



**Fear of Needles Among Children and Adolescents with Type 1
Diabetes Mellitus – Relationship with Metabolic Control (HbA1c)
and Quality of Life**

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Forewords and acknowledgements

This research thesis is submitted as a part of MSc degree in Clinical Psychology in Reykjavik University and is presented in the style of an article for submission to a peer-reviewed journal. The research presented in this thesis is the culmination of work over three semesters. In the first semester, literature review was written and the blueprint for the research drafted. The second semester involved writing proposals to the Bioethics committee of The National University Hospital of Iceland for permission to conduct the study, and other governing entities, as well as writing the first draft of the method section. Data collection started in the second semester but took place mostly in the third semester along with the writing of the final draft of this thesis. The thesis was executed under the supervision of Berglind Brynjólfsdóttir, a psychologist at The National University Hospital of Iceland and Dr. Jón Friðrik Sigurðsson, a professor at Reykjavik University.

There were two main aims with this study. First, to evaluate the prevalence of fear of needles among children and adolescents with type 1 diabetes mellitus. Second, evaluate the relationship between having fear of needles and the quality of metabolic control measured with haemoglobin A1c (HbA1c) and quality of life within this population. To evaluate fear of needles a questionnaire (D-FISQ) was first translated and later administered to both children and their caregivers. A quality of life measurement (DISABKIDS) was also translated for the study and later administered to children and their caregivers as well, to evaluate quality of life. To evaluate metabolic control, the patients' HbA1c levels were gathered from their medical history.

The research study was conducted at the children clinic at The National University Hospital of Iceland in cooperation with the diabetes team, including doctors, nurses and psychologists. The main reason for the study is that the diabetes team had noted that some patients had worse treatment adherence and worse metabolic control and wanted to know if

fear of needles could be the reason for that. I want to thank the diabetes team at The National University Hospital of Iceland for letting me conduct this research for them and for all their support and education through this process, especially Berglind my supervisor and Elísabet, a nurse in the diabetic team who I could always seek advice with. I also want to thank my other supervisor, Jón Friðrik for his great teaching throughout the master's program. My statistic teacher, Sævar, will receive special thanks for giving his time and help when most needed, at any time of the day. At last but not least, I want to give thanks to my friends in the program and my family for listening to me complaining at times when I was lost and for always believing in me and encouraging me to do my best.

Abstract

Objective: The aim of this study was to assess the prevalence of fear of needles among children and adolescents with type 1 diabetes mellitus and its effects on the quality of metabolic control measured with haemoglobin A1c (HbA1c) and quality of life.

Method: 33 patients aged 9-16 years old with type 1 diabetes mellitus were enrolled in the study as well as their primary caregiver. Patients and caregivers completed two questionnaires, D-FISQ (evaluating fear of needles) and DISABKIDS (evaluating quality of life), and caregivers answered a background questionnaire as well. Other data collected were HbA1c levels and average blood glucose levels obtained from the patient's medical records.

Results: Fear of self-injecting (FI) with insulin (or fear of infusion-site changes) was more common with children and adolescents with type 1 diabetes mellitus (30,3% - 33,3%) than fear of self-testing (FST) blood glucose (6,1% - 21,2%). Positive FI or FST did not significantly affect HbA1c levels, but children with positive FI, based on the caregivers' responses, had significantly lower scores on the DISABKIDS, demonstrating worse quality of life ($p < .05$). Patients using insulin pumps had significantly higher HbA1c levels ($p < .05$) than those on multiple daily injections.

Conclusion: Fear of needles is common among children and adolescents with type 1 diabetes mellitus. Based on the caregivers' responses, fear of needles seems to negatively affect quality of life but having fear of needles has no effect on metabolic control, which is inconsistent with previous studies.

Keywords: Fear of needles, quality of life, HbA1c, type 1 diabetes mellitus

Fear of Needles Among Children and Adolescents with Type 1 Diabetes Mellitus –
Relationship with Metabolic Control (HbA1c) and Quality of Life

Diabetes is one of the most common chronic diseases in the pediatric population and has major short-term and long-term consequences and impact on patients' lives (Daneman, 2006; Helgeson, Snyder, Escobar, Siminerio, & Becker, 2007). Diabetes mellitus is metabolic disease caused by defects in insulin secretion, defects in insulin action or defects in both. Diabetes mellitus is characterized by hyperglycemia because of these defects (American Diabetes Association, 2010). Diabetes mellitus falls into two categories, type 1 and type 2, the latter being far more prevalent. Type 1 diabetes mellitus, which accounts for only 5-10% of diabetic patients, is caused by an absolute deficiency of insulin secretion resulting from autoimmune destruction of the beta cells of the pancreas (American Diabetes Association, 2010). This deficiency of insulin secretion will eventually lead to hyperglycemia, so for patients to maintain a good metabolic control daily injections of insulin are needed (Silverstein et al., 2005). The disease needs to be managed effectively to avoid serious health consequences, such as blindness, kidney disease etc. Therefore, children with type 1 diabetes need to have good self-control and keep track of food intake, physical exercise, as well as other diabetes related management (Helgeson et al., 2007). Children with type 1 diabetes mellitus either have to inject insulin into their bodies multiple times per day (MDI) or use a continuous subcutaneous insulin infusion (CSII)/ insulin pump that requires infusion-site changes every three days. The insulin pump closely stimulates the physiological way of insulin secretion. In between the injections the children need to monitor their blood glucose with multiple finger prick measurements per day to provide data for insulin dose adjustments (Kordonouri, Hartmann, & Danne, 2011; Silverstein et al., 2005). Needles are therefore a big part of the daily lives of children with type 1 diabetes mellitus and an evaluation of needle phobia in this population essential for physicians, caregivers and the patients themselves.

Needle phobia, or blood-injection-injury phobia, is classified as a subtype of specific phobias whereas the needle itself or images in anticipation of injection is the stimulus for extreme anxiety and often leads to avoidance (American Psychiatric Association, 1998; Willemsen, Chowdhury, & Briscall, 2002). It is relatively common that children and adolescents in the general population experience needle phobia with a prevalence of 2-4%, however, a mild fear of needles and injections is far more common (Mark, 1988). Needle phobia has been thought to be one of the reasons for patients changing from multiple daily injections of insulin to insulin pumps and a recent study confirmed that higher severity of needle phobia was noted in an insulin pump group compared to injection group (Cemeroglu et al., 2015; Kordonouri et al., 2011).

There are indications that adherence to insulin treatment can be difficult among diabetic patients; however, the causes for this are not always known (Mollema, Snoek, Adèr, Heine, & van der Ploeg, 2001). Studies indicate that bad adherence with pediatric diabetes patients can possibly be a result of fear of needles (Cemeroglu et al., 2015; Mollema et al., 2001) and it is possible that fear of needles negatively impacts the metabolic control with children and adolescents through avoidance or postponing insulin injections or blood glucose monitoring (Cemeroglu et al., 2015; Zambanini & Feher, 1997). Results from a recent study on fear of needles among children with type 1 diabetes mellitus showed that children who experience fear of needles was inversely related to number of finger pricks per day (Cemeroglu et al., 2015).

HbA1c is the most useful measure to evaluate metabolic control and demonstrates levels of glycemia for the last 4-12 weeks. Recommended glycemic levels (HbA1c) for youth with type 1 diabetes are < 7.5% (Chiang, Kirkman, Laffel, & Peters, 2014). Mean HbA1c value in Icelandic pediatric diabetic patients was reported to be $8.16\% \pm 1.31$ in a cross-sectional study conducted at the pediatric clinic in 2008 (Þórisdóttir, Bjarnason,

Konráðsdóttir, & Þórsson, 2008). A major clinical study conducted in the late 20th century, The Diabetes Control and Complications trial, showed that patients who keep blood glucose levels close to normal reduce the risk of getting physical complications caused by diabetes (DCCT, 1993). A reliability study for a questionnaire assessing needle phobia with pediatric diabetic patients revealed that those with present fear of self-injecting with insulin had a trend toward higher HbA1c levels than those with no fear (Simmons et al., 2007). It is important to evaluate needle anxiety among diabetic children and how the fear may affect treatment adherence and metabolic control whereas the children may not express this fear and it can go unseen with caregivers. Fear of needles seems to be more prevalent with children and adolescents with type 1 diabetes than with the adult population whereas studies show that up to 30% of pediatric patients can be affected by fear of needles (Cemeroglu et al., 2015; Simmons et al., 2007). Inverse association has been noted between fear of injection and age of pediatric patients, showing younger children to be more likely to fear injections of insulin (Cemeroglu et al., 2015). The literature concerning needle phobia among diabetic patients is scarce and research among diabetic children in Iceland is non-existent.

Children and adolescents with chronic diseases will face various health-related problems, therefore, emphasis on identifying the factors that can influence their health related quality of life (HRQOL) is growing. Patients with diabetes are constantly dealing with their disease and the psychosocial toll of living with diabetes may eventually affect their quality of life. Previous researchers have considered the fact that it is likely that patients with needle phobia can only achieve good metabolic control at the expense of quality of life and are therefore burdened with more than a specific phobia of needles (Mollema et al., 2001). A study conducted in the Netherlands revealed that adult diabetes patients who had high scores in fear of self-injecting or fear of self-testing reported higher levels of anxiety and depression. This group of patients reported less frequent self-monitoring of blood glucose, feared

hypoglycemia and had other diabetes-related distress (Mollema et al., 2001). A study of adolescents with type 1 diabetes results indicated that better metabolic control or a lower HbA1c was significantly associated with a better quality of life. More worries and less satisfaction were noticeable with higher age as the metabolic control deteriorated and both were more noticeable with the girls than the boys (Hoey et al., 2001). Even though it is known that good metabolic control is associated with better quality of life more research is needed to determine whether needle phobia in children and adolescents is associated with poor metabolic control and how that may affect quality of life with this population. Quality of life should be identified by the patient's self-reporting and can be characterized as an intuitive perception of health in physical, mental, emotional, functional and social domains (Bullinger, Schmidt, Petersen & DISABKIDS Group, 2002).

In this study, prevalence of fear of needles among children and adolescents with type 1 diabetes mellitus was evaluated and its relationship with glycemic levels (HbA1c) and quality of life within this population assessed. Hypothesis were that children dealing with fear of needles would have worse metabolic control and quality of life.

Method

Participants

Participants in this study were 33 children and adolescents age 8-16 with type 1 diabetes and their primary caregivers. The participants were patients who attended routine check-ups at the diabetes clinic at The National University Hospital of Iceland and were currently receiving insulin via injection or insulin pump. All participants were Icelandic speaking. Demographic characteristics are listed in Table 2. Exclusion criteria were: patients who were diagnosed within six months of the study, if patients or their caregiver were not Icelandic speaking and if the child or adolescent arrived without a caregiver to the clinic.

Materials and Measures

Background Information

The caregivers answered a few background questions about their child in addition to answering the same questionnaires the patients did. These questions are listed in Table 1.

Table 1: Background information

Information about caregiver:

Mother vs. father

Education

Relationship status

Information about the patient:

Gender

Age

Time since diagnoses

Injection vs. pump

Severe hypoglycaemia

Emergency ward due to DKA

Other diseases

Nerve and/or mental disorders

Single vs. multiple homes

Diabetes Fear of Injecting and Self-testing Questionnaire (D-FISQ)

The Diabetes Fear of Injection and Self-Testing Questionnaire (D-FISQ) was developed in 1996 to estimate the fear of self-injecting (FI) and self-testing (FST) in adult diabetes patients. D-FISQ is a self-report questionnaire that contains two subscales, one

evaluating FI and the other FST, with the same 15 items. The items on the questionnaire are presented as statements and scored on a 4-point Likert scale, ranging from “Never” to “Always” (Snoek, Mollema, Heine, Bouter, & Van Der Ploeg, 1997). The list has demonstrated high internal consistency with Cronbach’s α of 0.94 and a confirmed construct validity with a correlation of 0.44 with Spielbergers Trait Anxiety Inventory. The D-FISQ was later shown to be reliable in the pediatric age group (age 2 to 21 years) with Cronbach’s α ranging from 0.874 to 0.935 and a valid tool to identify needle phobia in young diabetic patients (Cemeroglu et al., 2015; Simmons et al., 2007).

In the current study a shorter version of the D-FISQ was administrated containing 15 items, six items measuring FI and nine items measuring FST, this version was developed since exploratory factor analysis revealed that this extraction could be made (Mollema, Snoek, Pouwer, Heine, & van der Ploeg, 2000). Internal consistency ranged from Cronbach’s α of 0.81-0.95. The questionnaire was administered for both caregivers and children. The children got questions about their own experience when injecting with insulin and self-testing blood glucose and their caregivers got questions about how they evaluate their child’s experience. Answers on the questionnaire were scored as follows: 0 for never, 1 for sometimes, 2 for often and 3 for Always. Needle fear on the subscale evaluating fear of injections was considered to be present with a score of ≥ 4 and on the subscale evaluating fear of self-testing blood glucose needle fear was considered to be present with a score of ≥ 6 (Cemeroglu et al., 2015; Simmons et al., 2007; Mollema et al., 2000)

DISABKIDS

The DISABKIDS is an instrument to evaluate mental, social and physical components of quality of life in children and adolescents with chronic health conditions. The instrument contains self-report lists for children and adolescents from age 8 to 16 including both a

chronic generic part, measuring quality of life and distress levels caused by a chronic disease, and a condition-specific part (Bullinger et al., 2002; (Simeoni, Schmidt, Muehlan, Debensason, & Bullinger, 2007). One of the condition-specific parts looks at diabetes mellitus and therefore the DISABKIDS instrument can be chosen when assessing quality of life of diabetic children and adolescents.

A 10 item disease specific module was translated and used in this study to assess quality of life with children and adolescents with diabetes mellitus. These 10 items measured two domains: impact, emotional and functional on control of daily life, and treatment, planning and use of equipment. The list has a Cronbach's α of 0.85 (de Wit, Delemarre-van de Waal, Pouwer, Gemke, & Snoek, 2007; Ravens-Sieberer et al., 2007). Along with the 10 items about the disease there are three questions about how troubling the symptoms have been.

Caregivers and children got separate forms of the list where caregivers evaluated their children experience regarding the disease and the children evaluated their own experience regarding their disease. No specific cut-off scores are to be found on quality of life, scores are summed and higher scores on the DISABKIDS list demonstrated better quality of life.

Study Design and Procedure

This was a cross-sectional, prospective study approved by the Bioethics committee of The National University Hospital of Iceland and The Data Protection Authority. Ten independent variables and two dependent variables were used in this study. Independent variables were: fear of needles, age, gender, injection vs. pump, months since diagnosed, diabetic ketoacidosis (DKA), severe hypoglycaemia, other diseases, nerve- and/or mental disorders and living situations. The two dependent variables were: glycemic levels (HbA1c) and quality of life. When attending a routine check-up at the children's hospital both

caregivers and children/adolescents were informed about the ongoing study and referred to the study personnel where they got more information about the study and signed an informed consent. Children over the age of 12 years signed an informed consent but caregivers signed the consent for themselves and younger children. Caregiver and child were referred to a room or a seating area to complete the questionnaires which were handed out on paper. The study personnel helped the children to understand and answer the questions if needed. Completion of the questionnaires took approximately 10 minutes.

Data collection

The HbA1c levels for each patient were recorded from the most current hospital visit, reflecting the average blood glucose levels over the last three months. Blood glucose levels were obtained from two weeks prior to the visit by downloading them from the patients pump and/or glucometer via CarePro Link. At last, each participant's questionnaire answers were collected and recorded in IBM SPSS Statistics v. 24 software.

Statistical analysis:

Prevalence of fear of needles was evaluated by frequency of those with score of FI ≥ 4 or FST ≥ 6 on the D-FISQ questionnaire.

Independent *t* tests were used to compare mean value differences between groups with quantitative data. Difference in HbA1c levels and quality of life between those who reach criteria for fear of needles and those who do not were evaluated with independent *t*-tests. Crosstabs and χ^2 tests were used to evaluate nominal data. Pearson correlation coefficient was used to evaluate association between variables.

All analysis was processed using IBM SPSS Statistics v. 24 software and statistical significance was assessed at $p < .05$.

Results

Demographic characteristics are listed in Table 2. Age of patients ranged from 9 to 16 years and mean age was 13.5 years. Time since diagnosis ranged from seven months to 11 years with a mean of 3.8 years, 10 patients were receiving insulin via injections whereas 17 were receiving insulin via pump.

Table 2: Demographic characteristics of the patients

Demographic characteristics	
Sample size	33
Age (years)	m. 13.5 ± 2.2
Male:Female (child)	13:18
Time since diagnosis (years)	m. 3.8 ± 2.9
Injection/Pump	10:17
HbA1c (%)	m. 8.3 ± 1.3
HbA1c (mmol)	m. 67.3 ± 14
Average blood glucose	m. 11.2 ± 3

Figure 1 shows prevalence of fear of needles as measured by both caregivers and patients on the D-FISQ questionnaire. Caregivers (n = 33) evaluating their children's experience of injection of insulin and blood glucose testing responded that FST was present in 21.2% of participants and FI in 33.3% of participants. Patients (n = 33), children and adolescents, evaluating their own experience responded that FST was present among 6.1% of them and FI among 30.3% of them. Some inconsistency was noted between caregivers' and patients' responses on the D-FISQ questionnaire, where patients and caregivers did not agree

that fear of needles was present or not. Consistency was between 67% of the patients' and caregivers' responses but in 48% of occurrences either caregiver or patient reported positive FI.

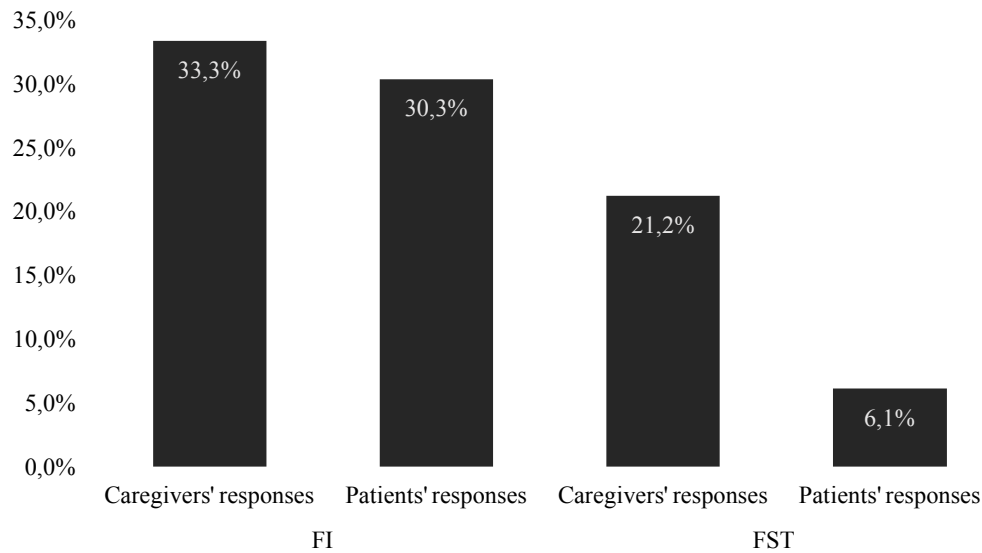


Figure 1. Prevalence of fear of needles as measured on D-FISQ self-report questionnaire

Data for quality of life scores, for both patients and caregivers, as they relate to either FI or FST are shown on Figure 2. Based on caregivers' responses, children who have positive FI or FST have significantly lower scores on the DISABKIDS questionnaire ($p < .05$), demonstrating worse quality of life.

Based upon both caregivers' and patients' responses there were no significant difference in HbA1c levels between those with positive FI or FST and those not affected by fear of needles and no significant correlation between higher HbA1c levels and higher score of the DFISQ questionnaire, indicating that fear of needles does not affect metabolic control with this population.

Mean HbA1c levels in the sample were $8.3\% \pm 1.3$. Six participants had HbA1c levels $<7\%$ and 11 participants had HbA1c levels ≥ 9 . A positive correlation was noted between

months since diagnosed and higher HbA1c levels ($r = .43, p < .05$). There was a significant difference in the HbA1c levels between those on multiple daily injections ($M = 7.7, SD = 0.9$) and insulin pump ($M = 8.8, SD = 1.2$); $t(34) = -2.57, p = 0.017$. Crosstabs revealed that those with positive FI or FST were proportionally more likely to be using insulin pump than those with no fear of needles even though χ^2 tests did not reach significance. No difference was noted in quality of life between those groups.

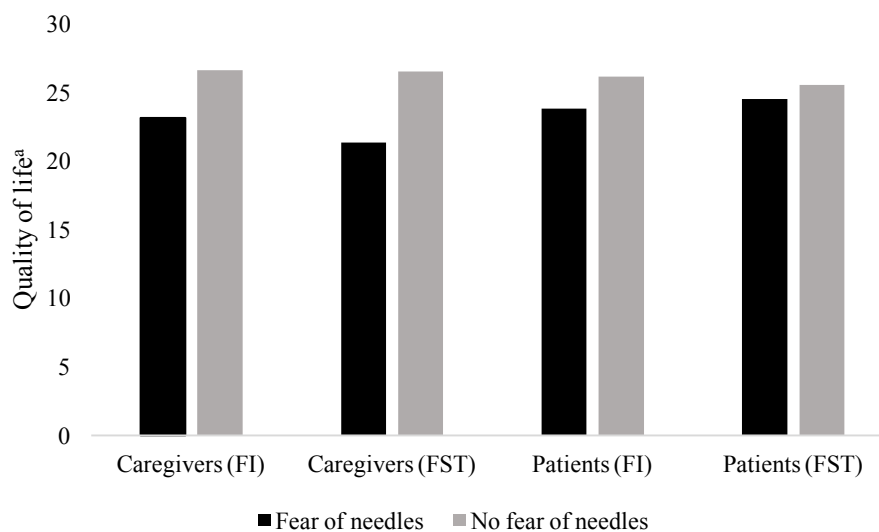


Figure 2. Quality of life scores as they relate to either FI or FST

^a Quality of life as measured by scores on the DISABKIDS questionnaire

When quality of life or scores on the DISABKIDS questionnaire were evaluated with other independent variables than fear of needles independent t -tests revealed that significant difference was on quality of life, based upon patients' responses, between those who had been to the emergency ward due to diabetic ketoacidosis (DKA) ($M = 22.5, SD = 3.5$) and those who had not ($M = 28.6, SD = 6.7$); $t(23) = -2.3, p < .05$. Additionally, children living in two homes reported worse quality of life ($M = 21.9, SD = 5.6$) than those living in a single home ($M = 28.7, SD = 5.4$); $t(29) = -3.04, p < .01$.

Finally, lower quality of life scores, based on the patients' responses on the DISABKIDS questionnaire, was associated with higher average blood glucose levels from the last two weeks ($r = -.43, p < .05$).

Discussion

The aim of this study was to evaluate fear of needles among children and adolescents with type 1 diabetes mellitus in Iceland and its effects on glycemic levels (HbA1c) and quality of life.

It seems that fear of needles in this population is relatively common, with a prevalence of around 30% when injecting with insulin or during infusion-site changes. As expected, the percentage of positive FI was higher compared to positive FST, whereas only two patients, or 6%, reported fear of needles. Caregivers seemed to evaluate FST to be present more often than their children did, but 21% of caregivers reported positive FST. The D-FISQ questionnaire used in this study was developed to evaluate fear of needles in adult diabetic patients but was later shown to be reliable in the pediatric population as well (Simmons et al., 2007). A shorter version of the questionnaire is now used in the adult population, but is yet to be validated in the pediatric population. In the current study this shorter version was translated and administered for the first time in an Icelandic pediatric population of children with type 1 diabetes mellitus. Studies regarding fear of needles among pediatric patients with type 1 diabetes mellitus is scarce and non-existent in the Icelandic literature but the prevalence of needle fear noted above is similar to the results from the few studies regarding this matter (Cemeroglu et al., 2015; Simmons et al., 2007).

It was hypothesised that fear of needles would negatively affect both glycemic levels (HbA1c) and quality of life among this population, but the results did not support the hypothesis, whereas no difference was noted between those with positive FI or FST and those

with no fear of needles. This is not consistent with previous studies where fear of needles has been associated with higher HbA1c levels demonstrating inferior metabolic control (Cemeroglu et al., 2015; Simmons et al., 2007). Evaluation with a larger sample is still needed. Mean HbA1c levels are $8.3\% \pm 1.3$ which is a little higher than measured in a previous Icelandic study of pediatric diabetic patients and higher than recommended for youth with type 1 diabetes (Þórisdóttir et al., 2008; Chiang et al., 2014). The results furthermore revealed that HbA1c levels were higher among those who had been diagnosed for a longer time and was also higher with those using insulin pumps. This might be valuable information for the diabetic clinic since children who have been diagnosed for a longer time ought to have their glycemic levels more under control than those who are still learning to deal with the disease. Furthermore, it is interesting that HbA1c levels were higher with those using insulin pumps whereas the pumps are supposed to stimulate a normal pattern of insulin secretion and therefore keep HbA1c levels within desired criteria (Kordonouri et al., 2011).

There are indications that quality of life is negatively affected by fear of needles among children and adolescents with type 1 diabetes mellitus. Significant difference was noted, based on the caregivers' responses, between those with positive FI or FST and those with no fear of needles. Mean scores on the DISABKIDS list were lower based on the patients' responses as well, even though a significant difference was not noted. Diabetic patients with fear of needles are therefore burdened with more than a specific phobia when it starts to take a toll of their quality of life. Since there was no difference found in HbA1c levels between those with positive FI or FST and those not, it is possible that the patients are achieving good metabolic control only at the expense of quality of life.

In this study, proportionally more patients using insulin pumps had positive FI or FST scores than those on multiple daily injections, this is consistent with previous studies and

maybe not surprising since fear of needles has been thought to be one of the reasons that patients choose to use insulin pumps (Cemeroglu et al., 2015; Kordonouri et al., 2011).

In previous studies, a positive FST has been found to be inversely related to number of blood sugar tests per day indicating that patients who fear self-testing their blood glucose try to postpone it or avoid it altogether (Cemeroglu et al., 2015; Simmons et al., 2007). Originally, the plan was to evaluate this in our study as well but because many of the participants were using a continuous blood sugar monitor that does not require them to perform multiple finger pricks per day to monitor their blood sugar, that kind of an evaluation was not possible.

Other background variables that were assessed in this study and not mentioned in the results showed no significant effect. Further research is needed and one variable that might be interesting to include is anxiety among caregivers and its effects on fear of needles among their children.

The results of this study must be interpreted with caution. First of all because the questionnaires used in this study were translated and used for the first time in an Icelandic sample and second of all because the sample only contained 33 patients and it might not be a good representation of the whole population. We have to consider how the patients who did not have the opportunity to participate in the study might have changed the results. At last, distribution in groups were uneven and that is a weakness that needs to be taken into account when interpreting the results.

For future research it might be better to make the questionnaires a part of the routine check-ups with a nurse or a doctor to ensure more participants whereas lack of participants in this study was often affected by cancellation of scheduled check-up by patients or the busy schedule of the study personnel. More research regarding this matter is still needed and

demonstrating the reliability of the two questionnaires used in this study could be a subject for further research.

Conclusion

In conclusion we can say that fear of needles is relatively common among children and adolescents with type 1 diabetes mellitus even though needles are a big part of their daily lives. This is valuable information for the diabetic clinic and more education about this might be helpful for the patients when they are first diagnosed with type 1 diabetes mellitus. No significant difference was noted of HbA1c levels from those with positive FI or FST indicating that fear of needles does not negatively affect metabolic control as the diabetic team at The National University Hospital of Iceland thought. Fear of needles seems to negatively affect quality of life though and it might be one possibility that patients are achieving good metabolic control by losing some of their quality of life. Identifying diabetic patients who fear needles and take appropriate measures might help them gain better control over their disease and eventually increase their quality of life.

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