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Two-stage surgery impact on the palatal repair in cleft lip and palate: a pilot study

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A B S T R A C T

Objective: This pilot study aims to assess the feasibility and effectiveness of a two-stage surgical strategy for CLP management, by being the first attempt to measure and obtain numerical data before and after palatal closure. This study is focused on the sequential approach of Delaire's primary Veloplasty, consisting in the closure of the soft palate (SP), followed by hard palate (HP). **Material and method:** This research constitutes a prospective pilot study analyzing patients with Non-Syndromic CLP who underwent surgeries between 2021 and 2022 at the Hospital Clínico San Borja Arriarán (HCSBA). Primary intervention, at six-months of age, involved Delaire palatoplasty aiming to repair the SP. Measurements were taken at specific landmarks (posterior nasal hemi-spines) and recorded. Second measurement was conducted during the HP closure to assess changes, one-year after.

Results: All measurements during both interventions demonstrated positive differences in all cases (mean difference between measurements: 7.02 mm). A statistically significant difference was shown before and after closure ($z = 2.366$, $p = 0.0180$).

Conclusion: Our study provides valuable insights into the effectiveness of the Delaire primary veloplasty technique within a two-stage surgical protocol for CLP management.

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Impacto de la cirugía en dos etapas en la reparación del paladar en pacientes con labio y paladar hendido: estudio piloto

R E S U M E N

Palabras clave:

Labio/paladar hendido, paladar duro, paladar blando, cirugía.

Objetivo: Este estudio piloto tiene como objetivo evaluar la viabilidad y efectividad de una estrategia quirúrgica en dos etapas para el manejo del labio y paladar hendido (CLP, por sus siglas en inglés), siendo el primer intento de medir y obtener datos numéricos antes y después del cierre del paladar. Este estudio se centra en el enfoque secuencial de la veloplastia primaria de Delaire, que consiste en el cierre del paladar blando (PB), seguido del cierre del paladar duro (PD).

Material y método: Esta investigación constituye un estudio piloto prospectivo que analiza a pacientes con CLP no sindrómico que se sometieron a cirugías entre 2021 y 2022 en el Hospital Clínico San Borja Arriarán (HCSBA). La intervención primaria, realizada a los seis meses de edad, consistió en una palatoplastia de Delaire con el objetivo de reparar el PB. Se tomaron mediciones en puntos anatómicos específicos (hemiespinas nasales posteriores) y se registraron. La segunda medición se llevó a cabo durante el cierre del PD, un año después, para evaluar los cambios.

Resultados: Todas las mediciones realizadas durante ambas intervenciones demostraron diferencias positivas en todos los casos (diferencia media entre mediciones: 7,02 mm). Se evidenció una diferencia estadísticamente significativa antes y después del cierre ($z = 2,366$, $p = 0,0180$).

Conclusión: Nuestro estudio aporta información valiosa sobre la efectividad de la técnica de veloplastia primaria de Delaire dentro de un protocolo quirúrgico en dos etapas para el manejo del CLP.

INTRODUCTION

Cleft lip and/or palate (CLP) is one of the most common congenital craniofacial anomalies, affecting thousands of newborns globally each year. This condition includes a spectrum of malformations, influencing the normal development of the upper lip and palate that often requires comprehensive surgical and multidisciplinary interventions to address associated functional and aesthetic challenges¹. Despite significant advances in understanding the etiology of CLP, several aspects regarding its precise pathogenesis, especially in the non-syndromic context, remain unclear². Such uncertainties primarily relate to the intricate interplay between genetic predisposition and environmental factors leading to the failure of embryonic tissue fusion during development³.

The existing scientific literature lacks a comprehensive exploration of the comparative effectiveness and patient outcomes related to different techniques for CLP closure, specifically the comparison between one-stage and two-stage approaches⁴. Current studies predominantly illustrate a divergence in both methodologies without establishing empirical and numerical evidence favoring either strategy. Although the purported advantages of a two-stage protocol over traditional one-stage methodologies have been suggested⁵, the validation of these assertions is notably lacking⁶, because there is no numerical data available to sustain this argument at the moment. Published studies indicate that using a two-stage protocol achieves a closure in the gap of the hard palate, but no data has been recorded of how much the gap is reduced during closure. Also, the two-stage protocol deprives itself from the use of vomerine flaps, which can cause a reduction of vertical facial

growth and development. This is mainly used when the closure is performed during a one-stage surgery⁷. There is a clear deficiency of long-term, multi-dimensional studies that investigate functional, aesthetic, and patient-reported outcomes between the two surgical methods. Addressing this scientific gap is essential to gaining a detailed understanding of the merits and potential drawbacks of each approach, thereby guiding the decision-making process for both surgeons and patients in selecting the optimal treatment modality.

This pilot study aims to assess the feasibility and effectiveness of a two-stage surgical strategy for CLP management, focused on the sequential approach of Delaire's primary veloplasty followed by a secondary hard palate closure. Also, this study aims to be the first approach ever recorded to measure the distance of the hard palate, before and after its closure, when using a two-stage protocol. The results will provide surgeons with quantitative data on the extent of gap reduction achieved through this surgical technique, serving as a reference for the expected decrease in the gap throughout the course of treatment.

MATERIALS AND METHODS

Study design

This research constitutes a prospective pilot study analyzing patients with Non-Syndromic CLP who underwent surgeries between 2021 and 2022 at the Hospital Clínico San Borja Arriarán (HCSBA). The study was conducted at the Maxillofacial Surgery Department of Hospital Clínico San Borja Arriarán, surgeries were performed between 2021 and 2023.

Inclusion/Exclusion criteria

Inclusion criteria comprised patients diagnosed with Non-Syndromic Unilateral or Bilateral CLP, receiving treatment at HCSBA. Patients' initial surgeries were performed in 2021 or 2022. Exclusion criteria involved patients whose legal guardians did not provide informed consent and those with syndromic associations with CLP.

Informed consent and ethics approval

Consent was obtained from the legal guardians of the patients before enrolling them in the study. Also this study was approved by the Ethics Board Committee of HCSBA (Number of approval: 51).

Surgical procedure

Primary veloplasty

First intervention is performed in an operating room (OR) under general anesthesia. A triangular incision is made at the medial face of the hemiuvula in order to expose the submucosal plane. This incision is extended posteriorly until exposure of the hemi-spine is accomplished. The hemi-spine is exposed and the dissection of the pharyngeal velum's musculature at the posterior edge of the palatal bone is complete. Measurements were taken using millimeter caliper between both hemi-spines (Figure 1). The measurement was repeated three times. Following, the muscular plane is sutured with Vicryl 3-0, uniting in the midline. Subsequently, the buccal mucosa is sutured with Vicryl 4-0. As needed, a Widmeier release incision is made on both sides in order to allow the closure of the buccal mucosa without tension.

Hard palate closure

This procedure is performed between 18-24 months of age. Incisions are made according to the previous design and the subsequent dissection of palatine, maxillary fibromucosa and the soft palate. The second measurement was done in the most posterior part of both hemi-spines (Figure 2). Closure by plane is performed, starting with the nasal plane, performing a continuous scalloped suture with Vicryl 4-0. Incisions at the limits of the palatine and maxillary fibromucosa are made in order to form bipedicle flaps which are released in order to allow a tension free closure.

Variable definitions

The variables examined included patient demographics (name, age, gender), cleft type, number and type of flaps performed, distance between the posterior nasal-spines at two different stages (veloplasty and hard palate closure), and surgery dates.

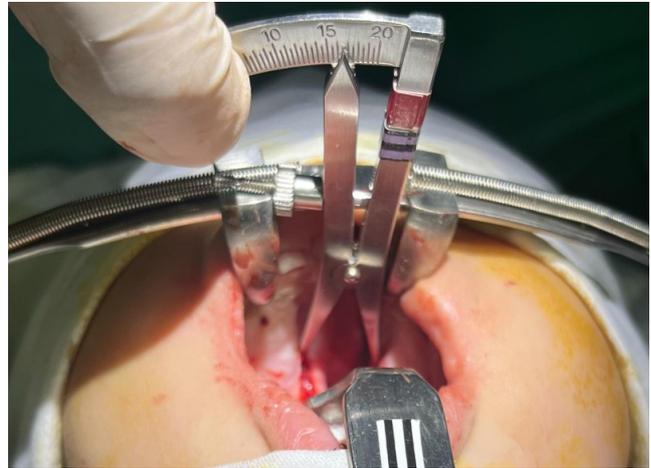


Figure 1. Photography of the first measurement of the distance between the posterior hemi-nasal spines, before performing Delaire's primary veloplasty. The measurement was taken using a millimeter caliper.

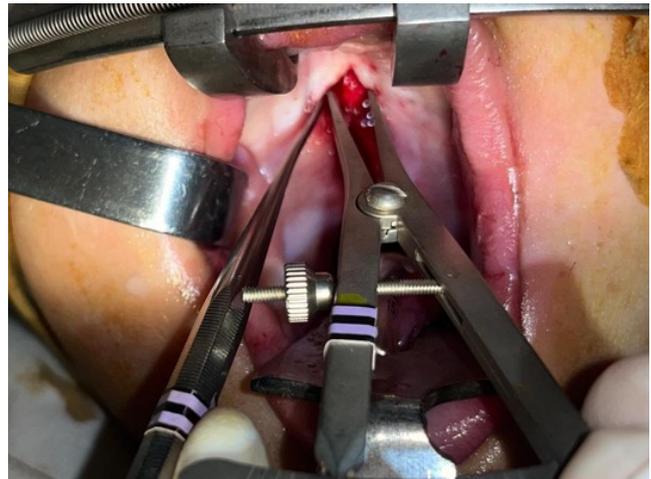


Figure 2. Photography of the second measurement of the distance between the margins of the hard palate 12 months after the primary veloplasty, before performing the hard palate closure. The millimeter caliper was placed in the most posterior section of the gap to measure.

Statistical analysis

Data was recorded in an Excel spreadsheet, allowing comparison between measurements to identify any significant differences. Wilcoxon signed-rank test was conducted because of the distribution of the data. STATA was used to conduct the statistical analysis.

RESULTS

During the study period, a total of seven patients met the inclusion and exclusion criteria and were included in the analysis. Patient characteristics are comprehensively described in Table I.

Table I. Data of each patient obtained at the time of primary veloplasty, first surgical intervention.

Patient characteristics	n.º (%)
Age in months (average/range)	7.5 / [7. 9]
Gender	
– Femenine	4 (57.14 %)
– Masculine	3 (42.85 %)
Type of Cleft	
– BCLP	2 (28.57 %)
– UCLP	2 (28.57 %)
– CP	3 (42.85 %)
Age at the time of primary Veloplasty (average)	7.5 months
Age at the time of hard palate closure (average)	20.5 months
Need of surgical releases during Veloplasty (yes or no/ Nº)	
– Patient 1	Yes / 2
– Patient 2	Yes / 2
– Patient 3	Yes / 2
– Patient 4	Yes / 2
– Patient 5	Yes / 2
– Patient 6	Yes / 2
– Patient 7	Yes / 2

BCLP: bilateral cleft lip and palate. UCLP: unilateral cleft lip and palate. CP: cleft palate (no compromise of the lip).

Upon completing hard palate closures for these seven patients, relevant data were meticulously recorded and organized. In the context of primary veloplasty, a notable 100 % of the patients required surgical releases to mitigate tension during palatal closure. The surgeries were performed between 7 and 9 months, with the prevailing diagnosis being complete CLP, either unilateral or bilateral, and three cases presenting isolated cleft palate without lip involvement. The average age for primary veloplasty was approximately 7.5 months.

For the subsequent hard palate closure surgery, patients underwent a second operation between 18 and 23 months. The average age for hard palate closure was 20.5 months. The average time elapsed between both surgeries was 13.0 months.

Remarkably, surgical releases were not deemed necessary for 100 % of the studied patients to achieve successful hard palate closure. Table II resumes all the measurements during the first and second intervention, demonstrating consistently positive differences in all cases, with no instances of negative differences (mean difference between measurements: 7.02 mm).

A Wilcoxon Signed Rank Test was conducted to assess whether there existed a statistically significant disparity in the distance of posterior hemi-nasal spines before and after the two-stage surgery. Seven patients were enrolled for the analysis. The test demonstrated a statistically significant difference in the distance of posterior hemi-nasal spines between the 165 two groups ($z = 2.366$, $p = 0.0180$).

These findings suggest that the two-stage surgery exerted a notable impact on the distance of posterior hemi-nasal spines.

DISCUSSION

The primary objective of this study was to assess the impact of the Delaire primary veloplasty technique on the distance between the bony edges of the hard palate and its subsequent influence during definitive hard palate closure. The results demonstrated a 100 % success rate in achieving bony palate approximation, indicating a positive correlation between the two-stage surgical protocol and a reduction in the distance between hard palate bone edges. Average values across the surgical stages revealed a consistent trend of decreasing palatal bone gaps, with an approximately 46 % reduction from veloplasty to hard palate closure. Gender analysis highlighted a male predominance among cleft palate patients, and the timing of surgeries deviated from standard recommendations. The absence of surgical releases during hard palate closure underscored the benefits of meticulous tissue preservation, contributing to high caregiver satisfaction in post-operative outcomes.

Comparison of our results with existing literature reinforces the effectiveness of the two-stage surgical protocol. The observed reduction in palatal bone gaps aligns with the goals of CLP management, supporting the notion that staged surgical approaches positively impact closure outcomes. The gender distribution and surgical timing variations observed in our study echo trends reported in prior research, adding further context to the broader understanding of CLP demographics.

Table II. Measurements in millimeters obtained before Veloplasty and hard palate closure in every patient.

Patient	Veloplasty measurement	Hard palate closure measurement	Difference between measurements
1	13.5 mm	10.0 mm	3.5 mm
2	20.1 mm	8.0 mm	12.1 mm
3	13.0 mm	7.0 mm	6.0 mm
4	16.0 mm	4.0 mm	12.0 mm
5	17.0 mm	8.0 mm	9.0 mm
6	14.5 mm	10.0 mm	4.5 mm
7	14.0 mm	12.0 mm	2.0 mm
Average measurement	15.44 mm	8.42 mm	7.02 mm

and intervention timelines⁸. The absence of surgical releases in the second stage aligns with the literature emphasizing the advantages of tissue preservation in promoting favorable growth and development⁹.

The implications of our findings underscore the clinical significance of adopting a two-stage surgical approach, specifically the Delaire primary veloplasty technique, for CLP management. Achieving bony palate closure without the need for surgical releases during hard palate closure has positive implications for both surgical outcomes and patient satisfaction¹⁰. The observed reduction in palatal bone gaps contributes to a more comprehensive understanding of the benefits of staged protocols in minimizing anatomical disparities. Moreover, this technique enables the reduction of the palatal gap without the need to use mucosal tissue from other anatomical regions, such as the vomer, which could potentially compromise the growth and development of the maxillary bone¹¹. These implications emphasize the importance of careful surgical planning and adherence to a two-stage timeline for optimal patient outcomes.

Despite the promising outcomes observed in this study, it is crucial to acknowledge its inherent limitations. The relatively small sample size employed may restrict the generalizability of our findings to a broader population. External factors, such as the occurrence of the HCSBA fire, posed interruptions to the study, impacting the availability of surgical facilities exerting an influence on both the timeline and outcomes of the investigation. Winter health campaigns advocate for avoiding public spaces particularly healthcare facilities unless strictly necessary, due to the high circulation of respiratory viruses. This circumstance led to a decreased frequency of patient participation. Furthermore, COVID-19 related protocols restricted the use of operating rooms and the availability of hospital beds for patients who were not in immediate life-threatening conditions. It is also noteworthy to consider that the absence of a blinded analysis in data examination represents an additional vulnerability in the study methodology. Recognizing these constraints is imperative for a comprehensive interpretation of the study's results within the defined scope of its limitations. Furthermore, the aforementioned considerations should be taken into account in future research. Increasing the sample size and enabling a direct comparison between two-stage and one-stage closure techniques would provide a more robust and accurate assessment of both surgical approaches in future studies.

In conclusion, our study provides valuable numerical data and insights into the effectiveness of the Delaire primary veloplasty technique within a two-stage surgical protocol for cleft palate management. The consistent reduction in palatal bone gaps of 7.02 mm in average and the absence of surgical releases of the adjacent mucosa or vomer flaps during hard palate closure highlight the positive outcomes associated with this approach. Measurements provided in this study will help surgeons to estimate how much the gap would be reduced when this technique is used. While acknowledging the limitations, our findings contribute to the growing body of literature supporting the benefits of staged surgical interventions for CLP.

Further research with larger sample sizes is recommended to enhance the robustness and generalizability of these findings, ultimately informing clinical practices, and optimizing patient care in the field of CLP surgery.

DECLARATION OF INTERESTS

None.

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