DOI: 10.4274/jcrpe.galenos.2021.2020.0191
Research article

An Evaluation of Glucagon Injection Anxiety and its Association with the Fear of Hypoglycemia among the Parents of Children with Type 1 Diabetes

Running Title: Parental Anxiety for Glucagon Injection

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What is already known on this topic?
Previous research has shown that anxiety of the parent and prior experiences of hypoglycemia can impair the management of diabetes and make parents more fearful about hypoglycemia. Research on parents' attitudes and beliefs towards glucagon administration is lacking.

What this study adds?
The current study shows a positive association between the parental FoH and parental anxiety for glucagon administration. Practical training should be carried out to improve caregivers' self-confidence.

Abstract
Objective: Hypoglycemia is a common acute complication of type 1 diabetes (T1D), which may cause seizure, loss of consciousness, temporary motor or sensory impairment. Glucagon administration is an effective way of treating severe hypoglycemia, especially in a free-living setting. Nonetheless, families have difficulties in managing severe hypoglycemia due to their anxiety and challenges in current glucagon administration techniques. The aim of the current study was to explore the associations between the parental fear of hypoglycemia (FoH) and their general anxiety level, in particular, their attitudes towards and thoughts on glucagon administration.
Methods: 68 parents of children with T1D completed questionnaires assessing background and clinical information, FoH, generalised anxiety disorder (GAD) and parental anxiety for glucagon administration (PAGA).
Results: A positive correlation was found between the FoH and the GAD scores of the parents. There was a positive correlation between the number of blood glucose measurements during night's sleep and the GAD scores; and a negative correlation with the child's age. On average, the parents evaluated their competence in glucagon administration as 6 on a scale of 0 to 10 (SD=2.9). The perceived proficiency in glucagon administration of parents was negatively correlated with the PAGA scores. There was no significant difference between children using continuous glucose monitoring system (CGMS) and self-monitoring of blood glucose (SMBG) in terms of their parents' FoH, anxiety and misconceptions about glucagon administration.
Conclusion: The results show that the parents of children with T1D had anxiety and fear connected with hypoglycemia and glucagon administration. A structured and practical training on glucagon administration is therefore needed.
Keywords: hypoglycemia, glucagon, anxiety, diabetes mellitus type 1

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17-Sep-2020
02-Jan-2021

1. Introduction

Hypoglycemia is a common complication in Type 1 diabetes mellitus (T1D) treatment and refers to conditions where blood glucose levels are ≤70 mg / dl (1). The symptoms of hypoglycemia include tremors, sweating, palpitations, hunger sensation, anxiety, nausea, headache, sleepiness, excessive fatigue, as well as attention difficulties. Hypoglycemia may also have more serious consequences such as coma, seizure, and temporary motor or sensory impairment (2).
The symptoms of hypoglycemia (which are acute, infrequently dramatic, and occasionally accompanied by convulsions), cause fear of hypoglycemia (FoH) in families, especially at night (3). This fear is more evident in the families of young children (<6 years) who are unable to recognize the symptoms of hypoglycemia in time, often causing these families to spend the night without sleeping (4). The feelings of families - especially the mothers' - regarding hypoglycemia vary according to local cultures (5). Although coma due to severe hypoglycemia is very rare and hypoglycemia related death is unclear, many families fear that they might find "their children dead in bed", even if their children have only had severe hypoglycemic convulsions once (1). This false notion may change their priorities in diabetes treatment. Although diabetes technologies (especially Continuous Glucose Monitoring (CGM) systems with alarms), have played an important role in reducing the fears of families in recent years, it is still known that fear of hypoglycemia could be a significant barrier for the improvement in glycemic targets (4).

Moreover, with regard to the treatment of severe hypoglycemia, for many years, the only available glucagon form has been the preparation of injecting the liquid into the powder drug (6). Recently launched intranasal and premixed glucagon has been inaccessible for most of the people with T1D outside of the United States. The most commonly used glucagon form is administered with the injector perpendicular to the front side of the arm or leg. Studies show that families have difficulty in managing the process of severe hypoglycemia especially when it is accompanied by impaired consciousness (7). Our clinical observations suggest that families tend to go to the hospital as a matter of urgency rather than using glucagon itself due to their anxieties involving glucagon administration. Consequently, this anxiety related to glucagon administration, in addition to the FoH may reduce the sufficient use and value of glucagon. Given that it is assumed that caregivers can easily administer glucagon in the treatment of severe hypoglycaemia, their concerns on this matter may not have been taken into account sufficiently in standard diabetes education by healthcare professionals.

While previous research has shown that anxiety of the parent and prior experiences of hypoglycemia can impair the management of diabetes (7,8), research on attitudes towards glucagon administration is lacking. The current study aims to explore the associations between parental FoH and their general anxiety level, in particular, their attitudes towards and thoughts on glucagon administration.

2. Methods

2.1. Study Sample

A total of 153 parents of children aged between 2 and 18 years who had been diagnosed with T1D at least 6 months previously and followed by our pediatric endocrinology department were invited to participate in the study. Of these, 96 accepted, and 68 parents completed all of the surveys. The participation flow chart is shown in Figure 1. At the beginning of the survey, the informed consents was obtained from the participants. There was no ethical committee application for the current study. Nonetheless, the Koç University Ethics Committee has concluded that the research had not violated the bioethical principles. The relevant letter from the committee is included in the supplementary file.

2.2. Measures

All forms were sent in a format that the participants could fill out online.

The Demographic form consisted of information about the child's gender, date of birth, date of diagnosis of diabetes, frequency of hypoglycemia, and information related to glucagon usage such as injection sites and deciding accurate doses. The parents were also asked to rate their competence in glucagon administration between 0 and 10 points.

The Fear of Hypoglycemia Questionnaire - Parent Form (FoH-P) was developed by Gonder-Frederick and his colleagues (8). The reliability and validity of the scale in Turkish was conducted by Şen and her colleagues (9). It measures parental FoH with a total of 25 items: 15 items for the anxiety subscale and 10 items for the behavior subscale. Increasing scores represent the increasing severity of fear.

The Generalized Anxiety Disorder Scale (GAD) was developed according to the DSM-IV-TR criteria (10) and its Turkish validity and reliability were confirmed (11). It is a short, self-report 7-item scale evaluating generalized anxiety disorder. Increasing scores represent the increasing severity of anxiety.

The Questionnaire Evaluating Parental Anxiety for Glucagon Administration (PAGA) is a 10-item questionnaire that aims to investigate the parents' misconceptions and perceptions of barriers to administration of glucagon. It is a 5-point Likert scale response eliciting how concerned they are about each statement. The questionnaire consists of statements including "the belief that the needle will hurt because of the size", "the belief that if I administer the glucagon, I will be too late to take him to the emergency room", "the belief that my child will not get better, even if I administer the glucagon". In many years of experience, our pediatric endocrinology team observed common misconceptions and barriers reported by families about glucagon usage. Due to the lack of any existing questionnaire regarding this matter, the questions were developed based on the clinical observations of the team. The internal consistency evaluated with Cronbach's alpha was found as 0.89. Increasing scores represent increasing misconceptions about glucagon administration. The questionnaire is shown in Appendix 1.

2.3. Statistical Analysis

Analyses were conducted using SPSS version 23.0. (IBM Corp., Armonk, N.Y., USA). Descriptive statistics (means, standard deviations, frequencies, and percent) were used to summarize demographic and clinical variables. T-tests were used to assess the associations between categorical variables and continuous variables. The group differences were analyzed using Mann-Whitney U test. Bivariate and partial correlations were used to determine the relation between continuous variables.

3. Results

A total of 68 parents who completed the survey were included in the study. The mean age of the children was 9.5 ±4.1 years and the mean diabetes duration was 2.9 ±2.2 years. Of the participants 14 (21%) were on insulin infusion pump therapy (IIP) and all the pumps were Medtronic ® 640G. The rest of the participants were on multiple dose injection therapy (MDI). The descriptive information is shown in Table 1. The analysis of the survey data showed that the education levels of the participants were as follows: two parents were primary school graduates, two were secondary school graduates, 20 of the parents were high school graduates, 36 parents had university degrees and eight had masters-degrees. Of the parents, 23 (34%) were unemployed. Ninety-three percent of the parents (n:63) stated that they were trained on glucagon administration and 13 reported administering glucagon to their child in severe hypoglycemia emergency. Glucagon was available in 65 of the houses and 29 of the schools of the children. On average, the parents evaluated their competence in glucagon administration as 6 out of 10 (SD=2.9). Of the participants, 85% (n:58) reported that they would administer glucagon immediately if there was a loss of consciousness.

The mean GAD score of the participants was 6.6 ±5.4 (0-21). According to the cut off points in the Generalized Anxiety Disorder Scale -7 (11), 30 of the parents had no anxiety, 20 of them had mild anxiety, 11 of them had moderate levels of anxiety and 7 of them had severe anxiety.

A positive correlation was found between the FoH and the GAD scores of the parents. This relationship was also significant when the education level of the parents, the time of diagnosis and the age of the child were controlled ($r=0.35$; $p<0.005$). There was a positive correlation between the number of blood glucose measurements during a night's sleep and the GAD scores; and a negative correlation with the age of the child. The perceived proficiency in glucagon administration of parents was negatively

correlated with the PAGA scores. Table 2 shows the correlation between the diabetes related variables and the scores in the questionnaires.

In the further analysis, the parents were grouped into 2 sub-groups – those whose children had loss of consciousness or seizures and those whose children did not. The two groups did not differ in terms of FoH, anxiety, misconceptions about glucagon administration, HbA1C levels, day and night-time measures (Table 3). There was no significant difference between the children using CGM and self-monitoring of blood glucose (SMBG) in terms of their parents' FoH, anxiety and misconceptions about glucagon administration (Table 4). Furthermore, there was no significant difference between the MDI and the IIP users in terms of GAD ($p = 0.38$) and FoH scores ($p=0.84$).

4. Discussion

Mostly, the parents of children with T1D have concerns about hypoglycemia and its unfavorable short-term and long-term effects. Severe hypoglycemia can be safely treated with glucagon administration by the caregivers in a free setting. Nonetheless, families have difficulties in preparing, drawing the correct dose and administering it during a severe hypoglycemia episode which, in turn, raises anxiety (7,12). In the current study, parents evaluated their competence in glucagon administration on average as 6 points out of 10 (SD=2.9) and 85% of them reported that they would administer glucagon immediately if there was a loss of consciousness. These results indicate some parents have hesitations and incompetency regarding glucagon administration. Diabetes teams should emphasize the importance of glucagon administration in their training on managing severe hypoglycemia. Moreover, structured and practical education should be given to caregivers in order to lessen their anxiety and increase self-confidence. According to our clinical experience, most families rarely need to use glucagon for severe hypoglycemia each year, consequently they may forget the details of the administration in an acute emergency situation. Therefore, a practical education for glucagon administration should be repeated annually (12).

Recently, nasal glucagon has become a rising and approved treatment for severe hypoglycemia. It is ready to use, needle-free and has a one-step administration compared to the other form. Pharmacodynamic studies support that intranasal glucagon had similar efficacy compared to intramuscular glucagon in the treatment of hypoglycemia in children and adolescents with T1D (13). Research reveals that caregivers and acquaintance administering intranasal glucagon have been able to administer it faster, more confidently and in accurate doses (14). Whereas intramuscular glucagon creates fear and anxiety (15), nasal glucagon seems an effective, user friendly and well tolerated method of treating hypoglycemia for caregivers in the home and school setting (16,17). In the current study, some of the PAGA questions included physical difficulties concerning the intramuscular glucagon administration such as "the needle will hurt because of the size". The parents stated that they had difficulty in these issues. They also reported a lack of confidence in glucagon administration. These results show that practical and simple administrations are needed for the correct use of glucagon. Expanding intranasal glucagon use could ease and strengthen the administration process before it becomes more serious (18) and would address an important unmet medical need (16). In turn, it may help to reduce parental concerns and pave the way for more effective use of glucagon. Although research is rare on the psychosocial impact of intranasal glucagon, caregivers stated it was less stressful to use compared to intramuscular glucagon (14). Therefore, in order to use nasal glucagon in all countries, an international initiative should be advanced under the leadership of the International Society for Pediatric and Adolescent Diabetes (ISPAD). Moreover, the health systems of the countries should reimburse nasal glucagon in the scope of emergency medicine.

Concerns about hypoglycemia may lead children with T1D and their parents to inject lower doses of insulin, over-eat or feed, limit their daily exercises and generally follow frequent blood glucose monitoring (8, 19). These interventions may cause undesirable elevations in blood glucose levels (20). Due to the fact that 75% of hypoglycemia in children is seen at night (21), some parents often wake up at night and measure blood glucose. This may cause anxiety in the children and parents (22). With increasing levels of anxiety, a decrease in quality of life and metabolic control and diabetes related burnout can be seen in both parents and children (8, 21, 23). It is also known that the prevalence of hypoglycemia and loss of consciousness or seizure as a result of hypoglycemia are associated with FoH among the parents (8,20,24,25). The current study supports the literature in these aspects. The mean GAD score of the participants was 6.6 ±5.4 (0-21). In the validity and reliability study of the Turkish adaptation of GAD scale, the patients who were diagnosed with GAD got score 12.03 (SD= 5.07) and the healthy control group got score 6.11 (SD= 4.35) (11). The mean GAD score of the participants show that the study group did not differ from the general population. It was found that the anxiety level of the parent was positively correlated with the frequency of glucose measurements during the night-time, FoH and misconceptions about glucagon administration. However, there was no association between HbA1c levels of the children and their parents' anxiety levels and FoH. Some research also reports that FoH and HbA1C has no direct association but does have indirect association with parenting stress (26).

The literature reveals both negative and positive psychological effects of CGM technologies in T1D treatment. Some research demonstrated that parental FoH and distress levels diminished with CGM use (27,28). On the other hand, there are studies indicating no alleviation in FoH in CGM use compared to the control groups (29,30). In the current study, we compared the parental FoH and their anxiety levels of CGM users and SMBG users. There was no significant difference between their anxiety level, FoH, and daily and nightly glucose measurements.

There are certain limitations to the current study. First of all, the number of cases in the study was small. In further research, the number of participants could be increased and grouped according to CGM and, or only insulin infusion pump and SMBG use. Another limitation was the lack of reliability and validity of the questionnaire used in the study. The PAGA questionnaire was generated by the study team because of the lack of a standardized measure regarding this issue. Further research may be needed to demonstrate that the PAGA questionnaire is a reliable measure to understand the misconceptions regarding glucagon administration of parents with T1D children. There is no doubt that when nasal glucagon is available in our country, it would be more enlightening to include parental experiences regarding the use of nasal glucagon in a future study. Despite the limitations, we feel that this pilot study is valuable as it is the first study which investigates the attitudes and misconceptions of the parents of children with T1D regarding intramuscular glucagon administration.

In conclusion, parents of children with T1D state their anxiety and fear associated with hypoglycemia and glucagon administration even without presence of prior experiences with severe hypoglycemia. Structured and practical training should

be carried out to increase parents' self-confidence. Moreover, the availability and widespread use of intranasal glucagon should be fixed for the reduction in administration failures and parental anxiety.

Disclosure:

The authors declare that they have no conflict of interest.

Acknowledgement

The authors would like to thank all the participants and Alan J. Newson for the English language editing.

Appendix 1: Questionnaire Evaluating Parental Anxiety for Glucagon Administration (PAGA)

Below are some concerns about glucagon use. Please mark how much you are concerned about each item.

	Not at all	**Slightly**	**Moderately**	**Very**	**Extremely**
1. The belief that my knowledge / experience is inadequate	0	1	2	3	4
2. The belief that because glucagon should only be injected into the muscle, I cannot accomplish it	0	1	2	3	4
3. The belief that the needle will hurt because of its length	0	1	2	3	4
4. The belief that blood sugar will increase too much	0	1	2	3	4
5. The belief that glucagon will harm my child as a medicine	0	1	2	3	4
6. The belief that my child won't get better, even if I administer the glucagon	0	1	2	3	4
7. The belief that I may panic and make a mistake that may harm my child	0	1	2	3	4
8. The fear of permanently damaging nerves / veins while administering glucagon	0	1	2	3	4
9. The concern that after administering glucagon side effects (nausea, vomiting, etc.)may occur	0	1	2	3	4
10. The belief that if I administer the glucagon, I will be too late to take him to the emergency room	0	1	2	3	4

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Table 1: Descriptives (*N*=68)

	% or Mean ± SD	Range
Sex (%female)	51.5	
Child's Age (years)	9.5 ±4.1	2.7-17.5
Diabetes duration (months)	2.9 ±2.2	0.5-9.6
HbA1C (%)	7.6 ±1.4	5.5-14
Insulin regimen (% pump)	21	
CGM usage (%)	57.4	
Number of the times blood glucose <50 mg/dl in the past 3 months	5 ±5.9	0-20
Glucagon administration or emergency room visit in the past 12 months	0.1 ±0.5	0-3
Number of times experiencing unconsciousness / seizures ever	0.3 ±0.6	0-4
Number of day-time glucose measurement		
<3 times/day	12	
4-6 times/day	35	
≥7 times/day	53	
Number of night-time glucose measurement:		
<1 time/week	28	
1 time/week	12	
2-4 times/week	23	
≥7 times/week	36	

Table 2: Correlation statistics between diabetes related variables and scores in the questionnaires

	Age in months	Diabetes duration	HbA1c	Day time glucose measurement	Nighttime glucose measurement	Perceived proficiency in glucagon administration	PAGA Score	FoH Score	GAD Score
Age in months	1								
Diabetes duration	0.450**	1							
HbA1c	0.257*	0.432**	1						
Day time glucose measurement	-0.217	0.054	0.087	1					
Nighttime glucose measurement	-0.375**	-0.029	-0.182	0.306*	1				
Perceived proficiency in glucagon administration	0.016	0.08	0.031	-0.012	-0.016	1			
PAGA Score	-0.186	-0.067	0.159	0.077	0.068	-0.541**	1		

FoH Score	-0.254*	0.045	0.121	0.140	0.088	-0.042	0.211	1	
GAD Score	-0.243*	-0.134	0.099	0.169	0.241*	-0.052	0.246*	0.395**	1

**. Correlation is significant at the 0.01 level (2-tailed).
*. Correlation is significant at the 0.05 level (2-tailed).

Table 3: The comparison of parents of children who had loss of consciousness/seizures and those whose children did not have

	Loss of consciousness/seizures (n=16)	Without loss of consciousness/seizures (n=52)	P value
PAGA Score	12.9 (0-25)	37.6 (2-30)	0.644
FoH Score	49.8 (27-81)	34.9 (21-91)	0.449
GAD Score	8.1 (0-21)	34.5 (0-21)	0.303
HbA1C	7.7 (5.7-12.3)	7.6 (5.5-14)	0.569
Day-time glucose measurement (≥7 times/day) (%)	37.5	58	0.327
Night-time glucose measurement(≥7 times/week) (%)	44	35	0.816

Mean and range values are given.

Table 4: CGM and SMBG Groups

	CGM Group (n=39)	SMBG Group (n=29)	P value
PAGA Total Score	32.2 (0-30)	37.6 (2-30)	0.267
FoH Total Score	34.2 (20-85)	34.9 (21-91)	0.896
GAD Total Score	34.5 (0-20)	34.5 (0-21)	1.000
Child's age (years)	2.5 (2.7-17.2)	3.3 (2.8-17.5)	0.051
Diabetes duration (months)	32.2 (6-116)	37.6 (6-107)	0.264

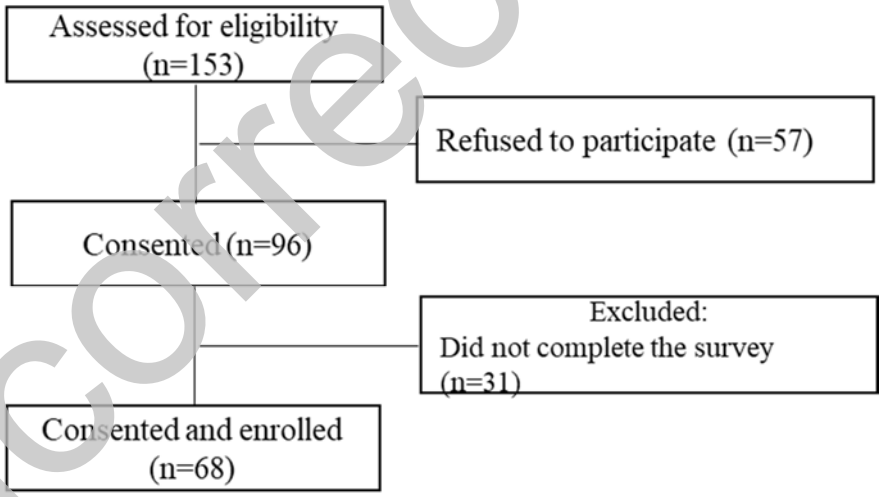

Figure 1. Study flow diagram