

## Quality Of Life among Youths Having Repaired Non-Syndromic Cleft Lip and Palate in Central Karachi

Syeda Arzoo Azeem<sup>1</sup>, Syed Mahmood Haider<sup>2</sup>, Zubair Ahmed Abbasi<sup>3</sup>, Zafar Abbas<sup>4</sup>, Hoor Ul Ain Iqbal<sup>5</sup>

### Abstract

**Objectives:** To compare youth's overall quality of life having repaired non-syndromic cleft lip and palate with controls using a generic quality of life instrument, Youth Quality of Life – Research Version (YQOL-R).

**Methodology:** The study was conducted from January 2017 to December 2018. Inclusion criteria were patients having repaired non-syndromic Cleft Lip and Palate, age 15 to 29 years, of either gender, while controls were healthy individuals of similar age. The participants were recruited through the non-probability convenience sampling technique. Written informed consent was obtained from all eligible participants before enrollment. Before the initiation of the study and recruitment and collection of data, ethical approval was sought from the Institutional Review Board of Karachi Medical and Dental College and the Patel Hospital. Quality of life was measured using the validated YQOL-R instrument. Data of 62 cases and 107 healthy controls consented to the study was analyzed using SPSS version 20.

**Results:** Cronbach's alpha for domains of sense of self was 0.630, relationship domain (0.795), environmental domain (0.826) and general quality of life domain was 0.688 and for YQOL-R was 0.866. No significant difference lied between cases in controls in terms of gender, age categories, education categories and household income. Significant difference was observed for self care category (63.10 vs. 73.50; p-value = 0.001), relationship category (79.5 vs. 83.73; p-value = 0.013), environmental category (70.89 vs. 84.60; p-value = 0.001), overall quality of life category (79.80 vs. 86.04; p-value = 0.012) and percent score of total perceptual score between cases and controls (73.32 vs. 81.97; p-value = 0.001).

**Conclusion:** Cronbach's alpha for domains of sense of self was 0.630, relationship domain (0.795), environmental domain (0.826) and general quality of life domain was 0.688 and for YQOL-R was 0.866. No significant difference lied between cases in controls in terms of gender, age categories, education categories and household income. Significant difference was observed for self care category (63.10 vs. 73.50; p-value = 0.001), relationship category (79.5 vs. 83.73; p-value = 0.013), environmental category (70.89 vs. 84.60; p-value = 0.001), overall quality of life category (79.80 vs. 86.04; p-value = 0.012) and percent score of total perceptual score between cases and controls (73.32 vs. 81.97; p-value = 0.001).

**Keywords:** Cleft lip and palate, Quality of Life, Youths, Youth Quality of Life – Research Version, YQOL-R.

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### Introduction

Cleft lip and palate (CLP) is a developmental anomaly with a significant genetic diversity and documented ethnic and geographical variation in prevalence around the globe. The collective findings of the evaluation of data of 57 registries from 1993-98 reported a variation of sevenfold (3.4% - 22.9% per 10,000 live births) among children born with cleft lip and palate<sup>1</sup>.

<sup>1</sup>Department of Oral and Maxillofacial Surgery, Landhi Medical Complex

<sup>2</sup>Department of Oral and Maxillofacial Surgery, Ziauddin University

<sup>3</sup>Department of Oral and Maxillofacial Surgery, Jinnah Sindh Medical University

<sup>4</sup>Department of Oral and Maxillofacial Surgery, Dow International Dental College

<sup>5</sup>Department of Oral and Maxillofacial Surgery, Hamdard College of Medicine and Dentistry

**Correspondence:** Dr. Syeda Arzoo Azeem

**Department of Oral Maxillofacial Surgery, Landhi Medical Complex**

**Email:** arazeem1983@gmail.com

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EUROCAT analyzed data from 1980-2000 of 14 European countries using 23 registries reported the prevalence of cleft lip and palate with 9.1% per 10,000 births<sup>2</sup>. A study from Iran<sup>3</sup> that reviewed the infants born alive during the period 2008-2012 reported the prevalence of CLP as 0.485/ 1,000 live births with greater prevalence among boys (54%) compared to girls (46%). Males have been reported with the greater incidence of CLP compared to females, and among the white population, the gender ratio of CLP for males and females is 2:14. The study conducted in Nagpur, India, during the period 2009-2011 reported CLP prevalence as 0.66 per 1,000 live births<sup>4,5</sup>.

The only study identified conducted in Agha Khan University Hospital, Pakistan during the year 1999-2002, reported one hundred and twenty-three patients with CLP provided sufficient evidence that Pakistan,

like other countries, experienced a higher incidence of CLP<sup>6</sup>.

Both genetic and environmental factors are involved in cleft etiology<sup>7</sup>. Psychological and social disturbances have been reported in CLP patients<sup>8</sup>. CLP individuals may have many complications, i.e., malocclusions, hearing disturbances, recurrent auditory and upper respiratory tract infections (URTI), pulmonary aspiration, and malnutrition<sup>9</sup>. Patients with cleft lip and palate had compromised HRQoL scores in social functioning and emotional role, but not in the physical functioning, pain, overall health, life, and mental health<sup>10</sup>. The quality of life among CLP patients has been evaluated using modes, including face-to-face interviews and self-administered questionnaires<sup>11</sup>. People aged 15 to 29 years are referred to as youth as per Common Wealth's definition<sup>12</sup>.

Limited findings about the quality of life among adults with non-syndromic CLP are available. Thus, the present study was conducted to compare youths' general quality of life having repaired non-syndromic CLP with controls using a generic quality of life instrument, Youth Quality of Life – Research Version (YQOL-R).

### Material and Methods

The study took place at two hospital settings, a public sector tertiary care hospital and Patel Hospital, a private secondary care hospital, from January 2017 to December 2018. The study participants, both cases and controls, were recruited from dental outpatients' clinics of both hospitals through a non-probability consecutive sampling technique. The inclusion criteria for cases were patients having repaired non-syndromic CLP, age 15 to 29 years, and either gender. Controls were healthy individuals aged 15 to 29 years of either gender and never had non-syndromic repaired CLP. Similar exclusion criteria were followed to recruit cases and controls where pregnant women and critically ill patients were excluded. The present study recruited 192 study participants, where cases were 64 in number, and 128 controls were recruited; thereby, the ratio of cases to controls was 1:2.

The sample size is calculated by using the WHO software. The reference studies<sup>13, 14</sup> reported the 61% and 43% are the quality of life among patients with cleft lip and palate. The values entered were as follows. Level of significance = 0.5, Power of the test (1- $\beta$ ) = 90, test value of the population proportion  $P_0$  = 61%, test value of the population proportion  $P_a$  = 43%. The sample size was calculated as 64. Thus, a minimum of 64 cases and 64 controls were recruited in this study. As in the Case-control study, ideally, the controls should be twice the ratio of cases; thus, the participants were recruited in the ratio of 1:2 (Cases: Controls). The final sample size considering the proportion of 1:2 was 64 cases and 128 controls, making the total sample size 192.

Primary data was collected using a closed-ended questionnaire by face-to-face interviews from all study participants. The questionnaire consisted of two parts; the first part collected information on variables like age, gender, household income, and education, while the second part consisted of a validated Urdu translated version of generic quality of life questionnaire; Youth Quality of Life – Research Version (YQOL – R). The Urdu translated version was validated by the Seattle Quality of Life Group at The University of Washington. Cases based on cleft laterality (unilateral or bilateral)/ (right or left) and completeness (complete or incomplete) were also collected.

YQOL-R is a tool that has previously been used among youths<sup>15</sup>. The YQOL-R measures four categories: self-sense, relationships, surroundings, and overall quality of life. The instrument's internal consistency is good and had high reproducibility as Cronbach's alpha for all categories exceeded 0.70. The YQOL-R consisted of 41 items to calculate the total perceptual score. The sense of self domain consisted of 14 items (1-12, 21 and 28), relationship domain also consisted of 14 items (13 – 20 and 22 – 27), environmental domain consisted of ten items (29 – 38), and general quality of life consisted of 3 items (39 – 41).

### The scoring of YQOL-R:

- The first 41 items except 1, 5, 12, 16, 17, 18, 21, 22, 24, 28, 29, 30, 31, 32, 37 and 39 used a rating scale having 11 points with options "Not at All" till

"Completely".

- While the rest of the items used "Not at All" till "A Great Deal" 21 and 28 for the sense of self domain were reversed coded.

Total Perceptual scores were calculated. The high score shows a better Quality of Life. The pilot testing of 150 participants was conducted at the study site (hospital), and the results were discarded.

The study took place as per ethical guidelines of the Helenski Declaration and PMRC. Before participating in this research, all the study participants obtained informed consent in writing. All study participants have completely explained the research objective, the method involved in data accumulation, and the expected risks and advantages of the research. Their anonymity, confidentiality, and non-traceability of participant responses were value during the whole study. Ethical approval was obtained from the Institutional Review Board (IRB) of the hospital. Data were analyzed using statistical software, SPSS version 20 (IBM). Once the data was entered, it was checked twice to eliminate the possibility of errors and for accuracy. The new variables, i.e., individual category scores (self-category, relationship category, environmental category, general quality of life category), were computed

Moreover, the total perceptual score for YQOL-R was also computed. Detailed calculations were done, and comparative items were shown as percentages and syllabic items as Mean  $\pm$  SD. The comparative items were compared between cases and controls, and the chi-square test was applied ( $p \leq 0.05$ ). The parametric/non-parametric distribution was analyzed using the Shapiro-Wilk test for quantitative variables. As the quantitative variables were normally distributed, an independent t-test was used to compare cases and control

## Results

The research recruited seventy cases and one hundred and forty controls. There were sixty-two cases and one hundred and seven healthy controls interested in participating in this research. The response distribution of cases and controls were 88.6% and

76.4%, respectively. Thus, a total of two hundred and ten participants was invited, but the data of one hundred and sixty-nine (80.5%) was analyzed.

Table 1 entails details of the characteristics of causes related to CLP. The majority (79.03%) had unilateral side affected, and forty (67.74%) had incomplete CLP. Moreover, the left side (66.13%) was more frequently affected among cases.

In the age group less than and equal to 40 years, 26 cases showed union, 1 patient lost to follow-up, and 1 implant break, respectively. In the age group older than 40 years, 16 cases showed union, 2 patients lost to follow-up, and 1 patient died, respectively. There was no case of non-union in both age groups. Among males, 32 cases were of union, 1 patient lost to follow-up, 1 patient died, 1 lost to follow-up, and 1 implant break, respectively.

Among females, 10 cases were of union, 2 patients lost to follow-up, 1 patient died, and 1 implant break, respectively. In patients with the right side of the fracture, 23 patients showed union, 2 lost to follow-up, 1 died, and 1 implant broke, respectively. In patients with the left side of the fracture, 19 patients showed union, 1 patient lost to follow-up, no patient died, and no implant break. There was no statistically significant difference observed between outcomes concerning age, gender, and fracture site ( $p > 0.05$ ) (Table 1).

**Table 1:** Features of Cases of (CLP).

Features		N (%)
Involved side	One-sided	49 (79.03)
	Bilateral	13 (20.97)
Entirety	Complete cleft	22 (32.26)
	Incomplete cleft	40 (67.74)
Right or Left-Sided cleft	Right-sided	21 (33.87)
	Left-sided	41 (66.13)

Table 2 gives details of Cronbach's alpha for four categories of YQOL.R. The Cronbach's alpha for domains of sense of self was 0.630, relationship domain (0.795), environmental domain (0.826), and overall quality of life category was 0.688. The overall Cronbach's alpha for YQOL-R was 0.866.

**Table 2:** Reliability analysis of YQOL-R.

YQOL-R	Items	Cronbach's alpha
Sense of self category	14	0.630
Relationships domain	14	0.795
Environment domain	10	0.826
The general quality of life domain	3	0.688
YQOL-R	41	0.866

Table 3 shows a comparison of age categories, gender, education, and household income between both groups. The study participant's mean (SD) age was 22.09 (5.04).

Moreover, no notable difference was observed for age categories, gender, education, and household income between cases and controls ( $p \geq 0.05$ ).

**Table 3:** Collation of anthropometric characteristics between the groups.

Anthropometric	Cases n = 62 Mean ± SD	Controls, n = 107 Mean ± SD	Total, n = 169 Mean ± SD	P-value	
Age (Mean±SD)	22.27 ± 5.03	21.98 ± 5.07	22.09 ± 5.04	0.717	
	n (%)	n (%)	n (%)		
Age Groups	Less than or equal to twenty years	26 (41.9)	50 (46.7)	76 (45)	0.711
	Twenty-one to twenty-five years	16 (25.8)	22 (20.6)	38 (22.5)	
	Greater than twenty-five years	20 (32.3)	35 (32.7)	55 (32.5)	
Sex	Males	38 (61.3)	64 (59.8)	102 (60.4)	0.872
	Females	24 (38.7)	42 (40.2)	67 (39.6)	
Education	Less than or equal to five years	4 (6.5)	7 (6.5)	11 (6.5)	0.852
	Six to ten years	20 (32.3)	39 (36.4)	59 (34.9)	
	More than ten years	38 (61.3)	61 (57)	99 (58.6)	
Household Income	Less than Pakistani rupee 20,000	19 (30.6)	38 (35.5)	57 (33.7)	0.374
	Pakistani rupee 20,000 – 30,000	25 (40.3)	48 (44.9)	73 (43.2)	
	Greater than Pakistani rupee 30,000	18 (29)	21 (19.6)	39 (23.1)	

A significant difference was observed for the following items of the self-care domain; even if I am unable to achieve success, I keep attempting (67.90 vs. 76.92;  $p$ -value = 0.020), whatever I want to, I am able to do most of it (67.26 vs. 75.89;  $p$ -value = 0.016), I feel good about myself (58.71 vs. 78.41;  $p$ -value = 0.001), I am at comfort with my sexual and behavioral emotions (64.03 vs. 75.79;  $p$ -value = 0.007), I am powerful enough to do what I want to (74.84 vs. 82.43;  $p$ -value = 0.007), I am satisfied with my looks (40.81 vs. 82.80;  $p$ -value = 0.001), I think there is no harm in making mistakes (59.52 vs. 47.76;  $p$ -value = 0.026), I feel strengthen with my beliefs (72.42 vs. 89.72;  $p$ -value = 0.001), I experience loneliness in my life (52.10 vs. 67.66;  $p$ -value = 0.002) and I experience being left out because of my appearance. (41.94 vs. 70.84;  $p$ -value = 0.001). Moreover, for the relationship domain, a significant difference between cases and controls were found for the following items; my family gives me the importance and find me useful (78.06 vs. 91.12;  $p$ -value = 0.001), I have a caring family (87.26 vs. 92.43;  $p$ -value = 0.035), I am encouraged by my family to give

my best (86.45 vs. 92.99;  $p$ -value = 0.006), I take part in all decisions related to me, and my parents allow me to do so (77.74 vs. 85.61;  $p$ -value = 0.021), my social life is satisfactory (69.02 vs. 79.44;  $p$ -value = 0.004), I can participate in all the activities like others of my age. (69.68 vs. 77.48;  $p$ -value = 0.023) and others have respectable behavior towards me (77.26 vs. 83.74;  $p$ -value = 0.022). When mean percent score for items of environmental domain was compared the significant difference between cases and controls were observed for following items: my life is full of interesting things (67.42 vs. 77.29;  $p$ -value = 0.006), I like trying new things (75.65 vs. 83.64;  $p$ -value = 0.009), I am hopeful for my future (83.39 vs. 94.21;  $p$ -value = 0.001), I have an economically stable family (60.97 vs. 86.82;  $p$ -value = 0.001), I am getting satisfactory education (65.32 vs. 94.95;  $p$ -value = 0.001), the needed information is I know how to get (75.81 vs. 86.45;  $p$ -value = 0.001), I enjoy learning new things (79.68 vs. 89.07;  $p$ -value = 0.001) and school is a safe place to me (51.29 vs. 80.56;  $p$  = 0.001). For the overall quality of life category, a significant difference between cases and

controls was observed only for item, my life is enjoyable and satisfactory (74.03 vs. 82.34; p-value = 0.021). It was observed that the mean percentile score

of all items in each domain was higher among controls than cases.

**Table 4:** Comparison of Percent Scores of YQL-R items between Cases and Controls.

Items of YQL-R domains	Cases, n = 62	Controls, n = 107	P-value
	Mean ± SD		
<b>Sense of self domain</b>			
Even I am unable to achieve success; I keep attempting	67.90 ± 23.48	76.92 ± 24.24	0.02
I can manage the difficulties that come in my way	71.61 ± 18.21	73.46 ± 21.68	0.573
Whatever I want, I am able to do it	67.26 ± 20.01	75.89 ± 23.27	0.016
I feel good about myself	58.71 ± 23.57	78.41 ± 19.96	0.001
Others give me the importance	69.35 ± 25.79	75.23 ± 19.39	0.095
I am at comfort with my sexual and behavioral emotions	64.03 ± 25.64	75.79 ± 27.71	0.007
I am powerful enough to do what I want to	74.84 ± 18.62	82.43 ± 16.53	0.007
I like my looks	40.81 ± 23.77	82.80 ± 17.31	0.001
I can easily handle the stresses of my life	63.23 ± 20.94	59.62 ± 27.12	0.369
I think there is no harm in making mistakes	59.52 ± 31.54	47.76 ± 33.63	0.026
I have a meaningful life	79.68 ± 16.59	72.52 ± 35.26	0.135
I feel strengthened with my beliefs	72.42 ± 21.40	89.72 ± 14.95	0.001
I experience loneliness in my life	52.10 ± 30.25	67.66 ± 30.76	0.002
I experience being left out because of my appearance	41.94 ± 70.84	70.84 ± 30.75	0.001
<b>Relationship domain</b>			
Others treat me fairly	83.71 ± 15.60	84.49 ± 18.39	0.78
My family gives me enough attention	83.55 ± 19.26	88.97 ± 17.32	0.061
I am being understood by my elders	85.65 ± 15.22	86.26 ± 19.70	0.832
My family gives me the importance and find me useful	78.06 ± 21.64	91.12 ± 14.82	0.001
I have a caring family	87.26 ± 15.17	92.43 ± 15.22	0.035
I am encouraged by my family to give my best	86.45 ± 15.37	92.99 ± 14.36	0.006
my parents or guardians get along well with me	79.68 ± 16.79	80.56 ± 21.49	0.781
I take part in all decisions related to me, and my parents allow me to do so	77.74 ± 21.20	85.61 ± 21.06	0.021
I try my best to be a role model for others	85.00 ± 15.86	78.69 ± 22.78	0.056
I can share my feelings with my friends	72.58 ± 25.47	67.94 ± 31.01	0.32
I am pleased with my friends	77.74 ± 24.92	82.43 ± 22.85	0.216
My social life is satisfactory	69.03 ± 24.54	79.44 ± 20.91	0.004
I can participate in all the activities like others of my age.	69.68 ± 23.12	77.48 ± 20.24	0.023
others have a respectable behavior towards me	77.26 ± 19.26	83.74 ± 16.40	0.022
<b>Environmental domain</b>			
my life is full of interesting things	67.42 ± 22.90	77.29 ± 21.70	0.006
I like trying new things	75.65 ± 19.13	83.64 ± 19.00	0.009
I like my neighborhood	55.81 ± 30.97	59.34 ± 31.84	0.483
I am hopeful for the future	83.39 ± 17.36	94.21 ± 8.47	0.001
I have an economically stable family	60.97 ± 25.59	86.82 ± 17.89	0.001
My home is a safe place	93.55 ± 11.47	93.64 ± 12.39	0.96
I am getting satisfactory education	65.32 ± 30.98	94.95 ± 12.39	0.001
The needed information is I know how to get	75.81 ± 24.93	86.45 ± 15.50	0.001
I enjoy learning new things	79.68 ± 21.42	89.07 ± 13.98	0.001
I feel safe when I am at school	51.29 ± 28.01	80.56 ± 20.09	0.001
<b>General Quality of Life domain</b>			
My life is enjoyable	78.55 ± 22.82	85.05 ± 17.98	0.042
My life is satisfactory right now	74.03 ± 24.53	82.34 ± 21.08	0.021
I feel life is worthwhile	86.77 ± 18.27	90.75 ± 15.88	0.14

Table 5 gives details of the comparison of mean percentile score self-care, relationship, environmental and general quality of life category between both the groups. Significant difference was observed for self-care category (63.10 vs. 73.50; p-value = 0.001), relationship category (79.5 vs. 83.73; p = 0.013),

environmental category (70.89 vs. 84.60; p-value = 0.001) and overall quality of life category (79.80 vs. 86.04; p-value = 0.012) between cases and controls. Importantly, a significant difference was also observed for the percent total perceptual score between cases and controls (73.32 vs. 81.97; p = 0.001).

**Table 5:** Comparison of Percent Scores of self-care, Relationship, Environmental, General quality of life and Total perceptual between Cases and Controls.

YQOL-R Domains	Cases, n = 62 Mean ± SD	Controls, n = 107 Mean ± SD	P-value
Self-Domain	63.10 ± 10.29	73.50 ± 9.22	0.001
Relationship Domain	79.53 ± 13.18	83.73 ± 8.45	0.013
Environment Domain	70.89 ± 16.41	84.60 ± 8.85	0.001
General Quality of life Domain	79.80 ± 19.12	86.04 ± 12.88	0.012
Total Perceptual	73.32 ± 12.98	81.97 ± 6.50	0.001

## Discussion

The present Case-Control research was conducted comparing youth's general quality of life having repaired non-syndromic CLP with healthy individuals by using (YQOL-R). The study results highlighted that healthy youth of age 15 to 29 years had a better overall quality of life than repaired non-syndromic CLP cases.

CLP occurs once in every 500-1000 births all over the world<sup>16</sup>. Patients with CLP meet challenges throughout their lives, i.e., socially failed relationships, deviance in looks, lacking self-respect, and health sufferings. Thus, the overall quality of life is sub-standard among cases with repaired CLP. A meta-analysis that compared the quality of life among individuals with CLP to those without CLP in three studies found the quality of life compromised among CLP adults. The mean score for life quality was lower among CLP adults than controls, though the difference was not statistically significant<sup>17</sup>. A case-control study that compared the life quality between bilateral CLP patients to healthy adults reported that for cases, the appearance of the upper lip and nose was less satisfactory and importantly had lower life quality in comparison to healthy controls<sup>18</sup>. The research conducted in Sweden in 2007 that evaluated the life quality through SF-36 questionnaire among adult patients aged 18 to 30 years with a repaired CLP reported that socially and emotionally, they had low scores<sup>19</sup>.

Research with 35 patients in each group reported that a higher percentage of the CLP group of children reported a substandard quality of life<sup>20</sup>. A systemic review done in the UK reported that in 2 of the 3 studies, the quality of life was found to be compromised in the cleft than in the non-cleft individuals (8-18 or 18-65 years of age), while in the third study, no notable difference was found among the groups<sup>21</sup>.

The study results highlighted that general life quality for all four categories, self-care, relationship, environmental, overall life quality domain, was significantly better among healthy youths compared to repaired CLP youths of age 15 to 29 years. Moreover, the mean percent of total perceptual score in youths was also found significantly higher among controls. The study that compared the life quality in adult Swedish subjects using the QL instrument reported that adults with repaired CLP rated their life quality substandard compared to the control group in meaningful life, partnerships, economics, social life, life disturbances, and health<sup>22</sup>. A qualitative study that recruited 18 adolescents with non-syndromic repaired CLP reported that most of the participants were well-adjusted and could get support from parents, friends, and professionals and thus had a good health status and were satisfied with the treatment<sup>23</sup>.

The study had certain limitations. Firstly, the sample size was limited. The present case-control study compared the quality of life of sixty-two cases and one hundred and seven healthy controls. Secondly, the study was conducted at two hospital settings, limiting the generalization and external validity of the study findings. Thirdly, both cases and control, the study participants were recruited through the non-probability convenience sampling technique, which might have induced the selection bias. Moreover, the cases and controls were not matched for age and gender; thus, age differences and differences in education and socio-economic conditions might have influenced the results as the study participants in the two groups were not comparable. Thus, in the future, to precisely compare the life quality between individuals of repaired non-syndromic CLP and healthy youth, a case-control study should be conducted with a larger sample size with study participants being recruited randomly from different cities of Pakistan.

## Conclusion

The study highlighted that in comparison to cases having non-syndromic CLP, healthy individuals had improved life quality. The healthy individuals were significantly better in terms of self-care, relationship, environment, the general quality of life domains, and mean perceptual percentage.

## Conflict of Interest

Authors have no conflict of interest and no grant/funding from any organization.

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