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## ASSESSMENT OF HEALTH-RELATED QUALITY OF LIFE IN PEDIATRIC PATIENTS WITH TYPE 1 DIABETES - A PRELIMINARY STUDY

*PROCENA KVALITETA ŽIVOTA POVEZANOG SA ZDRAVLJEM PEDIJATRIJSKIH PACIJENATA OBOLELIH OD DIJABETESA MELITUS TIP 1 – PRELIMINARNO ISTRAŽIVANJE*

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### Summary

**Introduction.** Diabetes mellitus is a chronic disease that affects all aspects of life of pediatric patients, especially the psychological aspect, and hence the health-related quality of life. The aim of the study was to evaluate the effects of sociodemographic and clinical factors of pediatric patients with type 1 diabetes mellitus on self-assessment of health-related quality of life. **Material and Methods.** The research was conducted as a cross-sectional study. The sample included 37 pediatric patients aged 8 to 18 years, who were diagnosed with the type 1 diabetes mellitus six months or longer before enrollment into the study. The research instruments used in the study were the Serbian version of child-friendly EuroQol-5D-Y youth questionnaire and medical history data (gender, age, time since diagnosis - in years, glycosylated hemoglobin values, type of insulin therapy). **Results.** The total score of general health on the visual analogue scale was 80.54 on average (standard deviation - 20.87). A negative correlation was found between the total score on the visual analogue scale and the duration of diabetes ( $p = -0.329, p < 0.05$ ). The statistical significance of the difference in the distribution of respondents' responses in relation to the type of insulin therapy was confirmed in the domain "Feeling of concern" ( $\chi^2(2) = 7.19, p < 0.05$ ). **Conclusion.** The key determinants that influenced the self-assessment of the health-related quality of life in pediatric patients with type 1 diabetes mellitus are duration of the disease and the use of insulin analogues.

**Key words:** Diabetes Mellitus, Type 1; Quality of Life; Child; Adolescent; Surveys and Questionnaires; Diagnostic Self Evaluation; Health Status; Glycated Hemoglobin A; Insulin

### Introduction

The concept of health-related quality of life (HR-QOL), as a subset of patient-reported health out-

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### Sažetak

**Uvod.** Dijabetes melitus je hronično oboljenje koje utiče na sve aspekte života pedijatrijskog pacijenta-posebno na psihološki i samim tim na kvalitet života uslovljen zdravljem. Cilj rada je bio da se proceni uticaj sociodemografskih i kliničkih karakteristika pedijatrijskih pacijenata obolelih od dijabetesa melitus tip 1 na samoprocenu kvaliteta života uslovljenog zdravljem. **Materijal i metode.** Istraživanje je sprovedeno kao studija preseka. Uzorak je obuhvatio 37 pedijatrijskih pacijenata uzrasta od osam do 18 godina, kojima je dijabetes tip 1 dijagnostikovao pre šest meseci ili duže pre uključivanja u studiju. Korišćeni instrumenti istraživanja su srpska verzija upitnika za mlade EuroQol-5D-Y i dokumentacioni list za prikupljanje podataka o pacijentu (pol, uzrast, vreme proteklo od postavljanja dijagnoze – u godinama, vrednost glikoziliranog hemoglobina i vrsta insulinske terapije). **Rezultati.** Ukupna ocena opšteg zdravstvenog stanja na vizuelno analognoj skali prosečno je iznosila 80,54 (standardna devijacija = 20,87). Zapažena je negativna korelacija između ukupnog skora na vizuelno analognoj skali i dužine trajanja dijabetesa ( $p = -0.329, p < 0,05$ ). Statistička značajnost razlike distribucije odgovora ispitanika u odnosu na vrstu insulinske terapije potvrđena je u domenu Osećaj zabrinutosti ( $\chi^2(2) = 7,19, p < 0,05$ ). **Zaključak.** Ključne determinante koje su uticale na samoprocenu kvaliteta života uslovljenog zdravljem pedijatrijskih pacijenata obolelih od dijabetesa melitus tip 1 su: dužina trajanja bolesti i upotreba insulinskih analoga.

**Ključne reči:** dijabetes melitus, tip 1; kvalitet života; dete; adolescent; istraživanja u upitnici; samoprocena; zdravstveni status; glikozilizirani hemoglobin; insulin

comes, has been the subject of research of many studies, since improvement of HRQOL is certainly the ultimate goal of modern therapeutic regimens. The HRQOL is closely related and affected by the disease itself, process of health care provision, health promotion, patient adherence, satisfaction with therapy effects, and provision of pharmaceutical services [1].

Type 1 diabetes mellitus (T1DM) is a chronic disease that affects all aspects of a pediatric patient's life, especially the psychological aspect and thus the HRQOL [2–4]. The life of these chronically ill chil-

### Abbreviations

HRQOL – health-related quality of life  
 T1DM – type 1 diabetes mellitus  
 HbA1c – glycosylated hemoglobin  
 VAS – visual analogue scale  
 CGM – continuous glucose monitoring  
 EQ-5D-Y – EuroQol-5D instrument, version EQ-5D-Y

dren is specific, because management of T1DM is often complex and requires a high degree of patient and family involvement, decision making and regular glucose monitoring, injections of insulin and dose adjustments, carbohydrate estimation, therapy adjustments according to physical activity, emotional status, illness or infections, alcohol intake. Children with T1DM rate their own HRQOL as similar to their healthy peers [2–5], but they report disease specific problems, which are described in the literature [2, 6–20]. Previous studies highlighted that several factors are associated with poor metabolic control and worse HRQOL in children with T1DM such as: female gender, older adolescents, lower family income, social minority status, single parenthood, and lower level of adherence to treatment [2, 3].

The analysis of the National Diabetes Registry of Serbia for 2010 [21], 2014 [22], and 2017 [23], showed a large annual increase of newly diagnosed pediatric patients with T1DM, especially in those aged 5 – 9 and 10 – 14 years. Todorović et al. found that during the ten-year period (from January 2007 to January 2017), 501 children with newly diagnosed T1DM were hospitalized at the Mother and Child Healthcare Institute of Serbia “Dr. Vukan Čupić” [6]. Therefore, the aim of the study was to assess the HRQOL in pediatric patients with T1DM and its association with sociodemographic (age, gender, and time since diagnosis in years) and clinical factors (glycosylated hemoglobin (HbA1c) levels and type of insulin therapy). The following hypothesis was made: age, duration of diabetes (in years) and HbA1c% are negatively associated with HRQOL. In addition, female gender and pediatric patients receiving insulin analogues are even more likely to have suboptimal HRQOL in at least one domain.

### Material and Methods

An observational cross-sectional study was conducted at the Mother and Child Health Care Institute of Serbia “Dr. Vukan Čupić” in the period from May 30, 2019 to July 4, 2019. The study protocol was approved by the Hospital Ethics Committee (No. 8/21 May 21, 2019) and was performed in accordance with the Declaration of Helsinki. A permission for using the Serbian version of child-friendly EuroQol-5D instrument (version EQ-5D-Y) (youth) was obtained from the EuroQol team.

The study included pediatric T1DM patients aged from 8 to 18 years, with multiple daily injections of insulin. Exclusion criteria were: children younger than 8 years at the time of recruitment, T1DM diagnosis made during the previous 6 months, subjects

with cognitive problems, and children and adolescents with other types of diabetes. The eligible patients were recruited by a medical doctor after medical examination. According to the ethical requirements, every pediatric patient and his/her parent were informed about the study objectives in writing and signed informed consent was obtained from both of them. The pediatric patients filled out the EQ-5D-Y instrument in a separate room to provide a suitable environment and privacy. Their parents were allowed to be present as well as researchers if they had problems and ambiguities with filling out the questionnaire. The survey included EQ-5D-Y instrument, documentation sheet (to collect demographic and clinical characteristics of patients) and informed consent of the patients/parents. Each of these documents was identically coded for each patient.

Basic characteristics of patients were presented dividing patients into two predetermined groups (8 – 12.9 and 13 – 18 years) following the classification of the Teens Eating for Energy and Nutrition at School study [24]. The quality of life of patients was compared between groups in respect to years when the diagnosis of T1DM was confirmed. Patients were divided into groups: 0 – 4.9; 5 – 9.9; 10 – 14.9; and 15 – 18 years, according to the form of the National Diabetes Registry in Serbia [21–23].

Socio-demographic and clinical data were collected from the electronic medical data records (Heliant Health Information System). The socio-demographic data of patients included: gender, age, and time since diagnosis in years. Clinical data included: HbA1c% values and type of insulin therapy.

The levels of HbA1c% (as an indicator of metabolic control of disease and risk of acute and chronic complications of T1DM) were measured by immunoturbidimetric method using automatic Roche Cobas c 501 analyzer, in the biochemical laboratory of the Mother and Child Health Care Institute of Serbia “Dr. Vukan Čupić”. The analyses were performed by a medical biochemistry specialist. According to the levels of HbA1c%, pediatric patients were divided into four groups: group with ideal metabolic control (HbA1c < 5.7%), group with good metabolic control (HbA1c% = 5.8 – 7.4%), group with unstable metabolic control (with HbA1c% = 7.5 – 8.5%) and group of patients with poor metabolic control (HbA1c% > 8.5%).

The child-friendly instrument EQ-5D-Y was used to assess the HRQOL. It consists of self-reported EQ-5D-Y descriptive system and a visual analogue scale (VAS). The descriptive system covers 5 domains/dimensions: mobility, self-care, usual activities, pain-discomfort, and anxiety/depression. The responses were graded using a 3-level Likert scale (no problems, moderate, and serious problems). The VAS describes the general health status on a scale from 0 (the worst health status) to 100 (the best possible health status). The self-reported EQ-5D-Y instrument is more comprehensible and suitable version than EQ-5D for children and adolescents, and it is an acceptable, valid and reliable in-

strument for evaluating the HRQOL in children and adolescents with T1DM [25–28].

All data were analyzed using descriptive statistics. The relationship between nominal data was analyzed using the Chi-square test of independence. The interval data analysis was done using the t-test of independent samples, one-way analysis of variance, and correlation analysis. Data analysis was performed using the Statistical Package for the Social Sciences for Windows (version 23.0, 2015.) and Microsoft Office Excel 2010.

## Results

Thirty-seven pediatric patients participated in the study. On average, they were aged 13.97 years (SD = 3.00, range: 8 – 18 years), and 63.89% of them were female. The average T1DM duration was 4.59 years (SD = 3.35, range 0.5 – 12.9 years). The lowest number of patients had ideal metabolic control, as opposed to good control of the T1DM disease. The data on therapy are presented in **Table 1** as well as the level of metabolic control in T1DM patients.

The results of patients' quality of life are presented in **Table 2** as health profile. Data are presented according to age groups, gender, and type of insulin therapy. The most frequent answer noted in every EQ-5D-Y domain was "no problems".

Most children and adolescents stated that they did not have health problems in EQ-5D-Y dimensions, but

when it comes to their therapy, children and adolescents who received insulin analogues reported significant worry/sadness/unhappiness ( $\chi^2(2) = 7.19, p = 0.02$ ).

The total VAS EQ-5D-Y score was 80.54 on average (SD = 20.87). The difference in mean values of VAS EQ-5D-Y scores in different age groups was not statistically significant; the same goes for gender, metabolic control, age at diagnosis (years), and type of insulin therapy (**Table 3**).

A statistically significant negative correlation was found between the duration of diabetes and the VAS score ( $\rho = -0.33, p < 0.05$ ). Opposite to this result, the correlation between the HbA1c% and VAS scores was not statistically significant ( $\rho = 0.15, p = 0.39$ ).

## Discussion

The assessment of HRQOL is increasingly recognized as an important measure of the overall treatment outcome of pediatric patients suffering from T1DM [29, 30]. To the best of the authors' knowledge, this is the first study in the Republic of Serbia that assesses the HRQOL in children and adolescents with T1DM.

### Results of hypothesis test

The following hypothesis was tested: age, duration of diabetes in years and HbA1C% values and female gender are negatively associated with HRQOL, pediatric patients who received insulin ana-

**Table 1.** Clinical data of pediatric patients  
*Tabela 1. Klinički podaci pedijatrijskih pacijenata*

	Total		8 - 12.9 years		13 - 18 years	
	No/Broj	% Procenat	No/Broj	% Procenat	No/Broj	% Procenat
<i>Type of insulin/Vrste insulina</i>						
Short-acting human insulin/ <i>Humani insulin kratkog dejstva</i> (Actrapid)	12	32.43	4	10.80	8	21.60
Intermediate-acting human insulin/ <i>Humani insulin srednje dugog dejstva</i> (Insulatard)	5	13.51	2	5.40	3	8.10
Fast-acting insulin analogue/ <i>Insulinski analog brzodelujući</i> (Insulin glulizin ( <i>Apidra</i> ))	2	5.40	0	0.00	2	5.40
Fast-acting insulin analogue/ <i>Insulinski analog brzodelujući</i> (Insulin aspart ( <i>NovoRapid</i> ))	22	59.45	5	13.51	17	45.95
Long-acting insulin analogue/ <i>Insulinski analog dugog dejstva</i> (Insulin glargin ( <i>Lantus</i> ))	11	29.72	0	0.00	11	29.72
Long-acting insulin analogue/ <i>Insulinski analog dugog dejstva</i> (Insulin detemir ( <i>Levemir</i> ))	15	40.54	6	16.21	9	24.32
Long-acting insulin analogue/ <i>Insulinski analog dugog dejstva</i> (Insulin degludek ( <i>Tresiba</i> ))	4	10.80	2	5.40	2	5.40
<i>Metabolic control of T1DM/Metabolička kontrola T1DM</i>						
Ideal/ <i>Idealna</i> (HbA1c < 5.7%)	5	13.51	2	5.40	3	8.10
Good/ <i>Dobra</i> (HbA1c% = 5.8 – 7.4%)	15	40.54	4	10.80	11	29.72
Unstable/ <i>Nestabilna</i> (HbA1c% = 7.5 to 8.5%)	10	27.03	2	5.40	8	21.60
Poor/ <i>Loša</i> (HbA1c% > 8.5%)	6	16.21	2	5.40	4	10.80

*Legenda: T1DM - Tip 1 dijabetesa melitus, HbA1C - Glikozilirani hemoglobin*



**Table 2.** Health profile of pediatric patients in regard to different EQ-5D-Y domains and age groups, gender and type of insulin therapy**Tabela 2.** Zdravstveni profil pedijatrijskih pacijenata u odnosu na EQ-5D-Y domene, starosne grupe, pol i vrstu insulinske terapije

EQ-5D-Y domains EQ-5D-Y domeni	Answer Odgovor	Age groups Starosne grupe		Gender Pol		Type of insulin therapy Vrsta insulinske terapije			All patients/ Ukupan broj pacijenata N (%) Broj (%)
		8 - 12.9	13 - 18	Male Muški	Female Ženski	Human Humani	Analogues Analozi	Combination* Kombinacija*	
		No (%) Broj (%)	No (%) Broj (%)	No (%) Broj (%)	No (%) Broj (%)	No (%) Broj (%)	No (%) Broj (%)	No (%) Broj (%)	
Mobility Pokretljivost	No problems Nemam problema	10 (27.03)	24 (64.86)	14 (37.83)	20 (54.05)	7 (18.91)	21 (56.75)	6 (16.21)	34 (91.87)
	Some problems Imam nekih problema	0 (0.00)	3 (8.10)	0 (0.00)	3 (8.10)	0 (0.00)	3 (8.10)	0 (0.00)	3 (8.10)
	A lot of problems Imam mnogo problema	0 (0.00)	0 (0.00)	0 (0.00)	0 (0.00)	0 (0.00)	0 (0.00)	0 (0.00)	0 (0.00)
Looking after myself Vođenje brige o sebi	No problems Nemam problema	10 (27.03)	25 (67.56)	14 (37.83)	21 (56.75)	7 (18.91)	22 (59.45)	6 (16.21)	35 (94.59)
	Some problems Imam nekih problema	0 (0.00)	2 (5.40)	0 (0.00)	2 (5.40)	0 (0.00)	2 (5.40)	0 (0.00)	2 (5.40)
	A lot of problems Imam mnogo problema	0 (0.00)	0 (0.00)	0 (0.00)	0 (0.00)	0 (0.00)	0 (0.00)	0 (0.00)	0 (0.00)
Doing usual activities Obavljanje uobičajenih aktivnosti	No problems Nemam problema	9 (24.32)	23 (62.16)	13 (35.13)	19 (51.35)	6 (16.21)	20 (54.05)	6 (16.21)	32 (86.48)
	Some problems Imam nekih problema	0 (0.00)	4 (10.80)	0 (0.00)	4 (10.80)	0 (0.00)	4 (10.80)	0 (0.00)	4 (10.80)
	A lot of problems Imam mnogo problema	1 (2.70)	0 (0.00)	1 (2.70)	0 (0.00)	0 (0.00)	0 (0.00)	0 (0.00)	1 (2.70)
Having pain or discomfort Imam bol ili nelagodnost	No problems Nemam problema	8 (21.60)	21 (56.75)	12 (32.43)	17 (45.94)	15 (40.54)	19 (51.35)	5 (13.51)	20 (54.05)
	Some problems/Imam nekih problema	2 (5.40)	6 (16.21)	2 (5.40)	6 (16.21)	2 (5.40)	5 (13.51)	1 (2.70)	8 (21.60)
	A lot of problems Imam mnogo problema	0 (0.00)	0 (0.00)	0 (0.00)	0 (0.00)	0 (0.00)	0 (0.00)	0 (0.00)	0 (0.00)
Feeling worried, sad or unhappy Osećaj zabrinutosti tuge ili nesreće	Not worried, sad or unhappy Nisam zabrinut, tužan ili nesrećan	6 (16.21)	15 (40.54)	8 (21.60)	13 (35.13)	1 (2.70)	15 (40.54)	5 (13.51)	21 (56.75)
	A bit worried, sad or unhappy/Pomalo sam zabrinut, tužan ili nesrećan	4 (10.80)	12 (32.43)	6 (16.21)	10 (27.03)	6 (16.21)	9 (24.32)	1 (2.70)	16 (43.24)
	Very worried, sad or unhappy Veoma sam zabrinut, tužan ili nesrećan	0 (0.00)	0 (0.00)	0 (0.00)	0 (0.00)	0 (0.00)	0 (0.00)	0 (0.00)	0 (0.00)

\*Combination of short-acting human insulin and a long-acting analogue: insulin detemir

\*Kombinacija humanog insulina kratkog dejstva i insulinskog analoga dugog dejstva

logues are even more likely to have suboptimal HRQOL in at least one domain.

Among the most important results, no statistically significant difference was found between the VAS EQ-5D-Y score and age, gender, HbA1c levels and type of insulin therapy. A statistically significant association between the total VAS EQ-5D-Y score and the duration of diabetes (negative correlation) was confirmed, that is, longer duration of T1DM was associated with a lower overall VAS EQ-5D-Y score, and vice versa.

Pediatric patients showed relatively few health problems in EQ-5D-Y domains and they were not statistically significant; however, when they were observed from the aspect of therapy, children and adolescents who injected insulin analogues reported significantly higher concerns.

The age of our subjects at the time of disease onset is in agreement with results of many researchers [31–38].

The duration of diabetes in our patients was similar to the study of Murillo et al. [3]. In another

**Table 3.** VAS EQ-5D-Y scores of different groups of pediatric patients**Tabela 3.** VAS EQ-5D-Y skor u odnosu na različite grupe pedijatrijskih pacijenata

VAS EQ-5D-Y <i>Vizuelno analogna skala EQ-5D-Y</i>	Average (SD)/Prosek (Standardna devijacija)	Range <i>Raspon</i>	Stat. test <i>Stat. test</i>
Total score/ <i>Ukupan skor</i>	80.54 (20.87)	4 – 100	
<i>Age groups/Starosne grupe</i>			
Group of patients 8–12.9 years/ <i>Grupa pacijenata 8 – 12,9 godina</i>	87.50 (11.61)	65 - 100	t = 1.24
Group of patients 13–18 years/ <i>Grupa pacijenata 13 – 18 godina</i>	77.96 (23.04)	4 - 100	p > 0.05
<i>Gender/Pol</i>			
Male patients/ <i>Muški pacijenti</i>	84.71 (14.69)	51 - 100	t = 0.94
Female patients/ <i>Ženski pacijenti</i>	78.00 (23.82)	4 - 100	p > 0.05
<i>Metabolic Control/Metabolička kontrola</i>			
Ideal metabolic control/ <i>Idealna metabolička kontrola</i>	91.00 (12.45)	70 - 100	
Good metabolic control/ <i>Dobra metabolička kontrola</i>	78.00 (24.90)	4 - 100	F= 1.03
Unstable metabolic control/ <i>Nestabilna metabolička kontrola</i>	77.00 (20.06)	30 - 100	p > 0.05
Poor metabolic control/ <i>Loša metabolička kontrola</i>	90.00 (6.32)	80 - 95	
<i>Age at diagnosis (in years)/Starost kada je dijagnostikovana bolest (u godinama)</i>			
0 – 4.9	83.30 (12.52)	65 - 95	
5 – 9.9	74.08 (26.34)	4 - 95	F = 1.32
10 – 14.9	80.69 (19.29)	30 - 100	p > 0.05
15 – 18	100.00 (0.00)	100 - 100	
<i>Type of insulin therapy/Vrsta insulinske terapije</i>			
Human insulin/ <i>Humani insulin</i>	88.57 (12.15)	70 - 100	
Analogues/ <i>Analozi</i>	75.21 (23.37)	4 - 100	F = 2.47
Combination of short-acting human insulin and a long-acting analogue: insulin detemir/ <i>Kombinacija humanog insulina kratkog dejstva i dugodeljujućeg analoga: insulin detemir</i>	92.50 (6.89)	80 - 100	p > 0.05

study of AlBuhairan et al. [29] the average duration of T1DM was longer (6.9 years) in population aged from 12 to 18 years, and even longer (10.1 years) in the study of Naughton et al. [30] in population aged from 10 to 16 years.

According to the results of this study, the largest number of pediatric patients received a fast-acting analogue, insulin aspart (NovoRapid) and the most commonly used long-acting insulin analogue, insulin detemir (Levemir). Using the  $\chi^2$  independence test, the statistical significance of the difference in the distribution of respondents' responses to different domains of EQ-5D-Y in relation to the type of insulin therapy was in the domain "Feeling of concern". Other examined differences in the distribution of responses showed no statistical significance in the given sample. In the most compatible study by Murillo et al. [3] 21.6% of children and adolescents reported feeling anxiety or depression.

In our study, a statistically significant negative correlation was found between the overall VAS EQ-5D-Y score and the duration of diabetes mellitus. This result is consistent with the results of the study conducted by Kalyva et al. [39], where the duration of diabetes was identified as one of the five significant predictors of HRQOL in both the generic and diabetes-specific questionnaires in pediatric patients.

However, in our study, a statistically significant difference in the mean values of VAS EQ-5D-Y scores was not confirmed related to patients' gender, age, type of insulin therapy, and metabolic control. Nevertheless, in a study by AlBuhairan et al. [29] the results indicate that significant predictors of quality of life were gender and age of respondents, and female respondents reported lower quality of life, while younger adolescents (13 – 15 years of age) achieved better VAS EQ-5D-Y scores in relation to older teenagers (16 – 18 years of age), and these results are consistent with the results of Murillo et al. [3] and Naughton [30]. Al-Hayek [40] assessed the quality of life of adolescents with T1DM, using the DMPediatric Quality of Life Inventory 3.0 Diabetes Module (PedsQL 3.0 DM) and found that female gender is one of the predictors of poorer HRQOL in at least one domain, that is similar to the conclusion of Kalyva et al. [39].

The highest VAS EQ-5D-Y scores were reported by our patients diagnosed with the disease at 15 – 18 years of age, while the lowest scores were found in pediatric patients diagnosed at the age of 5 – 9.9 years. However, statistically significant differences between mean values in different patient groups were not found. Opposite to these results, the study of Kalyva et al. [39] indicated that the age when the

diagnosis of diabetes was confirmed was a significant predictor of better HRQOL.

In our study, a correlation between the HbA1c and the total VAS EQ-5D-Y score was not confirmed, which contradicts the results obtained by the authors Kalyva [39] and Murillo et al. [3]. Also, in a review by Cameron et al. [41] it was confirmed that poorer metabolic disease control in adolescents is positively correlated with poorer QOL, which is consistent with the conclusions of numerous authors: AlBuhairan [29], Naughton [30], Al-Hayek [40], Alvarado-Martel [42] and Samardžić et al. [43].

The comparison of mean VAS EQ-5D-Y scores with respect to the type of insulin therapy was examined by one-factor analysis of variance and the difference was not statistically significant. However, the highest VAS EQ-5D-Y score was found in subjects receiving a combination of short-acting human insulin and a long-acting analogue followed by human insulin and insulin analogue therapy.

It should be noted that all our respondents had the opportunity to point out what would, in their opinion, significantly improve their HRQOL, and they all reported that they needed continuous glucose monitoring (CGM). Since November 2020, the National Health Insurance Fund provides CGM sensors ("List of aids" that came into force on 14<sup>th</sup> November, 2020) to all pediatric patients with diabetes [44]. A possible limitation of the present study is the small number of patients, from one tertiary-care

center, but the results are comparable with other studies [3, 29, 30, 39–43].

### Conclusion

In summary, this preliminary report suggests that health-related quality of life in Serbian children and adolescents with type 1 diabetes mellitus is similar to that in the general population of the same age and gender from Serbia and different countries. Among the most important results is that no statistically significant difference was found between the visual analogue scale EQ-5D-Y score and variables: age, gender, glycosylated hemoglobin values, and type of insulin therapy.

A statistically significant association between the total visual analogue scale EQ-5D-Y score and the duration of diabetes mellitus (negative correlation) was confirmed, with a longer duration of type 1 diabetes mellitus and a lower overall visual analogue scale EQ-5D-Y score, and vice versa. Higher concerns were reported by pediatric patients receiving insulin analogue therapy.

The present study provides initial data on the childhood population with type 1 diabetes mellitus. Similar studies need to be done in different pediatric hospitals. In the Republic of Serbia, there are no translated and culturally adapted disease-specific instruments for measuring health-related quality of life of pediatric patients with type 1 diabetes mellitus so it is the next task that needs to be done.

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