

9-Year Clinical Audit on Complications of Cleft Lip and Palate Charity Surgeries in China Shenzhen Area

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Abstract

Background: In developing countries, charity cleft surgical mission is always operated by sporadic surgical teams without systematic follow up and quality assurance. In the past few decades, many mission projects have been held regularly in China. The purpose of this audit was a retrospective analysis of a 9-year cleft lip and palate charity project operated in a tertiary hospital in China Shenzhen Area to evaluate perioperative and postoperative complications. Nevertheless, understanding the risk profile is essential for establishing a sustainable in-house cleft service in Shenzhen. **Methods:** A detailed analysis of hospital centralized record in the The University of Hong Kong-Shenzhen Hospital (HKUSZH) was reviewed since the first charity project held in 2015. The parameters of this audit were focused on perioperative complications including anesthesia related problems, early postoperative complications in patients who underwent primary or secondary cleft surgeries. A total of 430 consecutive admitted cases of 311 non-syndromic cleft lip & palate patients were enrolled into the charity project from June 2015 to July 2024. The main anesthesia related complications that occurred during general anesthesia were respiratory tract problems, while intraoperative complication was excessive bleeding, so as wound local infection and reaction were the main early postoperative complications. **Results:** In our 9-year clinical audit of 430 cleft lip and palate charity surgeries in Shenzhen, we observed no mortalities and a anesthesia-related complication rate of 1.16%. Specific intraoperative complications included excessive bleeding, while early postoperative issues were dominated by wound infections. The fistula rate of 18.7% post palate repair and the average hospital stay of 3.71 days complete the profile of our surgical outcomes. These data underscore the project's efficacy and offer a reference for international cleft missions aiming for safe and efficient surgical care.

Conclusions: This study provides a thorough data review of the complications in the past 9 years charity missions for cleft lip and palate surgery in a well-structured hospital infrastructure and logistic support by local surgical team. There were no perioperative or postoperative death during the study period and the overall short-term complication rate was low. Therefore, it could be a reference model for other international cleft mission in developing country for a safe and efficient service in future.

Keywords

Cleft Lip, Cleft Palate, Charity Surgery, Complication

1. Introduction

Cleft lip and palate are congenital deformities affecting the oral maxillofacial functional organs, with a prevalence in China of approximately 11.43 cases per 10,000 live births [1]. Therefore, the demand for cleft service is enormous. In the past few decades primary cleft lip and palate treatments were not covered by the China national medical insurance scheme, which made various charitable initiatives diligently to offer extensive cleft lip and palate surgical charity missions such as Operation Smile, Future Smile Charitable Foundation, China Population Welfare Foundation, China Red Cross Foundation, Smile angel Foundation [2]-[5]. Shenzhen is one of the newly developed cities in the Guangdong-Hong Kong-Macao Greater Bay Area in southern China. The HKUSZH is a tertiary hospital established in 2012 under the auspices of the University of Hong Kong medical system. Constant input of international medical expertise from Hong Kong is a key drive to cultivate the local service advancement.

The hospital places great emphasis on community public welfare activities covers various treatment programs for patients of underprivileged groups, such as cleft lip & palate deformities. Since the first public welfare activity was launched in 2015, the hospital has successfully held 13 such events. Over the past decades, the hospital has collaborated with charitable organizations & various volunteer surgeon teams to provide mainly primary lip and palate & some secondary revision surgeries for 430 consecutive admitted cases. The inherent risks of cleft surgery can be serious and life-threatening that forming a significant debate of mission surgery team operating in rural areas for many years. Consecutive operation missions in well-established hospital has become a trend in China. In this hospital setting, the in-house logistic support by local surgical team and anesthetists in the past 9 years, low complication rate was anticipated.

The purpose of this report is to review the past mission services in perioperative and postoperative complications as a quality assurance to benchmarking with international standard. Furthermore, we will discuss about the distinctive logistic for our hospital collaboration with mission teams to secure the best interest to patient's safety and evolving of local multidisciplinary cleft team as a sustainable

service parallel to the socioeconomic development in China.

2. Methods

This is a retrospective study of the central hospital record by analysis of 430 consecutive admitted patients who were receiving cleft surgery under the cleft lip and palate public welfare project of the HKUSZH between July 2015 and June 2024.

As this is a retrospective analysis of a charity project, the decision to include all consecutive cases ensures that the audit captures the complete spectrum of outcomes associated with the charity surgeries performed at our institution.

Selection and Enrollment Process:

i) The selection criteria for enrollment in the charity project were as follows:

a) Age and Weight Requirements: Patients had to be at least 3 months old and weigh more than 5 Kg for primary lip repair, and more than 8.5 Kg for cleft palate repair.

b) Hemoglobin Level: A hemoglobin level of more than 100 g/L was required.

c) Infection-Free Status: Patients must not have had any respiratory or gastrointestinal infections in the past 2 weeks prior to surgery.

ii) The enrollment process involved the following steps:

a) Identification of Eligible Patients: Potential candidates were identified through community outreach programs, referrals from local healthcare providers, and self-referrals by families seeking surgical intervention for cleft lip and palate.

b) Initial Screening: Eligible patients were initially screened by a social worker or project coordinator to ensure they met the basic criteria for the charity project.

c) Medical Evaluation: Patients who passed the initial screening were then subjected to a thorough medical evaluation by the medical team at HKUSZH. This evaluation included a complete medical history, physical examination, and necessary laboratory tests to confirm their fitness for surgery.

d) Informed Consent: Once a patient was deemed eligible and medically fit, the family was provided with detailed information about the surgery, potential risks, and benefits. Informed consent was obtained from the legal guardians before enrollment in the project.

e) Documentation and Registration: After obtaining consent, patients were registered in the hospital's centralized record system, which tracked all aspects of their care, from preoperative assessments to postoperative follow-ups.

A total of 311 patients enrolled into this charity project that 121 patients with cleft lip, 72 patients with cleft palate, and 118 patients with cleft lip and palate (**Table 1**). The patient's age ranged from 3 months to 29 years old the median age of the patients was 3.53 years-old (SD = 4.7 years).

There were 237 males and 193 females, resulting in a male-to-female sex ratio of 1.23. (M:F sex ratio 1.23). All patients were submitted for operation under general anaesthesia (**Table 2**).

To date, 13 missions have been organized and operated by various volunteer surgical teams, making it difficult to maintain a standardized protocol or consistent

surgical techniques. **Table 2** showed the different location of procedures including both primary and some secondary revision procedure either our own patients or patients with former primary surgery in other hospital.

Generally, the most commonly performed procedures including Millard rotation advancement method, Tennison-Randall technique and Fisher anatomical subunit technique for unilateral cleft lip repair. For primary cleft palate repair, most surgeons adopted either Von Langenbeck two flap technique or Furlow double opposing Z-plasty. Primary rhinoplasty as the Tajma alar lift and suture suspension technique might incorporate with primary lip surgery to provide immediate improvement of nasal form. For older patients with secondary nasal deformities could be corrected by open septo-rhinoplasty and strut or tip graft augmentation. In this cohort, all our patients received preoperative ear examination by otolaryngologist to decide myringotomy & grommet insertion during the palate repair session to alleviate the potential complication due to serous otitis media. For patients without former lip repair, with body weight > 8.5 Kg, one-stage cleft lip palate and nose repair were considered. Amongst 311 enrolled patient, 23 (7.4%) of them had submitted for one-stage surgery.

Evaluation of intraoperative complications, including complications related to general anesthesia and complications related to surgery performed. All observations during surgery or postoperative monitoring were responsible by either operating surgeon or local plastic surgical team.

Evaluation of Complications

Intraoperative Monitoring and Data Collection: All complications were meticulously monitored and recorded by the surgical team, which included the lead surgeon, anesthesiologist, and scrub nurse. A standardized checklist was used to ensure that all potential complications were identified and documented in real-time during each surgery. This checklist included items such as bleeding, technical issues with the surgical procedure, anesthesia-related events, and any unexpected patient responses.

Definition of Complications: To ensure consistency in the evaluation process, specific definitions for complications were established. For instance, excessive bleeding was defined as any instance requiring transfusion or additional surgical measures to control hemostasis.

Real-Time Documentation: Complications were documented in the patient's electronic medical record by the operating room staff as they occurred. This real-time documentation allowed for immediate medical intervention if required and provided a clear record for subsequent data analysis.

Data Analysis: The collected data on intraoperative complications were analyzed by a dedicated research team who were blinded to the patients' outcomes. This analysis included calculating the frequency and percentage of each type of complication.

Descriptive Statistics: Calculating the standard deviation (SD) of age to describe the distribution of age data.

Table 1. Categorization table for cleft lip and palate.

Cleft Lip	121	Left Side	62
		Right Side	25
		Bilateral	11
Cleft Palate	72	Not specified	72
Cleft Lip and Palate	118	Left Side	32
		Right Side	24
		Bilateral	38
		Not specified	24
Total	311		

Table 2. Demographics and surgical procedures for cleft lip and palate patients.

Age	Number
≤1	154
2 - 18	265
>18	11
The age range was 3 months to 29 years. The median age of the patients was 3.53 years-old (SD = 4.7 years)	
Sex	Number
Male	237
Female	193
Surgical Procedure	Case
Lip Repair (Primary /Secondary)	272
Palate Repair (Primary/Fistula Repair/Velopharyngeal)	211
Rhinoplasty	159
Ear Surgery (Myringotomy & Grommet M&G insertion)	40

3. Results

This study reviewing 430 consecutively admitted cases for surgery showed male predominance (M:F sex ratio 1.2) (**Table 2**). The age range at which patients received operation was 3 months to 29 years, the median age was 3.53 years old (SD = 4.7 years) shown in (**Table 2**). All patients were undergoing general anesthesia for surgery, and five patients who underwent local anesthesia were excluded. Two patients were also excluded due to a diagnosis of facial fissure. During the above period, a total of 682 surgical procedures were performed including 40 ear operations. Though all the procedures were performed by experienced cleft surgeons, the fistula rate was found to be with 18.7% amongst 163 primary palate repairs as shown in **Table 3**. In the past 9 years, we maintained zero perioperative or postoperative mortality due to diligent commitment from different departments in patient care. Only five patients needed immediate postoperative care in the Pediatric Intensive Care Unit (PICU) due to airway issues during intubation or recovery (1.16%); all were extubated uneventfully then transferred back to the general

ward. The overall average length of hospital stay was 3.71 days.

One case had excessive bleeding (hemorrhage) requiring transfusion, two cases of hypoproteinemia after surgery needed albumin infusion, and two patients experienced obvious oozing of blood after palate repair shortly after surgery, requiring the application of gauze packs soaked in adrenaline saline to compress the wound and achieve hemostasis.

Purulent lip wound infection was observed in two patients causing dehiscence needed repeated wound dressing for a month for delayed repair.

Another lip wound problem was observed in a patient who developed severe skin reaction due to non-resolving subcutaneous sutures knot, finally the stitch knot was removed after 3 weeks of wound cleansing then the wound healed uneventfully.

Of the 430 admitted cases, a total of 272 lipoplasty, 211 palateoplasty, as shown in **Table 2**. The incidence of complications after cleft lip surgery was lower than that after cleft palate.

Table 3. Complication in 430 surgical admissions.

Complication	Lip	Palate	Case	Percentage
Postoperative Transfer to PICU	4	1	5	1.16%
Difficulties in Intake need Albumin Infusion	0	2	2	0.46%
Bleeding needs to be stopped with pressure	0	2	2	0.46%
Blood Loss Requiring Red Blood Cell Transfusion	0	1	1	0.23%
Poor wound healing due to infection/ suture reaction	3	0	3	0.69%
Fistula rate <in 163 palate repair>	0	30	Redo in 30	18.4%
Fatal Case	0	0	0	0.00%

4. Discussion

China is the second largest populated country in the world means orofacial cleft deformities in newborns are enormous. Many patients seek surgery through charitable missions, these patients were seeking surgery through charitable missions. These patients were quickly evaluated shortly before surgery (within 24 hours), and postoperatively they were sent back to their home without any further follow-up. Thus, the medical teams conducting these charitable missions usually cannot have consistent patient documentation, treatment protocol and long-term follow-up of surgical results, research on the outcomes of these missions are always difficult.

In our hospital, before 2020 (pre-COVID period), the service was operated under regular visitation of mission teams either from Hong Kong SAR or United States. All the volunteer surgeons had over 10 years' experience in cleft surgery to perform operations with in-hospital and postoperative support. Surgical trainee surgeons served as assistants and may operate under close supervision for some simple procedures. The overall major complications were extremely low and achieved zero perioperative and postoperative mortality. We will prioritize our

discussion from perioperative anaesthetic related complications.

Anesthetic related complications: Most complications could happen during general anesthesia. Especially in cleft palatal repair, children are known to be at higher risk compared to adults under general anesthesia [6] [7]. Laryngopharyngeal edema, a frequent complication of general anesthesia, is often the result of challenging airways, multiple attempts at endotracheal intubation, or extended surgical duration. This condition usually manifests 4 to 6 hours postoperatively and can generally be alleviated with the appropriate administration of steroids. However, in severe instances, a tracheostomy may be necessary. Within the scope of this project, there were 5 cases (1.16%) associated with anesthesia that required postoperative admission to the PICU for further care, but none of these cases needed a tracheostomy.

Bleeding: This typically occurs on the day of surgery. Blood loss is a relatively common complication, and reducing the duration of surgery is an important factor [6]-[9]. However, in complex palatal repair more muscle dissection may be necessary inevitably prolonging surgical time. Postoperative evacuation of hematoma after palate repair was not uncommonly reported in literature requiring general anesthesia. In this audit, there were 3 cases (0.69%) of postoperative bleeding; one patient received a blood transfusion, and two patients recovered well after treatment measures involving local pressure. Therefore, it is necessary to achieve meticulous hemostasis during surgery. Particularly for relieving incisions, local packing and compression hemostasis may be required in addition to tight suturing and the application of adjunct hemostatic agents.

Some literature [7] [8] suggests that intraoperative blood transfusion is associated with potential postoperative complications in children with cleft palate. Although intraoperative blood transfusion can only replenish pack cell volume deficit, however, other constituents such as white cell and platelet active component not been supplemented. Therefore, it may reduce the body's macrophagic function for defending bacterial invasion so as platelet active substances may be a potential source of sepsis. Due to the small number of blood transfusions without any complications in this project, we did not have any similar observations.

Fistula Rate: The occurrence of palatal fistulas remains a common complication after most cleft palate repairs [8] [10]. Fistula rate was 18.4% in our project that is not uncommon in mission surgical service. Many contributing factors such surgical skills and techniques, types of clefts, width of the cleft, the age at the time of repair, nutritional factors and even poor home care, and feeding habits. Poor surgical skills, particular inadequate muscle dissection or flap relieving causing excessive wound tension or single oral layer closure technique that certainly increase chance of fistula formation. The type of cleft and the width of the cleft are significantly related to the occurrence of palatal fistulas, which often occur at the junction of the hard and soft palate, typically the widest part of the cleft palate cleft. It has been mentioned that the cleft width > 11.5 mm, fistula formation will significantly increase. Very often secondary cleft palate repair even higher incidence of

palatal fistula compared to primary repair because of tight and avascular scarily flap for tension-free double layer closure. Increasing in age of patient may also lead to higher chance of palatal fistula due to increase in width and depth of the palatal vault that demand a more meticulous flap mobilization and closure. Wound Infection: Postoperative infections can also increase the incidence of palatal fistula, therefore prophylactic use of antibiotics can effectively prevent postoperative infections. The one-compartmental oral-nasal structure in cleft palate patient inevitably disrupts the normal oral microecology. Mixed infections with various pathogens can lead to postoperative complications such as palatal fistula and oronasal fistula [11]. Similarly, lip repair surgical wound infections could be caused by local bacterial invasion, subcutaneous stitch knot as foreign body irritation or excessive wound tension, which are not uncommon encounter. In our series, 0.69% was extremely low that may be related to fine surgical skills and good aseptic control in a good operating room environment. Therefore, it is necessary to control potential pathogenic microorganisms in the oral, nasal, and pharyngeal areas before surgery to minimize the risk of postoperative complications.

In addition, the education level of cleft palate caregivers also has an impact. Parents of children with cleft palate generally lack knowledge about the disease, leading to inadequate oral hygiene and oral feeding habit for the children. When the caregivers have a lower level of education, improper postoperative home care can lead to a higher incidence of complications. Therefore, it is advocated to strengthen nursing education to deliver clear instructions for caregivers. Nowadays, special produced video clips in pre and postoperative care are the most effective adjunct tools for reducing the incidence of postoperative complications after repair.

In this project, there were 40 cases of cleft palate combined with otitis media and underwent surgery. Cleft palate is an independent high-risk factor for children's secretory otitis media (OME). Otolaryngologist consultation and perioperative Myringotomy & Grommet M&G are helpful in reducing future ear surgery and time cost of seeking medical treatment. Any delay in the management of ear diseases (such as serous otitis media, conductive hearing loss, or infections in cleft patients) needs timely assessment, treatment, and follow-up. Moreover, it should be noted that with the extension of the tube placement time, the rate of eardrum perforation increases [12].

Other reported complications include: epileptic seizures (0.1%), cardiac arrest, urinary tract infections, venous thromboembolism, stroke, acute renal failure, renal insufficiency, death, etc. [7], none of which occurred in this project.

These findings provide valuable experience for future charitable surgery for cleft lip and palate, helping to optimize treatment options and reduce the risk of complications, thereby improving patient outcomes and quality of life.

5. Conclusion

This study provides a thorough data review of the complications in the past 9 years charity missions for cleft lip and palate surgery in a well-structured hospital

infrastructure and logistic support by local surgical team. There were no perioperative or postoperative deaths during the study period, and the overall short-term complication rate was extremely low, with the anesthesia-related complication rate at only 1.16%. It could serve as a reference model for other international cleft mission in developing countries, aiming to provide safe and efficient service in future.

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Conflicts of Interest

All authors have disclosed no conflicts of interest.

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