

Type 2 diabetes mellitus and its effect on quality of life in adolescents: A retrospective cohort study in Saudi Arabia

Cukrzyca typu 2 i jej wpływ na jakość życia nastolatków: badanie retrospektywne w Arabii Saudyjskiej

Sireen Shilbayeh

Department of Pharmaceutical Practice, College of Pharmacy, Princess Nourah bint Abdulrahman University (PNU), Riyadh, Saudi Arabia

Abstract

Introduction: Quality of life (QoL) in adolescent patients suffering from type 2 diabetes mellitus (T2DM) has not been thoroughly explored in Saudi Arabia. Herein, we aimed to measure the health-related quality of life (HRQoL) in adolescent patients suffering from T2DM and explore the correlation between adolescents' self- and parent-reporting of QoL scores, and glycaemic control (HbA_{1c}).

Material and methods: A retrospective multi-centre cohort study was conducted at 4 hospitals in Riyadh, Saudi Arabia. The Paediatric Quality of Life Inventory (PedsQLTM) Diabetes Module 3.0 was completed by children and their parents in a confidential and anonymous manner through a phone interview.

Results: We recruited 49 paediatric patients for this study (mean age: 18.45 years; male: 55%). Both children and parents reported low cumulative mean scores for PedsQL™ (58.65 and 57.38, respectively) as compared to previous international studies. The lowest obtained score was noted for the diabetes symptoms domain (53.4). Comparing the magnitude of discrepancy between the adolescents' and parents' subscale scores revealed a non-significant difference, except for the 'worry' subscale, in which parents reported significantly higher mean scores (76.73 vs. 60.54, $p = 0.02$).

Comparison of mean scores reported by adolescents who met the target HbA_{1c} goal (<7%) and their counterparts revealed a non-significant difference, suggesting an irrelevant impact of this parameter on their perspectives or experiences.

Conclusions: The study findings emphasized the need to initiate further intensive awareness programs concerning this disease and its clinical implications in T2DM children to improve treatment adherence and symptoms, and consequently improve the perception of the patient and the family for HRQoL.

Key words:

adolescents, type 2 diabetes, health-related quality of life, Saudi Arabia, glycaemic control.

Introduction

The International Diabetes Federation (IDF) has classified diabetes as a global epidemic disease. Available data showed nearly 463 million people living with diabetes in the year 2019, which could increase to 700 million by the year 2045 [1].

With the increasing number of cases, the rate of diabetes in Saudi Arabia has been ranked second among middle-eastern countries and seventh in the world by the World Health Organisation (WHO) [2]. Earlier, type 1 diabetes (T1DM) was predominant among youths [3]. In the current scenario, type 2 diabetes mellitus (T2DM) in childhood has become a global public health issue leading to critical health outcomes due to increased levels of physical inactivity and obesity among children and adolescents [4, 5]. T2DM is a non-insulin-dependent type

of diabetes and is characterized by insulin resistance where the body is unable to use insulin properly or there is a relative insulin deficiency [6, 7]. According to the SAUDI-DM study, a population-based study done among children and adolescents in Saudi Arabia, newly identified cases of DM amounted to 4.24% along with 0.45% known cases of diabetes, of which 0.07% were known to have T2DM [3].

Because diabetes is a chronic disease it adversely affects the health of patients and their quality of life (QoL) in particular⁸. According to the WHO, "health is a state of complete physical, mental, and social well-being and not merely the absence of disease" [9]. Healthy lifestyle and habits, and the physical activity of the entire family need to be taken into consideration with the treatment approaches for adolescents with T2DM [10]. It has been shown that promoting QoL along with well-being of

diabetic children holds similar importance as controlling the disease metabolically for prevention of secondary morbidity [11]. This suggests that assessment of overall health-related quality of life (HRQoL) is important in the case of diabetic adolescents and is directly or indirectly related with the chronic illness and its management [12, 13]. Moreover, regular measurement of HRQoL outcomes has been proposed as an important aspect for improvement of health [14].

The Paediatric Quality of Life Inventory (PedsQL™) has been used as a marker of HRQoL for the assessment of perspective of both adolescent patients and their parents for youths' HRQoL in health research [15, 16]. On the national level, few studies were concerned with the assessment of HRQoL in adults [17, 18] or adolescents [13, 19] with T1DM only. To expand the knowledge about HRQoL among children and/or adolescents with T2DM in Saudi Arabia, this study was conducted for the evaluation of HRQoL and further exploration of the possible differences between the patient and the parents' perspectives using the PedsQL™ scale Diabetes 3.0 questionnaire for the young population of T2DM patients. In addition, the correlation between PedsQL scores and glycaemic control, which was measured by glycated haemoglobin (HbA_{1c}), was also established.

Material and methods

Study design and settings

A multi-centric, cross sectional cohort study was carried out during the period of 18/11/2018 to 25/4/2019. It was performed in 4 of the largest hospitals in Riyadh-Saudi Arabia: King Salman Hospital (KSH), King Fahad Medical City (KFMC), Prince Sultan Military Medical (PSMM) City, and the National Guard Hospital (NGH).

Population sample

Patients were recruited based on following inclusion criteria: Saudi paediatric/adolescents aged 19 years or younger and diagnosed with T2DM (according to the American Diabetes Association (ADA) 2020) [20]. Patients were excluded if they met any of these criteria: older than 19 years, diagnosed with T1DM, and off-label use of metformin. Initially, 400 paediatric patients were screened in KSH, KFMC, PSMMC, and NGH during a 9-month period, of whom 113 met the inclusion criteria. However, 64 patients were further excluded due to lack of required data: unavailable contact number ($n = 13$), no response ($n = 11$), refusal to respond ($n = 6$), unavailability/incompleteness of laboratory results ($n = 33$), or death ($n = 1$).

In total, 49 patients meeting the inclusion criteria agreed to participate in the study. Participants' socio-demographic and clinical data were extracted from their electronic records and paper files available in each setting. Confidentiality of the patients' records was maintained throughout the study by data documentation in an anonymous fashion, and the subjects were identified by a subject number and by their initials if required. Thereafter, a questionnaire concerning the QoL of the patients and their parents was administered through a phone interview.

Data collection

Initially, clinical information about the disease such as classical symptoms of diabetes, age at the time of diagnosis, family history of diabetes/obesity, relevant co-morbidities, and type of hypoglycaemic medications used, was retrieved from the patients' electronic medical records, using the patients' file numbers in the hospitals' systems. Continuous data concerning the progress of T2DM such as weight, height, calculated percentile of age and sex, thyroid hormone tests, vitamin D, insulin serum, and HbA_{1c} levels, which were recorded prior to the initiation of medication therapy and at the last clinic visit, were extracted from the hospitals' laboratory archives. Patients' compliance to medication and healthy lifestyle was verified from their health-care providers and as reported in their records. Afterwards, patients were contacted by phone to answer the HRQoL questionnaire; both the self- and parent-reports were conducted independently and in a confidential manner.

Measure

To measure HRQoL, the PedsQL™ Diabetes Module 3.0 questionnaire, comprising the T2DM paediatric population module and a parent module, were employed. This tool was specifically designed to assess the HRQoL of children with diabetes [14, 16].

Translation of the 2 parts of this instrument was done previously in Arabic and showed good reliability, good internal consistency, and constant validity [19, 21]. The Arabic version was provided by the Mapi Research Trust (<https://eprovide.mapi-trust.org>). Both instruments are multidimensional, including 28 items divided into 5 subdomains as follows: 1 – diabetic symptoms (11 items), 2 – treatment barriers (4 items), 3 – treatment adherence (7 items), 4 – worry (3 items), and 5 – communication (3 items).

The extent of a problem represented by each item during the last month was investigated by the instructions. Each item was scored on a 5-point Likert scale, from 0 = never a problem to 4 = always a problem. Higher patient scores reflect higher HRQoL. The responses of the questionnaire were filled in via a phone interview with the patients and their families. The phone interview was conducted first by obtaining approval from the hospital to get the contact numbers from the patients' files and then calling them in a professional manner.

A similar scoring algorithm was used for both the instruments; it reversed the 0–4 scale scores and linearly transformed them on a 0–100 scale so that 0 = 100 and 4 = 0. The scoring transformation means that the higher the score, the better the QoL of the patients.

Instrument validation

The reliability of the PedsQL™ Diabetes Module 3.0 questionnaire was examined in this study by using Cronbach's α test. The reliability of the children's and parents' questionnaire responses was 0.863 and 0.879, respectively. Both values are considered excellent in terms of reliability standards (which is greater than 0.8).

Data analyses

The distribution of the study variables and outcomes were tested for normality with the Kolmogorov-Smirnov test. Descriptive statistics were computed for the patients' characteristics. Categorical variables were recorded as count and percentage, and mean and standard deviation were used to summarize continuous variables. Comparison of patient's and

parents' reports for the PedsQL 3.0 Module was analysed using a 2-sample *t*-test. We used a correlation test to measure the degree of association between the instrument's subscales and the HbA_{1c} level. Furthermore, the possible impact of demographic or clinical characteristics on the mean difference in the patients' and their parents' responses to PedsQL™ were examined using one-way analysis of variance with Tukey's post hoc test for categorical variables or Pearson's correlation test for continuous variables. Determination of significant predictors of the QoL scores for each domain and overall score was analysed using multiple regression, and significant predictors of glycaemic control were determined using logistic regression analysis. SPSS software version 25 (SPSS Inc. Chicago, Illinois, USA) was used for all the statistical analysis, and *p* < 0.05 was considered as statistically significant.

Table I. Demographic characteristics and comorbidities

		N	Percentage (%)
Gender	Male	22	44.9
	Female	27	55.1
Hospitals	KFMC	18	36.7
	KSH	8	16.3
	NGHA	9	18.4
	PSMMC	14	28.6
Obesity		38	77.6
Family history of T2DM		42	85.7
Family history of obesity		20	40.8
History of gestational diabetes		18	36.7
History of dyslipidaemia		6	12.2
Compliance to medications		33	67.3
Compliance to healthy lifestyle	Poor diet and no exercise	26	53.1
	Controlled Diet and Exercise	20	40.8
Hypothyroidism		9	18.4
Vitamin D deficiency		25	51
Classical symptoms of DM		23	46.9
Bariatric surgery		7	14.3
Acanthosis nigricans		19	38.8

KFMC – King Fahad Medical City, PSMMC – Prince Sultan Military Medical City, NGHA – National Guard Health Affairs, KSH – King Salman Hospital.

Results

Demographics and comorbidities

The study included 49 subjects with T2DM. Gender distribution was 27 (55.1%) males vs. 22 (44.9%) females. The mean current age of adolescents was 18.45 ± 6.45 years, and the mean age at the time of diagnosis with T2DM was 13.90 ± 5 years. The majority of the recruited patients had a family history of T2DM (*n* = 42, 85.7%). Based on the calculated body mass index (BMI), 38 (77.6%) participants were obese. Most of the participants were compliant with their medications (*n* = 33, 67.3%), and 23 (46.9%) of the participants had classical symptoms of DM, such as polydipsia, polyphagia, and polyuria. *Acanthosis nigricans* was documented in 38.8% of the youth subjects. Only 9 patients (18.4%) had hypothyroidism, and nearly half of the patients (*n* = 25, 51%) had vitamin D deficiency. All the considered criteria are listed in Table I.

Glycaemic control

For glycaemic control and other clinical parameters, 2 readings for each patient were considered in the analysis: the baseline initial measurement (prior treatment) and the most recent clinic visit measurement. Most of the patients had class 1 obesity, and no differences were noted between the mean initial BMI (33) and the mean most recent BMI (34.67). The mean baseline HbA_{1c} value was 9.40% (79.2 mmol/mol), while the last corresponding clinic visit value was 9% (74.9 mmol/mol), indicating poor glycaemic control. As mentioned earlier, 18.4% of the recruited patients had hypothyroidism with a slight increase in the initial thyroid stimulating hormone (TSH) level (5.76) and normal free thyroxine hormone (FT4).

As shown in Table II, calculating the mean difference between related variables (including weight, height, BMI, percentile of age and sex, HbA_{1c}, insulin serum, TSH, FT4, and vitamin D) using the T-test for paired data revealed non-significant changes in all these parameters during the observed treatment period.

Pattern of antihyperglycemic therapy

The main treatment modality of T2DM used in our patients was metformin (93.9%) for an average duration of 49.5 months,

Table II. Clinical changes

Measures	Mean Diff.	SE	95% Lower CI	95% Upper CI	P-value
Height (cm)	4.9	5.83	-7.34	17.14	0.411
Weight (kg)	-0.596	7.28	-15.61	14.42	0.935
BMI (kg/m ²)	0	0.171	-0.364	0.364	1
Percentile of age and sex	1.44	2.46	-0.443	3.332	0.116
HbA _{1c} (%)	0.5	0.41	-0.324	1.323	0.228
Insulin (mIU/l)	800.32	607.42	-855.91	2517.03	0.243
TSH (mIU/l)	1.41	1.06	-0.809	3.642	0.198
FT4 (pmol/l)	-0.342	1.129	-2.723	2.038	0.765
Vitamin D (nmol/l)	-6.25	4.02	-14.73	2.228	0.138

Table III. Comparison of patients' and parents' reports for the PedsQL 3.0 module

	Patient	Parent	Mean Difference	95% Lower CI	95% Upper CI	P-value
Total scores	58.65	57.38	1.26	6.36	8.88	0.74
Diabetic symptoms	53.40	52.37	1.03	8.75	10.81	0.84
Treatment barriers	67.13	61.69	5.44	5.20	16.09	0.31
Treatment adherence	55.68	56.61	0.94	11.69	9.82	0.86
Worry	60.54	76.73	16.19	29.41	2.98	0.02
Communication	72.28	59.92	12.36	2.48	27.21	0.10

with a starting dose of 1000 mg/day and titrated up to 1500 mg/day (Table IA). Some patients were taking additional treatment with insulin or other oral hypoglycaemic drugs (Table IIA), with DPP-4 inhibitor being the most prescribed class of oral hypoglycaemic drug (16.3%) (Table IIIA). Additionally, 55.1% of patients were taking non-oral hypoglycaemic drugs and 46.9% were taking vitamin D supplements (Table IVA).

Corresponding HbA_{1c} levels before and after management for each treatment group are displayed in Table IV.

Adolescents' health-related quality of life

Mean scores of the PedsQL 3.0 (total/subscales) of all the recruited adolescents with T2DM and their parents are presented in Table III. The mean difference between the responses of patients and their parents are summarized for the total score as well as all the sub-domains. Consistently comparable scores were reported by both the parents and the children for most of the subdomains (p -value > 0.05). The lowest obtained scores for both children and their parents were noted for the "diabetes symptoms" domain (53.4 vs. 52.37, respectively).

However, there was significant differences between teenagers' and parents' reports for the worry subdomain, wherein the HRQoL score provided by parents was significantly higher (76.73 vs. 60.54, $p = 0.02$). This result reflects that both parents and children have different opinions about worry sense. Further scrutinization of the magnitude of discrepancy between adolescents' and parents' subscale scores revealed that parents expressed less satisfaction according to their HRQoL responses in 3 subdomains (diabetic symptoms, treatment barriers, communication). In contrast, parent expressed higher scores for "treatment adherence". However, all comparisons were deemed statistically nonsignificant except for worry ($p = 0.02$).

The results of multiple regression analysis for patients' total PedsQL 3.0 scores based on their demographic and clinical measures are displayed in Table IV. The value of the coefficient of determination for this model was 0.838, which indicated that 83.8% of the variability in patients' scores pertained to their included (fitted) variables (age, obesity, classical symptoms of DM, family history of obesity, compliance to medications,

Table IV. Regression analysis of children's scores

Model	Coefficients	SE	P-value
(Constant)	99.36177	129.4093	0.58314
Age	3.240372	5.033982	0.635896
Obesity	54.63731	56.85378	0.512655
Classical symptoms of DM	95.791	134.1409	0.605212
Family history of obesity	263.102	295.9253	0.537337
Compliance to medications	33.80925	37.38981	0.531988
History of gestational diabetes	90.12763	125.8627	0.604382
Vitamin D most recent	0.83093	0.930615	0.535989
Family history of T2DM	42.47605	40.00574	0.480939
Daily frequency of insulin - if the patient is not on insulin 0	12.95877	17.80965	0.599549
Vitamin D deficiency	90.66341	87.43484	0.488461

Table V. Correlations between patients' responses and their HbA_{1c} levels

	Diabetic symptoms	Treatment barriers	Treatment adherence	Worry	Communication	Total scores
Treatment barriers	0.16 (0.27)					
Treatment adherence	0.16 (0.26)	0.40* (0.00)				
Worry	0.46* (0.00)	0.19 (0.19)	0.20 (0.17)			
Communication	0.23 (0.11)	0.43 (0.00)	0.34* (0.02)	0.18 (0.23)		
Total scores	0.76* (0.00)	0.57* (0.00)	0.64* (0.00)	0.59* (0.00)	0.60* (0.00)	
HbA _{1c}	0.17 (0.26)	-0.02 (0.91)	0.06 (0.67)	-0.17 (0.26)	0.05 (0.73)	0.09 (0.55)

(Note: *p*-values are in brackets, and the numbers above them are *r* correlation coefficients) *Stars indicate significant correlations.

history of gestational diabetes, and vitamin D deficiency), while 15.2% of the inconstancy might be ascribed to other unknown factors. The negative coefficient values of some variables like classical symptoms of DM revealed that increased symptoms

of DM may result in lower HRQoL scores. However, none of the variables were statistically significant predictors of the patients' total PedsQL 3.0 score, considering a cut-off *p*-value of > 0.05.

Table VI. HbA_{1c} goal sub-categories for children and their parents

	Goals achieved (HbA _{1c} ≤ 7%)	Not achieved (HbA _{1c} ≥ 7%)	Mean Difference	95% Lower CI	95% Upper CI	P-value
Children	59.66	58.75	0.9015	-11.75	13.55	0.886
Parents	57.16	56.53	0.6247	-14.65	15.9	0.935

The impact of glycaemic control on quality of life

Correlation (*r* values) between the children’s subscale scores and HbA_{1c} levels (last visit) are presented in Table V. The results suggested significant positive correlation between “diabetic symptoms” scores reported by the diabetic paediatrics and their “worries” (*r* = 0.46), which indicated a possible linear association (i.e. an increase in diabetic symptoms leads to an increased level of worrying among patients). Both “treatment adherence” and “treatment barriers” scores were also found to be positively associated (*r* = 0.40). Interestingly, there was a significant positive association between HRQoL scores in the “communication” and “treatment adherence” subscales (*r* = 0.34). However, no significant association was noted between HbA_{1c} level and any of the patients’ subdomain scores.

The distribution of patient and their parent scores according to the HbA_{1c} subcategory (goal achieved or not) are displayed in Table VI. The independent, 2-sample t-test suggested no influence of HbA_{1c} goal status on either parents’ or children’s HRQoL responses in this cohort.

Discussion

Diabetes as a chronic disease can adversely affect the health of patients in general, and their QoL in particular [10, 12]. In the past, T1DM was the dominant diabetic type among youths; however, for the past 20 years T2DM has become more common in adolescents and children [3, 22]. Obesity is the main risk factor for T2DM, and it has been shown by many studies that the prevalence of increasing obesity is parallel to T2DM [1, 2, 23, 20].

Living with diabetes is challenging, especially for adolescents because the management of the disease does not only impact the patients but also their families. It includes medication adherence, dietary restrictions, regular exercise, monitoring of blood glucose, and self-care [3, 21, 24]. In fact, because not only the individual but also the parents are affected, and because they play an important role in diabetes management, it could be considered as a family disease [25].

Physical, psychological, and social health domains of an individual, which are affected by his/her beliefs, experiences, perceptions, and expectations, cumulatively refer to HRQoL [26–28]. It is important for health care providers to understand the impact of all the above-mentioned aspects of diabetes [27]. It is an important health endpoint to assess subjective well-being in domains directly and/or indirectly related to a chronic

illness and its management [12, 26–29]. HRQoL has been reported to be lowest for adolescents, thereby significantly increasing the risk of depression [30–32]. Therefore, the importance of QoL and its associations with diabetes management and control in the paediatric population has gained increasing attention [29–31].

Parental reporting of HRQoL could provide more information in the context of psychological components of HRQoL among adolescents [26, 27, 34]. Various studies have demonstrated that self-care by the individual with less involvement of parents could result in poor management of self-care, and poorly controlled diabetes is further associated with poor QoL [34, 35].

PedsQL is a standard and well-established scale for the measurement of HRQoL both in healthy children and adolescents as well as those suffering from acute or chronic health conditions [16]. Both generic (PedsQL 4.0 Generic Core Scales) and disease-specific (PedsQL 3.0 Diabetes Module Scales) modules are integrated perfectly into one measurement system in the PedsQL measurement model [14–16]. Many studies used the PedsQL 3.0 module, but mostly for T1DM patients, in various countries around the world such as Kuwait [36], Iran [37], Greece [38], Sweden [39], Italy [9], the United States (US) [12–16], and Hungary [40]. However, its implication with regard to children and adolescents with T2DM is less explored [12, 14–16]. In fact, very few studies worldwide have addressed QoL, the family’s role in anti-diabetes management, and its impact on glycaemic control and other health outcomes in children with T2DM [29, 41–44]. The estimated diabetic-specific QoL in T1DM children around the world was in the range 59.2 (Iranian children) [37] to 74.7 (American children) [15], while in the case of T2DM youths it was in the range 70.7 [12] to 71.5 [15].

In the context of paediatric Saudi healthcare, there have been 2 studies carried out in Saudi Arabia to assess the QoL in T1DM patients in parallel with glycaemic control and other clinical parameters^{13,19}. The diabetic-specific QoL in those 2 studies was reported to be lower than most of the other countries (range: 56.4–64.8). Only one of these studies involved application of the PedsQL parent module to assess their perspectives regarding the status of T1DM children.

However, recognizing the escalating incidence of T2DM in our paediatric population, and taking into consideration the value of treating all the patient domains including QoL, this study was conducted to gain some insight about diabetic-specific QoL from the prospective of our T2DM children and their parents using the PedsQL™ scale Diabetes 3.0 questionnaire.

The reliability and validity of the Arabic version of the PedsQL 3.0 Diabetes Module instrument in children with T2DM in Saudi Arabia was confirmed by the values of the Cronbach alpha coefficient calculated for both patients' reports (0.863) and for parents' reports (0.879). These results corroborated with earlier Arabic studies in T1DM [13, 19, 36].

Initially, in this study, the inspection of baseline and current patients' demographics revealed high prevalence of obesity (77.6%) and family history of T2DM (85.7%) among this cohort. Consistent with classical characteristics of T2DM [10, 20, 23], the included youths were generally found to be overweight, obese, had a BMI \geq 85th percentile, sedentary (poor diet and no exercise), and were frequently found to have acanthosis nigricans. In addition, most of the included children (60%) had poor glycaemic control (HbA_{1c} > 8), a feature which was less commonly observed in earlier research in T2DM [12, 15, 16] or even T1DM children [12, 15, 16, 36, 37].

Comparison of QoL scores to other studies

Consistent with most of the previous QoL comparison studies (T1DM vs. T2DM) [12, 29, 42], the children with T2DM in our study had significantly lower HRQoL than T1DM children for the total scales and subscales of PedsQL 3.0 DM. In fact, the Saudi children in this study reported the lowest score in total, diabetic symptoms, and treatment adherence subdomains among all the reviewed countries. Some previous studies [15, 16] attributed these results to the variabilities in the ethnic and socioeconomic differences between children with T1DM and T2DM. Lower socioeconomic status in ethnic minorities could lead to escalation of the obesity index, which is a significant risk factor associated with higher incidence of T2DM [23]. Interestingly, the scores of T2DM Saudi children in this study, particularly with regard to the treatment barriers, worry, and communication domains, were either comparable [38, 39] to or even higher [37, 38] than corresponding scores reported by their counterparts (T1DM) in some other countries (Iranian and Greek) and in other previous Saudi T1DM cohorts [13, 19].

This study, recruiting Saudi children with T2DM, showed significantly lower HRQoL than that in children with T2DM in a previous US study [12] for the total scales and all subscales of PedsQL 3.0 DM. A possible reason for this observed lower rate of QoL among our Saudi children is the relatively high proportion (59.2%) of insulin treatment in management (alone, or in combination with metformin and/or other oral hypoglycaemics). Previous research studies have pointed out more painful suffering and depression associated with insulin use among T1DM adults [18, 45] and children [13] compared to those receiving oral hypoglycaemic medications or diet and exercise only. Our result is consistent with earlier reports suggesting that insulin management enhanced the perception of disease burden [46]. Another possible reason for the observed lower scores in our cohort could be attributed to less healthy lifestyle, including diet and physical activity. However, we did not measure these parameters objectively in this cohort and they were not among the focus endpoints in this report.

In this study, we found a significant correlation between the diabetes symptoms and worry subscales, thus confirming earlier findings that indicated distinctive anxiety, depression, and worry to be associated with both types of diabetes [39, 40]. This result may also provide an indirect explanation for the lower observed scores in these domains and in total PedsQL compared to T2DM children in the US study [12].

HRQoL and HbA_{1c}

To prevent long-term complications associated with diabetes mellitus, medical practitioners were previously more focused on clinical parameters like HbA_{1c}. With the increased focus and studies on the role of QoL in diabetes management, medical practices have started paying attention to this aspect as well [29–31]. Earlier research findings have shown mixed results regarding the association between HRQoL and HbA_{1c} level. A few studies have shown small to moderate but significant negative correlations between HbA_{1c} and self-reporting of child and proxy-reporting scales of parents for total scales or some subscales (treatment barriers and treatment adherence) [12, 13, 15, 14, 29, 38, 36, 40, 42]. Conversely, many other studies did not find any significant correlation between HbA_{1c} and PedsQL self-reporting of child and parents proxy-reporting scales both in the case of T1DM or T2DM [14–16].

However, studies conducted in various countries including adult populations have shown a significant impact of clinically relevant diabetic complications on QoL [18, 45].

Additionally, a direct relationship has been established between long-term complications, specifically microvascular disease and poor glycaemic index [45]. Therefore, the long-term complications could serve as a better marker for poor QoL.

The present study did not show any significant linear correlation of HbA_{1c} with children's self-reporting or their parent's proxy-reporting scores in the total or any of the diabetic-specific subdomains. In addition, a comparison of mean scores reported by the 2 cohort subgroups of adolescents based on their achievement of the target HbA_{1c} goal (< 7%) revealed non-significant differences in both child classes and their counterparts in QoL estimations. This suggested an irrelevant impact of this parameter on their perspectives or experiences. In line with the observation of a US study [15], the similarity in the child and parent reports in our study based on the HbA_{1c} optimum target indicated that further awareness is mandatory to improve education about T2DM in Saudi Arabia. This is especially needed for parents, so they can deliver the best care to their children. However, this result might also have revealed the fact postulated in earlier literature [16, 47], which highlighted the individual significance of each outcome (QoL and HbA_{1c}) as a separate entity to target the global T2DM child health progress.

The impact of demographic factors on PedsQL scores

Based on the demographic factors of the patients, it has been indicated by various studies that adolescents within the age range 13–18 years have the lowest HRQoL specific to diabetes as compared to low age-group children, i.e. 5–7 years and 8–12 years of age. This difference is due to their longer

term of suffering with this chronic condition [9, 13, 19, 39, 40]. This could explain the poor QoL scores obtained in this cohort, because the majority of the recruited patients were in the upper range category (range: 12–20 years old). In contrast, some studies displayed improvement in the HRQoL report with increasing age, attributing it to enhanced ability to manage their therapy [29, 36]. Some other researchers did not find T2DM adolescent PedsQL scores to be associated with age [37, 44].

In terms of gender differences, the present study findings were consistent with earlier studies in T1DM and T2DM [13, 19, 29, 36, 38, 40, 43]. Gender differences were noted in this study, with T2DM females scoring significantly lower on the total PedQL (53.3 vs. 63.5, $p = 0.039$), treatment barriers (57.3 vs. 75.3, $p = 0.014$), and communication subscales (61.3625 vs. 81.8, $p = 0.043$). However, no further differences were noted regarding other subdomains. Also, parents did not show any differences (expressed similarity) in the context of the gender of their children.

PedsQL parent reports

Initially, as expected, in this study we observed a tendency for higher HRQoL scores among children in total and other PedsQL subdomains, except for the treatment adherence and worry. However, the discrepancy was only statistically significant for the worry construct, in which parents demonstrated greater confidence in this domain as compared to their children, “which means that teens were worried more about their diabetes than their parents”. A possible explanation for these discrepant reports could not be resolved in this cohort. Interestingly, similar discrepant statements in the worry domain were noted in a large-scale US multicentre observational study of youths diagnosed with T2DM (69.1 vs. 74.0 for children and parents, respectively) [12].

Much less parental contribution and responsibilities such as adjustment of multiple insulin doses and intense monitoring of blood sugar levels, at home in the case of T2DM children as compared to T1DM, was suggested to be a possible reason for this finding.

In contrast, studies from Sweden [39], Kuwait [36], and Saudi [19] revealed significantly lower parent scores in regard to both worry and treatment adherence domains in comparison to their children diagnosed with T1DM.

However, our findings concerning other disease-specific HRQoL subdomains (diabetic symptoms, treatment barriers, and communication) were consistent with those of earlier global research studies. Similarly to our data, studies have shown higher generic and diabetes PedsQL module scores of children with T1DM and T2DM, particularly in those older than 8 years of age, as compared to parent proxy scores [12–16, 19, 29, 36–40].

Furthermore, a previous validation study of the original version of PedsQL 3.0 mentioned that the inconsistency that can be perceived in the parent/child-report in research studies emphasizes the need for measuring the child’s and parent’s perspective for the evaluation of paediatric HRQoL [16]. In the case of younger children, the proxy report of parents holds great value because these children might be incompetent or

reluctant to complete the HRQoL measure. It could also be of importance when self-report scale of an immature child is not up to reliable standards. This fact was demonstrated in a previous US study [15], in which children within the age range 5–7 years suffering from T1DM rated their generic and diabetes PedsQL scores significantly lower than their parents’ proxy scores. However, in this study, due to the lower variability in the included age range, we did not examine the effect of the age factor on the observed discrepancy; therefore, it remains an issue for our future research.

Strengths and limitations of the study

The main strength of this study is the diversity of T2DM patients’ recruitment from 4 different main medical centres of Saudi Arabia. Additionally, being the first pilot attempt to evaluate the disease-specific HRQoL in Saudi T2DM children and adolescents based on self-reporting together with their parents’ proxy-reports, using internationally validated tools, also provided strength to this study by allowing cross-cultural comparisons. Added to this, the high Cronbach α values obtained in this cohort for both the patient and the parent scales (greater than 0.8) further supported the excellent reliability of the current findings.

However, this study has some limitations. First is the small sample size, which is primarily due to the relatively recent recognition of this chronic illness in our Saudi paediatric population, where some of them could have been misdiagnosed or falsely diagnosed with T1DM. This might have partly contributed to the smaller number of children in this study to examine the definite impact of sociodemographic factors on the self-reported QoL outcome. Second, social desirability bias could also have impacted the self-reported survey administered through telephone calls. Later studies should be planned to undertake a similar survey among children together with their caregivers during routine clinic visits, to gain more data that were missed in this report. Third, the retrospective cross-sectional nature of data collection in this study could have limited the prevalence of certain demographics and the definition of certain clinical variables influencing the children and parents for QoL, such as healthy lifestyles (only self-reported; not objectively measured). Also, cross-sectional studies will only provide an association, with no establishment of a definite causal relationship. Further Saudi studies are required to address factors underlying the poor glycaemic control in T2DM Saudi children and other factors predictive of poor or good QoL compared to T1DM. Additionally, prospective studies to evaluate long-term complications of T2DM in this young population of children should be more intensively examined in future research. Collectively, all these targets will identify precedence questions that will guide the development and implementation of new national strategies to promote the health of children with T2DM in Saudi Arabia.

Conclusions

In conclusion, the study findings revealed less than optimum scores for HRQoL for both T2DM children and their parents, as compared to previous studies in T1DM within Saudi

Arabia or in both types from other countries. In addition, the significant discrepancy in children's and parents' reports of worry reflects unsatisfactory parenteral knowledge of long-term T2DM complications and/or less involvement in their management monitoring. Collectively, these initial findings emphasize the importance of initiating further intensive awareness programs and health education plans regarding T2DM illness

and concerning the importance of short- and long-term clinical implications to improve treatment adherence, symptoms, and consequently enhance simultaneous improvements in our youths' self and family perceptions of HRQoL outcome. This would lead to better clinical outcomes in the treatment and consequent management of HbA_{1c} and avoid complications like depression.

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