Theory Clin Pract Pediatr, 2024, 5: 114-120
DOI: 10.25082/TCPP.2024.01.001

RESEARCH ARTICLE

Exploring quality of life disparities among 177 families with children affected by cleft lip and/or palate: A comprehensive analysis using the Impact on Family Scale

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Received: February 22, 2024;
Accepted: April 21, 2024;
Published: April 25, 2024.

Citation: Kabuyaya MK, Mukuku O, Kasereka JML, et al. (2024). Exploring quality of life disparities among 177 families with children affected by cleft lip and/or palate: A comprehensive analysis using the Impact on Family Scale. *Theory and Clinical Practice in Pediatrics*, 5: 114-120.
https://doi.org/10.25082/TCPP.2024.01.001

Abstract: Objective: This study aimed to assess the quality of life (QoL) of parents/caregivers of children with cleft lip and palate (CLP) using the Impact on Family Scale (IOFS). **Methods:** Families of children requiring primary or secondary CLP repair were recruited based on the inclusion criteria. The IOFS questionnaire was utilized to assess perceived QoL. Multiple logistic regression was employed to determine factors linked to impacted QoL. **Results:** Out of the 192 families contacted, 177 participated (92.2%). The patients had a mean age of 8.9 $\pm$ 5.4 months, with a majority of families residing in rural areas (67.2%). The questionnaires assessed QoL before surgery, revealing a mean total QoL score of 68.8 $\pm$ 19.4, with 49.7% of families experiencing affected QoL. The analysis demonstrated a significant association between the female sex of parents/caregivers and a more impacted QoL ($p = 0.018$), as well as between the absence of a history of CLP in the family and a more affected QoL (adjusted odds ratio = 3.0; 95% CI: 1.3 – 6.7; $p = 0.008$). **Conclusion:** Caring for a child with CLP significantly decreases parents/caregivers' QoL in all domains. The results emphasize the significance of considering the family history of CLP and the gender of the parents in the comprehensive care of affected families.

Keywords: cleft lip and palate, quality of life, psychosocial impact

1 Introduction

Cleft lip and palate (CLP) pose a significant public health concern, impacting the quality of life (QoL) of families globally. CLPs are the most prevalent non-syndromic craniofacial anomalies in humans, with a mean incidence of approximately 1 in 700 live births. The etiology of these malformations is complex, likely involving a combination of genetic and environmental factors [1]. Prenatal ultrasound is increasingly utilized for the early detection of CLP, although the diagnosis is typically confirmed during a clinical examination at birth [2]. Multidisciplinary management of CLP begins shortly after birth but can be challenging for families. The birth of a child with CLP can present significant psychological and social hurdles for families, such as anxiety, depression, and difficulty coming to terms with the diagnosis [3,4]. Families often encounter additional financial, personal, and social burdens associated with meeting the unique needs of an infant with CLP [5,6].

The implications of CLP are far-reaching, extending beyond physical symptoms to impact aspects of QoL, self-image, and social dynamics. The emotional and financial strain that these conditions impose on families is significant. The primary areas of focus include the QoL of these families and the psychosocial effects on the parents. Some studies have suggested that the aesthetic enhancements resulting from corrective surgeries may enhance the child's psycho-emotional integration into their social surroundings [7,8].

Despite recognizing these challenges, there is a critical need to comprehensively understand the overall impact of CLP on the QoL of Congolese families, with particular emphasis on the psychosocial and economic aspects associated with this condition.

This study aims to specifically evaluate the impact of CLP on the QoL of Congolese families, emphasizing the psychosocial and economic aspects associated with this condition. By focusing on this specific population, the study offers valuable insights into the experience of Congolese families in a particular cultural and social context. This study enriches the existing literature on CLPs by offering new and contextual perspectives. By identifying the challenges encountered by Congolese families and emphasizing areas requiring enhancement, this research furnishes valuable insights to steer clinical interventions and health policies aimed at enhancing the QoL of affected families.

2 Materials and Methods

2.1 Setting, type, and study population

This was a cross-sectional study to assess QoL in parents/caregivers of children with CLP before surgical interventions. Parents/caregivers of children born with non-syndromic CLP and who required surgical treatment to correct the defects were included in the study.

A total of 177 consecutive families with children with non-syndromic CLP aged 4 to 48 months were invited to complete a questionnaire. All children were treated during free care campaigns organized from January 2020 to December 2023 with financial support from Smile Train. The treatment took place at the HEAL Africa hospital in Goma, located in the province of North Kivu, Democratic Republic of the Congo (DRC). The questionnaires were distributed to parents/caregivers while their children were hospitalized for primary or secondary surgical repair of the CLP. Parents/caregivers were requested to respond to the questions together at least one week before the surgery, and a healthcare professional, not part of the study team, assisted families who were not fluent in French. All patients underwent surgical treatment tailored to their specific type of CLP.

2.2 Data collection and study variables

The questionnaire used was in French, and it included requests for personal details and medical history of all family members. The following preoperative data were collected and recorded in an Excel file (password protected) for each family: for the parents/caregivers, we recorded age (16-25 years, 26-40 years, or >40 years), gender (male or female), residence (rural or urban), religion (Catholic, Protestant, or others); and for the child, we recorded the age ($\leq$ 11 months or $\geq$ 12 months), sex (male or female), the history of CLP in the family (yes or no) and the type of CLP (unilateral cleft lip isolated, bilateral cleft lip isolated, cleft lip and palate, or cleft palate isolated). A QoL questionnaire was administered to the parents/caregivers of each child using the Impact on Family Scale (IOFS) [5, 6], which was used to detect subjectively perceived QoL in the affected family. The IOFS was developed in the Anglo-American literature as a self-report instrument to measure the effects of chronic illness and disability in childhood on the family. It consists of 33 items related to five dimensions, including financial impacts (4 items), social relationships (15 items), personal impacts (5 items), coping strategies (3 items), and brothers' concerns and sisters (if applicable; 6 items). Parents/caregivers were asked to indicate whether the item was "absolutely true," "true in most aspects," "not true in most aspects," or "not true at all." A total impact score was calculated by adding the scores of all items. The minimum possible total score was 33 and the maximum possible total score was 132. Scores from 1 to 66 indicated that QoL was not affected, while any score above 66 indicated that QoL was affected.

The internal consistency reliability coefficient (Cronbach's alpha) calculated for the IOFS items in this study was 0.9231.

2.3 Statistical analyses

The data collected were entered and encoded in Microsoft Excel, and statistical analyses were conducted using STATA version 16.0.

Descriptive analysis was conducted by calculating proportions for qualitative variables (frequencies, percentages) and determining means with their standard deviations (SD) and medians with interquartile ranges (IQR) for quantitative variables. As all quantitative variables were found to be non-normally distributed following verification through the Shapiro test, we employed the Mann-Whitney U test or the ANOVA test (when appropriate) to compare the medians of the IOFC total score across various categorical variables.

In the present study, affected QoL (IOFS total score $>$ 66 points) was the dependent variable. Bivariate analysis was performed using the Chi-square test. Then multiple logistic regression by

block entry method was used to identify factors associated with affected QoL. p-value < 0.05 was considered statistically significant.

2.4 Ethical considerations

The study obtained approval from the Medical Ethics Committee of the University of Goma (Approval number: UNIGOM/CEM/013/2022). The ethical principles of the Declaration of Helsinki were respected throughout the study, ensuring informed consent of participants, confidentiality of data, and respect for their well-being. Informed consent was obtained from each participant before interviews were conducted, and no compensation or incentives were paid to participants for this study. Prior to this, detailed information and explanations about the study were provided to each parent or caregiver. Parents/caregivers were also allowed to ask questions and seek clarification during the consent process. Confidentiality was ensured, and participants were informed that they had the right to withdraw from the study at any time without prior explanation on their part, without victimization or refusal of treatment.

3 Results

Of the 192 families invited to respond to the questionnaires, 177 participated in the study and completed the questionnaire (92.2%). The mean and median ages of patients at the time of the survey were 8.9 ± 5.4 months and 5 months, respectively (IQR: 4 and 10 months); while the mean and median ages of parents/caregivers were 30.8 ± 10.1 years and 30.0 years, respectively (IQR: 23.0 and 36 years). The majority of parents/caregivers were female (76.8%) compared to male (23.2%). In terms of residence, 119 (67.2%) respondents lived in rural areas and 58 (32.8%) in urban areas. Regarding religious affiliation, 33.3% identified as Catholic, 26.6% as Protestant, and 40.1% belonged to other religious faiths. Additionally, 22.0% of families had at least one child with CLP prior to the patient's birth.

Among the patients with a cleft, 82 (46.3%) were male and 95 (53.7%) were female. Specifically, 46 patients had CLP (26.0%), 97 patients had isolated unilateral cleft lip (54.6%), 19 patients had an isolated cleft palate (10.7%), and 15 patients had a bilateral cleft lip (8.5%). The diagnosis of CLP was established postnatally for all of our patients in Table 1.

Table 1 Sociodemographic characteristics of participants and their children with cleft lip and palate accompanied by means and medians of the total score of the Impact on Family Scale

Variable	Number	Percentage	Mean ± SD of total score	Median (IQR) of total score	p-value*
Total	177	100.0	68.8 ± 19.4	65.0 (54.0 – 82.0)	
Age of parent/caregiver					0.683
16-25 years	66	37.3	67.2 ± 19.1	62.0 (52.0 – 82.0)	
26-40 years	81	45.8	70.0 ± 20.3	67.0 (55.0 – 81.0)	
> 40 years	30	16.9	69.2 ± 18.1	67.0 (54.0 – 76.0)	
Gender of parent/caregiver					0.018
Male	41	23.2	62.5 ± 15.9	59.0 (51.0 – 69.0)	
Female	136	76.8	70.7 ± 20.1	68.0 (55.0 – 86.0)	
Residence					0.210
Rural	119	67.2	67.7 ± 19.3	64.0 (52.0 – 78.0)	
Urban	58	32.8	71.0 ± 19.7	67.0 (57.0 – 84.0)	
Religion					0.247
Catholic	59	33.3	65.4 ± 17.8	60.0 (52.0 – 76.0)	
Protestant	47	26.6	69.4 ± 19.0	68.0 (54.0 – 82.0)	
Others	71	40.1	71.2 ± 20.8	68.0 (55.0 – 87.0)	
Family history of CLP					0.011
Yes	39	22.0	61.1 ± 15.2	58.0 (51.0 – 69.0)	
No	138	78.0	71.0 ± 20.0	68.0 (54.0 – 85.0)	
Age of child					0.342
≤ 11 months	138	78.0	69.4 ± 19.0	66.0 (54.0 – 82.0)	
≥ 12 months	39	22.0	66.7 ± 21.0	58.0 (51.0 – 79.0)	
Gender of child					0.892
Male	82	46.3	68.1 ± 18.1	67.5 (54.0 – 78.0)	
Female	95	53.7	69.4 ± 20.6	65.0 (54.0 – 85.0)	
Type of CLP					0.088
Unilateral cleft lip	97	54.8	62.3 ± 14.2	63.0 (51.0 – 74.0)	
Cleft lip and palate	46	26.0	71.8 ± 21.7	66.0 (54.0 – 88.0)	
Cleft palate	19	10.7	66.7 ± 18.5	63.0 (53.0 – 76.0)	
Bilateral cleft lip	15	8.5	77.4 ± 19.8	77.0 (58.0 – 89.0)	

Note: CLP: cleft lip and palate; SD: standard deviation; IQR: interquartile range; * Mann-Whitney U test or ANOVA test.

The mean and median preoperative total QoL scores for the families were 68.8 ± 19.4 and 65.0 (54.0 – 82.0), respectively. The proportion of families whose QoL was affected was 49.7%. The mean and median scores of different domains assessed using IOFS (financial impact, social life, personal impact, coping capacity and sibling's domain) are presented in Table 2.

Table 2 Mean score before surgery in each domain

Domain	Total possible score	Mean ± SD	Median (IQR)
Financial impact	16	8.2 ± 3.4	8.0 (5.0 – 11.0)
Social impact	60	30.7 ± 10.7	28.0 (22.0 – 37.0)
Personal impact	20	10.8 ± 3.6	10 (8.0 – 13.0)
Impact on control and adaptation	12	9.0 ± 2.6	9.0 (7.0 – 12.0)
Impact on siblings	24	10.0 ± 3.4	9.0 (8.0 – 12.0)
Total	132	68.8 ± 19.4	65.0 (54.0 – 82.0)

Note: SD: standard deviation; IQR: interquartile range.

We observed that there was no influence of parents/caregivers' age, residence, religion, patient's age, sex, and type of CLP on the median total QoL scores. Additionally, we identified that the median total QoL score of female parents/caregivers was significantly higher than that of male parents/caregivers, indicating a notable impairment in QoL when the parent/caregivers were female (p = 0.018). Likewise, we found that families without a history of CLP were significantly more affected than those with a history of CLP in the family (68.0 versus 58.0; p = 0.011) (Table 1).

Table 3 compares the characteristics of families whose QoL was affected before surgery to those of families whose QoL was not affected in bivariate and multivariate analyses. In bivariate analyses, the factors associated with affected QoL were female sex (crude odds ratio = 2.0; 95% CI: 1.0 – 4.1; p = 0.049), the absence of CLP in the family (crude odds ratio = 2.8; 95% CI: 1.3 – 5.9; p = 0.007), and the presence of isolated cleft palate (crude odds ratio = 4.2; 95% CI: 1.0 – 18.0; p = 0.047). After multivariate analyses, we found that families without CLP in the family were 3 times more affected than those with CLP in the family (adjusted odds ratio = 3.0; 95% CI: 1.3 – 6.7; p = 0.008).

Table 3 Quality of life of the family before the surgical intervention according to the sociodemographic characteristics of the respondents

Variable	Total N = 177	Quality of life affected		cOR [95% CI]	p-value	aOR [95% CI]	p-value
		Yes (%) (n = 88)	No (%) (n = 89)				
Age of parent/caregiver							
16-25 years	66	31 (47.0)	35 (53.0)	1.0		1.0	
26-40 years	81	41 (50.6)	40 (49.4)	1.2 [0.6-2.2]	0.784	1.4 [0.7-2.9]	0.354
> 40 years	30	16 (53.3)	14 (46.7)	1.3 [0.5-3.1]	0.720	1.8 [0.7-4.7]	0.246
Gender of parent/caregiver							
Male	41	15 (36.6)	26 (63.4)	1.0		1.0	
Female	136	73 (53.7)	63 (46.3)	2.0 [1.0-4.1]	0.049	2.2 [0.9-4.8]	0.063
Residence							
Rural	119	58 (48.7)	61 (51.3)	1.0		1.0	
Urban	58	30 (51.7)	28 (48.3)	1.1 [0.6-2.1]	0.832	1.0 [0.5-1.9]	0.898
Religion							
Catholic	65	30 (46.1)	35 (53.9)	1.0		1.0	
Protestant	47	24 (51.1)	23 (48.9)	1.2 [0.6-2.6]	0.608	1.4 [0.6-3.3]	0.388
Others	65	34 (52.3)	31 (47.7)	1.3 [0.6-2.5]	0.483	1.7 [0.8-3.6]	0.190
Family history of CLP							
Yes	39	12 (30.8)	27 (69.2)	1.0		1.0	
No	138	76 (55.1)	62 (44.9)	2.8 [1.3-5.9]	0.007	3.0 [1.3-6.7]	0.008
Age of child							
≤ 11 months	138	69 (50.0)	69 (50.0)	1.1 [0.5-2.1]	0.888	1.0 [0.4-2.1]	0.936
≥ 12 months	39	19 (48.7)	20 (51.3)	1.0		1.0	
Gender of child							
Male	82	42 (51.2)	40 (48.8)	1.1 [0.6-2.0]	0.710	1.3 [0.7-2.6]	0.352
Female	95	46 (48.4)	49 (51.6)	1.0		1.0	
Type of CLP							
Bilateral cleft lip	15	6 (40.0)	9 (60.0)	1.0		1.0	
Cleft lip and palate	46	23 (50.0)	23 (50.0)	1.5 [0.5-4.9]	0.501	1.5 [0.4-5.1]	0.540
Unilateral cleft lip	97	45 (46.4)	52 (53.6)	1.3 [0.4-3.9]	0.644	1.3 [0.4-4.2]	0.640
Cleft palate	19	14 (73.7)	5 (26.3)	4.2 [1.0-18.0]	0.047	3.5 [0.8-15.6]	0.108

Note: cOR: crude odds ratio; aOR: adjusted odds ratio; 95% CI: 95% confidence interval.

4 Discussion

The present study contributes to the growing body of literature examining the impact of CLP on the QoL of affected families. Using the Impact on Family Scale (IOFS) to assess QoL, we aimed to provide insight into the unique challenges faced by families with young children with CLP.

The present study achieved a high participation rate, with 177 out of 192 families responding to our survey, resulting in a response rate of 92.2%. This high response rate reinforces the validity and generalizability of our results, ensuring that our results are representative of the population studied. Demographic analysis of participants showed a mean age of 30.8 $\pm$ 10.1 years for parents/caregivers. Interestingly, the majority of parents/caregivers were women (76.8%). A predominantly rural population was observed (67.2% of respondents), and a varied representation of religious beliefs was noted. A significant finding was that 22.0% of families had a history of CLP within the family. The finding that a majority of respondents resided in rural areas highlights the specific challenges faced by families with children with CLP in these areas. These families might face stigma and increased difficulties in accessing specialized health care, due to limited medical infrastructure and lack of qualified personnel in rural areas [9].

The QoL of these families was measured preoperatively using the Impact on Family Scale (IOFS), resulting in a mean score of 68.8 $\pm$ 19.4. This score indicates that a significant proportion of families, specifically 49.7% (88/177), reported a negative QoL. Our findings align with those of Kramer et al. [5], who also highlighted the emotional and financial challenges faced by families of children with CLP. In comparison to the study by Emeka et al. [6], which reported a mean score of 89.6 $\pm$ 2.4 and 95.7% of affected families, our study shows a lower preoperative QoL. This difference may be due to variations in participant demographics or healthcare systems in the study populations.

During our investigation, we observed no significant correlation between median total QoL scores and parents/caregivers' age, place of residence, religious affiliation, patient's age, gender, or type of CLP. However, when comparing gender-specific impacts, female parents/caregivers displayed significantly higher median QoL scores, indicating a more pronounced negative effect on their QoL compared to their male counterparts ($p = 0.018$). This suggests that female parents/caregivers may perceive and experience the impact of CLP differently than male counterparts. Possible explanations for this difference could include variances in coping strategies, social support networks, or caregiving responsibilities between genders. Further exploration of these gender differences is necessary to gain a better understanding of their implications for intervention and support services.

Additionally, families without a history of CLP reported being more affected ($p = 0.011$). Multivariate analysis reinforced the finding that families without a history of CLP were three times more likely to report compromised QoL (adjusted odds ratio = 3.0; $p = 0.008$). This suggests that families with previous experiences of CLP may possess certain resilience or coping strategies that help reduce the overall impact on their QoL. The association between decreased familial QoL and no family history of CLP may be attributed to various psychosocial factors. Financially, these families face additional challenges due to lack of experience managing the costs of health care and treatment associated with CLP. Without prior preparation, they may find themselves overwhelmed by unforeseen expenses and financial burdens directed towards traditional medicine which is powerless in the management of CLP. Socially, the absence of a family history of CLP can compound social stigma and restrict access to community support, leading to increased social and emotional isolation for affected families. In contrast, families with a family history of CLP may benefit from a pre-existing social support network, which could mitigate the negative effects on their QoL. On a personal level, family members may experience increased stress due to the absence of family role models to guide their experience and coping strategies. In contrast, families with a family history of CLP can draw on past experience to develop more robust coping mechanisms when facing the challenges inherent in caring for CLP. In terms of adaptation, families without a family history of CLP may experience increased difficulty adjusting to complex care demands and treatment decisions, whereas families with a family history of CLP may benefit from greater adaptive resilience, thereby facilitating a smoother transition into management of the condition. In sum, the absence of a family history of CLP may contribute to a deterioration in family QoL due to increased social, personal, and adaptation challenges, while families with previous experience may present a greater ability to cope with these challenges, thanks to pre-existing social and psychological preparation or adaptation and resilience strategies already put in place by family members. We found that families without prior experience with this condition may be particularly vulnerable to negative impacts on QoL. These findings highlight the importance of awareness, support, and targeted interventions to help families cope with the challenges associated with CLP.

Emphasis will be placed on early education, community resources, and access to specialized care.

Emeka et al. [6] had found that CLP has a significant impact on families' QoL, particularly financially and socially. Furthermore, families of children with bilateral cleft lip were the most affected, followed closely by those with unilateral cleft lip, suggesting that the severity of the malformation may influence the magnitude of the impact on families' QoL.

However, as emphasized in the study by Kramer et al. [5], results may vary depending on the specific type of cleft and time of diagnosis. Families with children with isolated cleft palate reported the greatest challenges before surgery, which may be attributable to the additional demands of care costs and complications associated with this condition in their study.

As suggested by the study by Emeka et al. [6], surgical intervention has been identified as a key factor in improving families' QoL. After surgery, they observed a significant reduction in the negative impact on parents' QoL, particularly in the social and personal domains. This supports the idea that surgery represents an important step in the care pathway for children with CLP and their families [6, 10].

Furthermore, previous studies have also highlighted the significance of social support and early information for affected families, which may help alleviate some of the challenges they face [11, 12]. This is consistent with our finding that families with a family history of CLP reported lower levels of impact on QoL, indicating that social support may play a protective role.

Despite its significant contributions, this study has some limitations to consider. First, it is based on data collected in a specific context, which could limit the generalization of the results to other populations or regions. Additionally, the use of a family impact scale to assess families' QoL may be subject to bias of perception or response. Furthermore, this study did not delve into other potential factors that could impact families' QoL, such as available community resources or social support. An important limitation of this study is the absence of evaluating patients' post-surgery. By solely focusing on assessing families preoperatively, we may not fully capture the effects of surgery on families' QoL. A postoperative evaluation would have enabled us to determine how much the enhancement in the health of children affected by CLP influences family QoL. Lastly, data on family history of CLP were collected retrospectively and may not be comprehensive, which could affect the interpretation of the results.

5 Conclusion

This study underscores the substantial impact of CLP on the QoL of families with affected young children. The findings demonstrate a notable prevalence of diminished QoL. The lack of a family history of CLP correlates with a more pronounced decline in family QoL, with non-CLP families being three times as affected. It is crucial to incorporate a systematic evaluation of family QoL into care initiatives for children with CLP and implement tailored interventions to assist susceptible families. Subsequent research endeavors could investigate the efficacy of interventions designed to enhance the welfare of affected families.

Abbreviations

95% CI:	95% confidence interval
aOR:	adjusted odds ratio
CLP:	cleft lip and/or palate
cOR:	crude odds ratio
DRC:	Democratic Republic of the Congo
IOFS:	Impact on Family Scale
IQR:	interquartile range
QoL:	quality of life
SD:	standard deviation

Conflicts of interest

The authors declare that they have no conflict of interest.

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