








Anxiety, depression, stress, and fear of COVID-19 in parents and caregivers of children with non-syndromic oral clefts: case-control study

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Editor: Dr. Altair A. Del Bel Cury

Received: November 15, 2023

Accepted: April 19, 2024

Aim: to assess the levels of anxiety, depression, stress, and fear of COVID-19 among parents and caregivers of children with nonsyndromic cleft lip and/or palate (NSCL/P).

Methods: cross-sectional, case-control study at a Craniofacial Anomalies Rehabilitation Center, Brazil. Non-probabilistic convenience sampling was used and data were collected between October 2021 and November 2022. Variables were assessed by Depression, Anxiety and Stress Scale (DASS-21) and Fear of COVID-19 Scale (FC-19S). Pearson's chi-square test and multivariate binary logistic regression model have been performed.

Results: data were obtained of 80 NSCL/P parents group and 130 by control group. Severe symptoms were higher in NSCL/P parents indicated by rates (8.8% vs 6.9% to anxiety; 12.5% vs 8.5% to depression and 17.5% vs 10.0% to stress). As for the predilection in case group there was an association ($p < 0.05$) for manifestation of mild stress (OR: 4.09; 95%CI 1.28-13.06). Levels of fear of COVID-19 were higher in control group (43.8% vs 28.7% $p < 0.05$).

Conclusions: a higher prevalence of anxiety, depression and stress extremely severe was observed in parents of children with NSCL/P. Control group was associated with higher fear of COVID-19.

Keywords: Cleft lip. Cleft palate. Anxiety. Depression. COVID-19.



Introduction

Cleft lip and/or palate (CL/P) is the most prevalent congenital craniofacial anomaly worldwide. In 70% of the cases, CL/P is nonsyndromic (NSCL/P)¹. From birth, children with CL/P should be followed-up by a multi-professional team. General health, aesthetics, nutrition, speech, audition, oral health problems, and psychosocial impacts are reasons for health monitoring².

The birth of children with CL/P impacts their family. Parents' expectations are shattered and a specific routine for CL/P childcare begins³. Qualitative research has shown that parents of children with CL/P experience feelings of distress, fear, mourning, and guilt after birth. These emotions are harmful to their mental health and can persist throughout early childhood and adulthood⁴.

In the literature, there are few quantitative results that have evaluated anxiety, depression, and/or stress symptoms in parents of children with NSCL/P. Therefore, there are publications⁵⁻⁹ with divergent results that may be caused by inconsistencies in the methods used and multiple non-standard instruments used to assess these symptoms⁶. Furthermore, most of the studies^{2,3,6,10} that evaluated CL/P children's parents' psychosocial impacts were not directed at anxiety, depression, and stress symptoms but focused on variables such as social support, quality of life, presurgical parental stress, or resilience in children with CL/P.

The coronavirus disease (COVID-19) pandemic has delayed the care of patients with NSCL/P, mainly because of the cancellation of elective surgeries. Studies showed that there were significant changes in the protocols used, delays in surgical repairs, increased time for care, maintenance of aesthetic and functional problems, and a reduction in the number of rehabilitation procedures^{11,12}. Changes in the care of children with CL/P during the pandemic have caused signs and symptoms in their parents' mental health¹². Moreover, fear provoked by COVID can be a potential trigger of harm to the psychological health of the population as well as a predictor of the adoption of preventive methods of contagion¹³.

Thus, the association between COVID-19 fear and the psychological impacts of children with NSCL/P children on parents and caregivers are still not well understood. No studies were identified in Brazil or Latin America that evaluated the presence of anxiety, depression, and stress symptoms in parents of children with NSCL/P. To date, no study has applied the Fear of COVID-19 Scale (FC-19S)¹³ to parents and caregivers of children with NSCL/P. Therefore, this study aimed to assess the levels of anxiety, depression, stress, and fear of COVID-19 among parents and caregivers of children with NSCL/P.

Material and methods

Study design and context

This was a quantitative, cross-sectional, case-control study. Non probabilistic convenience sampling was chosen because of the transpandemic period. Paired control

group was adopted in order to compare whether the outcome variables of the study group are different compared to the general population.

Study participants

The case group comprised parents and/or caregivers of children with NSCL/P. The children were treated at the Craniofacial Anomalies Rehabilitation Center, Dental School, Edson Antônio Vellano University (Minas Gerais, Brazil). The eligibility criteria were as follows: being a responsible caregiver for children with NSCL/P. The control group consisted of parents and/or caregivers of children without CL/P, systemic, or syndromic alterations. The control group was recruited from the Pediatric Dentistry Clinic of the same institution. Caregivers from both groups aged less than 18 years and older than 60 years were excluded. The instruments used were validated for adult population so the exclusion of participants from another age group.

Data collection

The studied variables were measured using three questionnaires: sociodemographic profile, Depression, Anxiety and Stress Scale (DASS-21)¹⁴, and Fear of COVID-19 Scale (FC-19S)^{13,15}. Trained researchers collected data between October 2021 and November 2022. Before data collection, the researchers conducted a pilot with 10% of the possible sample (which were not included in the final study results) for training. Socio-demographic variables included sex, age, child's age, marital status, kinship with child, monthly income, and education level.

The DASS-21¹⁴ was used to measure and classify the anxiety, depression, and stress symptoms. The instrument consisted of 21 questions. Responses were rated on a Likert scale with the scores 0 to three (totally disagree to totally agree). Of the 21 questions, questions 2, 4, 7, 9, 15, 19, and 20 were related to anxiety. The depression construct was measured using questions 3, 5, 10, 13, 16, 17, and 21. Stress was assessed using questions 1, 6, 8, 11, 12, 14, and 18. The total score is calculated based on the score sum of the seven items of each subscale, which is later multiplied by two.

The sum was interpreted as follows: 1) normal: 0-7, 0-9 and 0-14, for anxiety, depression, and stress, respectively; 2) mild: 8-9, 10-13 and 15-18, for anxiety, depression, and stress, respectively; 3) moderate: 10-14, 14-20 and 19-25, for anxiety, depression, and stress, respectively; 4) severe: 15-19, 21-27 and 26-33, for anxiety, depression, and stress, respectively; and 5) extremely severe: scores above 20, 28 and 34, for anxiety, depression, and stress, respectively.

The FC-19S is a validated instrument with psychometric properties that are robust and reliable for general population applications^{13,15}. The questionnaire consisted of seven Likert-type answers (1 = strongly disagree to 5 = strongly agree). The composite score ranged from 7 to 35, with a higher score indicating greater fear of COVID-19. The levels were classified as mild (7–19 points), moderate (20–26 points), or severe (> 27 points). The questionnaires were in the native Portuguese language as validation studies of the use in Brazilian territory.

Data analysis

The obtained data were entered into Microsoft Excel 2013 software and exported to the IBM Statistical Package for the Social Sciences (SPSS), version 22.0 for statistical analysis. Descriptive analyses of absolute (n) and relative (%) frequencies were performed for the categorical variables. Mean and standard deviation (SD) were calculated for continuous numeric variables. Bivariate analysis was performed using Pearson's chi-square test at two different time points with different dependent variables. Odds Ratio (OR) and Confidence Interval (CI95%) also were calculated Pearson's chi-square test.

First, the group (case/control) was selected as the dependent variable. Sociodemographic variables were selected as independent variables. A multivariate binary logistic regression model using the forced-entry method was used to test the prediction of symptoms between groups. In the forced-entry method, all predictor variables are included in the same block with no hierarchy between them. The Hosmer–Lemeshow test was used to test the goodness of fit and accuracy of the model (indicated by $p > 0.05$). Anxiety, depression, and stress were dichotomized (00: normal, mild and moderate symptoms; 01: severe and extremely severe symptoms) for bivariate analyses using sociodemographic variables. For all analyses, the significance level was set at 5% ($p < 0.05$).

Results

The final sample consisted of 210 parents and caregivers: 80 (38.1%) from the case group and 130 (61.9%) from the control group. The participants were predominantly female (90.0%), lived with a partner (65.2%), and had studied at least high school (35.2%). Their monthly income was 371.27 US\$ (SD: 290.92 US\$). Most caregivers were mothers (80.5%), fathers (8.6%), or other relatives (grandparents, uncles, stepfathers, or stepmothers, 11.0%). The associations of sociodemographic characteristics among the study groups are shown in Table 1.

Anxiety, depression, stress, and fear of COVID-19 are presented in Table 2. It is seen that even though there are no associations with anxiety, depression and stress levels, between the groups, case group had higher OR for severe form these symptoms. Being a caregiver of a child without NSCL/P was likely to lead to a greater fear of COVID-19.

Table 1. Bivariate analysis between groups (case/control) with sample sociodemographic characteristics (n=210), 2021-2022.

Variable	Control	Case	OR (95% CI)	p-value*
	n (%)	n (%)		
Sex				
Male	9 (6.9)	12 (15.0)	1	0.058
Female	121 (93.1)	68 (85.0)	0.42 (0.16–1.05)	
Age***	35.6 (9.5)	35.4 (8.7)	-	0.838

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Continuation				
Marital status				
No partner	52 (40.0)	21 (26.2)	1	0.042*
With partner	78 (60.0)	59 (73.8)	1.87 (1.01–3.44)	
Years of study				
Up to 8	68 (52.3)	41 (51.2)	1	0.882
More than 8	62 (47.7)	39 (48.8)	1.04 (0.59–1.82)	
Monthly income (minimum salary)				
Up to minimum	64 (50.8)	25 (32.9)	1	0.045*
One to two	34 (27.0)	27 (35.5)	1.57 (1.01–2.43)	
More than two	28 (22.2)	24 (31.6)	1.64 (1.05–2.56)	
Kinship with the child				
Other caregivers	20 (15.4)	3 (3.8)	1	0.009*
Father/Mother	110 (84.6)	77 (96.2)	4.66 (1.34–16.25)	
Child' age***	7.5 (2.2)	5.4 (5.7)	-	<0.001**

*Pearson's chi-square test significant statistical association ($p \leq 0.05$).

**Student t test significant statistical association.

***In these variables, values were described with mean and standard deviation values.

Table 2. Bivariate analysis by binary logistic regression between groups with psychological characteristics (n=210), 2021-2022.

Variable	Control	Case	OR (_{95%} CI)	p-value*
	n (%)	n (%)		
Anxiety levels				
Normal	65 (50.0)	44 (55.0)	1	
Mild	2 (1.5)	3 (3.8)	2.21 (0.35 – 13.80)	0.394
Moderate	23 (17.7)	14 (17.5)	0.89 (0.41 – 1.93)	0.785
Severe	9 (6.9)	7 (8.8)	1.14 (0.39 – 3.31)	0.797
Extremely severe	31 (23.8)	12 (15.0)	0.57 (0.26 – 1.23)	0.154
Depression levels				
Normal	62 (47.7)	40 (50.0)	1	
Mild	14 (10.8)	6 (7.5)	0.66 (0.23 – 1.87)	0.438
Moderate	14 (10.8)	7 (8.8)	0.77 (0.28 – 2.08)	0.614
Severe	11 (8.5)	10 (12.5)	1.40 (0.54 – 3.62)	0.476
Extremely severe	29 (22.3)	17 (21.2)	0.90 (0.44 – 1.86)	0.793
Stress levels				
Normal	61 (46.9)	33 (41.2)	1	
Mild	8 (6.2)	11 (13.8)	2.54 (0.93 – 6.93)	0.068
Moderate	19 (14.6)	4 (5.0)	0.38 (0.11 – 1.23)	0.110

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Continuation				
Severe	13 (10.0)	14 (17.5)	1.99 (0.83 – 4.73)	0.119
Extremely severe	29 (22.3)	18 (22.5)	1.14 (0.55 – 2.36)	0.710
Fear of COVID-19				
Mild	73 (56.2)	57 (71.2)	1	
Moderate to severe	57 (43.8)	23 (28.7)	0.51 (0.28 – 0.93)	0.029*

*Significant statistical association through binary logistic regression ($p \leq 0.05$).

Table 3 shows the prediction results of the binary logistic regression of the symptoms evaluated in parents of children with NSCL/P. The Hosmer-Lemeshow test results showed a well-fitted model ($p=0.662$). A negative correlation was observed between the development of extremely severe anxiety and moderate fear of COVID-19. A positive correlation was observed between the development of mild and severe stress.

Table 3. Predictive factors, through binary logistic regression, of psychological symptoms in parents of children with non-syndromic oral clefts ($n=210$), 2021-2022.

Variables	β	OR	95%CI	p-value
Extremely severe anxiety	-1.602	0.20	0.20 – 0.49	0.027*
Mild stress	1.410	4.09	1.28 – 13.06	0.017*
Moderate fear of COVID-19	-1.047	0.35	0.14 – 0.83	0.018*

Only variables that presents statistical significance (≤ 0.05) were included.

*Statistical significance ($p \leq 0.05$).

Among the population studied, associations were observed between being female and severe anxiety and depression symptoms, being a parent/caregiver of children average aged seven years and depression symptoms, and being very fearful of COVID-19 and all symptoms DASS-21 measured (Table 4).

Table 4. Association between severe and extremely severe psychological symptoms and characteristics of sample ($n=210$), 2021-2022.

Variables	Anxiety	OR (95%CI)	P-value*	Depression	OR (95%CI)	P-value*	Stress	OR (95%CI)	p-value*
Group									
Control	40 (67.8)	1		40 (59.7)	1		42 (56.8)	1	
Case	19 (32.2)	0.70 (0.37–1.32)	0.272	27 (40.3)	1.14 (0.63–2.07)	0.653	32 (43.2)	1.39 (0.78–2.49)	0.257
Sex									
Male	01 (1.7)	1		02 (3.0)	1		04 (5.4)	1	
Female	58 (98.3)	8.85 (1.16–6.75)	0.012*	65 (97.0)	4.98 (1.12–2.20)	0.020*	70 (94.6)	2.50 (0.80–7.27)	0.102

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Continuation

Age***	35.3 (8.6)	(-2.46-3.14) ^a	0.811	36,2 (9.9)	(-1.73-3.66) ^a	0.482	34,8 (8.6)	(-1.57-3.69) ^a	0.427
Marital status									
No partner	23 (39.0)	1.29 (0.69-2.40)	0.422	29 (43.3)	1.71 (0.94-3.12)	0.076	25 (33.8)	1	
With partner	36 (61.0)	1		38 (56.7)	1		49 (66.2)	1.06 (0.58-1.94)	0.826
Years of study									
Up to 8	36 (61.0)	1.67 (0.90-3.08)	0.099	38 (56.7)	1.32 (0.74-2.38)	0.339	41 (55.4)	1.24 (0.70-2.19)	0.454
More than 8	23 (39.0)	1		29 (43.3)	1		33 (44.6)	1	
Monthly income (minimum salary)									
Up to minimum	25 (44.6)	1.30 (0.58-2.87)	0.514	29 (44.6)	1.19 (0.56-2.51)	0.644	32 (43.8)	1.06 (0.51-2.17)	0.872
One to two	19 (33.9)	1.50 (0.64-3.50)	0.339	21 (32.3)	1.29 (0.58-2.88)	0.526	23 (31.5)	1.14 (0.52-2.47)	0.733
More than two	12 (21.4)	1		15 (23.1)	1		18 (24.7)	1	
Kinship with the child									
Other caregivers	05 (8.5)	1		07 (10.4)	1		05 (6.8)	1	
Father/Mother	54 (91.5)	1.46 (0.51-4.13)	0.472	60 (89.6)	1.08 (0.42-2.76)	0.873	69 (93.2)	2.10 (0.74-5.92)	0.151
Child' age***	7.38 (3.97)	(-2.10-0.36) ^a	0.166	7.58 (4.16)	(0.03-2.40) ^a	0.044**	6.83 (3.92)	(-1.29-1.04) ^a	0.835
Fear of COVID-19									
Mild	27 (45.8)	1		35 (52.2)	1		41 (55.4)	1.34 (0.61-2.91)	0.461
Moderate	10 (16.9)	1.15 (0.50-2.63)	0.730	10 (14.9)	0.82 (0.36-1.84)	0.635	11 (14.9)	1	
Severe	22 (37.3)	5.59 (2.56-12.22)	0.00****	22 (32.8)	3.98 (1.85-8.53)	0.00****	22 (29.7)	4.26 (1.65-11.01)	0.002*

*Pearson's chi-square test significant statistical association ($p \leq 0.05$).

**Student t test significant statistical association.

***|In these variables, values were described which mean and standard deviation values.

****Pearson's chi-square test significant statistical association ($p < 0.001$).

^aDifference between means confidence interval.

Discussion

In the present study, no statistical differences were identified in anxiety, depression, or stress levels between the parents and caregivers of children with NSCL/P and healthy children. However, the discussion of the results with these literature findings must be interpreted with caution. Even without the presence of statistical associations in the inferential tests, descriptive results showed a higher prevalence of extremely severe symptoms in the case group. In addition, the regression model showed predictions of some of these symptoms to the group of caregivers of children with NSCL/P.

Three studies⁷⁻⁹ used the DASS-21 to measure the psychological symptoms in parents of children with NSCL/P. An Indian study⁷ conducted with 50 parents of children with NSCL/P observed a positive association between parents' stress and depressive symptoms and the child's behavioral problems.

A second study was conducted in Belgium with 90 NSCL/P children's parents⁸, which, in addition to measuring psychological symptoms, also applied instruments to compare self-esteem and concerns about their social behavior. Anxiety, depression, and stress scores were normal, with no differences from the other studies analyzed in the discussion. Moreover, higher anxiety scores were significantly associated with an older parental age. Older parental age was associated with depression and a postnatal cleft diagnosis.

In Kumar et al.⁹ (2020) study, there was a similarity to the methodology applied in our study, mainly because of the presence of comparative groups. Parents of CL/P adolescents (10–17 years) showed a statistically significant association with higher levels of symptoms in the three dimensions measured by the DASS-21 ($p < 0.001$). Furthermore, the prevalence of severe and extremely severe depressive symptoms was 22.9% and 20%, respectively, in the group of children with CL/P, whereas, in the group of healthy children, the prevalence was 1% and 2% for the same symptom ratings. Regarding anxiety in parents of children with CL/P, the prevalence of extremely severe classification was 50%, whereas in the control group, the prevalence was 6.1%. Regarding stress, severe symptoms were 21.4% in case group, and 1% of patients in the case and control groups, respectively.

Similar to the present study, other study¹¹ have not shown an association between anxiety and depression in the investigated groups. However, findings on this subject are diverse. There are publications in which parents of healthy children scored more than NSCL/P caregivers^{16,17}, as well as contrary results^{5,6,9}. However, in most studies, symptom levels were measured using different instruments.

Self-perceived parental stress is a consistently evaluated variable in studies on parents and caregivers of children with NSCL/P^{3,6-16}. Jeong et al.¹⁶ (2013) showed that parents had lower scores on Beck's Anxiety and Depression Inventory had more stress. Furthermore, a reduction in stress levels was noted in parents of children with NSCL/P during childhood³. In addition, there was a correlation between these symptoms and children's behavior^{3,16}.

Only two studies that measured the psychological impact on parents of children with NSCL/P in Brazil were identified^{18,19}. The first was a cohort study¹⁸ that aimed to analyze parental stress in parents of children with NSCL/P before and after surgical procedures. This study found that the stress levels progressively decreased after the intervention. Carvalho et al.¹⁹ (2021) evaluated the emotions of parents and caregivers using an elaborate questionnaire. This patient did not show anxiety, depression, and/or stress symptoms, but feelings of fear, despair, sadness, and shock were more prevalent after cleft diagnosis.

Our study is the first to apply the FC-19S to parents of children with NSCL/P. Being a parent or caregiver was found to be a protective factor in relation to the parents or caregivers of healthy children. However, this remains unclear. However, it should be

noted that some patients with CL/P during the pandemic were assisted by teleorientation. This could have contributed to the fact that the caregivers of children with NSCL/P did not feel the impact of the pandemic more intensely and thus demonstrated less fear than the control group. Studies^{20,21} have also evaluated the fear of COVID-19 among parents of healthy children. However, they did not use FC-19S²⁰, and another aimed fear and breastfeeding effectiveness were associated²¹. This highlights the importance of verifying fear of COVID-19 as an aggravating factor in family cycle mental health^{20,21}.

Regarding group feature differences, parents of children with NSCL/P had a higher OR for having a partner and had a higher monthly income than the control group. However, no results in the literature explain this finding. It is necessary to point out that in Brazil, the treatment of CL/P is paid by the Unified Health Public System (SUS in Portuguese)²². Therefore, regardless of the family members' socioeconomic status, all patients with CL/P were treated in the same specialized center.

Similar to other studies, being female showed an association between anxiety and depressive symptoms^{23,24}. Publications suggesting that women have a higher OR for anxiety and depression symptom development are based on many factors, mainly physiological issues and social demands^{23,24}. In addition, women have historically sought health services where surveys are conducted. Furthermore, during the COVID-19 pandemic²³, there has been an increase in the number of domestic violence cases, which has contributed to the risk of developing mental disorders.

Children's age (mean, 7.5 years) was associated with their parents' depression symptoms. This result differs from that of an Indian study in which parents of NSCL/P children over ten years old had greater scores in DASS-21 all dimension compared to parents of clinically healthy children and younger CL/P children. However, in a study²⁵ of caregivers of children, it was found that mothers of younger children, regardless of the presence of disabilities or anomalies in their children, commonly presented some anxiety, depression, and stress levels.

Symptoms of anxiety, depression, and stress were strongly associated with severe fear of COVID-19. Thus, it can be inferred that individuals with more mental health problems were more afraid of COVID-19. Although a relatively new scale, some studies²⁶⁻²⁸ have used the FC-19S in conjunction with the DASS-21. Additionally, associations were found between fear of COVID-19 and higher scores for these symptoms²⁶. Furthermore, there was a strong correlation between instruments²⁷. However, it should be noted that such association measures may change over time. Some studies emphasize that data collection was conducted during the initial pandemic period or at the peak of the viral infection wave^{26,28}. These factors may interfere with the fear of COVID-19 scores, which have a predilection for psychological symptoms. A difference from our study is that the data collection was carried out over a year; thus, the participants experienced different pandemic phases, reducing possible bias regarding the high levels of fear of COVID-19.

This study has some limitations. As this was a convenience sampling study, the findings may be underreported because the COVID-19 pandemic has led to changes in the health habits of individuals with greater mental health problems. Another limita-

tion was the cross-sectional design of the study, which could not measure the causality of parenting with measured symptom development.

In conclusion, no differences were observed between anxiety, depression, and stress levels in the control group or in the parents and caregivers of children with NSCL/P. However, a predilection for severe symptoms was found in parents of children with oral clefts. Additionally, parents and caregivers of children with NSCL/P had less fear of COVID-19. Anxiety, depression, and stress symptoms were associated with female sex, responsible of seven year-old aged children and severe fear of COVID-19.

Acknowledgment

The authors would like to thank The Minas Gerais State Research Foundation – FAPEMIG, Brazil, National Council for Scientific and Technological Development – CNPq, Brazil and the Coordination for the Improvement of Higher Education Personnel, CAPES, Brazil.

Conflict of Interest

The authors have no conflict of interest to disclose.

Data availability

Datasets related to this article will be available upon request to the corresponding author.

Author Contribution

Samuel Trezena Costa: Conceptualization, methodology, data curation, writing – original draft preparation, review and editing. **Fabrcio Emanuel Soares de Oliveira:** Conceptualization, methodology, data curation, writing – original draft preparation, review and editing. **Cintia Eliza Marques:** Investigation and data curation. **Nádia Carolina Teixeira Marques:** Conceptualization, methodology and data curation. **Verônica Oliveira Dias:** Conceptualization, writing –review and editing. **Daniella Reis Barbosa Martelli:** Conceptualization, methodology, investigation, writing – original draft preparation, review and editing. **Hercílio Martelli Júnior:** Conceptualization, methodology, investigation, writing – original draft preparation, review and editing. All authors actively participated in the discussion of the manuscript's findings, revised, and approved the final version of the manuscript.

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