

SHORT THESIS FOR THE DEGREE OF DOCTOR OF PHILOSOPHY (PH.D.)

# **Physical fitness and health-related quality of life in children and adolescents with type 1 diabetes mellitus**

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The Examination takes place at the Faculty of Public Health, Medical and Health Science Center, University of Debrecen, on 27<sup>th</sup> June, 2013.

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## **1. INTRODUCTION**

The rapidly rising incidence of diabetes mellitus of both types in the young population is clear evidence. The latest survey about the incidence rate of childhood T1DM in Hungary presents a mean annual increase of 4.4% in the last two decades. The highest rate was observed in the youngest age group. The proper diabetes treatment and care is vital to avoid or delay the short-term and long-term complications from the very beginning. The diabetes management involves individualized insulin therapy, adjusted diet and regular exercise. In order to find the most appropriate insulin therapy for a patient, continuous monitoring of blood glucose levels is required. The frequency of blood glucose monitoring is correlated with improved HbA<sub>1c</sub> levels. The haemoglobin A<sub>1c</sub> test is the most accepted measure of glycemic control, and diagnostic test for diabetes. The higher the glucose levels over the previous 8-12 weeks, the higher the HbA<sub>1c</sub> level. The test is used as the gold standard for long-term follow-up of glycemic control.

Immediately after the diagnosis of the disease, the child must be under continuous treatment, care and education by a multidisciplinary team. Right now, there is no cure for diabetes, so patients will need treatment for the rest of their life. But with proper care and diabetes management, diabetic youths can live productive lives, just like their healthy peers. Integrated part of the diabetes management should be the regular exercise, with physically active lifestyle. Physiological, social and emotional benefits of regular exercise are well documented mostly in healthy population, but they are also prevalent for patients with T1DM. It helps to improve overall health and fitness; and reduces risk factors for vascular complications. Physically active diabetic youths have reduced blood glucose level and increased insulin sensitivity, primarily in the skeletal muscles, which leads to a reduced need for insulin.

Despite of importance of physical activity (PA) and fitness in youths with (and without) diabetes, very limited related data are available regarding children and adolescents with T1DM, and they are often conflicting and use small sample sizes.

Chronic condition like diabetes has an impact on many aspects of life. It is important to understand how the disease and the clinical conditions influence on patients' HRQoL. Glycemic control reflects the physiological outcomes of diabetes management, whereas HRQoL represents the psychological perspective of treatment and care. Patients' overall quality of life can influence coping with their disease successfully in the short and over the

long term. The diabetes specific measures are more suitable to assess the physical well-being, the health status of the patients as they are associated with diabetes management, including medical regimen adherence, metabolic control, and risk for long-term complications of diabetes. The treatment effectiveness in chronic conditions is increasingly acknowledged by clinicians and pharmaceutical firms as a criterion for licensing new medications. There is lack of validated age- and disease specific instruments for assessing HRQoL in Hungarian youths with T1DM.

## **2. AIMS OF THE RESEARCH**

The general aims of our study were to evaluate physical fitness (both motor performances and cardiorespiratory fitness) and HRQoL in children and adolescents with T1DM and compare with non-diabetic age-matched control subjects. For obtaining adequate results we carried out the following assessments:

Physical fitness assessments:

1. We measured motor performances and cardiorespiratory fitness using the internationally recommended and widely used across Europe Eurofit fitness test battery.
2. For assessing anthropometric parameters:
  - a. skinfold thickness measurements were made at four sites (biceps, triceps, subscapular and suprailiac) and they were summed to evaluate the body fat content
  - b. height and weight were measured to evaluate body max index ( $\text{kg}/\text{m}^2$ )
  - c. BMI z-scores adjusted to age and gender were computed using the national child health chart
3. We evaluated the PA using the Physical Activity Questionnaire for Older Children and Physical Activity Questionnaire for Adolescents. As these instruments were not translated into Hungary we carried out the linguistic validation of the questionnaires.
4. We looked for predictors of metabolic control (expressed by HbA<sub>1c</sub>).
5. We looked for predictors of cardiorespiratory fitness (expressed by VO<sub>2max</sub>).

Health-related quality of life assessments:

1. We culturally adapted the Pediatric Quality of Life Inventory (PedsQL) 3.0 Diabetes Module (DM) designed for children and adolescents:
  - a) We carried out the linguistic validation

- b) We evaluated the psychometric properties of the questionnaires (child and parent format) in Hungarian type 1 diabetic population. We measured the feasibility, internal consistency reliability, reproducibility, convergent validity, discriminant validity and concurrent validity.
- 2. We assessed the total quality of life scores and the subscale scores (diabetes symptoms, treatment barriers, treatment adherence, worry, communication) of diabetes module separately in girls and boys; and we compared the children and parental estimations.
- 3. We looked for factors affecting the patients' HRQoL.
- 4. We compared HRQoL, metabolic control and cardiorespiratory fitness of diabetic participants treated with continuous subcutaneous insulin infusion (CSII) to those being on multiple daily injections (MDI).
- 5. We compared the quality of life of diabetic patients with the non-diabetic participants using the PedsQL Generic Core Scale (GCS).
- 6. We looked for predictors of diabetes-specific and generic HRQoL from the clinical, anthropometric and cardiorespiratory fitness variables.

We obtained clinical parameters ( $\text{HbA}_{1c}$ , insulin dose, onset of diabetes, method of intensive therapy) from medical records of the study participants during the study.

### **3. MATERIAL AND METHODS**

#### *3.1. Subjects*

Subjects were recruited in two steps. For the physical fitness assessment 106 type 1 diabetic and 130 non-diabetic children and adolescents were measured. For the validation process of the PedsQL 3.0 DM 355 youths with T1DM and 294 control participants were evaluated. In the HRQoL assessments we enlisted 239 diabetic participants from 355 who had diabetes duration at least two years.

##### *3.1.1. Study participants for the physical fitness assessments*

One hundred and six diabetic (53 girls and 53 boys) and one hundred and thirty (69 girls and 61 boys) non-diabetic children and adolescents participated in the physical fitness survey. All the participants were between aged 8-18 years.

Diabetic patients were recruited from the patient population of the Pediatric Diabetes Centre of Borsod-Abaúj-Zemplén County University Hospital providing diabetes care for the Northern-East region of Hungary. The diabetes duration was at least 1 year and the participants had no evidence of diabetes complications by regular assessments for retinopathy (fundal photography), nephropathy (microalbuminuria) and neuropathy (nerve conduction velocity and cardiovascular reflex tests).

##### *3.1.2. Study participants for PedsQL 3.0 Diabetes Module validation process*

A total of 355 diabetic children and adolescents (171 girls and 184 boys) and 328 parents took part in this survey. The participants have had T1DM for more than six months. The diabetic patients were from diabetes-based summer camps which were supported by foundations; so the participation was made possible for everyone regardless of financial background of the families. There were 294 randomly chosen non-diabetic children and adolescents (aged 8-18 years) from schools of different parts of Hungary including 157 girls and 137 boys and their parents (n=294). The age of the patients and the controls did not differ significantly.

##### *3.1.3. Study participants for the HRQoL assessments*

For HRQoL assessments we picked out participants from diabetes camps who had diabetes duration at least two years. There were patients including 124 boys and 115 girls.

### *3.2. Health-related quality of life measurements*

The PedsQL is a multidimensional measurement for HRQoL of healthy and chronically or acute ill youths. It was developed in the United States by James W. Varni. This instrument has been used to describe the quality of life of healthy children and children suffering from various illnesses (diabetes, extreme obesity, cancer, asthma, cerebral palsy, brain tumor, fatigue, end stage renal disease, cardiac problems, rheumatology problems, neuromuscular problems, etc.) The modules are created as a self-administered instrument. It took 5-10 minutes to complete. The PedsQL has already been translated into multiple international languages from US English.

#### *3.2.1. PedsQL 4.0 Generic Core Scale*

The 23-item GCS encompasses four subscales: physical functioning (8 items), emotional functioning (5 items), social functioning (5 items) and school functioning (5 items). The Scale takes 5-10 minutes to complete and it is comprised of parallel self-report and parent proxy-report format. The participants rate how much of a problem they have had in the previous month on a five-point Likert response scale. (0 = never a problem; 1 = almost never a problem; 2 = sometimes a problem; 3 = often a problem; 4 = almost always a problem.) Items are reverse-scored and linearly transformed to a scale ranging from 0 to 100 (0 = 100, 1 = 75, 2 = 50, 3 = 25, 4 = 0). Total scores and subscale scores were computed as the sum of the items divided by the number of items answered. The higher score indicate better quality of life.

#### *3.2.2. PedsQL 3.0 Diabetes Module*

PedsQL™ 3.0 DM was developed to measure disease-specific HRQoL for T1D youths. The multidimensional 28-item DM encompassed 5 subscales including Diabetes symptoms (11 items), Treatment barriers (4 items), Treatment adherence (7 items), Worry (3 items) and Communication (3 items). The scoring method is the same as the GCS. Based on research of Nansel (2008) we used the total score of the DM for evaluating diabetic patients' global HRQoL, and for comparing them by age and gender.

### *3.2.2.1. Linguistic validation of the PedsQL 3.0 Diabetes Module*

For assessing the HRQL of the Hungarian young diabetic population we carried out the linguistic validation. We translated the questionnaire and made sure that both understandable and applicable in Hungary. For evaluating the cultural differences between the original and Hungarian versions of the questionnaires we conducted cognitive interviews both with children and parents. The linguistic validation of the 3.0 DM was carried out according to the linguistic validation guidelines of PedsQL. The linguistic validation process consisted of 3 phases: forward translation, backward translation and patient testing. The last work phase was the cognitive interviewing using the PedsQL Cognitive Interviewing Methodology<sup>SM</sup>. Item 20 ('It is hard for me to wear id bracelet.') had to be adjusted to the Hungarian custom, since the Hungarian diabetic youth used diabetes identity cards instead of id bracelets. The reports of the linguistic validation and the cognitive interviews were sent to the Mapi Research institute (Lyon, France) who accepted the Hungarian version.

### *3.3. Physical Activity Questionnaire for Older Children and Adolescents*

The Physical Activity Questionnaire for Older Children (PAQ-C) and the Physical Activity Questionnaire for Adolescents (PAQ-A) were developed for assessing PA at various ages. These are self-administered, 7-day recall instruments that provide general measure of PA for youths from ages 8-19. They classify children and adolescents into five different activity levels. There are nine items in the PAQ-C: physical activities during spare time, intensity of physical education class, recess time activities, lunch time activities, after-school activities, evening activities, weekend activities, activities in the past seven days, and activities on specific days of the week. The PAQ-A is a slightly modified version of PAQ-C, one item (recess time activities) has been removed. Calculating the mean of the 8 or 9 items will result the final score, where a score of 1 indicates low, whereas a score of 5 indicates very high PA. The last item ("Were you sick last week, or did anything prevent you from doing your normal physical activities?") is not included into the scoring method. There are no validated questionnaires for evaluating PA for children and adolescents in Hungary. For this reason we carried out the linguistic validation of PAQ-C. PAQ-A is a shorter version of PAQ-C so we focused only on PAQ-C validation.

### *3.3.1. Linguistic validation of Physical Activity Questionnaire for Older Children*

We performed the linguistic validation of the questionnaire. Because of the relatively small sample size the psychometric properties of the questionnaire were not measured. In the first phase two English teachers (one of them is English native speaker) translated the questionnaire from English into Hungarian independently. They discussed the translation and agreed on a single version. English version was translated back by two other English teachers who were not associated with the first translation phase. After comparison with the original questionnaire and after revision, the new version was tested on 8 children (4 girls and 4 boys). The purpose of this test was to ensure that the words chosen by the translators are easily and accurately understood by participants. Translation of the American sports made difficulties into Hungarian as some sports were unknown or not popular in Hungary.

### *3.4. Eurofit Fitness Test Battery*

The Eurofit Physical Fitness Test Battery was devised by the Committee of Experts for Sports Research of the Council of Europe (1988). This standardized test battery examines nine tests: eight motor performances and the cardiorespiratory fitness. Motor performance tests consist of the evaluation of the body balance (Flamingo test, FLB), the speed and coordination of upper limb movement (Plate tapping test, PLT), general flexibility (Sit and reach test, SAR), explosive strength of legs (Standing broad jump test, SBJ), static strength of the hand and forearm (Hand grip test, HGR), abdominal muscle strength (Sit-up test, SUP), upper body strength (Bent arm hang test, BAH), running speed (10 x 5 meter shuttle run test, SHR). Test for cardiorespiratory fitness utilizes the maximal oxygen consumption ( $\text{VO}_{2\text{max}}$ ) as the single best measure of maximal aerobic power. Maximal oxygen consumption was measured by 20 meter progression shuttle run test using the regression equation of Léger et al. (1988).

### *3.5. Anthropometric Assessments*

#### *3.5.1. BMI z-score*

Height and weight was measured in light sport clothing without shoes. Body max index (BMI) ( $\text{kg}/\text{m}^2$ ) was calculated and each BMI value was standardized by conversion to a z-score (BMI z-score) adjusted for child age and sex, using the national child health chart.

### *3.5.2. Skinfold thickness*

Skinfold thickness was measured at four sites (triceps, biceps, subscapular and suprailiac). As there is no gold standard to evaluate the body fat content in percentage for children and adolescents the four skinfold thickness were summed, and the total was used as a measure of total body fat.

### *3.6. Glycated haemoglobin*

The haemoglobin A<sub>1c</sub> (HbA<sub>1c</sub>) values were extracted from medical records. HbA<sub>1c</sub> levels are recorded as a percentage of the total haemoglobin. Currently there is not a scale to determine the clinical severity of T1D, as our participants had no complications. Therefore, the disease status was determined according to the target indicators of glycemic control recommended by ISPAD: HbA<sub>1c</sub> values below 7.5% were considered as optimal metabolic control, values between 7.5-9% were considered as suboptimal metabolic control, and values above 9% were defined as high risk metabolic control.

### *3.7. Statistical analysis*

SPSS 19.0 statistical analysis software was used for data analyses and p values at  $\leq 0.05$  were considered statistically significant. Descriptive characteristics (mean and standard deviation) were performed for all parameters. Correlation between the different fitness and anthropometric parameters was evaluated with Spearman's coefficients. In order to compare the diabetic and the healthy control groups as well as the different age or gender groups of the diabetic patients, t-test was employed. PA level (ordinal scale) was compared with Chi-squared test. Multiple regression analysis with stepwise method was carried out to establish predictors of physical fitness, metabolic control, generic and disease-specific health-related quality of life.

The psychometric properties of the PedsQL 3.0 DM designed for children and adolescents were analyzed jointly. Feasibility was determined from the percentage of missing values for each subscales of the PedsQL 3.0 DM and the floor and ceiling effects for both CSR and PPR versions. Internal consistency reliability was characterized by Cronbach's coefficient alpha. Reproducibility was measured with test-retest reliability using the Pearson correlation coefficient between total scales and subscales. The construct-related evidence was assessed using convergent and discriminant validities. The convergent

validity was determined through correlation coefficients between CSR and PPR. Intraclass correlations (ICCs) were also computed. The discriminant validity was evaluated through the metabolic control and the DM total scores, whether HbA<sub>1c</sub> was related to HRQoL of the patients. We used one-way ANOVA and LSD post-hoc multiple comparisons. In order to establish concurrent validity we selected the PedsQL GCS, that measure different aspect of the HRQoL and we tested if scores on the subscales of the DM would correlate with the total scores of the GCS. Intercorrelation was expected to demonstrate moderate to large effect sizes.

## **4. RESULTS**

### *4.1. Eurofit tests of children and adolescents with type 1 diabetes mellitus compared with non-diabetic controls*

#### *4.1.1. Anthropometric characteristics and physical activity levels*

No significant differences in body composition expressed by skinfold thickness and BMI z-score were observed between the diabetic and control groups.

PA levels of the patient groups did not differ significantly from the control youths as assessed by PAQ-C and PAQ-A, but there was significant difference between the boys and girls. Boys were more physically active than girls ( $p<0.001$ ).

#### *4.1.2. Physical fitness*

Eurofit test results in 5 and 4 of 9 tests applied were poorer in the groups of younger and older girls with diabetes as compared with their healthy peers, respectively. Younger girls with diabetes had significantly poorer results of PLT test, SUP test, BAH test, SHR test and  $\text{VO}_{2\text{max}}$  than control younger girls. Older girls with diabetes had significantly poorer results of PLT test, SUP test, BAH test and  $\text{VO}_{2\text{max}}$  than control older girls.

Results in 4 and 5 of 9 tests applied were poorer in the groups of child and adolescent boys with diabetes as compared with their non-diabetic controls, respectively. Younger boys with diabetes had significantly lower achievement of PLT test, SAR test, HGR test and SUP test than control younger boys. Older boys with diabetes produced significantly poorer results of PLT test, SAR test, SUP test, BAH test and  $\text{VO}_{2\text{max}}$  than control older boys.

#### *4.1.3. Predictors of metabolic control and cardiorespiratory fitness*

Out of the 9 Eurofit tests applied,  $\text{VO}_{2\text{max}}$  ( $\rho=-0.413$ ;  $p<0.001$ ), SUP test ( $\rho=-0.215$   $p=0.027$ ), SHR test ( $\rho=0.192$   $p=0.049$ ) and the skinfold thickness ( $\rho=0.231$ ;  $p=0.017$ ) correlated significantly with  $\text{HbA}_{1c}$  as measure of metabolic control. When  $\text{HbA}_{1c}$  was used as dependent variable in the multiple regression model, better  $\text{VO}_{2\text{max}}$  proved to be the single significant predictor of favourable  $\text{HbA}_{1c}$  ( $B=-0.077$ ,  $SE(B)=0.021$ ,  $\beta=-0.343$ ,  $t=-3.726$ ,  $p<0.001$ ;  $R^2=0.118$ ). Age, gender, diabetes duration, BMI z-score, skinfold

thickness, PA level, general balance, flexibility, speed of limb movement, running speed, static strength, dynamic strength and muscular endurance (independent variables) were not significant in the model. Therefore, in further analysis to establish predictors of physical fitness,  $\text{VO}_{2\text{max}}$  was used as dependent variable. In diabetic subjects, older age, female gender, higher skinfold thickness, lower PA level and higher  $\text{HbA}_{1\text{c}}$  proved to be significant independent predictors of poorer  $\text{VO}_{2\text{max}}$  explaining 65.1% of its variance. Age, BMI z-score and skinfold thickness as independent variables were not significant in the model.

#### *4.2. Reliability and validity of PedsQL 3.0 Diabetes Module*

For evaluating the psychometric properties of the PedsQL 3.0 DM in patient and control subjects feasibility, internal consistency reliability, reproducibility, convergent, discriminant and concurrent validities were evaluated.

##### *4.2.1. Feasibility*

For the PedsQL 3.0 DM, the percentage of missing item responses as a whole was 1.10% for CSR and 0.61 for PPR, respectively. The scale range was 0.00-4.23% in CSR and 0.35-1.16% in PPR. There were minimal floor effects in both versions (ranged 1.07-3.10% in CSR and 1.13-3.70% in PPR). However, moderate ceiling effects existed; the largest effects were for Treatment adherence (56.46% in CSR and 55.49% in PPR) and for Communication (48.17% in CSR and 46.50% in PPR).

##### *4.2.2. Internal consistency reliability*

Cronbach's alpha coefficients for the subscales of the DM ranged from 0.698 to 0.795 in CSR and from 0.747 to 0.848 in PPR. Subscales scores on the module exceeded the 0.70 standard. The Cronbach's alpha in total-items reliability approached the criterion of 0.90 recommended for analyzing individual patient scores (0.904 in CSR and 0.892 in PPR).

##### *4.2.3. Reproducibility*

To examine test-retest reliability, a random sample of 29 respondents (16 girls, aged 14.33  $\pm 2.66$  y/o and 13 boys, aged 14.01  $\pm 3.33$  y/o) and their parents were selected. The participants completed the questionnaires 3-4 weeks apart. The health condition of the

children was clinically similar in the second administration. Test-retest reliability was assessed through Pearson correlation coefficient between the total scores and between the subscales scores. The Pearson correlation coefficient ranged between 0.586-0.840 in CSR subscales, and 0.432-0.822 in PPR subscales. The correlations between the total scores were 0.877 in CSR and 0.834 in PPR. The lowest correlation (0.432) was found in the Communication subscale in PPR.

#### *4.2.4. Convergent validity*

Convergent validity was evaluated between the concordance of CSR and PPR. The effect size was large in all subscales of the DM; the Pearson correlation coefficients were between 0.617 and 0.764 in all subscales and 0.807 between the total scores ( $p<0.001$ ). The ICCs were between 0.763 and 0.865 in the subscales and 0.893 in the total items.

#### *4.2.5. Discriminant validity*

To assess whether the measure could differentiate between patients with varying degrees of disease severity, patients were categorized into 3 groups according to the HbA<sub>1c</sub> values as having optimal (<7.5%) (n=70), suboptimal (7.5-9%) (n=166) and high risk metabolic control (>10%) (n=119). Using one-way ANOVA we found significant differences among three sizes of HRQoL,  $F(2, 352)=3.099$ ,  $p=0.046$  in CSR and  $F(2, 325)=3.080$ ,  $p=0.047$  in PPR. LSD post-hoc multiple comparisons of the three groups indicate that the group of optimal metabolic control ( $M=74.73$ , 95% CI [72.09, 77.37]) in CSR and ( $M=72.31$ , 95% CI [69.54, 75.07]) in PPR gave significantly higher HRQL scores than the group of suboptimal metabolic control ( $M=70.73$ , 95% CI [68.77, 72.69]);  $p=0.027$  in CSR and ( $M=68.03$ , 95% CI [66.09, 69.98]);  $p=0.018$  in PPR; and the group of high risk metabolic control ( $M=70.33$ , 95% CI [67.92, 72.74]);  $p=0.021$  in CSR and ( $M=68.31$ , 95% CI [66.13, 70.48]);  $p=0.034$  in PPR, respectively.

#### *4.2.6. Concurrent validity*

The concurrent validity was examined through an analysis of the intercorrelation between the PedsQL GCS total scores and the PedsQL 3.0 DM subscales scores. Intercorrelations ranged from 0.463 to 0.593 in CSR and from 0.440 to 0.692 in PPR with medium to large effect size range. The smallest intercorrelations were observed between the GCS and

Worry subscale both in CSR and PPR. The intercorrelation between GCS and DM total scores were 0.689 in CSR and 0.762 in PPR.

#### *4.3. Health-related quality of life of children and adolescent with type I diabetes mellitus*

With the PedsQL Diabetes Module we evaluated the diabetic youths' HRQoL both from the children and from the parents' perspective. When we compared the HRQoL of diabetic boys and girls, we observed that boys had significantly better quality of life perception than girls (boys (n=184):  $72.77 \pm 12.95$  vs. girls (n=171):  $69.89 \pm 12.31$ ; p=0.033). This was confirmed by the parents' answers (boys (n=170):  $70.82 \pm 11.24$  vs. girls (n=158)  $66.86 \pm 12.16$ ; p=0.002). The parents significantly underestimated their children's HRQoL globally (CSR:  $72.08 \pm 12.35$  vs. PPR:  $68.91 \pm 11.84$ ; p<0.001) and in all subscales except of Communication subscale (Diabetes symptoms: CSR:  $64.57 \pm 13.27$  vs. PPR:  $62.60 \pm 12.30$ ; p<0.001, Treatment barriers: CSR:  $70.27 \pm 19.81$  vs. PPR  $65.47 \pm 20.03$ ; p<0.001, Treatment adherence: CSR:  $83.58 \pm 13.32$  vs. PPR:  $80.10 \pm 14.17$ ; p<0.001, Worry: CSR  $69.87 \pm 20.43$  vs. PPR:  $62.91 \pm 21.30$ ; p<0.001, Communication: CSR:  $78.30 \pm 22.17$  vs. PPR:  $76.93 \pm 22.39$ ; p=0.123). Analyzing the subscale scores of the DM we found that patients with T1DM had no problem with the treatment adherence and communication, but they had low scores in the diabetes symptoms, treatment barriers and the worry subscales. Similar pattern was found in the PPR.

We put the items into order according to the item scores. We found that treatment adherence /eating snack (86.60), taking insulin shots (85.90), carry fast-acting carbohydrate (84.21), exercise (82.87), taking blood glucose tests (82.75) and wearing id card (79.34)/ have no problems for the diabetic youths. Only exception is one item, keeping track of carbohydrates or exchanges (67.43) that can be problematic for the children. Patients have no real communication difficulties, they tell the doctors and nurses how they feel (80.32), ask questions (77.46), but reluctant to explain the illness to other people (74.34). The most problems are due to the somatic symptoms /getting sweaty (66.74), going to bathroom too often (65.81), getting shaky (64.24), getting irritable (56.94), feeling tired or fatigued (55.21), feeling thirsty (52.78), feeling hungry (49.88)/. The worst symptom is the hypoglycaemic episode (48.83). The diabetic youths seem to worry very much about the long-term complications (57.86).

#### *4.4. Health-related quality of life of children and adolescents treated with continuous subcutaneous insulin infusion versus multiple daily injections*

We grouped the patients according to the method of the intensive therapy. We measured the CSII and MDI groups both with the GCS and the DM. We observed significant differences in HRQoL between them regarding both the child self-report (CSR) ( $p<0.001$ ) and the parent-proxy report (PPR) ( $p=0.001$ ) according to the GCS total scores. The same significant differences were found in DM, both in CSR ( $p=0.020$ ) and PPR ( $p=0.033$ ). Youth with CSII therapy had higher scores. The difference was caused by the divergent emotional functioning (CSR:  $p<0.001$ ; PPR:  $p<0.001$ ) and better physical functioning (CSR:  $p=0.008$ ; PPR:  $p=0.005$ ) between the two groups. The youths treated with CSII reported significantly better school functioning than those with MDI therapy (CSR:  $p=0.004$ ). Regarding the diabetes-specific subscales, we found that CSII patients had significantly higher subscale index in Diabetes symptoms (CSR:  $p=0.001$ ; PPR:  $p=0.001$ ) and in Worry subscale (CSR:  $p<0.001$ ; PPR:  $p=0.002$ ).

We computed the maximal oxygen consumption ( $VO_{2\max}$ ) separately by gender and found no significant difference between the CSII and MDI groups either in boys or girls. The metabolic control between the CSII and MDI groups were similar without any notable differences.

#### *4.5. Health-related quality of life of children and adolescents with type I diabetes mellitus compared with non-diabetic peers*

Comparing the diabetic and the non-diabetic groups by gender on the basis of PedsQL GCS we found no statistically significant differences in quality of life neither in CSR or PPR, except of the Physical functioning in boys by the PPR. The parents rated the physical functioning significantly better for control boys than diabetic boys ( $p=0.005$ ).

The children and the parents' concordance showed similarity in healthy groups (Physical functioning CSR:  $82.19 \pm 12.81$  vs. PPR:  $80.4 \pm 14.24$ , Emotional functioning CSR:  $69.66 \pm 16.30$  vs. PPR:  $69.47 \pm 14.72$ , Social functioning CSR:  $86.79 \pm 14.01$  vs. PPR:  $87.07 \pm 14.68$ , School functioning CSR:  $72.15 \pm 14.78$  vs. PPR:  $72.57 \pm 15.48$ ).

The parents of the diabetic group significantly underestimated their children' HRQoL in all subscales of the GCS (Physical functioning CSR:  $82.50 \pm 10.90$  vs. PPR:  $78.83 \pm 10.23$ ;

$p<0.001$ , Emotional functioning CSR:  $71.30 \pm 16.73$  vs. PPR:  $66.97 \pm 16.36$ ;  $p<0.001$ , Social functioning CSR:  $90.22 \pm 13.86$  vs. PPR:  $87.23 \pm 15.08$ ;  $p<0.001$ , School functioning CSR:  $74.27 \pm 14.78$  vs. PPR:  $72.67 \pm 14.76$ ;  $p=0.003$ ).

#### *4.6. Predictors of health-related quality of life and metabolic control*

In the multiple regression models we analysed both the generic and diabetes-specific quality of life. The higher maximal oxygen uptake ( $B=0.650$ ,  $SE(B)=0.098$ ,  $\beta=0.386$ ,  $t=6.654$ ;  $p<0.001$ ) and the CSII therapy ( $B=-4.410$ ,  $SE(B)=1.160$ ,  $\beta=0.220$ ,  $t=-3.800$ ;  $p<0.001$ ,  $R=0.462$ ,  $R^2=0.214$  (CSII=0, MDI=1) were significant independent predictors of the better self-rated generic HRQoL. The metabolic control, gender, age, insulin dosage, BMI z-score, and the duration of diabetes as independent variables were not significant in the model.

When we put the self-rated DM into the model as dependent variable the higher maximal oxygen uptake ( $B=0.883$ ,  $SE(B)=0.122$ ,  $\beta=0.424$ ,  $t=7.255$ ;  $p<0.001$ ) and the CSII therapy ( $B=-2.798$ ,  $SE(B)=1.446$ ,  $\beta=-0.113$ ,  $t=-1.935$ ;  $p=0.054$ ,  $R=0.449$ ,  $R^2=0.202$ ) were significant predictors.

We ran the regression analysis again on the HbA<sub>1c</sub>, because we had now greater sample size and we analyzed the intensive therapy method as well. The result was similar to the previously got outcome. Predictors of the metabolic control (expressed by HbA<sub>1c</sub>) was the maximal oxygen consumption ( $B=-0.093$ ,  $SE(B)=0.016$ ,  $\beta=-0.353$ ,  $t=-5.813$ ;  $p<0.001$ ), explaining 12.5% of the variance. Increase of the VO<sub>2max</sub> associated with decrease of the haemoglobin A<sub>1c</sub> in tendency nature.

## **5. DISCUSSION**

In this research work we investigated the physical fitness including motor performances and cardiorespiratory fitness using the standardized Eurofit test battery, anthropometric characteristics of children and adolescents with T1DM, and compared the results with age-matched control groups; we also evaluated the clinical parameters. We determined the predictors of the metabolic control (expressed by HbA<sub>1c</sub>) and the cardiorespiratory fitness (expressed by VO<sub>2max</sub>). We carried out the linguistic validation of the Physical Activity Questionnaire. We culturally adapted the Pediatric Quality of Life Inventory 3.0 Diabetes Module designed for children and adolescents. We evaluated diabetes-specific quality of life and found the factors influencing on quality of life of patients with T1DM. We compared the diabetic patients' HRQoL and cardiorespiratory fitness treated with CSII versus to MDI. We assessed the children and parents' concordance on the basis of generic and diabetes-specific quality of life questionnaires. We compared the diabetic youths' HRQoL with the age-matched non-diabetic peers using generic instrument. We found the predictors of the generic and disease-specific HRQoL.

### *5.1. Physical fitness*

Diabetic patients of both sexes produced substantially poorer physical fitness levels in several tests than their non-diabetic peers. Female gender, increasing age, higher skinfold thickness, lower PA level and poor metabolic control were significant independent predictors of lower VO<sub>2max</sub> as a measure of cardiorespiratory fitness. Furthermore, out of the Eurofit tests, anthropometric and PA parameters used, VO<sub>2max</sub> influenced independently the metabolic control.

Few previous studies addressed assessment of physical fitness in children with T1DM. These studies investigated cardiorespiratory fitness comparing results with non-diabetic children. Except for one study, in which prepubertal boys were investigated, all investigations observed reduced cardiorespiratory fitness in children and adolescents with diabetes. To our knowledge, this is the first trial, in which parallel assessments of motor performances, cardiorespiratory function and anthropometric characteristics were carried out in youths with T1DM by the use of Eurofit test battery. According to the present results, all diabetic groups had impaired speed and coordination of upper limb movement and abdominal muscle strength. In addition, all girls with diabetes had less upper body

strength and lower maximal oxygen uptake; furthermore, younger diabetic girls had poorer running speed as well. Moreover, all boys with diabetes had poor general flexibility and younger diabetic boys had poor static strength of hand and forearm and older diabetic boys showed less upper body strength and maximal oxygen uptake.

The reason why diabetic youths showed impaired performances of various tests for physical fitness is not clear. It has been suggested that lower PA or physiological changes resulting from the diabetes pathology itself could result in reduced fitness in children. In the present study, PA level and skinfold thickness also influenced cardiorespiratory performance in healthy and diabetic subjects. Nevertheless, the diabetic groups did not differ from the control groups regarding body composition and PA level. Despite these facts, it is conceivable that diabetic youths, due to the fear of hypoglycaemia as a consequence of exercise, participate less intensively in sport activities, have less daily PA, and may have less skill to perform such tests than non-diabetic peers. However this concept should be assessed prospectively in the future.

Another assumption is that metabolic control influences the fitness of diabetic patients. Previous studies showed that poor metabolic control is associated with poor cardiorespiratory fitness in children with diabetes. In our study, HbA<sub>1c</sub> was independent predictor of VO<sub>2max</sub>. Interestingly, the VO<sub>2max</sub> was the only predictive parameter for metabolic control and the other tests representing motor performances had no effect. This finding emphasizes the importance of physical fitness in the care of diabetes and suggests that improvement in physical condition may contribute to better diabetes control which in turn leads to further improvement in physical performance. Our finding of VO<sub>2max</sub> being the only predictive parameter for HbA<sub>1c</sub> also suggest the importance of aerobic exercise in achieving and maintaining good glycemic control. Although, children and adolescents need all types of movements for improving different physical abilities and strengthen muscle groups, but the glycemic control seems to be influenced primarily by the aerobic exercise. This underlines the importance of the aerobic exercise in the treatment and care of T1DM in childhood.

Further possibility is that early subclinical complications of diabetes may contribute to reduced physical fitness achievements. Early complications can be present in children with diabetes and in a previous trial cardiovascular autonomic dysfunction interfered with exercise testing results. Subtle microangiopathic vascular lesions and peripheral nerve dysfunction may lead to disturbed muscle innervations and some impairment in motor

performances. However, in the present study patients with early complications were not involved. In order to investigate whether very early microvascular or neuropathic alterations may contribute to the impairment of motor or cardiorespiratory performances further studies are necessary.

Both motor performances and cardiorespiratory fitness can be impaired in youths with T1DM. Independent relationship exists between metabolic control and cardiorespiratory fitness underlying the importance of life style interventions in the complex treatment and care of childhood diabetes. Regular and parallel assessments of motor and cardiorespiratory functions by the Eurofit battery tests may help to identify the individual needs of special exercise activities which contribute to better physical condition and metabolic control of children and adolescents with T1DM. However, further studies are necessary to explain the mechanisms by which diabetes leads to reduced fitness and to examine the effect of lifestyle intervention on the feasibility of improving cardiovascular fitness.

### *5.2. Cultural adaptation of PedsQL 3.0 Diabetes Module*

The PedsQL 3.0 DM designed for children and adolescents has been translated into Hungarian and accepted by the Mapi Research Institute. Based on the results of the psychometric evaluation, it was confirmed that the Hungarian versions of the PedsQL 3.0 DM are generally comparably feasible, reliable and valid. There were hardly any unanswered items on the DM. Both patients and parents were able to complete the questionnaires and provide sufficient data regarding the child's HRQoL. The instrument has excellent internal consistency reliability. We demonstrated the test-retest reliability of the questionnaires that was missing in the original scales. We found great agreement between the children's and the parents' answers. The PedsQL 3.0 DM was able to differentiate between HRQoL of optimal, suboptimal and high risk metabolic control in the young patients. This result is underpinned by the answers of the parents. The DM subscales and the GCS total scale correlated well, except for the Worry subscale, both in CSR and PPR. The intercorrelations were from medium to large effect size that confirmed the concurrent validity of the instrument. The worry about the short- and long-term complications and the worry about the treatment efficacy are special characteristics of the diabetes disease, which explains why this subscale does not match the generic total score.

The nationally adapted versions of PedsQL 3.0 DM designed for children and adolescents are reliable and valid instrument for assessing HRQoL of children and adolescents with T1DM.

### *5.3. Health-related quality of life of children and adolescents with type 1 diabetes mellitus*

Most researchers known to us employed generic HRQoL questionnaire in their studies that are less sensitive to the impact of specific diseases than are disease-specific questionnaires. To our knowledge this is the first study that evaluated the effect of cardiorespiratory fitness parallelly, the diabetes-related clinical and anthropometric parameters on the youths' diabetes-specific quality of life from both children and parents' perspective.

Both our diabetic and non-diabetic female groups reported significantly poorer HRQoL perception than males. Multiple studies have shown these gender differences not only in healthy population, but in chronic diseases as well including diabetes. These differences are rather due to perception of health than the actual health status as there were no significant differences in clinical parameters in our patients.

We found that parents underestimated their diabetic children's HRQoL. This parental underestimation is known from the literature and our survey confirms these findings on the basis of both DM and GCS. We did not find this underestimation in the healthy youths. It raises the assumption that the parents may overprotect their diabetic children.

The diabetic patients cope with the treatment adherence very well and have no communication problems, but the presence of the diabetes symptoms and the worry about the short-term and long-term consequences of the disease has negative impact on their quality of life. The long-term parental fear may limit the diabetic child's self-esteem and build panic issues in children as well. Hypoglycaemia episodes have the greatest negative influence in the diabetic youths' HRQoL.

It is generally agreed that to achieve optimal glycemic control patients should be treated with intensive insulin therapy either with CSII or MDI. It is not clear that one of these two treatments is superior to other in clinical practice. In our study, there was no considerable difference in HbA1c between the two investigated groups suggesting that the method of the intensive therapy had no effect on metabolic control. We had no comparison data from the literature regarding the maximal oxygen consumption between the CSII and MDI groups. Studies examining the physical fitness in patients with T1DM did not distinguish

between the methods of intensive insulin therapy. Our result is unique in this field; the physical fitness level of the patients is independent from the method of the intensive therapy. However, patients treated with insulin pump therapy had better HRQoL than those treated with MDI. This result was confirmed by the parents' answers. Both the child self-report and the parent proxy-report indicated significantly more stable emotional and physical functioning due to flexibility of the use of insulin pump. Youths with CSII therapy reported better school achievement, although this was not confirmed by the parents' answer, and less diabetes-related somatic problems. Youths with CSII therapy and their caregivers worry less about the efficiency of the medical treatment, the short and long-term complications.

Two dominant variables were observed that explained the favourable generic and diabetes-specific quality of life, the higher level of maximal oxygen uptake and CSII therapy. The HbA<sub>1c</sub> was no predictive factor of the HRQoL and the CSII therapy did not predict the better HbA<sub>1c</sub> level. Although CSII therapy had no effect on metabolic control and cardiorespiratory fitness, this type of treatment influenced the HRQoL positively which is a remarkable finding. This could be due to greater emotional balance and less fear of diabetes related symptoms. The main goal in diabetes management is to achieve good metabolic control and improve the young patients' quality of life. CSII therapy seems to be more effective way to make the young patient feel better mainly to give psychological stability and disburden diabetes-related anxiety.

When we measured the diabetic youths' HRQoL with the GCS we found great similarity to their age-matched peers. Physical and psychosocial factors could not show differences between the diabetic and control youths, indicating that patients live similar lives as their non-diabetic peers. This may be due to the appropriate care of diabetes including proper continuous patient and parent education in Hungary.

## **6. CONCLUSION AND CLINICAL IMPLICATIONS**

- Both motor performances and cardiorespiratory fitness can be impaired in type 1 diabetes youths without differences in body composition. Independent relationship exists between metabolic control and cardiorespiratory fitness underlying the importance of life style interventions in the complex treatment and care of childhood diabetes. Regular and parallel assessments of motor and cardiorespiratory functions by the Eurofit tests may help to identify the individual needs of special exercise activities which contribute to better physical condition and metabolic control of children and adolescents with T1DM.
- The nationally adapted versions of PedsQL 3.0 DM designed for children and adolescents are reliable and valid instruments for assessing HRQoL of children and adolescents with T1DM. This is the only validated instrument in Hungary that can be applied for HRQoL assessments of Hungarian diabetic youths with age range 8-18.
- HRQoL is similar in type 1 diabetic and non-diabetic children and adolescents. In proper care and diabetes management diabetic youths can live as happy and productive lives as their non-diabetic peers. We assume that the diabetes care and management in Hungary is satisfactory.
- Both diabetic and healthy boys have better HRQoL than girls. These differences are rather due to perception of health than the actual health status or due to biological and psychological differences between the genders.
- Parents underestimate HRQoL of their diabetic children, but this is not the case in healthy population that may suggest parents overprotect their chronically ill children.
- Diabetic youths' quality of life is especially influenced by the presence of diabetes somatic symptoms and the worry about the improper medical treatment, long-term complications and hypoglycaemic episodes.
- Diabetic youths treated with CSII therapy have better HRQoL than those treated with MDI. It is due to the better physical and emotional functioning and less fear of improper medical treatment, long-term complications and hypoglycaemic episodes.

The physical fitness level and the metabolic control of the patients seem to be independent from the method of the intensive therapy.

- Good physical fitness has an important role in achieving better metabolic control and health-related quality of life which underlines the importance of the regular aerobic exercise in the treatment and care of type 1 diabetes in childhood.

## **7. SUMMARY AND KEYWORDS**

Type 1 diabetes mellitus is one of the commonest chronic diseases in childhood affected more and more children worldwide. In the routine care of diabetes, mostly the clinical parameters are controlled and little attention is paid to the physical fitness status and quality of life assessment.

In our research work we evaluated the physical fitness (both motor performances and cardiorespiratory fitness), anthropometric characteristics and health-related quality of life in children and adolescents with type 1 diabetes mellitus and compared with non-diabetic age-matched control subjects. For using an originally validated age- and disease specific health-related quality of life questionnaire in Hungary we carried out the linguistic validation and measured the psychometric properties in Hungarian type 1 diabetic pediatric population. The results demonstrated the feasibility, reliability and validity of the national adapted instrument for assessing health-related quality of life of children and adolescents with type 1 diabetes mellitus.

There were no differences between the diabetic and non-diabetic participants in anthropometric characteristics and PA, but the motor performances and the cardiorespiratory fitness were reduced in diabetic patients. Independent relationship existed between the metabolic control and cardiorespiratory fitness underlying the importance of life style interventions in the complex treatment and care of childhood diabetes. The health-related quality of life of diabetic youths was similar to the age-matched controls. The parents underestimated their diabetic child's health-related quality of life that was not the case in non-diabetic subjects. Both diabetic and non-diabetic boys had better health-related quality of life perception than girls. The presence of diabetes symptoms and the worry about the treatment efficacy, hypoglycemia and long-term complications adversely influenced the health-related quality of life of diabetic boys and girls. The better cardiorespiratory fitness and the insulin pump therapy are explaining factors of the favourable health-related quality of life on the basis of both generic and disease-specific modules.

This research work gave evidence that good physical fitness had an important role in achieving better metabolic control and health-related quality of life which underlined the importance of the regular aerobic exercise in the treatment and care of type 1 diabetes in

childhood. Clinicians should encourage their young patients to exercise regularly – especially to do aerobic sport – for its clinical and quality of life benefits.

**Keywords:** type 1 diabetes mellitus, health-related quality of life, physical fitness, glycaemic control, children, adolescents

## 8. PUBLICATIONS



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Register Number: DEENKÉTK/140/2013.

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Doctoral School: Doctoral School of Health Sciences

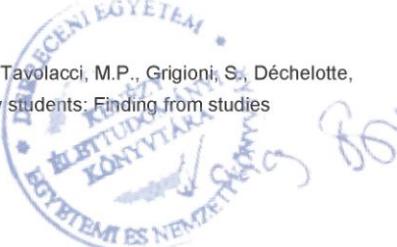
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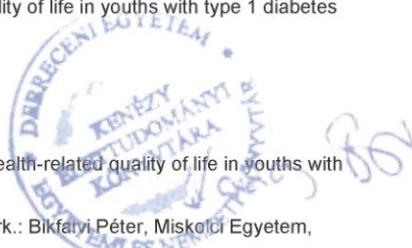
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