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Original Article

Health-Related Quality of Life in Children and Adolescents with Simple Congenital Heart Defects before and after Transcatheter Intervention Therapy: A Single-Center Study

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Objective: To explore the health-related quality of life (HRQoL) of children and adolescents with simple congenital heart defects before and after the transcatheter intervention.
Methods: The Pediatric Quality of Life Inventory 4.0 scale was used to assess the quality of life of 78 children and adolescents before and after the transcatheter intervention and to evaluate the parents' perception of their children's quality of life.
Results: In all, 76 patients were completed the study. The results showed that the scores of the four dimensions and the total score for the quality of life of the patients significantly improved 1 month after the intervention. At 6 months after treatment, the scores in all dimensions continued to improve. From the parents' perspective, the scores of the patients in all dimensions improved significantly at 1 month and 6 months after treatment. In terms of the quality of life assessment, the self-assessment results of the patients were more positive than those of their parents.
Conclusions: The results showed that the quality of life of children and adolescents with simple congenital heart defects can be positively affected by the transcatheter intervention. Moreover, this improvement is not transient and seems to increase over time.

Keywords: HRQoL, children, adolescents, CHD, intervention

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Introduction

Congenital heart defects are common and have a prevalence rate of 5.78 per 1000 people.[1)] Due to the development of medical imaging and the rational allocation of medical resources, increasingly more simple congenital heart defects are being diagnosed and treated in children.[2–4)] Due to factors such as unbalanced economic and social development, some patients do not receive a diagnosis or treatment until they are an adolescent.[5–7)] Studies on simple congenital heart defects should not only focus on the hemodynamic changes in heart malformations and the magnitude of the effect of correction but also on the changes in patients' quality of life in the later period. Health-related quality of life (HRQoL) is a complex concept involving many aspects, including not only physical functions but also psychological emotion, social interaction, and other

aspects.[8–12] Due to the development of the necessary techniques, the transcatheter intervention has been widely used for simple congenital heart defects in clinical practice.[13,14] However, previous studies have focused on the quality of life of patients with simple congenital heart defects before and after surgical treatment only, and there are still many gaps in the related field on patients who undergo the transcatheter intervention.[15–17] The objectives of this study were to explore the HRQoL of children and adolescents with simple congenital heart defects before and after the transcatheter intervention and to evaluate the difference in the HRQoL feedback of parents and their children. We believe that the results of this study will provide important information for determining the prognosis and treatment of children and adolescents with simple congenital heart defects.

Methods

This study was approved by the ethics committee of Fujian Medical University and was conducted in accordance with the Helsinki declaration.

Sample size

The sample size was determined with PASS 18.0. The alpha value was set as 0.05 with a power of 0.90. Based on the result of preliminary research calculation, the minimum sample size was calculated to be 66 patients. And considering the 15% dropout rate, 78 cases were eventually included for the research.

Patients

This study included children and adolescents aged 5–18 years who had undergone the transcatheter intervention for simple congenital heart defects in our department. There were 36 cases of atrial septal defect (ASD), 10 cases of ventricular septal defect (VSD), and 30 cases of patent ductus arteriosus (PDA) in this study. The inclusion criteria were as follows: (1) patients who were confirmed to have simple congenital heart defects by echocardiography and met the indications for the transcatheter interventional therapy, (2) patients who had not previously received any other cardiac surgery or intervention, (3) patients who had a normal mental state, without mental retardation or severe dysplasia, and (4) patients with the successful correction of cardiac malformation, as confirmed by postoperative echocardiography. All patients voluntarily participated in this study and signed informed consent forms. The inclusion criteria for transcatheter intervention of the above-mentioned three simple congenital heart defects were as follows: significant left-to-right shunt, restricted shunt, not accompanied by moderate-to-severe pulmonary hypertension, the size of defect was moderate and suitable for the closure of the occluder, and so on.

Procedure

Demographic and clinical data were collected before transcatheter intervention. The HRQoL outcome was recorded at 7 days before the treatment and 1 month and 6 months after the treatment. Moreover, parents' feedback on their children's quality of life was also collected. The tool used to assess HRQoL was the Pediatric Quality of Life Inventory 4.0 (PedsQL 4.0) scale, the universal core scale for assessing children's quality of life. The research team consisted of a cardiac surgeon, a statistician, medical assistants, and two cardiac nurses. During the survey, the researchers were allowed help the subjects understand the questions, but they were not allowed to induce or interfere with the answers to ensure the authenticity of the answers. Similarly, the autonomy of the answers was guaranteed to the parents when they were administered the survey.

Instrument

PedsQL 4.0 is a quality of life questionnaire for children and adolescents. It mainly contains four dimensions, including eight questions for physical functioning, five questions for emotional functioning, five questions for social functioning, and five questions for school functioning. The HRQoL responses for children aged 5–7 and their parents were graded on three scales: 0 for never, 2 for sometimes, and 4 for always. The HRQoL responses for children aged 8–18 years and their parents were scored on a 5-item Likert scale: 0 for never, 1 for almost never, 2 for sometimes, 3 for often, and 4 for always.[18,19] Scores ranged from 0 to 100 points. The total score for each dimension was calculated as the sum of the scores for all questions in that dimension divided by the number of questions for that dimension. The total score of the questionnaire was calculated as the sum of the scores of all the questions divided by the total number of questions. The total score and scores for each dimension ranged from 0 to 100, with higher scores indicating better HRQoL feedback.

Statistics

SPSS 22.0 was used for statistical analysis in the study. The continuous data were expressed as the mean ± standard

deviation, and the scores of each dimension were positively correlated with the evaluation of the children's quality of life. $p < 0.05$ indicated that the difference was significant. In the statistical analysis of the results, the scores of the children and parents recorded before and after the treatment did not follow a normal distribution according to a normality test. The Wilcoxon test was used to compare the scores from the self-evaluations and parental evaluations before and after the treatment. In the comparison between the self-evaluations and parental evaluations of the children, the scores for each dimension for the two groups did not conform to a normal distribution, and the Mann–Whitney U test was used.

Results

In this study, we recruited a total of 78 children or adolescents with simple congenital heart defects, and the final number of patients who completed the study was 76. Two patients who did not complete the study failed to come to the review on time due to a lack of time. Of the 76 patients who completed the study, 42 were males, and 34 were females. Their demographic and clinical data are reported in **Table 1**.

The quality of life of patients was assessed 7 days before the treatment and 1 month and 6 months after the treatment; the physical functioning, emotional functioning, social functioning, school functioning, and overall quality of life scores are reported in **Table 2**. The results showed that at 1 month after the interventional therapy, the total scores of the children's physical functioning, emotional functioning, social functioning, school functioning, and overall quality of life significantly improved compared with those before treatment ($p < 0.05$). At 6 months after treatment, the scores of the patients in all dimensions and the total quality of life score improved compared with those before treatment ($p < 0.05$). When the results at 1 month and 6 months after the treatment were compared, no significant difference in the feedback of patients' quality of life in the two dimensions of physical functioning and emotional functioning were found, while in the aspects of social function, school function and overall quality of life, the scores improved at 6 months after treatment compared with 1 month after treatment ($p < 0.05$).

Table 2 also shows the parents' feedback on the quality of life of the children at 7 days before the treatment and at 1 month and 6 months after the treatment. From the parents' perspective, the total score of the patients' quality of life and the scores of the patients' physical functioning, emotional functioning, social functioning, and school functioning quality of life improved significantly at 1 month and 6 months after the interventional treatment ($p < 0.05$). However, when the results at 6 months after the treatment and 1 month after the treatment were compared, from the perspective of the parents of the patients, the scores for the other dimensions, except for the school functioning of the patients, significantly improved ($p < 0.05$).

In terms of the assessment of quality of life, there were also some differences between the scores of the patients and parents. Before the treatment, the scores of the patients for the four dimensions were more positive than those of the parents, and the assessment of overall quality of life also showed this trend (**Fig. 1**). At 1 month after the treatment, the patients' scores for all four dimensions and overall quality of life were higher than were their parents' scores (**Fig. 2**). In a comparison of the outcomes at 6 months after the treatment, the patients themselves rated them to have higher quality of life than did their parents in terms of social functioning, school functioning, and overall quality of life, and the differences were statistically significant (**Fig. 3**).

In this study, we also studied whether different family income and parents' education level had an impact on the children's quality of life feedback. The results showed that different family income and parental education did not significantly change the children's quality of life feedback.

Discussion

Simple congenital heart defects are a common disease in children with congenital heart disease (CHD). In early studies, factors such as morbidity, mortality, complications, and changes in hemodynamics after surgical treatment received much attention.[20] With the development of medical technology and the rational allocation of medical resources, the survival rate of individuals with simple congenital heart defects after treatment has greatly improved, and the survival time of patients has also increased. Although it is meaningful to evaluate the postoperative complications and survival rate of children, these measures are not comprehensive. Therefore, this study focused on the quality of life of children with simple congenital heart defects; it is not only necessary for the clinical treatment effect of the transcatheter intervention therapy to be evaluated but also for the long-term outcomes after the treatment to be evaluated, among which HRQoL is a topic worth exploring.

Table 1 Demographic and clinical data of the subjects

Item		N (%)
Age (years)		9.1 ± 3.5
Gender	Male	42 (55.3%)
	Female	34 (44.7%)
Parents' education	Junior high school or lower	15 (19.7%)
	High school	38 (50.0%)
	bachelor's degree or higher	23 (30.3%)
Family income	Poor	15 (19.7%)
	Median level	52 (68.5%)
	Rich	9 (11.8%)
CHD	ASD	36 (47.4%)
	VSD	10 (13.2%)
	PDA	30 (39.4%)
NYHA	I/II	76 (100%)
	III/IV	0 (0%)
Qp/Qs		1.55 ± 0.17

ASD: atrial septal defect; CHD: congenial heart disease; NYHA: New York Heart Association; PDA: patent ductus arteriosus; VSD: ventricular septal defect

Table 2 Comparison of health-related quality of life scores among subjects before and after interventional therapy

Item	Before therapy	1 month after therapy	6 months after therapy
Children's self-assessment			
Physical functioning	70.39 ± 12.68	85.98 ± 7.78*	87.25 ± 8.40*
Emotional functioning	72.37 ± 11.65	85.13 ± 9.02*	85.33 ± 9.98*
Social functioning	70.26 ± 15.75	81.91 ± 13.76*	86.18 ± 10.39*#
School functioning	70.66 ± 13.38	82.76 ± 10.05*	86.45 ± 9.52*#
Total score	70.85 ± 7.50	84.21 ± 5.36*	86.43 ± 4.51*#
Parental assessment			
Physical functioning	64.97 ± 10.73	80.88 ± 6.98*	87.09 ± 5.98*#
Emotional functioning	69.41 ± 8.75	79.61 ± 7.11*	87.63 ± 6.14*#
Social functioning	66.12 ± 8.19	77.57 ± 6.40*	81.51 ± 5.54*#
School functioning	65.92 ± 9.62	77.17 ± 6.29*	78.22 ± 7.51*
Total score	66.39 ± 7.00	79.08 ± 3.69*	84.07 ± 3.81*#

*p <0.05 compared with before treatment; #p <0.05 compared with 1 month after treatment.

HRQoL refers to an individual's health status under the influence of illness and injury, medical intervention, aging, and changes in his or her social environment, as well as subjective satisfaction related to his or her economic and cultural background and value orientation. The quality of life of children can be studied to understand the long-term changes in children after treatment and provide a reference for the selection of clinical treatment plans. This study included 76 children and adolescents with simple congenital heart defects who underwent transcatheter interventional therapy in a heart center, and the results showed that such treatment can continuously improve the quality of life of children and adolescents.

Surgery has been used to treat simple congenital heart defects for a long period of time, but it also leads to more severe surgical trauma and longer hospital stays than this intervention.[21] In a study of post-treatment quality of life, Landolt suggested that children with CHD who undergo open-heart surgery have an impaired quality of life, which might be one of the factors driving the pursuit of less invasive treatments.[22] With the development of technology, the accuracy and stability of interventional therapies have also been greatly improved. Currently, the clinical application of transcatheter interventional therapy for simple congenital heart defects has been supported by many studies.[23,24] In some studies, the results have shown that the quality of life of children with simple congenital heart defects is poorer than that of their healthy peers.[25,26]

In this study, the changes in quality of life after treatment were encouraging. Not only in the physical and

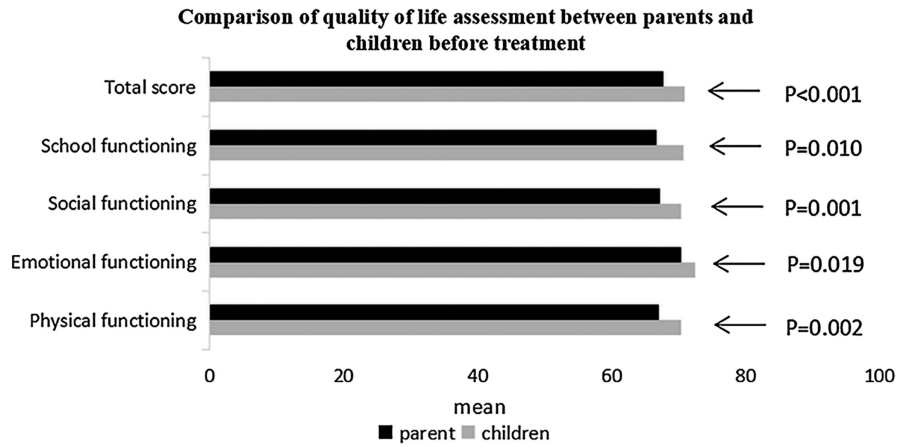

Fig. 1 Mean of ranking of Quality of life in patients before transcatheter intervention therapy. Comparison of quality of life assessment between parents and children before treatment. High value indicates positive ranking.

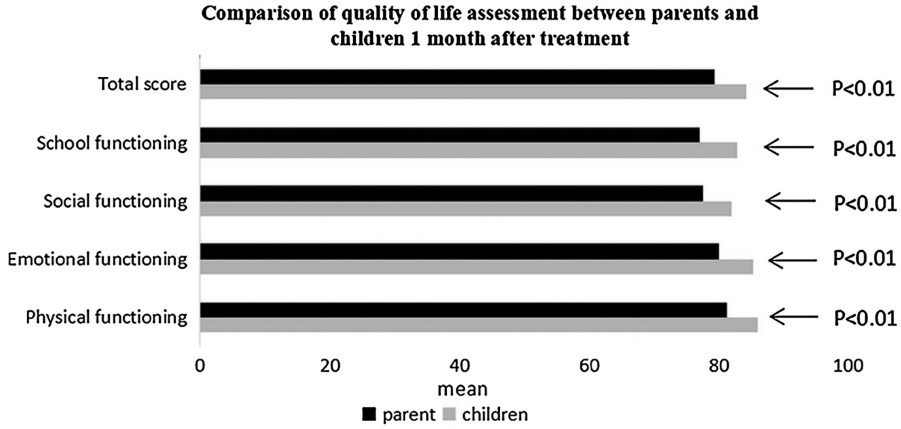

Fig. 2 Mean of ranking of Quality of life in patients 1 month after transcatheter intervention therapy. Comparison of quality of life assessment between parents and children 1 month after treatment. High value indicates positive ranking.

emotional aspects but also in social and school functioning aspects, as indicated by the quality of life scores of the children and their parents. The improvement in quality of life was not just a transient phenomenon; it was encouraging to observe that the quality of life of the children continued to improve to a certain extent at 6 months after treatment compared to 1 month after treatment. This result might indicate that the improvement in quality of life was a sustainable effect of the treatment, although a longer follow-up period is needed to determine whether this improvement persists in the long term.

Amedro et al.[27] noted that children with CHD have a more positive outlook on their own quality of life than their parents do. In our study, the children's self-assessment of quality of life before the treatment also showed the same trend compared with their parents' assessment. In the feedback at 1 month after the treatment, the children's self-reported scores in the PedsQL™ 4.0 dimensions and overall quality of life were higher than the parents' scores. However, in the comparison of the results at 6 months, the children's scores for social functioning and school functioning were still positive, while in the two dimensions of physical functioning and emotional functioning, there was no significant difference between the scores of the children and their parents. This result might have been caused by the children's improvement in both social and school functioning being more intuitive to the children than to their parents.

Although in this study, demographic factors did not significantly influence the results. But in some other studies, the quality of life of children with simple congenital heart defects was influenced not only by the disease but also by the family composition, family economic

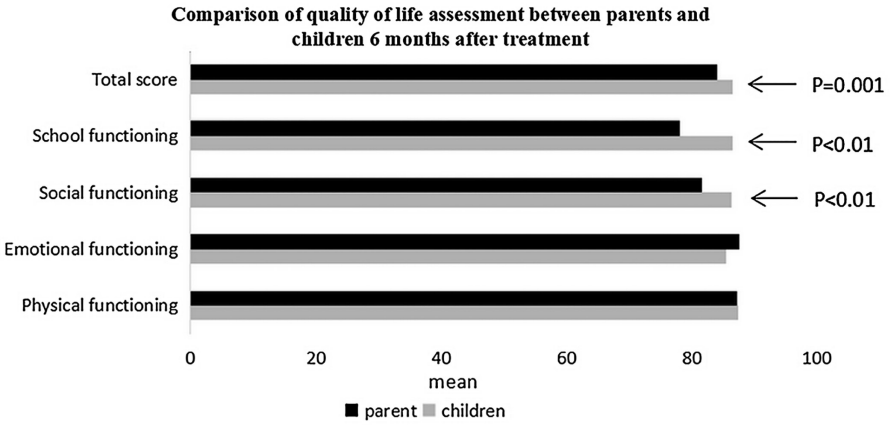

Fig. 3 Mean of ranking of Quality of life in patients 6 month after transcatheter intervention therapy. Comparison of quality of life assessment between parents and children 6 month after treatment. High value indicates positive ranking.

situation, parents' education level, and family's knowledge of the disease.[28,29] Moreover, it was also of great significance for the children and their parents to receive psychosocial guidance after the treatment, which may better help the children return to normal social and school life and achieve dual physical and psychological rehabilitation, which has been confirmed in some studies.[30] Therefore, we will further explore the influence of demographic factors on quality of life in the future study.

Limitations

The study had some limitations: (1) this study was a single-center study, and the results only represented the characteristics of individuals in southeast China. (2) The sample size of this study was relatively small, and the follow-up time was only 6 months. To obtain more accurate and longer-term results, studies with a larger sample size and longer follow-up time are still needed. (3) A group of untreated patients or a group of patients with surgical correction should be included as a control group for comparison to better assess the impact of the interventional therapy on the quality of life of patients and increase the comparability of results.

Conclusion

The HRQoL of children and adolescents with simple congenital heart defects improved after transcatheter intervention therapy, and the improvement was not transient but rather appeared to increase over time. Therefore, transcatheter interventional therapy is a treatment option that should be considered for children and adolescents with simple congenital heart defects, but long-term follow-ups on quality of life are still needed.

Authors' Contributions

K-pS, XN, and QC designed the study, performed the statistical analysis, participated in the operation, and drafted the manuscript. S-tH and HC collected the clinical data. All authors read and approved the final manuscript.

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Disclosure Statement

The authors declare that they have no competing interests.

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