THESIS FOR THE DEGREE OF DOCTOR OF PHILOSOPHY (Ph.D.)

MEASURING HEALTH-RELATED QUALITY OF LIFE IN HUNGARIAN CHILDREN WITH HEART DISEASE

Hungarian Validation of the Pediatric Quality of Life Inventory™ 3.0 Cardiac Module

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Abbreviations

QoL: quality of life

HRQoL: health-related quality of life

CHD: congenital heart-disease

PedsQL™: Pediatric Quality of Life Inventory™

PRO: patient-reported outcome

PCQLI: Pediatric Cardiac Quality of Life Inventory

QOL-SIG TCA: Quality of Life – Special Interest Group Translation and Cultural Adaptation

ICC: intraclass correlation coeffitient

LOA: limits of agreement

1. Introduction

1.1. Definitions of quality of life and health-related quality of life

In the late 1940s several articles were published signaled a shift in the way in which we would conceptualize health and evaluate medical interventions. In 1946, the World Health Organization gave a broadened definition of health as "a state of complete physical, mental and social well-being, and not merely the absence of disease and infirmity (1). According to this definition measurements generally used in clinical practice do not give an entire picture about patients' health (2). We offer a treatment to our patients if we believe that an intervention increases the length of life, prevents future morbidity or makes patients feel better. The first two are measurable with conventional medical methods. To get information about the third we need sophisticated measurements, which concentrate on aspects of personal experience that might be related to health and health care. Use of „quality of life (QoL) measures" has become widespread in recent years, but unfortunately there is no universally accepted definition of quality of life. Within the context of health care, it is important to distinguish „health-related quality of life" (HRQoL) from broader concepts of general well being. HRQoL refers to the subjective and objective impact of dysfunction associated with an illness or injury, medical treatment, and health care policy. According to the definition of Gill and Fenstein quality of life, rather than being a description of the patients' health status is a reflection of the way that patients perceive and react to their health status and to other, nonmedical aspects their lives (3, 4, 5).

One point of agreement in the literature is that QoL is a **multidimensional construct** comprising of several domains. The multidimensional approach originated with the World Health Organization's definition of health as that identified three dimensions: physical, mental, and social (1). This defintion has become the cornerstone of the QoL construct, and these three dimensions have been expanded to four „core" domains: disease state and physical symptoms, functional status, psychological functioning and social functioning.

1.2. Areas of application of quality of life measures

Quality of life measures can be used in many areas of health care:

Basic research of different populations, in sociological and anthropological studies, where the central interest is how different populations define and view quality of life.

Observational epidemiological studies, which focus on the incidence and prevalence of HRQoL impairments in specific populations.

Clinical trials, to demonstrate the effectiveness of prevention, treatment or rehabilitation programmes.

Health economic research with utility-measurements, assessing costs and benefits of interventions (6, 7).

Althoug the increasing application of quality of life measures and the results of several studies, which have shown that clinicians and parents find the information from these measures useful and informative, trials have found that the information does not greatly alter clinical decision. This can be arised from the inappropriate format and time of interpretation of data to clinicians (8).

According to Wirchow medicine is also a social science, just not all the doctors know it (9). The possible cause of forbearance from quality of life measures is the distance between health care professionals and social scientists. The other one is the missing knowledge about correct performance and interpretation of quality of life measures (5, 7).

1.3. Requirements of quality of life measurements

By a critical appraisal of previous literature on quality of life, Gill and Fenstein set up the main requirements of quality of life measurements as follows:

conceptualization of quality of life should be claryfied, which serves as a basis for selecting the instrument to be used in the study

according to the multidimensional construct of quality of life, investigators should state the domains they will measure as components of quality of life

the investigators need to state their reasons for choosing the instrument

aggregation results from multiple items, domains or instruments into a single score permits the the assessment of interrelationship between quality of life and other variables

although the conceptualization as a multidimensional construct, asking the patients to give their global rating for quality of life is useful

health related quality of life should be distinguished from overall quality of life

adequate measurement should provide the possibility for respondents to indicate and supplement the domains that are important for their quality of life. Preferably these supplemental domains and the importance ratings are incorporated into the final rating (3).

1.4. Main methodologic properties of health related quality of life measurements

1.4.1. Who and how should measure quality of life?

Quality of life can be assessed ideally directly by the patient, or if it is not posssible (young children, physically handicapped), by someone close to the patient, such as a family member, and finally by a health care provider. Low level of agreement betwen patient and physician agreement is reported, nurses and other ancillary health care personnnel may provide more reliable ratings than do pysicians.

Interviews can be applied to the broadest spectrum of people, can minimize the problem of missing data, but standardized data collection is difficult. Self-administered quastionnaires are practical, efficient, inexpensive, can be administered frequently in clinical settings (2, 10).

1.4.2. Types of health-related quality of life measures

Generic measures can be used with both sick and healthy populations, and therefore have special merit in situations where comparisons across disease groups or between sick and healthy groups are required. They are suitable to define population norms also. The

disadvantages reflect the fact that generic measures lack sensitivity. They do not reflect specific impacts of treatments on quality of life.

Such instruments can be used at the population level and are potentially suitable for a number of applications:

to evaluate multisectoral health policy interventions aimed at underpriviliged or disadvantaged people

use in epidemiological research investigating factors that might impact upon the HRQoL of people

use as screening tool for identifying patients in special need

use in population surveys characterizing the health and health behaviours of people assesssing the health needs of local population

to provide normative values with which to compare those frome ill people.

In contrast, **disease specific** measures can be more sensitive to implications of different treatments and probably more appropriate for evaluations of interventions or for comparing the impact of alternative treatments. Including only relavant dimensions increases responsiveness, but lack of comparability is a disadvantage of this type of instruments (2, 6, 8, 10, 11, 12, 13).

The most extensive literature of disease specific measures in pediatrics is in the field of pediatric oncology, asthma, diabetes (14, 15, 16, 17).

An alternative measurement model to the generic versus disease-specific dichotomy is an assessment strategy that combines both approches. In this **modular measurement** strategy, a generic core measure is paired with supplemental condition-specific modules. The supplemental modules assess specific disease or treatment effects and other relevant HRQoL issues not sufficiently covered in the core measure, whereas the core measure affords the opportunity to make comparisons across disease groups and with healthy population norms (2, 7, 19-21).

1.4.3. Statistical properties of HRQoL measures

The main required properties of HRQoL measures are the same as for other instruments assessing health status. Discriminative instruments which are designed to measure cross-sectional differences between people should be reproducible and valid. Evaluative instruments, designed to measure longitudinal differences within people over time should have sensitivity to change, so should be responsive also.

HRQoL measure instruments are designed for discriminative and evaluative studies, so all properties are required.

Validity

Face validity is concerned with whether an instrument measures what is intended. This can be evaluated quantitatively through factor analysis and comparisons with related variables. External construct validation includes comparisons with other quality of life instrument scores, with laboratory or clinical measures of severity of disease and with relating instrument scores to socio-demographic variables. Exact agreement with other instruments is not required since that would mean that quality of life scores were redundant (22, 23).

Reliability

All instruments must produce the same results on repeated use under the same conditions. Reliability is concerned whether an instrument is internally consistent or reproducible. Internal consistency is tested with a single administration of an instrument and assesses how well items within a scale measure a single underlying dimension. Test-retest reliability is designed to take account of variation over time in stable patients. The results of tests of internal consistency and test-retest reliability are usually presented with Cronbach's alpha and test-retest correlation coefficients (24, 25).

Responsiveness

Responsiveness or sensitivity of change focuses on the extent to which scores change when subjects improve or deteriorate. Responsiveness pertains to two measurement properties: changeability, which refers to the extent to with subjects'scores increase or decrease with change in their state, and the degree of variability which can not be attributed to true change.

Practicality

At present quality of life measurements are mainly used in clinical trials and formal evaluation studies. Great effort is needed to provide clinically meaningful data on quality of life with brief and simple instruments (2, 5, 7, 8, 10, 26, 27).

1.4.4. Time-frame

It is essential to limit the time-frame to a relatively short period, which generally ranges from „at this moment" to one month. If time frame is too long or undefined patients may be confused as to which period to report, and investigators should keep memory effects in mind as well (12).

1.4.5. Response scales

The most frequently used response scales are the Likert-type scale, linear analogue and hibrid scale. Likert-scale is categorical in nature and providing the patient with a set number of closed-ended response choices. A visual analogue scale is composed tipically of a 10 cm line. The patient is asked to mark the point that corresponds most closely to his experience, and the distance from the anchor points is measured. Hybrid form combines the categorical guides of the Likert-scale with the anchoring system employed in linear analogue scales (2).

1.5. Cross-cultural validation of HRQoL measures

The necessity of international collaboration in all fields of medical research, has gained the importance of developement of cross-culturally applicable QoL instruments.

Thinking about the main scopes of QoL instruments some special considerations are needed in an international aspect.

Cross-cultural differences are less relevant in basic research and epidemiologic studies, while cross-national distinctions are more relevant for clinical trials and health economic research.

There are cultural specific differences in the conceptualization of QoL and HRQoL, however there may be a universal meaning of having a good quality of life.

With the increasing importance of HRQoL measures a number of questionnaires have been developed in many countries in different languages (6, 28).

In order to use these questionnaires in other countries/cultures, they have to be translated and culturally adapted in a standardized way. It is important that research in HRQoL is conducted according to accepted scientific principles and practices. Combining data in multinational clinical studies for objective outcomes pose important data for overall analysis. In these studies one can have the confidence that the same feature is being measured in each country. For questionnaires, the task of establishing the validity of combining data from different countries is more complex. Internationally applicable instruments should have:

Functional equivalence, which pertains to whether or not the items in a translated version have a similar meaning to the source instrument

Operational equivalence, which pertains to the comparability of procedures (e.g. self versus interviewer administered questionnaire)

Scale equivalence, which pertains to the extent to which individuals in different cultural groups respond to the similar items in similar ways

Metric equivalence, which pertains whether or not a measure orders individuals along a continuum in a comparable way across language and cultural groups.

Internationally acceptable instruments can be developed in three principle ways:

Sequential approach includes forward and backward translations, followed by pilot testing.

Parallel approach means that the international diversity of the group of creators assure that culturally relevant input was present throughout the questionnaire contruction process.

Simultaneous approach means that an overall set of components for quality of life is developed internationally, from what working groups of different cultures formulate relevant questions (6, 29, 30).

The most frequently used way is the sequential process. In the adaptation of HRQoL measures for other languages and cultures has become a complex and specialized procedure. The questionnaire must retain the measurement properties of the original, and it must also be adjusted to the cultural differences in patient-perceived impairments (content validity). Series of forward and backward translations and testing in patients ensure content validity. Ideally, each translation should undergo a full validation process however it is costly and time-consuming process, so not always feasible.

After forward and backward translations preferably cognitive interviews are performed for testing questionnaires in the target population. Cognitive testing is concerned how people interpret and comprehend questions, recall information and events, make judgments about how to respond, and provide response. The intent of cognitive testing is to examine the question-answering process to identify and address errors being introduced into process. This knowledge can be used to improve the accuracy and reliability of survey responses. The approach to conduct cognitive interviews can be concurrent, when the respondent is asked to think aloud during answering a survey question, or retrospective (debriefing) when the interviewer asks about the respondent's experience and opinion after finishing the survey.

Paraphrasing also enables researchers to see whether respondents understand the questions and interpret as it is intended. This method can also elicit possible alternative wordings and help to develop better survey questions (30, 31).

Providing evidence of the comparability of new translations to the original is to examine cross-sectional and longitudinal correlations between translations and other measures of HRQoL. If correlations across countries are consistent, this would suggest that the new translations are measuring the same construct as the original. If results from clinical studies are consistent with other clinical indices across countries, this constitutes further evidence of the validity of the new translations (6, 28).

1.6. Special concerns about quality of life measures in pediatric populations.

Proxy problem

Children's conception about health is notably differs from that of adults. Health care interventions play much smaller part in their welfare than they do in older populations. There is much less agreement on the normal roles and functions of children at each age than there is for adults. Illness may be manifested by decelerations in the normal features rather than by evidence of abnormal function. Children with chronic diseases may have unique developmental sequences, and their life expectations can be quite different to those of other children (32). The subjectivism of quality of life gains a pronounced emphasis (23).

The assessment of quality of life in chronically ill children and adolescents has become increasingly important as the mortality rates associated with various chronic diseases have decreased and survival rates increased. Although medical intervention often results in the improved health status of pediatric patients, there is evidence to suggest that frequent hospitalizations, intrusive medical procedures, and uncertanity of survival, negatively impact childhood developement and adjustment (33). Consistently with the United Nations Convention on the Rights of the Child, there is a growing recognition that the views of the children should be sought with respect to decisions regarding their health (34). Therefore the measures of HRQoL should also reflect their views.

As studies have shown disagreement between the opinions of respondents, such as parents, nurses, physicians and children, others' information about children's HRQoL can not be considered sufficient (35, 36). Discrepancy between children's and their parents' judgments about quality of life is often cited in the literature. This lack of agreement among reporters of pediatric patients' functioning has been termed:"cross informant variance" (37). Children differ from adults in their understanding of health, the causes of illness, and their beliefs about how medications work. For all these reasons, we can not expect entire correlations between child and parent ratings. Parents are normally able to make accurate judgments on the illness' impact on the family, sibling relationships, and to a lesser extent school progress. Parents are less able to make judgments regarding symptom experience, peer relationships, or future worries.

This clearly underscores the need for pediatric patient self-report instruments with definitive measurement precision across the developmental stages of childhood and adolescence. According to an analysis of Pediatric Quality of Life Inventory™ children as young as 5 year old can reliably and validly self-report their HRQoL with an age-appropriate instrument (38).

Quality of life instruments for children should have the following properties:

Use an accepted, clear conceptualizaton of HRQoL

Its dimensions are acceptable for all children

Has parallel self- and parent proxy report forms

Dimensions with greater importance for children are emphasised

Has good psychometric properties

Gives equally acceptable values for the general and specific children populations

Developmental changes are taking into account – it has different forms for different age groups (39).

Parent proxy-report is also important beacause children are rarely in position to refer themselves for treatment, even when they are experiencing symptoms and health-related

problems, parents' perceptions of a child's HRQoL influences the likehood that health care will’be sought for the child. Parent proxy-report is necessary when the patient is unable or unwilling to complete the HRQoL measure because of young age or illness variables. Therefore the only solution is to regard both assessments as valid and contributing to the total picture regarding the child's quality of life (32).

1.7. Health related quality of life measures in pediatric cardiology

1.7.1. Effect of heart disease on HRQoL of children

Congenital heart diseases (CHD) present a special chronic condition from a number of aspects. These are the most frequent congenital anomalies. (39).

The birth prevalence of congenital heart diseases between 1971-1989 was 4,05 – 10,6‰, and 4,05-50,0‰ after 1989 according to the international literature (39-40). The higher rate of diagnosed congenital heart disease is due to the development in diagnostic techniques, especially to echocardiography.

The only epidemiologic study on congenital heart diseases in Hungary was performed by Mogyorósy et al. (41). The incidence of congenital heart diseases was evaluated in the period of 1994-1998 in Hajdú-Bihar county. For congenital heart disease 4,5 operations or interventional heart catheterizations were required /1000 live births, but this rate rised to 5,3/1000 taking account of cases died without surgery. This result corresponds well with that of Hoffman and Kaplan, who reported 6 therapeutic interventions for congenital heart disease per 1000 live births in the United States of America (39, 40).

There is a wide range of severity, from those with moderate clinical consequences to critical conditions that need intervention at birth, often with the requirement for multiple procedures. Progress in pediatric cardiology and pediatric cardiac surgery during the past decades has brought dramatic changes in the life expectancy of children with CHD. There are rarely untreatable cases any longer, with new surgical techniques providing surgical corrections for

previously palliative care cases and catheter interventions replacing some surgical procedures. Most of these characteristics are true not only for congenital heart defects but also for other types of heart diseases in children, such as acquired conditions (e. g. Kawasaki-syndrome) or those which have had no effective therapy (e. g. some cardiomyopathies). Certain new techniques in the therapy of arrhythmias (e.g. implantable cardioverter defibrillator) present solutions for previously untreatable situations.

These advances in survival rates have lead to concerns with the quality of long-term survivability. CHD patients are reaching adulthood in rapidly rising numbers, and face numerous problems in their daily lives.

According to the description made by Daliento et al the most critical phases in the life of a patient with congenital heart disease are the following:

Infancy: Cardiac surgery/frequent hospitalizations can cause interruption and/or modification of the relationship between child and parents. This is the onset of preschool physical activity limitations. Limiting the time the infant is separated from the parents to the surgical event and pain protection is essential. Psychosomatic support of the parents is often needed.

Childhood: Onset of school-learning difficulties. Psychosomatic integration of the child is needed.

Adolescence: Adolescence crisis, body image and sexuality. The importance of medical counselling usually increases, while parental controlling decreases.

Adult age: Questions about pregnancy, employment, insurability (42).

To gain information from a different point of view on the outcomes of this population quality of life measures has increasingly been addressed. This helps optimizing their clinical management, evaluating specific interventions and therapeutic modes.

Previous studies have investigated cardiac interventions from biological aspects (anatomic, hemodynamic, electrophysiologic sequelae, exercise capacity) or focused on specific HRQoL dimensions such as school function, neuropsychologic, cognitive status, participation in

activities in children, marital status, employment, health insurance coverage in adults (43-48). While standardized questionnaires that measure the patients' perspective have been used in research for decades, their length and complexity prevented their widespread use on the routine basis.

Although the extent of literature on quality of life measures in patients with heart disease is increasing continually, major conceptual and methodological drawbacks can be found.

Recent studies on QoL outcomes in children with CHD that were based on a multidimensional perspective were limited by small sample size and other methodologic issues, often relied on parental proxy-report of the child's QOoL, and reported health status or observed functional abilities at 12–14 years of age or focused on delineating developmental impairments at 15–17 years of age that may affect school functioning, a single dimension of QoL in children.

The interpretation of results is complicated when the investigators do not use a consistent conceptual basis to define quality of life. The term of quality of life is often used inappropriately; authors drew conclusions about patients' quality of life, even though it was not specifically measured. According to a review, performed by Moons and his study group in 2004 the poor conceptual and methodological basis used in quality of life studies in patients with congenital heart disease implies that many results are inconclusive (49-51). Need of a critical appraisal of the literature in this field remains essential.

1.7.2 Instruments developed for the measurement of HRQoL in pediatric cardiac populations

There are only a few studies which have been carried out in pediatric populations using a generic HRQoL instrument or a cardiac disease-specific instrument (21, 36, 48, 52, 53).

The first available disease specific instrument was the cardiac module of PedsQL™, which has the broadest age spectrum from 2-18 years of age for parent proxy-report, and from 5-18

years of age for child self-report form. The generic core scale and the numerous other diseases specific modules of PedsQL™ give the possibility to compare the HRQoL of children with heart disease to healthy peers and also with patients to other chronic conditions. Linguistic and cultural validation of PedsQL™ modules into many languages gives the opportunity of international, multicenter studies as well.

Results with PedsQL™ cardiac module demonstrate that approximately 20% of children with cardiovascular disease report significantly impaired psychosocial quality of life irrespective of the severity of the disease. As perceived by parents, worse physical and psychosocial QoL is related to more severe heart disease (21, 53).

Another instrument developed for the measurement of quality a life in this field is ConQol was developed using a child-centered philosophy, its items were derived from topics that children with heart disease considered important in determining their quality of life, and did not rely on views of experts, such as clinicians, psychologists or parents. ConQol has two versions, one for children aged from 8-11 years, and one for young people aged from 12-16 years. The correlations of ConQol scores with those of PedsQL™ cardiac module demonstrated good validity. ConQol index does not cover many cardiac-specific items of the PedsQ™L, such as experience with treatment or problems with medications, because children did not indicate these areas important in terms of their quality of life. The initial study with ConQol showed a trend towards young people reporting poorer quality of life. Complexity of heart disease was not a strong differentiator of quality of life, but there is not a universally agreed system for determining the severity of the disease (36).

The third remarkable instrument in this field is Pediatric Cardiac Quality of Life Inventory (PCQLI). The validity and reliability of Pediatric Cardiac Quality of Life Inventory was confirmed in a multicenter study, comparing the PCQLI scores with generic and disease-specific scores of PedsQL™, and with results of non-quality of life instruments. This instrument is developed to assess HRQoL in children with heart disease, aged 8-18 years. The

study result showed that lower HRQoL was associated with greater disease severity and medical care utilization, poorer patient self-perception and competency, and increased behavioral and emotional problems (54).

1.8. Introduction to the measurement model for the Pediatric Quality of Life Inventory™

The PedsQL™ Measurement Model is a modular approach to measure HRQoL for a wide age range of children and adolescents from 2 to 18 years of age. The PedsQL™ conceptualizes pediatric HRQoL as the patient's perceptions of the impact of disease and treatment in a variety of health and well-being domains.

Development of PedsQL™ is attached to J.W. Varni and his associates during the past 15 year. The PedsQL™ 1.0, originally derived from a pediatric cancer database, was designed as a generic quality of life inventory to be utilized noncategorically. The PedsQL™ 2.0 and 3.0 were further advancements in the measurement model, including additional constructs and items, a more sensitive scaling range, and a broader age range for patient self-report and parent proxy-report. PedsQL™Generic Core Scale 4.0 has been used since 2001, and the first study with PedsQL™Cardiac module 3.0 was puplished in 2008 (21,69).

The development, refinement and validation of the original instrument and linguistic validation to a number of European and other languages have been described in many papers (21, 53, 63-66). Results of research with disease-specific modules are available (19, 20, 21, 67, 68). Methodology of application and evaluation can be found in several previous presentations (20, 69). List of existing translations of the generic core scales and disease specific modules are avaible on the PedsQL™ web site (73).

The PedsQL™ generic module is a 23 item measure and takes less than 5 minutes to complete. The instrument certified good psychometric properties. The PedsQL™ generic core scales and condition-specific modules have demonstrated good internal consistency

reliability. Construct validity has been demonstrated for both item-level and scale-level analyses. Construct validity and known group validity and reliability has been confirmed in large samples of healthy and patient populations internationally (20, 70-72).

Clinical validity has been established by demonstrating that PedsQL™ scores distinguish between patients with different pediatric morbidities, and PedsQL™ scores are associated in the expected directions with the disease- and treatment related symptoms. The PedsQL™ generic core scales were designed to be used across various pediatric conditions. The PedsQL™ is continuously field tested in pediatric offices, hospitals, community settings, schools, as well as international field trials.

Missing data rates are generally about 0,001% of item responses, which means good practicality of the instrument.

2. Aims

2.1. General aims of the study

Patient-reported outcome (PRO) studies, including HRQoL studies have not appeared in Hungary until recent years, and were mainly carried out in adult populations (11, 55-60).

The dramatic progress in pediatric cardiology and pediatric cardiac surgery gives the opportunity for a significantly longer life for people with congenital heart disease, even with the greatest complexities, but data on HRQoL of patients with congenital heart diseases is wanting from European countries, and it has not been avaible from Hungary at all.

As the standards of care and results of medical care of children with heart disease in Hungary correspond to international recommendations, with very good biological prognosis, and because the incidence of psychosocial problems is even greater in the Hungarian general population than in other European countries we considered it important to assess the outcomes of Hungarian pediatric cardiology care from the patients' point of view (61, 62).

To realize a HRQoL study on Hungarian pediatric population with heart disease we found PedsQL™ to be the most appropriate method, as it has the broadest age spectrum, the most extent literature, proving good psychometric properties, and the availability of the generic core scale and numerous disease specific modules gives the opportunity of international comparison.

Consequently, the objective of the present study was to develop the Hungarian version of PedsQL™ cardiac module and test the Hungarian version of the PedsQL™ Generic Core Scales and Cardiac Module in a Hungarian pediatric cardiac disease sample.

2.2 Specific aims of the study

Provide data, suitable for international comparison, on health-related quality of life of Hungarian pediatric population.

Develop Hungarian version of a well validated, internationally widely used disease-specific instrument, to assess health-related quality of life of Hungarian pediatric population with heart disease.

Compare health-related quality of life of Hungarian children with heart disease with general pediatric population.

Compare health-related quality of life of children with different severity of heart disease, with that, of general Hungarian pediatric population.

Compare health-related quality of life of children with different severity of heart disease, with that of children with simple heart disease with generic and disease-specific instrument

Assess the consequence of therapeutic modalities on health-related quality of life in children with heart disease.

Compare data on health-related quality of life of Hungarian children with heart disease with results on U.S. patient sample.

3. Methods

3.1. Instrument

3.1.1. PedsQL™ 4.0 Generic Core Scales

The 23-item PedsQL™ 4.0 Generic Core Scales encompass:

Physical Functioning (8 items)

Emotional Functioning (5 items),

Social Functioning (5 items)

School Functioning (5 items).

It was developed through focus groups, cognitive interviews, pre-testing, and field testing measurement development protocols. Cognitive interviews were carried out with children attending the pediatric cardiology outpatient unit. Five children were chosen from each age group, with different severities of heart disease, from different places of residence. To get information on children without proven heart disease, interviews were performed with 4 children with innocent heart murmur.

The PedsQL™ 4.0 Generic Core Scales are comprised of parallel child self-report and parent proxy-report formats. Child self-report includes questionnaires for 5-7 (young child), 8-12 (child), and 13-18 (adolescent) years of age. Parent proxy-report includes ages 2-4 (toddler), 5-7, 8-12, and 13-18, and assesses parent's perceptions of their child's HRQoL. The items for each of the forms are essentially identical, differing in developmentally appropriate language, or first or third person tense. The instructions ask how much of a problem each item has been during the past one month. A 5-point response scale is utilized across child self-report for ages 8-18 and parent proxy-report (0 = never a problem; 1 = almost never a problem; 2 = sometimes a problem; 3 = often a problem; 4 = almost always a problem). To further increase the ease of use for the young child self-report (ages 5-7), the response scale is reworded and simplified to a 3-point scale (0 = not at all a problem; 2 = sometimes a problem; 4 = a lot of a problem), with each response choice anchored to a happy to sad face scale. Parent proxy-

report also includes the toddler age range (ages 2-4), which does not include a self-report form given developmental limitations on self-report for children younger than 5 years of age, and includes only 3 items for the school functioning scale.

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. If more than 50% of the items in the scale are missing, the Scale Score is not computed. In addition to the single scale scores there is the possibility to calculate summary scores: the Physical Health Summary Score is the same as the Physical Functioning Subscale, whereas to create the Psychosocial Health Summary Score, the mean is computed as the sum of the items divided by the number of items answered in the Emotional, Social, and School Functioning Subscales (20, 69, 73).

3.1.2. PedsQL ™ 3.0 Cardiac module

The PedsQL ™ 3.0 Cardiac Module consists of five scales related to symptoms (7 items), perceived physical appearance (3 items), treatment anxiety (4 items), cognitive problems (5 items) and communication (3 items) for child self-report ages 8-18 years, and parent proxy-report in all age groups. The communication scale was not included for toddlers and young children who lack the cognitive or linguistic ability to verbalize questions and explanations about the heart. An additional treatment barriers scale (5 items) measures the adherence issues in children taking cardiac medication (5 items) (21, 53).

3.2. Validation procedure

Validation of PedsQL™ generic core scales and condition-specific modules are carried out according to the instruction of the MAPI Research Institute, in accordance with the guidelines of the QOL-SIG TCA (Quality of Life – Special Interest Group Translation and Cultural Adaptation) group (74). The sequential validation procedure of the original U.S. version of

the PedsQL™ 3.0 Cardiac Module was carried out this way by our study group (6, 30, 31, 75).

The PedsQL™ 3.0 Cardiac Module was translated independently into Hungarian by two professional translators, native target language speakers, bilingual in the source language. The two translated versions of the questionnaires were discussed with both translator, a pediatric cardiologist, a pediatrician, a nurse in pediatric cardiology, and a teacher, and the final combined version was back translated into English. After review and comments by the instrument author, the new version was tested on 20 parents of children with heart disease aged 2-18 years and 15 children aged 5-18 years by cognitive interviews. Our study group has used concurrent and retrospective approach, and paraphrasing during the interviews. These interviews were performed to determine whether any questions were difficult to understand and/or irrelevant. After some modification on wording and proofreading, the final version was forwarded to the MAPI Research Institute, which gave the approval for the psychometric probe of the Hungarian PedsQL™ 3.0 Cardiac Module. The format, instructions, Likert response scale, and scoring method for the PedsQL™ 3.0 Cardiac Module are identical to the PedsQL™ 4.0 Generic Core Scales, with higher scores indicating better HRQoL (fewer symptoms or problems).

Our study group took part in the adaptation process for the PedsQL™ 3.0 Cardiac Module only; the Hungarian Generic Core Scale was already available through the MAPI Research Institute.

3.3. Participants and settings

Potential study subjects were recruited from the Pediatric Cardiology Outpatient Unit of the University of Debrecen Medical and Health Science Centre, Department of Pediatrics.

Participating families were given detailed written information about the methods, aims, and the voluntary nature of participation in the study. Subjects of the patient group filled in the

questionnaires in a room inside the outpatient clinic, while data collection from the comparison group was carried out through mail correspondence. Subjects of the patient group were excluded from participation if the child had associated non-cardiac chronic disease or major developmental disability, mental retardation that might affect health-related quality of life, and if the child was <2 months after surgical intervention. 38 children were excluded because the child had associated non-cardiac chronic disease or major developmental disability, severe mental retardation. The most frequent disorders were hematologic diseases, asthma bronchiale, diabetes mellitus, epilepsy, which were not results of any kind of heart diseases. Mild somatomental retardation, which was observable in some children with CHD of great complexity, could be a consequence of the heart disease, but these children were not excluded from the study. No children were excluded due to psychological problems. All the diagnoses of usual occurrence at a pediatric outpatient unit were represented in the patient sample. Patients with congenital heart disease were classified according to the guidelines set at the 32nd Bethesda Conference of the American College of Cardiology and they were categorized into three groups, namely simple congenital heart disease (such as isolated small or repaired atrial and septal defect without residua), congenital heart disease with moderate complexity (for example, coarctation of the aorta, moderate-to-severe pulmonary valvar disease or tetralogy of Fallot), and great complexity (such as double-outlet ventricle or conditions with conduits or after Fontan procedure) (76). Beside congenital heart defects the study sample included patients with cardiomyopathies, arrhythmias and acquired (such as carditis, Kawasaki syndrome) heart diseases.

Subjects of the comparison group were chosen by random selection from the general Hungarian population through the Population Register Office of the Ministry of the Interior, with distributional matching to the population treated at the pediatric cardiology outpatient unit on age, gender, and residence. Informed consent and child assent were obtained from the participating families.

The research protocol was approved by the Research Ethics Committee of The University of Debrecen.

3.4. Sample characteristics

The Hungarian translations of the PedsQL™ 4.0 Generic Core Scales and the PedsQL™ 3.0 Cardiac Module were administered to 195 children attending the cardiology outpatient unit aged 5-18 years and 254 parents of children aged 2-18 years. So we gathered information about health-related quality of life from 195 children by self- and proxy-report and 59 children by proxy-report only.

From the total investigated patient population (254) there were 59 (23,23 %)toddlers(2-4 years of age), 49 (19,29%) young children (5-7 years of age), 73 (28,74%) children (8-12 years of age) and 73 (28,74%) adolescents (13-18 years of age. Subjects included 148 boys (58,27 %) and 106 girls (41,73%).

It was the mother who answered the questionnaire in 92.52% of the patient sample, and it was the father in 7.48% of the sample. No parent in the patient group refused to participate in the study, 3 patients ages 5-7 years were unwilling to answer during the interview.

Of 1000 families approached by post, 525 families as subjects of the comparison group were recruited into the study (52.5%).

The response rate of the comparison group was acceptable for a postal survey according to the literature (77, 78).

In the comparison group there were 152 (28,95%) toddlers, 111 (21,14%) young children, 160 (30,48%) children and 102 (19,43%) adolescents. Subjects included 268 (51.05 %) boys and 215 (40.95%) girls and 42 (8%) of unknown gender.

It was the mother who answered the questionnaire in 89.5% of the sample, it was the father in 4.57% of the sample, and it was someone else in 6.28% of the sample.

Distribution of all participants in terms of gender and age group is shown in **Table 1**.

Distribution of patients into diagnostic groups by age groups is presented in **Table 2.**

Occurrence of certain diagnoses in the various diagnostic groups is shown in **Table 3.**

Our study ran its course from 2006. September till 2007. May.

3.5. Statistical analysis

Construct validity was determined using the known groups method. PedsQL™ Generic Core Scales scores were compared between groups differing in known health conditions. HRQoL scores of children from the general population and children with heart diseases were compared using t tests for independent samples. Effect sizes were evaluated using Cohen's d statistics (79). Construct validity of the Cardiac Module was further assessed by estimating the intercorrelations among the Cardiac Module scale scores and relevant Generic Core Scales scores.

Agreement between self-report and parent proxy-report was assessed using the Pearson correlation coefficient (with thresholds for medium and large correlation at 0.30 and 0.50, respectively), the intraclass correlation coefficient for absolute agreement (ICC, interpreted using thresholds for moderate and good agreement at 0.4 and 0.6, respectively) (80), Bland-Altman 95% limits of agreement (LOA) (77), and by evaluating parent vs. child mean score differences in paired t tests.

Feasibility of the Hungarian version of the Cardiac Module was determined from the average percentage of missing responses. The percentage of all possible item-responses left unanswered was calculated for each subject on each single and summary scale and averaged over subjects. The utility of the instruments in terms of distributional coverage overall and by subscale was evaluated by calculating the percentage of subscale-level average responses reaching the minimum (floor) or the maximum (ceiling) of the scoring scale.

Scale internal consistency reliability was determined by calculating Cronbach's coefficient α (24).

4. Results

4.1. Descriptive statistics

As evident from **Table 4.**, no floor effects were seen on the Generic Core Scales. We found ceiling effects both in child self- and parent proxy-reports ranging from a minimal 0.9 to a moderate 30.2% in the patient group and 2.1-31.7% in the comparison group, with highest values in the Social Functioning Scale for child self- and parent proxy-reports from the patient and comparison samples. We also observed greater ceiling (1.1-77. 9%) than floor effects (0.4-3.7%) in the Cardiac Module, with a notable ceiling effect in the Heart Symptoms scale and a moderate one in the Treatment II Scale, Perceived Physical Appearance, and Cognitive Problems Scales subscales for child self- and parent proxy-reports (**Table 5**.). Cronbach's coefficient estimates for the PedsQL™ Generic Core Scales and for the Cardiac Module across all ages of the patient and comparison groups are presented in **Tables 6.a**. and **Table 6.b**. The recommended standard of 0.70 for group comparison was exceeded in the majority of the scales, and all scales exceeded the satisfactory level of internal consistency reliability of at least 0.40.

Missing values were found for the patient group's Generic Core Scale (ranging 13.8-25.9%), with highest values in the school functioning domain both for both self- and parent proxy-reports, and in the Cardiac Module (ranging 0.5-66.2%) with highest values in the Treatment II Scale (problems with taking heart medicine) domain. The percentages of missing values (ranging 1.2 – 4.4%) in the comparison group were consistent with previous results (**Tables 4-5.**).

4.2. Construct validity

Assessing the construct validity of the PedsQL™ 4.0 Generic Core Scales, statistically significant difference was found between the patient group and the comparison group in

Physical Functioning Scale (p=0.003) scores of the child self-report for the Generic Core Scales. For parent proxy-reports, statistically significant difference was found in the Physical Functioning Scale (p=0.022), Emotional Functioning Scale (p=0.017), and Psychosocial summary score (p=0.019), and also in the Total Scale Score (p=0.034) **(Table 7.)**. Mean scores were consistently higher in the comparison group for all scales, with Cohen's d values indicating no other than small effects (range 0.02-0.31).

As the intercorrelations among the various Generic Core Scales and the Cardiac Module scales were estimated using Pearson correlation coefficients, a high correlation was found between the Physical Functioning Scale scores and Cardiac Symptoms Scale scores for children (r=0.63) and for parents (r=0.66). Cognitive Problems Scale scores of the Cardiac Module were highly correlated with the School Functioning Scale (self-reports r=0.57, proxy-reports r=0.60), the Psychosocial Summary scores (both reports r=0.58), and with the Total Scale Score (self-reports r=0.58, proxy-reports r=0.58) of the Generic Core Scale (**Table 8.**).

4.3. Parent-child agreement

Table 9. presents the ICCs between child self-reports and parent proxy-reports of the PedsQL™ 4.0 Generic Core Scales and the PedsQL™ 3.0 Cardiac Module. Moderate to good agreement was found in the Generic Core Scales of both the patient and comparison groups. ICCs were generally higher in the comparison group. Lower values were obtained in the Emotional and Social Functioning Scales across all age groups, and in the School Functioning Scale in 5-7 and 13-18 year-olds from the patient group. All ICCs showed good agreement in the comparison group, except for the Physical and Social Functioning Scale scores of children aged 5-7 years. ICCs for the Cardiac Module indicated similarly moderate to good agreement, with lower values for the Treatment II Scale, Perceived Physical Appearance Scale, and the Treatment Anxiety Scale in most age groups. Poor agreement was detected in the Perceived Physical Appearance Scale for the 5-7 year olds and in the Treatment II Scale for the 8-12

year olds. The ranges of LOA as calculated following the Bland-Altman procedure are consistent with the mainly moderate agreements between child self- and proxy-report scales. Neither the ICC nor the LOA values indicate any tendency of improvement in parent-child agreement as age advances.

4.4. Comparison of PedsQL™ Generic Core Scales scores of Hungarian children with heart disease with Hungarian general population data

For the PedsQL™ Generic Core Scales scores, a statistically significant difference between the entire patient group (not subdivided by severity of heart disease) and the general population for the child self-report was only found on the physical functioning subscale (p=0.0035). For the parent proxy-report, a statistically significant difference was found for the total PedsQL™ scale score (p=0.0189), and on the physical (p=0.0219), psychosocial functioning (p=0.0340) and emotional functioning (p=0.0171) subscales (**Table 10.a.,b**.).

No statistically significant differences were found for the parent proxy-report of toddlers (2-4 years) and teenagers (13-18 years) and for the child self-report of children (8-12 years) and teenagers (13-18 years). Statistically significant differences were observed for child self-reports of young children (5-7 years) in the PedsQL™ total scale score, physical, psychosocial, social and school functioning scores, and for the parent proxy-reports for the PedsQL™ total scale score, psychosocial, emotional and school functioning scores. Statistically significant differences for children (8-12 years) were observed for the parent proxy-report in the PedsQL™ total scale score and on the physical functioning subscale (**Table .11.**).

Comparing the PedsQL™ Generic Core Scales scores of the diagnostic groups with the general population, statistically significantly lower scores were observed for children with CHD of moderate and great complexity and for children with cardiomyopathy. For children with CHD of moderate complexity, a significantly lower social functioning score (p=0.0272)

was calculated from child self-reports, and lower total scale score (p=0.0039), physical (p=0.0033), psychosocial (p=0.00136) and social functioning subscale scores (p=0.0169) from parent proxy-reports. For children with CHD of great complexity, lower total scale score (0.0422), physical (p=0.0142) and social functioning subscale (p=0.0244) scores were seen in child self-reports and also lower psychosocial functioning scores in parent proxy-reports. For children with cardiomyopathy, the total scale score was significantly lower (p=0.0321) for child self-reports and the total scale score (p=0.0116), psychosocial (p=0.0014), emotional (p=0.0078), social (p=0.0061) and school functioning (p=0.00145) subscale scores for parent proxy-reports (**Table 10.a.b**.).

4.5. Comparing PedsQL™ scores of the different diagnostic groups and of patients with simple congenital heart disease

Comparing the scores of the PedsQL™ Generic Core Scales of the different diagnostic groups versus the scores of patients with simple congenital heart disease, we found statistically significant difference in total scale scores of patients with congenital heart disease with moderate (p=0.0338) and great complexity (p=0.0163) and in patients with cardiomyopathy (p=0.0308) according to parent proxy-reports. The physical functioning subscale scores were significantly lower in patients with great complexity by the opinion of the patients themselves (p= 0.0328) and also by the parents (p=0.0040) and in patients with moderate complexity by the opinion of the parents (p=0.0340). Significantly impaired psychosocial functioning was calculated for patients with CHD of great complexity (p=0.0475) and for patients with cardiomyopathy (p=0.0044) from the parent proxy-reports. Emotional functioning was observed to be negatively affected only in patients with cardiomyopathies (p=0.0494) by the opinion of the parents, while social functioning was significantly lower in patients with CHD of moderate (self: p=0.0059, proxy: p=0.0120) and great complexity (self: p=0.0113, proxy: p=0.0148) and patients with cardiomyopathies (self: p=0.0358 proxy: p=0.0160) according to

both self- and parent proxy-reports. School functioning was impaired by opinion of the parents among patients with CHD of great complexity (p=0.0326) and in patients with cardiomyopathies (p=0.0469) (**Table 12.a.b.).**

Significantly lower scores were obtained on the heart symptoms subscale of the cardiac module for patients with CHD of moderate and great complexity by the self- (p=0.0468, p=0.0273) and proxy-reports (p=0.0191, p=0.0203) as well. Parents of children of the ”Others” diagnostic group (children checked because of e.g., chest pain or innocent heart murmur) also reported significantly lower scores on the heart symptoms subscale (p=0.0052). The perceived physical appearance score was significantly higher in patients with cardiomyopathies (p=0.0070) by the opinion of parents. Correlating with the impaired school functioning we observed significantly lower cognitive functioning scores in patients with CHD of moderate (p=0.0150) and great complexity (p=0.0378) and in patients with cardiomyopathies (p=0.0316) according to the proxy-reports.Treatment anxiety –although without significancy- was found to be less expressed in children with CHD of great complexiy. (**Table 13.a.b.**).

4. 6. Differences in PedsQL™ scores by therapeutic modality

We analyzed the PedsQL™ Generic Core Scales and Cardiac Module scores across the patient groups with different therapeutic needs. (**Table 14.a**) Comparing the scores of children requiring no therapy with those who had cardiac intervention, the only significant difference is observed in the treatment anxiety subscale of the cardiac module where parents reported lower scores if their child had had an intervention. The need of taking heart medicine impacted the PedsQL™ total scale score (p<0.0090), the psychosocial (p<0.0032), social (p<0.0199) and school (p<0.0035) functioning scores of the Generic Core Scales according to the parents, and the perceived physical appearance (p<0.0432) subscale score of the Cardiac Module by the opinion of the children. Having had a cardiac intervention in addition to the

need for taking medication increased the number of domains impacted, as the physical functioning score ($p<0.0033$) of the Generic Core Scales was also lower according to parents. No influences on the PedsQL™ domains were observed comparing patients taking heart medicine versus patients with a cardiac intervention, but the perceived physical appearance subscale scores were significantly lower according to both children ($p<0.0080$) and parents ($p<0.0173$) if the former patient group was compared with those who have to take heart medication beside the intervention. Social functioning scores were significantly lower in children who had undergone intervention and were taking heart medicine by the opinion of the patients ($p=0.0198$) and their parents ($p=0.0179$) as well versus children only with an intervention, and the parents reported also impaired social functioning ($p=0,0008$) for this group in the comparison with children not needing any kind of therapy. **(Table 14.b.).**

4.7. Specific Concerns

Mean scores for items of PedsQL™ Generic Core Scales and Cardiac Module were ranked to identify the problems perceived most freqently by children with heart disease and their parents. The frequency of children and parents reporting ”often” and ”almost always” experiencing the problems with the lowest mean scores are presented in **Table 15.**

The most comon problems for the general dimensions of HRQoL were related to physical functioning according to the patients (hard to run, hard to do sports, hard to lift heavy things). On parent proxy-reports feeling angry was found to be the most frequent problem but parents reported common difficulty on physical functioning (hard to run) and on school functioning (paying attention in class) as well. For the disease-specific dimensions catching cold was the most frequent problem both for children and their parents. Children commonly felt difficulty to speak about their heart condition to others and they were frequently disturbed by their fast heartbeat. Parents reported on their child’s anxiety about going to the hospital and that their child’s communication with the medical staff was difficult for their children.

4.8. Comparing PedsQL™ data on Hungarian children with heart disease with results on a U.S. patient sample

Table 16. presents the comparison of the mean PedsQL™ scores of our entire patient sample with previous results from the PedsQL™ on U. S. children with heart disease. (21, 53)

In the study of Uzark et al. the investigated children were classified into the following categories: (1) mild CVD requiring no therapy or effectively treated nonoperatively (catheter therapy), (2) moderate CVD requiring no therapy or surgically corrected (curative), (3) surgically treated CVD (1 procedure) with significant residua or need for additional surgery, or (4) complex or severe CVD, uncorrectable or palliated (includes single ventricle). The patient population included 78 (16.4%) patients in category 1, 138 (29.1%) in category 2, 130 (27.4%) in category 3, and129 (27.2%) in category 4.

This means that the representation of congenital heart disease of great complexities was higher in this study population than that of in the patient group investigated by us.

For the Generic Core Scales significantly lower scores were observed for the Hungarian sample on the physical (p=0.0240) functioning subscales of self-reports and for the PedsQL™ total scale score (p=0.0150), physical (p=0.0009) and emotional (p=0.0002) functioning subscales of proxy-reports. The only significant difference among the disease-specific domains was in the heart symptoms subscale scores (p=0.0284) only by the opinion of parents.

5. Discussion

Our findings generally support the feasibility, reliability of the Hungarian translations of the PedsQL™ 4.0 Generic Core Scales and the PedsQL™ 3.0 Cardiac Modul to assess HRQoL of Hungarian children 2-18 years of age.

This first survey with PedsQL™ in Hungarian children with heart disease affirms the **construct validity** of the instrument in differentiating between healthy and chronically ill children and between patients with different levels of heart disease severity.

Perceived psychosocial functioning of Hungarian children 2-18 years of age with heart disease was found to be similar to that of their general population peers, but their physical functioning was significantly lower. In a previous study with PedsQL™ there were no significant differences in physical functioning between healthy children and a mixed sample of children with heart disease, but recent results with PedsQL™ showed impaired self-perceived physical functioning in children 5-18 years of age with increasing cardiac disease severity (21, 53). The physical functioning of Hungarian children with heart disease was observed to be worse also than that of the U.S. pediatric sample with heart disease by the opinion of children and parents as well.

Our finding could be a sign of poor physical state of Hungarian children with various levels of heart disease severity and it may reflect a general restrictive attitude of parents and health practitioners towards physical activities regardless of the severity of cardiac conditions. The parental underestimation of children's physical capacity coupled with overprotection leads to unnecessary limitation of social activities of chronically ill children resulting in poorer HRQoL (43, 46, 82). These findings emphasize the need for general actions in pediatric cardiology care in the field of physical activities. Cardiologists and pediatricians should help the patients and the families choose the proper kind of activity.

Although heart diseases from a medical point of view have influence primarily on physical states, the majority of HRQoL studies found expressed deficits in psychosocial dimensions (46, 83-85).

Lower psychosocial scores by the parents' opinion indicate the necessity of integration of psychosocial support in the care of chronically ill children and their families (21, 53).

Analyzing our data across the 4 age groups it is conspicuous that HRQoL of young children (5-7 years) is negatively affected by the illness through almost all HRQoL dimensions as perceived both by the children and their parents. The total HRQoL and physical functioning scores are significantly lower also in children 8-12 years of age according to the proxy-reports, but no further differences are observed in other age groups.

The reason why impairment is concentrated in the age group of young children may be that this is the time of entry into the community of other children, starting to go to nursery or school. This is when children with a chronic condition are faced for the first time with the stigmatization of being different. Besides awakening to the consciousness of their disease, this is often the period of reoperations which naturally can have expressed negative effects on HRQoL (86). A trend towards younger children reporting poorer quality of life was also observed by Macran et al. with the ConQol (36). These findings call attention to the need of support before and during first encounters with the peer community. This support should include detailed information given to the parents and the child about the disease and its potential associated problems. Detailed advice about physical activity is also essential for the family and also for the teachers. Results of previous studies indicate that children and their parents have limited knowledge of their cardiac condition, what they can and can not do, which makes it difficult to explain their condition to others (87-89).

An explanation for the lack of differences in HRQoL dimensions in children of 2-4 years of age according to the parents can be the relatively closed environment of the child and the family in this period, without the possibility of comparison to other children. Due to social

support this could be more expressed in Hungary. Owing to the dramatic development of pediatric cardiac surgery and cardiology, looking at the growing up of a ”healthy child” to all appearances after the shocking event of the birth of a critically ill baby can bring the family into an euphoric state, which can be another possible cause for the absence of perceived HRQoL impairment by the parents' during this period. Lower expectations of parents may lead to denial of physical or psychosocial problems (53). It is a limitation that parallel questioning was not performed in this age group. The need for parallel questioning of children and parents is obvious in HRQoL measures but in this age group it is not accomplishable. The poor agreement between child self-report and proxy-report on certain domains of HRQOL has already been demonstrated (32, 37, 90, 91).

The only significantly lower scores for children of 8-12 years were the PedsQL™ total scale score and the physical functioning score by the proxy-reports.

The discontinuance of HRQoL impairment to the older age groups may be a sign of good integration of children with heart disease into their society. Their capability and the effectiveness of coping mechanisms are often underestimated by clinicians, parents and teachers (89). Peers and teachers can have an important role, but they could also be sources of stress (92). It is important that there are systems within schools for ensuring that accurate information about children's health needs and impact of these on school life is passed to all those who teach the child (83).

The sample consisted of children with different severity of heart disease. The ratio of children with severe to those with simple heart diseases corresponded to the distribution of patients attending a typical pediatric cardiology outpatient unit. According to our and to previous results, overall quality of life of children with different severity of heart diseases – as a whole group – does not differ significantly from that of the general population (45). It means that the justification for stigmatization of heart disease, with its negative consequences, is strongly refuted by the children themselves. Thanks to the enormous advance in pediatric cardiac

surgery, most pediatric heart diseases can be resolved by interventions, ensuring good quality of life for children.

Corresponding to previous findings with PedsQL™ our data affirm the instrument's validity in differentiating between groups with different levels of chronic disease severity. Comparing the groups of different heart diseases with the general Hungarian population and with the group of children with simple CHD we could observe more impaired HRQoL functions in children with more severe heart disease. Lower physical and psychosocial scores, school and cognitive problems observed among children with the most severe diseases (CHD with moderate and great complexity and cardiomyopathies) show the necessity of identification of these problems in these patient groups to make early intervention programs possible. (43, 53) Similar to previous studies confirming an incremental decrease in psychosocial functioning with the severity of the disease, show the importance of psychosocial problems in children with chronic conditions, which has already been recognized as the "new hidden morbidity" (21, 47, 83 93, 94). The emotional (by parent-reports) functioning scores of Hungarian than U.S. children with heart disease stress the need for comprehensive pediatric cardiology care, which includes the involvement of experts in the psychosocial support of chronically ill children in Hungary (83-86)..

The fact that parents of children with moderate heart disease report lower physical functioning calls attention to the possibility that parents often underestimate their child's physical ability, imposing unnecessary restrictions on them and depriving them of the psychological benefits of exercise (43, 53). This can be related to the impaired social functioning in children with CHD of moderate complexity.

Analyzing our results of the disease specific Cardiac Module- in line with expectations- significantly lower scores were found on the heart symptoms subscale in patients with more severe CHD. Parents of children of the "Other" diagnostic group also reported significantly lower indices for this scale. It can be a consequence of the exaggeration of symptoms and of

unjustified fears about chest pain, which generally means heart disease in the adult population. The misinterpretation of this symptom and of heart murmurs can be countered by accurate information from the pediatric cardiologist (92). Perceived physical appearance score was significantly higher in patients with cardiomyopathies by parent opinion. This finding does not correspond with previous ones, as fears about the chronic condition and the need for continuous therapy can lead to decreased self-esteem in this patient group (89, 96). Correlating with the impaired school functioning we have observed significantly lower cognitive functioning scores in patients with CHD of moderate and great complexity and in patients with cardiomyopathies. These results are consistent with previous data and call attention to the need for early detection of school functioning deficits including attention problems and interventions for better neuropsychological development of these children (48, 83, 84). Treatment anxiety –although without significancy- was found to be less expressed in children with CHD of great complexiy. Regular visits and hospitalizations make these children get used to health-care interventions.

Analyzing our data with respect to various therapeutic needs, we could observe that parents reported negative affects in more HRQoL dimensions than children themselves, mainly if patient groups requiring heart medication were compared to those requiring no therapy at all or intervention only. Taking heart medication alone could negatively influence perceived physical appearance by the opinion of children. Treatment anxiety is more expressed according to the parents if their child had a cardiac intervention. Lower social functioning scores were obtained from self-reports, when the group requiring heart medication beside intervention was compared with the one requiring intervention only.

These findings indicate that the impact of health care interventions on children's life is overestimated by the parents, and taking medication has the most negative effect on HRQoL. In the exploration of health-related experiences of children with congenital heart disease, Birks et al found that medication was a problem only if it had an impact on school life (89).

The physical functioning of Hungarian children with heart disease was observed to be worse than that of the U.S. sample by the opinion of children and parents as well, which emphasizes the need for general actions in pediatric cardiology care in the field of physical activities. The expressed occurrence of items of physical functioning among the most frequently reported problems supports the weakness of physical ability of Hungarian children with heart disease. Cardiologists and pediatricians should help the patients and the families choose the proper kind of activity. Detailed information given to parents and teachers about the disease can help in stopping the serious restrictions rooting from the stigmatization surrounding heart disease.

The lower emotional (by the parent-reports) functioning scores stress the need for comprehensive pediatric cardiology care, which includes the involvement of experts in the psychosocial support of chronically ill children (46, 79, 83-85). The remarkably invariable scores of the disease specific dimensions indicate the children's similar attitudes to their illness and to its care. Comparison of a Hungarian nationwide population with a U.S. standard sample would improve the completeness of analysis of these differences.

The discordance between the children's and parents' answers – as parents reported impaired HRQoL functions in expressly more dimensions – has already been demonstrated (32, 38, 91, 95, 97). Since previous findings with the PedsQL™ has shown that children as young as 5 years old can reliably and validly self-report their HRQoL, results of self-reports and proxy-reports should be interpreted together according to the professional guidelines (32, 91, 95, 97, 98). Identification of differences between parents and older children may provide important insight into knowledge gaps or unrecognized psychosocial needs and supports the need to measure the perspectives of both child and parent (53).

Concordantly with these previous findings, our data on parent proxy-reports also showed significant differences in the Emotional Functioning Scale and the Psychosocial Summary Score, and in the Total Generic Core Scales Score. This observation may indicate the parental

underestimation of certain dimensions of HRQoL and the advanced levels of children's coping strategies (43, 97, 99).

The marked difference in missing values between the patient and the comparison group highlight the importance of situational circumstances at the time of the survey. In a medical institution, potential subjects tend to agree to participate much more willingly when asked by medical staff. On the other hand, patient and parent stress and time limitations could be factors that explain incompleteness of filling-in the questionnaire. In the postal survey of the comparison group, respondents' willingness was not influenced by any extraneous factors such as illness, fatigue and time limitations. Further, the general population was requested to only complete the Generic Core Scales, while the cardiac sample was additionally requested to complete the Cardiac Module, which may increase respondent burden.

For the Cardiac Module, extremely high frequencies of missing values were detected for the Treatment II Scale (taking heart medication) and in the Perceived Physical Appearance subscales. Although there is an instruction in the questionnaire to skip the Treatment II Scale if the child does not take heart medication, many respondents failed to take notice of it this instruction. A written or – when it is possible – verbal notice might induce more focused attention and decrease the bias due to missing values. By deleting the missing values from the Treatment II Scale from the calculations, missing value percentages for the total cardiac module decreased from 15.0% to 5.4% for child self-report, and from 14.6% to 4.8% for parent proxy-report. The high proportion of patients without surgical treatment could result in a similar augmentation for the Perceived Physical Appearance Scale. As Hungarian children under 7 do not attend school, and because the social support system allows schooling to be postponed for children with chronic conditions, an over-representation of pre-school respondents may have raised the missing value frequencies for the Cognitive Functioning Scale. Other European investigators also reported that the daycare or school functioning subscale is not applicable for children aged 2-7 years (38, 100).

Intercorrelations estimated by this study between generic core scales and cardiac module scales are consistent with the previous literature (21).

No (for Generic Core Scales) or minimal (for the Cardiac Module) floor effects and more accentuated ceiling effects for both scales means that distinction by the Hungarian translation of the instrument between persons who do extremely well or just well is less than excellent (19, 100-103). Child and parent scores from the comparison group showed stronger ceiling effects than those from the patient group, as would be expected. Highest values appearing on the Social Functioning Scale can also be a sign of the success of coping mechanisms or peer acceptance. The notable ceiling effect in the heart symptoms subscale of the Cardiac Module is understandable in a mixed population of children with different heart disease severity, where a considerable proportion of the sample do not have a severe condition which would be expected to influence markedly their daily lives. Moderate ceiling effects in the Treatment II, Perceived Physical Appearance, and Cognitive Problems Scales for child self- and parent proxy-report are also consistent with the diversity of disease severity of the studied population, with some patients not taking heart medicine and having had no cardiac intervention.

Consistently with previous findings, some lower internal consistency reliability values were calculated in younger age groups and for the Social and School Functioning Scales of the Generic Core Scales and for the Treatment II, Perceived Physical Appearance, and Cognitive Functioning Scales of the Cardiac Module, where small sample size could possibly compromise the precision of results (104, 105).

6. Conclusions

The first survey with PedsQL™ in Hungarian children with heart disease support the feasibility, reliability and validity of the Hungarian translation of PedsQL™ 4.0 Generic Core Scales and the PedsQL™ 3.0 Cardiac Module, but highlight the importance of situational settings during completion and the necessity of explicit instructions for several scales. Our results affirm the validity of the instrument in differentiating between healthy and chronically ill children and between patients with different levels of heart disease severity.

Hungarian patients of 2-18 years report significantly lower physical functioning than the general Hungarian child population and than U.S. children with heart disease. This observation emphasizes the need for proper informing of families and teachers regarding physical activity of children with any kind of heart disease. Corresponding to previous results, parents report lower HRQoL scores in more dimensions than their children do (38, 43, 95, 97).

Lower psychosocial scores by the parents' opinion indicate the necessity of integration of psychosocial support in the care of chronically ill children and their families. In the analyses of HRQoL scores of children with varied severities of heart disease, lower physical and psychosocial scores were observed among children with the most severe diseases (CHD with moderate and great complexity and cardiomyopathies). Parents reported lower emotional functioning, while children reported lower social functioning more often. School and cognitive problems were detected only among patients with CHD of great complexity and with cardiomyopathies. Therefore, identification of these problems is warranted in these patient groups to make early intervention programs possible (48, 53). The fact that deficits of the various HRQoL dimensions are focused in children 5-7 years of age shows the difficulties of chronically ill children during integration into society and the good coping mechanisms which resolve many of these problems by later ages.

Our data on groups with different therapeutic needs show that parents overestimate the effects of health care on their children's HRQoL. Heart medication alone can have a negative affect on perceived physical appearance, and intervention increases treatment anxiety by the opinion of children. Disease specific HRQoL scores of Hungarian children being similar to those of U.S. children, refers to some characteristics independent from the health care system and socio-economic status.

The results of this study, suitable for international comparison of children with heart disease in Hungary, highlight many questions about the effects of socioeconomic status of the population, of differences in standards of pediatric cardiology care, and of the customs and recommendations on physical activity for this population different from those in the U.S.A. or other countries with more experience in patient-reported outcome measurement. These questions could be answered by investigations on wider general and patient populations, exploring also the effects of socioeconomic factors influencing HRQoL.

Although the data from our study presents reasonable evidence for the psychometric properties of the Hungarian translation of the PedsQL™ 4.0 Generic Core Scales and PedsQL™ 3.0 Cardiac module for HRQoL studies in Hungarian children, future investigation with the instrument on larger samples of healthy children and on children with various levels of heart disease severity are recommended. Research focus should extend to other clinical populations, also testing sensitivity and responsiveness in longitudinal studies. The Hungarian translation of the PedsQL™ may further facilitate international comparisons and analysis of pediatric health care outcomes across countries (106).

Hopefully our study might stimulate this kind of research in Hungary and start the transition of health care of chronically ill children into a more comprehensive system. The wide international application of these measurements helps in improvement of health care by providing a better understanding of the function and effects of a diverse set of co-existing systems.

Hungarian patients of 2-18 years report significantly lower physical functioning than the general Hungarian child population and than U.S. children with heart disease. This observation emphasizes the need for proper informing of families and teachers regarding physical activity of children with any kind of heart disease. Corresponding to previous results, parents report lower HRQoL scores in more dimensions than their children do (38, 43, 95, 97).

Lower psychosocial scores by the parents' opinion indicate the necessity of integration of psychosocial support in the care of chronically ill children and their families.

7. Major findings of the thesis

Our results support the feasibility, reliability and validity of the Hungarian translation of PedsQL™ 4.0 Generic Core Scales and the PedsQL™ 3.0 Cardiac Module.

Measures with the Hungarian version of PedsQL™ 3.0 Cardiac Module will be suitable to provide data on the incidence and prevalence of health-related quality of life impairments in Hungarian children with heart disease.

Physical functioning of Hungarian children with heart disease significantly worse than that of the U.S. sample indicates a general restrictive attitude towards physical activities regardless of the severity of cardiac conditions. Choosing a physical activity adjusted to the type of heart disease, and proper information of parents and teachers give children the possibility to achieve a better quality of life.

Parental underestimation of children's physical ability with unnecessary restrictions causes impaired social functioning in children with CHD of moderate complexity.

Lower psychosocial scores by the parents' opinion, and lower than U.S. children's with heart disease stress the need of the involvement of psychosocial support of chronically ill children in Hungary.

Lower physical and psychosocial scores, school and cognitive problems observed among children with the most severe heart diseases show the necessity of identification of these problems to make early intervention programs possible.

Analyzing our data with respect to various therapeutic needs, we could observe that impact of health care interventions on children's life is overestimated by the parents.

Disease severity does not generally mean lower HRQoL.

Data suitable for international comparison give the possibility to assess the effect of differences in prevention, treatment and rehabilitation of children with heart disease.

Our study provides data for further measures on healthy population and on children with other chronic conditions.

Adjustment of HRQoL measures to health-care of chronically ill children can facilitate early intervention programs to decrease the negative consequences of the disease.

8. Summary

Background: The aim of quality of life measures is to give an entire picture about patients' health. Health-related quality of life (HRQOL) refers to the subjective and objective impact of dysfunction associated with an illness or injury, medical treatment, and health care policy. Congenital heart diseases (CHD) are the most frequent congenital anomalies. As the standards of care and results of medical care of children with heart disease in Hungary correspond to international recommendations, with very good biological prognosis, and because the incidence of psychosocial problems is even greater in the Hungarian general population than in other European countries we considered it important to assess the outcomes of Hungarian pediatric cardiology care from the patients' point of view. Aim: The first aim of our study was to develop the Hungarian version of PedsQL™ Cardiac Module and test the Hungarian version of the PedsQL™ Generic Core Scales and Cardiac Module in a Hungarian pediatric cardiac disease sample. The following objective of the study was to provide data, suitable for international comparison, on HRQOL of Hungarian pediatric population with heart disease; compare that with results of general pediatric population; compare HRQOL of children with different severity of heart disease, with that, of general Hungarian pediatric population; compare HRQOL of children with different severity of heart disease, with that of children with simple heart disease; assess the consequence of therapeutic modalities and compare our data with results on U.S. patient sample. Participants and settings: Subjects were recruited from the Pediatric Cardiology Outpatient Unit of the University of Debrecen Medical and Health Science Centre, Department of Pediatrics. The Hungarian translations of the PedsQL™ 4.0 Generic Core Scales and the PedsQL™ 3.0 Cardiac Module were administered to 195 children attending the cardiology outpatient unit aged 5-18 years and 254 parents of children aged 2-18 years. Results: This first survey with PedsQL™ in Hungarian children with heart disease affirms the construct validity of the instrument in differentiating between healthy and chronically ill children and between patients with different levels of heart disease

severity. Perceived psychosocial functioning of Hungarian children 2-18 years of age with heart disease was found to be similar to that of their general population peers, but their physical functioning was significantly lower. Lower psychosocial scores by the parents' opinion indicate the necessity of integration of psychosocial support in the care of chronically ill children and their families. HRQOL of young children (5-7 years) is negatively affected by the illness through almost all HRQOL dimensions as perceived both by the children and their parents. Comparing the groups of different heart diseases with the general Hungarian population and with the group of children with simple CHD we could observe more impaired HRQOL functions in children with more severe heart disease. Lower physical and psychosocial scores, school and cognitive problems were observed among children with the most severe diseases, but children with moderate heart disease reported lower physical functioning. Lower physical (by self- and proxy reports) and emotional (by parent-reports) functioning scores were obtained in Hungarian children than that of U.S. children with heart disease. Significantly lower scores were found on the heart symptoms subscale of the Cardiac Module in patients with more severe CHD and in parent-reports of children of the "Other" diagnostic group. Analyzing our data with respect to various therapeutic needs, we could observe that parents reported negative affects in more HRQOL dimensions than children themselves. Conclusion: Disease severity is not generally mean lower HRQOL. The impact of health care interventions and chronic disease on children's life is overestimated by the parents. Physical activity, adjusted to the type of heart disease, early identification of cognitive and psychosocial problems, with intervention programs, and proper information of parents and teachers give children the possibility to achieve a better quality of life.

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11. Appendix

11.1. Tables

Table 1. Sample characteristics by age and gender of the patient and comparison groups.

	Patient group						Comparison group							
	Total		Male		Female		Total		Male		Female		Unknown	
	N	%	N	%	N	%	N	%	N	%	N	%	N	%
Toddler (2-4 y)	59	23.23	34	23.29	25	24.27	152	28.95	81	30.22	63	29.30	8	19.05
Young child (5-7 y)	49	19.29	27	18.24	22	20.75	111	21.14	58	21.64	41	19.07	12	28.57
Child (8-12 y)	73	28.74	43	29.05	30	28.30	160	30.48	72	26.87	72	33.49	16	38.10
Adolescent (13-18 y)	73	28.74	44	29.73	29	27.36	102	19.43	57	21.27	39	18.14	6	14.29
All ages	254	100.00	148	58.27	106	41.73	525	100.00	268	51.05	215	40.95	42	8.00

Table 2. Distribution of patients into diagnostic groups by age groups.

Patient group	Total		Toddler (2-4 y)		Young child (5-7 y)		Child (8-12 y)		Adolescent (13-18 y)	
	N	%	N	%	N	%	N	%	N	%
Total	254	100	59	23.23	49	19.29	73	28.74	73	28.74
Simple CHD	113	44.49	30	50.85	22	44.9	29	39.73	32	44.44
CHD with moderate complexity	41	16.14	12	20.34	9	18.37	16	21.92	4	5.56
CHD with great complexity	23	9.06	3	5.08	5	10.2	8	10.96	7	9.72
Cardiomyopathies	15	5.91	0	0	1	2.04	7	9.59	7	9.72
Arrhythmias	16	6.29	5	8.47	6	12.24	1	1.37	4	5.56
Acquired	19	7.48	7	11.86	5	10.2	4	5.48	3	4.17
Others	27	10.63	2	3.39	1	2.04	8	10.96	15	20.83

Table 3. Occurrence of certain diagnoses in the various diagnostic groups

Diagnostic groups	Diagnosis	N	%	Diagnostic groups	Diagnosis	N	%
Simple CHD	Total	113	44.49	Cardio-myopathies	Total	15	5.91
	Atrial septal defect	34	30.09		DCM	8	53.33
	Ventricular septal defect	39	34.51		HCM	7	46.67
	Aortic stenosis	16	14.16	Arrhythmias	Total	16	6.29
	Aortic insufficiency	1	0.88		Pre-excitatory syndrome	4	25.00
	Mitral prolaps	23	20.35		Supraventricular tachycardia	3	18.75
					AVB III.	1	6.25
CHD with moderate complexity	Total	41	16.14	Aquired heart disease	RBBB	1	6.25
	Coarctation of the aorta	10	24.39		VES	4	25.00
	Patent ductus arteriosus	8	19.51		Ventricular tachycardia	2	12.50
	Tetralogy of Fallot	9	21.95		Atrial fluttern	1	6.25
	Atrioventricular septal defect	7	17.07		Total	19	7.48
	Ebstein amomaly	2	4.88		Kawasaki syndrome	10	52.63
	Pulmonary stenosis	3	7.32		Myocarditis	3	15.79
	Pulmonary insufficiency	1	2.44		Pericarditis	1	5.26
	PAPVC	1	2.44		Hypertension	1	5.26
CHD with great complexity	Total	23	9.06		Cardiac tumor	4	21.05
	Transposition of the great arteries	10	43.48	Others	Total	27	10.63
	Double outlet right ventricle	1	4.35		Innocent heart murmur	16	59.26
	Atresia of the pulmonary artery	4	17.39		Chest pain	7	25.93
	Truncus arteriosus communis	2	8.70		Unproved suspicion of hypertension	4	14.81
	Anomalous coronary artery	1	4.35				
	Univentricular heart	5	21.74				

Table 4. Scale descriptives, average missing item percentages skewness and Cohen's d values for the Pediatric Quality of Life Inventory™ 4.0 Generic Core Scales child self-report (195 patient and 373 comparison group subjects) and parent proxy-report (254 patient and 525 comparison group subjects), comparing the patient and comparison groups

	Patient group						Comparison group						
Scale	N	Mean	S.D.	Missing values (%)	Percent floor (%)	Percent ceiling (%)	N	Mean	S.D.	Missing values (%)	Percent floor (%)	Percent ceiling (%)	Cohen's d
Child Self-report													
Total Scale Score	164	76.86	14.64	14.30	0.00	0.00	366	79.33	12.35	2.00	0.00	2.50	0.19
Physical functioning	164	78.26	18.81	13.90	0.00	11.00	366	83.12	14.23	2.00	0.00	13.70	0.31
Psychosocial													0.09
functioning	164	76.09	14.47	14.50	0.00	3.00	366	77.29	13.39	2.10	0.00	3.00	
Emotional functioning	164	71.71	17.07	13.80	0.00	6.70	365	72.1	17.80	2.00	0.00	8.20	0.02
Social functioning	164	82.59	17.54	13.90	0.00	28.00	366	83.81	16.10	1.80	0.30	28.70	0.07
School functioning	160	73.94	16.82	15.80	0.00	7.50	364	75.84	16.65	2.30	0.00	10.70	0.11
Parent Proxy-report													
Total Scale Score	212	76.02	15.3	17.00	0.00	0.90	519	78.85	13.18	1.80	0.20	2.10	0.20
Physical functioning	212	77.66	18.73	15.30	0.00	14.60	519	81.03	15.88	1.30	0.20	13.10	0.20
Psychosocial													0.18
functioning	212	75.06	15.49	18.00	0.00	1.90	519	77.66	13.69	2.10	0.20	2.70	
Emotional functioning	212	68.45	18.06	15.00	0.00	5.20	519	71.79	16.76	1.20	0.20	7.50	0.20
Social functioning	212	82.13	19.68	15.30	0.00	30.20	518	84.45	16.31	1.50	0.20	31.70	0.13
School functioning	183	74.55	18.62	25.90	0.00	11.50	502	77.01	16.93	4.40	0.00	13.70	0.14

Table 5. Scale descriptives, average missing item percentages and skewness for the Pediatric Quality of Life Inventory™ 3.0 Cardiac Module child self-report (195 subjects) and parent proxy-report (254 subjects)

Cardiac module	N	Mean	S.D.	Missing values (%)	%Floor	%Ceiling
Child Self-report						
Total Scale Score	187	77.68	13.50	15.00	0.00	8.90
Heart problems-symptoms	191	76.42	17.08	0.50	0.00	66.30
Treatment II	83	93.19	13.09	66.20	0.00	39.50
Perceived physical appearance	172	83.14	19.45	9.90	1.60	37.20
Treatment anxiety	188	78.29	25.27	4.00	0.00	11.20
Cognitive problems	178	73.04	19.44	7.70	2.60	29.10
Communication	189	74.25	26.08	1.60	0.00	1.10
Parent Proxy-report						
Total Scale Score	251	76.19	14.62	14.60	0.00	7.90
Heart problems-symptoms	252	76.40	17.46	0.70	0.00	77.90
Treatment II	95	93.73	15.75	65.80	0.40	47.50
Appearance	223	82.83	23.00	11.60	1.20	24.80
Treatment anxiety	250	69.77	26.73	1.90	0.00	19.00
Cognitive problems	237	73.41	21.03	8.60	3.70	35.70
Communication	241	74.50	28.31	1.10	0.00	2.00

Table 6 a. Internal consistency reliability for Pediatric Quality of Life Inventory™ 4.0 Generic Core Scales child self-report and parent proxy-report

Scale	Total sample		Toddler (2-4y)		Young child (5-7y)		Child (8-12y)		Adolescent (13-18y)	
	Patient group	Comparison group	Patient group	Comparison group	Patient group	Comparison group	Patient group	Comparison group	Patient group	Comparison group
	Cronbach's α									
Child Self-report										
Total scale score	0.90	0.87			0.83	0.78	0.92	0.91	0.90	0.88
Physical functioning	0.82	0.75			0.67	0.62	0.89	0.80	0.79	0.80
Psychosocial f.	0.86	0.82			0.80	0.72	0.87	0.89	0.87	0.84
Emotional functioning	0.69	0.71			0.55	0.61	0.71	0.77	0.77	0.73
Social functioning	0.75	0.72			0.60	0.48	0.75	0.79	0.78	0.83
School functioning	0.68	0.68			0.59	0.51	0.66	0.78	0.74	0.74
Parent Proxy-report										
Total scale score	0.91	0.89	0.90	0.91	0.90	0.89	0.92	0.88	0.90	0.88
Physical functioning	0.84	0.82	0.86	0.87	0.76	0.78	0.87	0.80	0.82	0.82
Psychosocial f.	0.88	0.84	0.83	0.84	0.87	0.84	0.88	0.85	0.88	0.84
Emotional functioning	0.77	0.73	0.73	0.75	0.74	0.7	0.80	0.74	0.81	0.74
Social functioning	0.83	0.76	0.80	0.78	0.88	0.78	0.79	0.70	0.85	0.80
School functioning	0.75	0.71	0.59	0.43	0.74	0.70	0.79	0.74	0.70	0.75

Table 6 b. Internal consistency reliability for Pediatric Quality of Life Inventory™ 3.0 Cardiac Module child self-report and parent proxy-report

Scale	Total patient group	Toddler (2-4y)	Young child (5-y7)	Child (8-12y)	Adolescent (13-18y)
	Cronbach's α				
Child Self-report					
Total score	0.87		0.65	0.90	0.89
Heart problems-symptoms	0.75		0.58	0.77	0.81
Treatment II	0.64		0.50	0.56	0.73
Appearance	0.65		0.58	0.65	0.67
Treatment anxiety	0.89		0.92	0.87	0.89
Cognitive problems	0.72		0.60	0.76	0.78
Communication	0.76		0.75	0.74	0.83
Parent proxy-report					
Total score	0.89	0.70	0.70	0.89	0.91
Heart problems-symptoms	0.80	0.80	0.79	0.78	0.83
Treatment II	0.82	0.84	0.85	0.71	0.86
Appearance	0.73	0.54	0.49	0.73	0.72
Treatment anxiety	0.89	0.92	0.84	0.88	0.91
Cognitive problems	0.80	0.78	0.63	0.78	0.80
Communication	0.86	0.96	0.78	0.80	0.87

Table 7. Comparison of mean PedsQL™ Generic Core Scale scores of children of the entire patient group and of different diagnostic groups with those of controls.

Generic core scales	No. of items	Controls			Patients			
		N	Mean	S.D.	N	Mean	S.D.	p
Child Self-report								
Total	23	366	79.33	12.35	164	76.86	14.64	0.0610
Physical health	8	366	83.12	14.23	164	78.26	18.81	0.0035
Psychosocial health	15	366	77.29	13.39	164	76.09	14.47	0.3528
Emotional functioning	5	365	72.10	17.80	164	71.71	17.07	0.8135
Social functioning	5	366	83.81	16.10	164	82.59	17.54	0.4333
School functioning	5	364	75.84	16.65	160	73.94	16.82	0.2310
Parent Proxy-report								
Total	23	519	78.85	13.18	212	76.02	15.30	0.0189
Physical health	8	519	81.03	15.88	212	77.66	18.73	0.0219
Psychosocial health	15	519	77.66	13.69	212	75.06	15.49	0.0340
Emotional functioning	5	519	71.79	16.76	212	68.45	18.06	0.0171
Social functioning	5	518	84.45	16.31	212	82.13	19.68	0.1303
School functioning	5	502	77.01	16.93	183	74.55	18.62	0.1020

Table 8. Intercorrelations of subscales of the Pediatric Quality of Life Inventory™ Generic Core Scales and Cardiac Module assessed with Pearson correlation coefficient

	Cardiac module					
	Heart-problems-symptoms	Treatment II	Perc. Phys. appearance	Treatment anxiety	Cognitive problems	Communication
Generic core scales						
Child Self-report						
Total	0.5436	0.2739	0.4484	0.3904	0.5799	0.4629
Physical functioning	0.6250	0.2882	0.3523	0.3439	0.4616	0.4059
Psychosocial f.	0.4065	0.2279	0.4518	0.3684	0.5832	0.4380
Emotional functioning	0.3776	0.2409	0.4308	0.3766	0.4736	0.3796
Social functioning	0.3538	0.1314	0.3786	0.2749	0.4501	0.4054
School functioning	0.3218	0.2729	0.3495	0.2980	0.5732	0.3411
Parent Proxy-report						
Total	0.5728	0.4741	0.3971	0.3527	0.5746	0.4529
Physical functioning	0.6587	0.3311	0.3414	0.2911	0.4307	0.3630
Psychosocial f.	0.4318	0.4904	0.3754	0.3434	0.5833	0.4478
Emotional functioning	0.3274	0.4483	0.3858	0.3661	0.4062	0.3781
Social functioning	0.3177	0.3711	0.2766	0.2420	0.4421	0.3707
School functioning	0.4112	0.4252	0.2618	0.2172	0.6004	0.3700

Effect sizes are designated as small (0.10), medium (0.30) and large (0.50)

Table 9. Agreement between self-report and parent proxy-report Pediatric Quality of Life Inventory™ 4.0 Generic Core Scales and for the Pediatric Quality of Life Inventory™ 3.0 Cardiac Module scales

Scale	Intraclass correlation coefficients				Difference		
	5-7 y	8-12 y	13-18 y	All ages	Mean	p	LOA
Generic Core Scale Patient group							
Total	0.68	0.78	0.62	0.71	-1.28	0.161	-20.86; 23.42
Physical functioning	0.60	0.81	0.66	0.72	-1.01	0.360	-25.76; 27.77
Psychosocial f.	0.63	0.69	0.61	0.65	-1.45	0.152	-23.07; 25.96
Emotional functioning	0.47	0.56	0.50	0.52	-3.28	*0.020*	-30.75; 37.31
Social functioning	0.52	0.48	0.66	0.57	-0.86	0.529	-32.57; 34.30
School functioning	0.33	0.71	0.55	0.57	-0.48	0.722	-31.47; 32.43
Generic Core Scale Comparison group							
Total	0.73	0.75	0.75	0.74	-1.01	0.052	-16.86; 18.87
Physical functioning	0.53	0.63	0.74	0.64	-2.47	*0.001*	-22.72; 27.66
Psychosocial f.	0.75	0.78	0.73	0.76	-0.23	0.670	-18.25; 18.70
Emotional functioning	0.63	0.75	0.71	0.70	-1.14	0.146	-25.83; 28.10
Social functioning	0.54	0.73	0.63	0.66	0.62	0.416	-26.83; 25.60
School functioning	0.67	0.77	0.74	0.73	-0.08	0.906	-24.34; 24.51
Cardiac Module Patient group							
Heart problems-symptoms	0.73	0.84	0.71	0.77	-1.29	0.145	-21.57; 24.15
Treatment II.	0.47	0.39	0.65	0.54	-0.35	0.875	-32.44; 33.14
Appearance	0.18	0.55	0.58	0.53	-5.13	*0.004*	-36.83; 47.08
Treatment anxiety	0.59	0.46	0.61	0.55	-8.09	*0.000*	-39.01; 55.20
Cognitive problems	0.67	0.61	0.68	0.65	-2.88	*0.028*	-29.45; 35.21
Communication	0.70	0.69	0.54	0.64	-0.85	0.626	-44.23; 45.94

Negative signs in mean difference indicate proxy-report scores being lower; LOA = Bland-Altman 95% Limits of Agreement

Table 10.a. Comparison of mean PedsQL™ Generic Core Scale scores of children of the entire patient group and of different diagnostic groups with those of controls.

Generic core scales	No. of items	Controls			Patients				Simple CHD				CHD with moderate complexity				CHD with great complexity			
		N	Mean	S.D.	N	Mean	S.D.	p	N	Mean	SD	p	N	Median	Range	p	N	Median	Range	p
Self-report																				
Total	23	366	79.33	12.35	164	76.86	14.64	0.0610	70	78.75	12.62	0.7200	22	73.91	56.5-95.7	0.0937	16	69.57	26.1-96.7	0.0422
Physical functioning	8	366	83.12	14.23	164	78.26	18.81	0.0035	70	80.57	17.12	0.2447	22	81.25	53.1-100.0	0.0859	16	64.06	6.3-100.0	0.0142
Psychosocial functioning	15	366	77.29	13.39	164	76.09	14.47	0.3528	70	77.74	12.59	0.7950	22	74.17	46.7-96.7	0.1680	16	73.33	33.3-95.0	0.1128
Emotional functioning	5	365	72.10	17.80	164	71.71	17.07	0.8135	70	72.64	16.23	0.8138	22	72.50	40.0-100.0	0.5162	16	77.50	30.0-95.0	0.5530
Social functioning	5	366	83.81	16.10	164	82.59	17.54	0.4333	70	86.64	14.59	0.1723	22	75.00	30.0-100.0	0.0272	16	72.50	30.0-100.0	0.0244
School functioning	5	364	75.84	16.65	160	73.94	16.82	0.2310	68	73.82	16.09	0.3565	21	80.00	45.0-90.0	0.6774	16	70.00	35.0-95.0	0.1004
Proxy-report																				
Total	23	519	78.85	13.18	212	76.02	15.30	0.0189	93	77.86	13.35	0.5058	33	72.50	40.2-97.2	0.0039	19	68.48	27.2-95.8	0.0101
Physical functioning	8	519	81.03	15.88	212	77.66	18.73	0.0219	93	80.10	17.15	0.6077	33	75.00	18.8-100.0	0.0033	19	59.38	9.4-100.0	0.0025
Psychosocial functioning	15	519	77.66	13.69	212	75.06	15.49	0.0340	93	76.60	13.42	0.4907	33	73.33	36.7-95.0	0.0136	19	75.00	26.9-96.7	0.0297
Emotional functioning	5	519	71.79	16.76	212	68.45	18.06	0.0171	93	68.76	16.98	0.1096	33	70.00	40.0-90.0	0.0784	19	70.00	15.0-95.0	0.1333
Social functioning	5	518	84.45	16.31	212	82.13	19.68	0.1303	93	84.85	17.77	0.8300	33	80.00	35.0-100.0	0.0169	19	80.00	30.0-100.0	0.0149
School functioning	5	502	77.01	16.93	183	74.55	18.62	0.1020	80	76.69	17.76	0.8761	25	70.00	25.0-100.0	0.0593	16	65.00	35.0-100.0	0.0715

Table 10.b. Comparison of mean PedsQL™ Generic Core Scale scores of children of the entire patient group and of different diagnostic groups with those of controls.

Generic core scales	No. of items	Controls			Arrhythmias				Cardiomyopathies				Acquired heart diseases				Others			
		N	Mean	S.D.	N	Median	Range	p	N	Median	Range	p	N	Median	Range	p	N	Median	Range	p
Self-report																				
Total	23	366	79.33	12.35	14	87.50	54.4-97.8	0.2057	10	69.54	50.0-95.7	0.0321	10	78.26	55.4-95.7	0.4797	22	82.07	44.6-96.7	0.8658
Physical functioning	8	366	83.12	14.23	14	93.75	56.3-96.9	0.5058	10	75.00	25.0-100.0	0.1491	10	87.50	50.0-100.0	0.4178	22	82.81	40.6-100.0	0.3166
Psychosocial f.	15	366	77.29	13.39	14	86.67	53.3-100.0	0.1557	10	70.00	53.3-98.3	0.1241	10	75.83	56.7-93.3	0.5930	22	79.17	45.0-98.3	0.7519
Emotional functioning	5	365	72.10	17.8	14	82.50	45.0-100.0	0.5009	10	60.00	40.0-95.0	0.1567	10	80.00	45.0-90.0	0.7382	22	70.00	50.0-100.0	0.8714
Social functioning	5	366	83.81	16.1	14	95.00	65.0-100.0	0.1135	10	77.50	55.0-100.0	0.1308	10	80.00	60.0-100.0	0.4605	22	87.50	60.0-100.0	0.3896
School functioning	5	364	75.84	16.65	14	85.00	40.0-100.0	0.2204	10	70.00	55.0-100.0	0.4705	10	75.00	50.0-90.0	0.3642	21	75.00	20.0-100.0	0.8731
Proxy-report																				
Total	23	519	78.85	13.18	17	85.87	59.8-100.0	0.3289	10	68.35	54.0-95.7	0.0116	17	84.78	53.3-98.9	0.1673	23	80.43	46.7-94.6	0.9289
Physical functioning	8	519	81.03	15.88	17	93.75	59.4-100.0	0.4200	10	78.13	50.0-100.0	0.4137	17	90.63	59.4-100.0	0.0641	23	81.25	28.1-96.9	0.2789
Psychosocial f.	15	519	77.66	13.69	17	85.00	60.0-100.0	0.3775	10	64.58	45.0-93.3	0.0014	17	80.77	50.0-98.3	0.3828	23	81.67	55.8-96.7	0.5964
Emotional functioning	5	519	71.79	16.76	17	65.00	45.0-100.0	0.9904	10	55.00	20.0-80.0	0.0078	17	75.00	50.0-95.0	0.4371	23	70.00	40.0-100.0	0.8191
Social functioning	5	518	84.45	16.31	17	95.00	50.0-100.0	0.1902	10	70.00	25.0-100.0	0.0061	17	95.00	40.0-100.0	0.2170	23	90.00	60.0-100.0	0.3941
School functioning	5	502	77.01	16.93	14	77.50	45.0-100.0	0.7939	9	62.50	35.0-100.0	0.0245	17	75.00	50.0-100.0	0.8428	22	82.50	33.3-100.0	0.9114

Table 11. Comparison of mean PedsQL™ Generic Core Scale scores of children of the entire patient group with those of controls by age.

Scale	Patients				Controls			
	No. of items	N	Median	Range	N	Mean	S.D.	p
Toddler (2-4 y)								
Parent Proxy-report								
Total	21	47	82.14	43.3-98.8	150	79.34	15.09	0.7558
Physical functioning	8	47	87.50	18.8-100.0	150	80.86	18.11	0.7309
Psychosocial f.	13	47	80.77	47.7-98.1	150	78.43	15.04	0.8586
Emotional functioning	5	47	70.00	45.0-100.0	150	72.10	17.17	0.7734
Social functioning	5	47	90.00	40.0-100.0	149	84.12	17.45	0.5474
School functioning	3	28	83.33	25.0-100.0	137	80.29	17.32	0.7302
Young child (5-7)								
Child Self-report								
Total	23	38	70.65	45.7-95.7	109	79.20	11.17	0.0007
Physical functioning	8	38	79.69	25.0-100.0	109	84.26	12.97	0.0030
Psychosocial f.	15	38	70.00	43.3-100.0	109	76.50	12.44	0.0084
Emotional functioning	5	38	70.00	40.0-100.0	108	75.74	17.68	0.2397
Social functioning	5	38	70.00	30.0-100.0	109	78.35	15.06	0.0144
School functioning	5	36	70.00	30.0-100.0	108	75.19	16.72	0.0079
Parent Proxy-report								
Total	23	38	72.83	29.8-95.7	110	77.95	12.96	0.0108
Physical functioning	8	38	78.13	34.4-100.0	110	79.38	14.94	0.0924
Psychosocial f.	15	38	73.33	26.9-93.3	110	77.17	13.50	0.0058
Emotional functioning	5	38	62.50	15.0-90.0	110	72.68	16.15	0.0010
Social functioning	5	38	80.00	30.0-100.0	110	81.55	17.37	0.1222
School functioning	5	30	70.00	40.0-100.0	108	77.45	16.75	0.0439
Child (8-12 y)								
Child Self-report								
Total	23	63	80.43	26.1-96.7	157	79.47	13.49	0.2112
Physical functioning	8	63	81.25	6.3-100.0	157	82.32	14.83	0.0609
Psychosocial f.	15	63	80.00	33.3-96.7	157	77.94	14.66	0.6249
Emotional functioning	5	63	75.00	30.0-100.0	157	72.23	17.74	0.5086
Social functioning	5	63	90.00	30.0-100.0	157	84.39	16.51	0.8653
School functioning	5	62	80.00	35.0-100.0	157	77.20	17.28	0.6980
Proxy-report								
Total	23	64	76.09	27.2-97.8	159	78.30	12.23	0.0211
Physical functioning	8	64	75.00	9.4-100.0	159	81.44	14.66	0.0051
Psychosocial f.	15	64	75.00	31.7-96.7	159	76.61	13.23	0.0749
Emotional functioning	5	64	67.50	25.0-100.0	159	71.19	16.72	0.1513
Social functioning	5	64	85.00	20.0-100.0	159	83.72	14.85	0.1148
School functioning	5	63	70.00	25.0-100.0	158	74.84	16.92	0.2435
Teen (13-18 y)								
Self-report								
Total	23	63	83.70	44.6-98.9	100	79.23	11.82	0.6119
Physical functioning	8	63	84.38	40.6-100.0	100	83.15	14.62	0.7334
Psychosocial f.	15	63	80.00	41.7-100.0	100	77.14	12.31	0.3540
Emotional functioning	5	63	70.00	40.0-100.0	100	67.95	17.31	0.0754
Social functioning	5	63	95.00	30.0-100.0	100	88.85	14.82	0.8002
School functioning	5	62	75.00	20.0-100.0	99	74.42	15.53	0.5208
Proxy-report								
Total	23	63	82.61	40.9-100.0	100	79.99	11.80	0.5582
Physical functioning	8	63	81.25	28.1-100.0	100	82.45	15.22	0.5265
Psychosocial f.	15	63	78.33	39.3-100.0	100	78.71	12.47	0.6231
Emotional functioning	5	63	70.00	20.0-100.0	100	71.30	17.04	0.9080
Social functioning	5	63	95.00	25.0-100.0	100	89.30	14.69	0.2156
School functioning	5	62	80.00	35.0-100.0	99	75.43	16.06	0.7470

Higher values indicate better quality of life

Table 12.a. Comparison of mean PedsQL™ Generic Core Scale scores of children in different diagnostic groups with those of children with simple congenital heart disease.

Generic core scales	Simple CHD			CHD with moderate complexity				CHD with great complexity			
	N	Mean	SD	N	Median	Range	p	N	Median	Range	p
Self-report											
Total	70	78.75	12.62	22	73.91	56.5-95.7	0.1971	16	69.57	26.1-96.7	0.0554
Physical functioning	70	80.57	17.12	22	81.25	53.1-100.0	0.4829	16	64.06	6.3-100.0	0.0328
Psychosocial f.	70	77.74	12.59	22	74.17	46.7-96.7	0.1599	16	73.33	33.3-95.0	0.1045
Emotional functioning	70	72.64	16.23	22	72.50	40.0-100.0	0.4578	16	77.50	30.0-95.0	0.4947
Social functioning	70	86.64	14.59	22	75.00	30.0-100.0	0.0059	16	72.50	30.0-100.0	0.0113
School functioning	68	73.82	16.09	21	80.00	45.0-90.0	0.9063	16	70.00	35.0-95.0	0.2900
Proxy-report											
Total	93	77.86	13.35	33	72.50	40.2-97.2	0.0338	19	68.48	27.2-95.8	0.0163
Physical functioning	93	80.10	17.15	33	75.00	18.8-100.0	0.0340	19	59.38	9.4-100.0	0.0040
Psychosocial f.	93	76.60	13.42	33	73.33	36.7-95.0	0.0740	19	75.00	26.9-96.7	0.0475
Emotional functioning	93	68.76	16.98	33	70.00	40.0-90.0	0.5018	19	70.00	15.0-95.0	0.3083
Social functioning	93	84.85	17.77	33	80.00	35.0-100.0	0.0120	19	80.00	30.0-100.0	0.0148
School functioning	80	76.69	17.76	25	70.00	25.0-100.0	0.1352	16	65.00	35.0-100.0	0.0326

Table 12.b. Comparison of mean PedsQL™ Generic Core Scale scores of children in different diagnostic groups with those of children with simple congenital heart disease.

Generic core scales	Simple CHD			Arrhythmias				Cardiomyopathies				Acquired herat diseases				Others			
	N	Mean	SD	N	Median	Range	p	N	Median	Range	p	N	Median	Range	p	N	Median	Range	p
Self-report																			
Total	70	78.75	12.62	14	87.50	54.4-97.8	0.2015	10	69.54	50.0-95.7	0.0722	10	78.26	55.4-95.7	0.6072	22	82.07	44.6-96.7	0.9694
Physical functioning	70	80.57	17.12	14	93.75	56.3-96.9	0.3018	10	75.00	25.0-100.0	0.1196	10	87.50	50.0-100.0	0.8406	22	82.81	40.6-100.0	0.8840
Psychosocial f.	70	77.74	12.59	14	86.67	53.3-100.0	0.2149	10	70.00	53.3-98.3	0.1049	10	75.83	56.7-93.3	0.5191	22	79.17	45.0-98.3	0.8783
Emotional functioning	70	72.64	16.23	14	82.50	45.0-100.0	0.5708	10	60.00	40.0-95.0	0.1244	10	80.00	45.0-90.0	0.8021	22	70.00	50.0-100.0	0.9820
Social functioning	70	86.64	14.59	14	95.00	65.0-100.0	0.3304	10	77.50	55.0-100.0	0.0358	10	80.00	60.0-100.0	0.1858	22	87.50	60.0-100.0	0.9585
School functioning	68	73.82	16.09	14	85.00	40.0-100.0	0.1203	10	70.00	55.0-100.0	0.7349	10	75.00	50.0-90.0	0.6046	21	75.00	20.0-100.0	0.7319
Proxy-report																			
Total	93	77.86	13.35	17	85.87	59.8-100.0	0.2419	10	68.35	54.0-95.7	0.0308	17	84.78	53.3-98.9	0.1177	23	80.43	46.7-94.6	0.8099
Physical functioning	93	80.10	17.15	17	93.75	59.4-100.0	0.3637	10	78.13	50.0-100.0	0.5726	17	90.63	59.4-100.0	0.0632	23	81.25	28.1-96.9	0.4892
Psychosocial f.	93	76.60	13.42	17	85.00	60.0-100.0	0.2576	10	64.58	45.0-93.3	0.0044	17	80.77	50.0-98.3	0.2634	23	81.67	55.8-96.7	0.4001
Emotional functioning	93	68.76	16.98	17	65.00	45.0-100.0	0.4962	10	55.00	20.0-80.0	0.0494	17	75.00	50.0-95.0	0.1640	23	70.00	40.0-100.0	0.3384
Social functioning	93	84.85	17.77	17	95.00	50.0-100.0	0.2914	10	70.00	25.0-100.0	0.0160	17	95.00	40.0-100.0	0.3234	23	90.00	60.0-100.0	0.5202
School functioning	80	76.69	17.76	14	77.50	45.0-100.0	0.7679	9	62.50	35.0-100.0	0.0469	17	75.00	50.0-100.0	0.8091	22	82.50	33.3-100.0	0.8626

Higher values indicate better quality of life.

Table 13 a. Comparison of mean PedsQL™ Cardiac Module scores of children in different diagnostic groups with those of children with simple congenital heart disease.

Cardiac module	Simple CHD			CHD with moderate complexity				CHD with great complexity			
	N	mean	SD	N	mean	SD	p	N	mean	SD	p
Self-report											
Total	79	78.97	13.11	27	73.91	12.96	0.0855	19	73.34	20.14	0.2583
Heart problems-symptoms	82	80.10	13.67	28	73.98	14.58	0.0468	19	65.79	25.40	0.0273
Treatment	29	94.77	14.35	9	90.56	12.56	0.4349	14	95.24	5.62	0.8787
Perc. phys. appearance	71	83.69	19.49	24	83.33	18.22	0.9368	19	75.00	28.73	0.2262
Treatment anxiety	80	77.97	25.29	27	74.31	24.53	0.5139	19	86.84	23.19	0.1662
Cognitive problems	76	74.20	18.60	25	69.53	20.10	0.2883	19	64.45	22.98	0.0546
Communication	80	75.63	25.53	28	70.83	25.71	0.3946	19	63.16	33.94	0.0765
Proxy-report											
Total	112	78.48	13.49	41	72.06	13.52	0.0101	21	70.32	20.18	0.0880
Heart problems-symptoms	114	80.15	16.41	40	73.39	12.66	0.0191	21	67.01	23.17	0.0203
Treatment	35	97.10	10.12	18	97.78	7.12	0.8005	15	86.83	21.02	0.0890
Perc. phys. appearance	98	84.61	22.01	38	80.37	26.23	0.3417	21	75.40	26.55	0.0964
Treatment anxiety	112	70.87	26.78	41	61.08	29.36	0.0529	20	70.63	24.51	0.9703
Cognitive problems	107	76.42	19.49	38	67.06	21.84	0.0150	18	65.56	24.79	0.0378
Communication	107	75.55	28.44	39	71.58	31.74	0.4707	20	64.38	29.54	0.1115

Higher values indicate better quality of life.

Table 13 b. Comparison of mean PedsQL™ Cardiac Module scores of children in different diagnostic groups with those of children with simple congenital heart disease.

Cardiac module	Simple CHD			Arrhythmias				Cardiomyopathies				Acquired				Others			
	N	mean	SD	N	mean	SD	p	N	mean	SD	p	N	mean	SD	p	N	mean	SD	p
Self-report																			
Total	79	78.97	13.11	15	81.77	10.75	0.4386	11	77.39	12.51	0.7075	12	78.83	13.37	0.9726	24	78.11	10.41	0.7693
Heart problems-symptoms	82	80.10	13.67	15	80.71	17.22	0.8792	11	73.38	16.70	0.1394	12	80.36	17.06	0.9526	24	71.88	19.02	0.0576
Treatment	29	94.77	14.35	6	94.17	10.21	0.9234	11	87.58	19.44	0.2079	5	93.00	15.65	0.8028	9	93.89	9.93	0.8652
Perc. phys. appearance	71	83.69	19.49	15	84.44	16.02	0.8896	9	92.59	16.90	0.1949	10	90.00	17.92	0.3365	24	80.56	13.38	0.3854
Treatment anxiety	80	77.97	25.29	15	84.17	20.16	0.3724	11	73.86	32.93	0.6277	12	73.44	28.35	0.5703	24	77.86	25.80	0.9852
Cognitive problems	76	74.20	18.60	15	78.00	17.30	0.4668	8	70.63	16.57	0.6038	11	70.45	26.69	0.5572	24	78.68	15.39	0.2877
Communication	80	75.63	25.53	15	75.00	25.00	0.9301	11	74.24	26.99	0.8668	12	78.47	31.47	0.7283	24	79.86	17.53	0.3594
Proxy-report																			
Total	112	78.48	13.49	20	80.43	11.69	0.5452	11	74.94	14.08	0.4096	19	79.43	14.57	0.7795	26	71.80	15.48	0.0287
Heart problems-symptoms	114	80.15	16.41	20	80.54	15.52	0.9215	11	75.32	12.32	0.3444	19	81.39	10.49	0.6668	26	65.71	23.15	0.0051
Treatment	35	97.10	10.12	6	90.00	20.00	0.4305	10	80.33	28.04	0.0940	6	100.00	0.00	0.4914	5	100.00	0.00	0.5301
Perc. phys. appearance	98	84.61	22.01	18	83.80	24.67	0.8882	9	95.37	8.45	0.0070	14	88.10	22.34	0.5807	24	76.74	19.50	0.1115
Treatment anxiety	112	70.87	26.78	20	76.25	22.08	0.3982	11	76.14	18.71	0.5257	19	69.41	30.11	0.8295	26	69.47	26.77	0.8106
Cognitive problems	107	76.42	19.49	20	81.00	17.40	0.3290	9	61.39	24.66	0.0316	18	77.41	25.48	0.8494	26	70.26	16.76	0.1405
Communication	107	75.55	28.44	20	77.08	25.77	0.8232	10	71.67	23.64	0.6770	18	78.70	30.41	0.6676	26	77.56	24.01	0.7401

Higher values indicate better quality of life.

Table 14.a. Scale descriptives of PedsQL™ Generic Core Scale and Cardiac Module by therapeutic requirements.

Scale	0 Therapy			Heart medication			Intervention			Heart medication+Intervention		
	N	mean	SD	N	mean	SD	N	mean	SD	N	mean	SD
Generic Core Scales												
Self-report												
Total	69	78.38	13.12	44	76.07	14.92	15	79.50	12.20	36	73.80	17.70
Physical functioning	69	81.36	16.53	44	76.26	19.85	15	81.88	12.40	36	73.26	22.71
Psychosocial f.	69	76.74	13.57	44	75.98	14.69	15	78.24	13.07	36	74.07	16.65
Emotional functioning	69	72.32	15.73	44	71.36	18.53	15	68.00	18.69	36	72.50	17.51
Social functioning	69	84.28	16.30	44	82.39	16.05	15	88.67	11.87	36	77.08	22.15
School functioning	67	73.73	17.20	43	73.95	16.71	15	78.00	14.49	35	72.57	17.55
Proxy-report												
Total	95	79.89	13.08	49	73.67	13.87	25	77.18	13.82	43	69.48	19.48
Physical functioning	95	81.45	16.12	49	77.36	17.66	25	78.75	14.49	43	68.98	24.38
Psychosocial f.	95	78.93	13.13	49	71.65	14.96	25	76.20	14.89	43	69.72	18.94
Emotional functioning	95	70.84	16.45	49	65.94	18.23	25	69.40	18.05	43	65.47	20.93
Social functioning	95	87.22	15.90	49	79.29	20.41	25	84.55	15.54	43	72.73	24.56
School functioning	80	79.31	16.96	46	69.84	17.60	20	73.08	21.64	37	70.90	19.85
Cardiac module												
Self-report												
Total	69	76.86	12.90	58	78.69	12.37	17	77.09	14.23	43	77.87	15.80
Heart problems-symptoms	72	79.02	14.92	58	74.57	17.30	18	78.57	14.23	43	73.67	20.71
Treatment II.	0	.	.	48	92.12	15.23	0	.	.	35	94.67	9.43
Perc. phys. appearance	59	82.34	16.09	54	88.58	16.29	16	85.42	19.84	43	76.55	24.95
Treatment anxiety	70	75.63	26.20	58	78.23	26.63	17	76.10	23.72	43	83.58	22.29
Cognitive problems	66	74.31	17.99	53	73.74	20.29	17	73.82	23.62	42	69.83	19.09
Communication	71	74.53	26.42	57	72.51	26.58	18	75.93	25.23	43	75.39	25.97
Proxy-report												
Total	102	77.20	14.13	69	77.37	13.48	29	71.74	15.95	51	75.11	16.10
Heart problems-symptoms	104	78.23	17.13	69	76.09	16.82	28	75.89	14.86	51	73.39	20.12
Treatment II.	0	.	.	52	93.30	17.09	0	.	.	43	94.24	14.15
Perc. phys. appearance	81	85.80	20.93	64	85.68	20.28	27	82.25	25.78	51	74.84	26.33
Treatment anxiety	102	72.37	26.01	69	69.47	26.27	29	60.70	28.19	50	70.13	27.61
Cognitive problems	98	75.77	18.03	65	72.73	23.52	26	73.08	24.73	48	69.69	21.08
Communication	97	75.26	28.37	66	76.26	27.16	28	69.20	32.38	50	73.67	27.73

Table 14.b. Comparison of PedsQL™ Generic Core Scale and Cardiac Module scores by therapeutic requirements.

Scale	0 Th vs. Heart med.	0 Th. vs. Intervention	0 Th. vs. Heart med. + Int.	Heart med. vs. Int.	Heart med. vs. Heart med. + Int.	Int. vs. Heart med. + Int.
	p	p	p	p	p	p
Generic Core Scales						
Child Self-report						
Total	0.3873	0.7642	0.1758	0.4257	0.5352	0.2612
Physical functioning	0.1422	0.9098	0.0636	0.3091	0.5312	0.0892
Psychosocial health	0.7808	0.6974	0.3796	0.6006	0.5873	0.3926
Emotional functioning	0.7697	0.3543	0.9571	0.5471	0.7805	0.4160
Social functioning	0.5469	0.3270	0.0910	0.1704	0.2341	0.0198
School functioning	0.9468	0.3751	0.7487	0.4079	0.7234	0.2979
Parent Proxy-report						
Total	0.0090	0.3646	0.0022	0.3056	0.2444	0.0870
Physical functioning	0.1650	0.4489	0.0033	0.7354	0.0660	0.0421
Psychosocial f.	0.0032	0.3703	0.0053	0.2196	0.5853	0.1471
Emotional functioning	0.1051	0.7030	0.1055	0.4416	0.9069	0.4352
Social functioning	0.0199	0.4538	0.0008	0.2616	0.1658	0.0179
School functioning	0.0035	0.1685	0.0199	0.5235	0.7966	0.7026
Cardiac module						
Self-report						
Total	0.4204	0.9495	0.7149	0.6525	0.7701	0.8610
Heart problems-symptoms	0.1181	0.9091	0.1437	0.3758	0.8131	0.3637
Treatment II.					0.3508	
Perc. phys. appearance	0.0432	0.5217	0.1867	0.5188	0.0080	0.2068
Treatment anxiety	0.5789	0.9454	0.1007	0.7674	0.2885	0.2551
Cognitive problems	0.8729	0.9268	0.2213	0.9890	0.3407	0.5000
Communication	0.6695	0.8405	0.8661	0.6325	0.5902	0.9409
Proxy-report						
Total	0.9379	0.3646	0.4123	0.0772	0.4058	0.3686
Heart problems-symptoms	0.4193	0.5126	0.1214	0.9577	0.4261	0.5656
Treatment II.					0.7732	
Perc. phys. appearance	0.9711	0.4738	0.0091	0.4999	0.0173	0.2369
Treatment anxiety	0.4786	0.0385	0.0199	0.1431	0.8964	0.1510
Cognitive problems	0.3795	0.6074	0.0726	0.9503	0.4792	0.5366
Communication	0.8216	0.3368	0.7460	0.2793	0.6144	0.5224

Table 15. Specific concerns reported by patients and their parents

Generic Core Scale	%	Cardiac Module	%
Child self-report			
Hard to run	15.9	Catching colds easily	19.4
Hard to do sport activity or exercise	14.2	Telling others (nonmedical) about heart problem or surgery	17.6
Hard to lift something heavy	12.8	Fast heartbeat	15.7
Parent proxy-report			
Feeling angry	16.0	Catching colds easily	25.8
Hard to run	13.7	Getting anxious about going to the hospital	20.0
Paying attention in class	13.4	Asking the doctors or nurses questions	17.5

Percentage “often” or “almost” a problem.

Table 16. Comparison of PedsQL™ Generic Core Scale and Cardiac Module scores with previous data of Uzark, K. et al. (Progr. Pediatr. Cardiol., 2003, 18, 141-148.)

Scale	U.S. Sample			Hungarian sample			
	N	Mean	S.D.	N	Mean	S.D.	p
Generic Core Scales							
Child Self-report							
Total	250	77.47	14.51	164	76.86	14.64	0.6770
Physical functioning	250	82.28	15.68	164	78.26	18.81	0.0240
Psychosocial f.	250	74.88	16.10	164	76.09	14.47	0.4370
Emotional functioning	250	73.78	20.38	164	71.71	17.07	0.2650
Social functioning	250	78.74	19.52	164	82.59	17.54	0.0418
School functioning	249	72.09	19.01	160	73.94	16.82	0.3160
Proxy-report							
Total	344	79.44	16.50	212	76.02	15.30	0.0150
Physical functioning	344	83.11	18.73	212	77.66	18.73	0.0009
Psychosocial f.	343	77.36	17.27	212	75.06	15.49	0.1136
Emotional functioning	343	74.69	20.45	212	68.45	18.06	0.0002
Social functioning	343	82.52	20.11	212	82.13	19.68	0.8230
School functioning	296	73.09	20.35	183	74.55	18.62	0.4312
Cardiac module							
Self-report							
Total				187	77.68	13.50	
Heart problems-symptoms	248	76.02	17.03	191	76.42	17.08	0.8076
Treatment II.				83	93.19	13.09	
Perc. phys. appearance	239	79.34	25.33	172	83.14	19.45	0.0863
Treatment anxiety	247	82.26	22.20	188	78.29	25.27	0.0826
Cognitive problems	245	75.66	20.59	178	73.04	19.44	0.1867
Communication	217	78.84	23.00	189	74.25	26.08	0.0602
Proxy-report							
Total				251	76.19	14.62	
Heart problems-symptoms	343	79.60	17.62	252	76.40	17.46	0.0284
Treatment II.				95	93.73	15.75	
Perc. phys. appearance	336	82.90	22.96	223	82.83	23.00	0.9719
Treatment anxiety	338	71.24	28.84	250	69.77	26.73	0.5288
Cognitive problems	338	71.23	25.73	237	73.41	21.03	0.2655
Communication	273	74.59	26.76	241	74.50	28.31	0.9705

11.2. Hungarian version of PedsQL™ 3.0 Cardiac Module

Azonosító:_____

Dátum:_____

PedsQL™

Kardiológiai kérdőív

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2-4 ÉVES GYERMEKEK SZÜLŐI ÉRTÉKELÉSE

ÚTMUTATÓ

A szívrendellenességgel élő gyermekek sajátos gondokkal küzdhetnek. A következő oldalon olyan dolgok felsorolása található, amelyek gondot jelenthetnek **gyermeke** számára.
Minden pontnál karikázzon be egy választ annak megfelelően, hogy az **elmúlt EGY hónapban mekkora gondot** jelentett **gyermeke** számára az adott kérdés:

0 ha **soha** nem okoz gondot
1 ha **szinte soha** nem okoz gondot
2 ha **néha** gondot okoz
3 ha **gyakran** gondot okoz
4 ha **majdnem mindig** gondot okoz

Nincsenek helyes vagy helytelen válaszok.
Ha nem érti valamelyik kérdést, kérjen segítséget!

*Az elmúlt **EGY** hónapban mekkora **gondot** jelentettek gyermeke számára az alábbiak?*

SZÍVRENDELLENESSÉG ÉS KEZELÉS (*Okoz-e gondot…?*)	**Soha**	**Szinte soha**	**Néha**	**Gyakran**	**Majdnem mindig**
1. Kifullad amikor aktívan játszik vagy testmozgást végez.	0	1	2	3	4
2. Fáj vagy szorít a mellkasa amikor aktívan játszik vagy testmozgást végez.	0	1	2	3	4
3. Könnyen megfázik.	0	1	2	3	4
4. Szapora a szívverése.	0	1	2	3	4
5. Futáskor elkékül a szája.	0	1	2	3	4
6. Éjjel arra ébred, hogy alig kap levegőt.	0	1	2	3	4
7. Több pihenésre van szüksége, mint a barátainak.	0	1	2	3	4

Ha gyermeke jelenleg szed szívgyógyszert, válaszoljon az alábbi kérdésekre!
Ha nem, akkor ezeket hagyja ki, és folytassa a „Külső megjelenésről alkotott vélemény” résszel!

KEZELÉS II (*Okoz-e gondot…?*)	**Soha**	**Szinte soha**	**Néha**	**Gyakran**	**Majdnem mindig**
1. Nem hajlandó bevenni a szívgyógyszerét.	0	1	2	3	4
2. Gondot okoz neki bevenni a szívgyógyszerét.	0	1	2	3	4
3. Rosszul van a gyógyszerétől.	0	1	2	3	4

KÜLSŐ MEGJELENÉSRŐL ALKOTOTT VÉLEMÉNY (*Okoz-e gondot…?*)	**Soha**	**Szinte soha**	**Néha**	**Gyakran**	**Majdnem mindig**
1. Nem tartja magát szépnek.	0	1	2	3	4
2. Zavarja, ha mások látják rajta a hegeket.	0	1	2	3	4
3. Szégyelli magát, ha mások látják a testét.	0	1	2	3	4

*Az elmúlt **EGY** hónapban mekkora **gondot** jelentettek gyermeke számára az alábbiak?*

A KEZELÉST KÍSÉRŐ SZORONGÁS (*Okoz-e gondot…?*)	**Soha**	**Szinte soha**	**Néha**	**Gyakran**	**Majdnem mindig**
1. Félni szokott, amikor az orvosi vizsgálatra vár.	0	1	2	3	4
2. Félni szokott, ha orvoshoz kell mennie.	0	1	2	3	4
3. Félni szokott, ha kórházba kell mennie.	0	1	2	3	4
4. Félni szokott, ha orvosi kezelésre szorul.	0	1	2	3	4

KOGNITÍV PROBLÉMÁK (*Okoz-e gondot…?*)	**Soha**	**Szinte soha**	**Néha**	**Gyakran**	**Majdnem mindig**
1. Nem tudja eldönteni mit tegyen, ha valami zavarja.	0	1	2	3	4
2. Nehezen tud odafigyelni bármire.	0	1	2	3	4
3. Alig tud visszaemlékezni arra, amit felolvastak neki.	0	1	2	3	4

KOMMUNIKÁCIÓ (*Okoz-e gondot…?*)	**Soha**	**Szinte soha**	**Néha**	**Gyakran**	**Majdnem mindig**
1. Nehéz az orvosoknak, ápolóknak elmondania, hogy érzi magát.	0	1	2	3	4
2. Nehezen tesz fel kérdéseket az orvosoknak, ápolóknak .	0	1	2	3	4
3. Nehezen beszél másoknak a szívrendellenességéről.	0	1	2	3	4

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5-7 ÉVES KISGYERMEKEK ÖNÉRTÉKELÉSE

Instrukciók a kérdező számára:

Néhány kérdést fogok most feltenni neked olyan dolgokról, amelyek egyes gyerekek számára gondot jelenthetnek. Azt szeretném megtudni, hogy neked ezek mennyire jelentenek problémát, gondot a Te számodra.

Miközben olvassa a lehetséges változatokat, mutasson értelemszerűen a jelekre.

Ha <u>egyáltalán nem</u> jelent neked gondot, akkor mutass rá a mosolygós arcra!

Ha <u>néha</u> gondot jelent neked, akkor mutass rá a középső arcra!

Ha <u>gyakran</u> jelent gondot neked, akkor mutass rá a szomorú arcra!

Felolvasom a kérdéseket. Mutass rá arra az arcra, amelyik mutatja, hogy mekkora gondot jelent neked az amit kérdezek. Először próbáljuk ki!

	Egyáltalán nem	Néha	Gyakran
Nehezen tudsz csettinteni az ujjaiddal?	☺		

Annak megítélésére, hogy a gyermek helyesen válaszolt-e a kérdésre, kérje meg, hogy csettintsen az ujjaival. Ismételje meg a kérdést, ha a gyermek válasza különbözik attól, ahogy végrehajtja a feladatot!

Gondold végig, hogy hogyan érezted magad az elmúlt néhány hétben! Figyelmesen hallgasd végig a kérdéseket és mondd meg, hogy mekkora gondot jelent neked az, amit kérdezek!

Miután felolvasott egy kérdést mutasson az arcok felé! Ha a gyermek bizonytalan vagy úgy tűnik, nem érti a kérdést, ismételje meg a válaszlehetőségeket miközben a megfelelő arcra mutat!

SZÍVRENDELLENESSÉG ÉS KEZELÉS (*Okoz-e gondot…?*)	**Egyáltalán nem/soha**	**Néha**	**Gyakran**
1. Kifulladsz, amikor sportolsz vagy gyorsan vagy lépcsőn mész?	0	2	4
2. Fáj a mellkasod, amikor sportolsz vagy gyorsan mész a lépcsőn?	0	2	4
3. Gyakrabban fázol meg, mint más gyerekek?	0	2	4
4. Szokott a szíved gyorsan verni?	0	2	4
5. Szokták mások mondani, hogy futáskor elkékül a szád?	0	2	4
6. Szoktál arra ébredni éjjel, hogy alig kapsz levegőt?	0	2	4
7. Több pihenésre van szükséged, mint a barátaidnak?	0	2	4

Ha jelenleg szedsz szívgyógyszert, válaszolj az alábbi kérdésekre!
Ha nem, akkor ezeket hagyd ki, és folytasd a „Külső megjelenésről alkotott vélemény” résszel!

KEZELÉS II (*Okoz-e gondot…?*)	**Egyáltalán nem/soha**	**Néha**	**Gyakran**
1. Szoktál olyat ondani, hogy nem akarod bevenni a gyógyszeredet?	0	2	4
2. Nehéz bevenni a gyógyszeredet?	0	2	4
3. Rosszul vagy a gyógyszeredtől?	0	2	4

KÜLSŐ MEGJELENÉSRŐL ALKOTOTT VÉLEMÉNY (*Okoz-e gondot…?*)	**Egyáltalán nem/soha**	**Néha**	**Gyakran**
1. Nem tartod magad szépnek?	0	2	4
2. Nem szereted, ha mások látják a hegeidet?	0	2	4
3. A többi gyerek csúfol, ha látják a hegeidet?	0	2	4

A KEZELÉST KÍSÉRŐ SZORONGÁS (*Okoz-e gondot…?*)	**Egyáltalán nem/soha**	**Néha**	**Gyakran**
1. Szoktál félni, amikor az orvosra várakozol?	0	2	4
2. Szoktál félni, ha orvoshoz kell menned?	0	2	4
3. Szoktál félni, ha kórházba kell menned?	0	2	4
4. Szoktál félni, amikor a szívedet vizsgálják?	0	2	4

Gondold végig, hogy hogyan érezted magad az elmúlt néhány hétben! Figyelmesen hallgasd végig a kérdéseket és mondd meg nekem, hogy mekkora gondot jelent neked az, amit kérdezek!.

KOGNITÍV PROBLÉMÁK (*Okoz-e gondot…?*)	**Egyáltalán nem/soha**	**Néha**	**Gyakran**
1. Nehezen tudod eldönteni, hogy mit csinálj, ha zavar valami?	0	2	4
2. A számok vagy a számtani feladatok nehezek a számodra?	0	2	4
3. Nehezen tudsz betűket vagy a szavak leírni?	0	2	4
4. Nehezen tudsz a tanárra vagy az óvónénire figyelni?	0	2	4
5. Nehezen tudsz visszaemlékezni arra, amit felolvastak neked?	0	2	4

KOMMUNIKÁCIÓ (*Okoz-e gondot…?*)	**Egyáltalán nem/soha**	**Néha**	**Gyakran**
1. Nehéz elmondanod az orvosoknak és ápolóknak, hogy érzed magad?	0	2	4
2. Nehezen tudsz megkérdezni bármit az orvosoktól és ápolóktól?	0	2	4
3. Nehéz elmagyarázni másoknak a szívproblémádat?	0	2	4

Azonosító:_____

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5-7 ÉVES GYERMEKEK SZÜLŐI ÉRTÉKELÉSE

ÚTMUTATÓ

A szívrendellenességgel élő gyermekek sajátos gondokkal küzdhetnek. A következő oldalon olyan dolgok felsorolása található, amelyek gondot jelenthetnek **gyermeke** számára.
Minden pontnál karikázzon be egy választ annak megfelelően, hogy az **elmúlt EGY hónapban mekkora gondot** jelentett **gyermeke** számára az adott kérdés:

0 ha **soha** nem okoz gondot
1 ha **szinte soha** nem okoz gondot
2 ha **néha** gondot okoz
3 ha **gyakran** gondot okoz
4 ha **majdnem mindig** gondot okoz

Nincsenek helyes vagy helytelen válaszok.
Ha nem érti valamelyik kérdést, kérjen segítséget!

*Az elmúlt **EGY** hónapban mekkora **gondot** jelentettek gyermeke számára az alábbiak?*

SZÍVRENDELLENESSÉG ÉS KEZELÉS (*Okoz-e gondot…?*)	**Soha**	**Szinte soha**	**Néha**	**Gyakran**	**Majdnem mindig**
1. Kifullad amikor sportol vagy testmozgást végez.	0	1	2	3	4
2. Fáj vagy szorít a mellkasa amikor sportol vagy testmozgást végez.	0	1	2	3	4
3. Könnyen megfázik.	0	1	2	3	4
4. Szapora a szívverése	0	1	2	3	4
5. Futáskor elkékül a szája.	0	1	2	3	4
6. Éjjel arra ébred, hogy alig kap levegőt.	0	1	2	3	4
7. Több pihenésre van szüksége, mint a barátainak.	0	1	2	3	4

Ha gyermeke jelenleg szed szívgyógyszert, válaszoljon az alábbi kérdésekre!
Ha nem, akkor ezeket hagyja ki, és folytassa a „Külső megjelenésről alkotott vélemény” résszel!

KEZELÉS II (*Okoz-e gondot…?*)	**Soha**	**Szinte soha**	**Néha**	**Gyakran**	**Majdnem mindig**
1. Nem hajlandó beszedni a szívgyógyszerét.	0	1	2	3	4
2. Gondot okoz neki bevenni a szívgyógyszerét.	0	1	2	3	4
3. Rosszul van a szívgyógyszerétől.	0	1	2	3	4

KÜLSŐ MEGJELENÉSRŐL ALKOTOTT VÉLEMÉNY (*Okoz-e gondot…?*)	**Soha**	**Szinte soha**	**Néha**	**Gyakran**	**Majdnem mindig**
1. Nem tartja magát szépnek.	0	1	2	3	4
2. Nem szereti, ha mások látják a hegeit.	0	1	2	3	4
3. A többi gyerek csúfolja ha látják rajta a hegeket.	0	1	2	3	4

*Az elmúlt **EGY** hónapban mekkora **gondot** jelentettek gyermeke számára az alábbiak?*

A KEZELÉST KÍSÉRŐ SZORONGÁS (*Okoz-e gondot…?*)	**Soha**	**Szinte soha**	**Néha**	**Gyakran**	**Majdnem mindig**
1. Félni szokott, amikor az orvosra vár.	0	1	2	3	4
2. Félni szokott, ha orvoshoz kell mennie.	0	1	2	3	4
3. Félni szokott, ha kórházba kell mennie.	0	1	2	3	4
4. Félni szokott, ha orvosi kezelést kell kapnia.	0	1	2	3	4

KOGNITÍV PROBLÉMÁK (*Okoz-e gondot…?*)	**Soha**	**Szinte soha**	**Néha**	**Gyakran**	**Majdnem mindig**
1. Nem tudja eldönteni mit tegyen, ha valami zavarja.	0	1	2	3	4
2. Gondjai vannak a számokkal illetve a matematikai feladatokkal.	0	1	2	3	4
3. Nehezen ír betűket, szavakat.	0	1	2	3	4
4. Nehezen tud odafigyelni bármire.	0	1	2	3	4
5. Alig tud visszaemlékezni arra, amit olvastak neki..	0	1	2	3	4

KOMMUNIKÁCIÓ (*Okoz-e gondot…?*)	**Soha**	**Szinte soha**	**Néha**	**Gyakran**	**Majdnem mindig**
1. Nehéz az orvosoknak és ápolóknak elmondania hogy érzi magát.	0	1	2	3	4
2. Nehezen tesz fel kérdést az orvosoknak és ápolóknak.	0	1	2	3	4
3. Nehezen beszél másoknak a szívrendellenességéről.	0	1	2	3	4

Azonosító:_____

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8-12 ÉVES GYERMEKEK ÖNÉRTÉKELÉSE

ÚTMUTATÓ

A szívrendellenességgel élő gyerekek sajátos gondokkal küzdhetnek.
Minden pontnál karikázz be egy választ annak megfelelően, hogy az **elmúlt EGY hónapban mekkora gondot** jelentett neked az adott kérdés:

0 ha **soha** nem okoz gondot
1 ha **szinte soha** nem okoz gondot
2 ha **néha** gondot okoz
3 ha **gyakran** gondot okoz
4 ha **majdnem mindig** gondot okoz

Nincsenek helyes vagy helytelen válaszok.
Ha nem érted valamelyik kérdést, kérj segítséget!

*Az elmúlt **EGY** hónapban mekkora **gondot** jelentettek neked az alábbiak?*

SZÍVRENDELLENESSÉG ÉS KEZELÉS (*Okoz-e gondot…?*)	**Soha**	**Szinte soha**	**Néha**	**Gyakran**	**Majdnem mindig**
1. Kifulladok amikor sportolok vagy testmozgást végzek.	0	1	2	3	4
2. Fáj vagy szorít a mellkasom amikor sportolok vagy testmozgást végzek.	0	1	2	3	4
3. Könnyen megfázom.	0	1	2	3	4
4. Szapora a szívverésem.	0	1	2	3	4
5. Futáskor elkékül a szám.	0	1	2	3	4
6. Éjjel arra ébredek, hogy alig kapok levegőt.	0	1	2	3	4
7. Több pihenésre van szükségem, mint a barátaimnak.	0	1	2	3	4

Ha jelenleg szedsz szívgyógyszert, válaszolj az alábbi kérdésekre!
Ha nem, akkor ezeket hagyd ki és folytasd a „Külső megjelenésről alkotott vélemény” résszel!

KEZELÉS II (*Okoz-e gondot…?*)	**Soha**	**Szinte soha**	**Néha**	**Gyakran**	**Majdnem mindig**
1. Nem vagyok hajlandó beszedni a szívgyógyszerem.	0	1	2	3	4
2. Nehezemre esik bevenni a szívgyógyszerem.	0	1	2	3	4
3. Elfelejtem bevenni a szívgyógyszerem.	0	1	2	3	4
4. Rosszul vagyok a szívgyógyszeremtől.	0	1	2	3	4
5. Tartok attól, hogy a gyógyszereim árthatnak nekem.	0	1	2	3	4

KÜLSŐ MEGJELENÉSRŐL ALKOTOTT VÉLEMÉNY (*Okoz-e gondot…?*)	**Soha**	**Szinte soha**	**Néha**	**Gyakran**	**Majdnem mindig**
1. Nem tartom magam helyesnek.	0	1	2	3	4
2. Nem szeretem, ha mások látják rajtam a hegeket.	0	1	2	3	4
3. Szégyellem magam, ha mások látják a testemet.	0	1	2	3	4

*Az elmúlt **EGY** hónapban mekkora **gondot** jelentettek neked az alábbiak?*

A KEZELÉST KÍSÉRŐ SZORONGÁS (*Okoz-e gondot…?*)	**Soha**	**Szinte soha**	**Néha**	**Gyakran**	**Majdnem mindig**
1. Félni szoktam az orvosra való várakozás közben.	0	1	2	3	4
2. Félni szoktam, ha orvoshoz kell mennem.	0	1	2	3	4
3. Félni szoktam, ha kórházba kell mennem.	0	1	2	3	4
4. Félni szoktam, ha orvosi kezelést kell kapnom.	0	1	2	3	4

KOGNITÍV PROBLÉMÁK (*Okoz-e gondot…?*)	**Soha**	**Szinte soha**	**Néha**	**Gyakran**	**Majdnem mindig**
1. Nehezen tudom eldönteni mit tegyek, ha valami zavar.	0	1	2	3	4
2. Nehezen oldok meg matematikai feladatokat.	0	1	2	3	4
3. Gondot okoz iskolai fogalmazások megírása.	0	1	2	3	4
4. Nehezen tudok odafigyelni bármire.	0	1	2	3	4
5. Alig tudok visszaemlékezni arra, hogy mit olvastam.	0	1	2	3	4

KOMMUNIKÁCIÓ (*Okoz-e gondot…?*)	**Soha**	**Szinte soha**	**Néha**	**Gyakran**	**Majdnem mindig**
1. Nehéz az orvosoknak és ápolóknak elmondanom hogy érzem magam.	0	1	2	3	4
2. Nehezen teszek fel kérdést az orvosoknak és ápolóknak.	0	1	2	3	4
3. Nehezen beszélek másoknak a szívrendellenességemről.	0	1	2	3	4

Azonosító:_____

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8-12 ÉVES GYERMEKEK SZÜLŐI ÉRTÉKELÉSE

ÚTMUTATÓ

A szívrendellenességgel élő gyermekek sajátos gondokkal küzdhetnek. A következő oldalon olyan dolgok felsorolása található, amelyek gondot jelenthetnek **gyermeke** számára.
Minden pontnál karikázzon be egy választ annak megfelelően, hogy az **elmúlt EGY hónapban mekkora gondot** jelentett **gyermeke** számára az adott kérdés:

0 ha **soha** nem okoz gondot
1 ha **szinte soha** nem okoz gondot
2 ha **néha** gondot okoz
3 ha **gyakran** gondot okoz
4 ha **majdnem mindig** gondot okoz

Nincsenek helyes vagy helytelen válaszok.
Ha nem érti valamelyik kérdést, kérjen segítséget!

*Az elmúlt **EGY** hónapban mekkora **gondot** jelentettek gyermeke számára az alábbiak?*

SZÍVRENDELLENESSÉG ÉS KEZELÉS (*Okoz-e gondot…?*)	**Soha**	**Szinte soha**	**Néha**	**Gyakran**	**Majdnem mindig**
1. Kifullad amikor sportol vagy testmozgást végez.	0	1	2	3	4
2. Fáj vagy szorít a mellkasa amikor sportol vagy testmozgást végez..	0	1	2	3	4
3. Könnyen megfázik.	0	1	2	3	4
4. Szapora a szívverése.	0	1	2	3	4
5. Futáskor elkékül a szája.	0	1	2	3	4
6. Éjjel arra ébred, hogy alig kap levegőt.	0	1	2	3	4
7. Több pihenésre van szüksége, mint a barátainak.	0	1	2	3	4

Ha gyermeke jelenleg szed szívgyógyszert, válaszoljon az alábbi kérdésekre!
Ha nem, akkor ezeket hagyja ki, és folytassa a „Külső megjelenésről alkotott vélemény” résszel!

KEZELÉS II (*Okoz-e gondot…?*)	**Soha**	**Szinte soha**	**Néha**	**Gyakran**	**Majdnem mindig**
1. Nem hajlandó beszedni a szívgyógyszerét.	0	1	2	3	4
2. Gondot okoz neki bevenni a szívgyógyszerét.	0	1	2	3	4
3. Elfelejti bevenni a szívgyógyszerét	0	1	2	3	4
4. Rosszul van a szívgyógyszerétől.	0	1	2	3	4
5. Tart a gyógyszere mellékhatásaitól.	0	1	2	3	4

KÜLSŐ MEGJELENÉSRŐL ALKOTOTT VÉLEMÉNY (*Okoz-e gondot…?*)	**Soha**	**Szinte soha**	**Néha**	**Gyakran**	**Majdnem mindig**
1. Nem tartja magát helyesnek.	0	1	2	3	4
2. Zavarja, ha mások látják rajta a hegeket.	0	1	2	3	4
3. Szégyelli magát, ha mások látják a testét.	0	1	2	3	4

*Az elmúlt **EGY** hónapban mekkora **gondot** jelentettek gyermeke számára az alábbiak?*

A KEZELÉST KÍSÉRŐ SZORONGÁS (*Okoz-e gondot…?*)	**Soha**	**Szinte soha**	**Néha**	**Gyakran**	**Majdnem mindig**
1. Félni szokott, amikor az orvosra vár.	0	1	2	3	4
2. Félni szokott, ha orvoshoz kell mennie.	0	1	2	3	4
3. Félni szokott, ha kórházba kell mennie.	0	1	2	3	4
4. Félni szokott, ha orvosi kezelést kell kapnia.	0	1	2	3	4

KOGNITÍV PROBLÉMÁK (*Okoz-e gondot…?*)	**Soha**	**Szinte soha**	**Néha**	**Gyakran**	**Majdnem mindig**
1. Nem tudja eldönteni mit tegyen, ha valami zavarja.	0	1	2	3	4
2. Matematikai feladatokat nehezen old meg.	0	1	2	3	4
3. Gondot okoz számára az iskolai fogalmazások megírása.	0	1	2	3	4
4. Nehezen tud odafigyelni bármire.	0	1	2	3	4
5. Alig tud visszaemlékezni arra, amit olvasott.	0	1	2	3	4

KOMMUNIKÁCIÓ (*Okoz-e gondot…?*)	**Soha**	**Szinte soha**	**Néha**	**Gyakran**	**Majdnem mindig**
1. Nehéz az orvosoknak és ápolóknak elmondania hogy érzi magát.	0	1	2	3	4
2. Nehezen tesz fel kérdést az orvosoknak és ápolóknak .	0	1	2	3	4
3. Nehezen beszél másoknak a szívrendellenességéről.	0	1	2	3	4

Azonosító:_____

Dátum:_____

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TIZENÉVESEK ÖNÉRTÉKELÉSE (**13-18** évesek)

ÚTMUTATÓ

A szívrendellenességgel élő tizenévesek sajátos gondokkal küzdhetnek. Minden pontnál karikázz be egy választ annak megfelelően, hogy az **elmúlt EGY hónapban mekkora gondot** jelentett neked az adott kérdés:

0 ha **soha** nem okoz gondot
1 ha **szinte soha** nem okoz gondot
2 ha **néha** gondot okoz
3 ha **gyakran** gondot okoz
4 ha **majdnem mindig** gondot okoz

Nincsenek helyes vagy helytelen válaszok.
Ha nem érted valamelyik kérdést, kérj segítséget!

*Az elmúlt **EGY** hónapban mekkora **gondot** jelentettek neked az alábbiak?*

SZÍVRENDELLENESSÉG ÉS KEZELÉS (*Okoz-e gondot…?*)	**Soha**	**Szinte soha**	**Néha**	**Gyakran**	**Majdnem mindig**
1. Kifulladok amikor sportolok vagy testmozgást végzek.	0	1	2	3	4
2. Fáj vagy szorít a mellkasom amikor sportolok vagy testmozgást végzek.	0	1	2	3	4
3. Könnyen megfázom.	0	1	2	3	4
4. Szapora a szívverésem.	0	1	2	3	4
5. Futáskor elkékül a szám.	0	1	2	3	4
6. Éjjel arra ébredek, hogy alig kapok levegőt.	0	1	2	3	4
7. Több pihenésre van szükségem, mint a barátaimnak.	0	1	2	3	4

Ha jelenleg szedsz szívgyógyszert, válaszolj az alábbi kérdésekre!
Ha nem, akkor ezeket hagyd ki, és folytasd a „Külső megjelenésről alkotott vélemény” résszel!

KEZELÉS II (*Okoz-e gondot…?*)	**Soha**	**Szinte soha**	**Néha**	**Gyakran**	**Majdnem mindig**
1. Nem vagyok hajlandó beszedni a szívgyógyszerem.	0	1	2	3	4
2. Gondot okoz bevenni a szívgyógyszerem.	0	1	2	3	4
3. Elfelejtem bevenni a szívgyógyszerem.	0	1	2	3	4
4. Rosszul vagyok a szívgyógyszeremtől.	0	1	2	3	4
5. Tartok a szívgyógyszerem mellékhatásaitól.	0	1	2	3	4

KÜLSŐ MEGJELENÉSRŐL ALKOTOTT VÉLEMÉNY (*Okoz-e gondot…?*)	**Soha**	**Szinte soha**	**Néha**	**Gyakran**	**Majdnem mindig**
1. Nem tartom magam vonzónak.	0	1	2	3	4
2. Zavar, ha mások látják rajtam a hegeket.	0	1	2	3	4
3. Zavarba jövök, ha mások látják a testemet.	0	1	2	3	4

*Az elmúlt **EGY** hónapban mekkora **gondot** jelentettek neked az alábbiak?*

A KEZELÉST KÍSÉRŐ SZORONGÁS (*Okoz-e gondot…?*)	**Soha**	**Szinte soha**	**Néha**	**Gyakran**	**Majdnem mindig**
1. Szorongok az orvosra való várakozás közben.	0	1	2	3	4
2. Szorongok, ha orvoshoz kell mennem.	0	1	2	3	4
3. Szorongok, ha kórházba kell mennem.	0	1	2	3	4
4. Szorongok, ha orvosi kezelést kell kapnom.	0	1	2	3	4

KOGNITÍV PROBLÉMÁK (*Okoz-e gondot…?*)	**Soha**	**Szinte soha**	**Néha**	**Gyakran**	**Majdnem mindig**
1. Nem tudom eldönteni mit tegyek, ha valami zavar	0	1	2	3	4
2. Nehezen oldok meg matematikai feladatokat.	0	1	2	3	4
3. Gondot okoz az iskolai fogalmazások megírása.	0	1	2	3	4
4. Nehezen tudok odafigyelni bármire.	0	1	2	3	4
5. Alig tudok visszaemlékezni arra, hogy mit olvastam.	0	1	2	3	4

KOMMUNIKÁCIÓ (*Okoz-e gondot…?*)	**Soha**	**Szinte soha**	**Néha**	**Gyakran**	**Majdnem mindig**
1. Nehéz az orvosoknak és ápolóknak elmondanom, hogy érzem magam.	0	1	2	3	4
2. Nehezen teszek fel kérdést az orvosoknak és ápolóknak.	0	1	2	3	4
3. Nehezen beszélek másoknak a szívrendellenességemől.	0	1	2	3	4

Azonosító:_____

Dátum:_____

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TIZENÉVESEK SZÜLŐI ÉRTÉKELÉSE (13-18 évesek)

ÚTMUTATÓ

A szívrendellenességgel élő tizenévesek sajátos gondokkal küzdhetnek. A következő oldalon olyan dolgok felsorolása található, amelyek gondot jelenthetnek **tizenéves gyermeke** számára.
Minden pontnál karikázzon be egy választ annak megfelelően, hogy az **elmúlt EGY hónapban mekkora gondot** jelentett **tizenéves gyermeke** számára az adott kérdés:

0 ha **soha** nem okoz gondot
1 ha **szinte soha** nem okoz gondot
2 ha **néha** gondot okoz
3 ha **gyakran** gondot okoz
4 ha **majdnem mindig** gondot okoz

Nincsenek helyes vagy helytelen válaszok.
Ha nem érti valamelyik kérdést, kérjen segítséget!

*Az elmúlt **EGY** hónapban mekkora **gondot** jelentettek tizenéves gyermeke számára az alábbiak?*

SZÍVRENDELLENESSÉG ÉS	Soha	Szinte	Néha	Gyakran	Majdnem

KEZELÉS (*Okoz-e gondot…?*)		**soha**			**mindig**
1. Kifullad amikor sportol vagy testmozgást végez.	0	1	2	3	4
2. Fáj vagy szorít a mellkasa amikor sportol vagy testmozgást végez.	0	1	2	3	4
3. Könnyen megfázik.	0	1	2	3	4
4. Szapora a szívverése.	0	1	2	3	4
5. Futáskor elkékül a szája.	0	1	2	3	4
6. Éjjel arra ébred, hogy alig kap levegőt.	0	1	2	3	4
7. Több pihenésre van szüksége, mint a barátainak.	0	1	2	3	4

Ha gyermeke jelenleg szed szívgyógyszert, válaszoljon az alábbi kérdésekre!
Ha nem, ezeket hagyja ki és folytassa a „Külső megjelenésről alkotott vélemény” résszel!

KEZELÉS II (*Okoz-e gondot…?*)	**Soha**	**Szinte soha**	**Néha**	**Gyakran**	**Majdnem mindig**
1. Nem hajlandó bevenni a szívgyógyszerét.	0	1	2	3	4
2. Gondot okoz neki bevenni a szívgyógyszerét.	0	1	2	3	4
3. Elfelejti bevenni a szívgyógyszerét.	0	1	2	3	4
4. Rosszul van a szívgyógyszerétől.	0	1	2	3	4
5. Tart a szívgyógyszere mellékhatásaitól.	0	1	2	3	4

KÜLSŐ MEGJELENÉSRŐL ALKOTOTT VÉLEMÉNY (*Okoz-e gondot…?*)	**Soha**	**Szinte soha**	**Néha**	**Gyakran**	**Majdnem mindig**
1. Nem tartja magát vonzónak.	0	1	2	3	4
2. Zavarja, hogy mások látják rajta a hegeket.	0	1	2	3	4
3. Zavarba jön, ha mások látják a testét.	0	1	2	3	4

*Az elmúlt **EGY** hónapban mekkora **gondot** jelentettek tizenéves gyermeke számára az alábbiak?*

A KEZELÉST KÍSÉRŐ	**Soha**	**Szinte**	**Néha**	**Gyakran**	**Majdnem**

SZORONGÁS (*Okoz-e gondot…?*)		**soha**			**mindig**
1. Szorong, ha orvosi vizsgálatra vár.	0	1	2	3	4
2. Szorong, ha orvoshoz kell mennie.	0	1	2	3	4
3. Szorong, ha kórházba kell mennie.	0	1	2	3	4
4. Szorong, ha orvosi kezelést kell kapnia.	0	1	2	3	4

KOGNITÍV PROBLÉMÁK (*Okoz-e gondot…?*)	**Soha**	**Szinte soha**	**Néha**	**Gyakran**	**Majdnem mindig**
1. Nem tudja eldönteni mit tegyen, ha valami zavarja.	0	1	2	3	4
2. Nehezen old meg matematikai feladatokat.	0	1	2	3	4
3. Gondot jelent számára az iskolai fogalmazások megírása.	0	1	2	3	4
4. Nehezen tud odafigyelni bármire.	0	1	2	3	4
5. Alig tud visszaemlékezni arra, amit olvasott.	0	1	2	3	4

KOMMUNIKÁCIÓ (*Okoz-e gondot…?*)	**Soha**	**Szinte soha**	**Néha**	**Gyakran**	**Majdnem mindig**
1. Nehéz az orvosoknak és ápolóknak elmondania, hogy érzi magát.	0	1	2	3	4
2. Nehezen tesz fel kérdést az orvosoknak és ápolóknak.	0	1	2	3	4
3. Nehezen beszél másoknak a szívrendellenességéről.	0	1	2	3	4

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Candidate: Andrea Berkes

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Doctoral School: Doctoral School of Health Sciences

List of publications related to the dissertation

1. **Berkes, A.**, Pataki, I., Kiss, M., Kemény, C., Kardos, L., Varni, J.W., Mogyorósy, G.: Measuring health-related quality of life in Hungarian children with heart disease: Psychometric properties of the hungarian version of the Pediatric Quality of Life InventoryTM 4.0 Generic Core Scales and the Cardiac Module.
   Health Qual. Life Outcomes. 8 (1), 1-14, 2010.
   DOI: http://dx.doi.org/10.1186/1477-7525-8-14
   IF:1.86

2. **Berkes, A.**, Varni, J.W., Pataki, I., Kardos, L., Kemény, C., Mogyorósy, G.: Measuring health-related quality of life in Hungarian children attending a cardiology clinic with the Pediatric Quality of Life Inventory.
   Eur. J. Pediatr. 169 (3), 333-347, 2010.
   DOI: http://dx.doi.org/10.1007/s00431-009-1059-0
   IF:1.644

3. **Berkes A.**, Mogyorósy G.: Életminőség-mérések a gyermekkardiológiában.
   Orv. Hetil. 149 (37), 1761-1767, 2008.
   DOI: http://dx.doi.org/10.1556/OH.2008.28278

4. **Berkes A.**, Mogyorósy G.: Az életminőség-mérés alapjai és annak gyermekkori alkalmazása.
   Orv. Hetil. 149 (26), 1215-1224, 2008.
   DOI: http://dx.doi.org/10.1556/OH.2008.28241

5. **Berkes A.**, Kiss M., Kemény C., Mogyorósy G.: A Pediatric Quality of Life InventoryTM (PedsQLTM) gyermekkori életminőség-mérő kérdőív kardiológiai moduljának magyarországi validálása.
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   DOI: http://dx.doi.org/10.1556/OH.2008.28322

List of other publications

6. **Berkes A.**, Szegedi I., Szikszay E., Gulyás M., Oláh É.: Botulizmus csecsemőkorban-irodalmi áttekintés egy eset kapcsán.
Orv. Hetil. 148 (24), 1117-1125, 2007.
DOI: http://dx.doi.org/10.1556/OH.2007.27977

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