

# Evaluation of the Health-Related Quality of Life in Non-Syndromic Persian Toddlers with Orofacial Clefts Undergoing Team Care and Compared with a Control Group

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## ABSTRACT

### Objectives

Maintaining and enhancing patients' quality of life (QoL) are considered the most significant objectives in healthcare systems. These objectives are directly associated with the intervention of healthcare providers across the globe. This study aimed to evaluate the health-related quality of life (HRQoL) of toddlers who have undergone interventions for oral clefts and compare it with a healthy control group.

### Materials & Methods

The present study is cross-sectional. Thirty-six toddlers aged 18 to 36 months with oral clefts undergoing team care were recruited from a pediatric hospital and matched with healthy peers based on inclusion criteria. Demographic characteristics were collected before the TNO-AZL preschool children's quality of life (TAPQoL) questionnaire was completed.

### Results

The QoL was compared to an overall score and the average score of items and domains on the TAPQoL questionnaire between the groups. The results showed a significant difference between the two groups in social functioning ( $t=2.96$ ,  $p = 0.004$ ), cognitive functioning ( $t=2.21$ ,  $p = 0.03$ ), emotional functioning ( $t=3.99$ ,  $p<0.01$ ), and the total score ( $p<0.001$ ). However, no significant difference was observed in physical functioning ( $t= 0.78$ ,  $p=0.43$ ), and toddlers with oral clefts had more reasonable scores.

### Conclusion

The QoL of toddlers with oral clefts who received care from a multidisciplinary team was slightly better than that of the healthy group. Therefore, participating in these teams could lead these children to a similar QoL as their peers. Medical systems can provide easy accessibility to cleft care teams for patients and their families.

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## Introduction

The World Health Organization (WHO) defines health as the absence of disease and the presence of factors that increase physical, mental, and social well-being. This definition creates a broad concept of health aimed at improving people's Quality of Life (QoL). According to the WHO, QoL refers to an individual's perception of life within their cultural and value system. This concept is closely associated with the individual's objectives, aspirations, ideals, and apprehensions. In other words, QoL is a subjective assessment of one's health in the sociocultural environment (1). Health-related quality of Life (HRQoL) is one dimension of QoL encompassing perceptions of individuals' physical and mental health, including related health risks and conditions, functional capabilities, social support, and socioeconomic status (SES) (2). QoL is crucial in evaluating health-related programs and evidence-based practices, particularly for individuals with chronic conditions.

Cleft lip and palate (CL/P) is a congenital disorder causing malformation in craniofacial structures. Craniofacial disorders fall under the category of oral diseases and can significantly impact a person's QoL. These conditions can affect food choices, speech, and the social, emotional, and functional aspects of a person's life (3-5). Team-based cleft care is the gold standard of healthcare for children with CL/P, who might have multiple problems throughout development stages and require long-term interventions, including primary and secondary surgeries, nutritional and psychosocial counseling, audiometry, dentistry, and speech therapy (6). Primary surgical treatment in infants with CL/P significantly improves oral health-related quality of life (OHRQoL). Therefore, early surgical intervention can positively impact

these children's lives (7). After undergoing lip and palate surgeries, communication and aesthetic concerns become the primary factors influencing the HRQoL for families and patients (8). Hence, achieving positive outcomes in healthcare for children with oral clefts goes beyond just successful surgeries. The emphasis should be on enhancing their QoL (2, 3).

While the HRQoL of toddlers with CL/P is not explicitly addressed in many studies, the evidence suggests that the challenges faced by older children with CL/P, such as social and emotional difficulties, could also be relevant to toddlers (4, 9-11). Studies have reported the effects of OHRQoL on children and their families (12-14). The concept of OHRQoL has been expanded to assess both the physical and psychosocial effects of oral health. Thus, most studies in this area show that oral health significantly influences overall QoL.

During the preschool years, children experience significant development of their psychosocial characteristics, specifically as they attempt to achieve independence and engage in social interactions. This stage is marked by major cognitive, language, social, and behavioral changes. However, children with oral clefts face unique challenges due to facial differences, speech difficulties, abnormal dental growth, and hearing impairments, making social interactions more challenging (15). These issues often worry their parents, making it crucial to consider their concerns and understand how pediatric treatments affect the children's HRQoL during this critical period—assessing whether these issues persist into the school years and beyond is also necessary. In preschool-aged children, self-reporting is impossible, and no agreement exists between proxy reporting and self-report

measurement. Parents are often selected as proxy respondents when measuring the QoL in preschool children (16, 17). This knowledge provides vital information to healthcare professionals. Comprehensive assessment and ongoing care are crucial at different developmental stages for this vulnerable population. Despite its importance, a lack of published results exists for assessing HRQoL using validated measures among toddlers treated for CL/P. Accordingly, this study aims to investigate the QoL of Persian-speaking toddlers with CL/P who are receiving team care from their parents' perspective and compare it with a healthy control group. Additionally, the findings from this study can provide insight into the potential impacts on HRQoL in younger children with CL/P.

## Materials & Methods

### Participants

The present study employed a cross-sectional design with a convenient sampling method and was conducted with toddlers at a hospital specializing in CL/P surgeries in Isfahan, Iran (Imam Hossein Children's Hospital) in 2020. The hospital was a prominent center serving patients from across Iran. Every toddler treated at this facility has received primary repair surgery for CL/P and multidisciplinary care following the procedures.

Thirty-six toddlers, each with repaired CL/P, were selected based on inclusion and exclusion criteria. Among them, 24 were males, making up 66.7% of the group. The mean age of these toddlers was 25.94 months, with a standard deviation (SD) of 5.64. Among the participants, 12(33.3%) have cleft palate only (CPO), 15 (41.7%) have unilateral cleft lip and palate (UCLP), and 9(25%) have bilateral cleft lip and palate (BCLP).

Additionally, 36 toddlers without cleft palate or lip (CP/L) were recruited. This group included 24 males (66.7%) and 12 females (33.3%), all matched by age and gender to serve as a control group for comparison.

### Inclusion and exclusion criteria

The participants were divided into two groups. The first group included toddlers who had primary lip surgery at about 3 to 4 months old and primary palate surgery at around 12 to 15 months old. These children had no diagnosed syndromes. Their development was assessed using the Ages and Stages Questionnaire (ASQ), which evaluated various domains such as communication, fine motor skills, gross motor skills, personal and social skills, and problem-solving abilities. The ASQ scores for these children were within the normal range, defined as within  $\pm 1$  SD from the cutoff in each domain. Additionally, they were receiving care from a cleft team. The second group comprised healthy toddlers of similar age and gender who did not have CL/P. They were selected from various daycare centers and preschools located in multiple cities.

### Data collection

Data were collected using questionnaires given to parents in person at the hospital or sent to them via WhatsApp, Telegram, or mail to their home addresses. After being filled out by the parents, questionnaires were sent back to the first author. The parents of eligible participants signed informed consent before completing demographic characteristics and the questionnaire. The SES was evaluated by using a five-question questionnaire. These questions inquired about income level, economic class, parents' education level, and housing situation. Parents rated their responses on

a 5-point Likert scale, with one representing very low and five representing very high (18)

### Questionnaire

TNO-AZL preschool children's quality of life (TAPQoL) is a generic and multidimensional HRQoL instrument for 1-5-year-old children. The questionnaire includes four sub-scales: Physical functioning includes stomach issues, skin issues, lung issues, sleep, appetite, and motor; social functioning refers to the difficulties in behavior and social; cognitive functioning involves communications; emotional functioning includes positive emotional performance, anxiety, and excitement. This questionnaire consists of 43 statements divided into two parts: A single-item section and a two-item section. In the single-item section, each question consists of one item. In the two-item section, if the answer to the first part of the question is positive, the respondent proceeds to answer the second part. However, if the first part is answered negatively, there is no need to answer the second part. Questions in the two-item section are scored from 0 to 4. Questions 24, 25, 26, 30, 31, 23, 33, and 35 are scored in reverse; the minimum score is 0, and the maximum score is 134, with higher scores indicating better quality of life (19). The reliability and validity of TAPQoL in several languages have been reported (20-23). In the Persian language, content validity was used to assess the questionnaire's validity, Cronbach's alpha coefficient (0.80), and the correlation between the questions and corresponding subscales (higher than 0.60) was reported (24, 25).

### Statistical analysis

Seventy-two toddlers with and without oral clefts who met inclusion criteria participated in the

study. Demographic characteristics, including age, gender, cleft phenotype, age of surgery, and SES before completing the questionnaire, were collected. The analysis was carried out using descriptive and analytical statistics. Descriptive statistics were used to summarize demographic information and collected data, and analytical statistics were used to compare the two groups. The statistical analysis was carried out using the statistical software SPSS version 27.

In the first stage of the analysis, due to the unavailability of the total score for the five-question SES, the mean and SD for the patient and healthy groups were determined based on principal component analysis. A descriptive analysis of TAPQoL total scores, sub-scales, and demographic characteristics, as well as an analytical analysis of independent t-test and analysis of covariance, were conducted to compare the two groups and assess any differences between them.

### Results

The mean and SD for SES in both groups are 11.6 ( $\pm 3.30$ ) and 12.59 ( $\pm 1.77$ ), as shown in Table 1. Table 2 presents descriptive statistics of participants' demography characteristics (child age, mother age, children number, and grade of child) in both groups.

Table 3 shows the mean, SD, min, and max subscales and T scores using independent sample t-tests for patient and healthy groups. Four significant differences between both groups were found. The results indicate that the mean scores of children with CL/P in all sub-scales (physical, social, cognitive, emotional functioning, and T scores (total scores) were slightly higher than those of the healthy group.

**Table 1.** Descriptive statistics for participants' SES with and without oral clefts

Group	Mean	SD
Toddlers with CP/L	11.61	3.30
Toddlers without CP/L	12.59	1.77
Total	12.07	2.71

**Table 2.** Descriptive statistics of participants' demography characteristics with and without oral clefts

	Children with CP/L(N=36)				Children without CP/L(N=36)			
	Min	Max	mean	SD	Min	Max	mean	SD
Child age(M)	18	35	25.94	5.64	18	35	26.19	6.29
Mother age(Y)	0	38	27.94	6.86	18	40	28.78	5.89
Children number	1	4	1.89	.82	1	3	1.63	.66
Grad of child	1	4	1.86	.83	1	3	1.50	.62

**Table 3.** Comparison of TAP QoL subscales and total scores between toddlers with and without oral clefts

	Children with CP/L (N=36)				Children without CP/L (N=36)				t	df	p-value(2-tailed)
	Min	MAX	mean	SD	Min	Max	mean	SD			
Physical functioning	2.30	4	3.34	.41	2.95	3.60	3.28	.18	.78	66	.43
Social functioning	.40	2	1.36	.36	1	1.40	1.17	.11	2.96	66	.00
Cognitive functioning	1.25	4	2.62	.84	2	3	2.81	.26	2.21	66	.03
Emotional functioning	1	2	1.66	.24	1	1.67	1.45	.18	3.99	66	.00
T score	81	122	106.17	11.52	90	106	99.56	4.05	3.07	66	.00

T score, total score

T score, total score

As provided in Table 4, an analysis of covariance (ANCOVA) was conducted to compare toddlers grouped according to demographic

characteristics (independent variables) and QoL T score (dependent variable). Results of ANCOVA showed a significant effect of cleft phenotype on QoL for both groups ( $F=3.40, P=0.02$ ). Table 5

**Table 4.** ANCOVA of the interaction effect between QoL T scores and demographic characteristics for toddlers with and without oral clefts

Source	SS	df	F	p-value
SES	23.93	1	.29	.59
Child Age	91.32	1	1.11	.29
Gender	8.33	1	.10	.75
Cleft Type	837.40	3	3.40	.02
Gender*Cleft Type	59.83	3	.24	.86
Error	4759.13	58		

<sup>a</sup>R Squared=.193(adjusted R Squared=.068), SES

**Table 5.** Mean and SD of participants' T Stores with and without oral clefts based on ANCOVA

	Healthy group	CP	UCLP	BCLP
Mean (SD)	99.56(4.06)	106(12.91)	106.5(14.85)	109.89(8.42)

compares the mean and SD of the QoL T score between two groups based on cleft phenotype. The mean and SD in the oral cleft group were slightly higher than in the healthy group, and the patients with BCLP had the highest mean among other cleft types.

## Discussion

The QoL is assessed in children with CL/P according to two concepts: HRQoL and OHRQoL. The dimensions of HRQoL include Physical Health, encompassing the ability to perform daily activities, the presence of pain, and overall physical functioning; Psychological Health, dimension assesses emotional well-being, including symptoms of anxiety and depression, cognitive functioning, and overall mental health; Social Functioning, evaluating how health impacts social interactions, relationships, and the ability

to engage in community or family activities. OHRQoL is a more specific QoL concept and refers to how individuals perceive the functional and psychosocial impact of oral diseases and conditions on their lives (26).

This study is the first to examine the HRQoL in Persian toddlers with CL/P receiving team-based care. It also compares their HRQoL to that of a healthy control group, utilizing the TAPQoL questionnaire. The participant groups were homogeneous regarding sample size, gender, and age. These results revealed that toddlers with CL/P had higher HRQoL scores in social, cognitive, and emotional functioning dimensions than their peers (Table 3). It is postulated that this occurred as a consequence of repaired surgeries of the cleft during the earlier stages of childhood and the inclusion of all children in a healthcare program at a reference hospital, including follow-

up visits and psychological support for both the child and the family (6, 10, 27). These findings are consistent with studies that have shown a high QoL for children with CL/P who were under the care of cleft teams and received primary surgeries (28-30). Importantly, the TAPQoL is a generic HRQoL instrument that does not include OHRQoL components. It would be more appropriate to assess more typical QoL dimensions, such as appearance, social acceptance, and self-esteem. Although different instruments have been used to measure QoL, these instruments have been found to have reliability and validity values. The primary distinction between the instruments lies in the constructs they measure. Therefore, the results of these studies cannot be directly compared (14, 28, 31, 32). Nevertheless, indicatively, certain dimensions of QoL in children, adolescents, and adults with CL/P may be influenced (33). While some studies have indicated no significant differences in HRQoL between children and adolescents with and without CL/P, others have reported lower QoL scores in individuals with CL/P (34, 35). Additionally, evidence indicates that psychological health and vitality are the dimensions of HRQoL that are most affected by HRQoL in children with CL/P and adults, respectively. Conversely, physical health is the least affected for both children and adults. Consequently, advancing age, awareness, and cognition, particularly when considered in conjunction with the severity of the patient's condition and gender, SES, and education level of the family, can result in alterations to various dimensions of QoL (36, 37).

The WHO has highlighted the importance of assessing demographic characteristics (age, gender, the severity of the problem, culture, SES, and education level of the family) when assessing

the QoL (World Health Organization Quality of Life Group, 1995) because this information is specifically related to achieving a proper understanding of the results of QoL assessments (38-40). The obtained results demonstrated that demographic characteristics (age, gender, SES) did not affect QoL. However, a significant difference was observed between the two cleft types and the QoL (Table 4, 5). Participants with more cleft severity (BCLP) had a better QoL. Notably, the results of this part differ from those of previous studies (13, 30, 41). This can be attributed to the impact of multidisciplinary team care on the challenges that parents of severely cleft-affected toddlers face. These parents can successfully overcome significant challenges that other parents of children with less severe cleft conditions and healthy groups have not experienced. Importantly, the questionnaire was completed by parents who may have different perceptions and feelings than the children. Toddlers cannot yet understand the differences between themselves and their peers. Therefore, when evaluating the QoL of a child with CL/P, it is essential to consider both the child's perspective and that of the parents at different stages of development (42).

## In Conclusion

Receiving effective interventions under the supervision of a cleft team may lead these children to experience a normal QoL despite the various challenges they will face.

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IR.USWR.REC.1400.310). Informed consent was obtained from all participating families, and both the researcher and the participant signed the document, with a copy provided to the participant. The identities of study participants will remain confidential.

### Authors' Contributions

The authors (Neda Tahmasebi, Talieh Zarifian, Atieh Ashtari) contributed to the study's design, construction, writing, and interpretation of data, and (Mehrdad memarzadeh, siyamak Tahmasebi Garmatani, Marjan larimian) contributed to the sampling, conception, and acquisition of data

### Conflict of Interest

The authors have no conflicts of interest to declare.

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