Primary Palatal Surgery in Nonsyndromic Cleft Palate Children and Velopharyngeal Insufficiency Correction Outcomes

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Abstract: Speech has a very significant impact on the life quality of people with cleft and lip palate. Restore tissue anatomy and functionality is the main aim of primary palatal surgery. Multiple factors are associated with successful handling, including the need for a velopharyngeal insufficiency (VPI) secondary surgery. The study's aim is to determine speech and velopharyngeal function outcomes in children with cleft palate operated in our institution and to determine VPI secondary surgery outcomes, if appropriate. Clinical records of nonsyndromic patients with cleft palate born between January 2009 and December 2012, who performed their multidisciplinary care on our institution, were analyzed retrospectively. One hundred forty-two patients received primary palatal surgery. Eighty (56%) were male and 62 (44%) female. Twenty-two had soft cleft palate, 9 hard and soft cleft palate, 84 unilateral, and 27 bilateral cleft lip and palate. Twelve percent of patients presented palatal fistula, with a significantly higher presentation in Soft Cleft Palate and Hard and Soft Cleft Palate. Twenty-seven patients (19%) had surgical indication for VPI correction, and 20 of them received VPI surgery, before school age. Cleft type and gender were significantly associated with VPI surgery indication rate. Postsurgery, 80% presented normal resonance. Nasal emission improved in 85% of patients. Nasometry decreased from 45% to 31%. Hyponasality increased by 10%. One case presented total flap dehiscence. Preoperative planning must be done carefully and individualized to succeed. Future prospective research that considers all the variables for a correct analysis is advisable, to improve our results.

Key Words: Cleft palate, palatoplasty, pharyngoplasty, velopharyngeal insufficiency

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Worldwide, cleft lip/palate (CLP) is one of the most frequent craniofacial anomalies.[1] In Chile, cleft lip and palate are the first and third most common congenital malformation, respectively.[2] Incidence is 1 in 620 live newborns.[3]

People with CLP can present difficulties in feeding, facial aesthetics, hearing, breathing, teething, occlusion, speech, and velopharyngeal function.[4] It can also present syndromic association. Therefore, an early and efficient interdisciplinary management is essential for optimal results.[5]

The main aim of CLP surgery is to restore tissue anatomy and functionality.[5] At soft palate level, it is essential to restore velopharyngeal sphincter function, formed by veil and pharyngeal walls. In normal speech, these structures have a coordinated functioning, allowing oral and nasal phonemes during speech production. To articulate high-pressure oral phonemes, a complete and firm velopharyngeal sphincter closure is necessary.[4]

Several palatal closure techniques have been described: Bardach, Von Langenbeck, Sommerlad, 2-stage delayed hard palate closure technique, V-Y repositioning technique or veau, intravelar veloplasty, and furlow.[9] There is still no consensus on which is the most effective primary surgical technique. A recent systematic review concluded that there would be an association between velopharyngeal function, speech, and surgical technique, arguing that Sommerlad and Furlow palatoplasties would be the most effective and those with the lowest prevalence of nasal emission, hypernasality, and velopharyngeal dysfunction. The surgeon's experience is considered a fundamental factor, even greater than the technique itself.[10] Although other technical factors are also mentioned, such as the learning curve, which involves training, surgical volume, and each surgeon's skills.

The evidence indicates that primary palate surgery age should be early, since the earlier an anatomical compensation is generated, greater is the possibility to developing adequate speech.[8] Some consider an early age 12 months,[7,8] others suggest 6 months.[6] There is no significant variation between 12 and 18 months, but when they are operated after 2 years, frequency of compensatory articulation (CA) rises dramatically as age progresses.[12] Although evidence from centers with experience shows that early primary palatal surgery has lower rates of velopharyngeal insufficiency (VPI) and CA, there are still surgical groups arguing that delaying hard palate closure prevents maxillary growth alteration,[7] which has no solid foundation.[8] In contrast, it is noted that effect on maxillofacial growth does not vary significantly when patients are surgically operated at 6, 12, or 18 months.[13] That is, growth is equally affected in all cases, so orthopedic and orthodontic treatment will also be required in most patients. Worldwide, the current protocol in most centers is to repair the secondary palate as soon as possible, favoring speech and language development.

From the perspective of people with CLP, speech has a very significant impact on life quality (along with facial aesthetics in lip repair cases), because it is associated with teasing, which can trigger depressive symptoms.[4] A life quality study points out that people

with CLP or cleft palate (CP) have a greater tendency to social exclusion, low self-esteem, and introversion feelings.[14] Presence of scars, orofacial aesthetic alterations, and speech disorders increase stigma and affect social functioning. Finally, it indicates that there is a relationship between most affected cases in perceptual speech evaluation and anger feelings, depression, and difficulties in peer relationships.

Surgical palate outcomes are crucial for children and family. From a medical perspective, residual fistula presence has been used to estimate early palatal repair results.[15] Literature reports a post-primary palatoplasty fistula prevalence from 2% to 45%, between 1978 and 2011.[16] A systematic review in 2014 concluded an 8.6% general incidence of reported fistulas.[15] There is a significantly higher crude incidence in America (mainly South America), compared to Asia and Europe. Postoperative oronasal fistula occurs due to an inadequate healing of the palatal wound after surgical repair. It can be related to patient factors, such as surgical age, cleft type, and its extent. Factors related to surgeon's experience also influence, such as tension in the repair area and complications, including bleeding or infection.[15] Large fistulas can cause nasal regurgitation, nasal air escape, and speech articulation difficulty. Any of the above situations may require surgical repair.

Post-surgery palatal functionality is determined by assessing VPI absence or presence. Velopharyngeal insufficiency is defined as the velopharyngeal inability to create an efficient seal during speech.[17] Cleft type, its severity, surgical technique, surgeon experience, and primary palatoplasty age have been described as associated factors.[18–22]

Characteristic aspects of VPI are: mild, moderate, or severe hypernasality, which can affect speech intelligibility, and consistent or inconsistent nasal emission during high-pressure oral phoneme production.[22] Velopharyngeal insufficiency can also be associated with CA, defined as a speech disorder in which oral sounds, usually high pressure, are frequently posteriorized towards the glottis or larynx. The existence of a linguistic component in CA has also been raised, which makes correction even more difficult.[23]

The management of VPI depends on etiology and severity, indicating speech therapy, secondary surgery, or both.[19]

Another parameter to define primary palate surgery success is the need for VPI secondary surgery. The percentage of patients who need secondary VPI surgery varies widely in studies, between 9% and 42%.[5,24] Velopharyngeal insufficiency surgical management indications include a series of stages: perceptual speech assessment, intraoral examination, nasometry, and direct velopharyngeal sphincter exams with nasopharyngoscopy evaluation and/or video fluoroscopic speech study.[4] In addition to considering several factors such as VPI severity, desire for correction (child and/or their parents), peer pressure, speech therapist recommendation, previous surgical interventions, association with other abnormalities, language diseases, or difficulties and airway obstruction.[10,25] Surgery can be performed at any age, although it is preferred before school stage, to prevent psychosocial impact of speech difficulties.[26,27]

Several secondary surgery types have been described: primary palatoplasty revision, augmentation pharyngoplasty or posterior pharyngeal wall augmentation, pharyngeal flap pharyngoplasty, sphincter pharyngoplasty, and buccinator flap.[5,28,29] Speech prostheses are also a nonsurgical option.[5] The surgical technique type and specifications are mainly based on the velopharyngeal closure pattern visualized on video fluoroscopy and/or nasopharyngoscopy.[10]

The best secondary surgical technique is controversial. Among success parameters to consider is speech improvement and morbidity.[30] In terms of speech results, a 2018 systematic review indicated that the pharyngeal flap had, among the 4 surgical techniques mentioned above, the best results in speech correction and resonance normalization, which is a main VPI sign. It also described benefits in eliminating nasal emission and improving intelligibility, above general average.[30]

Regarding complications, the same publication mentioned that a pharyngeal flap has the lowest rate of subsequent surgeries needed, a rate of hyponasality below general average, but a higher rate of obstructive sleep apnea (OSA). The risk of this type of technique is the possibility of the person permanently obstructing, which can occur when there is no detailed velopharyngeal closure pattern study before determining the flap size, shape, and positioning.[31] Therefore, an individualized VPI surgical management indication in each subject is essential.

Aim

Our aim is to determine speech and velopharyngeal function outcomes in children with CP, in the Gantz Foundation, in Santiago, Chile; and to determine VPI secondary surgery outcomes of sample members that required it.

METHODS

A database of all patients born between January 2009 and December 2012 with CP, who performed their primary palate surgery and multidisciplinary care at Gantz Foundation, in Santiago, Chile, was reviewed. The sample amounted to 423 subjects, excluding syndromic patients, with cognitive impairment, hearing loss, or without adherence to speech therapy or surgical controls.

After exclusion criteria, 142 patients remained. Surgical and speech therapy history of their clinical records was examined, collecting data related to primary palate and secondary VPI surgery, if performed.

This study was approved by our institutional ethics committee.

All children treated at Gantz Foundation follow a pre- and postsurgical protocol, both for surgeries and velopharyngeal function evaluation, described below:

Pre- and Postsurgical Medical Protocol

Outpatient palate closure surgery is performed in our institution. In cases of surgical complications, the stay extends until the patient is stabilized or they are hospitalized at a referral center. Patients are followed up being called by a nurse 24 hours after surgery. They attend medical controls at 2, 7, 14, 30-, and 60-days postsurgery. They are cited more frequently if required.

Secondary VPI surgery management is performed in a private health institution, in agreement with our institution. These are performed with the patient hospitalized for 1 day. Medical checks are performed at 2, 7 days, 1, 3, 6-, and 12-months postsurgery.

Surgical Techniques

One hundred forty-two patients received primary CP surgery performed by the Gantz Foundation surgery team, at that time composed by 7 surgeons, 3 seniors, and 4 in-training. The surgical team of each palatal intervention always included 1 senior and 1 in-training surgeon.

Surgical techniques used for primary palatal closure were performed according to the following scheme (Supplementary Digital Content, Table 1, http://links.lww.com/SCS/C426).

Velopharyngeal insufficiency correction in our institution, through the analyzed period, was performed by the following procedures: superiorly based pharyngeal flap, plicated flap, and modified orticochea sphincter pharyngoplasty. The procedure indication decision was made based on nasopharyngoscopy findings during speech.

Surgical Procedures are Described Below

Superiorly Based Pharyngeal Flap

A superiorly based muscle-mucous flap is carved from the pharynx posterior wall. The posterior velum edge is split, the end of flap without distal mucosa is installed there, suturing in 3 planes. Flap width is defined based on lateral pharyngeal walls function and base height in relation to velum maximum displacement.

Plicated Flap

Following the same superiorly based pharyngeal flap procedures, but without removing flap distal mucosa. Pedicle bends forward, plicated on itself. The bloody muscular surface is sutured together, determining a volume or increase in posterior pharyngeal wall, covered by a mucous plane. The plication is sutured in 2 planes.

Modified Orticochea Sphincter Pharyngoplasty

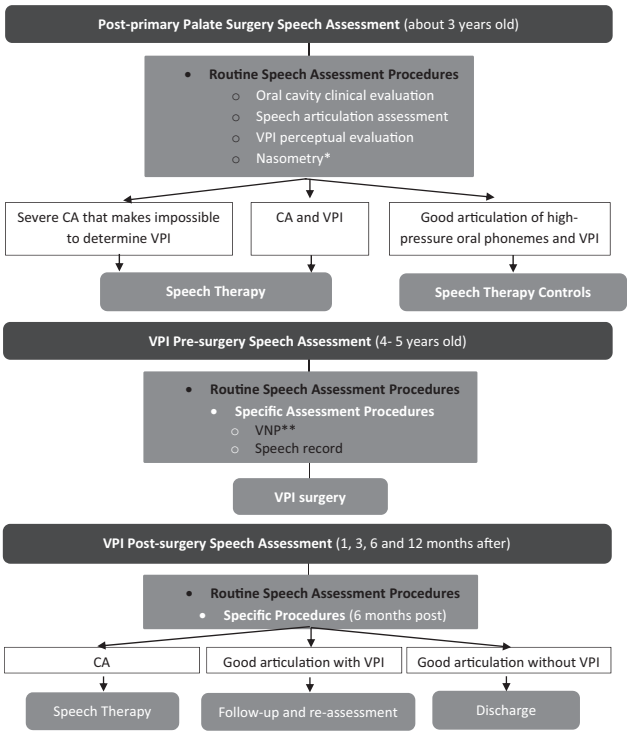
Superiorly based muscle-mucous flaps from both pharyngeal posterior pillars are carved, including a lateral wall segment if it is significantly atrophic. The posterior pharyngeal wall is split transversely at defined height in relation to velum maximum extension point. Distal end of both flaps and pharyngeal incision are sutured together in 2 planes.

Secondary VPI surgery was performed by a single senior surgeon with more than 35 years of experience in patients with cleft and lip palate, along with another surgeon from the Gantz Foundation staff.

Speech Assessment

All the evaluation procedures are described in the Figure 1.

The evaluation is applied by Speech & Language Pathology staff, with more than 15 years of experience in management of patients with CLP. Perceptual analysis is performed using international VPI evaluation parameters (Supplementary Digital Content, Table 2, http://links.lww.com/SCS/C427).[22]



VPI: Velopharyngeal Insufficiency. CA: Compensatoy articulation. VNP: Videonasopharyngoscopy.
*2 automatic repetitions of "1-10". Nasometer II: Model 6450 equipment: KayPENTAX, Montvale, NJ.
** Pediatric nasofibroscope Model FNL-7RP3, diameter 2.4mm; Pentax, Tokyo, Japan.

FIGURE 1. Postprimary palate surgery and VPI pre and postsurgery speech assessment procedures. VPI, velopharyngeal insufficiency.

Long-Term Complications

Data on long-term complications were obtained from surgical protocols of clinical records.

For primary palatal surgery, cases of palatal fistula were reported. Fistulas located between the incisive hole and soft palate end, including uvula (corresponding to secondary palate) were recorded. Alveolar or anterior fistulas were excluded.

In relation to secondary VPI surgery, pre- and postsurgical data associated with OSA were recorded through parent questionnaires that considered: salivation, restless sleep, fatigue in morning awakening, sleepiness, snoring, apnea, and difficulty removing secretions.

In case of finding severe signs of respiratory obstruction in the post-surgical period, the protocol includes polysomnography indication.

Complications are also considered: total flap dehiscence and need for a new corrective VPI surgery.

Statistical Analysis

Data was collected with Microsoft Excel and analyzed with the Statistical Package for Social Sciences, version 20. Comparisons between the groups were done with Pearson χ^2 test and Fisher exact test. Differences were considered significant when $P < 0.05$.

RESULTS

The characteristics of the 142 subjects in the sample are detailed in Supplementary Digital Content, Table 3, http://links.lww.com/SCS/C428.

Primary Palate Surgery

Surgical age according to diagnosis is shown in Supplementary Digital Content, Table 4, http://links.lww.com/SCS/C429 for the full sample and VPI surgical indication group.

Distribution of primary palate closure techniques, according to cleft type, are detailed in Supplementary Digital Content, Table 5, http://links.lww.com/SCS/C430.

The proportion of fistulas in the total sample and according to type of cleft, as well as their location and need for reoperation are detailed in Supplementary Digital Content, Table 6, http://links.lww.com/SCS/C431.

Cleft type was associated with fistula rate ($\chi^2 = 4{,}235$, $P = 0.040$, $df = 1$), considering 2 diagnostic groups, according to lip compromise: Soft Cleft Palate (SCP) and Hard and Soft Cleft Palate (HSCP) on 1 hand, and Unilateral Cleft Lip and Palate (UCLP) and Bilateral Cleft Lip and Palate on the other.

VPI Surgery

The percentage of patients with surgical indication for correction of VPI and its proportion by diagnostic group is shown in Supplemental Table 7, http://links.lww.com/SCS/C432. As well as the proportion of subjects with other types of management.

Cleft type was associated with VPI surgery indication rate ($\chi^2 = 12{,}461$, $P = 0.006$, $df = 3$). Twelve of them female (44%) and 15 males (56%). Gender was significantly associated with VPI surgery indication rate ($\chi^2 = 54{,}535$, $P = 0.000$, $df = 1$).

Fistula presence was also related to VPI surgery indication, not finding a statistically significant association ($\chi^2 = 1356$, $P = 0.244$, $df = 1$).

When analyzing senior surgeons responsible for the primary palate surgeries in these 27 patients, we can see a quite homogeneous distribution. Surgeon 1: 10 patients (37%); Surgeon 2: 10

patients (37%) and Surgeon 3: 7 patients (26%). Each surgeon had a very similar primarily operated children proportion, who had a VPI surgery indication.

Characterization of Patients Operated on VPI Surgery

At the time of this review, 20 of 27 patients with VPI surgical indication completed their surgery in our institution. The average surgical age of those who received VPI surgery was 5 years 7 months (5.7 years), with a range between 4.4 and 7.7 years. Velopharyngeal insufficiency surgical correction technique corresponded to a superior base pharyngeal flap in 19 of them and a plicated flap in the remaining case.

Regarding the pharyngeal flap width, 8 wide, 5 medium, and 6 narrow flaps were indicated.

Twelve patients presented CA pre VPI surgery and, therefore, required to continue with speech therapy afterward.

Regarding VPI resolution, following international perceptual parameters, evaluated results could be collected in pre and post VPI surgery evaluation. See Supplementary Digital Content, Table 8, http://links.lww.com/SCS/C433.

There was only 1 patient with OSA associated signs during the postoperative VPI surgery period, whose parents reported in the questionnaire had severe snoring and apnea episodes for the first week postsurgery. However, the apnea disappeared, leaving a slight and inconstant snoring. A second subject also reported snoring and presented a hyponasal voice resonance in post control.

One case presented total flap dehiscence, which required a reoperation to correct VPI.

DISCUSSION

Results audit is a fundamental procedure in work teams who treat subjects with CLP. Having good primary palatal surgery results is crucial to avoid difficulties in social integration, and personality and self-esteem problems in people with CLP. Management of variables that can negatively affect postoperative palatal functionality is a constant challenge. This article investigates which are most relevant.

Influential Factors of Primary Surgery Outcomes

Postoperative fistula is one of the most significant long-term CP repair complications. Nasal air escape impairs speech, and persistent oronasal regurgitation impacts dental, eustachian, and nasal hygiene.[11]

Many factors can influence fistula and VPI presence after primary palate surgery: cleft type, surgical technique, surgeon experience, and surgical age.[18,19,20,21] In a Canadian study of 2010, 458 consecutive cases primary palatal surgery outcomes were evaluated, single surgeon operated. It was concluded that gender, cleft type, length, and width are among significant VPI predictors.[32]

In 2018 a publication concluded, with 146 consecutive subjects, that fistulas were associated with increasing cleft severity, and also with technical factors.[11]

Cleft Type

Vomer importance and the extent of its fixation to palatal processes has been documented, as a differential anatomical finding between SCP and HSCP, as well as between UCLP and BCLP.[33] Marrinan et al[33] argue that in SCP and UCLP, the vomer is linked to both palatine processes, which would generate a longer palatal length. Although in HSCP and BCLP, the vomer is separated from nearby structures, which along with the shortening of processes would affect speech.[34] This would be reflected in the studies' results, where they found significant differences between groups.

The first publication studied 228 subjects and found there was a 10% flap rate for vomer junction CP types (SCP and UCLP) versus 23% rate for unattached vomer cleft type (HSCP and BCLP).[33] Bicknell analyzed cleft type in 114 patients. He found that 44% of those had HSCP and 50% had BCLP, while groups without vomer continuity required VPI secondary surgery. In contrast, only 12% with a SCP diagnosis and 21% with UCLP required it.[34] It should be noted that in the data described above, primary palatal repair surgical age must be added to the analysis.

When analyzing the 27 VPI surgical indication children by diagnosis, we found that the descending order group proportion was HSCP (56%), SCP (32%9, UCLP (14%), BCLP (11%). There was a significant difference between cleft type and VPI secondary surgery indication. The idea of vomer discontinuity does not seem to be a conclusive interpretation line in our study. Although the highest need group for VPI surgery had vomer discontinuity (HSCP group), the other group with this characteristic (BCLP group) had the least VPI surgical need.

When comparing our VPI surgical indication children diagnosis percentages with other publications which considered diagnostic groups like ours, we found that Lithovius et al[5] (2014) studied secondary palate surgery frequency after primary surgery in 138 patients. Their results reached 21% for HSCP group, 14% for SCP group, 26% for UCLP group, and 18% for BCLP group. No significant differences showed between cleft type and VPI secondary surgery need.

Ha et al,[35] in 2015, studied 292 people with nonsyndromic CP, separating them into 3 groups: HSCP (including SCP), UCLP, and BCLP. First group required secondary palatal surgery in 12.1%, second in 26.8%, and the third group in 27.7%. In these 3 previous publications comparable to ours, the percentage of VPI correction surgery indication was higher for CLP subjects versus those with SCP or HSCP. This differs from our findings.

Surgical Technique

The used surgical technique is closely linked to this discussion point. As already noted, in our research, the children group with HSCP obtained a significantly higher VPI surgery indication proportion, where mono or bipedicled flaps plus intravelar veloplasty were used. This also occurred in the CLP group, so it would not be a discussion point variability.

Publications report that technical details of the surgical procedure could be factors related to fistula appearance, such as the use of braided suture, tapered needles, and loupe magnification.[36] Also, a low fistula rate is explained by the use of large relaxing incisions, which would eliminate midline closure tension.[37] In this study we did not prospectively investigate the factors stated above.

Surgeon's Experience

All primary palate surgeries were performed by 1 of 3 senior surgeons. Case percentage of their primarily palate-operated patients, which required secondary VPI surgery, were quite similar: 37% surgeon 1, 37% surgeon 2, and 26% surgeon 3. But this data alone is inconclusive, as there are multiple variables to consider. It is complex to specify, for example, each surgeon in-training's participation, as a surgery assistant. A report has mentioned the "surgical learning curve" existence, related to speech outcome.[11] Previous training, surgical volume and skills vary among surgeons. This study in 2018 documented a gradual reduction in fistula rates, consistent with an individual learning curve. However, they also made surgical approach modifications, after having complications, identifying potential technical causes.

A systematic review in 2019 asserted that a CP repair is one of the most challenging procedures that a plastic surgeon can master, since it requires high skill and dexterity levels to manipulate delicate tissues, within a baby's small oral cavity.[38] The development of simulation models is indicated as a good alternative, so that surgeons acquire skills and reach competencies before performing the procedure on patients. Evidence that these training models generate better results is required.[38] In 2016, our Center began a preparation process for surgeons using simulation models, to benefit surgical results of their interventions. On the other hand, it seems very necessary to protocolize in detail surgical participation of surgeons in-training, specifying each procedure performed by them.

Surgical Age

Supplementary Digital Content, Table 2, http://links.lww.com/SCS/C427 shows that, by diagnosis, primary palatal closure average surgical age in VPI surgery indication subjects (n = 27), are not higher than the average of the group without indication (n = 88).

Gantz Foundation palatal surgery-related protocols are in accordance with the scientific evidence available, attempting an early palate primary closure. In this way, there is an age shortening in relation to our own previous studies. Cleft lip/palate patients surgical age is older, because they have a previous surgical time and receive NasoAlveolar Molding (NAM).

Gender

Gender influence as a VPI surgical management predictor is controversial. On 1 hand, Fisher et al[32] studied 485 cases obtaining that VPI surgical correction need is significantly higher in men. On the other, Lithovius et al[5] studied 138 cases, and also concluded that gender is a significant factor in determining secondary palatal surgery need. However, obtaining that girls with 27%, have a significantly higher tendency than boys (13%) to present VPI surgical management indication. Furthermore, Andersson et al[19] studied 351 cases, obtaining that sex is not significantly associated with the need for pharyngoplasty.

In the present study, with 142 cases, there was a significant difference by gender in relation to VPI surgery indication. Where, with 56%, most of subjects are male. Although this agrees with Fisher et al,[32] a variety of opposing results exist too,[5,19] maintaining debate.

Cleft Length and Width

In our institution cleft length and width measurements are not performed with a protocolized procedure. Therefore, for the purpose of this investigation, these aspects could not be considered. They have only been measured for specific prospective studies.

Fistula Presence

Investigations regarding incidence of palatal fistulas after primary palate closure show wide variability in results. This could be mainly related to fistula registration and nomenclature, not yet standardized.

In a 2014 systematic review, an 8.6% overall fistula incidence was reported, with 17.9% for CLP diagnosis, significantly higher than 5.4% of isolated CP.[15] Cleft subtype was the only significant influence on fistula presence, indirectly pointing towards cleft width. This, despite not making a specific analysis of the above. The conclusion of this review was that palatal fistulas were more likely in CLP cases, compared to isolated CP cases.

In our subjects' group, fistula percentage was 12%, higher than in the systematic review mentioned above. However, it is situated in the lower end of the 2% to 45% reference range, reported between 1978 and 2011.[16] Among South American studies referenced, there are 2 Brazilian publications. The first one from 2014, had a fistula prevalence of 27%, located mostly in the hard palate anterior region. Authors expressed concern about the results and difficulty in comparing values with those of other literature, due to the absence of standardized studies, related to sample size, and fistula definition, nomination, classification, and location.[16] The second publication, from 2011, showed 18% of fistulas in 459 patients. They concluded that these are more likely to occur in patients with wider clefts and without relaxing incisions.[37]

The CLP group in our sample (BCLP and UCLP) obtained a significantly lower rate of postprimary fistula surgery than the CP group (SCP and HSCP). 9% (7 of 31 cases) versus 22.5% (10 of 111 cases), respectively. This is consistent with Ha et al's[35] results, who argue that the CLP group may benefit from NAM use, unlike the CP group that generally does not receive presurgical orthopedics. NAM use could contribute to cleft narrowing, reducing post-surgery fistula rate. Similarly, in our institution, presurgical orthopedics' main use is NAM. However, concrete evidence is necessary to support this relationship.

From another angle, the significantly higher percentage of fistula cases came from SCP and HSCP groups, which are precisely the groups that presented a significantly higher VPI surgery indication. Accordingly, UCLP and BCLP groups had a lower fistula rate, and it also had the lowest population of VPI surgical resolution indication. Although fistula presence was not associated statistically with VPI surgery indication rate. Out of the 17 fistula presence cases, only 6 were reoperated. Considering that fistula location was mostly distal (velar and/or uvular), possibly the velar tissue conditions were not functionally suitable for velopharyngeal sphincter closure and that could be a VPI related factor. Moreover, 5 of 17 fistula cases (29.4%) subsequently had a VPI surgery indication. Only 1 of them had been reoperated from a fistula before pharyngeal flap.

VPI Surgery Outcomes

The majority of VPI corrective surgeries were performed before school age, around 5 years, between 4 years 4 months and 7 years 7 months. This follows our team purpose: improving speech early.

Regarding VPI surgery surgical results, data from a systematic review of 2018 showed that 78.8% of patients had an improvement in postoperative resonance, with a 70.7% achievement of normal resonance. Nasal emission improved in 72.2% of patients and was completely resolved in 65.3%. Specifically, for pharyngeal flap, there was a 76% normal resonance post VPI surgical correction.[30]

In the present study, positive resonance change after VPI surgery is remarkable, going from 0% of resonance within normal limits, to 80%, percentage higher than the reference. This is consistent with changes in nasalancia measurements, varied from 45% to 31%. Nasal emission of our sample improved in 85% of patients and was completely resolved in 50%, this being consistent only in 15% of cases and inconsistent in 35%. The latter result could be explained by presurgical CA presence. Out of 3 patients with consistent nasal emission, 2 had CA and, of 7 patients with inconsistent nasal emission, 3 had CA.

It should be considered there was a total pharyngeal flap dehiscence case, hypernasality and nasal emission persisted in moderate degree. Another case where nasal emission was not completely resolved, was in the only subject that received a plicated flap, remaining with inconsistent nasal emission. This VPI surgical technique is recently performed in our institution and is indicated individually, in those subjects whose hiatus require a posterior pharyngeal wall increment. A larger sample is needed to evaluate speech and VPI outcomes with this specific technique.

In terms of negative results, a systematic review of 2018 showed that 10.2% of patients had hyponasality postoperation, 4.1% developed OSA, and 8.7% required additional speech surgery.[30] Before surgery, our sample had hyponasal resonance characteristics (in combination with hypernasality, forming a mixed resonance), in 10% (2 cases).

In one of those cases, hyponasality was explained by chronic rhinitis, with recurrent rhinorrhea. In the other, due to septal deviation, which in our institution is not resolved until maxillofacial development ends. With the VPI surgery, both remained with their previous hyponasality. Then, hyponasality percentage increased by 10% (2 cases). One of them changed its resonance from moderate hypernasality to hyponasality, and the other from mild hypernasality to hyponasality.

In relation to OSA, the systematic review indicated found a postsurgical presence of 5.1% for pharyngeal flap surgery. In the present study, parents of 1 child reported signs of OSA in the questionnaire the week after surgery, with apnea and severe snoring. However, follow-up indicated that the apnea disappeared, leaving a slight and inconstant snoring. The above explanation could be related to the fact that the right flap portal was smaller than left one, as evidenced by control nasopharyngoscopy.

One case required subsequent reoperation, corresponding to 5% of the VPI surgery indication group. This subject had a total flap dehiscence, which may be due to a postsurgery cold, accompanied by a persistent cough. After recovery, he was indicated a second surgery, which was performed 16 months after the first. On this occasion, VPI absence was evidenced.

Investigations' results still show variability, making it difficult to specify which factors are more influential, specifically, in primary palatal surgery outcomes.

The main limitation of our study was the retrospective data collection. Additionally, some analyzed data had a qualitative nonhomogeneous record. Our center lacked a standard fistula nomination protocol that specified size, classification, location, impact on speech, and/or associated nasal regurgitation. Similarly, the exact cleft width and length, and variables related to the surgical technique and procedure, were not specified in all the clinical records.

CONCLUSIONS

From the perspective of velopharyngeal function restoration, our Center obtained similar results to recent international publications, both in the results of primary palatal surgery and in the need for secondary surgery. The rate of fistula after primary surgery was above the average of the most recently published systematic review, but well below of the Latin American context. Contrary to what was expected, fistulas were less frequent in CLP than in CP.

Cleft type and gender variables were associated with the indication rate for VPI surgery. The VPI surgical management was performed at an early age with good resolution of the resonance disorder and high improvement in nasal emission. Individualized studies in VPI management indication promote a successful surgical outcome.

In future studies, a prospective investigation would be desirable, allowing control of all variables for a more adequate and complete analysis. Likewise, extending the age of follow-ups to confirm findings stability.

In order to improve results and, consequently, the patient's life quality, Centers that care for children with CLP must continue working towards using unified evaluation parameters.

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We need calm seas.