International Journal of Pediatric Otorhinolaryngology 79 (2015) 803–807

Contents lists available at ScienceDirect

International Journal of Pediatric Otorhinolaryngology

journal homepage: www.elsevier.com/locate/ijporl

Prevalence, demographics, and complications of cleft palate surgery☆

Hossein Mahboubi [a], Adam Truong [a], Nguyen S. Pham [a,b,*]

[a] Department of Otolaryngology – Head and Neck Surgery, University of California, Irvine Medical Center, 101 The City Drive South, Orange, CA 92868, USA
[b] Division of Pediatric Otolaryngology, CHOC Children's Hospital, 1201 W. La Veta Ave., Orange, CA 92868, USA

ARTICLE INFO

Article history:
Received 30 December 2014
Received in revised form 20 February 2015
Accepted 25 February 2015
Available online 6 March 2015

Keywords:
Cleft palate
Palatoplasty
Complication
Perioperative risk

ABSTRACT

Introduction: Current published data on the demographics of cleft lip and palate is sparse and differs intranationally in reported incidence, demographics, and complication rates, making accurate local data both valuable and useful. We investigate the prevalence, demographics, and complications of cleft palate correction surgery in the inpatient setting over a 15-year period.
Methods: A retrospective review of The California Hospital Discharge Data sets of all pediatric patients who underwent cleft palate repair or cleft palate revision from 1997 to 2011. Children's hospitals (CHs) were analyzed as a separate group. For each record, age, gender, ethnicity, length of stay, total charges, principal payer, complications, and disposition were analyzed.
Results: 10,450 correction surgeries were performed during 1997–2011. This was an annual case-volume of 697 and annual population-adjusted rate of 2.0, neither of which changed over time ($p = 0.9$ and 0.06, respectively). Of all surgeries, 21.5% were revisions, 48.3% were performed in CHs, 56.2% were performed on males, and 65.5% were performed on Caucasians. The median length of stay was 1 day, which did not change over time ($p = 1.0$). The median total charges increased from $9.074 to $35,643 over the studied period ($p < 0.001$). Admission to CHs was associated with shorter stay (1–3 days vs. 1–4 days) and higher total charges ($15,560 vs. $13,242; both $p < 0.001$). Complications occurred in 393 (3.8%) of the surgeries. This percentage did not change over time ($p = 0.2$). The most common complication was fistula/abscess/infection, which occurred in 159 cases (1.5%). Respiratory complications requiring ventilation occurred 66 cases (0.6%). Complications were more common in CHs (4.8% vs. 2.8%; $p < 0.001$). Mortality rate was <0.1%.
Conclusions: Our study constitutes the entire surgical cohort within a state, allowing for an accurate representation of the true perioperative complication rate of these procedures. The prevalence, demographics, and outcomes of the cleft palate correction surgery have remained unchanged during 1997–2011. Collectively, our data suggest that primary and secondary palatoplasty present low perioperative risk.

1. Introduction

Cleft palate (CP) and cleft lip (CL) both result from the failures of frontonasal and maxillary prominence fusion during development and can occur together (CL + P) or in isolation. Although these two processes are often continuations of the same process, joint CL + P is considered epidemiologically and etiologically different from isolated CP [1]. Globally, the incidence of CL + P varies between different ethnicities: from 0.3 per 1000 in African American populations to 2.1 per 1000 in Japanese populations [2]. In contrast, the incidence of isolated CP is racially homogenous with a reported incidence of 0.5 per 1000 births [1,3]. Currently, the number of children born with congenital orofacial defects is now greater than neural tube defects or Down syndrome and the average lifetime medical cost per child has increased over time to an estimated $100,000 [3,4]. We focus our investigation on cleft palate repair and revision.

Previously published data in regards to the demographic data and complications associated with cleft palate surgery have historically consisted of single center case series or national surveys [5,6]. The largest study has been a quarter million surgeries by the Smile Train organization providing surgical cleft

☆ Presented at the American Society of Pediatric Otolaryngology Annual Meeting at COSM, May 14–18, 2014, Las Vegas, NV.

* Corresponding author at: Division of Pediatric Otolaryngology, CHOC Children's Hospital, 1010 W. La Veta, Ste 640, Orange, CA 92868, USA. Tel.: +1 714 633 4240; fax: +1 714 456 5747.
E-mail addresses: ?edu">hmahboub@uci.??edu (H. Mahboubi), adamt@uci.edu (A. Truong), nspham@gmail.com (N.S. Pham).

http://dx.doi.org/10.1016/j.ijporl.2015.02.032
0165-5876/

lip/palate treatment in developing countries [7]. There is a paucity of data on the trends and complication rates of CP surgeries in the recent literature. Even within countries, collected reports differ in reported incidence, demographics, surgical techniques, and complication rates, making accurate CL/CP data from large datasets both valuable and useful [3,5]. Recently, new access to hospital databases has allowed in-depth analysis of multicenter regional trends. By analyzing information from the California Hospital Discharge Database, we were able to obtain a broad based, multicenter assessment of demographic, prevalence, and inpatient complication rates of primary CP surgery and CP revision surgery.

Palate surgeons have long been wary of the complications related to performing palatoplasty. The surgery itself is very invasive, often involving the elevation of large mucoperiosteal flaps pedicled only on the greater palatine arteries. Meanwhile, the surgical wound is bathed in saliva and the oral flora. In addition, the airway becomes compromised after surgery due to swelling from oral retractors, and the physical narrowing of the palate itself after surgery. The techniques used for palatoplasty have changed within the past 15 years including the adoption of the Sommerlad-type radical intravelar veloplasty and the Furlow double opposing Z-plasty techniques, a trend toward one-stage palatoplasty repair, and the debated use of lateral releasing incisions to minimize the rate of fistulae formation [1,8–11]. Additionally, there is still much disagreement on the ideal timing of intervention, and ideal CP treatment strategy including pre and post-surgical care [12,13].

Post-operatively, children are usually observed as inpatients for 24 h after surgery to ensure adequate oral intake, pain control and a stable airway. Published data regarding the perioperative complications of cleft palate surgery have been from single center case series [6]. Meanwhile, other studies that look at cleft palate complications focus on the long term risk for oronasal fistula and velopharyngeal insufficiency, and not on the immediate perioperative risks [14]. Using data from the California Hospital Discharge Data set, our goal is to provide comprehensive data in regards to the risk of perioperative complications from multiple centers within the California region, as well as gain insight on the demographic trends of palate surgery.

2. Methods

2.1. Data source

The California Hospital Discharge Data sets are de-identified records of all inpatient hospital stays annually in the state of California. These data are gathered from all licensed hospitals including general acute care, acute psychiatric, chemical dependency recovery, and psychiatric health facilities. By definition, outpatient surgeries or surgeries performed in ambulatory surgery centers were not included. Data from the latest available data sets, 1997–2011, were obtained from the California Office of Statewide Health Planning and Development (OSHPD). Patient-level data such as demographics and diagnoses and procedures coded through *International Classification of Diseases, 9th edition, Clinical Modification* (ICD-9-CM). The data collection instruments and methodology for collection of data is available on the website of OSHPD [15]. The data set does not contain identifiable patient information thus approval for this study by our institutional review board was not required.

Pediatric records affiliated with ICD-9-CM procedural codes "27.62 Correction of cleft palate" and "27.63 Revision of cleft palate repair" were extracted. A record was considered pediatric if the associated age was less than 18 years old. The records with unknown age were excluded (8.1% of the records). Patients with Pierre Robin sequence were not excluded.

2.2. Variables and definitions

For each record, age, gender, ethnicity, length of stay, total charges, principal payer, complications, and disposition were analyzed. Institution type was classified as children's hospitals (CHs) versus non-children's hospitals (non-CHs) according to OSHPD list of licensed hospitals. Trends in total number of surgeries, population-adjusted surgery rates (number of surgeries per 100,000 California residents), percentage of revision surgeries, demographics, and complications were analyzed as well as compared between CHs and non-CHs. Data for the population of California were obtained from the Census Bureau [16].

Ethnicity was re-coded as Caucasian versus non-Caucasian (representing African-Americans, Native-Americans/Eskimo/Aleut, Asian/Pacific Islanders, and others). Length of stay by definition was counted as the number of days from admission to discharge. Total charges were calculated using all charges for services provided during hospital stay except for hospital-based physician fees. These charges were calculated and reported by the OSHPD and included, but were not limited to, daily hospital services, ancillary services and any patient care services. Prepayments (e.g. deposits and prepaid admissions) were not deducted from total charges. Principal payer was defined as the type of entity or organization expected to pay the greatest share of the patient's bill. The principal payer were re-coded as: (1) Medicare and Medi-Cal (Medicaid in California), (2) private insurance coverage (i.e. health maintenance organizations), and (3) other (this included self-pay, worker's compensation, county indigent programs, other government and indigent programs, research or courtesy patients where no payment was required, or unreported). Perioperative complications were identified using a series ICD-9-CM diagnosis and procedural codes (Table 1). Disposition status was re-categorized as: (1) routine discharge (patient's home or residence), (2) death, and (3) other-than-routine. Other-than-routine included any of the following: acute care within admitting hospital, other care within admitting hospital, long-term care within admitting hospital, acute care at another hospital, other care (not including long-term care) at another hospital, long-term care at another facility, residential care facility, prison/jail, left against medical advice, and home health service.

2.3. Statistical analysis

All variables were examined for whether they had a normal distribution. Mean ± standard deviation (SD) was calculated wherever appropriate. Nonparametric tests were used and median was calculated for age, total charges, and length of stay, which had positively skewed distributions. Linear regression analysis was used to evaluate the changes over time. Chi square test was used for analyzing categorical variables. Fisher's exact test was used where Chi

Table 1
List of ICD-9-CM diagnosis and procedural codes used to define complications.

Complications	ICD-9-CM codes
Venous thrombosis	453.4–453.42, 453.8, 453.9
Transfusion of packed erythrocytes	99.04
Hematoma/seroma	998.1–998.13
Seizure	436, 780.3–780.39
Wound infection/fistula/abscess	478.2–478.29, 478.79, 682.1, 686.9, 998.5–998.6
Pulmonary embolism	415.1–415.19
Pneumonia	480–486
Acute myocardial infarction	410–410.92
Sepsis	038–038.9, 995.9–995.94, 999.3–999.39
Postoperative shock	998.0
Airway compromise/ reintubation	96.7–96.72