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Five-fold Variation Among Surgeons and Hospital in the Use of Secondary Palate Surgery

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Abstract

Objective: To identify child-, surgeon- and hospital-specific factors at the time of primary cleft palate repair that are associated with use of secondary palate surgery.

Design: Retrospective cohort study

Setting: Forty-nine pediatric hospitals

Participants: Children who underwent cleft palate repair between 1998 and 2015.

Main Outcome Measure: Time from primary cleft palate repair to secondary palate surgery

Results: By five years after the primary palate repair, 27.5% of children had undergone secondary palate surgery. In multivariable analysis, cleft type and age at primary palate repair were both associated with secondary surgery ($p < 0.01$). Children with unilateral cleft lip and palate had a 1.69-fold increased hazard of secondary surgery (95% CI, 1.54–1.85) compared to children with cleft palate alone. Primary palate repair before 9 months had a 3.99-fold increased hazard of secondary surgery (95% CI, 3.39–4.07) compared to repair at 16–24 months of age. After

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adjusting for cleft type, age at repair, and procedure volume, there remained substantial variation in secondary surgery use among surgeons and hospitals ($p < 0.01$). For children with isolated cleft palate the predicted proportion of children undergoing secondary surgery within five years of primary repair ranged 8.5% - 46.0% across surgeons and 9.1% - 49.4% across hospitals.

Conclusions: There are substantial differences among surgeons and hospitals in the rates of secondary palate surgery. Further work is need to identify causes for this variation among providers and develop interventions to reduce the need for secondary surgery.

Keywords

Health Services; Cleft Palate; Secondary Surgery

Introduction

The objectives of cleft palate repair are to close the abnormal connection between the nasal passages and the oral cavity and to enable normal speech development. Failure to meet these goals can lead to oronasal fistula and velopharyngeal insufficiency (VPI). Both fistula and VPI may necessitate secondary palate surgery, and in the United States secondary palate surgeries addressing these complications account for 37% of all cleft palate surgeries (Thompson et al., 2017). Secondary palate surgery results in direct medical costs of approximately \$7,564 (in 2009 US dollars) (Thompson et al., 2017), in addition to morbidity for patients and time off work for caregivers. Identifying factors contributing to fistula and VPI after cleft palate repair may lead to improved outcomes for children with cleft palate and lower costs of treatment by reducing the need for secondary surgery.

Incidence of fistula and VPI after cleft palate repair varies substantially. The incidence of fistula ranges from 0% to 35.5% (Hardwicke et al., 2014). Incidence of VPI ranges from 4.6% to 42% (Mackay et al., 1999, Sommerlad, 2003, Lithovius et al., 2014). The causes of these broad variations in fistula and VPI rates remain incompletely understood, but have been attributed to patient factors (Mahoney et al., 2013, Hardwicke et al., 2014), the technique of palate repair (Williams et al., 2011), treatment protocols, surgeon expertise (Rautio et al., 2017), hospital expertise (Semb et al., 2005), and the patient's age at outcome evaluation (Sommerlad, 2003). Identifying the relative contribution for each of these components, and the interactions among them, may reveal effective methods for improving cleft care delivery that can be spread across surgeons and/or health systems.

The present study is an analysis of risk factors for secondary palate surgery at 49 free-standing children's hospitals participating in the Pediatric Health Information System (PHIS). Secondary palate surgery is an important outcome of palate repair for patients, families, and healthcare payers: the use of secondary surgery indicates definitive agreement that primary palate repair did not succeed, it requires a major operation with several weeks recovery, and it results in direct costs to the healthcare payer equivalent to the primary palate repair (Thompson et al., 2017). The objectives of this study were (1) to identify child-, surgeon- and hospital-specific factors at the time of primary palate repair that are associated with use of secondary cleft palate surgery, and (2) to estimate the magnitude of variation in secondary surgery that is attributable to differences in practice among surgeons and

hospitals. This work expands on prior studies of secondary palate surgery by evaluating the effect of cleft type and additional medical comorbidities, and by estimating the range in secondary surgery occurrence for 49 tertiary referral pediatric hospitals across the United States (US) and over 300 surgeons performing palate repairs at these hospitals.

Methods

PHIS is a comprehensive pediatric database containing administrative data from 49 children's hospitals in the US. PHIS includes patient demographics, diagnoses and procedures for all inpatient stays, observation unit encounters, ambulatory surgeries, and emergency department visits at participating hospitals. Investigators can identify sequential hospital encounters for an individual patient using a hospital-specific identifier present in the database.

We used the PHIS database to perform a retrospective cohort study of children undergoing cleft palate repair. We included all children with cleft palate or cleft lip and palate who underwent cleft palate repair between December 30, 1998, and September 30, 2015. We identified eligible children using *International Classification of Diseases, Ninth Revision (ICD-9) codes* for cleft palate (749.0) cleft lip and palate (749.2), and cleft palate repair (27.62). We excluded children older than 24 months at palate repair, as these children may have submucous cleft palate, non-cleft velopharyngeal dysfunction, or severe development delay. All of these conditions are likely to affect risk of secondary palate surgery. If a child underwent cleft palate repair at an individual hospital more than once during the study period, only the earliest repair was included; subsequent repairs were considered secondary palate surgeries.

For all children meeting inclusion criteria, we collected information on child demographics, medical conditions, and surgical care. Demographic data included gender, race, and median household income by ZIP code of residence. Race was included in the final model because prior research suggests variation among racial/ethnic groups in receipt of cleft palate surgery (Cassell et al., 2009, Thompson et al., 2017). Median household income by ZIP code of patient residence was obtained from 2010 US Census data and split into four categories based on US federal poverty guidelines for a family of four, as previously described (Fieldston et al., 2013).

We identified each child's cleft type and medical comorbidities from their discharge diagnoses. We categorized cleft type as cleft palate alone, unilateral cleft lip and palate, bilateral cleft lip and palate, and unspecified cleft lip and palate, using *ICD-9* codes. Children with additional congenital anomalies that might influence treatment of their cleft palate, including *22q.11* deletion syndrome, were identified using previously validated *ICD-9* codes (Feudtner et al., 2001).

We extracted details of surgical care at each child's initial palate repair. We categorized age at primary palate repair into three groups based on existing approaches to timing of primary palate repair: less than 9 months, 9 to 15 months, and 16 to 24 months (Dorf and Curtin, 1982, Haapanen and Rantala, 1992, Ysunza et al., 1998). We determined postoperative

antibiotic use, which we defined as receipt of any antibiotic on the first and/or second day after primary palate repair. We determined surgeon and hospital procedure volume for each child on the day of their palate repair by counting all cleft palate repairs (*ICD-9* codes 27.62 and 27.63) performed by that surgeon or hospital, respectively, in the prior 365 days. This approach decreases exposure misclassification compared to annual procedure volume for the same year the procedure was performed (McAteer et al., 2013). Counts included all cleft palate repairs in patients younger than 4 years of age as all palate repairs were predicted to increase the surgical team's experience with the procedure. For surgeons or hospitals who had reported in PHIS for fewer than 365 days at the time of a child's palate repair, procedure volume was calculated as the number of cleft palate repairs performed during their first 365 days of reporting. Procedure volume was categorized into tertiles. We categorized surgeon specialty as Plastic Surgery, Otolaryngology, and other/not specified.

For each included child, we identified all encounters at the hospital where primary palate repair was performed. We calculated time to secondary palate surgery for each child, which we defined as time from primary palate repair until the child underwent secondary palate surgery. We defined receipt of secondary palate surgery as any hospital encounter subsequent to the primary palate repair that included an *ICD-9* code for correction of cleft palate (27.62), revision of cleft palate repair (27.63), or other plastic repair of palate (27.69). Children not undergoing secondary surgery during the observation period were censored on the date of their last encounter at their initial treating hospital. No information was available on receipt of secondary palate surgery at hospitals other than the child's initial treating hospital.

The Institution Review Boards at Phoenix Children's Hospital and Cincinnati Children's Hospital Medical Center reviewed this study and determined it was not human subjects research, as defined by the Common Rule (45CFR46.102[f]), because the dataset was deidentified.

Statistical Analyses

We plotted Kaplan-Meier time-to-event curves for each hospital and each surgeon in the cohort. We then fit a three-level mixed-effects parametric time-to-event model with clustering of patients within surgeons and clustering of surgeons within hospitals. We assumed a Weibull distribution for this model, after confirming appropriateness of this assumption by visual inspection of log-log plots of survival. Random effects were assumed to have normal distributions with zero means. We tested for all two-way interactions. We adjusted for year of primary palate repair in the model. After fitting the full model, we estimated the variability in time to secondary surgery attributable to patients, surgeons and hospitals (Yang et al., 2009). We then used the model to predict the proportion of children undergoing secondary surgery during the first five years after primary palate repair for each surgeon and each hospital (Yang et al., 2009). We presented the predicted proportion of children undergoing secondary surgery in funnel plots with 99.8% (~3 sigma) control limits (Spiegelhalter, 2005). Hospitals outside the control limits can be interpreted as deviating significantly from the overall rates.

Sensitivity analyses were conducted to evaluate whether the choice of follow up time imposed bias through right censoring. Sensitivity analyses included: (1) censoring children two years after their last encounter; (2) censoring children four years after their last encounter; (3) censoring children at the end of the study observation period; (4) excluding children with less than one year of follow-up; and (5) excluding children with less than four years of follow up. Results of all sensitivity analyses were nearly identical to those of our main analysis and are available from the authors upon request.

Statistical analyses were performed using Stata version 14 (StataCorp, College Station, Texas). Statistical significance was set at $p < .01$.

Results

A total of 17,772 children underwent primary cleft palate repair at participating hospitals during the seventeen-year observation period. The median time from primary cleft palate repair to secondary palate surgery was 8.5 years (95% CI 8.3–8.7). Right-censoring occurred for 81.8% of the observations (N= 14,542). Characteristics of the study population are shown in Table 1.

Using a mixed-effects time-to-event model, we investigated the relationship between demographic, medical, and surgical factors and the use of secondary surgery (Table 2). Among the demographic and medical factors evaluated, child's race and cleft type were associated with time to secondary palate surgery ($p < 0.01$). Compared to white children, black children had a lower hazard of secondary palate surgery (hazard ratio [HR] 0.76, 95% confidence interval [CI] 0.65–0.89). Children with unilateral cleft lip and palate (UCLP) had 1.69-fold increased hazard of secondary surgery (95% CI, 1.54–1.85) compared to children with cleft palate alone (CP); for children with bilateral cleft lip and palate (BCLP) the hazard of secondary surgery was 2.06-fold higher (95% CI, 1.85–2.28). Child's gender, median family income, and the presence of additional congenital anomalies were not associated with time to secondary surgery.

Child's age at primary palate repair was associated with time to secondary palate surgery, with the hazard of secondary surgery increased for children who underwent primary palate repair before nine months of age ($p < 0.01$). Children who had repair before nine months of age had a 3.99-fold increased hazard of secondary surgery (95% CI, 3.39–4.07) compared to children who underwent repair at 16–24 months of age. This hazard was highest immediately following the primary repair and decreased as time from primary repair increased. For children who had repair before nine months of age and did not undergo secondary surgery during the first year after their primary palate repair, their hazard of secondary surgery diminished, with a hazard ratio of 3.11 (95% CI, 2.64–3.66). For children who received primary repair before nine months of age and reached the fifth anniversary of their palate repair without undergoing secondary surgery, their hazard of secondary palate surgery at any time in the future was similar to children who had primary repair at 9–24 months of age. The hazard of secondary surgery for children who underwent palate repair at 9–15 months of age was not significantly different than the hazard for children who underwent repair at 16–24 months of age (HR 1.06, 95% CI 0.94–1.19).

Among the other features of primary palate repair investigated, postoperative antibiotic use, surgeon procedure volume, hospital procedure volume, surgeon specialty, and year of repair were not associated with time to secondary surgery.

From the mixed-effects model, we estimated the remaining variation in time to secondary surgery attributable to hospitals, surgeons, and children (Yang et al., 2009). Differences in care delivery between hospitals accounted for 17.7% of the variation in secondary surgery ($p<0.01$); differences in care delivery between surgeons accounted for 16.3% of variation in secondary surgery ($p<0.01$); and differences between children accounted for 65.9% of variation in secondary surgery ($p<0.01$).

Variation Among Surgeons

For each surgeon performing at least ten repairs during the study period, the proportion of each surgeon's patients undergoing secondary palate surgery is shown in Figure 1A. These curves display the raw, unadjusted values as a function of time from primary palate repair. As time from primary palate repair increased, the proportion of children who have undergone secondary surgery also increased. Among the entire study population, 27.5% of children underwent secondary surgery by five years after primary palate repair. However, this ranged from 0.0% to 80.0% across surgeons.

Using results from the mixed-effects time-to-event model described above, adjusted time to secondary surgery curves were created for each surgeon (Figure 1B). These curves show the predicted proportion of children undergoing secondary surgery for white, male children with an isolated cleft palate who undergo palate repair at 16–24 months of age at a medium-volume hospital. The curves were adjusted for hospital performance, such that each surgeon's curve was generated assuming the primary repair was performed at a hospital whose hazard of secondary surgery was at the median of all hospitals in the study. Using these adjusted values and the standardized patient as described, the proportion of children undergoing secondary surgery by five years ranged from 8.5% to 46.0% across surgeons (Figure 1C). For the median surgeon in the study, the predicted proportion of children undergoing secondary surgery by five years was 18.7%.

Variation Among Hospitals

For each hospital in the study cohort, the proportion of their patients undergoing secondary palate surgery is shown in Figure 2A. These curves display the raw, unadjusted values, as a function of time from primary palate repair. The proportion of children undergoing secondary surgery by five years after primary palate repair ranged from 3.1% to 68.7% across the forty-nine hospitals.

Adjusted time to secondary surgery curves were created for each hospital (Figure 2B) using methods analogous to those described above for surgeons. These curves were adjusted for surgeon performance, such that each hospital's curve was generated assuming the surgeon performing the primary repair had a hazard of secondary surgery at the median of all surgeons in the study. Using these adjusted values and the standardized patient as described, the proportion of children undergoing secondary surgery by five years ranged from 9.1% to

49.4% across the forty-nine hospitals (Figure 2C). At the median hospital in the study, the predicted proportion of children undergoing secondary surgery by five years was 18.9%.

Figure 3 presents a funnel plot of the predicted portion of children undergoing secondary surgery within five years of primary palate repair against the number of children undergoing primary palate repair at each hospital during the observation period. In total, 34 (69.4%) hospitals fall within the 99.8% control limits, 7 (14.3%) above the upper, and 8 (16.3%) below the lower 99.8% control limits.

Discussion

In this study, we found broad variation in the use of secondary palate surgery. Use of secondary palate surgery was associated with both a child's cleft type and a child's age at primary cleft palate repair. However, the largest variation in secondary surgery use was attributable to unexplained differences among the surgeons and hospitals performing primary palate repair: the proportion of children receiving secondary palate surgery varied five-fold across surgeons and it varied five-fold again across hospitals. Of the 49 hospitals in this sample, seven hospitals (14.3%) had an incidence of secondary palate surgery substantially higher than the group as a whole. These results suggest that surgeon- and hospital-factors have substantial impact on a child's risk of secondary palate surgery.

Secondary palate surgery is an important outcome to patients, caregivers, and payers. The surgery requires a major operative procedure with several weeks recovery, in addition to time off work for caregivers. Secondary palate surgery also results in direct medical costs averaging \$7,564 per surgery (in 2009 US dollars) (Thompson et al., 2017). Given that currently 37% of all cleft palate surgeries in the United States are secondary surgeries (Thompson et al., 2017), there may be substantial opportunity to improve patient outcomes and achieve cost savings by reducing the need for secondary surgery.

The findings in this study are consistent with and extend those from prior reports. The increased hazard of secondary palate surgery for children with CLP, compared to CP, is consistent with the increased risks of fistula and VPI in children with CLP (Mahoney et al., 2013, Hardwicke et al., 2014, Bykowski et al., 2015). The variation in secondary surgery rates across surgeons and hospitals is consistent with prior studies showing similar differences in appearance, facial growth, and speech (Asher-McDade et al., 1992, Mars et al., 1992, Brattstrom et al., 2005, Semb et al., 2005, Daskalogiannakis et al., 2011, Britton et al., 2014, de Agostino Biella Passos et al., 2014, Lithovius et al., 2014). The present work expands on these prior studies by demonstrating that variation in surgical outcomes leads to differences in use of secondary surgery.

Differences in use of secondary surgery among surgeons and hospitals are multifactorial. At the surgeon level, both surgical technique and surgeon expertise may influence occurrence of fistula or VPI after palate repair. The evidence for an association of surgical technique is mixed: one randomized controlled trial found an association of technique with fistula and VPI (Williams et al., 2011), one randomized controlled trial found no association with either outcome (Rautio et al., 2017), and two systematic reviews found no association of technique

with fistula rate when results of observational cohort studies are included (Hardwicke et al., 2014, Bykowski et al., 2015). The evidence supporting the impact of surgeon expertise on fistula and VPI is more consistent (Williams et al., 1999, Williams et al., 2011, Aznar et al., 2015, Rautio et al., 2017). In the present study, we evaluated the effect of individual surgeons. We did not separate the effect of surgical technique from surgeon expertise; this is perhaps the most appropriate level for analysis, since surgeons routinely individualize techniques based on personal experience. When evaluating results among individual surgeons, we found use of secondary surgery varied five-fold. It may be possible to reduce this variation by identifying optimal techniques of palatoplasty and developing interventions that improve technical performance of surgeons.

Differences in secondary surgery use across hospital may be attributable to perioperative items such as anesthesia expertise, nursing care, or post-operative care instructions. Differences across hospitals may also be attributed to more long-range components of care, such as treatment protocols or hospital-specific thresholds for offering secondary palate surgery. In addition, variability among raters in describing the severity of velopharyngeal dysfunction (Ahl and Harding-Bell, 2018) may contribute to systematic differences in use of secondary surgery among hospitals. Given the present study's finding that almost one-third of hospitals perform secondary surgery at a rate substantially different from the group as a whole, it is imperative that further research be conducted to identify the causative factors of between-hospital differences and then use this knowledge to spread best practices.

The present analysis found no association of secondary surgery with presence of additional congenital anomalies, use of post-operative antibiotics after primary palate repair, year of primary palate repair, procedure volume of the surgeon and hospital, or with surgeon specialty. The absence of association with postoperative antibiotic use supports findings from a recent randomized controlled trial showing postoperative antibiotic therapy did not reduce fistula incidence (Aznar et al., 2015). The absence of association with year of primary palate repair suggests there has been no substantial change in use of revision surgery for children treated over the study period of 1998–2015. The absence of a volume-outcome relationship may be due to the paucity of very-low-volume operators included in this study (Williams et al., 1999, McAteer et al., 2013). The absence of an association between secondary surgery and surgical specialty suggests that factors other than specialty of residency training determine the outcomes of individual surgeon. These null findings suggest that among surgeons and hospital who routinely perform cleft palate repair, a deeper exploration of care delivery is necessary to understand the factors contributing to the broad variation in surgical outcomes.

The present study substantially extends our prior work evaluating secondary surgery use (Sitzman et al., 2017). While prior studies were restricted to children with nonsyndromic cleft lip and palate, the current study includes children with all cleft types and estimates the independent effect of cleft type on secondary surgery. Further, the present study provides adjusted estimates of secondary surgery use for each of the 49 hospitals in PHIS and over 300 surgeons operating at those hospitals. This is the first study to provide surgeon- and hospital-specific estimates of secondary surgery that are adjusted for patient risk factors. The 49 hospitals in PHIS provide 85% of all pediatric specialty care delivered in the US

(Goodman et al., 2014), suggesting the findings are broadly applicable to cleft care delivered in the United States.

The present study has two major implications. First, performing palate repair before 9 months of age is associated with an increased hazard of secondary surgery before age six. This risk may be due to the technical difficulties in operating on children with smaller oral passages. While this study does not prove causation, the large magnitude of effect suggests that surgeons and hospitals performing repair before 9 months should compare their incidence of fistula and VPI with peers before continuing with this practice, to determine if their rate of secondary surgery is substantially elevated. Further, if the ongoing Timing of Primary Surgery for Cleft Palate trial ([ClinicalTrials.gov](https://clinicaltrials.gov/ct2/show/study/NCT00993551) Identifier: NCT00993551) shows that palate repair at 6-months is more efficacious than repair at 12-months, then achieving effectiveness of early repair may require training of surgeons on how to successfully implement early palate repair.

The second major implication of this work is that surgeons and hospitals may be able to substantially reduce the need for secondary palate surgery by decreasing variations in care. We found that differences in care delivery between hospitals accounted for 17.7% of the variation in secondary surgery and differences in care delivery between surgeons accounted for 16.3% of variation in secondary surgery. As a result, we suggest that surgeons and hospitals could improve patient outcomes by identifying the causes of variation among surgeons and hospitals, establish evidence-based interventions and achievable targets for performance, and then implementing these interventions in clinical practice (Crandall et al., 2011, Anderson et al., 2014, Britto et al., 2018).

Limitations

These results must be interpreted in the context of the study design. No conclusions can be drawn about fistula, VPI rates, or quality of life outcomes from this study because these data are not present in the dataset. Unfortunately, no publicly available dataset in the US contains this data. Misclassification bias from coding inaccuracies in cleft type may bias results towards the null hypothesis; if children with CLP were coded as CP, the estimates of additional risk associated with UCLP and BCLP may be underestimated. Limited information was available on patient's concomitant medical conditions; while prior studies suggest that children with 22q deletion syndrome (Brandao et al., 2011, Bezuhly et al., 2012, Basta et al., 2014) and other syndromic diagnoses (Patel et al., 2012) have higher rates of VPI and secondary surgery, these specific diagnoses could not be reliably identified in the PHIS dataset. Referral of more complex patients to specific hospitals or surgeons within the study cohort could explain between-hospital and between-surgeon variation, although that is unlikely given the non-overlapping referral patterns of most participating hospitals (Fieldston et al., 2013). Finally, we may have underestimated time to secondary surgery for censored individuals. We classified children as lost to follow-up at their last visit to the initial treating hospital. If these children went on to receive secondary palate surgery at another institution after this visit, then results in the present study may be biased toward the null hypothesis. As a whole, these limitations may have led to underestimation of secondary surgery risk in this study.

An additional limitation to this study is that it does not identify the factors responsible for variations across surgeons and hospitals. The PHIS database, from which the data for this analysis were obtained, does not provide sufficient granularity on individual procedures or surgeons to evaluate the effect of surgical technique, treatment protocols, surgeon training, surgeon experience, or surgeon skill. Further research is necessary to identify whether these or other factors contribute to variation in use of secondary surgery.

Conclusions

Almost one-third of children with cleft palate undergo secondary palate surgery. However, there is substantial variation in secondary surgery based on child-, surgeon-, and hospital-specific factors. After controlling for cleft type and age at primary repair, there remains a five-fold difference in secondary surgery use across surgeons, and an independent five-fold difference in secondary surgery use across hospitals. These results suggest that there is substantial opportunity to reduce the use of secondary surgery by identifying the causes of variation among surgeon and hospitals, establish evidence-based interventions and achievable targets for performance, and then implementing these interventions in clinical practice.

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Figure 1. Time to secondary palate surgery for individual surgeons.

Each line represents the proportion of a surgeon's patients who have undergone secondary surgery. A, Unadjusted Kaplan-Meier curves for time until secondary palate surgery. Solid black line indicates outcome for all children in the cohort. B, Adjusted time to secondary surgery curves for white, male children with isolated cleft palate who undergo palate repair at 16–24 months of age at a medium-volume hospital. Solid black line indicates result for median surgeon in the cohort. C, Proportion of children who undergo secondary palate surgery within five years of their primary palate repair, adjusted for as in panel B. Box represents median and interquartile range, whiskers represent upper and lower adjacent values as defined by Tukey (1977)

Figure 2. Time to secondary palate surgery for individual hospitals.

Each line represents the proportion of a hospital's patients who have undergone secondary surgery. A, Unadjusted Kaplan-Meier curves for time until secondary palate surgery. Solid black line indicates outcome for all children in the cohort. B, Adjusted time to secondary surgery curves for white, male children with isolated cleft palate who undergo palate repair at 16–24 months of age by a medium-volume surgeon. Solid black line indicates result for median hospital in the cohort. C, Proportion of children who undergo secondary palate surgery within five years of their primary palate repair, adjusted for as in panel B. Box represents median and interquartile range, whiskers represent upper and lower adjacent values as defined by Tukey (1977)

Figure 3. Standardized rates of secondary palate surgery for each hospital.

Rates are the proportion of children undergoing secondary palate surgery within five years of their primary palate repair. Rates were adjusted for patient and surgeon risk factors, and represent results for white, male children with isolated cleft palate who undergo palate repair at 16–24 months of age by a medium-volume surgeon. Dashed lines indicate 99.8% (~3 sigma) control limits. Hospitals outside the control limits can be interpreted as deviating significantly from the overall rates.

Table 1.

Characteristics of patients and the care delivered at their initial palate repair.

Characteristic	n (%)
Total	17,772
Male gender	9,400 (52.9)
Race	
White	12,363 (69.6)
Black	1,393 (7.8)
Asian or Pacific Islander	961 (5.4)
Other	2,306 (13.0)
Not specified	749 (4.2)
Median annual household income of postal code	
\$33,525 or less (<1.5 FPL)	3,630 (20.4)
\$33,526 - \$44,700 (1.5–2 FPL)	4,551 (25.6)
\$44,701 - \$67,050 (2–3 FPL)	4,539 (25.5)
\$67,051 or more (>3 FPL)	1,414 (8.0)
No data available	3,638 (20.5)
Cleft type	
Cleft palate alone	11,110 (62.5)
Cleft lip and palate, Unilateral	3,753 (21.1)
Cleft lip and palate, Bilateral	1,864 (10.5)
Cleft lip and palate, Unspecified	1,045 (5.9)
Additional congenital anomalies present	3,982 (22.4)
Patient age at repair	
<9 months	3,509 (19.7)
9–15 months	11,991 (67.5)
16–24 months	2,272 (12.8)
Postoperative antibiotic use	
None	6,814 (38.3)
Yes	10,958 (61.7)
Surgeon procedure volume (on day of repair)	
Low (<10 repairs in preceding 12 months)	4,986 (28.1)
Medium (10–25)	8,110 (45.6)
High (>25)	4,676 (26.3)
Hospital procedure volume (on day of repair)	
Low (<25 repairs in preceding 12 months)	3,630 (20.4)
Medium (25–50)	9,326 (52.5)
High (>50)	4,816 (27.1)
Surgeon Specialty	
Plastic Surgery	14,202 (79.9)
Otolaryngology	2,014 (11.3)
Other/Not specified	1,556 (8.8)

¹FPL, US Federal Poverty Level for a family of four

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Table 2.

Adjusted hazard ratios for secondary palate surgery.

Risk Factor	Secondary Palate Surgery¹	
	Hazard Ratio	p-value
Gender		0.33
Male	Reference	
Female	1.04 (0.96–1.11)	
Race		<0.01
White	Reference	
Black	0.76 (0.65–0.89)	
Asian or Pacific Islander	1.18 (0.99–1.42)	
Other	0.91 (0.80–1.02)	
Median family income		0.75
\$33,525 or less (<1.5 FPL) ²	Reference	
\$33,526 - \$44,700 (1.5–2 FPL)	0.99 (0.89–1.11)	
\$44,701 - \$67,050 (2–3 FPL)	0.94 (0.84–1.05)	
\$67,051 or more (>3 FPL)	0.93 (0.79–1.09)	
Cleft Type		<0.01
Cleft palate alone	Reference	
Cleft lip and palate, Unilateral	1.69 (1.54–1.85)	
Cleft lip and palate, Bilateral	2.06 (1.85–2.28)	
Additional anomalies present		0.11
None	Reference	
Yes	0.93 (0.84–1.02)	
Patient age at repair		<0.01
9 months ³		
At baseline	3.99 (3.39–4.07)	
At 1 year after repair	3.11 (2.64–3.66)	
At 5 years after repair	1.15 (0.97–1.35)	
9–15 months	1.06 (0.94–1.19)	
16–24 months	Reference	
Postoperative antibiotic use		0.02
None	Reference	
Yes	0.89 (0.81–0.98)	
Surgeon procedure volume ⁴		0.13
Low (<10)	Reference	
Medium (10–25)	0.94 (0.84–1.06)	
High (>25)	1.06 (0.91–1.25)	
Hospital procedure volume ⁴		0.20
Low (<25)	Reference	
Medium (25–50)	1.04 (0.91–1.18)	

Risk Factor	<u>Secondary Palate Surgery</u> ¹	
	Hazard Ratio	p-value
High (>50)	0.93 (0.77–1.11)	0.48
Surgeon Specialty		
Plastic Surgery	Reference	
Otolaryngology	0.87 (0.68–1.11)	
Other/Not specified	1.03 (0.81–1.32)	

¹ Model assumes clustering of patients within surgeons and clustering of surgeons within hospitals; $p < 0.001$ for likelihood-ratio tests of $\theta = 0$ for both surgeon and hospital

² FPL, US Federal Poverty Level for a family of four

³ Age less than 9 months at primary repair is a time varying covariate, with baseline HR 3.99 (3.39–4.70) that decreases by 22.05% (18.96–25.01) each subsequent year

⁴ Procedure volume is the number of cleft palate repairs performed by that surgeon (or hospital) in the preceding twelve months