Velopharyngeal Surgery: A Prospective Randomized Study of Pharyngeal Flaps and Sphincter Pharyngoplasties

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Residual velopharyngeal insufficiency after palatal repair varies from 10 to 20 percent in most centers. Secondary velopharyngeal surgery to correct residual velopharyngeal insufficiency in patients with cleft palate is a topic frequently discussed in the medical literature. Several authors have reported that varying the operative approach according to the findings of videonasopharyngoscopy and multiview videofluoroscopy significantly improved the success of velopharyngeal surgery. This article compares two surgical techniques for correcting residual velopharyngeal insufficiency, namely pharyngeal flap and sphincter pharyngoplasty. Both techniques were carefully planned according to the findings of videonasopharyngoscopy and multiview videofluoroscopy.

Fifty patients with cleft palate and residual velopharyngeal insufficiency were randomly divided into two groups: 25 in group 1 and 25 in group 2. Patients in group 1 were operated on by using a customized pharyngeal flap according to the findings of videonasopharyngoscopy and multiview videofluoroscopy in each case. Those in group 2 received a sphincter pharyngoplasty also customized according to the findings of videonasopharyngoscopy and multiview videofluoroscopy. The median age of the patients in both groups was not significantly different ($p > 0.5$). The frequency of residual velopharyngeal insufficiency after the individualized velopharyngeal surgery was not significantly different between the patient groups (12 percent versus 16 percent; $p > 0.05$).

It seems that customized pharyngeal flaps and sphincter pharyngoplasties performed according to the findings of videonasopharyngoscopy and multiview videofluoroscopy are safe and reliable procedures for treating residual velopharyngeal insufficiency in cleft palate patients. (*Plast. Reconstr. Surg.* 110: 1401, 2002.)

Velopharyngeal insufficiency refers to excessive nasal resonance or hypernasality during speech as the consequence of anatomical abnormalities of the velopharyngeal sphincter involving the velum and/or pharyngeal walls. Hypernasality is the signature characteristic of persons with cleft palate. This disorder is diagnosed efficiently through a careful clinical examination and with the aid of procedures such as videonasopharyngoscopy and videofluoroscopy.[1–3] In our population, cleft palate occurs in approximately one in every 750 human births, making it one of the most common congenital malformations.[4]

Surgical closure of the palatal cleft does not always result in a velopharyngeal port capable of supporting normal speech. Residual velopharyngeal insufficiency is considered when palatal repair is unsuccessful in providing complete closure of the velopharyngeal sphincter during speech.[2,4–6] Residual velopharyngeal insufficiency varies from 10 to 20 percent in most institutions. In our center, 650 patients with cleft palate were operated on between 1995 and 2000. Residual velopharyngeal insufficiency was demonstrated in 71 (11 percent) of these patients.[4] Secondary velopharyngeal surgery to correct velopharyngeal insufficiency in cleft palate patients with residual velopharyngeal insufficiency is a topic frequently discussed in the medical literature.[4,7–12] Several reports have suggested that there cannot be one single operative approach to velopharyngeal insufficiency because velopharyngeal physiology varies so remarkably from one individual to another. Thus, a single operation is

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not likely to correct all cases of velopharyngeal insufficiency because closure defects at the velopharyngeal sphincter have been noted to vary in size, position, shape, and consistency between individuals presenting with velopharyngeal insufficiency.[4,7,10,12] Videonasopharyngoscopy and multiview videofluoroscopy provide visualization of the velopharyngeal sphincter during speech. These procedures provide the best assessments to help plan and direct the optimal treatment of velopharyngeal insufficiency.[1,2,4,12] Furthermore, several authors have reported that varying the operative approach according to the findings of videonasopharyngoscopy and multiview videofluoroscopy significantly improved the success of velopharyngeal surgery.[4,7,10,11]

The goal in treating velopharyngeal insufficiency is to restore a functional seal between the nasopharynx and oropharynx so that normal speech articulation occurs. Several options are available. Individualized velopharyngeal surgery is often performed when palatal closure fails to completely correct velopharyngeal insufficiency and residual velopharyngeal insufficiency persists. Individualized surgery includes customized pharyngeal flaps and sphincter pharyngoplasties performed according to the findings of videonasopharyngoscopy and multiview videofluoroscopy, as reported previously.[4,10,12,13] Pharyngeal flap is the mainstay of surgical therapy for velopharyngeal insufficiency in many facilities. Multiple modifications have been developed in an effort to optimize speech outcome. In general, most centers have reported resolution of velopharyngeal insufficiency in 80 to 90 percent of patients undergoing customized pharyngeal flap operations.[4,10,13,14] Sphincter pharyngoplasty is another surgical procedure frequently used for correcting residual velopharyngeal insufficiency. This procedure can be also planned according to the specific findings of the velopharyngeal sphincter in each case. The success rate for correcting velopharyngeal insufficiency with especially designed sphincter pharyngoplasty varies from 80 to 90 percent.[12,15–18]

Normality of the final speech results in all patients with velopharyngeal insufficiency depends on articulation as much as on normal resonance balance. Nasal resonance is corrected by physical management of the velopharyngeal sphincter (surgery or prosthetic appliances). Compensatory articulation disorder associated with velopharyngeal insufficiency requires speech therapy because of the dysfunction not only of the velopharyngeal sphincter but also of the entire vocal tract.[5,19–22] Therefore, articulation therapy before individualized velopharyngeal surgery is suggested to attempt to increase the movements of the velopharyngeal sphincter and thus reduce the degree of nasal obstruction necessary to eliminate velopharyngeal insufficiency.[5,10,20] Moreover, at the end of the operation articulation will be normal or nearly normal, so the postoperative result can be appreciated almost immediately. Even if surgery corrects velopharyngeal insufficiency before the elimination of compensatory articulation disorder, little change in speech is noticeable and it remains largely unintelligible. Although patients and parents can be counseled that speech therapy will still be necessary, at our center we believe that the largest trauma to the patient (i.e., surgery) should be saved for last and should result in a noticeable and important change in speech.[5,10]

This article compares two surgical techniques for correcting residual velopharyngeal insufficiency: pharyngeal flap and sphincter pharyngoplasty. Both procedures were carefully planned according to the findings of videonasopharyngoscopy and multiview videofluoroscopy. The size and form of the gap, lateral pharyngeal wall motion, and level of maximum displacement of the velopharyngeal sphincter were considered as criteria for individualizing the surgical procedure. However, before surgical planning, one of the two techniques was selected randomly in each case.

Patients and Methods

The sample size was calculated at an alpha 95 percent confidence interval and a beta power of 80 percent for a comparative study of the two treatment groups. The frequency of postoperative velopharyngeal insufficiency after individualized velopharyngeal surgery in cleft palate cases during 4 previous years at the cleft palate clinic was considered. We aimed to detect a 20 percent difference in proportion. These data indicated at least 23 patients for inclusion in each treatment group. A prospective study was completed of patients diagnosed with residual velopharyngeal insufficiency after unilateral cleft lip and palate had been surgically repaired at the cleft palate clinic of the Hospital Gea Gonzalez in Mexico City. All patients diagnosed with residual velopharyngeal

insufficiency from January of 1995 to December of 2000 were studied. During this period, 359 patients who presented with a repaired unilateral cleft lip and palate at our clinic were evaluated. The protocol was approved by the research and bioethics committee of the hospital. All parents and legal guardians were counseled before the patients were included in the study group. The study methods and surgical procedures were carefully explained to all parents and legal guardians. We were especially careful to point out that the surgical approach would be carefully planned according to the findings of videonasopharyngoscopy and multiview videofluoroscopy in each case, regardless of the random selection of one of the two surgical procedures. The goal was to achieve the best possible result with the surgical technique assigned to each case. The parents and legal guardians of all selected patients agreed to participate in the study.

To qualify for the subject group for this study, the patients had to meet the following criteria:

1. a diagnosis of nonsyndromic unilateral cleft lip and palate with no other medical condition;
2. velopharyngeal insufficiency with or without compensatory articulation disorder as demonstrated by phoniatric assessment, videonasopharyngoscopy, and multiview videofluoroscopy;
3. chronologic age between 4 and 8 years at the time of selection for the study;
4. normal hearing as demonstrated by conventional pure-tone audiometry;
5. language development within reference limits as demonstrated by the Speech Discrimination Score model[23];
6. absence of postoperative fistulas;
7. cleft palate width of grades I or II[24];
8. palatal repair of the unilateral cleft lip and palate performed according to the surgical routine of the cleft palate clinic (i.e., surgical repair of the lip and primary palate between 1 and 3 months of age, and surgical repair of the secondary palate before 8 months of age with a minimal-incision palatopharyngoplasty).[24]

A total of 50 patients met the criteria for inclusion in the study group. Twenty-seven patients with residual velopharyngeal insufficiency did not meet the criteria for this study.

Twenty patients showed velopharyngeal insufficiency and associated compensatory articulation disorder, as demonstrated by phonologic assessment, videonasopharyngoscopy, and multiview videofluoroscopy. These patients received speech therapy according to the guidelines reported previously, including phonologic approach and whole language intervention.[23,25] Speech therapy was continued until placement of articulation was adequate, even when hypernasality was present. At the end of the speech intervention, all patients were independently examined by two speech pathologists with 10 years of experience in evaluating and treating patients with cleft palate. The patients did not continue the study protocol until both pathologists were convinced that the compensatory articulation disorder had been corrected, at least during the production of selected speech samples, which are routinely used in our center.[23,25] Total time of speech intervention was considered to be the time from onset of therapy until normalization of placement of articulation, even when hypernasality was present. After the speech intervention, the 20 patients underwent additional videonasopharyngoscopy and multiview videofluoroscopy to record data of the velopharyngeal sphincter without the influence of compensatory articulation disorder. Finally, these 20 cases were included within the whole study group of 50 cases.

It should be noted that although surgery was indicated in these 20 patients at the time in which placement of articulation had been corrected, it was carefully explained to all parents that speech therapy must be continued until articulation was completely corrected during spontaneous connected speech.

For the surgical treatment, the patients were randomized to either the pharyngeal flap group or the sphincter pharyngoplasty group using block randomization. The precise method of block randomization was blind to the surgeons and involved balancing the number of patients recruited to both groups of the study, after every 20 recruits. This level of block randomization ensured that if the study had been stopped early, there would have been almost exactly the same number of operations. The blinding ensured that the surgeons did not obtain sufficient knowledge to enable them to second-guess the allocation of the next recruit.[26]

Twenty-five patients were included in group 1 and 25 in group 2. Patients in group 1 were

operated on by using a customized pharyngeal flap according to the findings of videonasopharyngoscopy and multiview videofluoroscopy in each case. Those in group 2 received a sphincter pharyngoplasty also customized according to the findings of videonasopharyngoscopy and multiview videofluoroscopy. As previously reported, the size and form of the gap, lateral pharyngeal wall motion, and level of maximum displacement of the velopharyngeal sphincter were considered as criteria for individualizing the surgical procedure; i. e., width, location, and level of insertion of the pharyngeal flap or the lateral flaps of the sphincter pharyngoplasty.[4,10,12,13] All procedures were performed by the same team, which included two of the current authors.

Four months after the surgical procedures, all patients underwent additional phoniatric evaluation. A blind procedure was used whereby all analyses were independently conducted by two speech pathologists with 10 years of experience in evaluating and treating cleft palate patients in our center. Only perceptual evaluations were used to keep the examiners blind to the surgical procedures that had been performed. Postoperative videonasopharyngoscopy and multiview videofluoroscopy were also performed 4 months after the surgical procedures. All of these evaluations were independently analyzed by two phoniatrists who had 10 years of experience in performing and assessing these procedures in our center. The presence or absence of velopharyngeal insufficiency, and the size and form of the defect at the velopharyngeal sphincter during speech, were determined. Concordance between each pair of examiners was evaluated using the kappa statistic; kappa >0.75 was considered as denoting excellent reproducibility.[26] When differences occurred, each case was discussed by the examiners until an agreement was reached.

The results from both groups of patients were compared. Age was considered as a one-dimensional variable and was analyzed by a Mann-Whitney rank sum test. Another dimensional variable was the size of the gap as observed by videonasopharyngoscopy and multiview videofluoroscopy, which was analyzed by Student's t test. Velopharyngeal insufficiency was considered as a binary variable (yes or no) and was analyzed with a Fisher's exact t test. For each variable, an alpha value of 0.05 was selected for considering the results as stochastically significant.[27]

RESULTS

The age of the patients in group 1 ($n = 25$) ranged from 4 years to 7 years, 7 months (median: 4 years, 7 months). In group 2 ($n = 25$), ages ranged from 4 years to 7 years, 4 months (median: 4 years, 5 months). A Mann-Whitney rank sum test revealed a nonsignificant difference in age between both groups ($p > 0.5$).

The total time of speech intervention in the 20 patients who presented with velopharyngeal insufficiency and compensatory articulation disorder ranged from 11 to 41 months (mean $\pm$ SD, 20.2 $\pm$ 9.5). Although 92 percent of the patients demonstrated an improvement in velopharyngeal movements and a reduction in gap size after correction of compensatory articulation, in none of the patients was velopharyngeal insufficiency corrected by speech therapy. Moreover, the form of the gap at the velopharyngeal insufficiency was not modified by speech therapy. The opinions of the examiners for the preoperative videonasopharyngoscopy and multiview videofluoroscopy coincided in most of the cases regarding the presence or absence (yes or no) of velopharyngeal insufficiency in each case. A kappa statistic of 0.90 was found between the pair of examiners analyzing videonasopharyngoscopies. However, it should be noted that a kappa statistic of <0.75 was found when the size of the gap was assessed by the pair of examiners. This value denoted a nonsignificant reproducibility.

Closure patterns of the velopharyngeal sphincter during speech were evenly distributed between the two treatment groups. Forty-five percent of the patients showed a coronal pattern, 47 percent showed a circular pattern, and 8 percent showed Passavant's ridge. The gap size of the velopharyngeal closure during speech as observed preoperatively by videonasopharyngoscopy and multiview videofluoroscopy was not significantly different between the groups (28.25 $\pm$ 7.82 percent in group 1; 29.25 $\pm$ 6.34 percent in group 2; $p > 0.5$).

A kappa statistic of 0.90 was found between the pair of examiners analyzing postoperative phoniatric assessment. When postoperative results of the videonasopharyngoscopy and multiview videofluoroscopy were examined, a kappa statistic of 0.90 was found between the pair of examiners regarding the presence or absence (yes or no) of velopharyngeal insufficiency in each case.

Both examiners noted that all the patients

who presented with postoperative velopharyngeal insufficiency showed only bubbling at the velopharyngeal sphincter during speech, but no gap could be defined (i.e., a "pinhole" gap). Thus, according to previous reports, all of these patients were recorded as having a defect of 10 percent.[1]

The success rate for correcting velopharyngeal insufficiency after the surgical procedures was not significantly different between the groups ($p > 0.05$). Three patients (12 percent) from group 1 and four (16 percent) from group 2 demonstrated postoperative velopharyngeal insufficiency. Complete closure of the velopharyngeal sphincter was achieved in 22 patients (88 percent) from group 1 and in 21 (84 percent) from group 2 (Table I).

DISCUSSION

The results of this study suggest that the frequency of velopharyngeal insufficiency was not significantly different when two methods of individualized velopharyngeal surgery were used. This study was undertaken to examine our experience with the sphincter pharyngoplasty and pharyngeal flap procedures after our clinical experience indicated that similar good results were being obtained with both procedures. Individually customized pharyngeal flaps and sphincter pharyngoplasties, according to the findings of videonasopharyngoscopy and multiview videofluoroscopy, seem to be similarly useful in treating residual velopharyngeal insufficiency in patients with cleft palate.

All patients operated on with these two procedures showed only bubbling at the velopharyngeal sphincter, with no defined gap postoperatively. Thus, the size of the gaps was reduced in all cases. No complications such as postoperative bleeding, fistulas, or upper airway obstruction were found in any of the patients operated on in this study.

TABLE I

Postoperative Frequency of Velopharyngeal Insufficiency

	Velopharyngeal Insufficiency		Complete Closure		
Group*	*n*	%	*n*	%	Total (*n*)
1	3	12	22	88	25
2	4	16	21	84	25
Total	7		43	50	
		$p > 0.05$			

* A Fisher's exact test demonstrated that the frequency was not significantly different, independently of the surgical procedure used in each group of patients (group 1, pharyngeal flap; group 2, sphincter pharyngoplasty).

Surgical management of velopharyngeal insufficiency presents the challenge of balancing acceptable nasal resonance and nasal obstruction. In this study, the surgical result was considered a success when oronasal resonance was normal and nasal air escape was absent; residual velopharyngeal insufficiency, however mild, was counted as such. We believe this to be a less biased way of reporting results. In this study, patients undergoing either procedure were at risk for obstructive airway symptoms.

None of the parents reported that a child had obstructive sleep apnea after surgery. As noted earlier, in our cleft palate clinic all patients who present with residual velopharyngeal insufficiency after palatal repair routinely undergo videonasopharyngoscopy and multiview videofluoroscopy. When the risk of obstruction is detected, tonsillectomy is performed before velopharyngeal surgery, and/or nasopharyngeal tubes are routinely used in the postoperative period.[28]

The relatively small number of patients and the homogeneity[29] of the sample included in this study do not allow definite conclusions. With these limitations in mind, we believe we can comment about speech outcome in patients undergoing pharyngeal flap and sphincter pharyngoplasty at our institution. Resonance and speech outcomes seemed similarly favorable after either a pharyngeal flap or a sphincter pharyngoplasty. Thus, it seems appropriate to approach residual velopharyngeal insufficiency after palatal repair with a carefully planned surgical procedure, individually customized for each case according to the findings of videonasopharyngoscopy and multiview videofluoroscopy. Furthermore, regardless of the selection of a pharyngeal flap or a sphincter pharyngoplasty, it seems that the planning of the surgical procedure to match the postoperative structure to the preoperative movements seen in the velopharyngeal sphincter[4,7,10,11] is one of the most important aspects of this surgery.

The variability of velopharyngeal valving in patients with velopharyngeal insufficiency stresses the importance of observing the component movements of velopharyngeal closure. Operations to correct velopharyngeal insufficiency provide tissue obturators (pharyngeal flap or lateral flaps of the sphincter pharyngo-

plasty) that will close the gaps during speech. The tissue obturator must be placed correctly. In our center, when surgery is indicated, the surgeon, phoniatrist, and speech pathologist review the studies immediately before treatment. The size and shape of the gap are considered for determining the width of the pharyngeal flap or the lateral flaps of the sphincter pharyngoplasty. The symmetry of displacement is considered for deciding if the flap should be skewed or if the width of one of the lateral flaps should be increased. The contour of the lateral pharyngeal walls and velum, which refers to the vertical extent of movement as observed by the frontal and lateral projections of the videofluoroscopy, should also be considered. The height of the pharyngeal flap or the lateral flaps is a key element. The tissue should be placed at the level of maximum movement.

In conclusion, we suggest varying the surgical approach to velopharyngeal insufficiency, using the pharyngeal flap or sphincter pharyngoplasty according to the relative contribution of the movements of the velum, lateral pharyngeal walls, posterior pharyngeal wall, and level of maximum displacement of the velopharyngeal sphincter. Surgeons who treat velopharyngeal insufficiency must critically assess their own outcomes to develop an appropriate treatment algorithm.

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