Outpatient versus Inpatient Primary Cleft Lip and Palate Surgery: Analysis of Early Complications

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Background: Fiscal constraints are driving shorter hospital lengths of stay. Outpatient primary cleft lip surgery has been shown to be safe, but outpatient primary cleft palate surgery remains controversial. This study evaluates outcomes following outpatient versus inpatient primary cleft lip and palate surgery.

Methods: The American College of Surgeons National Surgical Quality Improvement Program Pediatric database was used to identify patients undergoing primary cleft lip and palate surgery between 2012 and 2015. Patient clinical factors and 30-day complications were compared for outpatient versus inpatient primary cleft lip and palate surgery. Univariate and multivariate analyses were performed.

Results: Three thousand one hundred forty-two patients were included in the primary cleft lip surgery group and 4191 in the primary cleft palate surgery group. Patients in the cleft lip surgery group with structural pulmonary abnormalities had a significantly longer hospital length of stay (β, 4.94; $p = 0.001$). Patients undergoing outpatient surgery had a significantly higher risk of superficial (OR, 1.99; $p = 0.01$) and deep wound dehiscence (OR, 2.22; $p = 0.01$), and were at a significantly lower risk of reoperation (OR, 0.36; $p = 0.04$) and readmission (OR, 0.52; $p = 0.02$).

Conclusions: Outpatient primary cleft lip surgery is safe and has a complication profile similar to that of inpatient surgery. Outpatient primary cleft palate surgery is common practice in many U.S. hospitals and has a significantly higher rate of wound complications, and lower rates of reoperation and readmission. In properly selected patients, outpatient palatoplasty can be performed safely. (*Plast. Reconstr. Surg.* 141: 697e, 2018.)

CLINICAL QUESTION/LEVEL OF EVIDENCE: Therapeutic, III.

Cleft lip and palate anomalies are the most common birth defects affecting the face.[1] Fiscal constraints are becoming more significant in surgical delivery, including cleft surgery, which remains a significant source of health care expenditures. The search for determinants of cost in cleft surgery resulted in an improved understanding of expenditure patterns[2] and the nature of postoperative complications,[3] with resultant decrease in postoperative hospital length of stay and increase in procedures performed in the outpatient setting.[4]

Outpatient cleft lip surgery has been shown to be safe[5–7] and cost effective[8] in appropriately selected patients. Outpatient cleft palate surgery, in contrast, remains a controversial topic with limited data. Furthermore, available studies evaluating outpatient cleft lip surgery are limited by a small number of patients[5–7,9] or focus on the financial aspects associated with the procedure without emphasizing postoperative outcomes.[8]

The purpose of our study was to evaluate 30-day postoperative surgical outcomes and

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Received for publication September 18, 2017; accepted November 21, 2017.

DOI: 10.1097/PRS.0000000000004293

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

complications associated with outpatient primary cleft lip surgery and primary cleft palate surgery and identify risk factors associated with greater complications and length of stay. For the purpose of the study, we have evaluated a national cohort of patients from the American College of Surgeons National Surgical Quality Improvement Program Pediatric database. To our knowledge, our study is the first and the largest to analyze outcomes following primary cleft lip and primary cleft palate surgery.

PATIENTS AND METHODS

Database and Patient Population

Data were extracted from the American College of Surgeons National Surgical Quality Improvement Program Pediatric Participant Use Files for the years 2012 to 2015. The American College of Surgeons National Surgical Quality Improvement Program Pediatric is a prospective, risk-adjusted, clinical outcomes–based registry that records demographic, preoperative, perioperative, and 30-day postoperative deidentified patient information.[10] The database is compliant with the Health Insurance Portability and Accountability Act of 1996 and is exempt from institutional review board review. This study was conducted in accordance with the principles outlined in the Declaration of Helsinki.

A retrospective review of the American College of Surgeons National Surgical Quality Improvement Program Pediatric database was performed for the following Current Procedure Terminology codes: 40700 (plastic repair of cleft lip/nasal deformity; primary, partial or complete, unilateral), 40701 (plastic repair of cleft lip/nasal deformity; primary bilateral, one-stage procedure), 40702 (plastic repair of cleft lip/nasal deformity; primary bilateral, one of two stages), 42200 (palatoplasty for cleft palate, soft and/or hard palate only), and 42205 (palatoplasty for cleft palate, with closure of alveolar ridge; soft tissue only) (Fig. 1). The primary cleft lip surgery group included patients undergoing procedures with Current Procedure Terminology codes 40700, 40701, and 40702, whereas the primary cleft palate surgery group covered the Current Procedure Terminology codes 42200 and 42205. Current Procedure Terminology codes for revision cleft surgery and primary cleft palate surgery involving bone grafting were not included in the review to maintain a homogenous patient population.

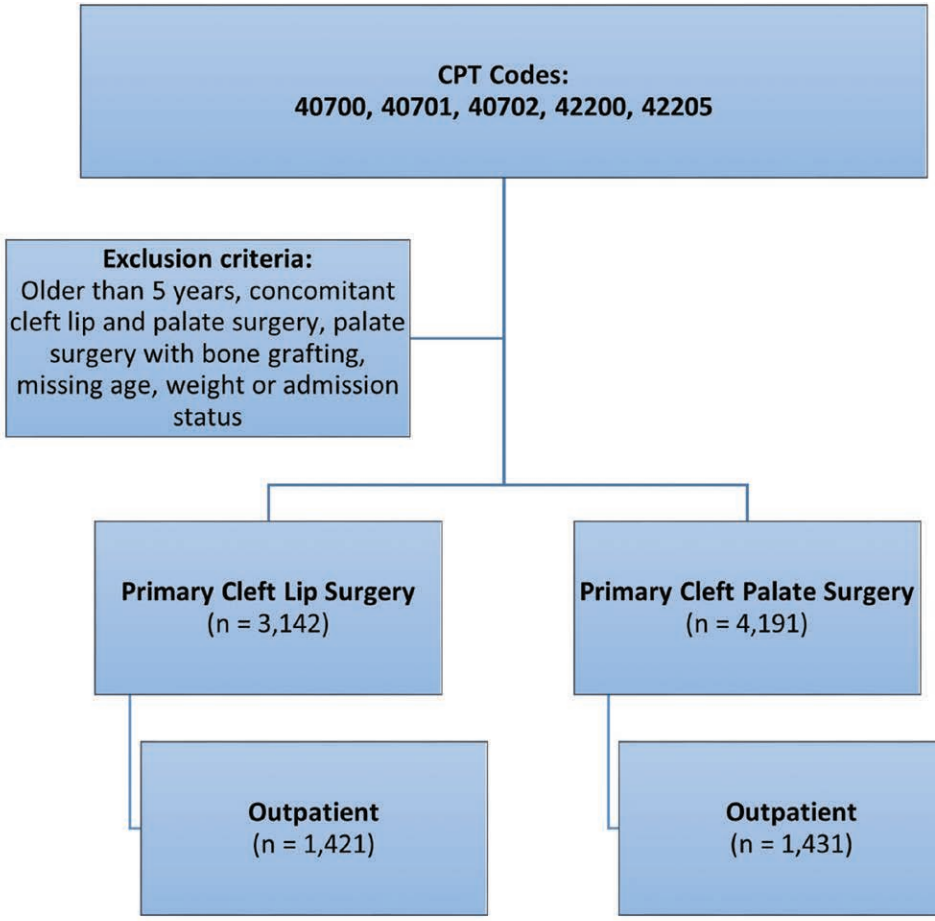
Study Design

Patients older than 5 years; patients undergoing concomitant cleft lip and palate surgery or palatoplasty with bone grafting; and cases without age, weight, or admission status information were excluded from analysis (Fig. 1). Review of the database for the selected Current Procedure Terminology codes identified 3142 patients who underwent primary cleft lip surgery and 4191 patients who underwent primary cleft palate surgery. The variable of interest was admission status (outpatient versus inpatient surgery). Patient preoperative demographic data, clinical factors, and medical comorbidities at the time of surgery were collected for all patients (Table 1). We also reviewed frequently performed concurrent procedures with primary cleft lip and primary cleft palate surgery (Table 2). Patient preoperative demographic data, clinical factors, and medical comorbidities at the time of surgery were also stratified and analyzed based on admission status (Table 3). Preoperative factors with predominantly missing data were excluded.

Primary surgical outcomes of the study included wound complications (i.e., superficial surgical-site infection, deep incisional surgical-site infection, deep space surgical-site infection, superficial wound and deep wound dehiscence) and all-cause reoperation and readmission rates. Secondary surgical outcomes evaluated included 30-day mortality, cardiac arrest requiring cardiopulmonary resuscitation, transfusion requirement, reintubation rates, hospital length of stay (in days), and operative time (in minutes). Postoperative medical complications evaluated included the following: pneumonia, urinary tract infection, deep vein thrombosis, sepsis, nutritional support at 30 days or discharge, oxygen support at 30 days or discharge, and duration of mechanical ventilation (in days).

Statistical Analysis

Continuous variables are reported as mean ± SD; categorical variables are reported as frequency and percentage to their corresponding groups. Univariate analysis was performed using chi-square or Fisher's exact test ($n < 10$) for categorical variables, and t tests for continuous variables (Table 4). Statistical significance was reached with values of $p \leq 0.05$. Multivariate logistic and linear regression analyses were performed to control for potential confounders (Table 5).



Surgery Group	CPT code	CPT code description	n (%)
Primary cleft lip surgery (n = 3,142)	40700	Plastic repair of cleft lip/nasal deformity; primary, partial or complete, unilateral	2467 (78.5)
	40701	Plastic repair of cleft lip/nasal deformity; primary bilateral, 1-stage procedure	523 (16.7)
	40702	Plastic repair of cleft lip/nasal deformity; primary bilateral, 1 of 2 stages	152 (4.8)
Primary cleft palate surgery (n = 4,191)	42200	Palatoplasty for cleft palate, soft and/or hard palate only	3968 (94.7)
	42205	Palatoplasty for cleft palate, with closure of alveolar ridge; soft tissue only	223 (5.3)

Fig. 1. Study design and Current Procedure Terminology (*CPT*) codes/description.

Variables with significant differences between the inpatient and outpatient groups were included in our regression model. Admission status and all significant outcomes were also included in our model. All the analyses described were performed for both primary cleft lip and primary cleft palate surgery groups. Data analysis was performed using IBM SPSS Version 21.0 (IBM Corp., Armonk, N.Y.).

RESULTS

Review of the listed Current Procedural Terminology codes and application of our exclusion criteria identified 3142 patients in the primary cleft lip surgery group and 4191 patients in the primary cleft palate surgery group eligible for analysis (Fig. 1). The majority of patients in the primary cleft lip surgery (54.8 percent) and in the primary cleft palate surgery (65.9 percent) groups were inpatients (Table 1). Plastic surgeons were the most frequent providers performing primary cleft lip surgery (85.1 percent) and primary cleft palate surgery (80.3 percent), followed by otolaryngologists for both procedures (Table 1). The most commonly performed concurrent procedures in the primary cleft lip surgery group included cleft lip rhinoplasty, including columellar lengthening involving the nasal tip only (24.2 percent) and tympanostomy tube insertion (4.7 percent), whereas gingivoperiosteoplasty and tissue grafting were each performed in 1.2 percent of patients. Tympanostomy tube insertion (17.1 percent) was the most commonly performed

Table 1. Preoperative Patient Characteristics, Clinical Factors, and Medical Comorbidities

Variable	Primary Cleft Lip Surgery (%)	Primary Cleft Palate Surgery (%)
No.	3142	4191
Mean age at surgery ± SD, days	200.8 ± 223.3	485.5 ± 319.2
Mean height at surgery, cm	63.6 ± 8.6	50.6 ± 84.7
Mean weight at surgery, kg	7.0 ± 3.2	9.6 ± 3.8
Male	1979 (63.0)	2204 (52.6)
Admission status		
Inpatient	1721 (54.8)	2760 (65.9)
Outpatient	1421 (45.2)	1431 (34.1)
Congenital abnormalities	345 (11.0)	995 (23.7)
Operation in the past 30 days	3 (0.1)	3 (0.2)
ASA class 3 or higher	293 (9.3)	667 (15.9)
Race		
American Indian or Alaska Native	27 (0.9)	21 (0.5)
Asian	197 (6.3)	382 (9.1)
Black or African American	263 (8.4)	330 (7.9)
Native Hawaiian or other Pacific Islander	16 (0.5)	25 (0.6)
White	2179 (69.4)	2905 (69.3)
Anesthesia		
General	3135 (99.8)	4186 (99.9)
Regional	1 (0.1)	—
Surgical specialty		
Plastic surgery	2672 (85.1)	3458 (80.3)
Otolaryngology	440 (14.0)	781 (18.7)
Pediatric surgery	9 (0.5)	12 (0.4)
Case status		
Elective	3129 (99.6)	4173 (99.6)
Urgent	3 (0.1)	3 (0.1)
Emergent	10 (0.3)	15 (0.4)
Wound classification		
Clean	191 (6.1)	171 (4.1)
Clean/contaminated	2935 (93.4)	3988 (95.2)
Contaminated	9 (0.3)	23 (0.5)
Dirty/infected	7 (0.2)	9 (0.2)
Comorbidities		
Neurologic		
Structural CNS abnormality	89 (2.8)	179 (4.3)
Stroke	4 (0.1)	26 (0.6)
Respiratory		
Ventilator dependence	14 (0.4)	34 (0.8)
Asthma	36 (1.1)	143 (3.4)
Chronic lung disease	37 (1.2)	81 (1.9)
Oxygen dependence	24 (0.8)	62 (1.5)
Structural pulmonary abnormality	152 (4.8)	542 (12.9)
Tracheostomy	28 (0.9)	101 (2.4)
Cardiovascular		
Cardiac risk factors	356 (11.3)	566 (13.5)
Previous cardiac surgery	81 (2.6)	162 (3.9)
Gastrointestinal		
Esophageal/gastric or intestinal disease	443 (14.1)	609 (14.5)
Nutritional support	145 (4.6)	372 (8.9)
Hematologic		
History of hematologic disorder	21 (0.7)	42 (1.0)
Metabolic		
Immunosuppression	3 (0.1)	8 (0.2)
Steroid use	15 (0.5)	36 (0.9)
Weight loss or failure to thrive	50 (1.6)	100 (2.4)

ASA, American Society of Anesthesiologists; CNS, central nervous system.

concurrent procedure in the primary cleft palate surgery group (Table 2).

In the primary cleft lip surgery cohort, there was a significant difference in age (182.9 ± 187.4 days versus 222.6 ± 258.7 days; $p < 0.001$), height (63.1 ± 7.9 cm versus 64.3 ± 9.2 cm; $p < 0.001$), weight (6.9 ± 3.5 kg versus 7.1 ± 3.2 kg; $p < 0.03$), American Society of Anesthesiologists class 3 or higher (10.6 percent versus 7.8 percent; $p < 0.03$), race ($p < 0.001$), and surgical specialty ($p < 0.001$) between the inpatient and outpatient groups, respectively (Table 3). Within the primary cleft lip surgery cohort, the rates of preoperative medical comorbidities such as history of structural central nervous system abnormality (3.4 percent versus 2.1 percent; $p = 0.03$), oxygen dependence (1.1 percent versus 0.4 percent; $p = 0.02$), structural pulmonary abnormality (6.0 percent versus 3.9 percent; $p = 0.01$), cardiac risk factors (12.9 percent versus 9.4 percent; $p = 0.002$), esophageal/gastric or intestinal disease (15.3 percent versus 12.6 percent; $p = 0.03$), nutritional support (5.3 percent versus 3.8 percent; $p = 0.05$), steroid use (0.7 percent versus 0.2 percent; $p = 0.05$), and weight loss or failure to thrive (2.1 percent versus 1.0 percent; $p = 0.03$) were significantly higher in the inpatient group. Within the primary cleft palate surgery group, there was a significant difference in age (473.2 ± 303.1 days versus 509.3 ± 346.9 days; $p < 0.001$), height (49.8 ± 85.2 cm versus 52.2 ± 83.9 cm; $p = 0.01$), frequency of congenital abnormalities (25.0 percent versus 21.2 percent; $p = 0.01$), race ($p < 0.001$), and surgical specialty ($p < 0.001$) between the inpatient and outpatient groups, respectively. Within the primary cleft palate surgery cohort, analysis of preoperative medical comorbidities showed a significantly higher rate of history of stroke (1.0 percent versus 0.3 percent; $p = 0.02$), asthma (3.8 percent versus 2.6 percent; $p = 0.03$), oxygen dependence (1.8 percent versus 0.8 percent; $p = 0.01$), cardiac risk factors (14.4 percent versus 11.7 percent; $p = 0.02$), previous cardiac surgery (4.3 percent versus 2.9 percent; $p = 0.02$), and esophageal/gastric or intestinal disease (15.3 percent versus 13.0 percent; $p = 0.04$) in the inpatient group (Table 3).

Univariate analysis revealed that patients undergoing outpatient primary cleft lip surgery had an expected significantly shorter hospital length of stay (0.7 ± 0.4 day versus 1.8 ± 7.1 days; $p < 0.001$) and duration of mechanical ventilation (0.01 ± 0.01 day versus 0.06 ± 0.1 day; $p = 0.03$) than inpatients (Table 4). Patients who underwent outpatient primary cleft palate surgery had

Table 2. Frequently Performed Concurrent Procedures

Surgery Group and CPT Code	CPT Code Description	No. (%)
PCLS		
30460	Cleft lip rhinoplasty including columellar lengthening, tip only	761 (24.2)
69436	Tympanostomy tube insertion	149 (4.7)
30462	Cleft lip rhinoplasty including columellar lengthening, tip, septum, osteotomies	77 (2.5)
20926	Tissue grafts, other	37 (1.2)
41872	Gingivoperiosteoplasty	37 (1.2)
42260	Repair of nasolabial fistula	34 (1.1)
30400	Rhinoplasty, primary, complete, external parts, including bony pyramid, lateral and alar cartilages, and/or elevation of the nasal tip	27 (0.9)
31231	Diagnostic nasal endoscopy	27 (0.9)
30520	Septoplasty or submucous resection, with or without cartilage scoring, contouring or replacement with graft	21 (0.7)
41874	Alveoloplasty	21 (0.7)
PCPS		
69436	Tympanostomy tube insertion	715 (17.1)
42235	Repair of anterior palate, including vomer flap	296 (7.1)
42281	Insertion palatal prosthesis	63 (1.5)
31231	Diagnostic nasal endoscopy	38 (0.8)
69421	Myringotomy including aspiration or eustachian tube inflation	29 (0.7)
31622	Bronchoscopy	23 (0.5)
21210	Graft bone nasal, maxillary or molar areas (includes obtaining graft)	21 (0.5)
31526	Laryngoscopy	21 (0.5)
20926	Tissue grafts, other	16 (0.4)
30462	Rhinoplasty for congenital deformity secondary to congenital cleft lip and/or palate including columellar lengthening; tip, septum, osteotomies	10 (0.2)

CPT, Current Procedural Terminology; PCLS, primary cleft lip surgery; PCPS, primary cleft palate surgery.

significantly higher rates of superficial wound dehiscence (3.5 percent versus 2.0 percent; p = 0.01) and deep wound dehiscence (2.2 percent versus 1.0 percent; p = 0.003), and significantly lower rates of reoperation (0.4 percent versus 1.2 percent; p = 0.02), readmission (1.5 percent versus 3.2 percent; p = 0.01), reintubation (0.1 percent versus 0.7 percent; p = 0.01), and nutritional (0.6 percent versus 4.5 percent; p = 0.001) or oxygen (2.3 percent versus 5.2 percent; p = 0.03) support at 30 days postoperatively or discharge, and a significantly shorter hospital length of stay (0.9 ± 0.2 day versus 1.9 ± 3.4 days; p < 0.001) relative to inpatients (Table 4).

Multivariate regression was performed for all outcomes with significant differences between inpatient and outpatient groups on univariate analysis within the primary cleft lip and primary cleft palate surgery cohorts. Patients in the primary cleft lip surgery group with underlying structural pulmonary abnormality had a significantly longer hospital length of stay (β, 4.94; 95 percent CI, 2.21 to 7.66; p = 0.001) (Table 5). Duration of mechanical ventilation in the primary cleft lip surgery group was not significantly associated with any variables in our regression model, including outpatient surgery status. In the primary cleft palate surgery group, patients undergoing outpatient surgery were at a significantly higher risk of superficial wound dehiscence (OR, 1.99; 95 percent CI, 1.22 to 3.24; p = 0.01) and deep wound dehiscence (OR, 2.22; 95 percent CI, 1.25 to 3.95; p = 0.01) and at a significantly lower risk of reoperation (OR, 0.36; 95 percent CI, 0.14 to 0.96; p = 0.04) and readmission (OR, 0.52; 95 percent CI, 0.31 to 0.88; p = 0.02) compared with inpatients. Cardiac risk factors in primary cleft palate surgery patients significantly increased the risk of reoperation (OR, 9.25; 95 percent CI, 1.38 to 61.82; p = 0.02). Patients with esophageal, gastric, or intestinal disease (OR, 1.78; 95 percent CI, 1.07 to 2.96; p = 0.03) and congenital abnormalities (OR, 1.88; 95 percent CI, 1.18 to 2.99; p = 0.01) in the primary cleft palate surgery group were at increased risk of readmission to the hospital (Table 5).

DISCUSSION

Health care expenditure is expected to reach 20 percent of the U.S. Gross Domestic Product in 2020.[11] Similar financial burdens worldwide are changing the global landscape of patient surgical care,[12] including cleft surgery. The mean health care expenditure per child with an orofacial cleft is estimated to be $22,642 compared with $3900 for an unaffected child.[2] Median health care cost in the first year of life for patients with isolated unilateral cleft lip is estimated to be $13,013,[13] and a value analysis showed that overnight admission to the hospital following cleft lip surgery

Table 3. Preoperative Patient Characteristics, Clinical Factors, and Medical Comorbidities Stratified by Admission Status

Variable	Primary Cleft Lip Surgery (n = 3142)			Primary Cleft Palate Surgery (n = 4191)		
	Inpatient (n = 1721) (%)	Outpatient (n = 1421) (%)	p	Inpatient (n = 2760) (%)	Outpatient (n = 1431) (%)	p
Mean age at surgery ± SD, days	182.9 ± 187.4	222.6 ± 258.7	<0.001*	473.2 ± 303.1	509.3 ± 346.9	<0.001*
Mean height at surgery ± SD, cm	63.1 ± 7.9	64.3 ± 9.2	<0.001*	49.8 ± 85.2	52.2 ± 83.9	0.39
Weight at surgery ± SD, kg	6.9 ± 3.5	7.1 ± 3.2	0.03*	9.6 ± 3.8	9.9 ± 4.0	0.01*
Male	1077 (62.6)	902 (63.5)	0.60	1428 (51.8)	776 (54.2)	0.13
Congenital abnormalities	203 (11.8)	142 (10.0)	0.11	691 (25.0)	304 (21.2)	0.01*
Operation in the past 30 days	2 (0.1)	1 (0.1)	0.86	3 (0.2)	1 (0.2)	0.72
ASA class 3 or higher	182 (10.6)	111 (7.8)	0.03*	445 (16.1)	222 (15.6)	0.63
Race						
American Indian or Alaska Native	19 (1.1)	8 (0.6)		19 (0.7)	2 (0.1)	
Asian	99 (5.8)	98 (6.9)		251 (9.1)	131 (9.2)	
Black or African American	160 (9.3)	103 (7.2)		237 (8.6)	93 (6.5)	
Native Hawaiian or other Pacific Islander	9 (0.5)	7 (0.5)		18 (0.7)	7 (0.5)	
White	1143 (66.4)	1036 (72.9)	<0.001*	1828 (66.2)	1077 (75.3)	<0.001*
Anesthesia						
General	1715 (99.7)	1420 (99.9)		2756 (99.9)	1430 (99.9)	
Regional	1 (0.1)	0 (0)	0.40	—		0.72
Surgical specialty						
Plastic surgery	1546 (89.8)	1126 (79.3)		2278 (82.5)	1087 (75.9)	
Otolaryngology	157 (9.1)	283 (20.0)		451 (16.3)	330 (23.1)	
Pediatric surgery	9 (0.5)	10 (0.7)	<0.001*	12 (0.4)	8 (0.6)	<0.001*
Case status						
Elective	1715 (99.7)	1414 (99.5)		2752 (99.7)	1421 (99.3)	
Urgent	5 (0.3)	5 (0.4)		6 (0.2)	9 (0.6)	
Emergent	1 (0.1)	2 (0.1)	0.72	2 (0.1)	1 (0.1)	0.11
Wound classification						
Clean	91 (5.3)	100 (7)		101 (3.7)	70 (4.9)	
Clean/contaminated	1619 (94.1)	1316 (92.6)		2637 (95.5)	1351 (94.4)	
Contaminated	6 (0.3)	3 (0.2)		15 (0.5)	8 (0.6)	
Dirty/infected	5 (0.3)	2 (0.1)	0.15	7 (0.3)	2 (0.1)	0.24
Comorbidities						
Neurologic						
Structural CNS abnormality	59 (3.4)	30 (2.1)	0.03*	129 (4.7)	5 (3.5)	0.07
Stroke		—		23 (1.0)	3 (0.3)	0.02*
Respiratory						
Ventilator dependence	9 (0.5)	5 (0.4)	0.47	23 (0.8)	11 (0.8)	0.83
Asthma	20 (1.2)	16 (1.1)	0.93	106 (3.8)	37 (2.6)	0.03*
Chronic lung disease	24 (1.4)	13 (0.9)	0.22	58 (2.1)	23 (1.6)	0.27
Oxygen dependence	19 (1.1)	5 (0.4)	0.02*	51 (1.8)	11 (0.8)	0.01*
Structural pulmonary abnormality	103 (6.0)	55 (3.9)	0.01*	350 (12.7)	192 (13.4)	0.50
Tracheostomy	19 (1.1)	9 (0.6)	0.16	70 (2.5)	31 (2.2)	0.46
Cardiovascular						
Cardiac risk factors	222 (12.9)	134 (9.4)	0.002*	398 (14.4)	168 (11.7)	0.02*
Previous cardiac surgery	53 (3.1)	28 (2)	0.05*	120 (4.3)	42 (2.9)	0.02*
Gastrointestinal						
Esophageal/gastric or intestinal disease	264 (15.3)	179 (12.6)	0.03*	423 (15.3)	186 (13.0)	0.04*
Nutritional support	91 (5.3)	54 (3.8)	0.05*	256 (9.3)	116 (8.1)	0.21
Hematologic						
History of hematologic disorder	13 (0.8)	8 (0.6)	0.51	33 (1.2)	9 (0.6)	0.08
Metabolic						
Immunosuppression	2 (0.1)	1 (0.1)	0.57	7 (0.3)	1 (0.1)	0.2
Steroid use	12 (0.7)	3 (0.2)	0.05*	29 (1.1)	7 (0.5)	0.06
Weight loss or failure to thrive	36 (2.1)	14 (1.0)	0.03*	73 (3.8)	27 (2.7)	0.13

ASA, American Society of Anesthesiologists; CNS, central nervous system.
*Statistically significant.

costs approximately $2930.[8] These significant expenses led to an extensive search for determinants of expenditure in cleft surgery, with a major emphasis on hospital length of stay.[8,9,13] Studies have suggested that outpatient cleft lip surgery could reduce hospital-associated costs by more

Table 4. Univariate Analysis of Surgical Outcomes and Medical Complications Stratified by Admission Status

Variable	Primary Cleft Lip Surgery (n = 3142)			Primary Cleft Palate Surgery (n = 4191)		
	Inpatient (n = 1721) (%)	Outpatient (n = 1421) (%)	p	Inpatient (n = 2760) (%)	Outpatient (n = 1431) (%)	p
Primary surgical outcomes						
Wound complications						
Superficial incisional SSI	7 (0.4)	5 (0.4)	0.80	2 (0.1)	1 (0.1)	0.98
Deep incisional SSI	1 (0.1)	3 (0.2)	0.23	2 (0.1)	0 (0)	0.31
Deep space SSI	1 (0.1)	0 (0)	0.36	0 (0.0)	2 (0.1)	0.06
Superficial wound dehiscence	17 (1)	16(1.1)	0.57	44 (2.0)	40 (3.5)	0.01*
Deep wound dehiscence	5 (0.3)	6 (0.4)	0.53	28 (1.0)	31 (2.2)	0.003*
Reoperation	17 (1)	8 (0.6)	0.18	32 (1.2)	6 (0.4)	0.02*
Readmission	85 (4.9)	48 (3.4)	0.06	87 (3.2)	21 (1.5)	0.01*
Secondary surgical outcomes						
30-day mortality	2 (0.1)	1 (0.1)	0.68		—	
Cardiac arrest requiring CPR	2 (0.1)	1 (0.1)	0.68		—	
Transfusion requirement	1 (0.1)	1 (0.1)	0.89	5 (0.2)	1 (0.1)	0.37
Reintubation	5 (0.3)	3 (0.2)	0.66	18 (0.7)	1 (0.1)	0.01*
Mean hospital length of stay ± SD, days	1.8 ± 7.1	0.7 ± 0.4	<0.001*	1.9 ± 3.4	0.9 ± 0.2	<0.001*
Mean operative time ± SD, min	124.3 ± 61.5	121.1 ± 61.0	0.15	130.5 ± 68.7	127.4 ± 65.0	0.32
Medical complications						
Pneumonia	3 (0.2)	4 (0.3)	0.59	7 (0.3)	4 (0.3)	0.79
UTI	5 (0.3)	1 (0.1)	0.16	1 (0.0)	0 (0)	0.47
DVT	1 (0.1)	0 (0)	0.36		—	
Sepsis	2 (0.1)	0 (0)	0.20	3 (0.1)	1 (0.1)	0.70
Nutritional support at 30 days or discharge	10 (0.6)	5 (0.4)	0.21	31 (4.5)	2 (0.6)	0.001*
Oxygen support at 30 days or discharge	11 (0.7)	4 (0.3)	0.13	36 (5.2)	8 (2.3)	0.03*
Mean duration of mechanical ventilation ± SD, days	0.06 ± 0.1	0.01 ± 0.01	0.03*	0.12 ± 1.4	0.1 ± 0.1	0.72

SSI, surgical-site infection; CPR, cardiopulmonary resuscitation; UTI, urinary tract infection; DVT, deep venous thrombosis.
*Statistically significant.

Table 5. Multivariate Analysis of Significant Outcomes

Surgery Group	Variable	Outcomes		
Primary cleft lip surgery	Structural pulmonary abnormality	**Hospital Length of Stay**		
		β Coefficient	**95% CI**	***p***
		4.94	2.21–7.66	0.001*
		Hospital Length of Stay		
		β Coefficient	**95% CI**	***p***
Primary cleft palate surgery	Oxygen dependence	1.26	0.33–2.19	0.01*
		Superficial Wound Dehiscence		
		OR	**95% CI**	***p***
	Outpatient surgery	1.99	1.22–3.24	0.01*
		Deep Wound Dehiscence		
		OR	**95% CI**	***p***
	Outpatient surgery	2.22	1.25–3.95	0.01*
		Reoperation		
		OR	**95% CI**	***p***
	Inpatient surgery	2.38	1.04–7.14	0.04*
	Cardiac risk factors	9.25	1.38–61.82	0.02*
		Readmission		
		OR	**95% CI**	***p***
	Inpatient surgery	1.92	1.14–3.23	0.02*
	Esophageal/gastric or intestinal disease	1.78	1.07–2.96	0.03*
	Congenital abnormalities	1.88	1.18–2.99	0.01*

than 10 percent[13] and lead to an average savings of $4261 per patient, with resultant national savings of $8,765,183 per year.[9] Optimal patient health care value remains the premier framework for medical and surgical performance improvement and takes into account balancing of cost and outcomes.[14] Our study uses the American College of Surgeons National Surgical Quality Improvement Program Pediatric database to examine the outcomes component in patients undergoing

primary cleft lip and palate surgery in the outpatient versus inpatient setting.

Outpatient cleft lip surgery is well described in the literature.[4–7,9,15] The percentage of patients undergoing outpatient primary cleft lip surgery in our study was 45.2 percent and is consistent with reports of an increasing number of procedures being performed in the outpatient setting.[4] Hopper et al. in 2009[4] and Paine et al. in 2013[9] reported outpatient primary cleft lip surgery percentages of 29.0 percent and 27.9 percent, respectively. This is a dramatic shift from the minimum 3-day admission following primary cleft lip surgery that Lees and Pigott suggested based on the finding that the majority of life-threatening complications occurred within 48 hours postoperatively.[3] These complications consisted mostly of respiratory adverse events and bleeding.[3]

Several reports have suggested that patients with diagnosed syndromes and cardiac or respiratory comorbidities should undergo inpatient primary cleft lip surgery.[4,5,7] Similarly, a study from the Children's Hospital of Pennsylvania defined predictors of ambulatory primary cleft lip surgery failure using regression modeling and receiver operating characteristic curves.[9] These predictors included American Society of Anesthesiologists class greater than 2, low birth weight, bilateral cleft lip and palate surgery, central nervous system abnormality, existing syndromes, and congenital abnormalities. The inpatient primary cleft lip surgery cohort in our study consisted of patients who were significantly younger, weighed less at surgery, and were more likely to be American Society of Anesthesiologists class 3 or higher. They also had significantly higher rates of structural central nervous system abnormalities, oxygen dependence, structural pulmonary abnormalities, cardiac risk factors, esophageal/gastric or intestinal diseases, nutritional support, and weight loss or failure to thrive than the outpatient primary cleft lip surgery group. Paine et al. previously identified congenital abnormalities, ventilator dependence, oxygen dependence, presence of tracheostomy, cardiac risk factors, central nervous system abnormalities, American Society of Anesthesiologists class 3 or higher, esophageal/gastric or intestinal disease, and nutritional support as risk factors for overall 30-day complications following primary cleft lip surgery.[16] These risk factors were determined based on unadjusted analyses, and the complications were not stratified into surgical and medical complications. Our study did not identify any significant differences in surgical and medical complications between the inpatient and outpatient primary cleft lip surgery groups after multivariate regression controlling for potential confounders. Patients with underlying structural pulmonary abnormalities were significantly more likely to have a longer hospital length of stay, as suggested by previous studies.[4,5,7]

Although the safety of outpatient primary cleft palate surgery remains controversial, many studies have evaluated the determinants associated with a prolonged hospital length of stay following the procedure.[3,17] Wood et al. evaluated the need for routine admission following primary cleft palate surgery in 100 consecutive cases.[18] All 100 patients had a hospital length of stay longer than 23 hours, with predictors of prolonged stay including female sex, syndromic diagnosis, longer operative and anesthetic duration, and longer time to postoperative oral intake. Interestingly, of 4191 primary cleft palate surgery cases, 34.1 percent were reportedly performed on an outpatient basis in our study. This surprising finding that one-third of cleft palate surgery in the United States is performed on an outpatient basis suggests that the frequency of outpatient palatoplasty is much higher than previously thought.

Patients undergoing inpatient primary cleft palate surgery had a worse comorbidity profile than their outpatient counterparts, with significantly higher rates of congenital abnormalities, stroke, asthma, oxygen dependence, cardiac risk factors, history of cardiac surgery, and esophageal/gastric or intestinal disease. Multivariate analysis adjusting for confounders showed that patients undergoing outpatient primary cleft palate surgery are almost twice as likely to develop superficial and deep wound dehiscence than inpatients. This could be related to patients traumatizing their fresh wound when they are in a less monitored setting at home and may be consistent with a study by Lees and Pigott,[3] which showed that the majority of wound complications associated with primary cleft palate surgery occurred on or after the third postoperative day. Parent nursing education regarding wound care might also be limited before patient hospital discharge in outpatient cases, which might lead to parent underpreparedness in caring for and protecting palatal wounds compared with parents who stay overnight in the hospital. Patients undergoing inpatient primary cleft palate surgery were almost twice as likely to have a subsequent operation and readmission within 30 postoperative days, which could potentially be explained by the higher comorbidity profile observed in that particular group.

The rates of cardiac risk factors (13.5 percent) and congenital abnormalities (23.7 percent) in the entire primary cleft palate surgery cohort are close to the rates of 15.0 percent[19] and 22.0 percent[20] reported in the literature. Cardiac risk factors were an independent risk factor for reoperation in patients undergoing primary cleft palate surgery in our study. Cardiac anomalies have been previously associated with complications following surgery for cleft palate and velopharyngeal insufficiency,[21] with some studies suggesting delayed cleft palate repair in patients with underlying cardiac conditions.[19,22] Esophageal/gastric or intestinal disease and congenital abnormalities were independent risk factors for all-cause readmission to the hospital. Inherent limitations to the American College of Surgeons National Surgical Quality Improvement Program Pediatric database, however, prevented us from determining the causes of readmission and reoperation in the primary cleft palate surgery group. Although this study does not provide data in clear support of outpatient primary cleft palate surgery, we demonstrate that outpatient primary cleft palate surgery is practiced more commonly than current literature suggests. Furthermore, it appears that in properly selected patients, palatoplasty can be safely performed as an outpatient procedure.

There are other secondary observations that can be gleaned from this study. First, the ages of cleft lip and palate repair in this study are almost 7 months and 1 year 4 months, respectively. These ages are much older than those at major cleft centers, which commonly perform cleft lip repair at approximately 3 months of age and palate repair by 1 year. Although it is not possible to determine which patients underwent cleft lip repair with a multidisciplinary team, we hypothesize that this relatively older age at primary repair may be attributable to patients undergoing cleft surgery in a community setting where protocol-driven care may be less prevalent. More concerning is the rather low rate of concurrent myringotomy tube placement (17 percent), suggesting that many patients with a cleft are not undergoing coordinated management with a pediatric otolaryngologist.

The American College of Surgeons National Surgical Quality Improvement Program Pediatric database and our study have several limitations. The database does not include detailed hospital definitions of outpatient surgery, type of palatal defect, surgical technique, wound descriptions, functional outcomes, and outcomes beyond 30 postoperative days. Furthermore, perinatal history and history of genetic diagnoses are not included in the database. The duration of hospital length of stay and mechanical ventilation are coded by number of days rather than hours, which prevented us from determining their exact duration. Another limitation is the inability to determine the exact temporal relationship of postoperative outcomes, such as time to wound complication. The reoperation and readmission rates reported in the database are overall, all-cause rates, which unfortunately prevented us from determining the exact cause of reoperation or readmission. Although we demonstrate that outpatient palatoplasty can be safely performed in properly selected patients, the structure of the American College of Surgeons National Surgical Quality Improvement Program Pediatric database limits our ability to identify the variables associated with safe outpatient cleft palate repair (such as Veau classification and palatoplasty technique) and the efficacy of palatoplasty. These issues are areas of interest and future study. Several variables had predominantly missing data; those with particular relevance to our study were details of readmissions and reoperations. Despite these limitations, our study is the largest reported cohort of patients undergoing primary cleft lip and primary cleft palate surgery and offers valuable insight into admission patterns, surgical specialties performing these procedures, frequently performed concurrent procedures, 30-day postoperative outcomes, and risk factors.

CONCLUSIONS

Outpatient primary cleft lip surgery is safe and has a perioperative complication profile similar to that of inpatient surgery. Outpatient primary cleft palate surgery is a common practice in many U.S. hospitals and has a significantly higher rate of wound complications and lower rates of reoperation and readmission. In properly selected patients, primary palatoplasty can be safely performed as an outpatient procedure. Surgeon clinical judgment and evaluation of overall patient condition are critical when selecting patients for outpatient cleft surgery.

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DISCLAIMER

The American College of Surgeons National Surgical Quality Improvement Program and the hospitals

participating in the American College of Surgeons National Surgical Quality Improvement Program are the source of the data used herein; they have not verified and are not responsible for the statistical validity of the data analysis or the conclusions derived by the authors.

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