Palatoplasty as the Technique of Choice for Prevention of Obstructive Sleep Apnea Secondary to Surgery for Velopharyngeal Insufficiency

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Objective: The aim of this study is to compare patients treated with pharyngoplasty and those treated with palatoplasty for velopharyngeal insufficiency to establish what surgical procedure poses the highest risk for developing sleep apnea. The hypothesis tested in this study is that the incidence of obstructive sleep apnea syndrome associated with pharyngoplasty is greater than that associated with palatoplasty for velopharyngeal insufficiency.

Subjects: Twenty patients were taken from the Institution FISULAB.

Design: Observational cohort analytic study.

Main Outcome Measures: An overnight polysomnographic study was used to determine the incidence and severity of obstructive sleep apnea syndrome.

Results: The incidence of obstructive sleep apnea syndrome following pharyngoplasty was shown to be significantly higher than after palatoplasty. The apnea-hypopnea index, also called the respiratory disturbance index, was 12.7 in the pharyngoplasty group and 1.35 in the palatoplasty group ($p < .001$). When obstructive sleep apnea syndrome was stratified into different levels of severity according to the values of respiratory disturbance index, there were noticeable differences between these two groups. In the palatoplasty group, one patient had mild obstructive sleep apnea syndrome. In the pharyngoplasty group, two patients had mild obstructive sleep apnea syndrome, one patient had moderate obstructive sleep apnea syndrome, and two patients had severe obstructive sleep apnea syndrome.

Conclusions: When comparing the apnea-hypopnea index (i.e., respiratory disturbance index) of patients treated for velopharyngeal insufficiency with palatoplasty versus pharyngoplasty, we observed an important difference between the groups, with the highest indices in the pharyngoplasty group.

KEY WORDS: apnea-hypopnea index, obstructive sleep apnea, palatoplasty, pharyngoplasty, polysomnography

Velopharyngeal insufficiency (VPI) is defined as an inability to close the velopharyngeal sphincter, which results in an inability to adequately separate the oral cavity from the nasal cavity during speech. It is common in persons with a cleft palate both before and after repair: It has been estimated that 5% to 30% of patients with cleft palate will need secondary surgical procedures to improve velopharyngeal closure after appropriate primary palatal repair and speech therapy (McWilliams et al., 1996; Bicknell et al., 2002). The goal of cleft palate and velopharyngeal surgeries are to restore normal anatomy or to modify existing anatomy to improve velopharyngeal function.

Several different surgical procedures have been described to correct VPI, including pharyngeal flap (Morris et al., 1995; Serres et al., 1999), sphincter pharyngoplasty (Pensler and Reich, 1991; Riski et al., 1992), and pharyngoplasty and Furlow palatoplasty (Chen et al., 1994; Hudson et al., 1995; D’Antonio, 1997). But complications related to the different surgical procedures have arisen. One of the serious complications is obstructive sleep apnea syndrome (OSAS).

Numerous studies have been conducted to examine the incidence of early postoperative respiratory obstruction by comparing pharyngeal flap and sphincter pharyngoplasty, but there are no studies comparing the incidence of postoperative respiratory obstruction in pharyngoplasty and palatoplasty (Ysunza et al., 1993; Sie et al., 1998; Liao et al., 2002). Therefore, the purpose of our study was to
investigate the incidence and severity of OSAS following pharyngoplasty versus palatoplasty in patients with cleft palate, at least 1 year postoperatively. It was hypothesized that the severity of OSAS associated with sphincter pharyngoplasty would be greater than that associated with palatoplasty.

**MATERIALS AND METHODS**

The present study was approved by the ethics committee of the Universidad Militar Nueva Granada, and an informed consent was obtained from all the patients’ parents when included in the study.

**Subjects**

Group 1 comprised 10 patients (three boys and seven girls) with repaired cleft palate who agreed to undergo palatoplasty for VPI. The surgical procedure realized was a Furlow palatoplasty; the double-opposing Z-plasty of the soft palate was performed as described by Furlow (1986), with a modification in which great care is taken to identify the abnormal course of the levator muscle and (1) dissect and free it from the posterior edge of the hard palate in the midline, (2) separate it from its abnormal association with the tensor aponeurosis along the lateral aspect of the posterior edge of the hard palate, and (3) radically reposition it from the sagittal anterior-posterior orientation to a completely coronal medial-lateral position, ultimately up to 1 cm or more from the posterior edge of the hard palate. The Furlow palatoplasty simultaneously lengthens the newly reconstructed velum as it narrows the nasopharyngeal aperture, with a secondary pharyngoplasty-type effect. Group 2 comprised 10 patients (all boys) with repaired cleft palate who agreed to undergo pharyngoplasty. Five patients underwent surgical procedures consisting of sphincter pharyngoplasties as described by Orticochea (1968), and five underwent pharyngoplasties as described by Jackson and Silverton (1977). The former incorporated bilateral palatopharyngeus myomucosal flaps elevated in the posterior tonsillar pillars, with the palatopharyngeus muscle enclosed from the lateral pharyngeal walls to the midsection of an inferiorly based flap on the posterior pharyngeal wall to which the tips of the pharyngoplasty flaps have been sutured. The latter incorporated bilateral superiorly based flaps from the posterior tonsillar pillars, with the palatopharyngeus muscles sutured together on the midline to be attached to the undersurface of a superiorly based posterior pharyngeal flap. All patients were recruited from Institution FISULAB (a rehabilitation center for children with cleft lip and palate). The patients from the palatoplasty group (Group 1) were operated upon by one senior surgeon (J.R.P.M.); whereas, the patients from the pharyngoplasty group (Group 2) were operated upon by other surgeons and were followed up in the Institution FISULAB. The mean age of all patients was 13.4 years.

All subjects underwent a thorough evaluation for VPI and symptoms consistent with OSAS, such as snoring, choking during sleep, excessive daytime sleepiness, fragmented sleep, nocturnal sweating, dyspnea, or witnessed apnea before and 1 year after the surgery. In addition, each subject underwent a sleep study at least 1 year postoperatively.

The 20 subjects were separated into two groups, as described previously, for statistical analysis on the basis of surgical procedure used.

**Inclusion Criteria**

Selection criteria for the present study included patients with cleft palate who developed VPI and were treated either with pharyngoplasty or palatoplasty.

**Exclusion Criteria**

Excluded from the study were (1) patients with cleft palate who developed VPI and were treated with other surgical procedures different from pharyngoplasty or palatoplasty; (2) subjects with associated craniofacial anomalies, such as Pierre Robin sequence, Crouzon syndrome, midface hypoplasia needing orthognathic surgery, velocardiofacial syndrome, or other systemic abnormalities; (3) subjects with alteration in velopharyngeal learning due to previously diagnosed deafness; and (4) patients with VPI secondary to tumor, trauma, or ablative surgery in the pharynx (tonsillectomy).

**VPI Assessments**

Velopharyngeal insufficiency assessments were completed by two experienced speech therapists before surgery. The clinicians engaged the subjects in conversation to determine the severity of hypernasality. Subjects with hypernasality received nasoendoscopy to confirm the diagnosis of VPI. The type of surgical procedure chosen was determined by the speech therapist after a conference with the surgeon.

The patients in this study were not randomly selected. Pharyngoplasty was practiced for patients having coronal and circular patterns of closure with adequate velar motion but with a moderate to large residual velopharyngeal gap (which was divided into small, moderate, and large: <33%, 33% to 66%, and >66%, respectively). Palatoplasty was recommended for the repair of small or moderate midline gaps.

**Polysomnographic Sleep Recordings**

An overnight polysomnographic sleep recording was performed on each patient. This included left and right central electroencephalograms, left and right electrooculograms, digastric muscle electromyogram, left and right anterior tibialis muscle electromyograms, respiratory airflow from sensors placed at the nasal and oral orifices, respiratory effort from sensors placed around the thorax.
and the abdomen, and oxyhemoglobin saturation with pulse oximetry. Cardiac rhythm was monitored with electrodes. Sleep efficiency was defined as the total sleep time divided by the time from sleep onset to final awakening in the morning.

Apnea was classified as central, obstructive, or mixed. **Obstructive apnea** was defined as absence of nasal and oral airflow with persistent respiratory movements for more than 10 seconds, **hypopnea** being a 50% decrease or more in airflow associated with a 4% fall in oxygen saturation. **Central apnea** was defined as a simultaneous cessation of both airflow and respiratory movements for at least 10 seconds. **Mixed apnea** has elements of both types. The respiratory disturbance index (RDI) was the total number of apneas and hypopneas divided by the total sleep time in hours. Respiratory disturbance index values of 1 to 4.9 were considered mildly abnormal; 5 to 10, moderately abnormal; and >10, severely abnormal. The lowest oxyhemoglobin saturation (LSAT) was recorded also.

### Statistical Analysis

**Power for a Test of the Null Hypothesis**

One goal of the proposed study was to test the null hypothesis that the two population means are equal. The criterion for significance ($\alpha$) has been set at .05. The test is two-tailed, which means that an effect in either direction will be interpreted.

With the sample size of 10 for each of the two groups, the study will have power of 80.5% to yield a statistically significant result.

This computation assumes that the mean difference is $-10.0$ (corresponding to means of 10.0 versus 20.0) and that the common within-group standard deviation is 7.5.

This effect was selected as the smallest effect that would be important to detect, in the sense that any smaller effect would not be of clinical or substantive significance. It is also assumed that this effect size is reasonable, in the sense that an effect of this magnitude could be anticipated in this field of research.

**Precision for Estimating the Effect Size**

A second goal of this study was to estimate the mean difference between the two populations. On average, a study of this design would enable us to report the mean difference with a precision (95% confidence level) of ±6.92 points. For example, an observed difference of $-10.0$ would be reported with a 95% confidence interval of $-16.92$ to $-3.08$.

The precision estimated here is the median precision. Precision will vary as a function of the observed standard deviation (as well as sample size), and in any single study will be narrower or wider than this estimate.

Variance is estimated ($t$ test).

### RESULTS

All subjects in both groups were free of symptoms consistent with OSAS prior to surgery, but four patients in the pharyngoplasty group (Group 2) and one patient in the palatoplasty group (Group 1) were symptomatic 1 year postoperatively. The tendency was the more severe the OSAS, the more symptoms consistent with the condition, such as dyspnea or apnea, were observed. In addition, the more severe the OSAS, the lower the LSAT.

The incidence of OSAS following pharyngoplasty (Group 2) was high and significantly different in comparison with that after palatoplasty (Group 1), as shown by the difference in the RDI between these two groups (pharyngoplasty RDI = 12.7; palatoplasty RDI = 1.35; $p < .001$) (Table 1). When OSAS was stratified into different levels of severity according to the RDI values, there were noticeable differences between these two groups (Tables 2 and 3). In the pharyngoplasty group (Group 1), one patient had mild OSAS (3 per hour, LSAT = 89%) with obstructive apnea pattern. In the pharyngoplasty group two patients had mild OSAS (Orticcochea’s pharyngoplasty: 3.9 per hour, LSAT = 88% and Jackson and Silverton’s pharyngoplasty: 3 per hour, LSAT = 89%) with mixed apnea pattern, one patient had moderate OSAS (Orticcochea’s pharyngoplasty: 6.3 per hours, LSAT = 86%) with obstructive apnea pattern and two patients had severe OSAS (Orticcochea’s pharyngoplasty: 22.8 per hour, LSAT = 85% and 28.3 per hours, LSAT = 82%) with obstructive apnea pattern.

Body mass index and age could influence the observed outcomes, but analysis with Student’s $t$ test showed no differences between the two groups for these variables.

Sleep efficiency was good in all the patients in the palatoplasty group (Group 1), corresponding to values

<table>
<thead>
<tr>
<th>Variable</th>
<th>Palatoplasty, n = 10</th>
<th>Pharyngoplasty, n = 10</th>
<th>p Value</th>
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</thead>
<tbody>
<tr>
<td>Gender</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Boys, n (%)</td>
<td>3 (43%)</td>
<td>10 (100%)</td>
<td></td>
</tr>
<tr>
<td>Girls, n (%)</td>
<td>7 (57%)</td>
<td>0</td>
<td></td>
</tr>
<tr>
<td>Average age (SD)*</td>
<td>15 (6.25)</td>
<td>11.8 (4.6)</td>
<td>.218</td>
</tr>
<tr>
<td>Body mass index</td>
<td>18.8 (3.27)</td>
<td>16.9 (2.21)</td>
<td></td>
</tr>
<tr>
<td>Apnea-hypopnea index (RDI)</td>
<td>1.3 (1.47)</td>
<td>12.7 (8.9)</td>
<td>.001</td>
</tr>
</tbody>
</table>

* SD = standard deviation; RDI = respiratory disturbance index.

<table>
<thead>
<tr>
<th>TABLE 2 Levels of Severity</th>
<th>Palatoplasty, n (RDI)</th>
<th>Orticochea, n (RDI)</th>
<th>Jackson and Silverton, n (RDI)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mild</td>
<td>1 (3/h)</td>
<td>1 (3.9/h)</td>
<td>1 (3/h)</td>
</tr>
<tr>
<td>Moderate</td>
<td>1 (6.3/h)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Severe</td>
<td>2 (22.8/h–28.3/h)</td>
<td></td>
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>90%, and was deficient in three patients in the pharyngoplasty group (Group 2), corresponding to values <70%.

**DISCUSSION**

The hourly frequency of apneas and hypopneas is used to assess the severity of OSAS and is called the apnea-hypopnea index or the RDI. It is clear that the RDI is the best measure of this disorder and is the one most commonly used. Other measures including oximetry, computerized electroencephalogram analysis, autonomic arousal detection, or body movements analysis may be equally as good at characterizing the severity of sleep apnea. Because these indices are defined in different ways in different centers, comparisons may be difficult; for that reason we chose the RDI in order to determine the outcomes for this study.

Obstructive sleep apnea syndrome has been reported as a complication of VPI surgery in the short-term as well as long-term follow-up of patients.

The prevalence of sleep-breathing disorders is probably highly variable depending on the surgical technique. There are only two retrospective studies (Pensler and Reich, 1991; Serres, 1999) comparing the prevalence of OSAS after pharyngeal flaps or sphincter pharyngoplasty; the results of the two studies are in agreement, showing a higher prevalence of OSAS after pharyngeal flaps. Conversely, in the study developed by Raymond (Christel et al., 2004), sphincter pharyngoplasty did not lead to long-term postsurgical OSAS; although, they found that there was an increase in subtle respiratory events after surgery that were undetected by the diagnostic tools they used. Such events are subtle but significant enough to slightly impair sleep quality.

Pharyngoplasty in conjunction with effective speech therapy remains the primary protocol for treating VPI in patients with cleft palate in our institutions.

Although OSAS following pharyngoplasty surgery is well documented, the actual incidence is variable in published reports, and there are no reports comparing the incidence of OSAS between palatoplasty and pharyngoplasty as the surgical methods for correction of VPI.

In a recent study developed by Liao et al. (2002) in which the objective was to investigate the incidence and severity of OSAS following Furlow palatoplasty for VPI in 10 children with cleft palate, the investigators concluded that OSAS in this situation was common but mild and temporary; however, they established that a large case series study should be conducted to confirm these findings.

The importance of this study is based on the clinical implications of sleep apnea in children. There has been a great deal of interest in the effect of OSAS on a child’s cognitive abilities. A number of studies have shown that OSAS is a significant risk factor for cognitive impairment. Language dysfunction, memory problems, attention difficulties, cardiac function impairment, metabolic disturbances, and immunologic and pulmonary alterations are some of the repercussions of this pathology (Leung and Bradley, 2001; Quan et al., 2006; Li and Nanayakkara, 2007; Golbin et al., 2008; Tasali and Ip, 2008). We believe the reduced morbidity of palatoplasty makes it the treatment of choice to treat VPI in patients with cleft palate.

A limitation of our study is the lack of preoperative polysomnography. The difference between the preoperative and postoperative polysomnography would have been a better measure of the true difference of the effect of sphincter pharyngoplasty versus palatoplasty on OSAS because some of these subjects may have had OSAS preoperatively. However, all of them were free of symptoms consistent with OSAS, such as snoring, prior to any of the surgical procedures. The incidence of OSAS in this sample before the surgery must have been extremely low.

In conclusion, when comparing the RDI of patients treated for VPI with palatoplasty versus pharyngoplasty, we observed an important difference between the groups, with highest indices in the pharyngoplasty group. Therefore, we support a protocol to treat patients with cleft palate and VPI with modified palatoplasty as the first-choice procedure in order to decrease the incidence of OSAS and its known morbidities. This option should be offered as the initial secondary procedure to improve speech, prior to pharyngoplasty with its associated morbidity, such as the well-documented lifetime risk of OSAS. With a Furlow double-opposing Z-plasty palatoplasty, both objectives of palatoplasty, primary palatal lengthening and levator sling reconstruction, are met with a single operation. In addition, the Furlow palatoplasty narrows the nasopharyngeal port by lengthening the velum. On the other hand, pharyngeal surgery alters the anatomy of the upper airway in order to decrease nasal escape during speech. In doing so, the nasopharyngeal port is narrowed in such a way that, although addressing VPI, carries the lifelong risk of significant morbidity, including OSAS, snoring, hyponasal speech, and mouth breathing.

We recommend that all patients presenting with postoperative VPI be considered first for a conversion Furlow palatoplasty prior to performing a pharyngoplasty and exposing patients to its unfortunate morbidities.

**REFERENCES**


