

Quality of Life Assessment in Children and Adolescents with type 1 Diabetes Mellitus

Maíra Yamaguchi¹, Taísa Yamaguchi¹, Giovani Bruno Bioni², Fernanda Secchi de Lima³, João Paulo Silva Leite⁴, Fabiano Sandrini⁵, Gleice Fernanda Pinto Gabriel⁶, Marcos Antonio da Silva Cristovam⁶

¹Undergraduate Western Paraná State University, School of Medicine, Cascavel-PR, Brazil

²Pediatric Resident Physician, 2nd year, Hospital da Criança Santo Antônio, ISCMPA, Porto Alegre, RS, Brazil.

³Pediatrics Resident Physician, 3rd year, Western Paraná State University, Cascavel, PR, Brazil

⁴Assistant Professor of Pediatrics, Western Paraná State University, School of Medicine, Cascavel, PR, Brazil

⁵Ph. D. Assistant Professor of Pediatrics, Western Paraná State University, School of Medicine, Cascavel, PR, Brazil

⁶M. D. Assistant Professor of Pediatrics, Western Paraná State University, School of Medicine, Cascavel, PR, Brazil

Abstract:

Background: Type 1 Diabetes Mellitus (DM1) is a multifactorial metabolic disorder and one of the most common chronic illnesses in childhood. Keeping normal growth, development and emotional maturity are among the objectives of DM1 treatment. Thereby, the knowledge about health-related quality of life (HRQoL) becomes important. The purpose of this study was to apply the Pediatric Quality of Life Inventory™ 3.0 - Type 1 Diabetes Module (PedsQL™ 3.0 Diabetes Module) scale in children and teenagers with DM1 diagnosis, in addition to their parents or caregivers to evaluate the factors that influence the HRQoL.

Method: Cross-sectional epidemiological study, observational, carried out by the application of the PedsQL™ 3.0 Diabetes Module questionnaire to children and teenagers of both sexes, between 5 and 18 years old, diagnosed with DM1 and to their parents or caregivers, being that, the higher the score, the higher the quality of life. The data analyzed in the charts were: age, sex, body mass index (BMI), time of diagnosis, and presentation or not of diabetic ketoacidosis. The diabetes duration was divided into two groups: subjects that presented diagnosis and treatment for less than 36 months (≤ 3 years) and more than 37 months (> 3 years). Regarding the BMI, participants were classified as underweight, normal range, overweight, obese, and severe obesity.

Results: The PedsQL™ 3.0 Diabetes Module score varied from 41.07 to 80.35 (average: 61.39) on the children and teenagers report and from 21.43 to 84.82 (average: 59.74) on the parents or caregivers report. The estimated correlation between both the reports was equal to 0.79 ($p < 0.001$). There was no significant difference in the total score related to sex, age, BMI, presence or not of ketoacidosis, and duration of disease between the groups. The same happened with the scores of the subscales "diabetes symptoms" and "treatment adherence". Bigger values in the "treatment adherence" score were directly proportional to "diabetes symptoms" in the questionnaire answered by children and teenagers, with the estimated correlation equal to 0.36 ($p = 0.017$).

Conclusion: From the perspective of the children, better treatment adherence represented more HRQoL. The evaluation of life quality and its influence factors became important tools to promote health.

Key Word: diabetes mellitus insulin dependent, child, quality of life, adolescents.

Date of Submission: 04-09-2022

Date of Acceptance: 19-09-2022

I. Introduction

Type 1 Diabetes Mellitus (DM1) is a chronic metabolic disorder caused by the autoimmune or idiopathic destruction of the insulin producer beta-cells in the islets of Langerhans [1]. It has multifactorial etiology that involves genetic susceptibility and environmental factors. It is one of the most common chronic diseases in childhood and studies endorse the increase of its prevalence worldwide [2]. It is estimated that 1,211,900 of the patients below 20 years old have DM1 and that 108,200 children below 15 are diagnosed yearly all around the world [3].

DM1 treatment goals are to keep normal growth, development and emotional maturity [4]. During the routine follow-up of those patients, information about health-related quality of life (HRQoL) is important. Measuring life quality helps the objective identification of themes that raise concerns and it is an important resource in pediatric practice, once small children have difficulty expressing what they feel. Furthermore, HRQoL

analysis benefits include symptoms monitoring, disease progression and treatment, which improves communication and satisfaction of patients. Nowadays, standardized questionnaires evaluate HRQoL according to patients age and reflect children and teenagers experiences, as their parents or caregivers [5]. Several instruments were developed to analyze HRQoL and one of the examples for children with DM1 is the Pediatric Quality of Life Inventory™ 3.0 - Type 1 Diabetes Module (PedsQL™ 3.0 Diabetes Module) scale.

The objective of this study was to apply PedsOL™ 3.0 Diabetes Module to children and teenagers diagnosed with DM1 and in their parents or caregivers.

II. Method

The cross-sectional epidemiological study, observational, developed with the application of PedsOL™ 3.0 Diabetes Module questionnaire in children and teenagers of both sexes, ages between 5 and 18, diagnosed with DM1 followed up at university hospital pediatric endocrinology outpatient clinic and by two other private clinics. Demographic data analyzed on the charts were: age, sex, body mass index (BMI), time of diagnosis (disease duration) and the presentation or not of diabetic ketoacidosis.

After the written authorization through the Free and Informed Consent Form filling by those responsible or caregivers and the Free and Informed Assent Form by teenagers over 12 years old, the PedsOL™ 3.0 Diabetes Module questionnaire was applied to the participants and to their parents or caregivers, through phone calls or during the medical appointment.

The PedsOL™ 3.0 Diabetes Module questionnaire is internationally distributed by Mapi Research Trust group [6], and its Brazilian-Portuguese translated version was validated in 2017 by Ph.D. Leila Ferreira dos Santos Garcia [7]. Authorization of questionnaire use was obtained via e-mail contact. It evaluates the life quality of DM1 patients by means of self-reports (children/teenagers report) associated with answers from the perspective of parents or caregivers (parents report). Each questionnaire presents 28 questions that evidence disease-related adversities, divided in 5 groups: diabetes symptoms, treatment I (treatment barriers), treatment II (treatment adherence), worry, and communication. They are divided according to the age group in 2 to 4 years, answered by parents or caregivers; 5 to 7 years, 8 to 12, and 13 to 18. Between 5 and 7 years old, the alternatives to the items “not at all”, “sometimes a problem” and “a lot” are represented through a facial scale, composed by a smiling, neutral and sad face, to improve the understanding of the child. The questions to the parents of the children between 5 and 7 and other age groups have 5 options as alternatives (0 = never, 1 = hardly ever, 2 = sometimes, 3 = frequently and 4 = almost always). The alternatives are scored in reverse form, Likert scale, in ways that the answer 0 is equivalent to 100 points, 1 to 75, 2 to 50, 3 to 25 and 4 to 0. Thus, each of the 28 items own the possibility to score between 0 and 100 and the final score is the average of the answered items, with bigger values compatible with a better quality of life.

The duration of diabetes was divided into two groups: subjects that presented diagnosis and treatment of the disease for more than 37 months (> 3 years), to exclude the honeymoon period [8], and for less than 36 months (≤ 3 years). The BMI of the participants was calculated and they were classified in underweight, normal range, overweight, obese and severe obesity, according to the World Health Organization (WHO) growth chart for BMI of 2017.

The data were tabled in Excel software, 2021, USA. Quantitative variables were statistically described through average, median, minimum, and maximum values, and standard deviation. Qualitative variables were sorted by means of frequency and percentages. A two-class comparison was made considering Student's T test for independent samples. Three-class or more, a quantitative variable-related comparison was made through the non-parametric test of Kruskal-Wallis or the Variance Analysis with a variation source. Linear association between two quantitative variables was performed by estimating the Pearson correlation coefficient. Statistic relevance was indicated by $p < 0.05$.

This study was approved by the Western Paraná State University's Research Ethics Committee under the number 4,046,840/2020.

III. Results

Forty-three children participated in the survey, of which seven were between 5 and 7 years old, 23 between 8 and 12 years old and 13 between 13 and 18 years old. Gender-related, 23 (53.5%) were male and 20 (46.5%) were female. Regarding the BMI, two (4.6%) were classified as underweight, 22 (51.2%) were normal range, 14 (32.5%) were overweight, three (6.9%) were obese and two (4.6%) were severe obesity. Among the participants, 27 (62.8%) presented diabetic ketoacidosis (DKA). The duration of the disease was categorized in ≤ 3 years e > 3 years, being 18 (41.86%) and 25 (58.13%) of the included participants, respectively.

The PedsOL™ 3.0 Diabetes Module score ranged from 41.07 to 80.35 (average: 61.39) in the report of children and teenagers. In parents and caregivers report, it varied from 21.43 to 84.82 (average: 59.74). The estimated correlation between the two reports was equal to 0.79 ($p < 0.001$). There was no significant difference

between the groups regarding sex, age, BMI, presence or not of DKA, and duration of the disease in the total score of the questionnaires answered by children and parents (tables 1 and 2).

Table 1: PedsOL™ 3.0 Diabetes Module score correlation answered by children or teenagers and the analyzed epidemiological variables.

	n	Average	Median	Minimum	Maximum	SD**	p values*
Gender							
Male	23	59.62	62.50	41.07	73.21	10.36	0.220*
Female	20	63.44	60.27	51.78	80.36	9.57	
Age							
5 to 7 years old	7	63.26	60.71	46.42	76.78	10.15	0.791*
8 to 12 years old	23	61.61	61.60	41.07	79.46	9.24	
13 to 18 years old	13	60.03	60.71	41.07	80.36	11.94	
BMI[§]							
Underweight	2	63.84	63.84	63.39	64.28	0.63	0.424*
Normal range	22	62.90	62.50	41.07	80.36	12.18	
Overweight	14	58.99	58.48	41.07	78.57	8.55	
Obese	3	62.20	62.50	58.93	65.18	3.14	
Severe obesity	2	58.03	58.03	57.14	58.92	1.26	
Diabetic ketoacidosis							
Yes	27	60.84	60.71	41.07	79.46	10.74	0.645*
No	16	62.33	62.05	41.07	80.36	9.08	
Duration							
≤ 3 yeas	18	61.31	60.71	41.07	79.46	9.36	0.961*
> 3 years	25	61.46	61.60	41.07	80.36	10.74	

*p values below 0.05 indicates statistical relevance. **SD: standard-deviation. [§]BMI: Body Mass Index.

Table 2: PedsOL™ 3.0 Diabetes Module score correlation answered by parents or caregivers and the analyzed epidemiological variables.

	n	Average	Median	Minimum	Maximum	SD**	p values*
Gender							
Male	23	59.28	62.50	21.43	76.78	13.64	0.809*
Female	20	60.27	59.38	41.96	84.82	12.93	
Age							
5 to 7 years old	7	64.41	63.39	50.00	83.93	12.58	0.601*
8 to 12 years old	23	58.89	62.50	21.43	79.46	13.16	
13 to 18 years old	13	58.72	58.93	36.61	84.82	13.96	
BMI[§]							
Underweight	2	63.84	63.84	58.03	69.64	8.21	0.384*
Normal range	22	62.90	63.39	36.61	84.82	13.59	
Overweight	14	55.55	56.69	21.43	77.68	12.86	
Obese	3	57.44	60.71	41.96	69.64	14.13	
Severe obesity	2	53.57	53.57	43.75	63.39	13.89	
Diabetic ketoacidosis							
Yes	27	59.62	63.39	36.61	83.93	12.87	0.941*
No	16	59.93	61.16	21.43	84.82	14.07	
Duration							
≤ 3 yeas	18	60.81	63.39	21.43	79.46	13.65	0.655*
> 3 years	25	58.96	58.93	36.61	84.82	13.03	

*p values below 0.05 indicates statistical relevance. **SD: standard-deviation. [§]BMI: Body Mass Index.

In the “diabetes symptoms” domain, the obtained average was 58.82 in the questionnaire answered by the children and 57.60 in the one answered by the parents. The average in “treatment II (treatment adherence)” was 70.42 for the children and 69.51 for the parents. The groups’ scores in this domain did not have significant differences related to sex, age, BMI, and presence or not of DKA.

Table 3: Correlation between “diabetes symptoms” and “treatment II” scores in the reports answered by children and teenagers and its epidemiological variables.

	n	“Diabetes Symptoms”				SD**	p values*
		Average	Median	Minimum	Maximum		
Gender							
Male	23	57.01	59.09	27.27	77.27	12.16	0.288*
Female	20	60.91	61.36	34.09	81.81	11.41	
Age							
5 to 7 years old	7	62.98	68.18	40.90	77.27	12.97	0.564*
8 to 12 years old	23	58.59	61.36	27.27	77.27	10.79	
13 to 18 years old	13	56.99	56.81	34.09	81.81	13.39	
BMI[§]							
Underweight	2	62.50	62.50	61.36	63.63	1.61	0.697*
Normal range	22	59.91	62.50	27.27	81.81	14.59	
Overweight	14	57.30	56.81	40.90	72.72	9.10	
Obese	3	56.06	59.09	47.72	61.36	7.31	
Severe obesity	2	57.95	57.95	50.00	65.90	11.24	
Diabetic ketoacidosis							
Yes	27	57.32	59.09	27.27	77.27	11.70	0.285
No	16	61.36	63.63	40.90	81.81	12.03	
“Treatment II (adhesion)”							
Gender							
Male	23	69.87	71.43	25.00	92.86	16.85	0.810*
Female	20	71.07	64.28	50.00	100.00	15.41	
Age							
5 to 7 years old	7	64.28	64.28	50.00	78.57	12.37	0.551*
8 to 12 years old	23	71.58	71.43	25.00	100.00	16.35	
13 to 18 years old	13	71.70	75.00	35.71	100.00	17.46	
BMI[§]							
Underweight	2	73.21	73.21	57.14	89.28	22.73	0.364*
Normal range	22	72.73	73.22	35.71	100.00	16.29	
Overweight	14	67.85	67.85	25.00	96.43	16.69	
Obese	3	75.00	78.57	64.28	82.14	9.45	
Severe obesity	2	53.57	53.57	50.00	57.14	5.05	
Diabetic ketoacidosis							
Yes	27	69.18	67.86	35.71	100.00	15.38	0.512*
No	16	72.54	75.00	25.00	100.00	17.34	

*p values below 0.05 indicates statistical relevance. **SD: standard-deviation. [§]BMI: Body Mass Index.

Table 4: Correlation between “diabetes symptoms” and “treatment II” scores in the reports answered by parents or caregivers and its epidemiological variables.

"Diabetes Symptoms"							
	n	Average	Median	Minimum	Maximum	SD**	p value*
Gender							
Male	23	58.49	59.09	18.18	88.63	16.66	0.679*
Female	20	56.59	57.95	38.63	86.36	12.75	
Age							
5 to 7 years old	7	61.68	63.63	40.90	68.18	9.77	0.713*
8 to 12 years old	23	56.32	59.09	18.18	75.00	13.93	
13 to 18 years old	13	57.69	54.54	31.81	88.63	18.80	
BMI[§]							
Underweight	2	65.91	65.91	59.09	72.72	9.64	0.360*
Normal range	22	59.81	63.63	18.18	88.63	17.58	
Overweight	14	52.59	53.41	31.81	68.18	11.34	
Obese	3	62.87	59.09	56.81	72.72	8.60	
Severe obesity	2	52.27	52.27	45.45	59.09	9.64	
Diabetic ketoacidosis							
Yes	27	58.92	61.36	31.81	75.00	10.77	0.525*
No	16	55.39	52.27	18.18	88.63	20.16	

"Treatment II"							
	n	Average	Median	Minimum	Maximum	SD**	p value*
Gender							
Male	23	68.32	78.57	0.00	96.43	22.46	0.679*
Female	20	70.89	71.43	46.43	100.00	17.12	
Age							
5 to 7 years old	7	70.92	60.71	50.00	100.00	18.38	0.953*
8 to 12 years old	23	68.63	78.57	0.00	89.28	20.63	
13 to 18 years old	13	70.33	75.00	21.43	100.00	21.05	
BMI[§]							
Underweight	2	69.64	69.64	57.14	82.14	17.68	0.255*
Normal range	22	73.70	78.57	21.43	100.00	18.52	
Overweight	14	67.35	71.43	0.00	100.00	23.73	
Obese	3	60.71	57.14	46.43	78.57	16.37	
Severe obesity	2	51.79	51.79	46.43	57.14	7.57	
Diabetic ketoacidosis							
Yes	27	69.31	75.00	21.43	96.43	16.99	0.938*
No	16	69.86	78.57	0.00	100.00	24.81	

*p values below 0.05 indicates statistical relevance. **SD: standard deviation. [§]BMI: Body Mass Index.

It was found a correlation between the total score of PedsOL™ 3.0 Diabetes Module and the score of the item "symptoms of diabetes" – an estimated correlation equal to 0.72 ($p < 0.001$) in the children report and equal to 0.68 ($p < 0.001$) in both questionnaires (children and parents). Bigger scores on the item "treatment adherence" were related to bigger scores on "symptoms of diabetes" in the questionnaire answered by the subjects, with an estimated correlation of 0.36 ($p = 0.017$). However, this relation was not observed in the report answered by the parents, with an estimated correlation of 0.25 ($p = 0.107$).

IV. Discussion

The present study assessed the life quality of children and teenagers with DM1 diagnosis, regarding self-reports and evaluation by parents or caregivers. Total average score found in PedsOL™ 3.0 Diabetes Module answered by children, teenagers and parents was similar to the results of a Brazilian study [7], yet inferior to those obtained in other studies [9-12].

Although the questionnaires answered by the parents had lower scores compared to the self-reports, there was an association between the answers of the subjects and the answers of their parents or guardians, which matches what was found in other works [7,11].

Literature shows better HRQoL in boys diagnosed with DM1 when compared to girls [9, 10, 14, 15], however, this study did not find such a relation, as in others [11,16].

Regarding the age, lower PedsOL™ 3.0 Diabetes Module scores were observed in younger patients, as in the perspective of children and teenagers as of parents or caregivers, which corroborates with other studies [7]. Although some studies associate aging with HRQoL reduction in children with DM1 [10], in the present study there was no such relation as in the literature [9, 11, 13, 16, 17].

While there was no association between DKA and the subscales “diabetes symptoms” and “treatment adherence” in this research, studies show the worst HRQoL in patients who had episodes of DKA [9]. Furthermore, as evidenced in other studies, quality of life did not relate to BMI [9, 14] and duration of the disease [9, 11, 14, 16].

The present study showed some limitations: cross-sectional, it was not able to evaluate the cause and consequences of the results, and the reduced sample that, despite representing the population of the city, one must have caution when extrapolating the data to the whole country.

V. Conclusion

This study showed that better treatment adherence represents more health-related quality of life from the perspective of the patient. Diabetes treatment must aim, beyond glycemic control, for a better life quality, once the glucose control improves the physical, mental and social aspects of the patient.

Therefore, the evaluation of life quality and the factors that influence it to become important tools to further information and health promotion.

References

- [1]. Atkinson MA, Maclaren NK. The pathogenesis of insulin-dependent diabetes mellitus. *N Engl J Med*. 1994 Nov 24;331(21):1428-36. doi: 10.1056/NEJM199411243312107. PMID: 7969282.
- [2]. Mayer-Davis EJ, Kahkoska AR, Jefferies C, et al. ISPAD Clinical Practice Consensus Guidelines 2018: Definition, epidemiology, and classification of diabetes in children and adolescents. *Pediatric Diabetes*. 2018;19:7-19. doi:10.1111/pedi.12773
- [3]. IDF Diabetes Atlas 10th Edition. www.diabetesatlas.org
- [4]. American Diabetes Association. 13.Children and adolescents: Standards of medical care in diabetes—2021. *Diabetes Care*. 2021;44:S180-S199. doi:10.2337/dc21-S013
- [5]. Varni JW, Burwinkle TM, Lane MM. Health-related quality of life measurement in pediatric clinical practice: An appraisal and precept for future research and application. *Health and Quality of Life Outcomes*. 2005 May 16(3):34. doi:10.1186/1477-7525-3-34
- [6]. Varni JW, Burwinkle TM, Jacobs JR, Gottschalk M, Kaufman F, Jones KL. *The PedsQL™ in Type 1 and Type 2 Diabetes Reliability and Validity of the Pediatric Quality of Life Inventory™ Generic Core Scales and Type 1 Diabetes Module*. *Diabetes Care*. 2003 Mar;26(3):631-7. doi: 10.2337/diacare.26.3.631. PMID: 12610013.http://www.pedsq.org.
- [7]. Garcia LFDS, Manna TD, Passone CGB, Oliveira LS. Translation and validation of Pediatric Quality of Life Inventory™ 3.0 Diabetes Module (PedsQL™ 3.0 Diabetes Module) in Brazil-Portuguese language. *J. Pediatr. (Rio J.)*. 2018 Dez [citado 2022 Jul 18]; 94(6):680-688. https://doi.org/10.1016/j.jpmed.2017.09.009
- [8]. Zhong T, Tang R, Gong S, Li J, Li X, Zhou Z. The remission phase in type 1 diabetes: Changing epidemiology, definitions, and emerging immuno-metabolic mechanisms. *Diabetes Metab Res Rev*. 2020;36(2):e3207. doi:10.1002/dmrr.3207
- [9]. Dłużniak-Gołaska K, Szostak-Węgierek D, Panczyk M, Szypowska A, Sińska B. May gender influence the quality of life in children and adolescents with type 1 diabetes? *Patient Preference and Adherence*. 2019;13:1589-1597. doi:10.2147/PPA.S206969
- [10]. Anderson BJ, Laffel LM, Domenger C, et al. Factors associated with diabetes-specific health-related quality of life in youth with type 1 diabetes: The global teens study. *Diabetes Care*. 2017;40(8):1002-1009. doi:10.2337/dc16-1990
- [11]. Predieri B, Bruzzi P, Bigi E, et al. Health-related quality of life and metabolic control in immigrant and Italian children and adolescents with type 1 diabetes and in their parents. *Pediatric Diabetes*. 2020;21(6):1031-1042. doi:10.1111/pedi.13042
- [12]. Álvarez Casañó M, Alonso Montejo M del M, Leiva Gea I, et al. Study of the quality of life and adherence to treatment in patients from 2 to 16 years-old with type 1 diabetes mellitus in Andalusia, Spain. *Anales de Pediatría*. 2021;94(2):75-81. doi:10.1016/j.anpedi.2020.03.016
- [13]. Babiker A, al Aqeel B, Marie S, et al. Quality of Life and Glycemic Control in Saudi Children with Type 1 Diabetes at Different Developmental Age Groups. *Clin Med Insights Endocrinol Diabetes*. 2021 Feb 11;14:1179551421990678. doi: 10.1177/1179551421990678.
- [14]. Varni JW, Delamater AM, Hood KK, et al. Diabetes management mediating effects between diabetes symptoms and health-related quality of life in adolescents and young adults with type 1 diabetes. *Pediatric Diabetes*. 2018;19(7):1322-1330. doi:10.1111/pedi.12713
- [15]. Mozzillo E, Zito E, Maffei C, et al. Unhealthy lifestyle habits and diabetes-specific health-related quality of life in youths with type 1 diabetes. *Acta Diabetologica*. 2017;54(12):1073-1080. doi:10.1007/s00592-017-1051-5
- [16]. Girma D, Abita Z, Wale A, Tilahun S. Reliability and Validity of Ethiopian Amharic Version of the PedsQL™ 4.0 Generic Core Scales and PedsQL™ 3.0 Diabetes Module. *Adolescent Health, Medicine and Therapeutics*. 2021; 12:77-89. doi:10.2147/ahmt.s312323
- [17]. Samardzic M, Tahirovic H, Popovic N, Popovic-Samardzic M. Health-related quality of life in children and adolescents with type 1 diabetes mellitus from Montenegro: Relationship to metabolic control. *Journal of Pediatric Endocrinology and Metabolism*. 2016;29(6):663-668. doi:10.1515/jpem-2015-0420