

Fear of hypoglycemia changes nutritional factors and behavioral strategies before the exercise in patients with type 1 diabetes mellitus

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Received: 13 January 2022 / Accepted: 23 May 2022 / Published online: 17 June 2022

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Abstract

Objective The study aimed to evaluate the fear of hypoglycemia (FoH), nutritional factors, and behavioral strategies before exercise in children and adolescents with type 1 diabetes (T1D).

Materials and methods A total of 116 patients with T1D aged 6–18 years were included in the study. FoH was evaluated with the Virginia University Child/Teen Low Blood Sugar Scale. The nutritional and physical activity habits of the patients were evaluated.

Results FoH scores of patients who generally missed meals were higher than those who did not miss ($p < 0.05$). No significant relationship was found between the FoH and the energy, carbohydrate, lipid, and sucrose intakes of the patients. FoH scores were higher ($p = 0.041$) and HbA1c% was lower in patients who exercised regularly ($p < 0.05$). The behavioral subscale score of the patients who kept their blood glucose in the safe range before exercise ($p < 0.001$) and the anxiety subscale score of the patients who measured their blood glucose during exercise were higher ($p < 0.05$). Patients who reduced their insulin dose independently of blood glucose level before exercise had higher behavioral subscale scores ($p < 0.05$). There was a significant positive correlation between the FoH score and the number of hypoglycemia episodes in the last 1 month ($r = 0.251$, $p < 0.001$), and a negative significant correlation between the diet compliance score and HbA1c% ($r = -0.266$, $p < 0.001$).

Conclusions Evaluating the FoH and applying healthy behavioral and nutritional practices to prevent hypoglycemia will help patients reduce their stress perception and fear of hypoglycemia and contribute to the goal of glycemic control.

Keywords Fear of hypoglycemia · Nutrition · Exercise · Type 1 diabetes

Introduction

Hypoglycemia is one of the most fearing common complications of type 1 diabetes (T1D) and insulin therapy, which remains to be a barrier to glycemic control with an increase in psychosocial burden in pediatric patients with T1D [1]. Evidence has indicated that around 90% of all patients who receive insulin have experienced hypoglycemic episodes [2]. The incidence of hypoglycemia is reported to be between 3

and 27 episodes and for severe hypoglycemic coma between 3 and 7 per 100 patient year children with T1D [2, 3]. In the Diabetes Control and Complications Trial (DCCT), it was reported that children and adolescents had considerably more severe hypoglycemic events than adults regardless of the type of treatment [4].

The symptoms of severe hypoglycemia (coma and convulsions, requiring the assistance of other people) have negative psychosocial consequences. These symptoms can lead to the patients avoiding social, academic, and physical activities. The stress related to hypoglycemia may induce anxiety and higher levels of anxiety may lead to having problems in patients' daily activities and suboptimal management of diabetes. Individuals with T1D and their parents are at risk for elevated levels of anxiety, restless sleep, and reduced quality of life [1, 3, 5].

Fear of hypoglycemia (FoH) is a specific and extreme fear evoked by the risk and/or occurrence of hypoglycemia [6].

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FoH may develop for many reasons such as previous experience of a traumatic hypoglycemic episode, awareness of hypoglycemic symptoms, the autonomic symptoms of hypoglycemia (e.g., tremors, sweating, and palpitations) are similar to anxiety symptoms, and limited understanding of hypoglycemia and skills in preventing, recognizing, and treating hypoglycemia. A majority of patients with T1D report experiencing FoH in their life [7]. Böhme et al. [8] found that 70% of patients with the under the age of 50 and 43.5% of patients with the under the age of 18 reported FoH.

FoH remains to be a greater problem in pediatric patients with T1D and also their parents, especially overnights. FoH can lead to the acceptance of high blood glucose levels by the patients and having “hypoglycemic avoidance behaviors.” These behaviors include keeping high glucose levels by intentionally reducing insulin dose, eating extra snacks, avoiding physical activity, or overtreatment of hypoglycemic events. This fear may adversely affect diabetes management and glycemic control. While some degree of fear is considered appropriate and adaptive given the potential danger of hypoglycemia, for some patients it may become more dangerous and problematic [7]. Despite advances in technology, insulin analogs, and evidence-based diabetes management, the problem with hypoglycemia and FoH remains [9]. A longitudinal study by Anderbro et al. [10] showed that FoH is stable over time if untreated.

In the literature, there are studies examining the relationship between FoH and quality of life or psychological well-being or between FoH and metabolic control [1, 3, 5, 10]. However, there are very few studies in the literature that investigate FoH and dietary intake [11, 12] and behavioral strategies of patients with T1D [8, 13]. In addition, to our knowledge, there is no finding on FoH and associations with nutritional factors and behavioral strategies before the exercise among the pediatric Turkish population. Because of a very small number of studies conducted in this field, there is a clear need to provide more findings to the limited data on FoH and dietary and behavioral factors in pediatric patients. Therefore, this study was conducted to evaluate the FoH, nutritional factors, and behavioral strategies before the exercise in children and adolescents with T1D.

Materials and methods

This cross-sectional study was conducted at the Mustafa Eraslan and Fevzi Mercan Children’s Hospital, Erciyes University in Turkey. A total of 116 patients with T1D who have been treated with basal-bolus insulin regimen were included in the study. Pediatric patients with T1D are followed up with a routine control every 3 months. Data were collected

for 12 weeks, from December 2018 to February 2019, to include all patients under routine follow-up in the outpatient clinic and to minimize the risk of recurrence.

The Erciyes University Faculty of Medicine Non-Interventional Clinical Research Ethics Committee granted the ethics committee approval with the approval number (2019/62). All patients and their parents were informed about the study and informed consent was obtained.

The sample size was calculated as a minimum of 112 patients based on the expectation of the correlation coefficient ($r = 0.30$) between the scale score and the frequency of hypoglycemia to be found statistically significant ($\alpha = 0.05$, $1 - \beta = 0.80$). One hundred sixteen patients were included in the study who filled out completely the questionnaire out of 120 patients who agreed to participate in the study.

Exclusion criteria included patients who (i) had any diabetes complications (nephropathy, retinopathy, or neuropathy); (ii) diagnosed for < 1 year; (iii) were < 6 years old; and > 18 years old. A questionnaire was used to collect data on patients’ characteristics and their FoH. The eating habits were evaluated by food consumption records questionnaire. Dietary compliance was evaluated by asking patients to rate their dietary compliance by numbering from 1 to 5. Weight and height measurements of patients were measured by researchers. HbA1c levels were assessed using the method of turbidimetric inhibition (ELISA kit).

The fear of hypoglycemia

The FoH was evaluated with the University of Virginia Child/Teen Low Blood Sugar Survey. The survey was developed by Green et al. [14] and revised by Gonder-Frederick et al. [15]. Turkish adaptation and validity of the survey were performed by Şahin and Özçelik [16]. Cronbach’s alpha was 0.84 and the test-retest correlation coefficient was 0.997. Turkish version consisted of two subscales; the behavior subscale has 10 items (items 1 to 10) and the worry subscale has 15 items (items 11 to 25). The behavior subscale contains the behaviors of children and adolescents with diabetes to prevent low blood sugar, and the worry subscale lists the items that children and adolescents worry about low blood sugar relating to anxiety-provoking aspects of hypoglycemia. The lowest score on the scale is 0, and the highest score is 100. The scale does not have a cut-off point. Higher scores indicate an increased FoH.

Although the scale measures the FoH, the scale has the name of “University of Virginia Child/Teen Low Blood Sugar Scale.” The researchers explain it as; the word “fear of hypoglycemia” may lead children/adolescents to feel fear or worry and it is considered appropriate to use this name because the answers may be biased.

Statistical method

Statistical analysis of the study was performed using the IBM SPSS Statistics 22.0 package program. Continuous variables were expressed as the mean and standard deviation. The normality of the distribution of all parameters was tested by the Shapiro–Wilk test. Chi-square and one-way ANOVA tests were used in accordance with the variables for between-group comparisons. The associations between the FoH score and metabolic control parameters were analyzed with Pearson's correlation. A statistically significant difference was considered with the level of $p < 0.05$.

Results

A total of 56 males and 60 females participated in the study. The mean age of patients was 11.42 ± 2.94 years (range 6 to 18 years) and the mean duration of diabetes was 5.30 ± 2.90 years (range 1 to 13 years). Mean body mass index (BMI) SDS was 0.21 ± 1.13 (range -2.23 to 3.09) for males and 0.34 ± 1.17 (range -1.48 to 3.85) for females; mean HbA1c% was 9.08 ± 1.72 (range 5.0 to 14.0%). The mean hypoglycemic episode for the last 1 month was 1.62 ± 3.82 (range 0 to 25). All of the patients have basal bolus insulin regimen with multiple dose injection short acting insulin and long acting insulin and most of our patients ($n = 100$, 86.2%) have poor glycemic control (HbA1c $\geq 7.0\%$) (Table 1).

The mean FoH score of patients was 32.07 ± 10.72 . Among the subscales, the mean behavior subscale score was 19.18 ± 7.26 , and the mean worry subscale score was 13.13 ± 6.63 (Table 2). There was no difference on FoH score for gender (male/female: 32.03 ± 12.23 vs. 32.11 ± 9.19 , $p > 0.05$). Although the FoH score was higher in patients with

Table 1 Patients' clinical characteristics ($n = 116$)

Age (year) (mean \pm SD)	11.42 \pm 2.94
Gender n (%)	
Male	56 (48.3)
Female	60 (51.7)
BMI SD (mean \pm SD)	
Male	0.21 \pm 1.13
Female	0.34 \pm 1.17
Diabetes duration (years) (mean \pm SD)	5.30 \pm 2.90
Hypoglycemia episodes (last 1 month) (mean \pm SD)	1.62 \pm 3.82
Insulin administration (IU/kg/day) (mean \pm SD)	1.08 \pm 0.56
HbA1c (%) (mean \pm SD)	9.08 \pm 1.72
< 7.0 (%) n (%)	16 (13.8)
≥ 7.0 (%) n (%)	100 (86.2)

Table 2 Fear of hypoglycemia scores of patients' ($n = 116$)

	(mean \pm SD)
Fear of hypoglycemia total score	32.07 \pm 10.72
Behavior subscale score	19.18 \pm 7.26
Worry subscale score	13.13 \pm 6.63

poor glycemic control, the difference among groups was not statistically significant (32.64 ± 10.08 vs. 28.56 ± 13.94 , respectively; $p > 0.05$). There were no differences among the total score and subscales scores and dietary compliance, meal consumption (n/day), and insulin dosing or not dosing based on carbohydrate counting. We found no difference for gender on dietary factors ($p > 0.05$). No correlation was found between total and behavior and worry subscale scores and energy, carbohydrate, and sucrose intakes of patients (data not shown in table). Besides these, it was found that 53.4% of patients missed the meal, and the patients who generally missed the meal had a higher score for FoH than those who did not miss the meal (33.87 ± 10.68 vs. 30.01 ± 10.48 ; respectively, $p < 0.05$). The mean dietary compliance score of the patients was 2.97 ± 1.39 (range 1–5) (Table 3).

It was found that 53.4% of the patients exercise regularly and the mean total FoH score of those who exercise regularly was higher than those who did not (33.93 ± 1.77 vs. 29.94 ± 9.00 ; respectively, $p < 0.05$) (Table 4); and the HbA1c levels were lower than those who did not (8.79 ± 1.56 vs. 9.42 ± 1.85 ; respectively, $p < 0.05$) (data not shown in table).

When the attitudes of individuals before exercise to prevent hypoglycemia were examined, most common attitudes were “keeping blood glucose levels within safe range before exercise,” “consuming food (especially carbohydrate-containing) regardless of the blood glucose level before exercise,” and “keeping carbohydrate-containing foods (sugar, juice, etc.) with always during exercise due to the risk of hypoglycemia.” It was determined that patients who keep blood glucose levels within safe range before exercise ($n = 77$, 66.3%) had a higher behavior subscale score than those who do not keep (22.61 ± 6.11 vs. 17.44 ± 7.21 ; respectively, $p < 0.001$). Patients who measure blood glucose during exercise ($n = 23$, 19.8%) had a higher worry subscale score than those who do not measure (13.77 ± 6.62 vs. 10.69 ± 6.36 ; respectively, $p < 0.05$). And patients who reduce the bolus insulin dose regardless of pre-exercise blood glucose level had a higher behavior subscale score ($n = 25$, 21.5%) than those who do not reduce (35.64 ± 12.80 vs. 31.09 ± 9.93 ; respectively, $p < 0.05$) (Table 4). There was a positive correlation between FoH total score and the number of hypoglycemic episodes in the last 1 month ($r = 0.251$, $p < 0.001$) and a negative correlation between the dietary compliance and HbA1c% ($r = -0.266$, $p < 0.001$) (Table 5). The calculated power value was (0.80) at the

Table 3 Fear of hypoglycemia scores of patients according to patients' nutritional habits ($n = 116$)

		Fear of hypoglycemia score (mean \pm SD)	p	Behavior subscale score (mean \pm SD)	p	Worry subscale score (mean \pm SD)	p
Meal (n/day) ($\bar{x} \pm SS$) (4.89 \pm 1.16)							
2	1 (0.9%)	49.00	0.130	32.00	0.514	17.00	0.977
3	16 (13.8%)	31.06 \pm 9.61		18.37 \pm 6.63		12.81 \pm 5.39	
4	29 (25.0%)	35.58 \pm 11.97		19.44 \pm 7.43		13.24 \pm 6.47	
5	20 (17.3%)	31.00 \pm 8.73		19.65 \pm 7.15		12.90 \pm 5.38	
6	50 (43%)	30.46 \pm 10.64		19.18 \pm 7.62		13.40 \pm 7.63	
Missing meal							
Yes	62 (53.4%)	33.87 \pm 10.68	0.048*	19.01 \pm 7.58	0.627	12.16 \pm 6.34	0.064
No	54 (46.6%)	30.01 \pm 10.48		19.68 \pm 7.12		14.4 \pm 6.78	
Snack consumption							
Yes	87 (75.0%)	31.29 \pm 10.90	0.177	18.74 \pm 7.30	0.141	13.05 \pm 6.72	0.641
No	29 (25.0%)	34.41 \pm 9.95		21.06 \pm 7.34		13.72 \pm 6.38	
Carbohydrate counting							
Yes	22 (19%)	32.95 \pm 12.60	0.672	17.90 \pm 5.43	0.317	12.68 \pm 5.24	0.671
No	94 (81%)	31.87 \pm 10.25		19.65 \pm 7.71		13.35 \pm 6.92	
Dietary compliance (1-5) ($\bar{x} \pm SS$) (2.97 \pm 1.39)							
1	23 (19.8%)	32.08 \pm 11.49	0.430	18.08 \pm 8.84	0.597	12.60 \pm 6.28	0.288
2	18 (15.6%)	33.72 \pm 9.39		19.61 \pm 6.49		12.50 \pm 6.11	
3	36 (31.0%)	33.27 \pm 9.47		20.72 \pm 7.08		14.30 \pm 7.83	
4	17 (14.7%)	32.82 \pm 12.05		17.70 \pm 6.64		10.64 \pm 4.40	
5	22 (18.9%)	28.18 \pm 11.74		19.36 \pm 7.42		14.68 \pm 6.39	

* $p < 0.05$ **Table 4** Fear of hypoglycemia scores of patients according to patients' attitudes to minimize hypoglycemia before the exercise ($n = 116$)

		Fear of hypoglycemia score (mean \pm SD)	p	Behavior subscale score (mean \pm SD)	p	Worry subscale score (mean \pm SD)	p
Exercise							
Yes	62 (53.4%)	33.93 \pm 11.77	0.041*	19.04 \pm 6.81	0.834	12.72 \pm 5.99	0.476
No	54 (46.5%)	29.94 \pm 9.00		19.33 \pm 7.80		13.61 \pm 7.33	
Keeping BG levels within safe range before the exercise							
Yes	77 (66.3%)	31.10 \pm 10.05	0.170	22.61 \pm 6.11	< 0.001**	12.59 \pm 6.53	0.219
No	39 (33.6%)	34.00 \pm 11.82		17.44 \pm 7.21		14.20 \pm 6.79	
Getting measure BG before the exercise							
Yes	67 (57.8%)	32.02 \pm 11.04	0.956	18.88 \pm 7.41	0.605	13.11 \pm 6.88	0.972
No	49 (42.2%)	32.14 \pm 10.38		19.59 \pm 7.11		13.16 \pm 6.34	
Getting measure BG during the exercise							
Yes	23 (19.8%)	32.34 \pm 13.10	0.884	18.82 \pm 7.38	0.744	13.77 \pm 6.62	0.047*
No	93 (80.2%)	31.97 \pm 10.17		19.38 \pm 7.22		10.69 \pm 6.36	
Consuming food regardless of the BG level before the exercise							
Yes	80 (69.8%)	31.70 \pm 9.97	0.574	19.56 \pm 7.48	0.401	13.20 \pm 7.25	0.881
No	36 (30.2%)	32.91 \pm 12.33		18.33 \pm 6.77		13.00 \pm 5.10	
Keeping carbohydrate-containing foods(sugar, juice, etc.) with always during exercise due to the risk of hypoglycemia							
Yes	100 (86.2%)	31.85 \pm 10.59	0.570	19.25 \pm 7.06	0.799	12.98 \pm 6.31	0.524
No	16 (13.8)	33.50 \pm 11.75		18.75 \pm 8.63		14.12 \pm 8.56	
Getting reduce the bolus insulin dose regardless of pre-exercise BG level							
Yes	25 (21.5%)	35.64 \pm 12.80	0.047*	18.88 \pm 6.71	0.816	11.84 \pm 5.08	0.217
No	91 (78.5%)	31.09 \pm 9.93		19.26 \pm 7.44		13.49 \pm 6.98	

BG blood glucose, * $p < 0.05$, ** $p < 0.001$

Table 5 Correlation between the fear of hypoglycemia scores and the metabolic control parameters and the dietary factors

	Hypoglycemia episodes	Fear of hypoglycemia total scores	Behavior subscale score	Worry subscale score	Hb A1c%	Dietary compliance	Sucrose consumption
Hypoglycemia episodes	1						
Fear of hypoglycemia total scores	0.251**	1					
Behavior subscale score	− 0.121	− 0.132	1				
Worry subscale score	− 0.115	− 0.070	0.213*	1			
Hb A1c%	− 0.037	− 0.011	− 0.092	− 0.107	1		
Dietary compliance	− 0.129	− 0.134	0.045	0.071	− 0.266**	1	
Sucrose consumption	0.061	0.105	− 0.124	− 0.076	− 0.092	0.173	1

* $p = 0.05$ ** $p = 0.01$

beginning and the observed power value was found (0.99) at the end of the study.

Discussion

The significance of FoH is mainly related to the actions taken to keep the blood glucose at a safely high level which may lead to have adverse behavioral changes on glycemic control include avoiding physical activity, maintaining higher blood glucose levels, or administering low insulin doses. In this study, the FoH and associated nutritional factors, and behavioral strategies before the exercise in children and adolescents with T1D were investigated. As a result of our study, we found a positive correlation between FoH score and the number of hypoglycemic episodes. Another outcome of the study was that the mean FoH score of patients who exercised regularly was higher than those who did not. Additionally the patients who have behavioral strategies to minimize the risk of hypoglycemia during exercise such as reducing the bolus insulin dose, keeping blood glucose levels within safe range before exercise, and measure blood glucose during exercise was found to have higher FoH scores.

In the literature although many factors were mentioned to affect the occurrence of FoH, the frequency of hypoglycemic episodes is the main factor associated with FoH. Our results on the frequency of hypoglycemic episodes and FoH were in accordance with the previous study results. In a study by Polonsky et al. [17], the worry score on the hypoglycemia fear survey was positively associated with a history of hypoglycemic episodes. Similarly, in a study conducted by Anderbro et al. [18], a higher FoH was associated with an increased frequency of severe hypoglycemic episodes. Haugstvedt et al. [19] found a higher frequency of problematic episodes in the past year was associated with a higher worry score.

The factors leading poor management of diabetes including high frequency of hypoglycemic episodes and poor glycemic

control may effect FoH. But the association between glycemic control and FoH is not fully established, and mixed results were obtained from the studies. Roberts et al. [20] showed HbA1c levels were positively correlated with FoH, leading to poor glycemic control. Anderbro et al. [18] reported that FoH was related to higher HbA1c levels. Böhme et al. [8] found no relationship between FoH and HbA1c levels. Al Hayek et al. [21] found no significant difference in the FOH subscales among adolescents with HbA1c < 7% compared to those with HbA1c \geq 7%. Similarly in this study, although the FoH score was higher in patients with poor glycemic control, the difference among groups was not statistically significant. And we found no correlation between FoH and HbA1c levels.

Exercise may be a major fearing factor for hypoglycemic episodes for patients with T1D. Prior studies identified FoH as a major cause of inactivity on patients with T1D [11, 22]. A diabetes-specific barriers to regular physical activity were reported by patients [23]. Although patients exercise less due to FoH, in line with this, patients who exercise regularly may have also higher FoH. Recently published data by Roberts et al. [20] showed that increased levels of physical activity were associated with increased FoH behavior subscale score in patients with T1D. Similarly, in this study, we found the mean FoH score was higher in patients who exercise regularly than in those who did not.

In the current study, we also evaluated the behavioral strategies to minimize the risk of hypoglycemia before and during exercise. The most common attitudes were found “keeping blood glucose levels within a safe range before exercise,” “consuming food regardless of the blood glucose level before exercise,” and “keeping carbohydrate-containing foods always during exercise due to the risk of hypoglycemia.” We found that patients who keep blood glucose levels within a safe range before exercise ($p < 0.001$) and patients who reduce the bolus insulin dose regardless of pre-exercise blood glucose level ($p < 0.05$) had a higher behavior subscale score, and patients who measure blood glucose during exercise had a

higher worry subscale score than patients who do not ($p < 0.05$). But we found no difference on consuming food before the exercise and FoH score. In a study by Böhme et al. [8], they found that of the patients 23% reduced insulin dose, 20% increased sugar intake, and 12% ate extra snacks to minimize the risk of hypoglycemia. In a study by Savard et al. [13], 73% of patients with T1D reported they have excess food ingestion to minimize the risk of hypoglycemia and overtreat their hypoglycemia. Ahola et al. [12] found that FoH was associated with a higher number of reported self-monitoring of blood glucose in patients with T1D.

Although there are several studies evaluating behavioral strategies to minimize the risk of hypoglycemia, there are very limited studies on FoH and dietary intake. No other study was found evaluating the effect of meal plan and missing meal on FoH in the literature. We found only one study on compliance with dietary advices and FoH but FoH and compliance with dietary advices are unrelated and no finding on the effect of compliance with dietary advice on FoH was studied [24]. Comparing our results with previous research is difficult because the association between FoH and dietary factors has not been extensively studied. In a study by Martyn-Nemeth et al. [11], it was reported that a higher calorie intake ($r = 0.492$, $p = 0.003$) was associated with increased FoH. In another study, Ahola et al. [12] showed that FoH was associated with higher energy and carbohydrate intake. FoH is associated with excessive food intake and more frequent eating snacks [8] and any particular eating style is not associated with FoH [25]. A small number of studies conducted in this field shows that there is a need for more studies on the association between FoH and dietary factors. In this study, we evaluated the association between diet composition, dietary compliance, and dietary factors with FoH, which affects the glycemic control of patients. Missed meal is also evaluated in this study, by the reason of being one of the common clinical precipitant for hypoglycemia. We found no association between FoH and dietary compliance, energy, carbohydrate, lipid, and sucrose intakes of patients; but among dietary factors, we found 53.4% of patients missed the meal, and the patients who generally missed the meal had a higher score for FoH than those who did not miss the meal.

In this study since the observed power value (0.99) is greater than the calculated power value (0.80), it is thought that this study can be generalized to the accessible population, and this generalisability is practically significant to provide the external validity.

Limitations

The study recruited a sample of patients with basal-bolus insulin therapy with injections. The pump therapy offers patients more flexibility on timing and dosing of insulin, which may help to reduce some part of the stress related to diabetes

control. Examining the differences in the stress and behavioral strategies of children with T1D based on the type of insulin regimen may contribute to the evaluation of the management of FoH.

Conclusion

In conclusion, this study showed that FoH affects physical activity habits and behavioral strategies to minimize the risk of hypoglycemia during the exercise of patients with T1D. The study highlights the importance of assessing for these variables in children and adolescents with T1D and providing interventions including healthy behavioral and nutritional implementations to prevent hypoglycemia could help them reduce their perceptions of stress and FoH which could have an important impact on the management of diabetes.

Acknowledgment This study received no financial support. The authors would like to thank all the participants in the study.

Author contributions NK designed and conducted the study and HT contributed to the study conception and design. NK provided essential constructs and databases necessary for this study. NK wrote the first draft of the manuscript and all authors read and approved the final manuscript. NK had primary responsibility for the final content.

Declarations

Ethics approval and consent to participate The Erciyes University, Faculty of Medicine Non-Interventional Clinical Research Ethics Committee granted the ethics committee approval with the approval number (2019/62). Written informed consent was obtained from all patients and their parents. The procedures used in this study adhere to the tenets of the Declaration of Helsinki.

Conflict of interest The authors declare no conflict of interest.

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