of life scores of all patients were compared.*

Results: *The mean age of the patients was 13.1 and average duration of diabetes was 8.4 years. HbA1c levels were significantly lower in the IIPT period compared to the FIT period (p:0.011). However, there was no difference in other parameters. A significant decrease in the frequency of hypoglycemia was observed in the IIPT period compared to the other period (p:0.032). No significant differences were found between the two periods in BMI, insulin doses, and lipid levels (except for the increase in LDL cholesterol). When the quality of life of patients after IIPT was examined, significant improvement was observed in general health and mental health parameters compared to the FIT period.*

Conclusion: *IIPT provide significant improvements in metabolic parameters and quality of life in children and adolescents with T1-DM compared to FIT treatment methods. IIPT has also been shown to reduce the frequency of hypoglycemia.*

Keywords
Type 1 diabetes, Flexible insulin therapy, Insulin infusion pump therapy, Quality of life.

Introduction
Diabetes mellitus (DM) is a chronic disease characterized by impaired carbohydrate, protein, and fat metabolism resulting from a true or functional deficiency of insulin [1]. DM has many complications that can occur in the early and late stages. Especially onset of late-stage complications is rooted in childhood and adolescence and can be prevented or delayed with good metabolic control [2]. The main goals of type 1 diabetes (T1-DM) treatment are to achieve glycemic control and minimize acute and chronic complications, thereby improving quality of life [3]. A report published by the Diabetes Control and Complications Research Group (DCCT) found that metabolic control was better achieved with intensive insulin therapy compared to conventional treatment, and that the frequency of microvascular complications decreased [2]. Therefore, in the treatment of type 1 diabetes today, FIT and insulin infusion pump therapy (IIPT) are used in conjunction with

carbohydrate counting [3]. In this study aimed to investigate the effects of flexible insulin therapy (FIT) and insulin infusion pump therapy (IIPT) on metabolic and clinical parameters, as well as quality of life, in patients diagnosed with type 1 diabetes and followed up.

Materials and Methods

Cases and Study Periods

The study included 50 patients diagnosed with type 1 diabetes and followed up at our hospital's pediatric endocrinology outpatient clinic. These patients had passed the honeymoon period. These patients started on FIT by being taught carbohydrate counting by a dietitian and a diabetes nurse. For all cases, the following parameters were recorded before and 6 months after the start of FIT: body mass index (BMI), blood glucose measurements taken by glucometer and continuous subcutaneous glucose monitoring (CSGM), HbA1c, blood lipid profiles, average monthly frequency of hypoglycemia, calculated basal, bolus and total insulin requirements, and quality of life scale scores. Of the cases followed for 6 months with FIT, 20 patients who met the criteria were switched to IIPT, and the same parameters were checked again after 6 months.

Calculation of insulin doses during FIT and IIPT periods

In patients undergoing FIT, the carbohydrate/insulin (CH/I) ratio was calculated based on a 500/day insulin dose ratio, while in IPD, it was calculated based on an 1800/day insulin dose ratio. Basal and bolus insulin doses were adjusted according to fasting and postprandial blood glucose levels. Before starting IIPT, patients were hospitalized and their required insulin amounts were determined using a three-day fixed diet. The basal insulin dose was reduced by 15–20%, and this dose was divided by 24 to calculate the hourly rate. Bolus doses were calculated according to the CH/I ratio. Patients were called for regular check-ups to monitor their carbohydrate counting practices.

Laboratory Measurements

Patients HbA1c levels were measured. Total cholesterol, triglycerides, HDL, and LDL cholesterol levels were measured in all patients after at least eight hours of fasting. Patients were asked to record fingerstick blood glucose measurements with a glucometer at least two days prior to each check-up, in the morning (fasting), morning (with food), midday (fasting), midday (with food), evening (fasting), evening (with food), 24:00 (midnight), and 03:00 (night). Average blood glucose levels were determined based on these records.

Continuous subcutaneous glucose monitoring (CSGM)

Patients were evaluated with CSGM at the beginning of FIT and at the sixth month of treatment. The CSGM was worn for at least one day, and average blood glucose levels were recorded throughout the day. Blood glucose measurements were taken every 10 seconds, and averages were recorded every 5 minutes (288 measurements in 24 hours). All measured blood glucose levels were also classified as hypoglycemic (<70 mg/dl), normoglycemic (70–140 mg/dl), and hyperglycemic (>140 mg/dl), and their percentages were compared throughout the day. The CSGM was applied to the abdominal area of the patients. Throughout the day, all patients were asked to measure their fasting and postprandial blood glucose levels four times using their fingertips, and to take additional blood glucose measurements if they experienced signs of hypoglycemia or if the device triggered a hypoglycemia alarm. The device was calibrated at least twice a day with fingertip blood glucose measurements, as per the instructions for use, while it was attached. Data was recorded online.

Patients' Quality of Life

At the beginning of FIT and six months later, a short health questionnaire with 36 questions and the Turkish version of the quality-of-life scale [Medical Outcomes Study 36-Item Short Form (Mos Sf-36)] were used to assess the quality of life. With this scale, quality of life scores were calculated based on 8 functions: general health, physical function, mental function, social function, pain, mental health, and energy. The Turkish validity study of SF-36 was conducted by Koçyiğit et al. [4].

The study was conducted in accordance with the rules of the Helsinki Declaration and prior ethical committee approval was obtained. All patients participating in the study were informed about the study and their written consent was obtained.

Statistical Analysis

SPSS 15.0 software was used for statistical analysis. Friedman analysis of variance, a non-parametric test, was used to compare the parameters of each period. If a statistically significant difference was found in the variance analysis, the Wilcoxon test was performed to determine which period the difference originated from. A p-value < 0.05 was considered statistically significant. This study was approved by our hospital's ethics committee (25.05.2023/19).

Results

Of the 50 patients, 25 were girls and 25 were boys, with an average age of 13.1±3.59 years and an average duration of diabetes of 8.4±3.28 years. No significant differences were found in BMI SDS of patients after IIPT compared to FIT. When blood glucose levels were assessed using CSGM, there was no statistically significant difference between the two groups (Table 1). Of the 20 patients who switched to IIPT, 12 were girls and 8 were boys, with an average age of 12.9±3.25 years and an average duration of diabetes of 5.9±2.49 years. No significant differences were found between the IIPT and FIT periods in terms of mean blood glucose levels, BMI SDS, hypoglycemic, normoglycemic, and hyperglycemic phases throughout the day, and basal, bolus, and total insulin requirements. However, a statistically significant decrease in HbA1c values was observed in patients who switched to IIPT compared to the FIT period (8.48% and 7.08%, p:0.011) (Figure 1). While there were no significant differences in triglyceride, total cholesterol, and HDL levels between the IIPT and FIT periods, LDL levels were significantly higher in the IIPT period compared to the other period (p:0.042) (Table 2). The monthly frequency of hypoglycemia during the 6-month follow-up of 20 patients receiving IIPT was found to be lower compared to FIT period (p:0.032) (Figure 2). Furthermore, only the general health (p:0.025) and mental health (p:0.018) parameters of the quality of life scale showed significant improvement after the IIPT period compared to first period (Table 3). No ketoacidosis was observed in any patient during the study period, and no skin infections were reported in any patient using IIPT.

Table 1: Comparison of blood glucose levels of patients during 6-month follow-up.

	FIT Period	IIPT Period	P value
Fasting mean blood sugar (mg/dl)	181±62,95	173±56,65	0,417
Mean postprandial blood glucose (mg/dl)	207±73.18	166±42,87	0.539
Average daily blood sugar (mg/dl)	204±54.66	181±49.80	0.213
Hypoglycemia/day %	1,32±3,65	0,00	0,312
Normoglycemia /day %	27.57±24.08	28.53±19.31	0.732
Hyperglycemia/day %	70.92±20.89	72.21±24.59	0.881

Table 2: Comparison of blood lipid levels FIT and IIPT periods.

	FIT Period	IIPT Period	P-value
Triglyceride (mg/dl)	78.7±25.19	88±26.17	0.677
Total Cholesterol (mg /dl)	157.3±19.61	166.1±26.52	0.426
HDL (mg/dl)	62.8±13.5	59.3±14.21	0.210
LDL (mg/dl)	77.6±19.45	92.2±21.42	**0.042**

Table 3: Comparison of patients' quality of life scales the FIT and IIPT periods.

	FIT Period	IIPT Period	P-value
General health	60.88±19.25	69,41±21,08	**0,025**
Physical function	86.27±11.45	89.12±11.79	0.095
Physical role	78.59±28.21	82.56±22.11	0.249
Mental function	75.13±27.32	80.25±28.18	0.416
Social function	84.42±20.23	88.54±18.76	0.283
Pain	92,14±12,79	89,67±8,26	0,086
Mental health	62.87±23.34	72±28.45	**0.018**
Energy	66.78±18.16	70.53±20.92	0.392

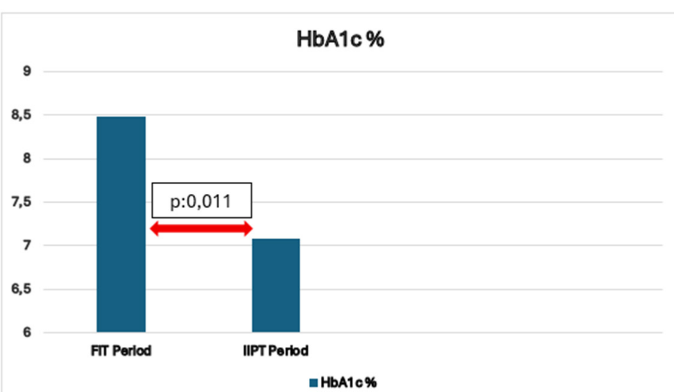

Figure 1: HbA1c values FIT and IIPT periods.

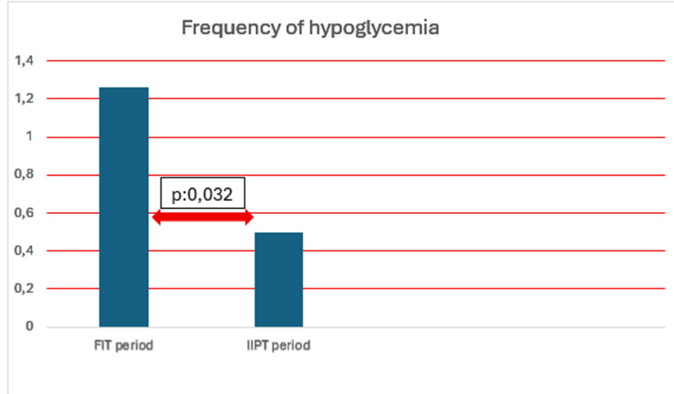

Figure 2: Frequency of hypoglycemia during FIT and IIPT periods.

Discussion

It is known that long-term complications related to diabetes accelerate during puberty and adolescence, and metabolic control achieved during this period is important for preventing complications [5]. In adolescent patients, who experience difficulties with treatment adherence, regulating their nutrition and insulin therapy is quite challenging. One of the important nutritional plans developed for this purpose is the carbohydrate counting method [1]. While carbohydrate counting combined with intensive insulin therapy achieves success in glycemic control, excessive weight gain is reported as a frequently observed complication [6]. There are also studies reporting no weight gain with carbohydrate counting [7-9]. In our study, while we observed improvement in metabolic control of the cases after carbohydrate counting, we did not observe a significant increase in BMI SDS values (p:0.23). Some studies report that the carbohydrate counting method is no different from standard nutritional recommendations and that education is essential for successful treatment [10]. We think that our results may be related to the importance given to education as well as the strict monitoring of patients' diets.

In patients experiencing injection problems, IIPT is a suitable alternative to multiple-dose injection therapy. Many studies have shown that IIPT provides better metabolic control in patients [11,12]. In addition, insulin infusion pumps make it possible to adjust different basal insulin requirements throughout the day [11,12]. In addition, many studies have shown that intensive insulin therapy leads to weight gain along with improved metabolic control [13,14]. However, there are also studies that show no change in BMI [15]. Although an increase in BMI SDS was detected with IIPT in our study, it was found not to be statistically significant.

In our study, although there was a general tendency to decrease in mean blood glucose levels with IIPT, no significant difference was detected. There are many studies in the literature showing that there are significant improvements in HbA1c values in patients who switch to IIPT [16]. However, Hanas et al. [13]; in their study that completed a 5-year period with IIPT, found that it provided improvement in metabolic control in the first 3 years, but there was a tendency for HbA1c values to increase after the 3rd year. In this study, after a 6-month follow-up, a significant decrease in mean HbA1c values was observed with IIPT compared to the first group (p:0.011). In 35.5% of patients who underwent IIPT, a reduction of more than 1% in HbA1c was achieved. A 1% decrease in HbA1c is important in terms of reducing microvascular complications. These results suggest that FIT is an effective method for achieving metabolic control in the adolescent age group.

Dyslipidemia is an important factor in the development of microvascular and macrovascular complications due to type 1 diabetes [17]. In our study, a significant increase in LDL levels was detected compared to previous period. High LDL levels may be related to the neglect of proteins and fats when counting carbohydrates. These results suggest that lipid profiles of patients followed with IIPT should be monitored more closely.

While some studies report a decrease in the frequency of hypoglycemia in patients who switch to IIPT, there are also studies showing that it did not change or increased [7,16,18]. In our study, we found that the frequency of hypoglycemia in patients treated with IIPT decreased statistically significantly compared to FIT period. We believe this may be due to IIPT being a more physiological treatment, as well as increased self-monitoring in patients and their improved education level regarding acute problems. Furthermore, hypoglycemia leading to loss of consciousness was not observed in any case. Studies have shown that IIPT prevents insulin resistance and absorption problems, reducing patients' total insulin requirements [7,15,18]. A meta-analysis reported a 0.58 U/kg/day reduction in insulin doses, representing a 14% reduction in average glucose requirements [18]. In this study, a 12% reduction in patients' total insulin requirements was observed after switching from FIT to IIPT, consistent with the literature. However, this was not statistically significant. Many studies have reported no increase in the frequency of diabetic ketoacidosis (DKA) with IIPT [19]. In our study, no DKA was observed in any patient receiving IIPT.

Diabetes is a chronic disease that impairs quality of life. It has been reported that 95% of patients using IIPT do not want to switch to multiple dose insulin injection therapy due to the flexible lifestyle provided by the insulin infusion pump [20]. When we evaluated the patients receiving IIPT in our study, we found that there was a statistically significant improvement in general health and mental health parameters. Other common complications of IIPT application are skin infections and irritation at the site of the infusion catheter [21]. In our study, no serious infection related to the infusion catheter was detected in any of our patients.

The most significant limitation of our study is the small number of patients, especially those in the IIPT group. However, legal regulations and financial difficulties in our country are the main reasons for this. We are continuing to evaluate these patients, aiming for a follow-up period of five years.

Conclusion

In conclusion, IIPT treatment resulted in a significant reduction in HbA1c levels in Type 1 DM after 6 months without increasing BMI or hypoglycemia. Furthermore, significant improvements were observed in some parameters of quality-of-life scales. Further technological advancements, financial support, and research are needed to improve these methods and enhance the treatment and quality of life for diabetic patients.

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