

Health-Related Quality of Life and Metabolic Control in Children with Type 1 Diabetes Mellitus in Bosnia and Herzegovina

Husref Tahirović¹, Alma Toromanović², Elnur Tahirović³, Hidajeta Begić² and James W. Varni⁴

¹ University Clinical Centre Tuzla, Department for Research and Education, Tuzla, Bosnia and Herzegovina

² University Clinical Centre Tuzla, Department of Paediatrics, Tuzla, Bosnia and Herzegovina

³ Clinical Center University of Sarajevo, Heart Center Sarajevo, Sarajevo, Bosnia and Herzegovina

⁴ Texas A&M University, College of Medicine, Department of Pediatrics, College of Architecture, Department of Landscape Architecture and Urban Planning, Texas College Station, TX, USA

ABSTRACT

The primary objective of the study was to examine the relationship between generic and disease-specific HRQOL scores and metabolic control in children with Type 1 Diabetes Mellitus (T1DM). This cross-sectional study included 65 consecutive children between ages 5 and 18 years with T1DM. According to their values of glycosylated hemoglobin (HbA_{1C}), the children were assigned to one of two groups. In Group 1 (N=21) were the children with HbA_{1C} values <8% (good to moderate metabolic control) and Group 2 (N=44) were children with >8% (poor metabolic control). To evaluate generic and disease-specific HRQOL scores in children with T1DM in relation to metabolic control, we used the PedsQL™ 4.0 Generic Core Scales and the PedsQL™ 3.0 Diabetes Module. The patients in Group 1, by pediatric patient self-report and parent proxy-report, had statistically better disease-specific HRQOL scores on the diabetes symptoms, treatment barriers, treatment adherence and worry domains in comparison with Group 2. We also found significant correlations between the total generic HRQOL scores and HbA_{1C} for both parent proxy-reports' Spearman's coefficient of rank correlation $\rho=-0.257$; $p=0.0412$ and pediatric patients' Spearman's coefficient of rank correlation $\rho=-0.269$; $p=0.0313$. The current findings suggest that poor glycemic control in children with T1DM is associated with lower generic and disease-specific HRQOL scores in developing and transitional countries.

Key words: quality of life, type 1 diabetes, children, PedsQL, metabolic control

Introduction

Diabetes in children significantly affects the daily lives of children and their parents¹⁻⁴. Particularly in developing and transitional countries in which social and health security systems are not well-developed, pediatric diabetes can have a profound negative impact on children and their families⁵.

The chronic complications of Type 1 diabetes mellitus (T1DM) that are of concern for both parents and pediatric patients with diabetes may be prevented by good glycemic control^{6,7}. However, achieving good blood glucose control in children with diabetes is complex and time-consuming⁸. It requires time, education, personal motivation, and active ongoing communication between patients, families and caregivers. The chronic nature of

T1DM requires consistent daily management (insulin injections, testing of blood glucose levels, monitoring meals and exercise) primarily by the caregiver and the child with diabetes and frequent consultations with health care providers⁹.

In contrast to HbA_{1C}, which is recognized as a conventional biological indicator of metabolic control in patients with diabetes, health-related quality of life (HRQOL) focuses on the patients' perceptions of their daily functioning. However, often the primary interest of physicians, health professionals and parents tends to focus on the biological and physical aspects of the disease, giving only little importance and attention to the psychosocial concerns and HRQOL of pediatric patients with diabetes¹⁰.

Although metabolic control is an essential outcome measure, HRQOL is increasingly recognized internationally as an important overall health outcome in patients with diabetes^{11,12}. Some studies have shown that better metabolic control was associated with higher HRQOL^{11,13}, while others did not find any correlation^{14,15}.

Consequently, the primary objective of the present study was to examine the relationship between metabolic control and generic and diabetes-specific HRQOL scores in children with T1DM from Bosnia and Herzegovina. To our knowledge, there is no other study available in the extant literature which has investigated the relationship between generic and disease-specific HRQOL scores and metabolic control in pediatric patients with T1DM in Bosnia and Herzegovina. We hypothesized that better metabolic control would be associated with higher generic and disease-specific HRQOL scores.

Methods

Demographic data

The Tuzla Canton area is situated in the northern-eastern part of Bosnia and Herzegovina and has an area of 2,649 km² with a population in 2008 of 496,380 with 106,092 children aged 0–18 years¹⁶.

Patient population

Our sample was taken from successive admissions to the Regional Centers for the management of diabetes in childhood at the outpatient diabetes clinic in Tuzla, University Clinical Center Tuzla between June and August 2008. This cross-sectional study included 65 consecutive children between ages 5 and 18 years who had more than 6 months duration of diabetes (median of diabetes duration was 3.8 years, range: 0.65–16), with 64.6% males. Patients were treated with an intensified insulin regimen (52.3%) and conventional treatment (47.7%). Diabetic children attend the clinic at last once every three months. All patients and their mothers completed all the questionnaires in the waiting room area before their scheduled appointment. Written informed consent was obtained from participating mothers for their child to take part in the study. Also, informed assent was obtained from each diabetic child.

Glycemic control was assessed by glycosylated hemoglobin (HbA_{1C}). For the study, we calculated all the mean HbA_{1C} values for each patient in the 12 month period preceding the study. On average we had 3 HbA_{1C} findings for each patient. HbA_{1C} was determined using the dimension clinic chemistry system HbA_{1C} Kit from Dade Behring (Newark, DE 19714, U.S.A.). Normal values for HbA_{1C} were considered in the 4.4–6.3% range.

According to their HbA_{1C} values, the children were assigned to one of two groups. In Group 1 (N=21) were children with HbA_{1C} values <8% (good to moderate metabolic control) and in Group 2 (N=44) were children with HbA_{1C} values >8% (poor metabolic control). The pa-

tients' demographic and Clinical characteristics are presented in Table 1.

Measures and procedures

To evaluate generic and disease-specific HRQOL scores in children with T1DM in relation to metabolic control, we used the previously translated unpublished Croatian version of the PedsQL™ Generic Core Scales¹⁷ The PedsQL™ 3.0 Diabetes Module¹⁸ was not available in the Bosnian language, and was consequently translated for the present study according to standard language validation processes. The translated version underwent a linguistic validation process. In early 2008 a pilot study was conducted on a sample of 10 respondents according to the PedsQL™ protocol requirements to determine acceptability of the translated version.

The PedsQL™ Generic Core Scales and Diabetes Module scales are brief and very easy to use, resulting in minimal missing data, and include both parent proxy-report and child self-report with age-appropriate versions. A user agreement was signed with the MAPI Research Institute, Lyon, France, prior to using the PedsQL™ questionnaires.

The 23-item PedsQL™ 4.0 Generic Core Scales encompass Physical Functioning (8 items), Emotional Functioning (5 items), Social Functioning (5 items), and School Functioning (5 items) scales¹⁹. The PedsQL™ scales are composed of parallel child self-report and parent proxy-report formats. Child self-report and parent proxy report includes ages 5 to 7, 8 to 12, and 13 to 18 years¹⁹. For creating the Psychosocial Health Summary Score, the mean is computed as the sum of the items divided by the number of items in the Emotional, Social, and School Functioning Scales. The total scale score is calculated as the average of the individual item responses.

The PedsQL™ 3.0 Diabetes Module is a multidimensional instrument and has five scales related to About My Diabetes (eleven items), Treatment Barriers (four items), Treatment Adherence (seven items), Worry (three items), and Communication (three items) for parent proxy-

TABLE 1
PATIENTS CHARACTERISTICS

Characteristics	Group 1 (N=21)	Group 2 (N=44)
Age (yr)		
X (SD)	12.8±3.3	11.3±3.3
Range	5.0–17.5	5.1–18.0
Sex (N; %)		
Boys	14 (66.7)	28 (63.6)
Girls	7 (33.3)	16 (36.4)
Diabetes duration (yr)		
Median	4.5	3.79
Range	0.68–9	0.64–16
HbA _{1C} (%; Median; Range)	7.3 (5.6–7.9)	8.8 (8–14.8)

-report and child self-report for ages 5 to 18 years. Child self-report and Parent proxy-report includes ages 5 to 7 years, 8 to 12 years, and 13 to 18 years¹⁸.

A 5-point Likert scale is used across child self-report for ages 8 to 18 years and parent proxy-report (0, never a problem; 1, almost never a problem; 2, sometimes a problem; 3, often a problem; 4, almost always a problem). For additional ease of use for the young child self-report (ages 5–7 years), the Likert scale is reworded and simplified to a 3-point scale (0, not a problem; 2, sometimes a problem; 4, a lot of a problem). Items are reverse-scored and linearly transformed to a scale from 0 to 100 points such that higher scores indicate better HRQOL²⁰.

The PedsQL™ was self-administered for parents and for children and adolescents aged 8 to 18 years and administered by an interviewer for children aged 5 to 7 years. The estimated time to complete the PedsQL™ 3.0 Diabetes Module for children and parent was 10 to 15 minutes. Scale internal consistency reliability for the PedsQL™ Generic Core Scales and Diabetes Module was determined by calculating Cronbach’s coefficient alpha.

The Cronbach’s alphas for the PedsQL™ 4.0 Generic Core Scales and the PedsQL™ 3.0 Diabetes Module in the study ranged from 0.73 to 0.84, which is in the acceptable range for group comparisons.

Statistical analysis

Data are presented as absolute and relative numbers, median and interquartile range (IQR). Comparisons between groups on the PedsQL™ Diabetes Module were made by using Mann-Whitney U-test. Spearman rank correlation was used to examine relationships between HbA1c values and the PedsQL™ Generic Core Scales to-

tal scale scores. Level of significance was defined with $p < 0.05$. In the analysis, we used the statistical package Arcus QuickStat Biomedical version²¹.

Results

Table 2 contains diabetes-specific HRQOL scores for child self-report and parent proxy-report by disease severity. Higher scores indicated a better quality of life. Across all dimensions of the PedsQL™ 3.0 Diabetes Module, better HbA_{1c} values were associated with higher disease-specific HRQOL scores, except for the communication dimension.

Significant correlations were found between patient self-reported PedsQL™ 4.0 Generic Core Scales total scale score and HbA_{1c}, Spearman’s coefficient of rank correlation $\rho = -0.269$; $p = 0.0313$; 95% Confidence Interval for ρ -0.482 to -0.027), and for parent proxy-reported PedsQL™ 4.0 Generic Core Scales total scale score and HbA_{1c}, Spearman’s coefficient of rank correlation $\rho = -0.257$; $p = 0.0412$; 95% Confidence Interval for ρ -0.473 to -0.012).

Discussion

The results of this study support our hypothesis that better metabolic control is associated with better generic and disease-specific HRQOL scores. Namely, the patients in the good metabolic control group (Group 1), by pediatric patient self-report and parent proxy-report, had statistically better disease-specific HRQOL scores in the diabetes symptoms, treatment barriers, treatment adherence and worry domains in comparison with patients

TABLE 2
DIABETES-SPECIFIC HEALTH-RELATED QUALITY OF LIFE SCORES ACCORDING TO METABOLIC CONTROL: CHILD SELF-REPORT AND PARENT PROXY-REPORT

PedsQL™ Diabetes Module Scales	Children with Type 1 diabetes				p
	Group 1 (N=21) (<8%)		Group 2 (N=44) (>8%)		
	Median	IQR*	Median	IQR*	
Child self-report					
Diabetes symptoms	86.4	77.2–94.1	76.2	68.2–81.8	0.0029
Treatment barriers	100	90.6–100	87.5	75–93.7	<0.0001
Treatment adherence	92.8	82.1–100	88	78.5–92.9	0.0179
Worry	92.8	70.8–100	66.6	50–91.6	0.0049
Communication	100	100–100	100	83.3–100	0.1786
Parent proxy-report					
Diabetes symptoms	86.4	75–97	75	65.9–81.2	0.0008
Treatment barriers	100	85.5–100	82.2	68.2–98.5	0.0042
Treatment adherence	95.7	87.1–98.2	89.1	78.5–92.8	0.0354
Worry	91.6	66.6–100	75	50–87.7	0.0435
Communication	100	83.3–100	100	66.6–100	0.6642

*Interquartile range. Higher scores equal better HRQOL.

with poor metabolic control (Group 2). In communication domain, there were no statistically significant differences between these two groups. We also found significant correlations between the PedsQL™ 4.0 Generic Core Scales total scale score HbA_{1C} by both patient self-report and parent proxy-report. These findings are consistent with results of studies by the Hoey and Hvidoore Study Group members^{11,22}, and Wagner et al.¹³.

It is interesting to note that in our study both children and their mothers in both groups had very similar responses to questions concerning HRQOL. This knowledge could indicate that children with diabetes and their mothers perceive the patients' problems related to diabetes symptoms, treatment, care and certain restrictions imposed by the disease in the same way regardless of the degree of metabolic control. In fact, all the mothers of our patients are the primary caregivers of their child, and together with their child had the same patient education training in order to control and treat the child's diabetes in the home setting. Most of the mothers were not employed, allowing more involvement in the day to day management of their child's disease.

In contrast to our findings, Graue et al.¹⁴ and Grey et al.¹⁵ found that better metabolic control was not linked to better generic HRQOL scores. In both studies the investigators used different generic HRQOL instruments, and it is therefore difficult to directly compare their findings with our findings. In addition the differences could be because of the different ages of our patients and patients in these studies. Namely, the above mentioned studies included only adolescents, whereas in our study we included a broader age range.

In our opinion, the routine evaluation of generic and disease-specific HRQOL scores should be performed at least once every six months and the findings presented and interpreted to both parents and child together, pointing out the relationship between good metabolic control and generic and diabetes-specific HRQOL scores. In this way, the parent and child will have the opportunity to

monitor the health outcomes of their daily efforts to manage the child's disease.

Limitations of the research

The present study has several limitations. First, the study is limited by its small sample size stemming from the low prevalence of the T1DM in Tuzla Canton, so further reports for Bosnia and Herzegovina are needed to confirm our findings. Second, the current study only included mothers, which could have affected the results and thereby limiting the conclusions that may be drawn regarding fathers of children with T1DM, which may be very important to consider. The inclusion of fathers in future research would result in an alternative view of specific problems encountered by children with diabetes. Third, the study was cross-sectional, limiting conclusions regarding causality; a longitudinal design is required to understand the true causal nature of the relationship between diabetes-specific problems and HRQOL scores.

Conclusions

Despite these limitations, the current findings suggest that poor glycemic control in children with T1DM is associated with lower generic and disease-specific HRQOL scores in Bosnia and Herzegovina. In addition, the findings of the study suggest that clinicians should be mindful of the potential quality-of-life impairments of children with T1DM and the need for the routine evaluation of individual quality of life from the perspective of pediatric patients and their parents. Most patients and parents can complete the PedsQL™ 3.0 Diabetes Module scales in less than 5 minutes, and the results can also be scored in less than 5 minutes. This easy of use and scoring enables patients, parents, and clinicians to discuss the results of HbA_{1C} testing and the results of the HRQOL evaluation at the time of the clinic visit, with these findings then compared to previous findings to determine positive or negative trends in both metabolic control and HRQOL outcomes.

REFERENCES

1. JASER SS, WHITTEMORE R, AMBROSINO JM, LINDEMANN E, GREY M, *J Pediatr Psychol*, 33 (2008) 509. — 2. GINSBURG KR, HOWE CJ, JAWAD AF, BUZBY M, AYALA JM, TUTTLE A, MURPHY K, *Pediatrics*, 116 (2005) 1095. — 3. MARVICIN D, *Diabetes Educ*, 34 (2008) 477. — 4. LANDOLT MA, RIBI K, LAIMBACHER J, VOLLRATH M, GNEHM HE, SENNHAUSER FH, *J Pediatr Psychol*, 27 (2002) 647. — 5. TAHIROVIC H, TOROMANOVIC A, *Eur J Pediatr*, 169 (2010) 961. — 6. THE DCCT RESEARCH GROUP, *Diabetes Care*, 11(1998) 725. — 7. THE DIABETES CONTROL AND COMPLICATIONS TRIAL RESEARCH GROUP, *N Engl J Med*, 329 (1993) 977. — 8. GALLEGOS-MACIAS AR, MACIAS SR, KAUFMAN E, SKIPPER B, KALISHMAN N, *Pediatr Diabetes*, 4 (2003) 19. — 9. THOMPSON SJ, AUSLANDER WF, WHITE NH, *Health Soc Work*, 26 (2001) 7. — 10. NARDI L, ZUCCHINI S, D'ALBERTON F, SALARDI S, MALTONI G, BISACCHI N, ELLERI D, CICOGNANI A, *Pediatr Diabetes*, 9 (2008) 496. — 11. GUTTMANN-BAUMAN I, FLAHERTY BP, STRUGGER M, MCEVOY RC, *Diabetes Care*, 21 (1998) 915. — 12. NELSON EC, MOHR JJ, BATALDEN PB, PLUME SK, *Jt Comm J Qual Improv*, 22 (1996) 243. — 13. WAGNER VM, MÜLLER-

-GODEFFROY E, VON SENGBUSCH S, HÄGER S, THYEN U, *Eur J Pediatr*, 164 (2005) 491. — 14. GRAUE M, WENTZEL-LARSEN T, HANESTAD BR, SOVIK O, *J Pediatr Nurs*, 20 (2005) 373. — 15. GREY M, BOLAND EA, YU C, SULLIVAN-BOLYAI S, TAMBORLANE WV, *Diabetes Care*, 21 (1998) 909. — 16. ANONYMOUS, Statistical data on economic and other trends (Federal office of statistics, Sarajevo, 2007). — 17. VARNI JW, SEID M, RODE CA, *Med Care*, 39 (1999) 800. — 18. VARNI JW, BURWINKLE TM, JACOBS JR, GOTTSCHALK M, KAUFMAN F, JONES KL, *Diabetes Care*, 26 (2003) 26. — 19. VARNI JW, SEID M, KURTIN PS, *Med Care*, 39 (2001) 800. — 20. VARNI JW. Mapi Research Trust, 2007, Lyon. Available from: URL: www.pedsqol.org. — 21. BUCHAN IE, Arcus QuickStat Biomedical version (Adisson Wesley Longman Ltd., Cambridge, 1997). — 22. HOEY H, AANSTOOT HJ, CHIARELLI F, DANEMAN D, DANNE T, DORCHY H, FITZGERALD M, GARANDEAU P, GREENE S, HOLL R, HOUGAARD P, KAPRIO E, KOCOVA M, LYN-GGAARD H, MARTUL P, MATSUURA N, MCGEE HM, MORTENSEN HB, ROBERTSON K, SCHOENLE E, SOVIK O, SWIFT P, TSOU RM, VANELLI M, Aman J, *Diabetes Care*, 24 (2001) 1923.

H. Tahirović

University Clinical Centre Tuzla, Department for Research and Education, Trnovac bb, 75 000 Tuzla, Bosnia and Herzegovina

e-mail: husref.tahirovic@untz.ba

KVALITETA ŽIVOTA POVEZANA SA ZDRAVLJEM I METABOLIČKA KONTROLA BOLESTI KOD DJECE OBOLJELE OD ŠEĆERNE BOLESTI TIP 1 U BOSNI I HERCEGOVINI

S A Ž E T A K

Istraživanje je provedeno s ciljem da se procijeni kvaliteta života povezana sa zdravljem djece oboljele od dijabetes melitusa tipa 1 (T1DM), u odnosu na stupanj metaboličke kontrole bolesti. U transverzalnoj studiji sudjelovalo je 65 djece oboljele od T1DM, u dobi od 5 do 18 godina. U odnosu na vrijednosti glikoziliranog hemoglobina (HbA1c) djeca su podijeljena u dvije skupine. Prvu (N=21), u koju su svrstana djeca s vrijednostima HbA1c <8% (dobra do umjerena metabolička kontrola bolesti) i drugu (N=44), u koju su svrstana djeca s vrijednostima HbA1c >8% (slaba metabolička kontrola). Pomoću upitnika »PedsQL™ Generic Core Scale« i »PedsQL™ 3,0 Diabetes Module« ispitana je kvaliteta života djece, povezana sa zdravljem. Djeca iz prve skupine prema samoizvješću i izvješću njihovih roditelja imala su statistički bolju kvalitetu života povezanu sa zdravljem u domenama koje se odnose na simptome bolesti, poteškoće tretmana, provođenje tretmana i postojanje zabrinutosti u odnosu na djecu iz druge skupine. Također smo našli značajnu povezanost između ukupnog rezultata kvalitete života povezanog sa zdravljem i HbA1c-a, prema procjeni roditelja (Spearmanov koeficijent korelacije rangova $\rho = -0,257$; $p = 0,0412$) i prema procjeni djece (Spearmanov koeficijent korelacije rangova, $\rho = -0,269$; $p = 0,0313$). Rezultati ove studije pokazuju da je slaba kontrola glikemije u djece s T1DM usko povezana s nižom kvalitetom života povezanom sa zdravljem u zemljama u razvoju i tranziciji.