Original Article

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Dentistry Section

Evaluation of Quality of Life of Parents and Growth Parameters of their Infants with Cleft Lip and Cleft Palate before and after Primary Surgery: An Observational Study

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ABSTRACT

Introduction: Cleft Lip (CL) and Cleft Palate (CP) are associated with several complications that have a significant negative impact on the Quality of Life (QoL) of affected children and caregivers. Compared to their healthy counterparts, children with these conditions experience feeding difficulties, cosmetic abnormalities, and, most importantly, diminished physical and cognitive growth, especially during the first year of their lives.

Aim: To evaluate the growth parameters in CL and/or CP infants and the QoL of parents with a CL and/or CP child before and after primary surgery.

Materials and Methods: For this observational study, data was collected longitudinally from the same set of Cleft lip and cleft palate (CL/CP)/CL&CP infants and their parents before and after the primary surgery. The study was conducted at the Department of Paediatric and Preventive Dentistry, Guru Nanak Institute of Dental Sciences and Research, West Bengal, ABMSS Kolkata Comprehensive Cleft Care Centre, West Bengal, and IMA Vaccination Centre Barasat, West Bengal, India, from December 2020 to May 2022. In this study, 66 children and 64 parents were included in each study and control group. Growth parameters {weight, length, Head Circumference (HC)} were measured using a weight analogue machine, infantometer, and HC measuring tape, and compared with those of healthy infants. The QoL of parents with CL and/or CP infants was quantified using a questionnaire form of "Revised Impact on Family Scale (RIOFS)" filled out by parents before and after six months of primary surgery and compared with the QoL of same-age healthy infants. The responses to the RIOFS questionnaire were scored according to recommended guidelines. The Statistical Package for Social Sciences (SPSS) Statistics 23.0 was used for data analysis.

Results: Among the study groups, statistically significant differences in mean height, weight, and HC were observed between the groups of all infants with CL, CP, and CL with CP before and after the primary surgery ($p<0.001$). The QoL of parents from the study group improved post-surgery. The difference in mean RIOFS score between study Group-3 and study Group-4 after the primary surgery was statistically significant ($p<0.001$).

Conclusion: The growth of CL and/or CP infants and the QoL of their caregivers are compromised compared to healthy infants. After primary surgery, the growth of CL and/or CP infants and the QoL of their parents partially improved.

Keywords: Head circumference, Infantometer, Paediatric dentistry, Questionnaire

INTRODUCTION

The CL/CP and CL&CP are the most common congenital craniofacial malformations characterised by complete or partial clefts of the lip and/or palate. According to Global Burden of Disease (GBD) 2016 data, the estimated incidence of CL&CP in India is around 0.25 to 2.29 per 1000 births, with a calculated prevalence rate of 33.27 for males and 31.01 for females per 100,000 population [1]. The condition has a multifactorial aetiology, where the interaction between environmental and genetic factors plays a key role [2]. Numerous issues linked to CL and CP have a considerable detrimental effect on the QoL for parents or caregivers. When compared with their healthy counterparts, children with these conditions experience reduced physical and cognitive growth [3,4]. Proper treatment in a timely manner is required to improve QoL and lead a socially acceptable life; however, many patients receive sub-optimal, limited, or no treatment at all [5]. Primary surgery (primary lip surgery at 3-6 months and primary palate surgery at 6-12 months) may improve facial symmetry and functional activity in CL/CP/CL&CP patients, thus enhancing the physical growth of infants and ultimately the QoL of their parents [6,7].

Studies have been conducted on the effect of CL with or without CP (CL&CP) on Oral Health-Related Quality of Life (OHR-QoL) or Health-Related Quality of Life (HR-QoL) among children [8-12]. However, only a limited amount of literature [3,13] in this field explores the comparison of the QoL of parents with children with CL, CP, or both CL&CP with their healthy counterparts after primary surgery.

Against this backdrop, the current study aims to comparatively assess the QoL of parents and the growth parameters of their infants with CL, CP, or both CL&CP before and after primary surgery.

MATERIALS AND METHODS

An observational study was conducted at ABMSS Cleft Care Centre, Kolkata, Guru Nanak Institute of Dental Sciences and Research, and IMA Vaccination Centre, Barasat, West Bengal, India. The study period was from December 2020 to May 2022. Ethical clearance was obtained from the institute (Ref No. GNIDSR/IEC/20-23/04), and informed consent was obtained from the parents of the children. Data was collected longitudinally from the same set of CL/CP/CL&CP infants and their parents before and after the infants' primary surgery.

Inclusion criteria:

- **For study Group-1:** Infants with CL/CP/CL&CP of both sexes aged 3-6 months, admitted to the above-mentioned hospitals before primary surgery.
- **For control Group-1:** Age and sex-matched healthy infants aged 3-6 months (According to the World Health Organisation (WHO) Child Growth Standards, 2006) [14].
- **For study Group-2:** The same infants (9-12 months of age) included in study Group-1 (with CL/CP/CL&CP of both sexes) after six months of primary surgery.
- **For control Group-2:** Age and sex-matched healthy infants aged 9-12 months (According to the WHO Child Growth Standards, 2006).
- **For study Group-3:** Either of the parents of 3-6 months infants with CL/CP/CL&CP (study Group-1) admitted to the same hospital before primary surgery.
- **For control Group-3:** Either of the parents of healthy infants between 3 to 6 months of age (control Group-1), and sex-matched.
- **For study Group-4:** Either of the parents (parents of the study Group-2) of 9-12 months infants of both sexes with CL/CP/CL&CP after 6 months of primary surgery.
- **For control Group-4:** Either of the parents of healthy infants between 9 to 12 months (parents of the control Group-2) of age, and sex-matched.

Exclusion criteria:

- **For study Group-1 and 2:** Infants with CL/CP/CL&CP associated with different syndromes and chronic systemic diseases like cerebral palsy, cardiac problems, etc.
- **For control Group-3 and 4:** Parents who have infants 3-12 months of age with different syndromes like Down Syndrome, Fragile X Syndrome, and parents who have infants 3-12 months of age with different congenital systemic diseases like thalassemia, congenital cardiac diseases, Cerebral palsy, etc.

Sample size calculation: The sample size was calculated using GPower 3.1 software, with the level of significance at 5% and the study power at 80%. A minimum of 128 samples (64 infants with CL/CP/CL&CP and 64 healthy controls of the same age and sex; assuming a 1:1 ratio) was required for the current study.

Procedure

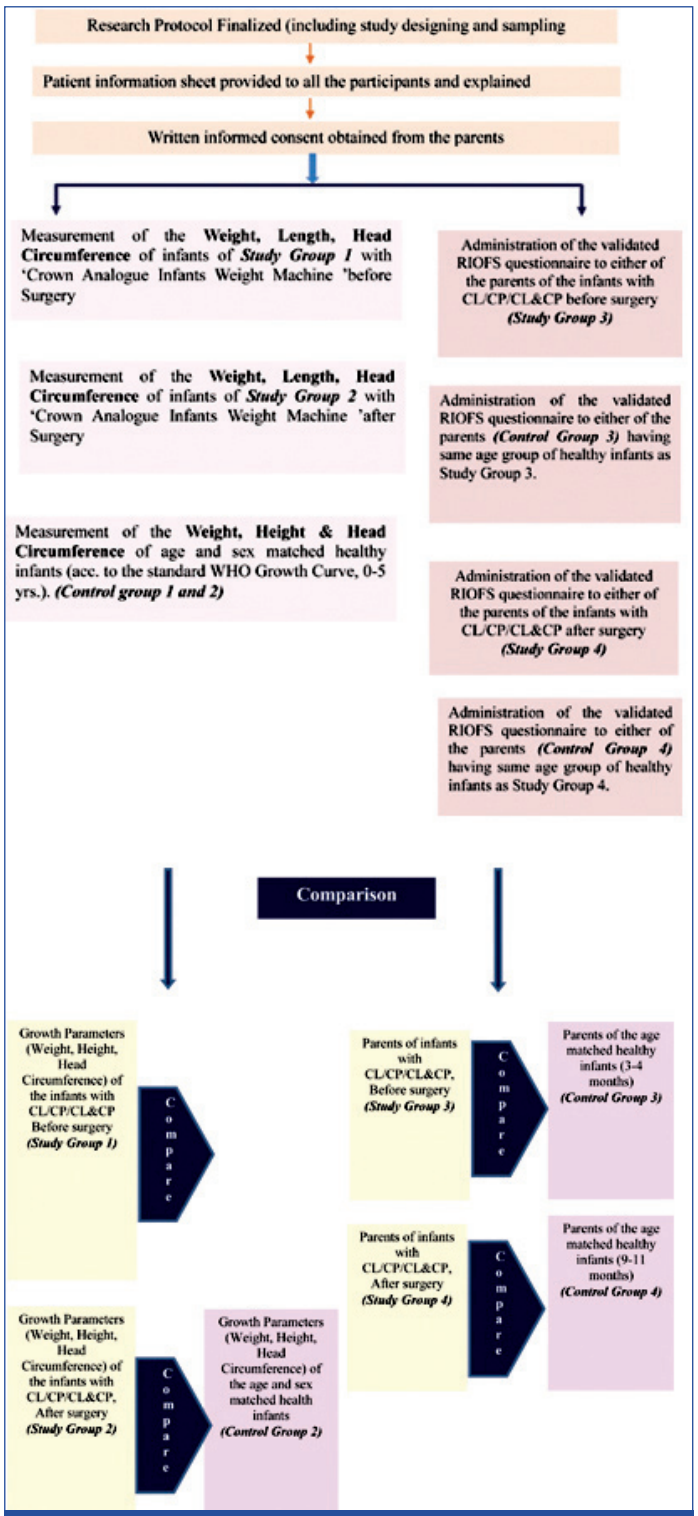
After obtaining ethical permission, 66 children with CL/CP who were admitted to the hospital for primary surgery and met the inclusion criteria were included in this study. The study subjects were divided into three groups as presented in [Table/Fig-1].

	Subgroups	Study group	Control group
Group-1	A (N=15)	Infants with CL before primary surgery	Age and sex matched healthy Infants
	B (N=20)	Infants with CP before primary surgery	Age and sex matched healthy Infants
	C (N=31)	Infants with CL&CP before primary surgery	Age and sex matched healthy Infants
Group-2	A (N=15)	Infants with CL after primary surgery	Age and sex matched healthy Infants
	B (N=20)	Infants with CP after primary surgery	Age and sex matched healthy Infants
	C (N=31)	Infants with CL&CP after primary surgery	Age and sex matched healthy Infants
Group-3	(N=64)	Either of the parent of infants of study Group-1	Either of the parent of infants of control Group-1
Group-4	(N=64)	Either of the parent of infants of study Group-2	Either of the parent of infants of control Group-2

[Table/Fig-1]: Distribution of study samples.

Study Groups 2A, 2B, and 2C consisted of the same children from Study Groups 1A, 1B, and 1C after six months of their primary surgery. Corresponding age and sex-matched children were selected as controls and divided into three groups (Control Groups 1A, 1B, 1C and Control Groups 2A, 2B, 2C) as shown in [Table/Fig-2].

Growth parameters {weight, height, and Head Circumference (HC)} of all children were measured before primary surgery and six months after their primary surgery using a crown analogue weight machine, infantometer, and HC measuring tape, respectively. Children in the control group who matched the age and sex criteria of the WHO Child Growth Standards (2006) were included, and their growth parameters were evaluated. Study Group-3 comprised the parents of Study Groups 1A, 1B, and 1C, while Study Group-4 included the parents of Study Groups 2A, 2B, and 2C. They were asked to complete a questionnaire before and after their children's primary



[Table/Fig-2]: Overview (Flowchart).

surgery. For Control Groups 3 and 4, parents with children of the same age were requested to fill out the questionnaire.

Questionnaire: The RIOFS, a modified 15-item questionnaire [15], which was originally developed from the 'Impact on Family Scale' (IOFS) questionnaire, was used to assess the subjectively perceived QoL in the affected families. The RIOFS measured QoL using a four-point Likert scale (strongly agree-1, agree-2, disagree-3, strongly disagree-4). The overall score ranged from 15 to 60, with higher scores indicating better QoL. This modified version of RIOFS (translated into Bengali from English) was a reliable, valid, self-administered, and simple tool that demonstrated better psychometric properties than the original IOFS. Prior to using the RIOFS scale in this study, the reliability and validity of the scale for the study population were assessed. The conversion rate ranged from 0.8 to 1, which was within the acceptable limit, and the Cronbach's alpha value was 0.771, indicating good reliability and validity of the scale in the study population [16].

STATISTICAL ANALYSIS

Microsoft Excel was used to tabulate data, generate graphs, tables, etc., while the statistical software IBM SPSS Statistics 23.0 (IBM Corporation, Armonk, NY, USA) was employed for data analysis. The mean difference in growth parameters between the study and control groups both before and after primary surgery was analysed using an unpaired t-test. The level of significance was set at p=0.05, and any value less than or equal to 0.05 was deemed statistically significant. The responses to the RIOFS questionnaire were scored as per the recommended guidelines. Participants who were unable to complete the questionnaire were excluded from the final analysis. The difference in overall scores between the study and control groups was assessed using an independent sample t-test. A p-value of <0.05 was considered statistically significant.

RESULTS

A total of 66 children with CL/CP/CL&CP who met the inclusion criteria were included in the current study. Each child's parent was approached to participate in the study and complete the questionnaire, but the parents of two infants were unwilling to fill out the questionnaire. Therefore, 64 parents were included in the final analysis.

The difference in the mean age of Study Group-1 (4.42±0.48) and Control Group-1 (4.43±0.48) was not statistically significant (p-value=1.00). The frequency distribution of gender (male and female) was similar in each group as no statistically significant difference was found between the two groups [Table/Fig-3a]. Similarly, the difference in the mean age and gender distribution between Study Group-2 and Control Group-2 was not statistically significant, confirming that the pattern of gender distribution was similar in the study and the corresponding control group [Table/Fig-3b].

Part-1: Comparison of growth parameters of infants with CL/CP/CL&CP before vs. after primary surgery.

This study found that the mean weight, height, and HC of the control groups before surgery were higher than their corresponding study groups. The difference in mean weight between Study Group-1A and Control Group-1A was statistically significant (p-value=0.001), whereas the differences in mean height and HC were not statistically significant (p-value=0.432, 0.160). The differences in mean height and weight between Study Group-1B and Control Group-1B were statistically significant (p-value=0.006, <0.001). However, no statistically significant difference in mean HC was observed between Study Group-1B and Control Group-1B (p-value=0.188). Statistically significant differences in mean height, weight, and HC were observed between Study Group-1C and Control Group-1C (p-value=0.018, 0.002) [Table/Fig-4a-c].

Parameter	Study Group-1 (N=66)	Control Group-1 (N=66)	p-value
Mean age	4.42±0.48	4.43±0.48	1.00
Gender distribution	Male=25 (37.89%) Female=41 (62.12%)	Male=25 (37.89%) Female=41 (62.12%)	1.00

[Table/Fig-3a]: Age and sex distribution for study Group-1.
(p-value <0.05 indicates a statistically significant difference; [†]p-value of chi-square statistics)

Parameter	Study Group-2 (N=66)	Control Group-2 (N=66)	p-value
Mean age	10.43±0.48	10.42±0.48	1.00
Gender distribution	Male=25 (37.89%) Female=41 (62.12%)	Male=25 (37.89%) Female=41 (62.12%)	1.00

[Table/Fig-3b]: Age and sex distribution for study Group-2.
(p-value <0.05 indicates a statistically significant difference; p-value of chi-square statistics)

Growth parameters	Study Group-1A (Mean±SD) (N=15)	Control Group-1A (Mean±SD) (N=15)	p-value
Weight (kg)	6.94±0.38	7.64±0.57	**0.001**
Height (cm)	64.03±1.30	64.66±2.75	0.432
Head Circumference (HC) (cm)	41.62±0.68	42.07±0.98	0.160

[Table/Fig-4a]: Comparison of growth parameters of infants with CL (study Group-1A) before primary surgery with healthy infants (Control Group-1A).
(p-value <0.05 indicates statistically significant difference)

Growth parameters	Study Group-1B (Mean±SD) (N=20)	Control Group-1B (Mean±SD) (N=20)	p-value
Weight (kg)	6.05±0.60	6.91±0.36	**<0.001**
Height (cm)	62.57±1.71	63.93±1.21	**0.006**
Head Circumference (HC) (cm)	41.55±0.65	41.89±0.90	0.188

[Table/Fig-4b]: Comparison of growth parameters of infants with CP before primary surgery (study Group-1B) with healthy infants (Control Group-1B).
(p-value <0.05 indicates statistically significant difference)

Growth parameters	Study Group-1C (Mean±SD) (N=31)	Control Group-1C (Mean±SD) (N=31)	p-value
Weight (kg)	5.99±0.47	6.79±0.24	**<0.001**
Height (cm)	62.67±1.92	63.59±0.87	**0.018**
Head Circumference (HC) (cm)	41.33±0.44	41.93±0.94	**0.002**

[Table/Fig-4c]: Comparison of growth parameters of infants with CL&CP before primary surgery (study Group-1C) with healthy infants (Control Group-1C).
(p-value <0.05 indicates statistically significant difference)

This study found that the mean weight, height, and HC of the control groups after surgery (Control Group-2A, 2B, 2C) were higher than their corresponding study groups. The differences in mean weight and HC between Study Group-2A and Control Group-2A were statistically significant (p-value <0.001, 0.034). The differences in mean weight and HC between Study Group-2B and Control Group-2B were statistically significant (p-value <0.001, 0.022), whereas no statistically significant difference in mean height was observed between the study and control groups (p-value=0.974). Statistically significant differences in mean height, weight, and HC were observed between Study Group-2C and Control Group-2C (p-value <0.001, <0.001, 0.002) [Table/Fig-5a-c].

Growth parameters	Study Group-2A (Mean±SD) (N=15)	Control Group-2A (Mean±SD) (N=15)	p-value
Weight (kg)	8.90 ± 0.34	11.15±0.70	**<0.001**
Height (cm)	72.54±2.60	73.06±1.11	0.483
Head Circumference (HC) (cm)	41.62±0.68	45.21±1.02	**0.034**

[Table/Fig-5a]: Comparison of growth parameters of infants with CL after primary surgery (study Group-2A) with healthy infants (Control Group-2A).
(p-value <0.05 indicates statistically significant difference)

Growth parameters	Study Group-2B (Mean±SD) (N=20)	Control Group-2B (Mean±SD) (N=20)	p-value
Weight (kg)	8.86±0.32	10.95±0.73	**<0.001**
Height (cm)	72.95±2.53	72.97±1.06	0.974
Head circumference (HC) (cm)	44.19±1.57	45.17±0.93	**0.022**

[Table/Fig-5b]: Comparison of growth parameters of infants with CP after primary surgery (study Group-2B) with healthy infants (control Group-2B).
(p-value <0.05 indicates statistically significant difference)

Growth parameters	Study Group-2C (Mean±SD) (N=31)	Control Group-2C (Mean±SD) (N=31)	p-value
Weight (kg)	8.76±0.23	10.56±1.24	**<0.001**
Height (cm)	72.64±0.76	74.38±1.97	**<0.001**
Head Circumference (HC) (cm)	44.84±0.56	45.79±1.54	**0.002**

[Table/Fig-5c]: Comparison of growth parameters of infants with CL&CP after primary surgery (study Group-2C) with healthy infants (control Group-2C).
(p-value <0.05 indicates statistically significant difference)

There was a significant improvement in all three growth parameters in the study group before and after surgery (p<0.001) [Table/Fig-6a-c].

Growth parameters	Study Group-1A (Mean±SD) (N=15)	Study Group-2A (Mean±SD) (N=15)	p-value
Weight (kg)	7.64 ± 0.57	11.15±0.70	**<0.001**
Height (cm)	64.66±2.75	72.54±2.60	**<0.001**
Head circumference (HC) (cm)	42.07±0.98	44.35±1.08	**<0.001**

[Table/Fig-6a]: Growth parameters among groups of infants with CL before primary surgery (study Group-1A) vs infants with CL after primary surgery (Study Group-2A).
(p-value <0.05 indicates statistically significant difference)

Growth parameters	Study Group-1B (Mean±SD) (N=20)	Study Group-2B (Mean±SD) (N=20)	p-value
Weight (kg)	6.05±0.60	10.95±0.73	**<0.001**
Height (cm)	62.57±1.71	72.95±2.53	**<0.001**
Head Circumference (HC) (cm)	41.55±0.65	44.19±1.57	**<0.001**

[Table/Fig-6b]: Growth parameters among groups of infants with CP before primary surgery (Study Group-1B) vs infants with CP after primary surgery (Study Group-2B).
(p-value <0.05 indicates statistically significant difference)

Growth parameters	Study Group-1C (Mean±SD) (N=31)	Control Group-1C (Mean±SD) (N=31)	p-value
Weight (kg)	5.99 ± 0.47	10.56±1.24	**<0.001**
Height (cm)	62.67±1.92	74.38±0.87	**<0.001**
Head Circumference (HC) (cm)	41.33±0.44	45.79±1.54	**<0.001**

[Table/Fig-6c]: Growth parameters among groups of infants with CL&CP before primary surgery (Study Group-1C) vs infants with CL&CP after primary surgery (Study Group-2C).
(p-value <0.05 indicates statistically significant difference)

Part-2: Comparison of the RIOFS Score of parents before vs. after primary surgery.

The subjectively perceived QoL was better in parents of healthy children compared to parents of children with CL/CP/CL&CP both before and after surgery. The difference in mean RIOFS score between Study Group-3 and Control Group-3 before primary surgery was statistically significant (p<0.001) [Table/Fig-7]. Similarly, the difference in mean RIOFS score between Study Group-4 and Control Group-4 after primary surgery was statistically significant (p<0.001) [Table/Fig-7].

The QoL of parents from the study group improved after surgery. The difference in mean RIOFS score between Study Group-3 and Study Group-4 after primary surgery was statistically significant (p<0.001) [Table/Fig-8].

DISCUSSION

Growth is a key component of nutritional status and an indicator of health and well-being for individuals and populations. Growth in children is typically steady and predictable, with good references available for assessing and comparing growth in children [17]. For infants and toddlers under two years of age, anthropometric measurements at each well-visit include weight, length, and HC. For children over two years of age, measurements typically include weight and length [18]. The concept of QoL incorporates six broad domains: physical health, psychological state, levels of independence, social relationships, environmental characteristics, and spiritual matters [19]. QoL is an important supplementary measure for clinical indicators to assess the family impact of these infants. The presence of orofacial deformities can result in speech difficulties, airway infections, breathing problems, and feeding challenges, leading to nutritional deficiencies and subsequently impaired physical growth [20].

This study measured the key growth parameters of height, weight, and HC in infants with CL/CP/CL&CP both before and after primary surgery, comparing them with their healthy counterparts to determine if a significant difference exists between healthy children and those affected with clefts. Additionally, a comparative evaluation of the QoL of parents of infants with CL/CP/CL&CP and CP was conducted before and after primary surgery to assess the impact of surgical intervention. In the study, for CL defects, only the mean weight differed significantly (p-value=0.001) between infants and the control group, while the height and HC (p-value=0.432 and 0.160) did not show significant differences. The difference in physical growth indices was less significant in infants with CL compared to infants with CP and CL&CP. For isolated CP and CL with CP defects, except for HC in the before-surgery group and height in the after-surgery group, all growth parameters showed significant differences (p-values: weight <0.001, height 0.006, HC 0.188, respectively) between the study and control groups. Cordero E et

Groups	N	Mean±SD	Mean difference	95% CI (U, L)	t	df	p-value Sig. (2-tailed)
Study Group-3 (Parents of infants with CL/CP, before surgery)	64	32.42±3.48	-25.3750	(-24.3365, -26.4135)	-48.83	63	**<0.001**
Control Group-3 (Before surgery)	64	57.80±1.78					
Study Group-4 (Parents of infants with CL/CP, after surgery)	64	48.00±2.32	-10.5000	(-9.7660, -11.2340)	-28.59	63	**<0.001**
Control Group-4 (after surgery)	64	58.50±1.32					

[Table/Fig-7]: Comparison of mean RIOFS Score among the parents of infants with CL/CP before surgery (study Group-3) and before surgery control group (Control Group-3).
(p-value <0.05 indicates statistically significant difference)

Groups	N	Mean	Std. Deviation	Mean difference	95% CI (U, L)	t	df	p-value Sig. (2-tailed)
Study Group-3 (Parents of infants with CL/CP, before surgery)	64	32.42	3.4815	-15.5781	(-14.5279, -16.6283)	-29.64	63	**<0.001**
Study Group-4 (Parents of infants with CL/CP, After surgery)	64	48.00	2.3231					

[Table/Fig-8]: Comparison of mean RIOFS Score among the parents of infants with CL/CP before surgery (study Group-3) and after surgery (study Group-4).
(p-value <0.05 indicates statistically significant difference)

al., concluded that children with CL&CP receive less breastfeeding and have lower stature-weighted growth than children without CL&CP during the first year of life [21]. Weight was found to be the most affected growth parameter in this population.

In this study, for all three parameters-height, weight, and HC, the mean values significantly increased following surgery with a p-value of <0.001. These findings were supported by the concept of 'catch-up growth' after the early lag period following surgical intervention, especially in the first two years of the infant's life. In a similar study, Wu W et al., reported that physical growth issues, i.e., lower weight for age and length for age, were more prevalent in CL/CP infants than in healthy infants due to differences in the food supplied to the patients [6].

In this study, the mean RIOFS Score was higher in the study group constituting the parents of infants with CL and CP of both sexes after primary CL/CP surgery compared to the mean RIOFS Score of the study group consisting of parents of infants with CL and CP of both sexes before primary CL/CP surgery, and the mean difference was statistically significant. This indicates a marked improvement in the QoL of the parents/caregivers of children with CL/CP following surgery. This finding was supported by the study conducted by Emeka CI et al., [3]. A cross-sectional research study by Ruiz-Guillén A et al., also demonstrated similar findings, indicating that patients perceived an improvement in their QoL as a result of the treatments received [22]. Beluci ML and Genaro KF also reported that the QoL of individuals with CL and CP improved after treatment in the physical, psychological, and environmental domains [23].

Limitation(s)

The present study had several limitations. Firstly, it was a single-centred hospital-based study, which means that generalising the findings to other settings may not be warranted. Additionally, various confounding factors were not considered, such as age, sex, socio-economic background of the participants, educational qualifications of the parents, and dietary habits. Finally, the impacts of each type of cleft on the QoL of the parents or caregivers were not explicitly evaluated. Therefore, it is recommended to conduct a multicentre study with a more diverse study population and a larger sample size for further evaluation.

CONCLUSION(S)

It can be concluded that the physical growth status of infants with CL/CP/CL&CP defects has shown significant improvement after primary surgery, as evidenced by the findings of the present study. Although the growth was slightly lagging compared to healthy infants of the same age/sex group, all growth parameters-height, weight, and HC-improved considerably, depicting 'catch-up growth' after the primary surgery. The QoL was better in parents of healthy children when compared to parents of children with CL/CP/CL&CP. The QoL also significantly improved post-primary surgery. To overcome the limitations of this study, it is necessary to evaluate the growth parameters of infants and the QoL of parents with CL and CP infants before and after primary surgery in multiple centre across the country with a larger population sample.

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