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Comparison of Two Models of Surgical Care for Patients with Cleft Lip and Palate in Resource-challenged Settings

Percy Rossell-Perry · Eddy Segura · Lorgio Salas-Bustinza · Omar Cotrina-Rabanal

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Abstract
Background The Peruvian health system is limited in providing specialized care for patients with clefts because there are an insufficient number of hospitals and few specially trained doctors in rural areas of the country. The most common model of care in these areas is the surgical mission wherein experienced cleft surgeons perform surgeries and teach local doctors. The purpose of this research was to identify the differences in outcome between the surgical mission trip and the referral center model of care provided by the same team.
Methods A retrospective analysis (2002–2012) was performed on data from surgical outcomes provided by the Outreach Surgical Center Lima that utilized both models of care (surgical mission and referral center). A total of 935 procedures were performed in 680 patients with clefts who were treated by the Outreach Surgical Center Program Lima since 2002. Patients in both groups were identified from our records (medical records and screening-day registries). All patients underwent a physical examination, had photographs taken, and any unfavorable results and complications were documented. Comparison of categorical variables (including outcomes) between care models was performed using Pearson's χ^2 test or Fisher's exact test when appropriate. In all cases a two-tailed test was performed and the p value for rejecting the null hypothesis (no difference or no association) was set at 0.05.
Results We found significant differences between the two models of care with respect to unilateral cleft lip and cleft palate dehiscence ($p = 0.02$ and $p = 0.04$, respectively), palate postoperative hemorrhage ($p < 0.01$), and palatal fistula ($p < 0.01$) outcomes.
Discussion Differences in observed surgical outcomes between the two models might be attributed to the surgeon's performance and/or the patient's age, and these factors are also considered with respect to the model of care. Limitations in long-term medical evaluation at each site should be identified and strategies to improve surgical outcomes must be developed to ensure that patients served by surgical missions obtain the same results achieved at a referral center.
Level of Evidence Therapeutic III.

P. Rossell-Perry (✉)
Faculty of Medicine, San Martin de Porres University, Lima, Peru
e-mail: prossellperry@gmail.com

E. Segura
School of Medicine, Universidad Peruana de Ciencias Aplicadas, Lima, Peru

L. Salas-Bustinza
Department of Pediatric Surgery, Hospital Nuñez Butron, Puno, Peru

O. Cotrina-Rabanal
Department of Dental, ARMONIZAR Foundation, Lima, Peru

Introduction

Cleft lip and palate are a common deformity disease in Peru [1, 2]. Our health system is limited in providing specialized care for these patients because there are not enough hospitals and few specially trained doctors in the rural areas of the country. Since the 1960s, international teams have been providing free cleft care for these patients. The model of care during those years was the surgical mission whereby experienced cleft surgeons performed surgeries and taught local doctors. Since 1999, Interplast (now ReSurge International), in association with The Smile Train, had local teams as Incubator Programs (in 2003 the

name changed to Outreach Surgical Center Programs) in seven countries around the world [3]. Based on a new philosophical model (observation, integration, and independence), ReSurge International embarked on a program that guaranteed patient safety, preserved indigenous culture, and taught local surgeons the multidisciplinary approach to cleft care [4]. These programs received medical support from ReSurge and financial support from Smile Train to provide free cleft surgeries for the needy and underserved.

The Outreach Surgical Center in Lima was created in 2002 and since then has provided care using both models (mission trips and referral center) for patients with clefts in Peru. The World Health Organization has stressed the importance of research on outcomes of missions trips [5, 6]. Incorporating data collection and follow-up into organizations providing mission trips is important for estimating the global burden of surgical disease and ensuring that quality care is delivered on these trips [7, 8].

There are no previous studies that have compared surgical outcomes between these two models in the same country. The purpose of this study was to identify the differences in outcome between the surgical mission trip and the referral center model of care provided by the same team. This study focused on both short- and long-term perioperative and postoperative outcomes.

Patients and methods

This retrospective study compared two groups of patients who underwent primary and secondary cleft repair by the Outreach Surgical Center Program Lima beginning in 2002 through September 2012. All surgeries were performed by one plastic surgeon (lead author), a well experienced cleft surgeon with 20 years of experience and more than 2,000 cleft surgeries performed since 1996. The Outreach Surgical Center Lima Protocol [2] was used for surgery on all patients. The operative techniques used are presented in Table 1 [2, 9–12].

Table 1 Operative techniques used by the outreach surgical center program Lima 2002–2012

Outreach surgical center Lima cleft lip and palate operative techniques
Incomplete unilateral cleft lip (rotation advancement modification)
Complete unilateral cleft lip (upper double rotation advancement)
Symmetric bilateral cleft lip (Chen and Nordhoff's bilateral cheiloplasty)
Asymmetric bilateral cleft lip (upper double advancement and lateral rotation)
Mild cleft palate (raw area free palatoplasty + intravelar veloplasty)
Moderate cleft palate (two flap palatoplasty + intravelar veloplasty)
Severe cleft palate (soft palate repair + Vomer flap)

Patients in both groups were identified from our records (medical records and screening day registries) and underwent a physical examination and had photographs taken and the presence of unfavorable results and complications was documented. Patient and caregiver interviews provided demographic information and past medical and surgical histories.

The evaluated surgical outcomes were clearly defined as follows:

- *Lip revisions:* the number of repaired cleft lips that required reoperation. This outcome was evaluated at 1 year after surgery. Patients who were keloid formers were excluded.
- *Wound infection:* clinical evidence of infection (increased inflammatory response and wound exudates) confirmed by blood tests. It is often associated with wound dehiscence. This outcome was evaluated during the first week after surgery.
- *Wound dehiscence:* the opening of the wound closure after surgery, may be related to a deficiency of the surgical technique and wound infection and may be partial or total. We excluded the cases related to wound infection in this outcome. This outcome was evaluated during the first week after surgery.
- *Postoperative hemorrhage:* significant postoperative bleeding from the wound site that required surgical revision. This outcome was evaluated during the first week after surgery.
- *Palatal fistula:* the presence of communication between the nose and oral cavity in the hard or soft palate after primary palatoplasty. Nasoalveolar (anterior) fistulas were excluded. This outcome was evaluated 1 month after surgery.
- *Velopharyngeal insufficiency (VPI):* the inability of the velopharyngeal sphincter to produce normal speech. For practical purposes it was considered as the nasal escape of air with increased resonance during speech (hypernasality). This outcome was evaluated postoperatively at 5 years.

The models for delivery of care were defined as follows:

- *Surgical mission* (model A): Treats patients with clefts in rural areas of Peru where there are no surgeons specializing in cleft care. Three hospitals from the three geographic regions of Peru were included in our study: (1) Regional Hospital of Puno (located in the highlands), (2) Regional Hospital of Tarapoto (located in the jungle), and (3) San Borja Clinic of Lima (located

on the coast). A basic medical team comprises a plastic surgeon, pediatric anesthesiologist, pediatrician, and nurses who travel to the site and work for 5–7 days. Selected patients are scheduled for each mission trip. Follow-up of operated patients occurs at postoperative days 1 and 7, 1 month, 1 year, and 5 years after each mission. A local surgeon provides the postoperative report at 1 week after surgery.

- *Referral center* (model B): Treats patients at the referral center in Lima and provides cleft management for the poor and underserved living in the marginal areas of the city or selected patients from rural areas of Peru who receive funding for transportation and lodging expenses. Patients are cared for by the surgeon with staff privileges at the Jockey Salud Clinic of Lima and are scheduled for surgery at the Los Andes Clinic of Lima. Patients are referred for interdisciplinary treatment at our partner, the local foundation ARMONI-ZAR. Follow-up of treated patients occurs on postoperative days 1 and 7, 1 month, 6 months, 1 year, and 5 years after surgery.

Statistical analysis

All data were downloaded from online medical records accessible only to the medical staff. No names or other identifiers were extracted from the original archives. All outcomes of this study (surgical adverse events) were treated as categorical dichotomous variables and computed as percentages for each substudy group (care models). All categorical variables (lip and palate complications, type of surgery, type of cleft palate, and sex) are described as absolute numbers as well as relative percentages with respect to the total number of patients and/or surgical procedures in each type of care model. Numerical variables (age) are summarized by using means, medians, and maximum-minimum ranges. Comparison of categorical variables (including outcomes) between care models was conducted using Pearson's χ^2 test or Fisher's exact test where appropriate. In all cases a two-tailed test was conducted and the p value for rejecting the null hypothesis (no difference or no association) was set at 0.05. All analyses were conducted using Stata 12.1 software (StataCorp., College Station, TX, USA).

Results

A total of 935 procedures were performed on 680 patients with clefts by the Outreach Surgical Center Program Lima since 2002. A total of 423 patients (62.2 %) were treated using model B and 257 patients (37.8 %) were treated using model A. A total of 504 procedures (53.90 %) from both models were evaluated at least 1 year after surgery (Fig. 1). Only 97 of those procedures (27.62 %) were from model A (Table 2). A total of 13 patients were contacted for speech evaluation at 5 years postoperatively (Fig. 1). The number of surgeries scheduled per day in the model A group was 4–6 (median = 4.8). A total of 407 procedures (70.21 %) that were evaluated at least 1 year after surgery were from the model B group, and 104 patients were contacted for speech evaluation at 5 years postoperatively (Fig. 1). The number of surgeries scheduled per day in the model B group was 1–3 (median = 2.21). All contacted patients and relatives agreed to participate in the study.

Tables 2, 3, 4 and 5 summarize the demographic and surgical outcomes data by model of care.

Discussion

In the scientific literature the limitations of delivering care by surgical mission trips for patients with cleft lip and

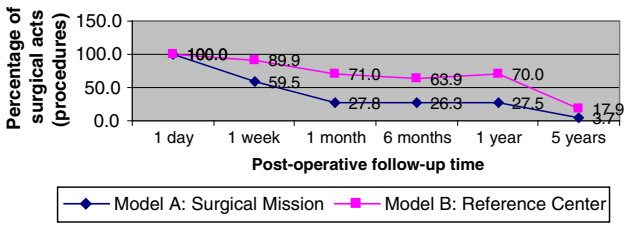

Fig. 1 Lost to follow-up comparison between care models over 5 years: percentage of surgical procedures still on follow-up at each check point over time

Table 2 Age and sex of subjects who underwent cleft lip and/or palate surgery stratified by model of care (680 subjects and 935 surgical procedures)

Characteristics	Model A: surgical mission (n = 257)	Model B: referral center (n = 423)	p value**
Sex (n = 680)			
Female [n (%)]	148 (57.6)	235 (55.6)	0.60
Male [n (%)]	109 (42.4)	188 (44.4)	
Age at surgical procedure (n = 680)			
Primary cheiloplasty*	24; 15–84; 3–648	5; 3–8; 3–19	<0.05
Primary palatoplasty*	20; 13–115; 10–492	16; 12–21; 10–29	<0.05
Secondary cheiloplasty*	46; 25–84; 7–504	62; 27–142; 12–576	0.16
Secondary palatoplasty*	82; 41–100; 17–660	53; 37–62; 27–70	<0.05

*Values are median, interquartile range (pp 25–75), and absolute range (minimum–maximum) of ages of subjects measured in days

**χ^2 test for all tests

Table 3 Type of cleft palate of subjects who underwent cleft lip and/or palate surgery stratified by model of care (680 subjects and 935 surgical procedures)

Type of cleft palate ($n = 319$)	Model A: surgical mission ($n = 90$)	Model B: referral center ($n = 229$)	p value**
I (Soft palate only)	13 (14.4)	24 (10.4)	0.68
II (Hard and soft palate)	9 (10.0)	25 (10.9)	
III (Unilateral cleft lip and palate)	40 (44.4)	115 (50.2)	
IV (Bilateral cleft lip and palate)	28 (31.2)	65 (28.3)	

*Values are number (%)

**χ^2 test

Table 4 Types of surgical procedure performed on subjects who underwent cleft lip and/or palate surgery stratified by model of care (680 subjects and 935 surgical procedures)

Type of surgical procedures performed ($n = 935$)	Model A: surgical mission ($n = 353$)	Model B: referral center ($n = 583$)	p value**
Primary unilateral cheiloplasty	105 (29.7)	206 (35.4)	<0.05
Primary bilateral cheiloplasty	15 (4.2)	59 (10.1)	
Primary palatoplasty	90 (25.5)	229 (39.3)	
Secondary unilateral cheiloplasty	54 (15.3)	28 (4.8)	
Secondary bilateral cheiloplasty	43 (12.2)	24 (4.2)	
Secondary palatoplasty	46 (13.1)	36 (6.2)	

*Values are number (%)

**χ^2 test

Table 5 Surgical adverse outcomes of subjects who underwent cleft lip and/or palate surgery stratified by model of care (680 subjects and 935 surgical procedures)

Outcomes	Model A: surgical mission	Model B: referral center	p value*
Wound dehiscence			
Wound dehiscence in UCL (1 week)	3/28 (10.7)	2/186 (1.1)	**0.02**
Wound dehiscence in BCL (1 week)	2/7 (28.6)	6/47 (12.8)	0.28
Wound dehiscence in CP (1 week)	8/35 (22.9)	21/215 (9.8)	**0.04**
Lip complications			
Lip postoperative hemorrhage (1 day)	3/120 (2.5)	4/265 (1.5)	0.68
Lip wound infection (1 week)	2/35 (5.7)	3/233 (1.3)	0.13
Lip revision in UCL (1 year)	3/14 (21.4)	15/148 (10.1)	0.19
Lip revision in BCL (1 year)	1/3 (33.3)	8/37 (21.6)	0.54
Palate complications			
Palate postoperative hemorrhage (1 week)	6/35 (17.1)	5/215 (2.3)	**<0.01**
Palate wound infection (1 week)	1/35 (2.9)	0/215 (0.0)	0.14
Palatal fistula (1 month)	4/16 (25.0)	7/183 (3.8)	**<0.01**
Velopharyngeal insufficiency (5 years)	1/3 (33.3)	3/32 (9.4)	0.31

Bold values are statistically significant

1 day, 1 week, 1 month, 1 year, and 5 years are time of assessment after surgery. Denominators are the number of subjects assessed at that point of time for that specific complication in each model of care. Numerators are the number of subjects having the specific complication. Numbers in parenthesis are %

UCL unilateral cleft lip, *BCL* bilateral cleft lip, *CP* cleft palate

*Fisher's exact test

palate have been thoroughly identified. These include performing a high number of surgeries in a short period of time, difficulties with the long-term follow-up of the patients (many of the patients live in remote areas and few return for evaluation), lack of proper interdisciplinary care, and inclusion of surgeons without enough experience with cleft repairs [13–15]. A large number of unfavorable outcomes and complications have been observed as a result of this approach. Nonetheless, this model of care is quite prevalent in Peru, including many rural areas and also the large cities such as Lima.

In this study we observed some important differences between the two studied groups. We did not find significant demographic differences between the two studied groups except for age. The number of older patients who underwent primary surgery in the mission model was greater ($p < 0.05$), except for secondary cheiloplasty cases ($p = 0.16$). Gender ($p = 0.60$) and type of cleft ($p = 0.68$) were similar for both groups (Table 1). Even though the rates of lip revision were different, there were fewer in the referral center, there was not a statistically significant difference between the two models: unilateral cleft lip ($p = 0.19$) and bilateral cleft lip ($p = 0.54$). The difference in the numbers of patients in the groups that were evaluated is the reason for this result. Studies done in wealthier countries' centers have reported higher rates of unilateral lip revision: 35 % [16], 31 % [17], and 17–45 % [18]. These rates are lip revisions for unilateral and bilateral cleft lip and are higher than our rates. These studies did not

differentiate between major and minor revisions which may be the reason for the observed differences. Salyer et al. [19] reported a 33 years experience repairing unilateral cleft lips and observed that the majority of patients had a minimal deformity and approximately 35 % of them required minor secondary procedures. That study did not report the rate of major lip revisions.

Patients with unilateral cleft lip and cleft palate were significantly more likely to develop wound dehiscence ($p = 0.02$) in the mission model. As the surgeon and the surgical technique are the same in both models and the types of cleft lip were similar in the studied groups (Table 1), we may assume that the reason for the higher rate of wound dehiscence is related to one of the only two variables, the surgeon's performance or the patient's age. There was no statistically significant difference between the two groups with respect to bilateral cleft lip patients ($p = 0.28$). The wound dehiscence rate in bilateral cleft lip patients is more likely related to the severity of the cleft than to surgeon competence or the age of the patient [20, 21]. The rates of lip wound infection and postoperative hemorrhage were low and there was no statistically significant difference between the two models of care ($p = 0.13$ and $p = 0.68$).

Even though wound healing after cleft surgery may depend on good nutrition and oral health, there are few well-designed studies supporting this concept [22]. The nutritional status of patients cared for at plastic surgery missions has not been well characterized in studies [7]. Of importance is that the health status of the population in the rural areas of Peru and the marginal areas of Lima are similar [23]. Patients with similar health conditions who were operated on under these two models had different surgical outcomes, with an increased number of unfavorable results and complications in the surgical mission model (Table 2). These results support the hypothesis that the difference is not a result of the health condition of the patients. Nutritional and oral status of the patients were not considered in this study, which is a limitation of this research. Future activities should incorporate prospective data collection, including health status, to better understand the impact on surgical outcomes.

There are no reports of lip revision, wound infection, dehiscence, and postoperative hemorrhage rates of surgical missions in low- and middle-income countries with which to compare our rates. Postoperative palatal fistulas occurred in 25 % of the evaluated children treated during surgical missions in comparison with the rate of 3.82 % for children treated in the referral center model. This difference was statistically significant ($p < 0.01$). Both rates are similar to those reported from centers in upper-income countries (0–58 %) [24–27]. Most recent reports have quoted rates of 11–25 % [28–30].

Previous studies have associated surgeon experience, procedure selection, severity of the cleft, patient age, number of stages, and poor oral health with higher rates of palatal fistula [22, 24, 28, 31]. As our study considered the work of one single surgeon, similar surgical techniques, and similar types of cleft in both groups, we may assume that the surgeon's performance (related to the model of care) and/or the patient's age would be the primary factors related to the development of fistulas. Cleft severity and surgical technique deficiencies have been described before as the primary reasons for unfavorable surgical outcomes [32–35]. The nutritional status and oral status were not studied, but, as indicated, these parameters are similar in both studied groups. Maine et al. [31] concluded in their study in Ecuador that the primary reason for an increased rate of fistulas compared with that of a referral center in the US is poor oral health. There are no studies comparing oral health status between populations in Ecuador and Peru but we consider these countries to be similar. Close to 20 % of Ecuadorian children under the age of 5 are malnourished [36] and 19.5 % of children in Peru are in a similar condition [7]. A few studies support the concept of a direct relationship between the preoperative health of the patients and undesirable surgical outcomes [22, 37, 38].

Postoperative hemorrhage was significantly higher in the mission model ($p < 0.01$) and this may be a result of the older age of the patients in this group (Table 2). Postoperative velopharyngeal insufficiency (VPI) was observed in 33.3 and 9.37 % of the patients treated in models A and B, respectively. These rates are similar to those of other studies. VPI following cleft palate repair has been found to be as high as 30 % [39–41]. However, we did not observe significant differences between the two groups in our study.

There are some limitations to the analysis of the surgical outcomes as the number of patients in each group was small. Only 20 % of the patients were 5 years of age when evaluated. Previous studies suggest that older patients are more likely to develop palatal fistulas, VPI, and postoperative hemorrhage after cleft palate repair [30, 42–44]. Zhao et al. [45] observed an increased incidence of postoperative VPI with increased age at the time of palatoplasty. Older palatoplasty patients in the mission model may contribute to the increased rate of VPI in that group. In rural areas the limited access to early treatment and lack of awareness among health-care providers and the public regarding possible surgical repair contribute to palatoplasty occurring in older patients [6, 46]. Further investigation into the effect of older age at primary repair in our population is needed. Another result of the small number of cases studied is that the rates of palatal infection were low and not statistically different between the two models.

The performance of the surgeon may be affected by the high number of surgeries performed per day, the environmental conditions (e.g., temperature, altitude), and technological and medical deficiencies of the hospitals visited.

In our study, the same surgeon had different surgical outcomes in each model of care. A similar result was observed in the Ecuadorian study where a well-experienced surgeon had 10 times more palatal fistula in the mission model than in his private practice [31]. Even though the complication rates of our mission model surgical outcomes are better than those of other surgical missions in low- and middle-income countries and are similar to some referral centers' outcomes in upper-income countries, they are higher than the rates for our referral center model. Based on these results, we are now caring for more patients using the referral center model thereby changing the traditional model of care for patients with clefts in Peru. More people are contacting us through the internet and telephone and we are providing lodging and travel expenses for the patients in need who come from rural areas of the country.

The retrospective nature of the study limited the evaluation of potential causes of undesirable surgical outcomes. Lack of contact information for many patients treated on missions makes follow-up difficult. This is the primary limitation of this research. Although all the evaluated outcomes were better using the referral center model, most of the differences were not statistically significant. The lower number of follow-up patients in the mission model accounts for this outcome. Only 27.62 % of the patients were contacted at least 1 year after surgery in the surgical mission model (Fig. 1). This situation could be a result of the high number of operations performed which limits the opportunity to teach individuals about the importance of the long-term medical evaluation. In addition, remote home location and lack of telephone and mail service for many patients treated on missions makes follow-up studies difficult. Based on these findings, educational material and food and transportation reimbursement are considered for the patients in order to improve this condition.

Better prospective documentation of health status will allow analysis of its impact on cleft lip and palate surgical outcomes in this population. In the 21st century, the most common model of care for patients with clefts in our country is the mission trip model. As similar results have been reported from other low- and middle-income countries like Ecuador [31], we believe our results could be of value to those countries, at least in Latin America.

Conclusions

Better outcomes were observed with the reference center model in this study. Observed surgical outcome differences between the two models studied might be attributed to surgeon performance and/or patient age and these have a direct relationship with the model of care. This situation should be improved or changed. Limitations in long-term medical evaluation at each site should be identified and strategies to improve surgical outcomes must be developed to ensure that patients treated on surgical missions obtain the same results achieved at a referral center. Similar outcome studies should be developed at other mission sites around the world to better understand the population treated using this model.

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