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Preadolescents and adolescents with type I diabetes mellitus: health related quality of life, family conflicts and fear of injecting

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Abstract: A good management of diabetes requires at the same time self-regulation behaviour and a balanced involvement of family components. This study's aims were: understanding fear of injections and perceptions of family conflicts in preadolescents and adolescents with type 1 diabetes mellitus and their mothers, comparing their perceptions, and identifying the risk factors impacting patients' quality of life. Participants were one hundred and two patients (Mean age = 14.63, SD = 2.43; age range = 10-19 years; Females = 52) and their mothers (Mean age = 46.94, SD = 6.2, age range = 27-63 years), who filled in self and proxy-report questionnaires. Twenty % of patients and 14.7% of their mothers reported clinical score for fear of self-injection and blood testing. Mothers reported higher fear of injecting and family conflicts compared with the patients. Age, fear of injecting and family conflicts impacted significantly on patients' quality of life perceptions. Clinical consideration and recommendations are given basing on the empirical results.

Keywords: adolescents; diabetes type I; quality of life; family conflicts; fear of injecting

1. Introduction

Type 1 diabetes (T1D) is one of the most common chronic diseases among the pediatric population. Worldwide annual incidence is 98,200 (128,900) new cases in childhood and adolescents [1]. Type 1 diabetes requires a demanding and time-consuming treatment regimen, that includes blood glucose monitoring, multiple insulin doses, carbohydrate counting and physical activity [2]. A good management of diabetes requires at the same time self-regulation behavior [3] and a balanced involvement of family components [4]–[6]. Specifically, sharing diabetes tasks and responsibility between parents and pediatric patients is associated with better diabetes outcomes [7]. A collaborative partnership with open communication and emotional support by parents positively intervenes in diabetes management [8]. Parental responsibility decreases with time, and adherence and metabolic control can deteriorate, especially during preadolescence and adolescence [9]. In this period teenagers have to balance their dependence on parents and to acquire higher autonomy in diabetes management [10]. During the transition from childhood to adolescence, patients experience difficulty in management behavior, and in some cases family conflicts, diabetes distress and poor psychological outcomes could emerge [11], [12].

Indeed, children and adolescents with T1D are more likely to suffer from depression, anxiety and psychological distress with negative negative impacts on their quality of life perceptions [13], [14]. In particular, adolescents with T1D exacerbate more externalised problems and report more family conflicts, with an important impact on glycaemic control [15]. Family conflicts can be associated with youth diabetes adjustment in a direct or indirect way [16]. The first way includes open expression of anger concerning diabetic management. The second way includes different types of conflicts not related to diabetes adherence but associated with having T1D [17].

Researches show that family conflicts are associated with lower quality of life and higher glycated haemoglobin (HbA1c) [15], [18].

Moreover, another aspect that significantly impacts on glycemic control and psychological distress in youth with type 1 diabetes is fear of self-injecting [19], [20]. Research shows that fear of needles is common among patients with T1D [21]–[23]. More intense needle phobia is associated with poor management, such as higher HbA1c level, rare glucose monitoring [21] and higher risk of long term complication [24]. Parents of children with type 1 diabetes also experience fear and distress during insulin injection and glucose testing procedures. Previous research shows that 13.6% of mothers reported needle phobia and distress during procedure after the diagnosis as well [25]. To the best of our knowledge few studies analyse this aspect among parents of T1D patients [25], [26].

Many factors influence the quality of life (QOL) of patients with T1D: sociodemographic, personal, diabetes specific and family factors. [16], [27]–[29]. Children with T1D report higher quality of life than adolescents (Wagner et al., 2005). Moreover, some specific diabetic variables affect quality of life: good metabolic control and intensified insulin therapy are associated with better quality of life [29]. Conversely, fear of insulin and injection constitute risk factors for poor glycemic control, psychological maladjustment and poor general well-being [19]. In addition to medical and personal factors, family variables impact on quality of life, emphasising the role of quality of family interactions, parental monitoring and family communication. In particular, intrusive parental involvement is associated with lower quality of life in adolescents with T1D and with greater family conflicts [15], [30]. Adolescents, in a qualitative study, reported that parental intrusiveness, blame and lack of understanding are connected with family conflict [31].

The purpose of the current study is to explore psycho-social well-being in preadolescents and adolescents with T1D and their mothers, taking into account sociodemographic variables, such as age and gender, specific diabetes variables, such as fear of self-injection and self-testing, and family factors, such as family conflict.

The present study has three goals. The first goal is to assess fear of injections and the level of perceived family conflicts in a group of T1D pediatric patients and their mothers.

The second goal is to investigate the possible differences between patients and their mothers regarding fear of injection and perception of family conflicts.

The third purpose is to test possible differences between preadolescents and adolescent patients in quality of life, perception of family conflicts and fear of injections.

The last goal is to identify patients' (age, gender, HbA1c, fear of injecting, family conflict) and mothers' factors (age, years of schooling/level of education, family conflict, fear of injecting) that may impact on patients' quality of life.

2. Materials and Methods

2.1 Participants

Participants of our study were enrolled at the Department of Woman and Child's Health of University Hospital of Padova. One hundred and two patients and their mothers (N tot = 204) were recruited during periodic follow-up visits at the Diabetes Unit. Eligibility criteria were: treatment for T1D, patient's age between 10 and 19 years and a T1D diagnosis at least 6 months prior to data collection. Exclusion criteria were: intellectual disabilities, inability to complete questionnaires alone and neuropsychiatric illness with active pharmacotherapy.

Patients' mean age was 14.63 (SD = 2.43); 52 were female and 50 were male. Mothers' mean age was 46.94 (SD = 6.2 range 27-63). Of the included mothers 1% had primary school graduation, 39.2% had a middle school diploma, 42.2% had a high school diploma, 13.7% had a university degree and 3.9% had a post-lauream degree.

Table 1 shows the socio-demographic information on the participants.

Table 1: Socio-demographic characteristics of participants

	N	%
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Gender	Male	50	49
	Female	52	51
Age levels	Preadolescents (range: 10-14 years)	48	47.1
	Adolescents (15-19 years)	54	52.9
Mothers' level of education	Primary school	1	1
	Secondary school of first grade	40	39.2
	Secondary school of second grade	43	42.2
	University Degree	14	13.7
	Ph.D. or Master degree	4	3.9
		Mean	SD
HbA1c	Range: 5.5-11.1	7.65	0.99
Mothers' age	Range: 27-63 years	46.94	6.2

2.2 Procedure

The sample enrolment and questionnaire administration were conducted during scheduled diabetic visits by a clinical psychologist. The research project was presented to preadolescents and adolescents' patients and their parents, who signed the informed consent at the Hospital. The recruitment period lasted 2 months according to the Hospital ward and Ethical Committee. All subjects were informed of the confidentiality of data and that they could withdraw from the study at any moment. The study procedure followed the Declaration of Helsinki (Italian law 196/2003, UE GDPR 679/2016). The questionnaires were given to patients and parents during their diabetic visit and were completed on this occasion or at home and then returned at the next visit.

2.3 Measures

Diabetes Quality of Life for youth-short form (DQOL-SF) [32, 27]

The DQOL-SF consists of 18 items scored using a five-point Likert scale (from 0 = "never" to 4 = "all the time"), administrable from 10 years of age. Higher scores indicate a poorer Quality of life. In this study it showed a good internal consistency, both for the global scale ($\alpha = 0.74$; N item = 18) and for the two subscales: impact of diabetes on daily life ($\alpha = 0.65$; N item = 11) and worries about diabetes ($\alpha = 0.96$; N item=7).

Revised diabetes family conflict scale (DFCS-R) [33].

The DFCS-R was completed by pediatric patients and their parents. It includes 19 diabetes management tasks to assess the degree of family conflict. The self-report score is on a three-point Likert scale (from 1 = never argue to 3 = always argue). Higher scores indicate higher level of conflicts. In this study internal consistency was good in both versions: $\alpha = 0.96$ for children/adolescent version and $\alpha = 0.98$ for parent version.

Diabetes Fear of Injecting Questionnaire (D-FISQ)[23]

Children/adolescents (self-report) and parents (proxy-report) completed D-FISQ to assess fear of self-injection and blood glucose testing. This questionnaire is composed of 30 items, divided into two subscales: fear of self-injecting, fear of blood glucose testing. The score is attributed on a four-point Likert scale (from 0 = never to 3 = always). A score ≥ 6 indicates a clinical needle fear. In our study internal consistency was: fear of self-injection, $\alpha = 0.84$ for the children/adolescents version, $\alpha = 0.88$ for the parent; fear of blood glucose testing, $\alpha = 0.93$ for the children/adolescents version, $\alpha = 0.88$ for the parent version.

Diabetes information

The diabetes-related information, such as the participants' age at type 1 diabetes onset, current diabetes duration, insulin regimen and glycemic control (measured as the most recent HbA1c value) were collected.

2.4 Statistical Methods

Descriptive measures of central tendency and variability were computed for all the dependent variables.

In order to identify possible differences between patients with T1D and their mothers regarding fear of injections (assessed by *D-FISQ* self-report and proxy-report) and perception of family conflicts (assessed by *DFCS-R* with children and parent version), a *t*-test for independent samples was performed.

To test possible differences between preadolescent and adolescent patients in all variables (quality of life, perception of family conflicts and fear of injections), we performed two different analyses. At first, we divided our sample into two groups: preadolescents (10-14 years) and adolescents (15-19 years). Second, we performed a *t*-test for independent samples to compare preadolescents' and adolescents' scores.

Pearson's correlations were run to identify the possible associations between the variables. A hierarchical regression model was run to identify which factors impacted significantly on patients' quality of life.

Statistical analyses were carried out using IBM Corp SPSS Statistics 22.0. A *p*-value < 0.05 was considered statistically significant.

3. Results

3.1. Quality of life and family conflicts of patients and their mothers compared with norms

Descriptive analysis of fear of injecting and of blood control, family conflicts and quality of life are reported in Table 2.

Table 2: Mean scores of fear of injecting, family conflicts and quality of life

Variable		Mean	SD	Minimum-Maximum
D-FISQ patients	FSI	1.36	2.31	0-12
	FST	1.61	2.61	0-13
D-FISQ patients Global score	FSI+FST	2.97	4.25	0-22
D-FISQ mothers' reports on their own experience of injecting (N = 54 for FSI and 48 for FST)	FSI	1.46	2.75	0-12
	FST	1,56	3.55	0-21
D-FISQ mothers Global score	FSI+FST	3.72	5.95	0-32
DFCS patients		16.99	10.60	0-49
DFCS mothers		20.97	11.57	0-54
DQOLY		16.30	7.24	3-34

Legend: D-FISQ: Diabetes Fear of Self-Injecting Questionnaire; FSI: Fear of Self-Injecting; FST: Fear of Self Testing; DFCS = Diabetes Family Conflict Scale; DQOLY: Diabetes Quality of Life for Youth

Assuming a score ≥ 6 indicating a clinical level for fear of needle, as indicated from D-FISQ authors, we found that 20% of patients (N = 21) and 14.7% of their mothers (N= 15) reported clinical levels of fear according to D-FISQ Global scores.

Regarding perceived family conflicts, patients reported a mean score of 16.99 (SD = 10.60), while mothers reported a mean of 20.97 (SD = 11.57). The conflict ratings attested to a low level both for pediatric patients and for their mothers, considering that the scale ranged from 19 (= no conflict) to 57 (= high level of conflict).

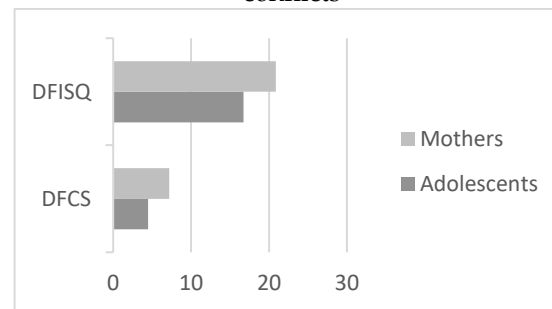
Health related quality of life for our patients showed a mean score of 16.30 (SD = 7.24). Higher scores indicate a more negative impact of diabetes and poorer QoL, and lower scores indicate better QoL. These pediatric patients reported lower Quality of Life perceptions.

3.2. Comparison between patients' and their mothers' reports on patient's fear of injecting and family conflicts

A *t*-test for dependent samples was run to identify possible differences between patients' self and mothers' proxy reports on patients' means of fear of injections. A significant difference between means of fear of self-injections were found in 99 out of 102 patient-mother couples ($t = -2.9$, $df = 98$; $p = 0.005$), with patients reporting a lower mean of fear (Mean = 4.49, SD = 6.74) compared with that reported by their mothers about their sons/daughters (Mean = 7.20; SD = 9.60). No difference was shown for the fear of self testing ($p > 0.05$).

Another T-test for dependent samples was run to identify possible differences between patients' and mothers' family conflicts in 101 of 102 patient-mother couples. Results showed a significant difference between mothers and their daughters/sons ($t = -3.51$; $df = 98$; $p = 0.001$), with patients declaring a lower score in their family conflicts (Mean = 16.71; SD = 10.52) compared with that reported by their mothers (Mean = 20.87; SD = 11.59) (Figure 1).

Figure 1: Differences between patients and their mothers regarding fear of self-injecting and family conflicts



Legend: DFISQ: diabetes fear of self-injecting questionnaire; DFCS = diabetes family conflict scale

3.3. Factors impacting on patient's quality of life

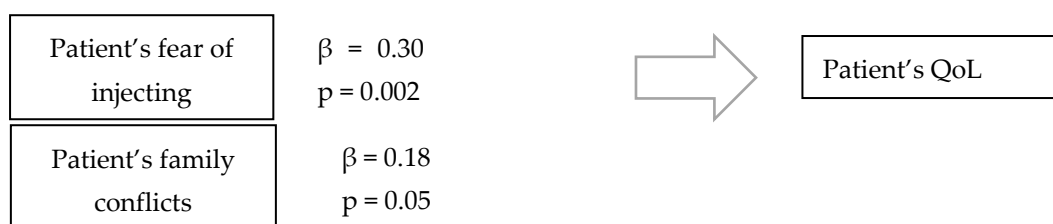
We ran Pearson's correlations to identify the possible significant associations between patients' and mothers' socio-demographic and adherence factors (age, gender, HbA1c) and patients' quality of life. Only patients' age and mothers' age were identified as factors associated respectively with patients' quality of life ($r = 0.27$, $p = 0.006$) and with mothers' perceived fear in self-testing and self-injecting of their children ($r = -0.26$, $p = 0.03$).

Patients' global quality of life was significantly associated with their own perceived fear in self-testing and self-injecting ($r = 0.36$; $p = 0.0001$) and with their reported family conflict score ($r = 0.24$; $p = 0.014$).

A series of hierarchical regression models were run to understand which factors predicted patients' quality of life and the DQOLY subscales (respectively Impact of diabetes and Diabetes worries). In the first block we inserted patient's age and HbA1c, while in the second one we inserted family conflict self-reported score and the reported global fear of injecting score. Quality of life ($R^2 = 0.20$; $F = 7.30$, $p = 0.0001$) was predicted by patient's age ($\beta = 0.28$; $p = 0.002$), reported global fear of injecting score ($\beta = 0.30$; $p = 0.002$) and family conflict self-reported score ($\beta = 0.18$; $p = 0.05$). Impact of diabetes subscale ($R^2 = 0.20$; $F = 5.89$, $p = 0.0001$) was predicted by patient's age levels ($\beta = 0.19$; $p = 0.04$), reported fear of self-injecting and self-testing score ($\beta = 0.30$; $p = 0.002$) and family conflict self-reported score ($\beta = 0.19$; $p = 0.05$). Only adolescent's age band ($\beta = 0.20$; $p = 0.04$) and reported fear of self-injecting and self-testing score ($\beta = 0.18$; $p = 0.06$) impacted on Diabetes worries subscale ($R^2 = 0.09$; $F = 3.37$, $p = 0.03$) (Figure 2).

Figure 2: Significant factors impacting on patient's quality of life

Patient's age	$\beta = 0.28$	$R^2 = 0.20$
	$p = 0.002$	$F = 7.30$
		$p = 0.0001$



4. Discussion

This pilot study examined quality of life, family conflicts and fear of injections in preadolescents and adolescents with Type 1 Diabetes (T1D) and their mothers in an Italian cohort. Results showed that 20% of patients and 14% of their mothers reported clinical scores of fear of injection and fear of self-testing of blood glucose. This result is consistent with the literature, which underlines the same percentages of fear of needles in patients with T1D [23]. Even if this fear seemed to be not so common in pediatric patients, and only a few studies analysed this aspect in pediatric patients with T1D [20], [23], [34], [35], an Italian study [26] showed that parental fear about their children's self-injection of insulin was identified as a key element impacting on externalising/internalising symptoms and on worries about the illness.

Compared to other studies on this topic [21], our results did not show an association between HbA1c and needle phobia.

It might be useful in future researches to compare scores of needle phobia with the novel glycemic metrics derived from the use of Continuous or Fast Glucose Monitoring (CGM or FGM) systems [36]: TIR ("time in range": the time the patient spends in the optimal glycemic interval of 70-180 mg/dl), TAR ("time above range" of 180 mg/dl) and TBR ("time below range" of 70 mg/dl). These core metrics can express better than HbA1C glycemic variability, acute excursion of glucose change and severity of hypo and hyperglycemia, all clinical situations that could require a more intensive self monitoring of blood glycemia or insulin self administration, which might instead be voluntarily omitted due to the level of needle phobia.

Mothers and patients highlighted significant differences in fear of injection and family conflicts scores: patients reported significantly lower levels regarding these two dimensions compared with their mothers. Previous research reported higher level of family conflict in pediatric patients than in parents [37], [38]. Only one study reported not significant discrepancies in this dimension between young adults and parents [39]. This result showed differences in perceptions. Probably mothers seemed to perceive lower ability in their sons/daughters to self-inject and self-test, and the strength needed to maintain the daily balance was so great that they perceived more conflict relationship with their sons/daughters.

As observed in previous research, risk factors for a lower quality of life in T1D pediatric patients are the following: the older age associated with higher quality of life perceptions also in not-clinical population [29], the higher presence of needle fear very common in patients with T1D [19] and family conflicts, with the important role of family interactions and communication [31].

The major limitations of the present study are its cross-sectional nature, the small sample size, the exclusion of fathers and the single centre study. More studies on a larger scale including fathers are needed to address these limitations.

Despite these limitations, a number of clinical implications from this study that can improve clinical practice and guide future research could be suggested.

Fear of injection both in patients and in mothers confirms the close association between this psychological/behavioral aspect and the nature of Type 1 Diabetes treatment [40]. Therefore, preventive care and tailored psychological interventions are required to improve mental health and prevent long term complications of T1D both in young patients and in their mothers [21]. Research shows evidence to support the efficacy of hypnosis and distraction in reducing needle fear [41], [42]. Moreover literature shows that relaxation technique, such as muscular relaxation, guided imagery and deep breathing could be useful in mild needle fear [43]. Exposure based therapy, both in vivo and non-in vivo, is recommended for individuals with high levels of needle fear, if older than 7 years of age [44]. In order to plan a needle phobia intervention it is important to take into account relevant family factors and possible past traumatic events [43].

Additional research is needed to identify effective psychological interventions regarding needle phobia and fear of injection in the pediatric population with Type 1 Diabetes.

Our findings highlight discrepancies in perceptions of family conflicts and of quality of life between patients and mothers and, in particular, between preadolescents and adolescents, suggesting that it could be useful to adopt screening tools to investigate family functioning, poor glycemic outcome and psychological disease during risk periods, such as adolescence. Motivational interview could be useful facing high levels of conflict and low glycemic control [45]. Psychological intervention focused on family communication might be beneficial to motivate parents to communicate in a non-judgemental way with their sons [46] and to promote family cohesion and preserve youths' overall quality of life [15]. Moreover, it is important to take into account the parental distress of mothers facing diabetes management during the transitional period of adolescence. In fact, adolescent mental health seems to be connected with family climate cross time [47].

In conclusion, the promotion of psychological well-being of pediatric patients with type 1 diabetes requires a close cooperation between different sources of care, such as diabetologist, dietician, psychologist and the family context [12].

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