



ORIGINAL ARTICLE

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Effect of presurgical orthopedics on oral-health related quality of life in Chilean children with cleft lip and palate. A pilot study.

Abstract: The aim of this pilot study was to evaluate the effect of Pre-surgical Orthopedics (PSO) on the oral health-related quality of life (OHR-QoL) in Children with Cleft Lip and Palate (CLP) treated in two hospitals in Chile using the Spanish version of the Child Oral Health Impact Profile (COHIP-Sp). Method: Cross-sectional study, involving 42 children with CLP (mean age 12±2.1 years; 28 men) who attended their annual checkup at the main Hospital of Valdivia and at the Hospital Fundación Gantz in Santiago, Chile, between March and April 2016. Those who met the selection criteria were applied the COHIP-Sp scale. Based on their medical records, patients who used PSO as treatment protocol were classified as "PSO". Those who did not receive treatment with the appliance were classified as "Non-PSO". The score of the COHIP-Sp scale and its domains between the two groups was compared (t-test, p<0.05). Results: Twenty-five patients (59.5%) used PSO. COHIP-Sp score was 91.7±26.2 points in the PSO group, and 81.2±30.9 points in the Non-PSO group. There was no statistically significant difference (p=0.24). Conclusion: OHRQoL of patients with CLP treated with PSO was similar to that of patients not treated with PSO.

Keywords: Cleft palate, Cleft Lip, Orthopedics, Quality of life, Chile, Children.

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INTRODUCTION.

Cleft Lip and Palate (CLP) is one of the most prevalent congenital malformations. It is an alteration in the fusion of tissues that form the upper lip and palate during embryonic development. Global frequency is 1 per 1,200 live births. In Chile its prevalence is twice the global rate with 1.8 per 1,000 live births. Therefore, since 2004 diagnosis, treatment, rehabilitation and follow-up are covered by the State.¹

Presurgical Orthopedics (PSO) in children aims to correct the abnormal position of the alveolar ridges before primary surgery in patients born with CLP.² PSO improves the shape of the maxillary arch, facilitating the surgical closure, feeding and speech.³ However, some authors emphasize negative aspects of PSO, such as the complexity of its manu-

facture, high economic costs, higher rates of postoperative complications, and accumulation of plaque.³⁻⁵ Consequently, there is no agreement regarding the use and effectiveness of PSO in children with CLP.⁶

The quality of life of children with CLP is an important and integral health indicator, observable in functional and psychosocial outcomes.^{7,8} To date, several authors have evaluated the oral health-related quality of life (OHRQoL) in patients with CLP.⁹⁻¹⁴ However, no data are published in electronic databases reporting the effect of PSO on OHR-QoL. The "Child Oral Health Impact Profile" scale (COHIP) is one of the instruments used to measure OHRQoL.¹⁵ A Spanish version of this scale (COHIP-Sp) was validated in a sample of the Chilean population with CLP.¹⁴ Results

show that children with a history of CLP have lower levels of OHRQoL in areas such as speech difficulties and development in the school environment. The above has motivated the evaluation of OHRQoL in children with CLP subjected to different interventions, including the use of PSO.¹⁴

The aim of this pilot study was to evaluate the effect of PSO on OHRQoL in children with CLP treated at two Chilean hospitals by means of the COHIP-Sp scale. The hypothesis of this study is that there is no difference in OHRQoL of children with CLP treated or not treated with PSO at Chilean hospitals.

MATERIALS AND METHODS.

A pilot cross-sectional study was conducted between March and April 2016. The study was approved by the Research Ethics Committee of the Health Service of the city of Valdivia, Chile (Ord No. 096/2016).

Population.

The target population consisted of children and adolescents with CLP, 8 to 15 years old, who had been surgically treated and were attending their annual checkup at the General Hospital of Valdivia and at the Hospital Fundacion Gantz in Santiago, Chile.

Selection criteria and sample size.

The group of children with a history of CLP was selected by a non-probabilistic convenience sampling according to the number of medical records available at the hospitals participating in this study.

Inclusion criteria included patients with CLP between 8-15 years of age, able to read and write, and agreeing to participate voluntarily through an informed consent signed by the child's parent or guardian. Children or adolescents diagnosed with a disabling medical condition, or CLP associated with mental syndromes and disorders were excluded from the study.

Given the nature of the pilot study, a minimum of 25 patients were estimated for the evaluation, considering an average COHIP-Sp scale of 98.8 ± 18.3 ,¹⁴ with a difference of 13.3 points between patients who used and did not use

PSO,¹⁵ and a statistical power of 80%.

Groups.

Children who used presurgical orthopedic appliances according to protocol treatment of the participating hospitals were classified as "PSO". Children treated at the same hospitals but without using orthopedic appliances were classified as "Non-PSO".

Data collection.

The Spanish version of "Child Oral Health Impact Profile (COHIP)" scale was used for measuring OHRQoL.¹⁴ This scale comprises five domains (oral health, functional well-being, social-emotional well-being, school environment, and self-image) with a total of 34 items. Each item is rated from 0 to 4 in ordinal format. Responses are recorded as never=4, almost never=3, sometimes=2, fairly often=1 and almost all the time=0, except for the domain "self-image", which had an score assigned in an opposite way, in an ordinal fashion but with ascending values. The total score of the scale ranges from 0 to 136, where a higher score means a better OHRQoL.¹⁵

Researchers attended the annual checkups of patients within the study period in order to recruit participants. Once the subjects agreed to participate in the study, two researchers (M. B. and F.K.) applied the COHIP-Sp scale and collected the subjects' medical history and personal data in an *ad-hoc* form.

The objective of the scale was verbally explained to the subjects of both groups. To ensure the correct use of the instrument and avoid response bias, the instrument had a sample question. Participants were given no time limit to respond. Data collected from the COHIP-Sp scale were tabulated in a Google Drive spreadsheet (Google Inc., USA).

Data analysis.

Data collected were age (years), sex (male, female), type and side of cleft (cleft palate, cleft lip/palate, right side, left side, middle or bilateral), partial score of each item and total score of the COHIP-Sp scale. Variables were summarized in frequency tables, measures of dis-

persion and central tendency (mean±standard deviation).

The scores for each domain and the total score between the PSO group and the Non-PSO group ($p<0.05$ t-test) were compared using STATA v10.0 (STATA Corp®, USA).

RESULTS.

Forty-two patients with an average age of 12 ± 2.1 years (age range: 9-15 years) participated in the study. Of these, 59.5% (25 subjects) used PSO. Demographic characteris-

tics and type of cleft are detailed in Table 1.

All scores of the COHIP-Sp scale showed a parametric distribution ($p<0.05$). The overall average score of the COHIP-Sp scale was 91.7 ± 26.2 points in the PSO group and 81.2 ± 30.9 points in the Non-PSO group.

There was no statistically significant difference between both groups ($p=0.24$). The comparative analysis of the scores of the domains of the COHIP-Sp scale is presented in Table 2.

Table 1. Demographic characteristics and type of cleft of participants in the study (n=42).

Variable		Use of presurgical orthopedics	
		No (n=17)	Si (n=25)
Sex (n)	Male	9	19
	Female	8	6
Age in years	(mean±SD)	12.2±2.3	11.9±1.9
Hospital 1 st surgery (n)	Fundacion Gantz	6	15
	Hospital of Valdivia	11	10
Type of cleft (n)	Palate	6	2
	Lip-Palate	11	23
Side of cleft (n)	Middle	6	2
	Left	3	5
	Right	1	10
	Bilateral	7	8

Table 2. Scores of COHIP-Sp scale and its domains according to the use of presurgical orthopedics.

COHIP-Sp Domains (n° of items)	Use of presurgical orthopedics						p ³
	No (n=17)			Yes (n=25)			
	Mean	SD ¹	95% IC ²	Mean	SD ¹	95% IC ²	
Oral Health (10)	21.9	7.4	18.1-25.7	22.4	8.6	18.8-26	0.84
Functional Well-being (6)	14.6	6.3	11.3-17.9	16	5.9	13.5-18.4	0.48
Social and Emotional Well-being (8)	19	10.3	13.7-24.2	23.5	8.6	19.9-27.1	0.13
School Environment (4)	11.5	4.4	9.2-13.7	13	3.5	11.5-14.1	0.23
Self-Image (6)	14.1	7.5	10.2-18.1	16.7	5.6	14.4-19.1	0.21
COHIP-Sp (34)	81.2	30.9	65.3-97.2	91.7	26.2	80.8-102.5	0.24

1. SD: Standard deviation.

2. 95% CI: Confidence interval.

3. t-test ($p<0.05$).

DISCUSSION.

OHRQoL of children with CLP treated with PSO at two Chilean hospitals showed similar levels to those of children not treated with PSO. Similarly, in various domains of the scale there were no statistically significant differences between the two groups. These results are consistent with previous studies that have not found a positive and significant effect of PSO on aspects such as speech and language development in children with CLP.³ Consequently, there are no studies providing a high level of evidence to support the use of PSO in children.¹⁶

In addition, regarding facial aesthetics, it is reported that the transverse dental arch relationships do not differ in children aged 9 to 12 years treated or not treated with PSO.¹⁷ This finding is relevant because aesthetics and sequelae in language seem to be the most important factors affecting the quality of life in children with oral clefts, especially from 8 years onwards, when the acceptance by peers becomes more critical.¹⁸

The highest proportion of the sample consisted of male subjects with left CLP. These data are similar to those reported in Dutch and Colombian populations.¹⁹ Although in this study the participants were volunteers contacted by convenience while attending their annual checkups, the number and characteristics of participants are similar to those reported in Chile.^{1,14}

In the present study it was not possible to establish a significant statistical association between OHRQoL and the use of POS. This is consistent with a systematic review by Bessell *et al.*²⁰ This pilot study presents data confirming previous reports, which may prove useful to make researchers

and clinicians assess the benefits of using POS in children. This study agrees with the findings of Papadopoulos *et al.*²¹, who expose the lack of evidence on the short and long term effectiveness of POS in the treatment of patients with CLP.

Within the limitations of this study, it is possible to mention that modifying or confounding variables of the POS-OHRQoL relationship were not analyzed, such as the age of children, the length of time patients used POS, attendance to the annual checkups assessed by the multi-disciplinary team, as well as the socio-cultural environment of the patients. In addition, a convenience sample was used and some medical records were incomplete and/or illegible, which may have negatively affected the quality of the data collected.

Longitudinal studies should be conducted to assess the impact of POS on aesthetic and functional aspects in adolescent and adult patients with CLP.

CONCLUSION.

OHRQoL of patients with CLP treated with POS was similar to the one shown by patients not treated with POS.

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Efecto de la ortopedia prequirúrgica sobre la calidad de vida relacionada con salud oral en niños chilenos con fisura labio palatina. Estudio piloto.

Resumen: El objetivo de este estudio piloto fue evaluar el efecto de la Ortopedia Pré-Quirúrgica Infantil (OPQI) sobre la calidad de vida relacionada con salud oral (CVR-SO) en niños con Fisura Labio Palatina (FLP) tratados en dos hospitales de Chile usando la versión española del Child

Oral Health Impact Profile (COHIP-Sp). Método: Estudio de corte transversal. Participaron 42 niños y niñas con FLP (edad promedio 12±2.1 años; 28 hombres) que asistieron a su control anual del Hospital Base de Valdivia y la Fundación Gantz en Santiago entre marzo y abril del año 2016. A quienes cumplieron los criterios de selección, se les aplicó la escala COHIP-Sp. Basándose en las fichas clínicas, se clasificó como "OPQI" aquellos pacientes que usaron OPQI

como protocolo de tratamiento; y como grupo "No-OPQI" aquellos que no recibieron el tratamiento con la placa. Se comparó el puntaje de la escala COHIP-Sp y sus dominios entre ambos grupos (t-test, $p < 0.05$). Resultados: Veinticinco pacientes (59.5%) usaron OPQI. La puntuación COHIP-Sp fue 91.7 ± 26.2 puntos en el grupo OPQI y 81.2 ± 30.9 puntos

en grupo No-OPQI, diferencia estadísticamente no significativa ($p = 0.24$). Conclusión: La CVRSO de pacientes con FLP tratados con OPQI fue similar a pacientes no tratados con OPQI.

Palabras clave: Fisura del paladar, Labio leporino, Ortopedia, Calidad de Vida, Chile, Niño.

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