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ORIGINAL PAPER

Validation of the Ukrainian version of the PedsQLTM 4.0 Generic Core Scales in children and adolescents with vasovagal syncope

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ABSTRACT

Introduction: The aim of the study was to assess the psychometric properties of the Ukrainian translation of the PedsQL™ 4.0 Generic Core Scales for Ukrainian children and adolescents with vasovagal syncope, as well as to study health-related quality of life in this group of paediatric patients.

Materials and methods: We studied 56 children, aged eight to 17 years, with a history of vasovagal syncope, and 41 healthy volunteers. Health-related quality of life assessment was performed using the Ukrainian version of the PedsQL™ 4.0 Generic Core Scales for child self-reporting and parent proxy-reporting.

Results: There were no significant floor or ceiling effects for any of the summary or scale scores for patient self-reporting and parent proxy-reporting. Cronbach's α coefficient for PedsQL total score for patient self-reporting was 0.90, and for parent proxy-reporting it was 0.88. Paediatric patients with vasovagal syncope (67.92 ±14.52; 77.36 ±21.73; $p = 0.01$) and their parents (65.13 ±13.94; 71.77 ±13.76; $p = 0.02$) reported worse PedsQL total scores than healthy children. According to the results of exploratory factor analysis, almost all items of child self-reporting and parent proxy-reporting had a clear factor loading. Regarding construct validity, the results revealed a positive linear relationship between the PedsQL™ 4.0 Generic Core Scales and Modified Calgary Syncope Seizure Score, PedsQL™ General Well-Being Scale, and PedsQL™ Multidimensional Fatigue Scale. Calculation of Pearson's correlation index revealed moderate (0.41–0.60) to good (0.61–0.80) child-parent agreement.

Conclusions: The results demonstrate the feasibility, reliability, validity, and agreement between child self-reporting and parent proxy-reporting of the Ukrainian version of the PedsQL™ 4.0 Generic Core Scales for health-related quality of life assessment in children and adolescents with vasovagal syncope. These patients have lower psychosocial health, emotional functioning, and social functioning in comparison to healthy children and adolescents.

KEY WORDS:

vasovagal syncope, health-related quality of life, validation of the PedsQL™ 4.0 Generic Core Scales, children, adolescents.

INTRODUCTION

Syncope is defined as transient loss of consciousness due to cerebral hypoperfusion, characterised by a rapid onset, short duration, and spontaneous complete recovery [1]. During the first two decades of life approximately 15% of children experience at least one episode of syncope, and the chief complaint of syncope accounts for 1% of all paediatric emergency department visits. Vasovagal syncope (VVS) is the most common cause of loss of consciousness

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in childhood. VVS is characterised by inappropriate vasodilatation leading to neutrally mediated systemic hypotension and subsequent decreased cerebral blood flow [2].

There can be a little doubt that frequent, recurrent syncope has a significant impact on health-related quality of life (HRQOL) for the majority of sufferers. This impact ranges from effects on education in the young, through impaired social life and ability to drive in adolescence, curtailed career opportunities in adult life, and risk of fractures and other injuries in later years [3]. VVS patients have a reduced HRQOL and poorer psychological profile compared to healthy subjects [4, 5]. They also have lower HRQOL scores than patients with diabetes mellitus and similar scores to patients with asthma, end-stage renal disease, obesity, and structural heart disease [6].

Assessment of chronically ill children and adolescents with quality of life instruments provides subjective information about well-being in various domains of daily life. Better understanding of the HRQOL of these patients may enable health practitioners to better understand disease-specific symptoms, their association with psychosocial functioning, and the development in the daily life of children [7, 8]. This may ultimately help clinical decision-making and parent counselling [9]. The development of measurement scales to assess this impact that are easy to use in clinical settings is crucial [10]. There are limited data comparing the HRQOL and psychological profile between VVS patients and healthy individuals, mostly due to lack of national versions of questionnaires with proven psychometric properties. This study aimed to assess the psychometric properties of the Ukrainian translation of the PedsQL™ 4.0 Generic Core Scales for Ukrainian children and adolescents with VVS, as well as to study HRQOL in this group of paediatric patients.

MATERIAL AND METHODS

STUDY POPULATION

We studied 56 children, ages 8 to 17 years, with a history of VVS. The control group consisted of 41 healthy volunteers without a history of VVS or any acute and chronic diseases. The parents of 56 patients with VVS and 41 healthy children were also enrolled in the study. For the diagnosis of VVS we used the diagnostic criteria of the European Society of Cardiology (2018) [1]. Children enrolled in the study had to meet the following inclusion criteria: 1) a minimum of one event of VVS during the last month; 2) normal response during active standing test; 3) absence of structural heart diseases or electrocardiography findings suggesting arrhythmic syncope; 4) absence of electroencephalography signs of epilepsy; 5) absence of any other evident aetiology for syncope; and 6) no concomitant chronic or acute disease. The main demographic and clinical characteristics of VVS and control groups are presented in Table 1.

This study was approved by the Ethics Committee of the Ivan Horbachevsky Ternopil National Medical University of the Ministry of Health of Ukraine. All procedures performed in studies involving human participants were in accordance with the ethical standards of the institutional and/or national research committee and with the 1964 Declaration of Helsinki and its later amendments or comparable ethical standards. All participants gave their written informed consent before participation.

MEASURES

PedsQL™ 4.0 Generic Core Scales

The HRQOL assessment was performed using the Ukrainian Version of PedsQL™ 4.0 Generic Core Scales, after the completion of the relevant user agreement form (MAPI Research Institute, Lyon, France). All the patients and their parents completed study questionnaires and health surveys at the time of their initial appointment in the Syncope Unit. Patients with cognitive and mental disabilities and patients who were unable to speak and write in Ukrainian language were excluded. The patients and parents were instructed on how to complete the various measurement instruments and to complete them independently, so as to minimise any respondent cross-

TABLE 1. Demographic and clinical characteristics of patients

Parameter	VVS ($n = 56$)	Control ($n = 41$)
Age, years*	14.00 ±2.24	12.5 ±2.66
Sex, M/F	32/24	17/24
BMI*	19.70 ±2.85	18.8 ±2.44
Number of patients with a past medical history	–	–
Age of the first syncopal event, years*	12.70 ±2.88	–
Number of syncopal events*	3.38 ±5.29	–
Calgary Syncope Seizure Score*	1.50 ±2.2	–
Modified Calgary Syncope Seizure Score*	–2.00 ±1.7	–
Number of patients with orthostatic dysregulation, *n* (%)	26 (46.43)	3 (0.73)

*VVS – vasovagal syncope, * values are presented as mean ±standard deviation*

contamination. Patients and their parents were given ample time and privacy to complete the study forms.

The 23-item PedsQL™ 4.0 Generic Core Scales encompass the following: 1) physical functioning (eight items); 2) emotional functioning (five items); 3) social functioning (five items); and 4) school functioning (five items). The Physical Health Summary Score (eight items) is the same as the Physical Functioning Scale. To create the Psychosocial Health Summary Score (15 items), the mean is competed as the sum of the items divided by the number of items answered in the emotional, social, and school functioning scale. If more than 50% of the items in a scale were missing, the scale score was not computed [11].

The PedsQL™ 4.0 Generic Core Scales are comprised of parallel child self-reporting and parent proxy-reporting formats. Child self-reporting format includes ages 8 to 12 years, and 13 to 18 years. The items for each of the forms are essentially identical, differing in developmentally appropriate language. Parent proxy-reporting includes ages 8 to 12 years, and 13 to 18 years, and assesses the parent's perception of their child's HRQOL. The instructions ask how much of a problem each item has been during the past month. A five-point response scale is utilised across child self-reporting for ages 8–18 years and parent proxy-reporting (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 0–100 scale (0 = 100; 1 = 75; 2 = 50; 3 = 25; 4 = 0), so that higher scores indicate better HRQOL.

Disease-specific indicators

The number of syncopal events was retrieved from the child's medical chart. The symptoms of orthostatic dysregulation assessed by the questionnaire include five major symptoms and six minor symptoms. A positive questionnaire result was defined according to the criteria proposed by the Japanese clinical guidelines for juvenile orthostatic dysregulation [12]. Active standing test was used for all patients for exclusion of orthostatic hypotension and postural orthostatic tachycardia syndrome [1]. The protocol for the Active Standing Test was established by Tanaka [12]. Calgary Syncope Seizure Score and Modified Calgary Syncope Seizure Score was used for differential diagnosis between syncope and epilepsy in paediatric patients [13]. The PedsQLTM General Well-Being Scale [14] and PedsQLTM Multidimensional Fatigue Scale [15] were also used as additional instruments of HRQOL assessment.

STATISTICAL ANALYSIS

The feasibility of the PedsQL™4.0 Generic Core Scales was determined from the percentage of missing values for each item and from the distribution of item responses. The range of measurements was further tested based on the percentage of scores at the extremes of the scaling range, i.e. the maximum possible score (ceiling effect) and the minimum possible score (floor effect). Ceiling and floor effects were determined to show whether more than 15% of the participants achieved the highest or lowest score, respectively. Surveys with small floor or ceiling effects (1–15%) were considered as meeting acceptable measurement standards, whereas surveys with moderate floor or ceiling effects (more than 15%) were considered as less precise in measuring latent constructs at the extremes of the scale [16]. Scale internal consistency reliability was determined by calculating Cronbach's α coefficient. Scales with reliabilities of 0.70 or greater are recommended for comparing patient groups, while a reliability criterion of 0.90 is recommended for analysing individual patient scale scores [17].

Discriminant validity for the PedsQL™ 4.0 Generic Core Scales was determined utilising the known-groups method. The known-groups method compares scale scores across groups known to differ in the health construct being investigated. Independent samples *t* tests were used to compare paediatric patients with VVS to a matched sample of healthy children on the PedsQL™ 4.0 Generic Core Scales. Effect sizes were calculated in order to determine the magnitude of the differences between paediatric patients with VVS and healthy children. The effect size as utilised in these analyses was calculated by taking the difference between the healthy sample mean and the VVS sample mean, divided by the pooled standard deviation. Effect sizes for differences in means are designated as small (0.20), medium (0.50), and large (0.80) in magnitude [18].

Construct validity was evaluated using exploratory factor analysis to examine the structure of relationships between the items of the PedsQL™ 4.0 Generic Core Scales [19]. Regarding Prof. Varni's results, school functioning items where loaded on two separate factors; we expected to find a five-factor structure. To extract factors, we applied Principal Component Analysis with oblique rotation (Direct Oblimin). Factors with an eigenvalue less than 1 were disregarded.

Criterion validity was further examined by exploring the Pearson's (*r*) intercorrelations between and among PedsQL subscales. Correlations are designated as small (0.10–0.29), medium (0.30–0.49), and large (≥ 0.50) [20].

An agreement between child self-report and parent proxy-report was estimated by the intraclass correlation coefficient (ICC). For the interpretation of ICC values, the following classification was used: < 0.40 = poor agreement, 0.41–0.60 = moderate agreement, 0.61–0.80 = good agreement, and 0.81–1.00 = excellent agreement [18]. Mean values between patient and parent scores were compared using paired sample t tests. To determine the magnitude of the differences between paediatric patients with VVS and their parents, effect sizes were calculated.

As previously noted, effect sizes for differences in means are designated as small (0.20), medium (0.50), and large (0.80) in magnitude [18]. Statistical analyses were conducted using SPSS version 10.0 for Windows.

RESULTS

FEASIBILITY

The feasibility of the PedsQL™ 4.0 Generic Core Scales was evaluated by determining the percentage of missing data and ceiling and floor effects. Children and their parents left 0.9% and 0.6% of questions unanswered, respectively. Total missing items were less than 5%, which showed satisfactory feasibility.

We did not show any floor effects, while ceiling effects were observed for a maximum of 12.50% for social functioning in child self-reporting and parent proxy-reporting (Table 2), meaning that there were no significant floor or ceiling effects for any of the summary or scale scores for patient self-reporting and parent proxy-reporting.

INTERNAL CONSISTENCY RELIABILITY

Table 2 presents the internal consistency reliability α coefficients for VVS samples on the PedsQL™ 4.0 Generic Core Scales. Cronbach's α coefficients for child self-reporting and parent proxy-reporting all exceeded the minimum reliability standard of 0.70. The α values were higher for the school functioning of the child self-reporting and lower for the total score and psychosocial health of parent proxy-reporting.

DISCRIMINANT VALIDITY

Paediatric patients with VVS and their parents reported statistically significantly worse PedsQL total score than healthy children (Table 2). By the results of child self-reporting, physical health and school functioning were not affected. Parent proxy-reporting confirmed the absence of differences in school functioning only between healthy children and children with VVS. All other PedsQL scales were considerably decreased in comparison with healthy sample. All effect sizes were in the small and medium range for both patient self-reporting and parent proxy-reporting.

CONSTRUCT VALIDITY

Table 3 show the factor loading of scales in the PedsQL™ 4.0 Generic Core Scales for child self-reporting and parent proxy-reporting. As can be seen, all loadings are over 0.5, which indicates that the scales and first-order factor fit well with their respective factors.

Factor analysis with varimax rotation extracted five factors from the thePedsQL™4.0 Generic Core Scales in the VVS sample for child self-reporting, and parent proxy-reporting is shown in Tables 4 and 5.

CRITERION VALIDITY

Table 6 shows the intercorrelations among the PedsQL™ 4.0 Generic Core Scales and disease indicators for paediatric patients with VVS. Intercorrelations between parent proxy-reporting and Calgary Syncope

TABLE 2. Scale descriptives for the PedsQL™ 4.0 Generic Core Scales child self-reporting and parent proxy-reporting: vasovagal syncope (VVS) and healthy sample

PedsQL scales	VVS sample					Healthy sample		*p*	Mean differences	Effect size
	Mean	SD	% floor	% ceiling	α	Mean	SD			
Child self-reporting										
Total score	67.92	14.52	0	0	0.90	77.36	21.73	0.0119	9.44	0,511
Physical health	72.27	15.44	0	3.57	0.93	76.89	17.40	0.1702	4.62	0,281
Psychosocial health	65.54	15.52	0	1.79	0.90	77.61	30.33	0.0121	12.07	0,584
Emotional functioning	60.18	19.42	0	5.36	0.93	82.07	82.19	0.0472	21.89	0,367
Social functioning	72.97	19.86	0	12.50	0.93	82.38	14.98	0.0124	9.41	0,534
School functioning	63.61	16.50	0	1.79	0.94	68.54	17.26	0.1596	4.93	0,292
Parent proxy-reporting										
Total score	65.13	13.94	0	0	0.88	71.77	13.76	0.0219	6.64	0,479
Physical health	67.18	16.58	0	1.79	0.93	75.48	17.15	0.0180	8.30	0,492
Psychosocial health	64.06	15.47	0	1.79	0.88	69.73	14.71	0.0420	5.67	0,376
Emotional functioning	60.71	18.13	0	3.57	0.90	68.32	18.75	0.0470	7.61	0,413
Social functioning	71.96	19.74	0	12.50	0.91	78.41	15.22	0.0441	6.45	0,366
School functioning	60.46	17.18	0	1.79	0.91	64.20	18.54	0.4564	2.74	0,209

SD – standard deviation, α – Cronbach internal consistency reliability coefficient α; p is based on independent sample t tests, effect sizes are designated as small (0.20), medium (0.50), and large (0.80)

TABLE 3. Factor loading of scales in the PedsQL™4.0 Generic Core Scales: child self-reporting and parent proxy-reporting

PedsQL scales	Factor	
	Child self-report	Parent proxy-report
Total score	–0.997173*	–0.988593*
Physical health	–0.852618*	–0.684726*
Psychosocial health	–0.984876*	–0.975628*
Emotional functioning	–0.843636*	–0.838058*
Social functioning	–0.841272*	–0.826405*

* *highest factor loading for each scale*

Seizure Score, Modified Calgary Syncope Seizure Score, and orthostatic dysregulation were generally statistically significant. Most of the PedsQL™ 4.0 Generic Core Scales were correlated with Modified Calgary Syncope Seizure Score and orthostatic dysregulation in the patient self-reporting sample. The only intercorrelation between social functioning and number of syncopal events was significant for child self-reporting. There were significant intercorrelations with medium and large effect size ranges for the PedsQLTM General Well-Being Scale and PedsQLTM Multidimensional Fatigue Scale in both child self-reporting and parent proxy-reporting.

PARENT/CHILD AGREEMENT

Calculation of Pearson's *r* correlation index revealed moderate to good agreement in child-parent pairs (Table 7). Emotional functioning, psychosocial health, and total score had the highest intraclass correlation coefficients in the group of patients with VVS.

Mean scores for 56 children with VVS and their parents, who both completed the PedsQL™ 4.0 Generic Core

TABLE 4. Factor loading of items for the five-factor model in the PedsQL™4.0 Generic Core Scales: child self-reporting

Factor and item	Factor 1	Factor 2	Factor 3	Factor 4	Factor 5
Physical health					
1. Hard to walk more than one block	–0.482030	–0.452434	–0.441520	–0.472550	–0.071680
2. Hard to run	–0.778683*	–0.756991*	–0.750374*	–0.757973*	–0.072979
3. Hard to do sports or exercises	–0.677222*	–0.651888*	–0.655573*	–0.648006*	–0.101523
4. Hard to lift something heavy	–0.664397*	–0.619792*	–0.648892*	–0.631202*	0.035465
5. Hard to take bath or shower	–0.547461*	–0.529657*	–0.546828*	–0.527022*	0.165257
6. Hard to do chores around house	–0.580075*	–0.586422*	–0.555799*	–0.571433*	–0.140345
7. Hurth or ache	–0.586633*	–0.575790*	–0.540158*	–0.553110*	–0.459851
8. Low energy	–0.675117	–0.670334*	–0.660205*	–0.646807*	–0.260549
Emotional functioning					
1. Feel afraid or scared	–0.683546*	–0.697050*	–0.682438*	–0.679725*	0.062180
2. Feel sad or blue	–0.646251*	–0.677369*	–0.646962*	–0.638038*	–0.158449
3. Feel angry	–0.656907*	–0.690644*	–0.643082*	–0.667363*	–0.177409
4. Trouble sleeping	–0.538396*	–0.575403*	–0.512357*	–0.530893*	–0.418411
5. Worry about what will happen	–0.423788	–0.461107	–0.412745	–0.420373	–0.345977
Social functioning					
1. Trouble getting along with peers	–0.645035*	–0.645142*	–0.689348*	–0.643863*	0.480555
2. Other kids not wanting to be friend	–0.626282*	–0.619579*	–0.665809*	–0.632834*	0.188575
3. Teased	–0.560468*	–0.566447*	–0.624640*	–0.583345*	0.404619
4. Doing things other peers do	–0.612532*	–0.603194*	–0.628565*	–0.611015*	–0.051194
5. Hard to keep up when play with others	–0.688532*	–0.676511*	–0.700886*	–0.679407*	0.140883
School functioning					
1. Hard to concentrate	–0.585347*	–0.599440*	–0.598644*	–0.644921*	0.081273
2. Forget things	–0.581791*	–0.589262*	–0.608363*	–0.626781*	0.442259
3. Trouble keeping up with schoolwork	–0.541770*	–0.536439*	–0.556730*	–0.593143*	0.416082
4. Miss school – not well	–0.188487	–0.182426	–0.159609	–0.215806	–0.565916*
5. Miss school – doctor appointment	–0.114463	–0.122348	–0.104052	–0.142544	–0.574415*

* *highest factor loading for each item*

TABLE 5. Factor loading of items for the five-factor model in the PedsQL™4.0 Generic Core Scales: parent proxy-reporting

Factor and item	Factor 1	Factor 2	Factor 3	Factor 4	Factor 5
Physical health					
1. Hard to walk more than one block	–0.540979*	–0.457870	–0.472180	–0.505370*	0.415530
2. Hard to run	–0.629354*	–0.545703*	–0.524048*	–0.562698*	0.514502*
3. Hard to do sports or exercises	–0.517572*	–0.436613	–0.422457	–0.483687	0.504913*
4. Hard to lift something heavy	–0.550720*	–0.493500	–0.497071	–0.484095	0.181116
5. Hard to take bath or shower	–0.476682	–0.389423	–0.391941	–0.437455	0.477309
6. Hard to do chores around house	–0.508484*	–0.417796	–0.411811	–0.445952	0.467279
7. Hurth or ache	–0.443443	–0.423077	–0.370623	–0.417825	0.186621
8. Low energy	–0.610905*	–0.611151*	–0.585234*	–0.590149*	–0.047446
Emotional functioning					
1. Feel afraid or scared	–0.640425*	–0.655806*	–0.642303*	–0.609839*	–0.098333
2. Feel sad or blue	–0.673063*	–0.731289*	–0.692844*	–0.679857*	–0.190846
3. Feel angry	–0.677320*	–0.720119*	–0.685294*	–0.688362*	–0.145714
4. Trouble sleeping	–0.538753*	–0.612462*	–0.576612*	–0.565145*	–0.262184
5. Worry about what will happen	–0.520776*	–0.602469*	–0.586121*	–0.527870*	–0.483533
Social functioning					
1. Trouble getting along with peers	–0.574770*	–0.578926*	–0.630782*	–0.591107*	–0.129193
2. Other kids not wanting to be friend	–0.529083*	–0.601296*	–0.635506*	–0.558353*	–0.547052*
3. Teased	–0.578534*	–0.640861*	–0.682054*	–0.609917*	–0.514427*
4. Doing things other peers do	–0.599565*	–0.627696*	–0.653629*	–0.620225*	–0.305408
5. Hard to keep up when play with others	–0.566268*	–0.612169*	–0.633121*	–0.589789*	–0.343053
School functioning					
1. Hard to concentrate	–0.631459*	–0.601733*	–0.627031*	–0.675729*	0.147479
2. Forget things	–0.499509	–0.555702*	–0.565372*	–0.572594*	–0.330497
3. Trouble keeping up with schoolwork	–0.519782	–0.507755*	–0.525473*	–0.571620*	0.066560
4. Miss school – not well	–0.309172	–0.282355	–0.244726	–0.335802	0.375329
5. Miss school – doctor appointment	–0.439931	–0.380301	–0.364123	–0.436578	0.568581*

** highest factor loading for each item*

Scales, are presented in Table 8. Across all PedsQL scales, children self-reported significantly similar HRQOL as their parents. There was no effect size between paediatric patients with VVS and their parents' reports.

DISCUSSION

Simplifying and standardising the approach to the assessment of the impact of syncope on a patient's life offer a number of potential advantages, particularly the opportunity to encourage simple, large studies of intervention for patients with syncope. For some patients, a couple of episodes of syncope a year may have little impact on their lifestyle, and they often cope admirably with such situations. Others are more seriously affected by the apparent inability of the medical system to deal with their episodes and may risk alienation within an unsympathetic system, resulting in inappropriate or unhelpful referral for alternative management [21]. For many patients, syncope is a persistent, intermittent symptom, which may be ameliorated by treatment but rarely "cured" [22]. To that end, searching for a new, simple tool to assess the impact of syncope on HRQOL offers an additional opportunity to help the patient to explore his or her own coping mechanisms as part of the overall approach to managing their clinical problem. The main aim of the present study was to assess the psychometric properties of the Ukrainian translation of the PedsQL™ 4.0 Generic Core Scales for Ukrainian children and adolescents with VVS, as well as to study HRQOL in this group of paediatric patients.

The Ukrainian version of PedsQL™ 4.0 Generic Core Scales showed minimal missing responses for patient self-reporting and parent proxy-reporting, demonstrating that paediatric patients with VVS and their parents are able to provide good-quality data regarding their HRQOL. A range of measurement was demonstrat-

TABLE 6. Intercorrelations among the PedsQL™ 4.0 Generic Core Scales and disease indicators for paediatric patients with vasovagal syncope (VVS)

PedsQL scales	Calgary Syncope Seizure Score	Modified Calgary Syncope Seizure Score	Orthostatic dysregulation	Number of syncopal events	PedsQLTM General Well-Being Scale		PedsQLTM Multidimensional Fatigue Scale			
					General well-being	General health	General fatigue	Sleep/ rest fatigue	Cognitive fatigue	Total score
Child self-report										
Total score	–0.21	0.38*	–0.48*	0.03	0.45*	0.47*	0.69*	0.64*	0.54*	0.77*
Physical health	–0.01	0.30*	–0.61*	0.04	0.35*	0.45*	0.70*	0.51*	0.32*	0.61*
Psychosocial health	–0.30*	0.38*	–0.35*	0.02	0.45*	0.43*	0.61*	0.63*	0.59*	0.76*
Emotional functioning	–0.22	0.20	–0.27	–0.09	0.32*	0.33*	0.59*	0.64*	0.33*	0.63*
Social functioning	–0.22	0.34*	–0.27	0.30*	0.36*	0.45*	0.55*	0.50*	0.45*	0.62*
School functioning	–0.24	0.39*	–0.30*	–0.02	0.41*	0.23	0.29	0.37*	0.65*	0.57*
Parent proxy-report										
Total score	–0.30*	0.36*	–0.40*	–0.08	0.51*	0.41*	0.59*	0.66*	0.52*	0.70*
Physical health	–0.24	0.22	–0.43*	–0.02	0.47*	0.19	0.59*	0.62*	0.31*	0.59*
Psychosocial health	–0.44*	0.57*	–0.41*	0.02	0.46*	0.37*	0.45*	0.53*	0.51*	0.60*
Emotional functioning	–0.30*	0.37*	–0.37*	–0.07	0.36*	0.35*	0.77*	0.54*	0.30*	0.51*
Social functioning	–0.38*	0.59*	–0.31*	0.26	0.30*	0.41*	0.33*	0.38*	0.53*	0.51*
School functioning	–0.39*	0.41*	–0.34*	–0.05	0.47*	0.16*	0.32*	0.39*	0.41*	0.45*

** $p < 0.05$, effect sizes are designated as small (0.10–0.29), medium (0.30–0.49), and large (≥ 0.50) for Pearson's product moment correlations*

TABLE 7. Intraclass correlation coefficients (ICC) between child self-reporting and parent proxy-reporting in vasovagal syncope sample

PedsQL scales	Parent-child agreement	
	r	*p*
Total score	0.734487	0.000000
Physical health	0.550812	0.000013
Psychosocial health	0.744967	0.000000
Emotional functioning	0.759720	0.000000
Social functioning	0.698844	0.000000
School functioning	0.624242	0.000000

ICCs are designated as < 0.40 = poor agreement, 0.41–0.60 = moderate agreement, 0.61–0.80 = good agreement, and 0.81–1.00 – excellent agreement

ed, with no significant floor or ceiling effects across the PedsQL scales. Internal consistency reliability was satisfactory, with Cronbach's α coefficient > 0.70 for all scales. The results of our study are comparable with other translational research [18, 23, 24]. Cronbach's α coefficient for PedsQL total score for patient self-reporting was 0.90, which makes the PedsQL total score suitable as a summary score for the primary analysis of HRQOL in clinical trials for paediatric patients with VVS [18].

Children with VVS are highly symptomatic and have a reduced HRQOL. There are limited data comparing HRQOL between VVS patients and healthy individuals [4–7, 10]. Children with VVS were reported to experience lower total score, psychosocial health, emotional

TABLE 8. Comparisons between the PedsQL™4.0 Generic Core Scales for child self-reporting and parent proxy-reporting in vasovagal syncope sample

PedsQL scales	Child self-report		Parent proxy-report		*t*	*p*	Mean differences	Effect size
	Mean	SD	Mean	SD				
Total score	67.92	14.52	65.13	13.94	1.0383	0.3014	2.79	0.126
Physical health	72.27	15.44	69.18	16.58	1.6973	0.0944	3.09	0.193
Psychosocial health	65.54	15.52	64.06	15.47	0.5045	0.6150	1.48	0.096
Emotional functioning	60.18	19.42	60.71	18.13	–0.1509	0.8803	–0.53	–0.028
Social functioning	72.97	19.86	71.96	19.74	0.2684	0.7889	1.01	0.051
School functioning	63.61	16.50	60.46	17.18	1.2973	0.1973	3.15	0.187

SD – standard deviation; p is based on independent sample t tests, effect sizes are designated as small (0.20), medium (0.50), and large (0.80)

functioning, and social functioning in comparison to healthy children. Discriminant validity of the PedsQL™ 4.0 Generic Core Scales was proven. However, there was no significant difference in the physical health and school functioning between healthy and unhealthy children in this study. The results of our study are partially comparable with other research in children with VVS [6]. Compared with healthy controls, these patients had lower PedsQL total score, physical health summary, psychosocial health summary, emotional functioning, and school functioning. No difference was seen in social functioning in this study. Considering previously published literature, we were unable to find more studies concerning the use of the PedsQL™ 4.0 Generic Core Scales in paediatric patients with VVS.

The result of the factor analysis resembles Varni's five-factor structure in the original PedsQL™ version. Like the results of Varni *et al.* [19], two of the five items (4 and 5) related to school functioning were loading to another factor. Almost all items of child self-reporting and parent proxy-reporting had a clear factor loading. These results help to confirm the construct validity of the Ukrainian version of the PedsQL™ 4.0 Generic Core Scales, and are comparable with other studies [20, 23, 24].

Regarding construct validity, the results revealed a positive linear relationship between the PedsQL™ 4.0 Generic Core Scales and the Modified Calgary Syncope Seizure Score, PedsQL™ General Well-Being Scale, and PedsQL™ Multidimensional Fatigue Scale. These results are related to how each scale measured these domains as they focus on different aspects.

Although the current study included both child and parent proxy reports, it should be stressed that it is the child self-reporting that is considered the standard for measuring HRQOL, while the parent proxy assessment may serve a complementary tool because it can give the attending physician a parent's perspective of their child's illness and thus better insight into the HRQOL issues that may ultimately affect the health care utilisation of the respective patients [25]. Our findings suggest that paediatric patients with VVS display statistically significant agreement with their parents in terms of how they perceive HRQOL. The observation of good correlation between child self-reporting and parent proxy-reporting in the current study was also documented in earlier studies [7, 26, 27]. This finding is not consistent with results of other studies [28, 29]. This may be due to the parents' higher degree of concern, frustration, and more guarded view of their child's well-being and their tendency to be overprotective of their chronically ill child [25].

Currently it is recognised that the measurement of quality of life in paediatric patients is important and is a factor to be considered in clinical decision making. Therefore, it is necessary to make available HRQOL assessment instruments in Ukraine for use in children with VVS and other paediatric diseases. Furthermore, to optimise the management of chronic illness in young patients, as well as being familiar with the different ways in which a state of ill-health may be perceived, it is important to foster cross-communication amongst all those involved. In light of the key role played by parents in the care and treatment of a sick child, it is vital to attend to patients' mental health and their perception of their own lives and that of their child [7]. Further research is needed to evaluate the influence of disease-specific, patient-related, and parent-related factors on the HRQOL outcome in the group of children and adolescents with VVS in Ukraine.

CONCLUSIONS

The results demonstrate the feasibility, internal consistency reliability, validity, and agreement between child self-reporting and parent proxy-reporting in the Ukrainian version of the PedsQL™ 4.0 Generic Core Scales for HRQOL assessment in children (8–12 years old) and adolescents (13–17 years old) with VVS. Paediatric patients with VVS have lower HRQOL, especially in psychosocial health, emotional functioning, and social functioning domains, in comparison to healthy children and adolescents.

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DISCLOSURE

The author declares no conflict of interest.

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