Health-Related Quality of Life after Open-Heart Surgery

Helene Werner, PhD[1], Beatrice Latal, MD[2,3], Emanuela Valsangiacomo Buechel, MD[3,4], Ingrid Beck[2], and Markus A. Landolt, PhD[1,3]

Objectives To determine health-related quality of life (HRQoL) in 1-year-old infants with congenital heart disease (CHD), to follow-up with these children at age 4 years, and to examine predictors of HRQoL.

Study design Parents of 144 infants who had undergone cardiopulmonary bypass surgery for CHD before age 6 months were prospectively included in this cohort study. Parents completed a standardized questionnaire on child HRQoL at 1 year and 4 years of age; medical data were extracted from the patients' hospital records.

Results Parents reported a significant reduction of the children's physical functioning compared with healthy controls at age 1 year. At age 4 years, children with CHD had poorer cognitive functioning but better social functioning compared with healthy controls. Lower HRQoL at age 4 years was not significantly predicted by univentricular or biventricular CHD but was predicted by the presence of an underlying genetic defect, tube feeding at 1 year, and lower HRQoL at 1 year.

Conclusion This study shows that HRQoL of infants and preschool-age children with CHD is impaired in physical and cognitive dimensions. Children with lower overall HRQoL at age 1 year, an underlying genetic defect, and tube feeding need to be monitored carefully to provide appropriate and timely interventions. *(J Pediatr 2014;164:254-8)*.

Over the last 2 decades, advances in diagnostic, medical, and surgical techniques have significantly increased the survival of patients with congenital heart disease (CHD), and current treatment interventions allow an almost normal life, even for many children with severe CHD.[1] However, studies indicate that children with CHD may face deficits in fine and gross motor functioning and in other neurodevelopmental dimensions,[2-4] possibly accompanied by decreased health-related quality of life (HRQoL).

Measures of HRQoL follow the World Health Organization's definition of health as "a state of complete physical, mental, and social well-being, and not merely the absence of disease or infirmity"[5] and focus on the subjective perception of the impact of disease on the physical, emotional, social, and cognitive dimensions of health. HRQoL is a dynamic, multidimensional concept influenced by the subject's beliefs and cultural context; by intrapersonal factors, such as temperament and coping skills; by sociodemographic factors, such as age and developmental stage; and by characteristics of the disease.[6-12] Knowledge of important predictors may allow for early identification of children at greatest risk, which in turn may allow timely interventions to prevent long-term negative effects on HRQoL.

Measuring HRQoL in children with CHD is a relatively new technique. Findings of previous studies are inconsistent, owing mainly to methodological differences.[13-17] Knowledge of HRQoL at this young age, a critical time during which most surgical and medical interventions are carried out, may help identify those dimensions of health in which children with CHD are most strongly affected.

The aim of the present study was to prospectively examine HRQoL in young children with different types of CHD at age 1 year and 4 years compared with healthy controls. We hypothesized that young children with CHD would have decreased HRQoL at both assessments compared with healthy controls, and that significant impairments in their physical and cognitive functioning would be evident. We also expected to find a significant increase in HRQoL scores from age 1 year to 4 years owing to recovery after surgery. Second, we examined the extent to which sociodemographic, diagnostic, and surgery-related characteristics predicted HRQoL at age 4 years. We hypothesized that diagnostic factors and lower HRQoL at age 1 year would be significantly predictive of lower HRQoL at age 4 years, with no significant effect of sociodemographic variables.

Methods

The flow chart of study participants is shown in the **Figure** (available at www.jpeds.com). Children with CHD who underwent cardiopulmonary bypass surgery at University Children's Hospital Zurich before age 6 months and with a parent fluent in German were recruited consecutively over a 2-year period. Overall, 188 children in this age group underwent surgery during the study period, 161 of whom were eligible for inclusion. The excluded

CHD	Congenital heart disease
HRQoL	Health-related quality of life
SES	Socioeconomic status
TAPQOL	Netherlands Organisation for Applied Scientific Research Academic Medical Centre Preschool Children Quality of Life

From the [1]Department of Psychosomatics and Psychiatry, [2]Child Development Center, [3]Children's Research Center, and [4]Department of Cardiology, University Children's Hospital Zurich, Zurich, Switzerland

Supported by the Foundation Mercator (Switzerland). The authors declare no conflicts of interest.

 http://dx.doi.org/10.1016/j.jpeds.2013.10.022

children did not differ from the eligible children with regard to sex ($P = .14$), but they did differ in terms of the presence of univentricular vs biventricular CHD ($P = .002$) and socioeconomic status (SES) ($P = .005$). Compared with the excluded children, more eligible children had biventricular CHD and a higher SES. Of the 161 eligible children, 17 declined to participate in the study. Participants did not differ from nonparticipants in terms of sex ($P = .44$), presence of univentricular vs biventricular CHD ($P = .37$), or SES ($P = .44$). The final sample was 144 1-year-old children (response rate, 89%). Twenty-nine children dropped out of the study between the 1-year follow-up (T1) and the 4-year follow-up (T2). Thus, at T2, 114 children (71%) were available for study.

The study was approved by the state's Institutional Review Board and was performed in full accordance with the Declaration of Helsinki. Parents were approached by a study nurse either immediately before or after their child's surgery. After providing written consent, parents filled out a demographic questionnaire. Standardized questionnaires were mailed to participating parents approximately 1 month before the child's routine medical follow-up visit at 1 year (mean age, 1.1 ± 0.1 years) and 4 years (mean age, 4.3 ± 0.1 years). Parents filled out the questionnaires at home and brought them to the medical follow-up visit at the hospital.

HRQoL was assessed by parent reports, using the authorized German version of the 43-item Netherlands Organisation for Applied Scientific Research Academic Medical Centre Preschool Children Quality of Life (TAPQOL) questionnaire.[18,19] The TAPQOL is a validated multidimensional generic instrument measuring the frequency of a child's health problems in the last 3 months (never, occasionally, often), weighted by the degree to which a child feels negative emotions about such problems (good, not so well, rather bad, bad). The TAPQOL can be applied to children aged 9 months to 6 years, with the number of scales varying with age. For children older than 18 months, the TAPQOL consists of 12 scales: sleeping, appetite, lungs, stomach, skin, behavior problem, anxiety, positive mood, liveliness, motor functioning, social functioning, and communication. For children aged 9-18 months, the motor functioning, social functioning and communication scales cannot be assessed. Scales were linearly transformed to a 0-100 scale, with higher scores indicating better HRQoL. Four dimension scores (physical, emotional, social, and cognitive functioning) were calculated by averaging the underlying scales. To obtain a measure of overall HRQoL, a total score was calculated by averaging the 12 available scales for the 4-year-old children, respectively the 9 available scales for the 1-year-old children. Normative data were available for 251 healthy Dutch children aged 1-5 years.[19] At T1, children aged 0.8-2.5 years (n = 125) and at T2, children of 2.5-4.8 years of age (n = 125) were included in the control group. In the present study, the internal consistency was acceptable to good for most scales and the overall HRQoL score, except for the scales measuring lung problems at T1/T2 and stomach problems at T2, which revealed poor internal consistencies **(Table I)**.

Diagnostic data (ie, type of CHD, underlying genetic disorder) and surgery-related characteristics (ie, surgical risk, age at first surgery, number of open-heart surgeries, length of hospital stay, duration of cardiopulmonary bypass) were extracted from the patients' hospital records. Surgical risk was classified according to the Risk Adjustment for Congenital Heart Surgery risk stratification scheme.[20] If a child had undergone more than 1 open-heart surgery within the first year, then the overall length of hospital stay and overall duration of cardiopulmonary bypass were calculated. Patients with a cardiac malformation suspected to be associated with any genetic abnormality were screened for underlying genetic disorders by determining karyotype, microdeletions, or specific genetic defects if applicable. Genetic disorders were defined as either identifiable chromosomal disorders (eg, Down syndrome, microdeletion 22q11) or nonidentifiable dysmorphic syndrome (ie, other genetic defects). Cardiac status at T1 was operationalized based on the present need for cardiac medications and for tube feeding, yielding 2 dichotomous variables (no/yes) as reported by the parents.

Child nationality and SES were assessed with a short demographic questionnaire. SES was calculated as a continuous score ranging from 2 to 12 points, subsuming maternal education and paternal occupation (each score 1-6). Based on the SES score, 3 social groups were assigned: lower (score 2-5), middle (score 6-9), and upper (score 10-12). This measure has been used in previous studies and has proven reliability and validity as an indicator of SES in Switzerland.[21]

Data were analyzed using SPSS 20.0 for Windows (IBM, Armonk, New York). All statistical tests were 2-sided, with a predefined significance level of $P < .05$. Descriptive results for nominal variables are presented as number of cases and percentages. Data are reported as mean ± SD for continuous variables and median (range) are given for variables with a nonnormal distribution according to the Kolmogorov-Smirnov test. The χ^2 test and Mann-Whitney U test were used to compare sociodemographic and diagnostic variables between participants and nonparticipants as well as between eligible and excluded patients. The Mann-Whitney U test was used to compare HRQoL values at T1 and T2 with the population norms. The Wilcoxon signed-rank test was performed to compare HRQoL values at T1 and T2. For all comparisons, effect sizes by Cohen d were computed (0.20, small effect; 0.50, medium effect; >0.80, large effect).[22]

A stepwise linear multiple regression model was generated using the normally distributed overall HRQoL score at 4 years as a dependent variable. The predictors were entered as follows: step 1, overall HRQoL score at 1 year; step 2, sociodemographic characteristics; step 3, diagnostic characteristics; step 4, surgery-related characteristics. Selection of predictors was based on a priori considerations and on the statistical significance of bivariate correlations with the dependent variable. In a preliminary analysis, a number of possible interactions (eg, between genetic defect and tube feeding) were examined by ANOVA, but none was found to be significant on overall HRQoL at T2; thus, we decided to not include any interaction in the multiple regression analysis.