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Research Article

Comparison Between the Frequency of Osahs in Children with Cleft Palates Before and After Primary Palatoplasty

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Abstract

Objective: To evaluate OSAHS in children with cleft palate aged 6 to 24 months, before and after primary palatoplasty, at two institutions in Bogotá, Colombia, over a period of 4 years. *Materials and Methods:* A prospective cohort study, before and after primary palatoplasty, in patients who consulted for cleft palate, underwent a polysomnography prior to the procedure, and were compared with another study conducted 6 to 12 months after the procedure. Additionally, follow-up was conducted through researcher-designed questionnaires to assess the presence and severity of OSAHS. *Results:* From January 2016 to January 2018, 43 patients were recruited. The most frequent symptoms prior to primary palatoplasty, measured by prevalence, were snoring and sweating, at 30.2% and 34.9%, respectively, both of which improved in the postoperative period. The prevalence of OSAHS was confirmed through pre and post surgical polysomnography, with no significant differences between the two. The evolution of OSAHS severity after surgery showed an increase in the number of patients classified as normal, mild, and moderate, with no cases of severe OSAHS in the postoperative period, indicating improvement. *Conclusions:* This study compares the presence of OSAHS before and after primary palatoplasty in patients with cleft palate, using polysomnography and surveys to evaluate symptoms of upper airway obstruction. The presence of OSAHS associated with the congenital malformation is identified during the preoperative period, where there are limited information and few studies at this age. However, improvement is most clearly identified during patient follow-up.

Keywords

Cleft Palate, Apnea, OSAHS, Palatoplasty, Obstructive Sleep Apnea, Sleep Syndrome, Prevalence, Polysomnography

1. Introduction

Cleft palate (CP) is the most common craniofacial malformation in our population [1, 2]. Its presentation alone results in both anatomical and functional alterations to the upper airway, necessitating studies and comprehensive management to address issues such as speech and feeding difficulties, delayed growth and development, and respiratory

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sleep disorders, which have a high incidence in this population with this malformation [3]. Primary management of the palate in this service is performed between 6 and 18 months of age, with surgery aimed at improving speech and swallowing. However, due to the closure of the oropharyngeal space, a hypothesis arises regarding the potential development of airway obstruction.

Sleep-disordered breathing can range from simple snoring, the least severe condition, to Obstructive Sleep Apnea Syndrome (OSAHS) with all its associated characteristics. A high prevalence of OSAHS has been observed in patients with cleft palate (CP) following surgery to correct the palate, with obstruction occurring at different levels of the upper airway in a multifactorial manner [4]. A review of the literature reveals several studies linking cleft palate with the presence of OSAHS, particularly in relation to pharyngoplasty and secondary palatoplasty. However, its association with primary palatoplasty has not yet been clearly defined.

This study aims to evaluate patients with cleft palate before and after primary palatoplasty, looking for sleep-related breathing disorders; this information remains scarce and will aid in the comprehensive and appropriate management of this population.

2. Materials and Methods

This is a before-and-after study. The 'before' phase corresponds to the pre-surgical evaluation of patients with cleft palate who underwent a polysomnography and a questionnaire on symptoms related to the presence of Obstructive Sleep Apnea Hypopnea Syndrome (OSAHS) one month before undergoing primary corrective surgery (palatoplasty). These patients were followed up for 6 months postoperatively with clinical questionnaires to assess symptoms, as well as a new polysomnography conducted between 6 months and one year to evaluate the presence of Obstructive Sleep Apnea Hypopnea Syndrome (OSAHS).

Patients with a diagnosis of cleft palate who arrived at the Hospital de San José, Hospital Infantil Universitario San José, and FISULAB for consultation in the Plastic/Craniofacial Surgery department, and who required primary palatoplasty and met the inclusion criteria, were referred to the Hospital Universitario San Ignacio for polysomnography testing and interpretation by the same specialist in Pediatric Pulmonology, a co-author of this article.

The diagnosis of OSAHS is based on the patient's medical history, clinical questioning, and requires additional paraclinical confirmation through polysomnography, considered the gold standard. This test involves an overnight procedure that monitors various parameters, including electroencephalogram, electro-oculogram, chin electromyography, microphone for snoring, thermometer, 9-lead electrocardiogram, pulse oximetry, tibialis anterior electromyography for leg movement, capnography, airflow, and thoracic and abdominal bands [5].

The result of each of the monitoring is recorded, but especially in terms of obstruction we speak of apnea, which is considered the cessation of breathing for more than 10 seconds. It should be clarified if it is an obstructive episode, which is when effort is evident but is ineffective, which differentiates it from a sleep apnea of central origin (no effort) [6].

Hypopnea is defined as a decrease of more than 50% in flow or volume for more than 10 seconds or less than 50% but accompanied by desaturation greater than 3% and arousals or less than 50% with electrocardiographic abnormalities and arousals [5].

Snoring is turbulence at the level of the upper airway, which generates vibration in soft tissue structures [5]. The severity of this type of respiratory disorder is given by the number of apneas-hypopneas for one hour (apnea-hypopnea index). hypopnea or AHI). In children we find some differences such as that obstructive apneas - hypo apneas are rarely found. It is normal to find respiratory effort in them, desaturation does not normally fall below 90% and can last 10 - 15 seconds and there is an increase in CO2 of 3-4 mmHg during non-REM sleep [7, 8]. Obstructive hypopneas that last between 3.5-5 seconds and are combined with desaturation, bradycardia, tachycardia or arousals should be recorded, depending on age. In children, no standardization has been established for the evaluation of these results, thus, it is suggested to complement it with a nasolaryngoscopy and cephalometry [9]. However, the general recommendation is to correlate with the patient's symptoms. There are degrees of severity for OSAHS in children classified on Table 1.

Table 1. *Levels of severity of OSAHS in children, as determined by the Apnea-Hypopnea Index (AHI) recorded in the polysomnography.*

Level	Apnea-Hypopnea Index (events per hour)
Normal	<1
Mild	1-4.9
Moderate	5-14.9
Severe	>15

The inclusion criteria were diagnosis of cleft palate confirmed during the Plastic Surgery consultation; patients with a BMI for age percentile <90, reviewed during the pre-surgical preparation of the child and documented in the pediatric clinical history, according to growth charts; and patients aged 6-18 months. The exclusion criteria were: previous palatoplasty, as indicated in the clinical history, by the guardian of the child, or diagnosed during the Plastic Surgery consultation; frequent colds (6 or more per year), as noted in the clinical history, by the guardian of the child, or diagnosed during the Plastic Surgery consultation; syndromic cases (cleft palate

associated with another malformation), as reported in the clinical history, by the guardian of the child, or diagnosed during the Plastic Surgery consultation; Robin sequence, as reported in the clinical history, by the guardian of the child, or diagnosed during the Plastic Surgery consultation; and congenital heart disease, as reported in the clinical history, by the guardian of the child, or diagnosed during the Plastic Surgery consultation. These exclusion criteria were considered to eliminate possible biases due to pathologies and history that may include respiratory disorders per se.

The variables we analyzed included demographics (age at surgery, sex, pre- and post-surgery weight), characterization of the malformation (laterality, type), surgical technique, associated symptoms in the preoperative state (snoring, arousals, daytime sleep, sweating, apnea, cyanosis, kicking, getting out of bed, feeding frequency during the day, duration of intake, gastroesophageal reflux, choking), presence of OSAHS before surgery (as diagnosed by polysomnography), severity of the syndrome before surgery (Apnea-Hypopnea Index), preoperative and postoperative polysomnography results (snoring, central apnea, obstructive apnea, hypopneas, mixed apnea, maximum oxygen saturation, minimum carbon dioxide saturation), and signs and symptoms of OSAHS in the postoperative period. All data were collected through questionnaires completed by one of the authors via telephone or in person at the office, with input from the parents or legal guardians of the patients, and with the polysomnography results sent directly from the sleep center.

Data processing was conducted in a spreadsheeet, where each of the measurements was recorded on a weekly basis. Statistical analysis was performed using the STATA 12.0 software. To compare the proportion of OSAHS before and after palatoplasty, the McNemar chi-square test was applied. The following system of hypotheses was tested

H_0: The percentage of patients with OSAHS before palatoplasty is equal to the percentage of patients with OSAHS after palatoplasty.

H_1: The percentage of patients with OSAHS before palatoplasty is different from the percentage of patients with OSAHS after palatoplasty, with a p-value < 0.05 indicating statistically significant differences.

The demographic and clinical characteristics were summarized using frequencies, measures of central tendency, and dispersion, according to the type of variable. The frequency of symptoms associated with OSAHS before and after surgery was assessed for each control. The levels of severity of pre- and postoperative OSAHS were evaluated using frequencies (Table 1). The incidence of OSAHS was calculated using the total number of participants undergoing primary palatoplasty as the denominator.

The research was conducted in accordance with international guidelines for research involving human participants, as established in the Declaration of Helsinki (latest revision, Brazil, 2013) and the Belmont Report. Informed consent was obtained, in compliance with national legislation regarding research involving minors. The recommendations outlined in Resolution 8430 of 1993 by the Colombian Ministry of Health were also followed.

3. Results

A total of 43 patients were included in this analysis, of whom 51.2% (22 patients) were male and 48.8% (21 patients) were female. The demographic characteristics are summarized in Table 2. Among the patients without cleft lip, there were 14 cases (36.2%). In the group with the malformation, the lowest percentage of laterality was on the right side, with 7 patients (16.3%). The bilateral and left-sided clefts both had the same percentage, with 11 patients (25.6%) in each group. When evaluating the extent of the cleft, the most common presentation was a complete unilateral cleft, with 18 cases, followed by incomplete unilateral clefts, with 2 patients.

Table 2. *Demographic characteristics and proportions.*

	N	%
Study population	43	100
Sex		
Male	22	51,2
Female	21	48,8
Cleft lip		
None	14	32,6
Left	11	25,6
Right	7	16,3
Bilateral	11	25,6
Cleft lip and palate		
Complete unilateral	18	41,9
Complete bilateral	13	30,2
Incomplete U*	2	4,7
Incomplete B*	10	23,3

* U - unilateral, B - bilateral

The symptoms related to sleep apnea syndrome were analyzed in all 43 patients one month before surgery, during the preoperative period. It was found that no patient experienced daytime sleep, defined as more than 14 hours of sleep-in total. The least frequent clinical symptoms were apnea and cyanosis, present in 1 patient (2.3%), followed by arousals in 3 patients (7%), kicking in 8 patients (18.6%), getting up from bed in 9 patients (20.9%), choking in 10 patients (23.3%), and gastroesophageal reflux in 12 patients (27.9%). The most fre-

quent symptoms were snoring, reported by 13 patients (30.2%), and sweating, reported by 15 patients (34.9%).

Polysomnography was performed at an average age of 10.49 months (SD ±2.26) with an average weight of 8.95 kg (SD ±1.02) before surgery. It was found that 79.1% (34 cases) of the patients had a polysomnographic diagnosis of OSAHS, with 7% of patients not undergoing the study (3 patients could not complete the test). Notably, the clinical sign of snoring, which is commonly associated with the disease and frequently observed in the study patients, was found in only 23.3% of those diagnosed with cleft lip and palate on the polysomnographic test. This contrasts with the 30.2% of patients for whom snoring was reported by parents or legal guardians.

A total of 42 patients underwent palatoplasty surgery at an average age of 12.21 months (SD ± 2.60). The most used surgical technique was the Bardach palatoplasty (two-flap technique), performed on 30 patients (69.8%), followed by the Furlow (opposite double Z-plasty) and Vea-Wardill-Killner (Push-Back) techniques, each used in 5 patients (11.6%). Lastly, the Von Langenbeck (mucoperiosteal flap) technique was used in 2 patients (4.7%). All surgeries were performed by three plastic surgeons from the service.

Regarding the evolution of clinical signs of OSAHS in the postoperative period, symptoms were evaluated weekly during the first month, and subsequently at weeks 12 and 24. This evaluation was based on the quantification of symptom absence, where the preoperative group served as a baseline, and changes in the postoperative period were observed. These changes indirectly demonstrate a reduction in signs following surgery (Table 3). Starting from the second postoperative week, there was an increase in the proportion of non-snorers, reaching 98% by week 24 (compared to 68% preoperatively), with statistically significant differences ($p = 0.00$) compared to the preoperative period. Additionally, improvements in sweating were observed from the third postoperative week, continuing through weeks 4 and 24 ($p = 0.04$, $p = 0.04$, and $p = 0.00$). The absence of getting up increased from 78% preoperatively to 95% by week 12 ($p = 0.04$). Symptoms such as arousals and kicking showed improvement after surgery, but without statistically significant differences.

The average age at the time of the polysomnography control was 12.81 months (SD ±2.60), with an average weight of 12.49 kg (SD ± 2.88), performed after surgery. When analyzing the polysomnographic variables between the preoperative and postoperative periods, no statistically significant differences were found in the apnea/hypopnea index ($p = 0.238$), duration of the polysomnography ($p = 0.973$), or latency ($p = 0.238$). Additionally, the identification of central apneas ($p = 0.280$), obstructive apneas ($p = 0.715$), hypopneas ($p = 0.38$), and mixed apneas ($p = 0.655$) did not show significant differences.

Regarding the clinical signs and symptoms, we observed a statistically significant difference between the preoperative and postoperative results for weight ($p = 0.00$), night arousals ($p = 0.077$), CO2 saturation ($p = 0.060$), and minimum oxygen saturation ($p = 0.017$). Weight was expected to increase over time as the patient grew. A decrease in nocturnal arousals after palatoplasty was observed, as well as a significant increase in CO2 saturation, indicating improved pulmonary ventilation following surgery. Regarding minimum oxygen saturation, a significant reduction in periods of desaturation was noted, with the mean preoperative value of 77.8% increasing to 83.14% postoperatively (Table 4).

On the other hand, the analysis with polysomnography comparing the preoperative and postoperative periods (note that 8 patients could not undergo follow-up polysomnography and are considered lost to follow-up) showed no statistically significant change in the presence of OSAHS and snoring before and after palatoplasty (Table 5). However, when analyzing the variables of the exam, there was an improvement in minimum oxygen saturation during sleep, with the average increasing from 77.8% to 83.13% ($p = 0.017$, < 0.05) (Table 5).

Table 3. *Evolution of Clinical Signs Preoperatively and at 1, 2, 3, 4, 12, and 24 Weeks Postoperatively: Evaluation of the Absence of Symptoms.*

	Preoperative		**Postoperative**					
	n = NO	**%**	**POST 1 SEM**	**POST 2 SEM**	**POST 3 SEM**	**POST 4 SEM**	**POST 12 SEM**	**POST 24 SEM**
SNORING	28	68%	80%	90%	98%	98%	95%	95%
p-Value			0,13	0,00	0,00	0,00	0,00	0,00
AROUSALS	38	93%	88%	98%	100%	100%	98%	100%
p-Value			0,63	0,63			0,63	
SWEATING	27	66%	80%	80%	88%	88%	100%	97%
p-Value			0,18	0,18	0,04	0,04		0,00
KICKING	34	83%	85%	88%	88%	88%	90%	95%

	Preoperative		Postoperative					
	n = NO	%	POST 1 SEM	POST 2 SEM	POST 3 SEM	POST 4 SEM	POST 12 SEM	POST 24 SEM
p-Value			1,00	0,73	0,73	0,73	0,51	0,13
GETTING UP	32	78%	90%	93%	93%	90%	95%	100%
p-Value			0,18	0,07	0,07	0,13	0,04	

Table 4. *Comparison of variables: Pre-surgical and Post-surgical polysomnography.*

VARIABLE		PRE	POST	*p-Value*	
WEIGHT	Mediana	9,00	12,00		
	IQR	(8,42; 9,42)	(10; 15)	0,000	**
AHI	Mediana	3,55	2,80		
	IQR	(1,5; 7,0)	(1,5; 6,0)	0,238	
DURATION PSG	Mediana	428,50	413,00		
	IQR	(368,5; 475,7)	(393; 440)	0,973	
LATENCY	Mediana	3,45	7,00		
	IQR	(0,025; 17,50)	(1,7; 31,9)	0,238	
EFFICIENCY	Mediana	86,15	89,00		
	IQR	(82,1; 90,6)	(84,0; 92,1)	0,078	*
AROUSALS	Mediana	10,20	8,90		
	IQR	(9; 12)	(7,0; 10,9)	0,077	*
CENTRAL APNEAS	Mediana	1,15	1,80		
	IQR	(0,5; 2,0)	(0,9; 2,6)	0,280	
OBSTRUCTIVE APNEAS	Mediana	0,00	0,00		
	IQR	(0,0; 0,0)	(0,0; 0,0)	0,715	
HYPOAPNEAS	Mediana	2,00	1,10		
	IQR	(0,7; 3,2)	(0,4; 3,2)	0,138	
MIXED APNEAS	Mediana	0,00	0,00		
	IQR	(0,0; 0,0)	(0,0; 0,0)	0,655	
SAT CO2	Mediana	34,00	35,00		
	IQR	(31; 36)	(32,0; 39,5)	0,060	*
***SAT M Ín O2	Media	77,80	83,14		
	DE	9,86	8,20	0,017	**

* Significant values with α = 0,10

** Significant values with α = 0,05

*** Test t and for the rest of the variables Wilcoxon rank test

When evaluating severity, we found that prior to pala-

toplasty, the predominant clinical form of OSAHS was mild, affecting 51% (18 patients), followed by moderate in 34% (12 patients), and severe in 3% (1 patient). Patients with snoring were more likely to have moderate to severe OSAHS, while those without snoring were more commonly associated with mild forms of the disease.

Table 5. *Differences in pre- and postoperative polysomnography results.*

	PRE		POST		
	n = 35*	**%**	**n = 35**	**%**	***p-Value***
OSAHS	31	88,57	29	82,86	0,73
SNORING PSG	9	25,71	9	25,71	1,00

* Group homogenization was performed by accounting for the losses in both the preoperative and postoperative periods

Test: McNemar

After conducting the postoperative assessment, a variation in the severity of the disease was observed. The proportion of patients in the normal stage or without the disease increased to 17% (6 patients), while the mild form remained the same. The moderate form decreased, and no patients were classified as having severe OSAHS (11 patients and 0 patients, respectively) (Figure 1).

Within the improvement groups, 11% of patients progressed from mild to normal, 3% from moderate to normal, 17% from moderate to mild, and 3% from severe to mild. These findings demonstrate an overall improvement in the severity of the disease following palatoplasty.

When evaluating severity, we found that prior to palatoplasty, the predominant clinical form of OSAHS was mild, affecting 51% (18 patients), followed by moderate in 34% (12 patients), and severe in 3% (1 patient). Patients who snore were more likely to have moderate to severe OSAHS, while those without snoring were more commonly associated with mild forms of the disease. After the postoperative assessment, a change in disease severity was observed: 17% (6 patients) of patients had improved to the normal AHI stage, while the mild AHI stage remained stable. The moderate and severe stages were no longer present in the postoperative control. When evaluating the changes in the severity of the disease from the preoperative to postoperative period, no statistically significant differences were observed across the different AHI stages. Mild OSAHS remained the predominant clinical form, followed by moderate OSAHS, with no severe cases observed postoperatively (Table 6 and Figure 1).

Table 6. *Proportion in the severity of OSAHS before palate surgery and postoperative control.*

GRADE	**PRE**	**POST**	***p-Value***
Normal	11,4%	17,1%	0,50
Mild	51,4%	51,4%	1,00
Moderate	34,3%	31,4%	0,80
Severe	2,9%	0,0%	0,31

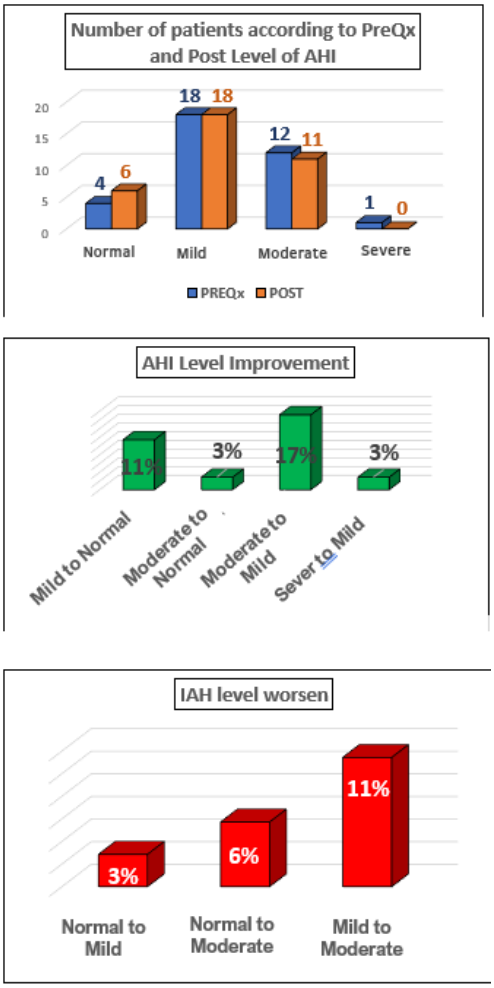

Figure 1. *Number of patients according to Pre and Post Surgical Level of AHI.*

4. Discussion

Cleft palate (CP) is one of the most common congenital craniofacial deformities, often occurring in conjunction with cleft lip (CL). Together, they are referred to as cleft lip and palate (CLP), with an incidence of approximately 1 in 700 live births. Isolated cleft palate occurs in 1 in 2,000 live births in our population. The severity of cleft palate can vary, ranging from cases with a bifid uvula (often associated with submucosal cleft palate) to complete cleft palate, which may be unilateral or bilateral [1, 3, 4].

Cleft palate has a multifactorial etiology, and its exact causes remain unclear. This condition is associated with anatomical compromises, including abnormalities in the nasal vestibule, septum, and floor, as well as maxillary and mandibular hypoplasia. These anatomical features are strongly associated with respiratory disorders, particularly Obstructive Sleep Apnea Hypopnea Syndrome (OSAHS).

These findings may vary depending on the type of cleft palate present, as patients may or may not be syndromic, with a prevalence of 30% and 70%, respectively. Defining the presence of any associated syndrome in patients with cleft palate (CP) is crucial, as it could influence the appearance of respiratory alterations. Recent studies published by Ho ACH and cols, retrospectively using questionnaires identified a greater association of the risk of presenting OSAS with the presence of secondary palate, considering that it can be influenced by factors of the disease itself as well as those associated with its treatment [10]. In syndromic cases, congenital abnormalities may affect various levels of the respiratory tract, contributing to these disorders. Additionally, functional and metabolic alterations are common, and if Obstructive Sleep Apnea Hypopnea Syndrome (OSAHS) is left untreated, mortality rates can increase by up to 30% by the age of 15 [11].

Patients with Obstructive Sleep Apnea Hypopnea Syndrome (OSAHS) and bilateral cleft lip and palate (CLP) who present sleep-associated respiratory syndromes share similar anatomical characteristics at the craniofacial, craniocervical, and pharyngeal levels. These include greater craniocervical angulations, reduced depth from the tip of the soft palate to the oropharynx, and a lower position of the hyoid bone. However, patients with bilateral CLP also exhibit greater retrusion of the maxillary bone, a condition that develops during growth and is influenced by surgical interventions at the level of the palate. These anatomical and functional alterations lead to developmental issues, including dental and bite problems, speech disorders, sleep-related respiratory disturbances, and cognitive deterioration. Consequently, an interdisciplinary management protocol has been established to address these issues comprehensively, facilitating early diagnosis and treatment. This approach aims to improve behavior and enhance school performance [12].

On the other hand, in the clinical evaluation, obstructive respiratory problems in children are of critical importance as they can lead to a range of symptoms, including snoring, arousals during sleep, sleep fragmentation, diaphoresis, enuresis, intermittent hypoxemia and hypercapnia, and nocturnal hypertension. These symptoms can result in daytime sleepiness, which negatively impacts concentration and interferes with short-term academic development. In the long term, untreated obstructive respiratory issues can contribute to hypertension, cardiorespiratory and cerebrovascular diseases, neurobehavioral alterations, and even death [3, 13, 14]. For this reason, our questionnaires asked parents or legal guardians to report these symptoms and compare them six months post-surgery. The results showed that most symptoms improved, particularly the two most frequent ones: snoring and sweating, consistent with findings in the existing literature.

The most reported form of these respiratory alterations is Obstructive Sleep Apnea Hypopnea Syndrome (OSAHS), which has a reported prevalence of 2-3% in the general pediatric population. However, the risk is higher in patients with craniofacial abnormalities, particularly those with cleft palate. Studies exploring the relationship between cleft palate and OSAHS show that the risk of developing OSAHS in patients

with cleft palate ranges from 22% to 65%, with an additional increase in risk due to the surgical procedures these patients undergo [3, 4, 15, 16]. Although we cannot discuss prevalence in this study due to the small sample size, we found that 89% of the patients had some form of OSAHS. When evaluating the severity of OSAHS, we observed that prior to palate surgery, the most common clinical form was mild, followed by moderate, with severe cases being less frequent. These findings are consistent with those reported by MacLean et al. [16, 17].

Respiratory sleep disturbances in children are most often associated with hypertrophy of the tonsils and adenoids, conditions that should be ruled out when diagnosing sleep-disordered breathing, as they are treatable causes. Overweight and obesity should also be considered significant risk factors for this pathology. For this reason, we excluded patients whose weight fell outside the normal growth charts for our population in Colombia. In children with cleft palate, the primary factor influencing respiratory sleep disturbances is the impaired growth of the jaws due to the condition itself. This is compounded by the response to the surgical correction (palatoplasty), which can lead to a decrease in facial height, hypoplasia of the middle third of the face, and maxillary retrognathia. These anatomical changes reduce the space in the pharyngeal airway, putting these patients at risk from birth. However, no conclusive results have been found regarding the direct impact of these factors on sleep-disordered breathing [4, 18].

It is important to mention the significance of identifying the underlying cause of upper airway obstruction, as this allows for more targeted and effective treatment. While determining the exact cause is not the primary focus of this study, it is still a key consideration. Obstructive sleep apnea (OSA) can be associated with alterations in the oropharyngeal muscles, which contribute to structural dysfunction. Upper airway obstruction and the posterior displacement of the tongue, which obstructs airflow by closing against the soft palate, primarily occur during non-REM sleep. During REM sleep, the obstruction tends to be more pronounced at the lower pharyngeal level [19]. Infants and preschool-aged children are particularly vulnerable to upper airway obstruction during sleep [7].

In terms of managing OSA in children, surgical options include adeno-tonsillectomy (first-line treatment), mandibular distraction (in cases of Robin sequence), and craniofacial advancement (in craniosynostosis) [20, 21]. Tracheotomy is considered in cases of severe, refractory OSA. Non-surgical alternatives include treatments such as type 1 cysteinyl leukotrienes [22], dental appliances, weight management, oxygen (though not a definitive treatment), and continuous positive airway pressure (CPAP), which is generally not the first choice in children [23].

In this study, the most common symptoms observed in patients with cleft palate were apnea, cyanosis, nocturnal arousals, snoring, and night sweating. Notably, daytime sleepiness was not reported by any of the caregivers interviewed. The proportion of patients presenting snoring in our study differed from that described by Fernandes et al. [24], who found OSAHS symptoms in 34% of children with non-syndromic cleft lip and palate (CLP), with a high frequency of snoring, increased work of breathing, and apnea during sleep. On the other hand, Muntz et al. reported that patients with syndromic CLP have more sleep-related respiratory symptoms compared to those with non-syndromic CLP, with a prevalence of 34% vs. 17%, respectively ($p<0.01$) [15].

Questionnaires are an important clinical tool in the study of obstructive sleep apnea syndrome (OSAHS), although they have a low negative predictive value, meaning they do not rule out the disease [22]. The clinician must still carefully assess the sleep patterns of patients with cleft palate (CP), specifically investigating symptoms related to OSAHS [15]. In 1984 and 2000, two key questionnaires were developed to evaluate children with obstructive sleep apnea. The first, a three-item scale, was validated for the general pediatric population (aged 1–10 years) and assesses shortness of breath, the presence of apnea, and snoring. The second, the Pediatric Sleep Questionnaire (PSQ), is a more comprehensive tool with 22 items validated for children aged 2 to 18 years and was proposed by Chervin.

MacLean et al. identified that both questionnaires are validated against polysomnographic criteria for moderate to severe OSAHS, but they tend to underestimate mild cases. Additionally, these questionnaires are not validated for children under 1 year of age, who often exhibit a different clinical presentation [25].

In 2014, Cielo et al. evaluated the PSQ in a group of 83 patients with craniofacial malformations, including 19 with cleft lip and palate. They found that the PSQ did not correlate well with polysomnography results, indicating that its sensitivity, specificity, and both negative and positive predictive values are low. As a result, the PSQ is not a particularly useful tool for screening sleep disorders in patients with craniofacial malformations [26]. However, Jost et al. conducted a study in Brazil, where they adapted the PSQ, administering it to 195 patients, finding a high risk in all presentations of cleft lip and palate of developing OSAS (51.3%), even after management with tonsillectomy within the variables with statistical significance (OR=6.948) [27]. Similar results can be found in other studies, with the limitation of the age at which these questionnaires are administered, keeping in mind the multiple factors that have been discussed [28].

In our study, the questionnaire we used focused on sleep-related symptoms in children under 2 years of age, and the results presented here reflect these variables. However, we did not find a direct correlation between the symptoms reported in the questionnaire and the polysomnography findings.

McLean conducted a prospective study with 50 children with cleft palate, including syndromic cases, and found that 75% of the children exhibited symptoms of obstruction. Upon

performing polysomnography, they discovered that 100% of the children presented with OSAHS, as indicated by an apnea-hypopnea index (AHI) greater than 1 [29]. In the general pediatric population, it is reported that 3–12% of children snore, but only 1–3% of these children will develop OSAHS [13], which is more in line with the results observed in our cohort.

When performing the polysomnography test, we found that obstructive sleep apnea syndrome was not diagnosed in 11% of the study group compared to the postoperative group corresponding to 17% with no statistically significant differences (p= 0.727), and Additionally, snoring was not widely reported in either group, with 74% of both the preoperative and postoperative groups showing no snoring (p=1.0). Our findings suggest a higher incidence of respiratory sleep disturbances in males, with the incidence increasing with age [5].

Rose et al. conducted a study involving 43 children with cleft palate, none of whom were diagnosed with sleep-associated respiratory disorders. Despite this, the study found significant statistical correlations in terms of respiratory symptoms and snoring, though no significant differences were noted regarding the incidence of apnea. Based on these findings, Rose et al. concluded that primary palatoplasty in children with cleft palate may lead to microsymptoms of nocturnal airway obstruction during sleep [30].

In contrast, Akita et al. conducted a study involving patients with various craniofacial conditions who were scheduled for surgery, which included 8 children with cleft palate. Their study did not find any significant differences in OSAHS-related changes, as assessed by AHI and snoring characteristics [31].

The primary objective of cleft palate repair is to realign the palatal muscles, which are in abnormal positions, to facilitate phonation. The choice of surgical technique is individualized, depending largely on the surgeon's experience and the specific type of cleft the patient presents. In this service, the most used technique is the Bardach (two-flap technique), followed by Furlow (opposite Z-plasty) and Veau-Wardill-Kilner (Push Back), in that order of frequency [32].

Orr et al. conducted a study in which they used the Von Langenbeck technique in a group of 10 patients with cleft palate, combining it with intravelar veloplasty. They found a low incidence of obstructive apnea, with obstruction occurring in just one patient during the 2-3 days postoperatively due to severe edema, which resolved within 3 months. This led the authors to conclude that the association between palatoplasty and upper airway obstruction is rare [33] and there is no evidence statistically significant that show relationship of palatoplasty and respiratory problems [34].

In a study by Liao et al., it was reported that patients who initially did not present with OSAHS after undergoing secondary palatoplasty (Furlow type) developed some degree of respiratory sleep disorder. Six months following the procedure, 10% of the patients continued to show symptoms of the syndrome [35, 36]. Conversely, Sobral et al. conducted a study involving 23 patients aged 7 to 12 years who had previously undergone treatment for cleft lip and palate malformations. They performed polysomnography and found that 30.4% of these patients had OSAHS, with an AHI >1.4/h, and a maximum of 2.7/h for mild forms of the disease [37].

Studies examining the association between palatoplasty, pharyngoplasty, and OSAHS typically focus on secondary surgical interventions, which are linked to an increased risk of developing obstructive sleep apnea-hypopnea syndrome (OSAHS). Prada et al. conducted a cohort study comparing the Furlow palatoplasty technique to pharyngoplasty for managing velopharyngeal insufficiency in patients without pre-existing respiratory obstruction. Their findings showed significantly higher rates of apnea/hypopnea in the pharyngoplasty group, with mean AHI values of 12.7 versus 1.3 for pharyngoplasty and palatoplasty, respectively (p = 0.001) [38]. Additionally, studies have reported a high prevalence of OSAHS in patients undergoing Orticochea pharyngoplasty, with rates as high as 81% [39]. Other treatments for velopharyngeal insufficiency, such as posterior pharyngeal flaps, are also associated with airway narrowing due to the closure of the donor site, as noted by Prabhu et al. [40]. Given these findings, we present this study to screen for the prevalence of breathing disorders in the cleft palate population prior to any surgical interventions.

On the other hand, studies conducted on children with cleft palate found an altered ventilatory response to hypoxia [18], finding obstructive causes at different levels; For example, at the nasal level, patients with CP generally present septum deviation, deformity of the nasal floor and posterior alteration of the vomer due to the use of this mucosa for palatal reconstruction. At the level of the oropharynx, there is a decrease in the growth of the jaws due to alterations in the anatomical structures both before and after surgery [15, 34]. The AHI is the strongest way to measure respiratory sleep disturbances and their severity, corresponding to the desaturation that the patient is presenting and the intermittent exposure to hypoxia [18].

However, few studies include preoperative polysomnographic assessments of these patients, and those that do often report results with limited statistical significance. This is primarily due to the variability in patient characteristics and the presence of additional comorbidities, which can introduce biases into the findings [17, 41].

5. Conclusions

It is crucial to assess the impact of primary palatoplasty on respiratory sleep disorders, particularly OSAHS, in patients with cleft palate, both in terms of incidence and severity. Since this procedure is indicated for all patients with cleft palate and plays a key role in the management of future speech disorders, understanding its effects on sleep apnea is essential. Our findings indicate that OSAHS is present in 85% of patients preoperatively, suggesting that the origin of this

pathology is closely related to the underlying cleft palate malformation. Furthermore, 6 to 12 months post-surgery, OSAHS persists in 82% of patients, though with variations in severity. Specifically, there was a shift in the Apnea-Hypopnea Index (AHI) as follows: 11% improved from mild to normal, 3% from moderate to normal, 17% from moderate to mild, and 3% from severe to mild, effectively controlling the most severe cases. Symptomatic improvements in nighttime arousals, sweating, and snoring were observed, with statistically significant results. These findings support the importance of evaluating all patients with cleft palate for respiratory sleep disorders, given the high correlation between these conditions. This study serves as a foundation for further research into the long-term outcomes of OSAHS and the effects of primary palatoplasty beyond 24 months.

This study was limited by the availability of surgical opportunity depending on the country's health care insurance, as well as the travel costs for polysomnography test, despite funding for the exam. This ultimately meant that not all patients initially included could be analyzed. Although, the literature on the relationship between OSAHS and primary palatoplasty in patients younger than 2 years is limited, these results are considered a significant contribution to the study population.

Abbreviations

OSAHS	Obstructive Sleep Apnea Hypopnea Syndrome
CP	Cleft Palate
AHI	Apnea Hypopnea Index
CO2	Carbon Dioxide
O2	Oxygen
SAT	Saturation
CL	Cleft Lip
CLP	Cleft Lip and Palate

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Author Contributions

José Rolando Prada Madrid: Conceptualization, Supervision, Validation, Visualization, Writing – review & editing

Diana Carolina Gómez Prada: Conceptualization, Data curation, Formal Analysis, Funding acquisition, Investigation, Writing – original draft, Writing – review & editing

Olga Patricia Panqueva Centanaro: Supervision, Visualization

Carlos Augusto Perez: Writing – original draft

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Data Availability Statement

Not applicable.

Conflicts of Interest

The authors declare no conflicts of interest.

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Biography

Jose Rolando Prada Madrid is a Plastic Surgeon who graduated from the Autonomous University of Mexico in 1992. He has been practicing plastic surgery for 33 years in Bogotá, Colombia, and has taught at several schools. He is currently a Professor of Plastic Surgery at the Hospital Infantil Universitario de San José and Coordinator of Craniofacial Surgery at the Fundacion Universitaria de Ciencias de la Salud. He practices plastic surgery at the Fundacion Universitaria Santa Fe of Bogotá and in private practice. He is a member of the Colombian Society of Plastic Surgery, the Ibero-Latin American Federation of Plastic Surgery, and the International Society of Craniofacial Surgery. He has written three books on plastic surgery and several chapters in various books. He has published several articles in national and international journals and is an international speaker on Aesthetic Surgery, Craniofacial Surgery, and Cleft Lip and Palate Surgery.

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Carlos Augusto Perez is a specialist in Plastic, Aesthetic, and Reconstructive Surgery from the Fundación Universitaria de Ciencias de la Salud (FUCS). He develops his practice in Bogotá, working in clinical institutions and private consultation, with an emphasis on reconstructive and aesthetic surgery. He remains in continuous professional development through congresses and international programs, integrating technical advances supported by scientific evidence. He is an active member of the Colombian Society of Plastic Surgery.

Research Field

Jose Rolando Prada Madrid: plastic surgery, craniofacial surgery, cleft lip and palate, craniosynostosis, facial trauma, genetics
Diana Carolina Gómez Prada: plastic surgery, craniofacial surgery, cleft lip and palate, craniosynostosis, facial trauma,
Patricia Panqueva: Pulmonary pathology in children, asthma, OSAHS, pediatric lung disease, respiratory disorders in children
Carlos Augusto Perez: plastic surgery, hand surgery, cleft lip and palate, General surgery, medicine