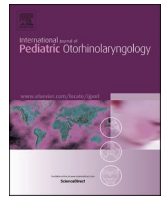




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## Protocol for outpatient management in cleft lip and palate repair

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## A B S T R A C T

Cleft lip is a common malformation in Chile. The standard care for cleft lip and palate repair is inpatient admission; this is mainly to observe complications and administer intravenous fluids, antibiotics, and analgesics. In our center, however, a strict selection of patients undergo ambulatory surgeries. In this paper, we illustrate our experience managing outpatient cleft lip and palate repair and show that it is possible to carry out a successful ambulatory surgery with few to no complications in children and adults with cleft lip and palate.

## 1. Introduction

Cleft lip is present in 1 in 714 live births (1.4 in 1000), making it the third most common malformation in Chile after Down syndrome and polydactyl [1]. Cleft palate is present in 1 in 1428 live births (0.7 in 1000) [1]. The standard care for lip and cleft palate repair is inpatient admission; this is mainly to observe complications and administer intravenous fluids, antibiotics, and analgesics. There has recently been a shift toward short hospital stays; in developed countries, outpatient management has become increasingly popular [2,3].

Complications that arise from lip and cleft palate surgery can be categorized as either minor or major. The latter include airway obstruction, pneumonia, and bleeding to such an extent that the patient requires a transfusion. These complications normally manifest by the second post-operative day. Patients who suffer these major complications need immediate medical attention [4]. Minor complications include dehiscence, stitch abscess, and local infection, none of which typically require hospital admission.

Despite several studies showing no difference in complications between inpatient and outpatient surgery [5], the general trend is to admit patients after surgery. Here, we present our experience with and protocol for the management of outpatient lip and cleft palate repair in an ambulatory surgical center in Chile (Fundación Gantz).

## 2. Methods

We retrospectively reviewed all patients charts who received surgery at Fundación Gantz under the outpatient cleft lip and palate repair (CLPR) protocol. A total of 4015 surgeries were done at Fundación Gantz

between 2006 and 2018. This protocol consists of the ambulatory management of patients with lip and/or cleft palate, including: lip surgery, palatal surgery (velopalatal closure and isolated velar closure), lip revision, alveolar bone graft, fistula closure, and definitive rhinoplasty.

8 plastic pediatric surgeons work at Fundación Gantz, which use the same surgical principles with slight modifications, following the same protocol and no difference in complications related to surgeon are observed. For unilateral lip surgery the techniques used derive from rotation-advancement techniques; such as modified Millard technique and Mohler. For bilateral repair each surgeon may have small variants but they all use the principles of Trott, Cutting and Mulliken. For cleft palate repair it will depend of the type of cleft; for isolated velar closure, Furlow and Kriens (intravelar veloplasty) are the techniques of choice. For velopalatal closure, Von Langenbeck (bipediculated flap), Killner (push back) or hybrid technique such as Clarke (one monopediculated flap and one bipediculated flap) are used.

Lip revision is very heterogenous and will depend on the secondary lip defect of each patient, but the main techniques used are: V-Y flap, rhomboid and Z-plasty with incisions in the nasal margin and alar cartilages. Alveolar bone graft surgery is done at 10 years of age, before eruption of the canines and autogenous graft from iliac crest is used. Finally, for definitive rhinoplasty, open technique is used, with correction of the septum, asymmetry, turbines and elevation of the nasal tip, achieving morphological and functional correction.

Our protocol's inclusion criteria for patients to be treated at Fundación Gantz are:

- Healthy patient (ASA I).

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- ASA II patient, with prior specialist authorization.
- Telephone access.
- Access to a close emergency department (Agreement with Clínica Alemana Santiago).
- Access to proper transport.
- Availability of diligent guardians.

The exclusion criteria are

- Airway problems.
- Carrier of severe malformation or syndromic patient.
- High surgical risk.
- Inadequate guardian availability.
- Low weight.

After confirming in an initial visit that patients fulfill all inclusion criteria, they are admitted the day of their scheduled surgery. Anesthesiologists do an evaluation prior to pre-operative airway care. Special care is taken to minimize opiate doses to avoid respiratory depression and vomiting. Multimodal anesthesia is provided followed by general anesthesia and a bilateral infra-orbital nerve block to minimize post-operation pain.

During the immediate post-operative period, nurses are responsible for restarting feeding, managing pain, and educating guardians on how to assist the patients. Feeding is started 1 h after surgery with oral liquids in every patient, in infants special baby bottles with squeezable pacifiers are used to help suction. After discharge, a nurse will control the patient the day after surgery; the guardians have 24 h of access to phone calls to a health care professional for any necessary queries. Additionally, patients from other cities are given a place to stay near the center in order to be nearby for the post-op visits.

Surgeon follow-up is done a week, and then a month, after surgery. Further follow-ups are done according to the necessity of specific cases (often 3–6 months). References to other specialists and healthcare professionals are also made on a case-by-case basis.

We conducted a record search in PubMed using the terms “outpatient AND cleft” and “ambulatory AND cleft” in November 2019, to review international management protocols, including post-operative complications, and compare them with ours.

### 3. Results

Of 4015 surgeries that were done at Fundación Gantz, 3559 (88.6%) were outpatients. The most common surgery was lip closure (total of 843, 648 unilateral and 195 bilateral) followed by lip revision (775 surgeries), 675 velopalatine closure, 241 isolated velar closure, 166 fistula closure, 284 alveolar bone graft and 575 definitive rhinoplasty. The total rate of complications was 3.4%. Complications were largely minor: local infection, dehiscence, bleeding, necrosis, flap detachment, residual fistula and nasal septum perforation. Lip revision surgery had no complications and definitive rhinoplasty was the surgery with the least complications (1.4%), 3 bleeding, 3 infection and 2 dehiscence. Lip closure had 2.1% of complications, alveolar bone graft 4.2%, isolated velar closure 7%, velopatine closure 7.5% and fistula closure 10% with residual fistula being the most common. (surgery specifications and complications shown in Table 1). Only four sentinel events required urgent medical assistance: two patients suffered airway complications after palate surgery; one suffered bleeding after palate surgery and needed a transfusion; and one suffered cardiorespiratory arrest after extubation (diagnosed afterwards with an unsuspected 4p chromosomal disorder). For these rare instances, our center has an agreement with emergency departments; these four patients all had adequate access to the necessary care in a tertiary center.

A review of PubMed was made using the terms “outpatient AND cleft” and “ambulatory AND cleft” in November 2019. A total of 248 articles were found; six were deemed to be relevant to our topic.

**Table 1**  
Surgeries done at Fundación Gantz from 2006 to 2018 and its complications.

Surgery	TOTAL NUMBER OF SURGERIES											TOTAL						
	2006	2007	2008	2009	2010	2011	2012	2013	2014	2015	2016		2017	2018				
Lip Closure	18	Unilateral	Dehiscence	7	2.1	37	43	43	62	41	60	61	60	55	52	49	48	648
			Infection	5														
Velopalatine closure	51	Bilateral	Dehiscence	3		10	13	11	6	23	15	16	16	16	20	18	13	675
			Infection	3														
Isolated velar closure	17	Dehiscence	Dehiscence	22	7.5	35	39	41	52	45	56	60	70	62	59	66	57	241
			Fistula	27														
Fistula closure	17	Infection	Flap detachment	1		17	21	20	12	24	23	20	22	33	12	9	7	166
			Fistula	6	7													
Alveolar bone graft	12	Dehiscence	Dehiscence	11	10	19	24	15	5	12	10	6	10	15	8	12	19	284
			Infection	2														
Definitive rhinoplasty	8	Necrosis	Residual fistula	2		105	56	9	30	37	47	24	42	78	54	69	42	775
			Flap detachment	2														
Lip revision	12	No complications	No complications	0	0	115	14	24	27	12	28	18	32	27	21	25	36	3559
			Infection	6	4.2	11	9	14	24	27	12	28	18	32	27	21	25	36
Definitive rhinoplasty	8	Dehiscence	Bleeding	1		30	44	44	47	27	33	26	49	77	70	66	42	575
			Bleeding	3	1.4	20	44	44	47	47	27	33	26	49	77	70	66	42
Definitive rhinoplasty	8	Infection	Infection	3		252	254	247	241	221	272	231	301	363	296	314	291	3559
			Dehiscence	2														
Definitive rhinoplasty	8	Dehiscence	Total complications	120	3.4	276	254	247	241	221	272	231	301	363	296	314	291	3559
			Total complications	120	3.4	276	254	247	241	221	272	231	301	363	296	314	291	3559

The first article found was on outpatient management in Boston in 1994 [6]. Its aim was to analyze the reduction of hospital stay length (by days). They conclude that reducing hospital stay length does not affect morbidity. They note the following benefits of hospital stay: post-op administration of intravenous fluids, analgesics and antibiotics; time for parents to adjust and be educated on care requirements; and observation of potential complications.

Fahradyan et al. [5] retrospectively compare cleft lip repair between outpatients and inpatients over seven years. They conclude that there is no significant difference in re-admissions or emergency department visits and recommend hospitalization for patients with comorbidities or airway malformations.

Al-Thunyan et al. [7] also retrospectively compared outpatients and inpatients who underwent primary cleft lip repair. They found no differences in re-admissions, complications, or emergency department visits. However, they did find a difference in reasons for re-admission; ambulatory patients were often re-admitted for respiratory complications while hospitalized patients were typically re-admitted for delayed wound dehiscence. They suggest hospital admission for patients with pre-existing cardiac problems or those who experience any respiratory problems in the immediate post-operative period.

In contrast to the studies reviewed so far, Kantar et al. [8] concluded that outpatient primary cleft palate surgery has a significantly higher rate of wound complications and a lower rate of re-operation and re-admission.

Paine et al. [9] analyze the risk factors for ambulatory cleft lip repair and concluded that 49.5% of children may be safely eligible for ambulatory surgery. They review the charts of all patients who underwent cleft lip repair and analyze desaturations, poor oral intake, and failure to stop intravenous narcotics over the first 24 h after surgery. They conclude that patients who evolved with any of these were poor candidates for outpatient surgery.

In line with Paine et al., Chang et al. [10], aimed to predict the ideal patient for ambulatory cleft lip repair. They found that approximately 40% of patients would benefit from an ambulatory cleft lip repair. The inclusion criteria for outpatient management would be as follows: younger than one year old; no respiratory or neurologic diagnosis; and non-syndromic.

#### 4. Discussion

The international literature shows results that differ from ours. The main difference is the percentage of outpatient surgery; the literature generally argues that only 40–49% [9,10] of patients are candidates for outpatient surgery—at our center, 88.6% undergo ambulatory treatment. Regarding outpatient complications, Al-Thunyan et al. [7] report a 12.1% rate while Paine et al. [9] claim a 26.1% rate—our center sees a 3.4% complication rate.

We experienced just four sentinel events across 3559 outpatient surgeries (0.11%). These complications received the necessary medical attention swiftly due to our agreement with emergency departments and references to specialists. These incidents could have not been prevented by prior hospitalization. The other minor complications resulted from the surgery, meaning they probably could not have been prevented by

hospitalization either.

For palate (complete velopalatine) outpatient closure, out of 675 ambulatory surgeries over 13 years, we have a 7.5% complication rate. Ours is considerably lower than the rate from Al-Thunyan et al. [7], 51% for inpatients and 48% for outpatients. Our rate is closer to that from Kantar et al. [8], 8% for outpatients and 10% for inpatients, which show that there is no significant difference in complication rate between inpatients and outpatients.

It is interesting to note that, in our experience, palate closure does not have a significant higher incidence of complications than velar closure alone (7.5% compared to 7%).

We think our results stem from good teamwork management on the part of our varying specialties. We begin with a meticulous selection of patients and conduct a very detailed, strict, and early process of preparation and post-operative care.

The advantages of outpatient surgery include the reduction of costs, lower risk of hospital-acquired infection, and psychological benefits for patients and their families.

#### 5. Conclusion

Our experience shows that, with a multidisciplinary team using strict inclusion criteria, outpatient management for lip and cleft palate repair is both safe and feasible.

Under strict rules of nursing, anesthesia, and surgery, ambulatory treatment can be provided without major complications.

#### Declaration of competing interest

We disclose no conflicts of interest or funding.

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