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ORIGINAL ARTICLE
Craniofacial/Pediatric

Cleft Lip and Palate Surgery during COVID-19 Pandemic

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Background: The COVID-19 pandemic has caused a negative impact in every sector of life, especially in the health sector. Patients with different medical conditions are suffering delays in their surgical treatments. Cleft lip and palate is a common congenital disease that requires early interdisciplinary attention, and there is uncertainty about the safety of performing its surgical treatment during the COVID-19 pandemic. The objective of this study was to evaluate the safety of a surgical cleft protocol for cleft lip and palate used during the COVID-19 pandemic at a high volume cleft center in Lima, Peru.

Methods: This is a comparative study between two groups of patients with nonsyndromic cleft lip and palate who were operated on before and during the COVID-19 pandemic. Data collection was done by evaluation of presurgical condition, and surgical and nonsurgical postoperative outcomes and complications.

Results: Significant differences were observed regarding both the age of the patients at the time of the primary surgeries, and surgical times between the two groups. Nonstatistical significant differences were observed between the two groups regarding the presurgical conditions, postoperative outcomes, and complications. Rate of COVID-19 infection was 1.25%.

Conclusions: The surgical protocol used for cleft lip and palate repair during the COVID-19 pandemic is a safe method based on the observed postoperative outcomes. However, the COVID-19 pandemic caused delays of the time of the primary cleft lip and palate repair, and its long-term impact should be well evaluated.
(Plast Reconstr Surg Glob Open 2021;9:e3692; doi: 10.1097/GOX.0000000000003692; Published online 29 June 2021.)

INTRODUCTION

The COVID-19 pandemic has negatively impacted every sector of life, especially healthcare. Patients with different medical conditions are suffering treatment delays, including suspension of elective surgeries. Cleft lip and palate is a common congenital disease that requires early interdisciplinary attention, but there is uncertainty regarding the safety of performing surgery during the COVID-19 pandemic and the functional impacts of delaying treatment. Surgery delays are associated with poorer prognosis, and the increased morbidity and mortality cannot be ignored.[1–3]

In response to the development of the COVID-19 pandemic, different organizations such as the American Cleft Palate Craniofacial Association recommend prioritizing patient and provider safety when considering cleft lip and palate repair.[4] Since the World Health Organization declared the pandemic on March 11, 2020,[5] Peru, and specifically the city of Lima, has had one of the highest rates of associated deaths.[6,7] As a result, surgical scheduling for cleft lip and palate surgeries in our center was delayed until the pandemic is controlled or the transmissibility and severity indicators decrease. The objective of this observational cohort study was to evaluate the safety of a surgical cleft protocol for cleft lip and palate used during the COVID-19 pandemic at a high-volume cleft center in Lima, Peru.

MATERIAL AND METHODS

This is an observational cohort study.

Subjects

Two groups of Peruvian infants from Lima, Peru with nonsyndromic cleft lip and palate underwent

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Received for publication March 12, 2021; accepted May 14, 2021.

DOI: 10.1097/GOX.0000000000003692

Disclosure: *The authors have no financial interest to declare in relation to the content of this article.*

primary repair before and during the COVID-19 pandemic. Ninety-two patients underwent the same procedure during 2019, and 80 patients were operated on by a single surgeon during the COVID-19 pandemic (from December 1, 2020 to January 15, 2021) in two different centers in Lima, Peru.

Both centers have pediatric intensive care unit facilities. Surgeries during the COVID-19 pandemic were performed under the lowest rates of transmissibility and severity indicators (R0, percentage of positive tests, and daily number of deaths) in the city of Lima according to the information provided by the Ministry of Health of Peru.[7,8] Intergroup comparisons were performed.

The inclusion criteria were nonsyndromic cleft lip and palate patients who had undergone complete presurgical screening (blood and urine tests, pediatric and cardiologic evaluation). Patients were excluded if they had syndromic cleft lip and palate, incomplete presurgical screening, or contraindication for surgery was found during pediatric and/or cardiologic evaluation.

COVID-19 Protocol for Cleft Lip and Palate Surgery (Fig. 1)

The protocol for elective surgery during the COVID-19 pandemic was developed considering surgical center and COVID-19 testing facilities; protective personal equipment (PPE) levels; and adequate monitoring for patients, parents, and providers. To overcome pandemic-associated challenges, we advocated the following strategy: minimize chances of exposure (N95 masks for patients and parents, adequate PPE for providers, social distancing, and proper hand hygiene techniques), adherence to the protocol, perioperative patient care, limiting number and movement of personnel within the operating room (OR), and COVID-19 testing and monitoring.

Health Provider PPE

- Full facepiece mask and gowns for surgeons.
- KN95 surgical masks, gowns, and face shields for anesthesiologists.
- KN95 surgical masks and gowns for nurses in the OR.

Patient and Health Provider Monitoring

Patients underwent real-time polymerase chain reaction (RT-PCR) testing 48 hours before surgery, and serologic (IgM) testing the day before. Parents underwent only the latter test. Postoperative serologic and/or RT-PCR testing was performed at one month (RT-PCR testing depending on symptoms). Health providers underwent weekly serologic tests with RT-PCR if they exhibited COVID-19 symptoms.

Patients were scheduled for primary repair in an interday program (Monday/Wednesday/Friday) in groups of four patients (two in the early morning and two before 2 pm). All operations were an inpatient surgery (one night) with postoperative telemedicine consultation. Any surgical postponements were rescheduled on Saturdays depending on the nature of the medical condition and after pediatric evaluation. Any patients with COVID-19 positive tests (RT-PCR (+) or IgM (+)) were rescheduled at least 15 days later and after a pediatric evaluation.

Preoperative Screening

1. Plastic surgery, pediatric, and cardiologic (electrocardiogram) evaluations.
2. Blood (hemoglobin, white blood cell and platelet counts, glucose, urea, creatinine, serology for hepatitis B and human immunodeficiency virus, and hemostasis tests) and urine tests.
3. COVID-19 viral and antibody testing with RT-PCR and serology, respectively. RT-PCR (48 hours before) and serologic test (the day before) for patients, and serologic test the day before the surgery for parents.
4. Vital signs registered by the nurse after surgical center admission.

Postoperative Screening

1. Oxygen saturation levels and vital signs in the Post Anesthesia Care Unit (PACU) during the first 3 hours after surgery recorded by the anesthesiologist and nurse.
2. Vital signs recorded by nurses during first 24 hours after surgery.
3. In-person clinical evaluation during the first 5 days after surgery and later depending on signs and symptoms.
4. Virtual plastic surgery consultation during the first week and in-person after 1 month (postoperative evolution was evaluated using photographs and videos).
5. COVID-19 tests: serologic testing for patients 2 weeks after surgery and RT-PCR depending on symptoms.
6. Parent survey after 1 month by telephone, reporting postoperative evolution.

The pre-pandemic group was evaluated in the same form without virtual consultations and COVID-19 testing. The surgical protocol is shown in Table 1 which was previously described elsewhere.[9,10] Postoperative medical indications were the same in both groups: amoxicillin or azithromycin, acetaminophen for lip and palate surgery pain, and bacitracin ointment for the lip.

Postoperative Measurements

Data collected included COVID-19 monitoring, physical examination, and laboratory test findings. The six surgical outcomes are listed below.

1. Surgical time: minutes spent in the OR from incision to closure;
2. Postoperative hemorrhage: significant postoperative bleeding from the wound site that required surgical revision in the OR;
3. Palatal fistula: communication between the nose and oral cavity in the hard or soft palate after primary palatoplasty (anterior nasoalveolar fistulas were excluded);
4. Wound infection: clinical evidence of infection (increased inflammatory response and wound exudates) confirmed by blood tests.
5. Wound dehiscence: opening of the wound closure after surgery may be related to a deficiency of the surgical technique and/or wound infection and may be partial or total.

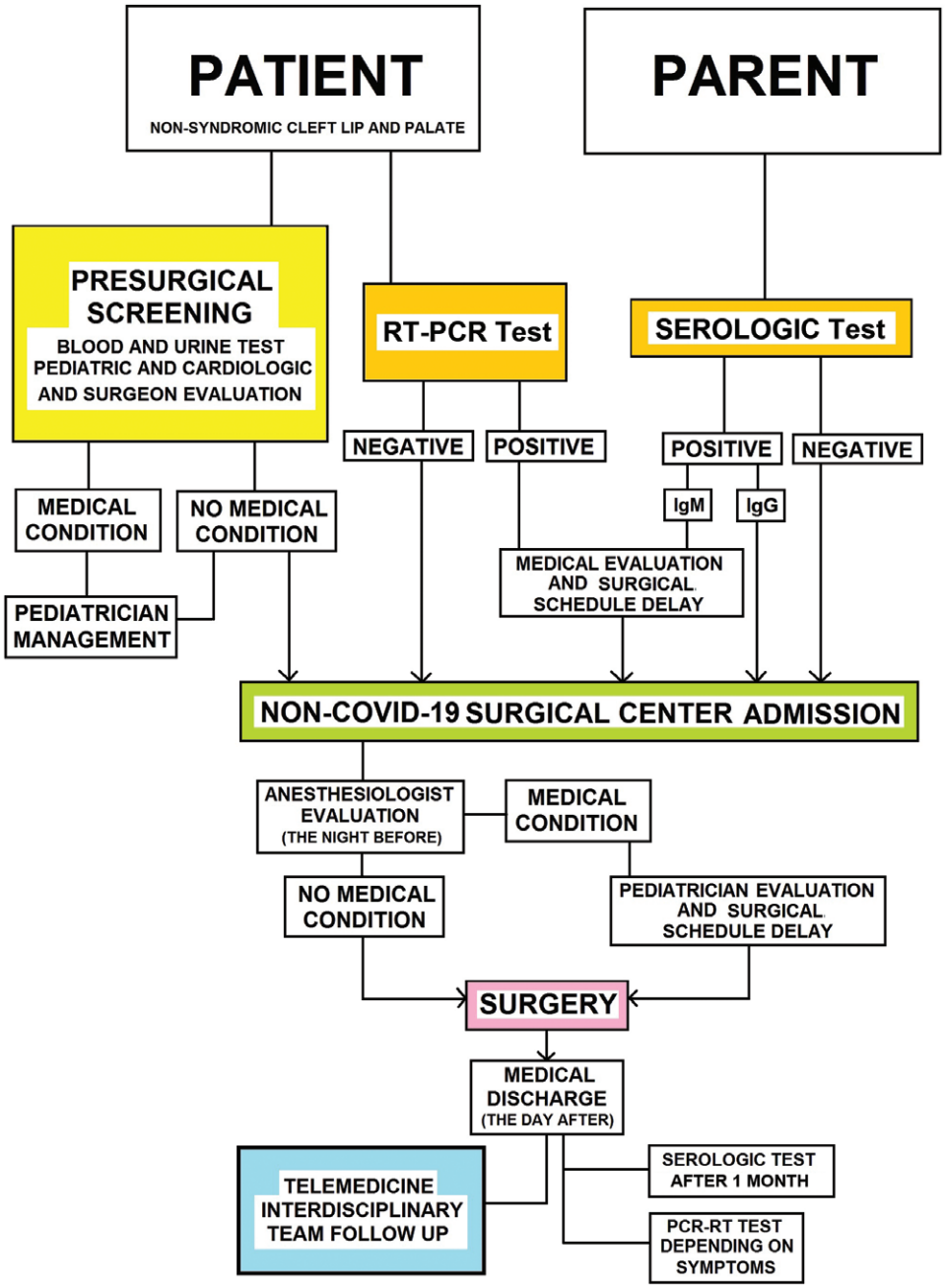

Fig. 1. Flowchart diagram of COVID-19 protocol for cleft lip and palate surgery.

Table 1. Protocol for Primary Cleft Lip and Palate Repair

Cleft Type	Surgical Technique
Cleft lip nose	
Unilateral cleft lip	Modification of Pool's technique + VYZ rhinoplasty (rotational composite flap rhinoplasty for the pandemic group)
Bilateral cleft lip	Straight lines closure + VYZ rhinoplasty (rotational composite flap rhinoplasty for the pandemic group) Bilateral lip adhesion for severe forms
Cleft palate*	
Incomplete cleft palate	Furlow or Von Langenbeck techniques
Unilateral cleft palate	One flap technique
Bilateral cleft palate	Von Langenbeck technique or delayed hard palate closure (severe forms)

*According to the Lima Protocol for primary cleft palate repair.[9]

6. Suture granulomas: benign tumor (consisting of granulation tissue) caused by the presence of surgical suture material.

Vital signs were recorded by nurses during the first 24 hours in the PACU, and signs and symptoms were reported by parents during the postoperative period. Recorded signs and symptoms included those associated with acute respiratory, digestive, and dermatologic diseases. Signs and symptoms associated with SARS Cov-2 virus infection were bronchitis or pneumonia, gastrointestinal symptoms (vomiting and/or diarrhea), and multisystem inflammatory syndrome in children. All infections were confirmed with positive COVID-19 tests.

Statistical Analysis

We used Chi-squared, Fisher exact, and nonpaired *t*-tests to identify significant differences between the 2 methods. An alpha error of 0.05 or less was considered statistically significant. The data were analyzed with Minitab 17.0 software (Minitab Inc., State College, Pa.).

Ethics

This study protocol adhered to the Declaration of Helsinki. Signed informed consent was obtained from all the parents, regarding potential complications associated with surgery during the COVID-19 pandemic and acceptance of postoperative follow-up through telemedicine.

RESULTS

A total of 172 patients with cleft lip and palate were operated on by a single surgeon before and during COVID-19 pandemic and followed for at least two months (pandemic group) (range: 2–4 months, mean: 3.3 months).

The gender and cleft type are presented in Table 2. Significant group differences were observed for age at the time of the primary surgery and surgical time. (Figs. 2, 3) (Tables 3, 4) Nonsignificant differences were observed between groups regarding the presurgical screening with exception of the hemoglobin levels (Table 5) (p: 0.0002). There were no differences in postoperative vital signs or surgical and nonsurgical postoperative complications between the two groups (Tables 6–8). No patient experienced postoperative hemorrhage, and none of the patients in the pandemic group had complications associated with COVID-19 infection.

Table 2. Characteristics of the Studied Groups

	Pre-pandemic (N = 92)	Pandemic (N = 80)	*P**
Gender			
Boys	52 (56.52%)	44 (55%)	0.841
Girls	40 (43.48%)	36 (45%)	
Type of cleft			
Unilateral cleft lip	25 (27.17%)	22 (27.5%)	
Bilateral cleft lip	16 (17.39%)	15 (18.75%)	
Incomplete cleft palate	11 (11.95%)	8 (10%)	0.995
Unilateral cleft palate	26 (28.26%)	23 (28.75%)	
Bilateral cleft palate	14 (15.21%)	12 (15%)	

*Chi-squared test; CI level: 95%.

Preoperative screening yielded positive COVID-19 tests in 2.5% (2/80) of patients. The first case was an symptomatic patient (fever) with negative preoperative RT-PCR, and the surgery was rescheduled. However, the serologic test taken during the pediatric evaluation was positive (IgM +). The surgery took place two weeks later, and the patient evolved without complications. The second case was a positive serologic test (IgG) that did not require postponement.

The two different scenarios of transmissibility in Lima, Peru (December 2020 and January 2021) did not affect the patient rate of infection. The overall rate of COVID-19 infection in the pandemic group was 1.25% (1/80). A 1-year-old patient who was operated on for cleft palate had fever and diarrhea during his sixth postoperative day. The pediatric evaluation revealed pharyngitis, and the RT-PCR test was positive. Both parents were also infected, but all three evolved without complications. It remains unclear where the patient was infected (perioperatively or later). No involved healthcare workers were infected with COVID-19 during the study period.

The presented protocol for cleft lip and palate surgery has an increased cost per surgery when compared with the regular surgery due to the COVID-19 tests (199.99 US dollars) and protective measures.

DISCUSSION

Following the first outbreak of the severe acute respiratory syndrome coronavirus 2 (SARS Cov-2) in December 2019, COVID-19 was declared a pandemic in March 2020.[5] COVID-19 outbreak was initially noted in Peru on March 6, 2020, and the rapid spread of infection had serious impacts on the healthcare system. Peru has a decentralized healthcare system administered by five different entities, resulting in multiple service providers and overlapped functions with minimal coordination. In addition, almost 50% of healthcare providers work in Lima, creating geographic inequalities.[11]

As a result, the country had the world's highest death rate from COVID-19 in August 2020, and close to 300 doctors and 150 nurses have died as a result of the pandemic in Peru.[7,8] Under this challenging scenario, different organizations around the world recommended postponing elective and nonessential surgeries to prioritize patient and provider safety.

By definition, an essential surgery is "an operative procedure that is considered to be vitally necessary for treating a disease or injury. Postponing or deciding against an essential procedure may result in a patient's death or permanent impairment." Therefore, the cleft lip and palate surgery may be considered as essential due to the permanent impairment associated with the treatment delay.

Surgical treatment delays can negatively impact patients with cleft palate. Repair at later age can lead to compensatory articulation patterns and hypernasality. To ensure patient and provider safety during a pandemic and still provide healthcare services, it is necessary to develop guides and protocols for safe cleft lip and palate surgery. To our knowledge, this is the first reported protocol for cleft lip and palate surgical patients during the COVID-19 pandemic.

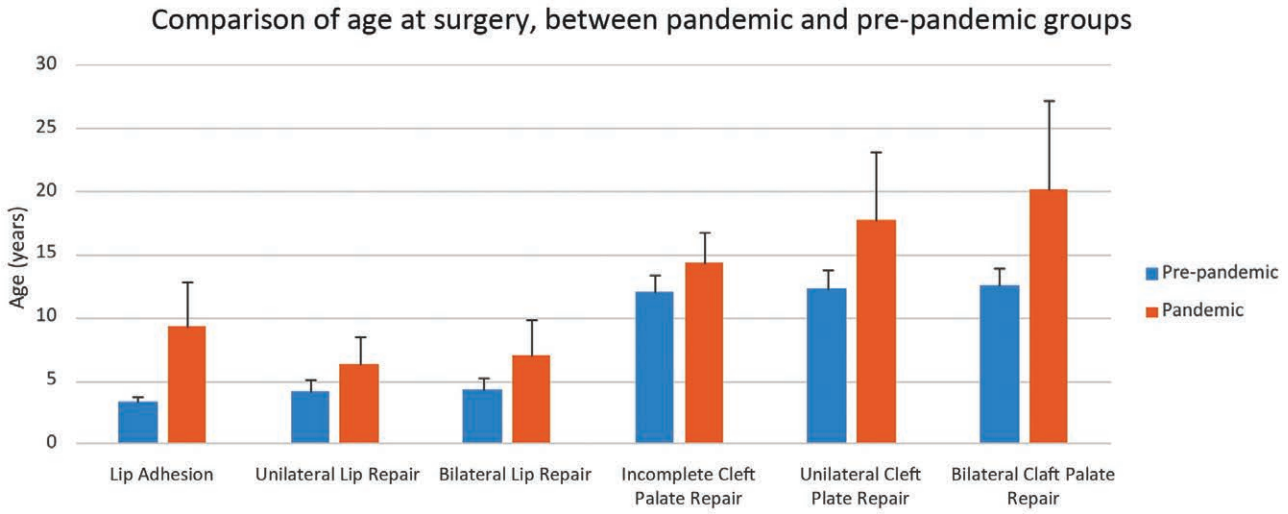

Fig. 2. Comparison of age at the time of surgery, between pandemic and pre-pandemic groups.

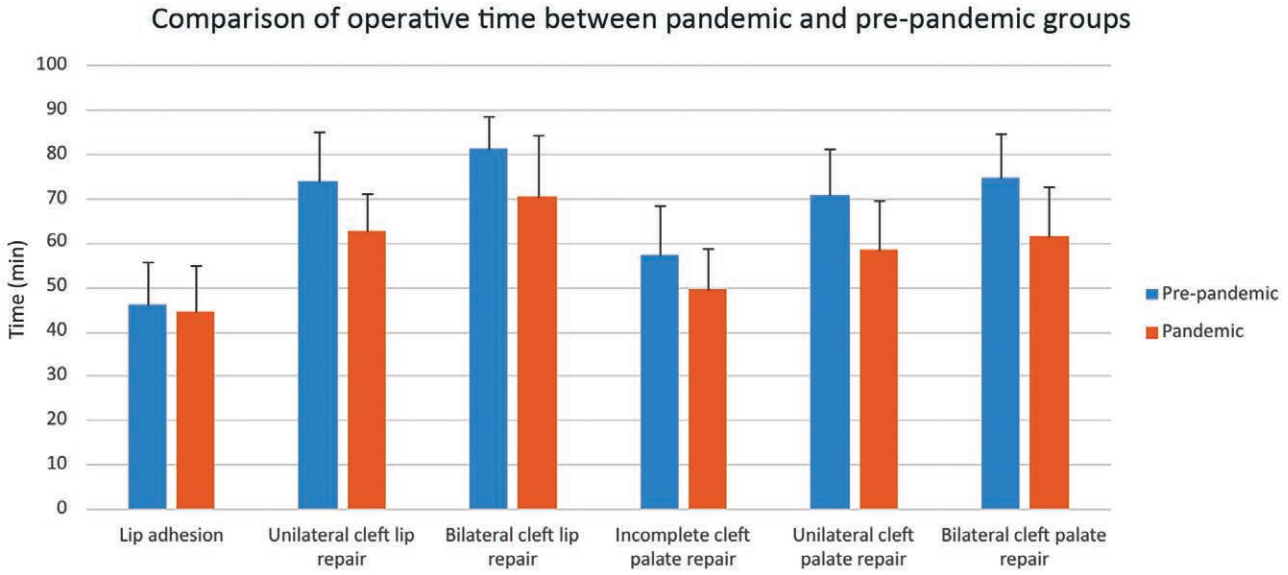

Fig. 3. Comparison of operative time, between pandemic and pre-pandemic groups.

We would like to highlight the following findings of our study. The gender, cleft type, and preoperative condition of the patients were similar in both groups, and these variables did not influence the observed outcomes (Table 2). One exception was the hemoglobin level, which may be explained because of the different mean ages of the two groups (older patients in the pandemic group). Two preoperative variables were statistically significantly different between groups: age at the time of the primary surgery and surgical time. A significant delay in cleft surgery occurred because of the limited ability of the Peruvian healthcare system to provide nonessential surgeries during the pandemic. All types of clefts were affected and ultimately received surgical treatment several months after the usual age (Fig. 2 and Table 3). Cleft lip repair is usually performed when the child is around 3 months old; however, there is limited scientific evidence about the impact of cleft lip surgery at an older age. The situation is different for cleft palate surgeries performed after 18–24 months of age because these patients may experience delayed speech development.[12] Under these considerations, cleft palate surgery during a pandemic should prioritize the oldest patients to prevent negative outcomes. The combination of cleft lip and palate surgery is not recommended during pandemics, considering the potential increased risk of complications and the limited access for emergency attention.

We observed a significant reduction of surgical times in comparison with the cleft surgeries practiced before

Table 3. Age at the Time of Surgery Comparison between Pandemic (N = 80) and Pre-pandemic Groups (N = 92)

	Age (mo)*		
Type of Surgery	Pre-pandemic	Pandemic	*P*†
Lip adhesion	3.25 (0.5)	9.25 (3.5)	0.01
Unilateral lip repair	4.12 (0.97)	6.27 (2.19)	0.0001
Bilateral lip repair	4.33 (0.89)	7 (2.86)	0.006
Incomplete cleft palate repair	12 (1.41)	14.25 (2.43)	0.01
Unilateral cleft palate repair	12.3 (1.43)	17.65 (5.47)	0.00001
Bilateral cleft palate repair	12.57 (1.28)	20.08 (7.14)	0.0007

*Values given are in mean (SD).
†Student's *T*-test; CI level 95%.

Table 4. Comparison of Operative Time between Pandemic (N = 80) and Pre-pandemic Groups (N = 92)

	Operative Time (min)*		
Type of Surgery	Pre-pandemic	Pandemic	*P*†
Lip adhesion	46 (9.69)	44.5 (10.47)	0.84
Unilateral cleft lip repair	74.04 (11.09)	62.68 (8.43)	0.0003
Bilateral cleft lip repair	81.42 (7.32)	70.36 (13.77)	0.002
Incomplete cleft palate repair	57.36 (11.26)	49.5 (9.17)	0.12
Unilateral cleft palate repair	70.73 (10.65)	58.57 (11.02)	0.0003
Bilateral cleft palate repair	74.64 (10.12)	61.67 (11.04)	0.005

*Values given are in mean (SD).
†Student's *T*-test; CI level 95%.

Table 5. Comparison of Preoperative Screening between Pandemic (N = 80) and Pre-pandemic Groups (N = 92)

Measurements (units)	Pre-pandemic*	Pandemic*	*P*†
Hemoglobin (g/dL)	11.37 (0.85)	11.89 (0.93)	0.0002
Leukocytes (10^9/L)	9.56 (2.28)	9.17 (2.3)	0.27
Platelets (10^9/L)	343.76 (63.88)	340.19 (64.67)	0.87
Clotting time (min)	6.97 (0.75)	6.85 (0.88)	0.89
Bleeding time (min)	2.01 (0.31)	1.98 (0.45)	0.54
Glucose (mg/dL)	86.80 (6.67)	88.26 (7.56)	0.67
Urea (mg/dL)	22.40 (4.29)	22.31 (5.30)	0.90
Creatinine (mg/dL)	0.54 (2.79)	0.26 (0.05)	0.36

*Values given are in mean (SD).
† Student's *T*-test; CI level 95%.

the COVID-19 pandemic (Fig. 3 and Table 4). There is no evidence supporting an association between surgical time and infection risk, but the World Health Organization considered that the time of exposure increases the risk of infection in other situations.[13] These recommendations are based on published studies and support the hypothesis about the time of permanence in operative room and the risk of infection.[14,15]

Based on this concept, the time of the surgical procedure would be an important consideration in cleft lip and palate surgery during the pandemic. The low rate of postoperative COVID-19 infection with this protocol supports this hypothesis; however, further studies are required to confirm the association between the operative time and risk of COVID-19 infection.

The reduction in surgical time was a result of some changes in our surgical protocol, such as the use of simpler primary rhinoplasty during cleft lip repair and reducing the extension of relaxing incisions during primary palatoplasty (based on the Lima Protocol for cleft palate repair)[9] (Table 1).

Table 6. Comparison of Postoperative Vital Signs between Pandemic (N = 80) and Pre-pandemic Group (N = 92)

Measurements	Pre-pandemic*	Pandemic*	*P*§
Oxygen saturation PACU† (%)	98.17 (0.76)	98.03 (0.81)	0.22
Temperature PACU† (Celsius)	36.56 (0.35)	36.35 (0.34)	0.96
Pulse rate PACU†	118.9 (7.56)	118 (10.36)	0.51
Respiration rate PACU†	24.57 (2.62)	24.78 (2.99)	0.64
Temperature‡ (Celsius)	37.26 (0.60)	37.09 (0.59)	0.05
Pulse rate‡	124.46 (6.32)	123.03 (8.89)	0.22
Respiration rate‡	25.62 (2.24)	25.68 (2.26)	0.87

*Values given are in mean (SD).
† Last measurements in PACU.
‡ Vital signs during first 24 horas after PACU and registered by nurses.
§ Student's *T*-test; CI Confident level 95%.

Table 7. Comparison of Surgical Complications between Pandemic (N = 80) and Pre-pandemic Group (N = 92)

Measurements	Pre-pandemic	Pandemic	*P**
Lip	N = 41	N = 37	
Infection	1 (2.43%)	2 (5.40%)	0.74
Granuloma	5 (12.19%)	3 (8.10%)	0.53
Dehiscence (partial)	2 (4.87%)	2 (5.40%)	0.56
Palate	N = 51	N = 43	
Infection	1 (1.96%)	0	
Dehiscence (partial)	2 (3.92%)	1 (2.32%)	0.72
Fistula	2 (3.92%)	2 (4.65%)	0.56

* Fisher's exact test; CI level 95%.

Table 8. Comparison of Nonsurgical Complications between Pandemic (N = 80) and Pre-pandemic Groups (N = 92)

Measurements	Pre-pandemic	Pandemic	*P**
Lip nose surgery	N = 41	N = 37	
Fever during first 72 h	10 (27.02%)	11 (29.72%)	0.51
Fever after 72 h	5 (12.19%)	1 (2.70%)	0.44
Diarrhea	7 (17.07%)	4 (10.81%)	0.36
Cough	9 (21.95%)	6 (16.21%)	0.64
Palate surgery	N = 51	N = 43	
Fever during first 72 h	33 (64.70%)	25 (58.13%)	0.37
Fever after 72 h	7 (13.72%)	6 (13.95%)	0.61
Diarrhea	10 (19.60%)	6 (13.95%)	0.62
Otitis	4 (7.84%)	2 (4.65%)	0.55
Cough	17 (33.33%)	12 (27.90%)	0.35

* Fisher's exact test; CI level 95%.

The rate of postoperative COVID-19 infection in the studied group was low (1.25 %) in comparison with the rate of infection of the population in the city of Lima during December 2020 and January 2021 (7% and 15%, respectively). This may be an indicator of success of the presented protocol; however, more studies are necessary to evaluate its impact under a different model (eg, in public hospitals). Each center should carefully evaluate its individual situation before scheduling a cleft surgery during the pandemic.

The similar rates of other postoperative outcomes (vital signs, postoperative hemorrhage, palatal fistula, wound infection, granuloma, and/or dehiscence) also support the efficacy of the presented protocol during the COVID-19 pandemic (Tables 6, 7).

Fever during the first 72 hours is a common complication after cleft surgery and has been reported by different authors.[16,17] A high rate of fever during this period (50%–70% after palatoplasty) was observed in both groups of

patients without a significant difference. This rate is also similar to previous reports.[16,17] Most cases were transitory and benign.

Postoperative fever after 72 hours was observed less frequently and only associated with COVID-19 infection in one case. No differences were observed between the studied groups regarding the development of postoperative fever, diarrhea, otitis, and respiratory disease (Table 8).

Different scenarios have been observed regarding the rate of COVID-19 infection in Lima; during the first half of December, the rate of infection was 5%–6% compared with 9% during the second half. In early January 2021, the rate increased to 14%. Despite this dramatic increase, there were no differences in the rates of postoperative COVID-19 infection over this time period. This suggests that the protocol is useful for cleft lip and palate surgeries during increased infection rates in the city, but additional studies are needed.

No other studies have evaluated surgical care of patients with cleft lip and palate during the COVID-19 pandemic, so our results cannot be compared. Increased COVID-19 infection rates and associated morbidity and mortality have been reported by other authors in noncleft elective and surgical emergencies.[3,18,19] The low morbidity rate and no deaths observed in our study and other differences may be explained by patient condition, type of surgery, model of surgical care, and the transmissibility rate of COVID-19. The role of vaccination was not considered in this study because the first vaccines arrived in Peru on February 7, 2021.

We would like to emphasize the role of telemedicine during the pandemic. A higher risk activity for COVID-19 infection is in-person medical attention, as it is usually performed in a confined space, where the virus concentration increases. Further investigations could help define the most useful aspects of telemedicine-based clinician–patient relationships in delivering cleft care.

Postoperative follow-up and interdisciplinary protocols were successfully developed during the study, which likely contributed to the lower rate of postoperative complications. The observational, retrospective nature of this study and biases due to confounding variables are the main limitations of this research. As final recommendations, we would like to highlight the key points of the presented protocol:

1. Start working only under a lower local rate of transmissibility;
2. Mandatory PPE for patients, parents, and healthcare providers;
3. Reduce number of surgeries per day and interday (or daily by different teams);
4. Decrease surgical time;
5. Prioritize cleft palate surgeries for patients older than 18 months;
6. Pre- and postoperative COVID-19 testing of patient/parents and healthcare providers;
7. Use telemedicine for patient follow-up and interdisciplinary care;
8. Consider COVID-19 vaccination of parents and health providers depending on availability.

CONCLUSIONS

Our surgical protocol for cleft lip and palate repair during the COVID-19 pandemic is a safe method based on the observed postoperative outcomes. The rates of infection among patients who underwent operation and surgical providers were low. There were no complications associated with COVID-19 infection in the studied group. However, the pandemic delayed surgical repair of primary cleft lip and palate during this time, and the long-term impacts of this delay should be evaluated in future studies.

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