2021

Practice Makes Perfect: The Volume-Outcome Association in Pediatric Stoma Closure Surgery

Stephen P. Sales
Medical University of South Carolina

PRACTICE MAKES PERFECT: THE VOLUME-OUTCOME ASSOCIATION IN PEDIATRIC STOMA CLOSURE SURGERY

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Stephen P. Sales

A doctoral project submitted to the faculty of the Medical University of South Carolina
in partial fulfillment of the requirements for the degree
Doctor of Health Administration
in the College of Health Professions

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Approved By:

Committee Chair	Annie Simpson, PhD	Date
Committee Member	Kit Simpson, DrPH	Date
Committee Member	Elinor C. G. Borgert, PhD, MSc	Date

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ABSTRACT

Children with anorectal malformations often receive a temporary colostomy or ileostomy before surgical repair of the anomaly to divert stool and allow their anatomy time to heal. Once their bodies have healed, the stoma is taken down, a standard procedure for pediatric general surgeons. However, for decades, stoma takedown surgery has been associated with a high risk of postoperative complications. This study seeks to determine if hospital prior-year stoma closure case volume influences pediatric patients' quality outcome measures.

Population. This study identified 340 pediatric patients having undergone stoma closure surgery during the study period at hospitals in a representative sample of seven states; Arkansas, Florida, Georgia, Maryland, Mississippi, New York, and Washington.

Study Design. This study is a retrospective analysis of archival billing data for pediatric stoma closure patients. The billing data source is the 2016 - 2017 Agency for Healthcare Research and Quality's (AHRQ) Healthcare Cost and Utilization Project (HCUP) database.

Outcome Measures. This study uses generally accepted surrogate measures of a quality outcome. The quality outcome measures for this study are the rate of in-hospital mortality during the index admission, readmission to the hospital within 30 days of discharge, and length of stay (LOS) during the index admission.

Results. One mortality occurred in the study population (.29%), while 39 patients were readmitted (11.5%). Logistic regression analysis found no significant volume-outcome association between volume and the outcome measures. However, when categorized into age groups, a statistically significant association exists between hospital prior-year volume and readmission ($p < .04$) in the infant age group (Age < 1). A similar association was found between hospital prior-year volume and LOS ($p < .002$) in the infant group compared to the non-infant group. With each prior-year increase of 10 cases, the likelihood of readmission decreases by 52% and expected hospitalization days decreases by 25%.

Conclusion. This study validates an inverse hospital volume-readmission association in infant stoma closure surgery and an inverse volume-LOS association among all pediatric patients, with the magnitude of the association being most significant in the infant population.

CHAPTER 1. Introduction

Children in the United States suffer from congenital anorectal malformations, or Hirschsprung's Disease, at a rate of 1 per 5000 live births (Wood & Levitt, 2018). Various surgical procedures address specific malformations, but a common element of many treatments is a temporary colostomy or ileostomy to divert stool from the newly repaired colon, rectum, or anus to allow the anatomy time to heal. Approximately three months postoperatively, the patient returns to the hospital for evaluation of the repair. If the repair is functional and has sufficiently healed, the surgeon removes the diverting ostomy to allow the stool to flow naturally through the lower gastrointestinal tract. However, unlike the colorectal surgery itself, the stoma creation and subsequent takedown are not considered a procedure requiring a sub-specialized pediatric surgeon or even a pediatric surgeon at all. General surgery residents often perform these procedures under the supervision of a faculty surgeon (Yajko et al., 1976; Krebs et al., 2019).

The relevant literature lacks agreement on the existence of a definitive volume-outcome association in many surgical procedures. Studies demonstrating an association often have significant flaws that jeopardize their findings' validity (Hoshijima et al., 2019). Five decades of study have uncovered many significant findings, but there is still much to discover.

What we know (and have known for 44 years)

Contrary to its reputation as a bread and butter case, the complication rate following colostomy or ileostomy closure surgery in adults is 25% (Krebs et al., 2019), a rate little improved since the 28% complication rate identified in a 1976 study of 100

Colostomy reversal patients in a Denver teaching hospital 1969 – 1974 (Yajko et al., 1976). Pre-operative preparation and surgical technique are significant factors in low complication rates for stoma closure surgery. However, surgical technique aside, colostomy or ileostomy closure surgery is still associated with significant morbidity (Yaiko et al., 1976; Bischoff et al., 2010).

Bowel surgery presents surgeons with several unique and significant risk factors. Heavy bacteria load within the digestive tract makes bowel surgery a high-risk procedure for infection and sepsis. Other common complications of stoma closure surgery include dehiscence of the intestinal anastomosis, anastomotic leak, anastomotic stricture, bleeding, small bowel adhesions, and intestinal obstruction (Mollitt et al., 1980; Bischoff et al., 2010).

Over the past four decades, research has focused on single-institution efforts to reduce the complication rate associated with stoma closure surgery. Some of the notable studies identified specific surgical techniques or approaches for stoma takedown that were statistically significant in reducing postoperative complications (Bischoff et al., 2010; Ahmad et al., 2020). Other studies identified anatomic placement of the diverting stoma, pre-operative preparatory actions such as a mechanical bowel cleanse or prophylactic antibiotic administration, or duration of the diverting stoma to be significant factors in reducing postoperative complications (Mollitt et al., 1980). Despite some success in single institutions, overall complication rates have not improved significantly in many years.

As early as 1988, researchers identified surgeon experience as a statistically significant factor influencing morbidity in adult patients receiving stoma closure surgery. "*Senior surgeons"* had a complication rate much lower than that of *"junior surgeons,"* 9.3% versus 23.2% ($p<.05$) (Demetriades et al., 1988).

In 1998 Colin Begg, Ph.D., found the mortality rate for high-risk, infrequently performed surgeries such as esophagectomy were 3% at high-volume hospitals and 17% at low-volume hospitals. Mortality rates for pancreatectomy were 6% and 13%, respectively. Begg also found that the magnitude of the effect diminished as the case's complexity was reduced (Begg et al., 1988). Based on these findings, the Institute of Medicine, in its report Interpreting the Volume-Quality Relationship in the Context of Cancer Care, recommended regionalization of these two high-risk procedures (Institutes of Medicine et al., 2001). In other specific procedures such as coronary artery bypass grafting, research has shown institutional volume does influence mortality (Urbach & Baxter, 2004; Hollis et al., 2016; Nimptsch & Mansky, 2017; Halm et al., 2002).

What we do not know

Many studies have examined hospital and surgeon procedure volume and its influence on postoperative complication rates, with the consensus being that an inverse association does exist, that as a procedure is performed more often, complications associated with its use decrease. Today, the U.S. News and World Report, arguably the premier hospital ranking publication, uses procedure volume as one measure of hospital quality (Olmstead et al., 2020). However, using volume as a quality measure ignores the implication of the case-mix and assumes a causal relationship among the variables, which may not exist.

Demetriades et al. identified surgeon seniority as a statistically significant factor in predicting postoperative complications in adult stoma closure surgery. We do not know how surgeon seniority was measured in this study or at what volume threshold the experience factor ceased to remain significant. We do not know if procedure volume alone is critical in predicting complications or if the total surgical experience is a better indicator. A senior pediatric colorectal surgeon commented recently during a morbidity and mortality discussion about a patient's anastomotic leak following stoma closure surgery, "I can teach a student where to place a stitch, but I cannot teach them how much tension to create in the stitch. They must learn to feel when the tension is right. Too much tension can tear the intestine, while too little can allow an anastomotic leak and sepsis. The optimal tension must be learned through repetition and study of results (Wood, 2020)." Surgeon experience *can be* a causal factor of surgical complications. But is it a significant factor? Additionally, is institutional procedure volume also a causal factor in the postoperative complication rate?

Notable studies have shown a volume-outcome association in abdominal aortic aneurysm repair, esophageal resection, pancreatic resection, and coronary artery bypass grafting, but have not shown a similar colon resection association (Urbach & Baxter, 2004; Nimptsch & Mansky, 2017; Hoshijima et al., 2019; Halm et al., 2002). The influence of volume as a significant factor in the rate of postoperative complications must be empirically demonstrated for each procedure type while accounting for differences in case-mix. A study examining stoma closure procedures in a pediatric population that often lacks severe comorbidities achieves both objectives.

While Colin Begg identified an association between institutional surgical volume and mortality, we do not know if the institutional volume is a factor in postoperative *morbidity*. Whether factual or imaginary, patients worldwide travel to Houston seeking cancer care at MD Anderson Cancer Center and to Cleveland Clinic seeking cardiac surgery. Many of these patients believe procedure volume to be a significant factor in whether they will experience a complication from treatment. Do these patients seek a specific surgeon or seek specific institutions with high volume and the best outcomes? When needing a heart valve repair, would one choose the local hospital that performs the procedure once a month or a hospital that performs the procedure 60 times each month? Patients with options often choose high-volume centers for their care, but are their outcomes any better than those of lower-volume hospitals?

Several studies have focused on the complication rate following stoma closure surgery in adult patients (Yajko et al., 1976; Demetriades et al., 1988), but there is no evidence that those findings are valid in a pediatric population. A study of morbidity following colostomy closure in children found an overall morbidity rate of 28.6% and a mortality rate of 1.8% (Chandramouli et al., 2004). A more recent study examining postoperative surgical site infections (SSI) in pediatric stoma closure patients at a tertiary, free-standing pediatric hospital found that 21.4% of patients developed an infection (Ahmad et al., 2019). Another study found a rate of anastomotic dehiscence as high as 12.5%, a rate of SSI as high as 45%, and incidence of anastomotic stricture, bleeding, and death also reported (Bischoff et al., 2010). These results support the position that, as with adults, the complication rate following stoma closure surgery in the pediatric population is high and has remained so for many years.

Lastly, if the institutional volume is a factor in determining the postoperative complication rate, at what volume level does additional experience cease to provide statistically significant improvement in a hospital's complication rate? In 1979, Harold Luft et al. found that hospitals performing as few as 50 procedures per year reached nearly the same mortality rate as hospitals doing 200 or more for hip replacement surgery. Perhaps 50 is an adequate minimum number of hip replacements a hospital must perform to be considered safe. What is the minimum number of stoma closure surgeries necessary for a hospital to be considered safe enough for a child? This study will seek to answer these questions related to stoma closure surgery in the pediatric population. Awareness of quality outcomes as a product of procedure volume would help guide care in the future, perhaps directing patients to high-volume pediatric centers for stoma closures. Such awareness may result in a lower cost of care for these patients by reducing complications that increase the LOS, induce the need for additional procedures, and result in additional medications, readmissions, and in-hospital mortality. Parents deserve to know what may influence their children's outcomes for the hospitals where their children will receive care. This study will add to the body of literature related to delivering safe, effective, and efficient surgical care for pediatric patients undergoing colostomy or ileostomy closure surgery. Clinicians, administrators, insurance carriers, and families can use these findings to inform their decision to conduct these common yet riskier procedures.

CHAPTER 2. Background

A literature search using PubMed using the terms "morbidity" and "colostomy closure" yielded 98 results. This list was filtered only to identify articles published within ten years, yielding 15 articles. From these first 15 articles, 23 additional literature sources were discovered, for a total of 38 published papers thought to be relevant to this study. These 38 papers reveal agreement regarding the complexity of stoma closure surgery and the proper design of a research study to divine a surgical volume-outcome association, but little agreement on one's existence. The literature falls into four distinct groups; those supporting the complexity and high morbidity rate of colostomy and ileostomy closure surgery, of which there are 12, those concluding surgical volume-outcome associations exist, of which there are 16, those concluding surgical quality-outcome associations do not exist or that studies finding an association are inconclusive or poorly designed, of which there are seven, and those articles that provided relevant information but did not draw a conclusion regarding a surgical volume-outcome association, of which there are three.

The three primary findings of the literature support the position that colostomy or ileostomy creation is a standard surgical procedure in the treatment of pediatric patients with anorectal malformation or malignancy (Ekenze et al., 2007); that stoma closure surgery is complex and has a complication rate between 6.5% (Nour et al., 1996) and 28.6% (Chandramouli et al., 2004) and a mortality rate between 0% and 3% (Ekenze, 2007); and that consistent evidence does not exist demonstrating a surgeon or hospital volume-outcome association for stoma closure surgery in pediatric patients. One study posits that there may be insufficient surgeon sub-specialization in the pediatric general surgery specialty, unlike adult general surgery, to make a valid argument for or against such an association specific to surgeon volume (Rich et al., 2020). Based on this finding, surgeon volume may be synonymous with hospital volume in a children's hospital. Therefore, this study focuses only on the pediatric population and does not attempt to identify a surgeon volume-outcome association, only a hospital volume-outcome association.

Most studies gathered surgeon and hospital procedure volume through administrative datasets, mostly hospital charge data employing International Classification of Disease codes, for the study period. Many studies used 30-day mortality, readmission, or return to the operating room as the primary quality measure. The length of stay (LOS) as a surrogate quality measure also has support in the literature (Pucciarelli et al., 2017). Univariate and multivariable regressions were commonly used to determine if an association exists between procedure volume and quality outcome utilizing a p-value < 0.05 to indicate statistical significance. Standard statistical tests were used to analyze the distribution of variables, such as chi-square for categorical variables, with a Student's *t*-test used to analyze continuous variables. The preponderance of studies followed these same basic statistical analysis methods, which will add both internal and external validity to this study. Some studies included additional variables such as patient age, gender, race, and insurance status, to gain additional insight into variables predictive of postoperative complications. Future research will benefit from increased access to administrative and medical data to further clarify if postoperative complications occurred,what type of complications, and in which patients. Each surgical procedure will require study since it is difficult to extrapolate results from one procedure to another. Therefore, this research study will move to a more patient-focused, individualized, and equitable standard of care.

A thorough reading of all articles identified three main points of contention related to study design that must be addressed. Firstly, what is volume, and how is it measured? Hospital volume is the number of cases of the type in question performed at a hospital during a defined period, but how is it operationalized, and how does that choice impact the findings? An oft-repeated critique of many studies is the stratification and use of surgical case volume as a categorical variable rather than a continuous variable. A 2013 study examining the association between surgical readmission rates and hospital care quality stratified hospital surgical case volume into quartiles and made volume a categorical variable. The authors mentioned that calculations from a sensitivity analysis with volume as a continuous variable did not qualitatively change the results of their study, but those analyses were not published (Tsai et al., 2013). A study from Germany examined a more expansive list of 25 surgical procedures that used volume as a categorical variable (Nimptsch & Mansky, 2017). The authors made no mention of how volume as a continuous variable might have changed the results. Most studies used volume as a continuous variable.

The second common critique of many early studies relates to risk adjustment, or rather the lack thereof. The more widely accepted studies created a case mix-based risk adjustment to control for the confounding variable of disease progression and patient comorbidities. Some studies employed the Elixhauser Comorbidity Index (6), others used the Charlson Comorbidity Index (3), and two addressed case mix index using locally developed methods. Lack of any risk adjustment left studies open to the criticism that results were likely biased in favor of high volume, low complexity hospitals, or surgeons. This bias may be an unintended consequence of physician referral patterns, geography, or patient preference. Risk adjustment is an essential aspect of research studying the quality of clinical outcomes.

The third area of critique of many studies was the use of administrative data that lacks the depth of more clinically rich electronic health record or registry data to measure disease progression, operative technique, or operative time. These factors may influence postoperative morbidity but are not discernable from administrative datasets.

Unlike volume as a predictor, a widely accepted definition of surgical outcomes is not hard to discern from the literature. Most researchers accept higher in-hospital mortality and 30-day readmission as a proxy for low-quality surgical outcomes. Unlike medical patients, if a surgical patient returns to the hospital within 30 days, the reason is most likely connected to the surgery rather than an exacerbation of the original diagnosis or a side effect of treatment (Hollis et al., 2016). The Hollis study found that hospital surgical readmissions are explained by factors unique to the patient or to the procedure more so than by hospital or even surgical department factors. The hospital was responsible for 0.7% of the readmission rate variance and the surgical department for 6.3% (Hollis et al., 2016). Researchers using internal datasets were able to expand their definition of quality to include mortality, return to the operating room, and readmission within 30 days and infections, wound dehiscence, and bowel obstruction, which would not be identifiable in archival hospital billing data. The use of LOS as a surrogate quality measure is an excellent way to pick up on less acute complications of the surgery, not resulting in mortality or readmission (Pucciarelli et al., 2017).

Previous studies of a volume-outcome association in surgical procedures indicate that archival hospital billing data using ICD-9 or ICD-10 codes is adequate to identify how often a hospital has performed a procedure and if a severe postoperative complication occurred. Readmission within 30 days and length of stay during the reference admission are widely accepted quality measures, perhaps more so than traditional quality measures, because they will capture unexpected problems other measures do not. However, they may not identify the nature of the problem, only the existence of it.

The body of literature examining the association between surgical volume and quality appears to support the position that an association does exist, but its existence is not universal to all procedures or patient phenotypes. Previous studies have identified an inverse volume-quality association in highly specialized, complex surgeries but not in other, less specialized cases. Some studies found surgeon-specific factors to be more influential in quality outcomes than hospital factors. Most volume-quality studies examined surgical results in an adult population. Few studies have examined such an association in a pediatric population. This study seeks to elucidate the association between hospital volume and postoperative mortality, readmission, and length of stay for pediatric patients undergoing colostomy and ileostomy closure surgery and identify the threshold of volume beyond which additional improvement in the outcome measures is no longer significant.

CHAPTER 3. Methods

Study Objectives

The study's objective is to perform a retrospective analysis of billing data for a cohort of children who received a colostomy or ileostomy closure surgery at U.S. hospitals to determine whether those treated at hospitals with higher stoma closure volume have lower rates of postoperative complication and shorter LOS. If they do, at what volume do improvements in outcome measures cease to be significant. Stated another way, what should the minimum volume level be for a hospital to perform stoma closure procedures in pediatric patients?

Hypothesis

Hypothesis: Patients treated at hospitals with a higher volume of pediatric colostomy and ileostomy closure procedures in the calendar year preceding their closure surgery experience a lower rate of in-hospital mortality, readmission, and LOS, than patients treated at lower-volume hospitals. Secondary hypothesis: If a volume-outcome association exists between hospital volume and in-hospital mortality, readmission, and LOS, is there a volume level above which outcomes no longer improve?

Study Design

This study is a retrospective analysis of archival billing data for pediatric stoma closure patients. This design facilitates the use of extensive administrative datasets that will allow for robust statistical analysis of the outcomes of interest across large numbers of patients receiving care at many institutions. The volume of pediatric stoma closure surgeries per hospital in the base year will be the primary independent variable used to analyze surgical procedure LOS and readmission during the subsequent (study) year.

Outcome Measure

Based on the paucity of rich clinical data in archival medical claims, this study uses surrogate measures of surgical quality. The quality outcome measures for this study are readmission to the hospital within 30 days of discharge and LOS during the index admission. Readmission is a long-accepted measure of unanticipated surgical outcome. The use of LOS in this study will measure less acute postoperative complications that were treated before discharge. The assumption of LOS as a surrogate for complications is that patients who do experience an adverse event will remain inpatient longer than patients who do not.

Risk Adjustment

This study used the Pediatric Chronic Conditions Classification System, version 2 (PCCS), to control for comorbid conditions (Feudtner et al., 2014). The PCCS system is used extensively in studies of children with medical complexities that can be expected to last longer than a year and are associated with higher morbidity, mortality, and use of resources. No patients were excluded from this study. Table 1 displays this study's population relating to the number of chronic comorbid conditions.

Pediatric Complex Chronic Conditions (CCC)		
# of Comorbid Conditions	**N**	**Percent**
1	235	69.32
2	64	18.88
3	30	8.85
4	< 11	< 3
5	< 11	< 3
Total	339	100

Table 1: Pediatric Complex Chronic Conditions

Pediatric Complex Chronic Conditions (CCC)		
Type of comorbid condition	**N**	**Percent**
Renal/Urologic	35	10.32
Congenital Defect	27	7.96
Cardiovascular	25	7.37
Neurologic	18	5.31
Metabolic	14	4.13
Respiratory	12	3.54
Hematologic Malignancy Transplant	< 11	< 3
Total	339	100

Table 2: Number and Type of Comorbid Conditions in this Population

Variables

Hospital procedure volume in the base year, the year before the index procedure, is the primary independent variable. This study will treat hospital procedure volume as a continuous variable rescaled by dividing the original volume variable by 10 for interpretation. Patient readmission and LOS are the primary dependent variables. The number of chronic comorbid conditions determined by the PCCS is a patient-level variable for which the study will control. Other covariates considered were age group (defined as infants and non-infants), sex, and race (defined as Black, White and Other).

Population

The study group includes pediatric patients age 0-17 who were discharged following a colostomy or ileostomy closure procedure during the study period (See Table 3). No patients were excluded from the study. The patient population in this study is adequately diverse in terms of race, gender, and age category to draw conclusion.

Population Characteristic	N	Percent
Race		
Black	62	18.29
White	158	46.61
Other	119	35.1
Gender		
Female	138	40.71
Male	201	59.29
Total	339	100

Table 3: Demographics of Study Population

Data Collection

The source of archival billing data is the 2016 - 2018, depending on state data availability. The Agency for Healthcare Research and Quality's (AHRQ) Healthcare Cost and Utilization Project (HCUP) database, a national resource of encounter-level healthcare data, was used in this analysis to ensure the inclusion of all pediatric stoma closure cases completed at hospitals are included in the study regardless of payer. The advantage of using the HCUP database is its comprehensive, longitudinal nature enabling the capture of all inpatient postoperative care utilization for millions of individuals (AHRQ, 2020). The HCUP database, however, does not include comprehensive data from all states. Therefore, seven states were chosen as a representative sample to include in this study, for which 100% of claims (including readmission data) are available: **Arkansas, Florida, Georgia, Maryland, Mississippi, New York, and Washington**.

The 50 hospitals included in the study have performed at least one of the procedures of interest on a pediatric patient during the study period (see Table 4).

Demographics of Study Hospitals		
State	**Hospitals, N**	**Cases, N (%)**
AR	< 11	11 (3.24)
FL	12	50 (14.75)
GA	< 11	52 (15.34)
MD	< 11	25 (7.37)
MS	< 11	14 (4.13)
NY	24	143 (42.18)
WA	< 11	33 (12.98)
Total	50	339 (100)

Table 4: Demographics of Study Hospitals

These comprehensive collections of data allow for analysis of both diagnoses and procedures using International Classification of Disease, 10th edition, Clinical Modifications (ICD-10-CM) codes, and International Classification of Disease, 10th edition, Procedure Classification System (ICD-10-PCS) codes for which inpatient, medical, or procedural claims were submitted. Both diagnosis and procedure codes are necessary to identify patients for inclusion in this study.

One of the following ICD-10-CM diagnosis codes; Z93.2, Presence of an ileostomy, Z93.3, Presence of a colostomy, Z43.2, Encounter for attention to ileostomy, or Z43.3, Encounter for attention to colostomy, will identify patients with an ileostomy or colostomy or who received medical care related to their ostomy. Having an ostomy or receiving care for it is insufficient to determine if the ostomy was taken down. Therefore, ICD-10-PCS procedure codes are required to identify patients whose stomas were taken down. Procedure codes with the first digit of 0 (Medical-Surgical); the second digit of D (Gastrointestinal); the third digit of B (Excision), S (Reposition), N (Release), or Q (Repair); and the fourth digit of either B (Ileum), E (Large Intestine), F (Large Intestine (right)), G (Large Intestine (left)), K (Ascending Colon), L (Transverse Colon), M (Descending Colon), or N (Sigmoid Colon) depending on where the surgeon placed the stoma and how the hospital codes its stoma closure surgeries. Together, these combinations of diagnosis and procedure codes will identify patients receiving a colostomy or ileostomy closure surgery. Table 5 illustrates the query methodology.

Digit Position	**1**	**2**	**3**	**4**	**5**	**6**	**7**
Medical and Surgical	0						
Gastrointestinal		D					
Excision			B				
Reposition			S				
Release			N				
Repair			Q				
Ileum				B			
Large Intestine				E			
Large Intestine, Right				F			
Large Intestine, Left				G			
Ascending Colon				K			
Transverse Colon				L			
Descending Colon				M			
Sigmoid Colon				N			
Any Character					*	*	*

Table 5: Matrix of ICD-10 PCS Codes

Statistical Analysis

Logistic regression models were used to determine the association between a continuous independent variable, prior year hospital procedure volume, and hospital readmission, a dichotomous dependent variable. A p-value < 0.05 was considered statistically significant in the regression models. Odds ratio estimates were estimated as the effect size of each of the logistic regression models. A generalized linear model (GLzM), with a Negative Binomial distribution and Log link, was used to estimate the association between prior year hospital procedure volume in the base year and patient LOS (days in hospital) in the study year. Percentage change in length of stay associated with increased hospital procedure volume is the effect size estimated in the GLzM.

All analyses were performed using SAS software, version 9.4 (Cary, NC). All hypothesis tests are two-sided with alpha < 0.05. Applying the PCCS (Feudtner index) calculations for comorbidities will add another continuous independent variable to the equation: The number of chronic conditions per patient.

Hypothesized Expected Findings

Based on a review of the literature and experience in a pediatric colorectal surgery practice, this study's expected outcome is the identification of an inverse volume-quality association in pediatric ileostomy and colostomy closure surgery. Volume and *"poor"* quality measures should exhibit an inverse relationship with a declining complication rate as volume increases. The line's slope is expected to decrease as volume increases and gradually flattens as volume continues to increase. Figure 1 is a graphical representation of the expected relationship.

Additionally, the slope of the line is expected to flatten at some level of volume. Beyond this point, the additional volume will fail to produce further reductions in the rate of complications.

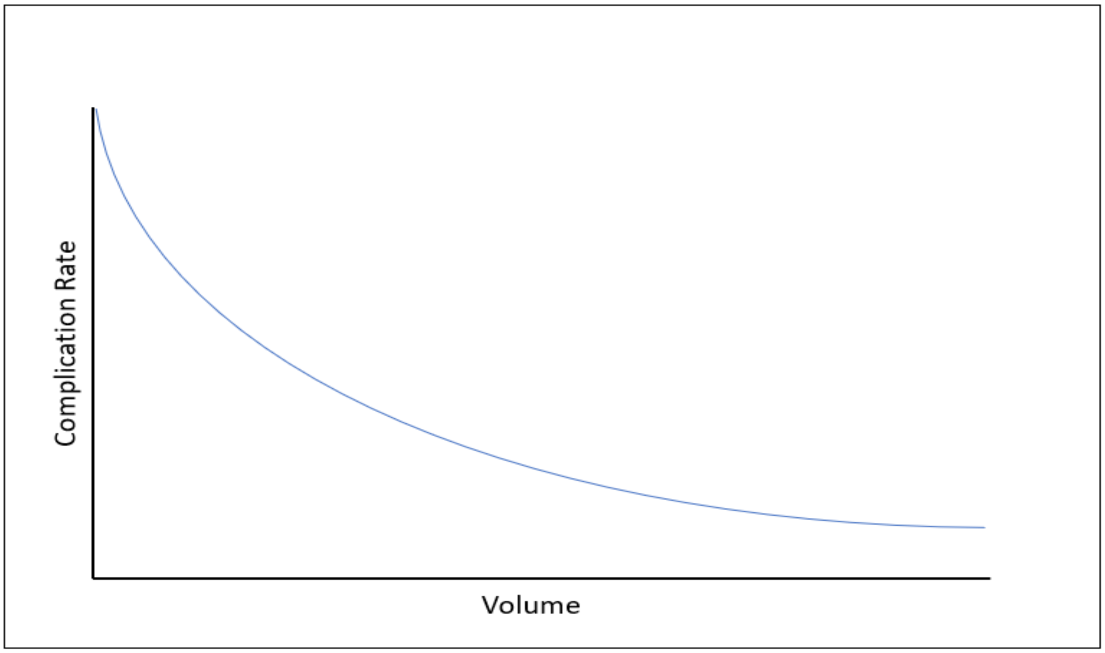

Figure 1: Expected Volume-Outcome Association

Significance of Expected Findings

The field of pediatric general surgery needs evidence to indicate if sending children to specialty centers for stoma closure is a better value than keeping them close to home, even if some of them will experience complications. A value equation must be empirically demonstrated if specialized care centers are indeed a better choice for patients needing complex surgical care.

Awareness of quality outcomes as a product of procedure volume would help guide care in the future, perhaps directing patients to high-volume pediatric centers for stoma closures. Such awareness may result in a lower cost of care for these patients by reducing complications that increase the length of stay, induce the need for additional procedures, additional medications, readmission, and other adverse outcomes. Parents deserve to know the importance of quality outcome measures for the hospitals where their children will receive care.

CHAPTER 4. Results

Odds of Readmission

One patient suffered mortality following stoma closure surgery (0.294%). Based on a population size of one, no further analysis was performed on the mortality outcome variable. The rest of this analysis is based on a population size of 339 patients, 133 of them were infants under the age of one year, and 206 were between one and 18 years of age. The population was appropriately distributed based on race and gender (see Table 6).

Characteristics of the Population	
Population Characteristic	**N (%)**
Race	
Black	62 (18.29)
White	158 (46.61)
Other	119 (35.1)
Gender	
Female	138 (40.71)
Male	201 (59.29)
Age Category	
Infant	133 (39.23)
Non-infant	206 (60.77)
Total population	339 (100)

Table 6: Study Population and Outcomes

For the second dichotomous outcome variable, readmission within 30 days of discharge, 39 patients (11.5%) required readmission to the hospital within 30 days of discharge. Table 7 contains data on patient population size and the number of patients experiencing readmission within 30 days of their procedure.

Study Population and Outcomes	N (%)
No Readmission	300 (88.5)
Readmission	39 (11.5)
Number of Observations	339 (100)

Table 7: Study Population and Outcomes

Logistic regression analyses found no statistically significant relationship between hospital volume in the base year and patient readmission in the study period ($p < 0.19$), while controlling for race and gender. The analysis also found no significant relationship between hospital prior-year volume and readmission based on patient race ($p < 0.74$), gender ($p < 0.23$), or age (p < 0.07). Table 8 presents the results of logistic regression by race, gender, infant status, number of comorbid conditions, hospital prior-year volume, and infant by volume interaction.

Logistic Regression Results for Readmission					
Variable	Estimate	OR	95% CI		p-value
Infant	1.0479	2.85	0.94	8.64	0.064
Non-infant	Ref				
Procedure volume	0.2371	1.27	0.89	1.80	0.1868
Volume X infant	-0.7404	0.48	0.24	0.95	0.0358
Race					0.74
Black	0.0495	1.05	0.64	2.03	0.9143
Other	-0.295	0.74	0.47	1.39	0.4895
White	Ref				
Gender					
Female	-0.4541	0.64	0.30	1.33	0.2274
Male	Ref				
# of comorbid conditions	0.4675	1.60	1.10	2.32	0.0142

Table 8: Readmission by Race, Gender, Infant Status, and Hospital Volume

A visual representation of the data showing the volume of the hospital prior-year stoma closure surgeries by readmission shows similar distributions of volume within this study population. Figure 2 is a box and whisker plot of stoma closure surgery volume by readmission status.

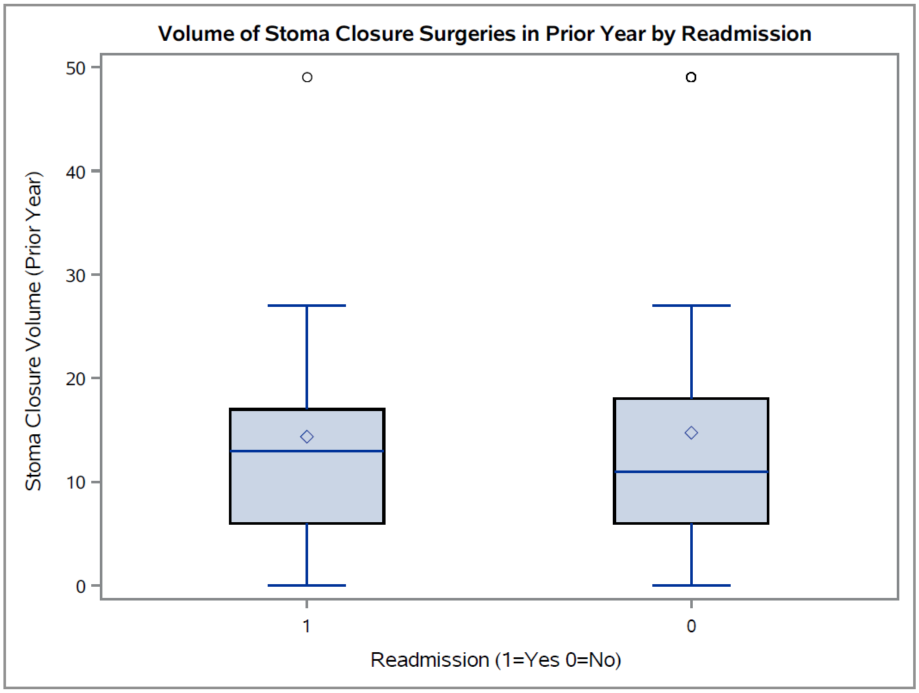

Figure 2: Volume in Prior Year by Readmission

Odds of Readmission by Patient Age Group

While age alone was not found to be a significant factor in readmission, further analysis was conducted on the data to determine if an interactional relationship exists between hospital prior-year volume, patient age group, and readmission. Patients were stratified into two groups based on age: Infant, (age < 1) or non-infant (1-18).

Statistical analysis conducted on data stratified by patient age group revealed a striking finding. In the infant age group, readmission exhibits a strong interactional association between readmission and hospital prior-year surgical volume ($p < 0.04$).

Figure 3 is a side-by-side Box and Whiskers plot illustrating the difference between the infant group's volume-readmission relationship and that of non-infant group. A statistically significant inverse volume-readmission association exists with infants that does not exist with non-infants. As hospital procedure volume increases, the likelihood of readmission decreases in the infant population. Further analysis is required to demonstrate the effect size of the relationship between the two groups and what it signifies.

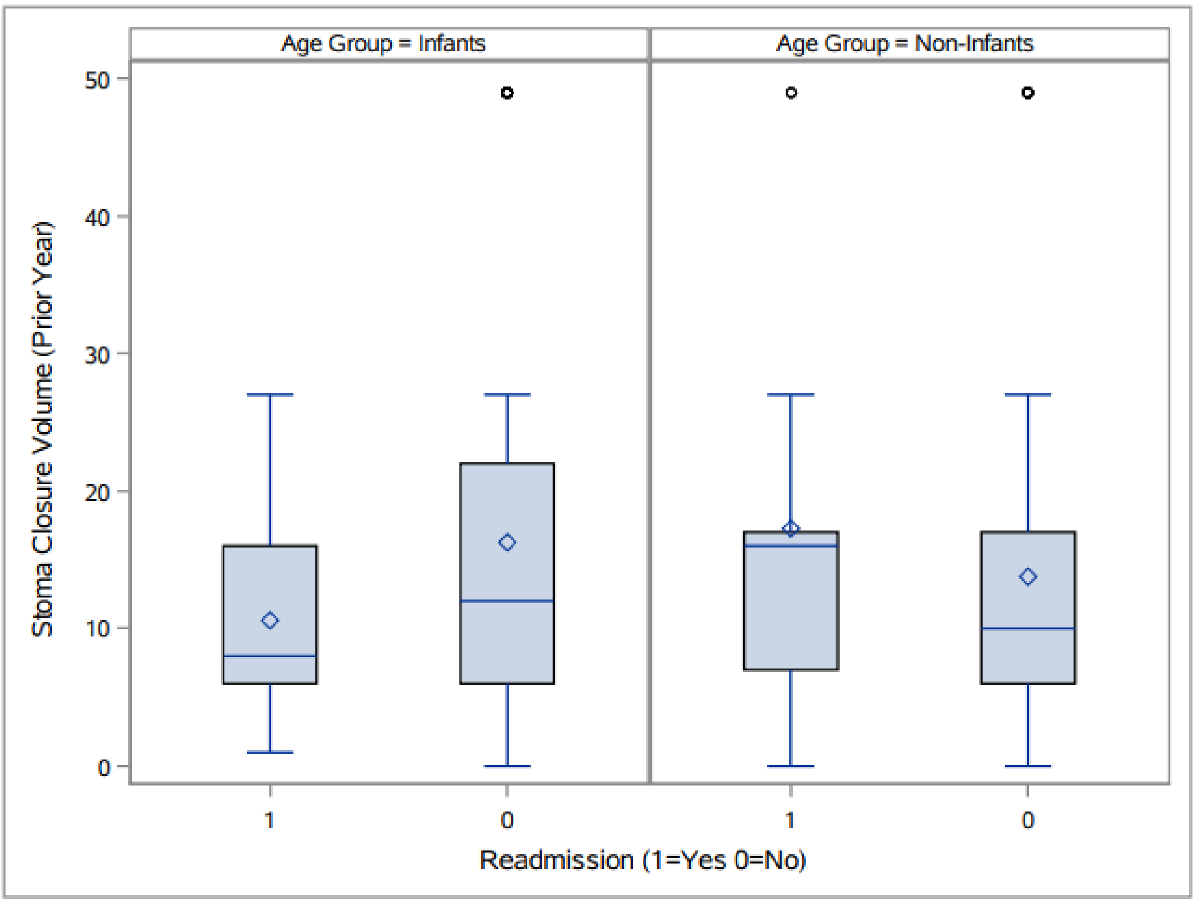

Figure 3: Volume in Prior Year by Readmission, Infants

Adjusted Odds Ratio of Infant Readmission

The key finding of the logistic regression analysis is the interaction between prior-year volume and the infant age group (See Table 8). The results indicate the interaction of prior-year hospital procedure volume with the infant age group has a statistically significant association to readmission ($p < 0.036$), but how strong is that association? Figure 4 is a Forest Plot showing the adjusted odds ratio and 95% confidence intervals of readmission for each covariate included in the final model.

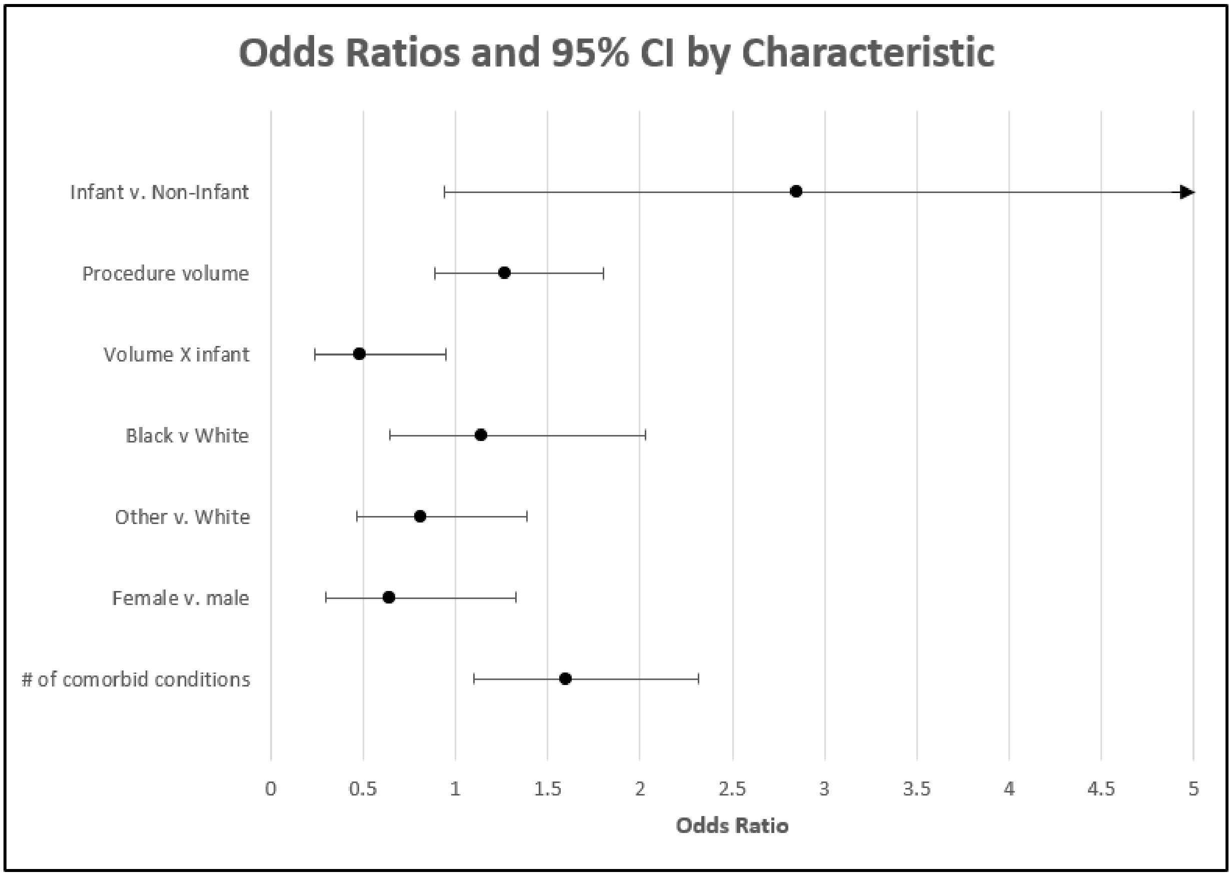

Figure 4: Odds Ratio with 95% Confidence Interval for Readmission

The model results suggest ***the likelihood of an infant requiring readmission following stoma closure surgery decreases by 52% for every ten stoma closure surgeries performed by a hospital in the prior year while controlling for race, gender,***

and number of comorbid conditions[1]. If one believes readmission to the hospital in the 30 days following a surgical procedure to be a true measure of surgical quality of care, these findings indicate hospital volume to be a factor influencing quality outcomes.

Length of Stay

Analysis of patient LOS, another surrogate measure of the quality outcome associated with stoma closure surgery, was done using a Generalized Linear Model (GLzM) with a Negative Binomial distribution and Log Link function to account for the right skewed nature of the outcome. Figure 4 is a scatter diagram displaying length of stay by the hospital's prior-year volume for both infants and non-infants.

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[1] The odds ratio of readmission in the infant population is calculated using the following formula: (1 - (e^(estimate)) X 100) = (1 – (e^(-0.7404)) X 100) = (1 – (0.477) X 100) = **52.3%**.

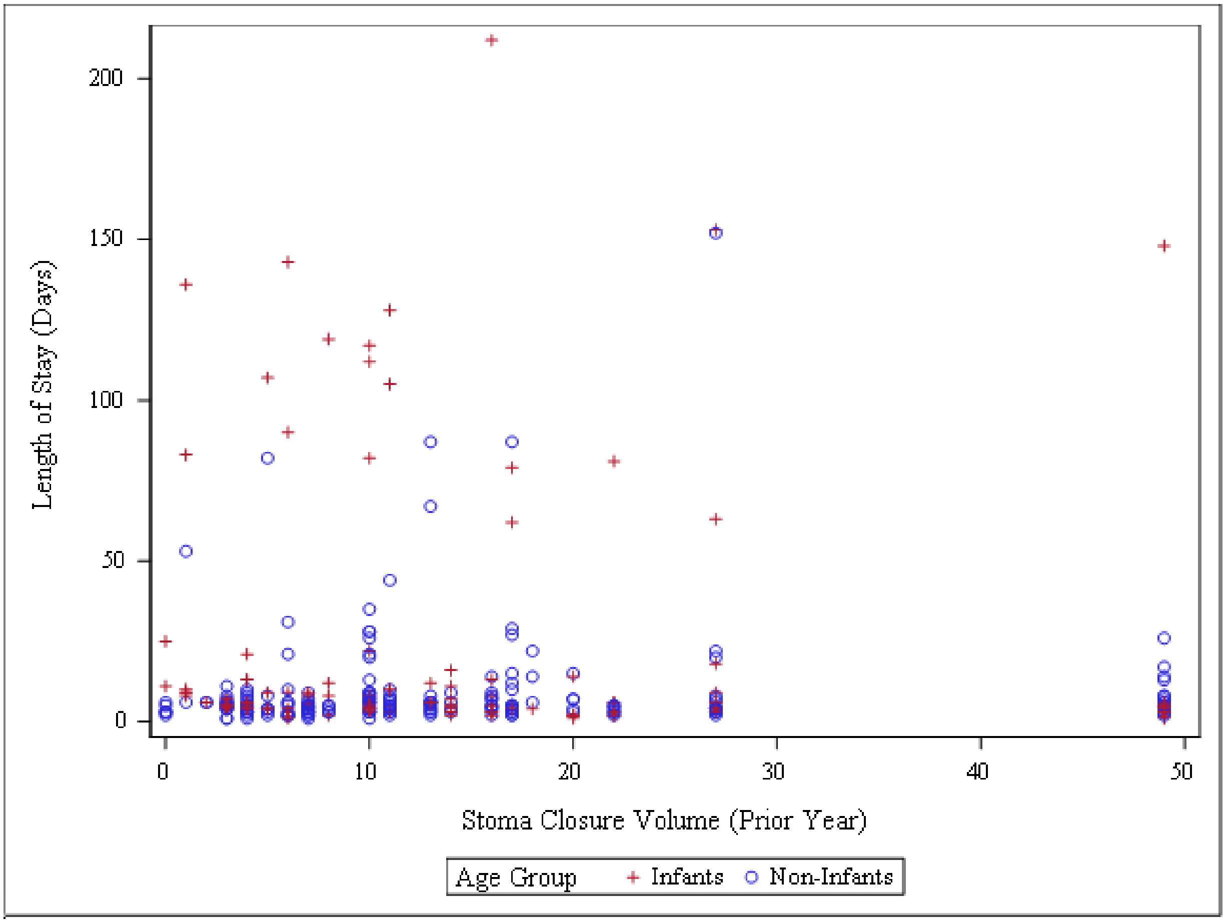

Figure 5: Length of Stay by Prior Year Volume, Infants

Length of Stay Analysis Using a Generalized Linear Model

Further analysis was conducted on the LOS data using a Generalized Estimating Equation (GEE) to estimate the effect of volume on LOS in both the infant and non-infant populations undergoing stoma closure surgery. The GEE utilized the Negative Binomial distribution and Log Link and also accounted for the within versus between variation differences of children treated within versus between hospitals. The adjusted model results are presented in Table 9 and demonstrate that ***prior-year hospital procedure***

volume exhibits a statistically significant relationship with LOS in the infant population ($p <$ .002).

Generalized Linear Model Results for Length of Stay						
Variable	**Estimate**	**Standard Error**	**OR**	**95% CI**		**p-value**
Intercept	1.0295	0.1662	2.8	2.02	3.88	<.0001
Infant	0.8355	0.1746	2.3	1.64	3.25	<.0001
Non-infant	Ref					
Procedure volume	0.0376	0.0655	1.04	0.91	1.18	0.5662
Volume X infant	-0.2865	0.0915	0.75	0.63	0.9	0.0017
Race						
Black	-0.0681	0.1498	0.93	0.7	1.25	0.6492
Other	0.0862	0.1251	1.09	0.85	1.39	0.4909
White	Ref					
Gender						
Female	-0.1535	0.1109	0.86	0.69	1.07	0.1662
Male	Ref					
# of comorbid conditions	0.7797	0.0747	2.18	1.88	2.52	<.0001
Dispersion	0.8592	0.0651	2.36	2.1	2.71	

Table 9: Results of Analysis on Length of Stay

The analysis using the SAS PLM procedure demonstrates that ***the predicted number of days an infant can expect to remain hospitalized following stoma closure surgery decreases by approximately 25% with every 10 case increase in a hospital's surgery volume in the previous year while adjusting for race, gender and number of comorbidities[2].***

The best way to grasp the nature and magnitude of the statistical analysis relationships is to view them graphically. Figure 5 is a bar graph showing expected LOS (Y-axis) for infants and non-infants undergoing stoma closure surgery at hospitals based on increments of 10 surgeries

[2] The calculation for the approximation is: <u>(e^(estimate) – 1) X 100</u> = <u>(e^(-0.2865) – 1 X 100</u> = <u>(0.75087-1) X 100</u> = <u>**-25%.**</u>

performed in the prior year (X-axis). Both groups show improvement (a decrease) in expected LOS as volume increases with a diminishing marginal impact as volume grows. Both groups exhibit a relationship; however, the effect size is much larger in the infant group than in the non-infant group.

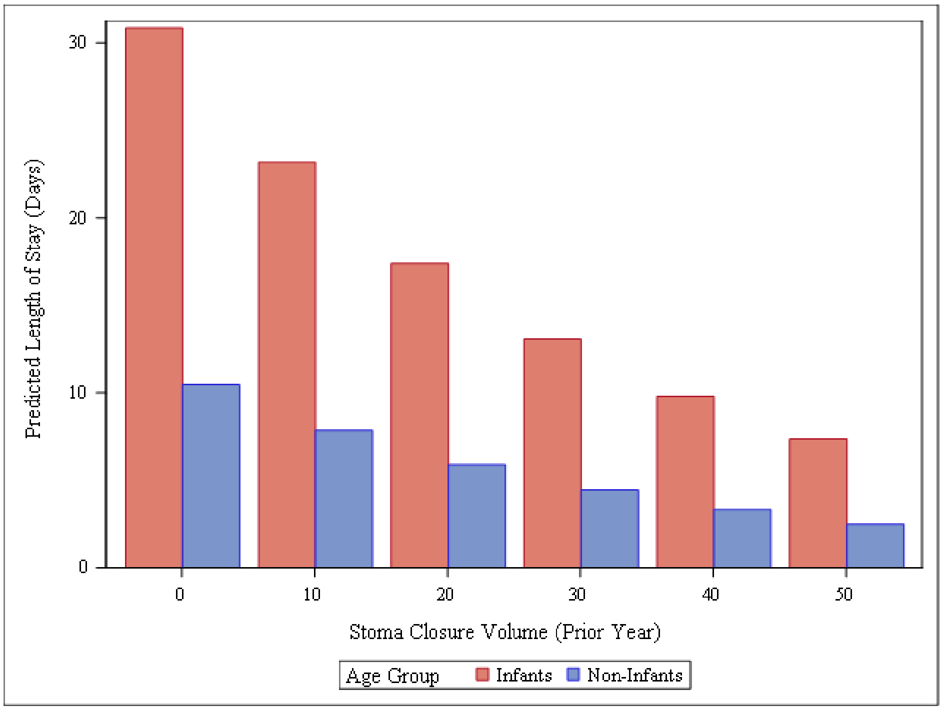

Figure 6: Length of Stay by Procedure Volume

CHAPTER 5. Discussion

Mortality

The mortality rate associated with stoma closure surgery in this study was 0.29%, a rate similar to that of other studies of stoma closure patients. A 2004 study of 56 stoma closures in children found a mortality rate of 1.8% (Chandramouli et al., 2004). Another older study found a mortality rate in pediatric stoma closure surgery to be 6.5% (Nour et al., 1996). A 2009 study found that surgeon volume was a factor in postoperative mortality following colon resection in adults, but hospital volume did not influence mortality (Karanicolas et al., 2009).

These findings indicate that while stoma closure remains a procedure associated with a relatively high complication rate, the mortality rate following the procedure has decreased significantly in the past 25 years. Whether postoperative mortality is influenced more by the surgeon or hospital factors requires additional study.

Readmission

The patient readmission rate in this study was 11.5%. This rate is consistent with the readmission rate found in a study at Texas Children's Hospital in 2019, where two cohorts of pediatric stoma closure patients were monitored for postoperative complications and readmission. That study found a 13% and 16% readmission rate in its two cohorts (Rosenfeld et al., 2019). A 2017 study of adults following colorectal surgery found a 30-day readmission rate of 11.2% (Hechenbleikner et al., 2017). The readmission rate following colorectal surgery does not seem to vary significantly in adults versus children, with one exception: Infants.

In this study, patients' age group expressed as a dichotomous variable, infant (1) or non-infant (0), and hospital prior-year procedure volume together become a statistically significant predictor of 30-day readmission following stoma closure surgery. Stated another way, hospital procedure volume in the year before surgery is a significant predictor of readmission in the infant population undergoing stoma closure surgery. This study empirically demonstrates that ***for every increase of 10 pediatric stoma closure procedures a hospital does in the prior year, an infant is 52% less likely to be readmitted within 30 days of a stoma closure surgery.***

Prior studies have validated an inverse volume-outcome association in more complex surgeries while refuting the existence of one in less complicated surgeries in an adult population (Wang, 2003). Colorectal resections have been identified as a procedure not exhibiting a volume-outcome association in adults (Urbach & Baxter, 2004; Nimptsch & Mansky, 2017). This study's findings indicate that prior year hospital surgical volume mediates the likelihood of readmission in complex patients, notwithstanding the surgery's complexity. This study accounted for patient complexity by employing the widely accepted Feudtner pediatric Complex Comorbid Condition index and controlling for the number of comorbid conditions. After controlling for the number of comorbid conditions, the analysis still found a relationship between hospital prior-year procedure volume and readmission in the infant population, indicating infants may be a more complex patient group beyond merely the existence of any comorbid conditions.

One potential explanation for the reduced readmission rate in infants versus non-infants is that infants remain hospitalized longer following surgery than older children. The bar graph in Figure 5 shows that infants remain admitted nearly three times longer than non-infants following surgery, at all volume levels, which provides time for postoperative complications to manifest and resolve before discharge. However, this comparison between patient groups does not diminish the finding that the odds of infants' readmission decrease significantly as hospital prior-year procedure volume increases.

Another point of discussion involves the hospital's prior-year procedure volume itself. Is the volume of *"stoma closure"* surgery the critical, independent variable, or could the number of *"bowel surgeries"* performed be a better measure? In this study, the volume of stoma closure surgeries may be acting as a surrogate for bowel surgery experience as the two are very likely related. Postoperative treatment of a stoma closure patient may differ little from that of other bowel surgery patients. In a study of postoperative mortality, Urbach & Baxter (2004) found that overall hospital surgical volume was a better predictor of mortality than was the volume of the specific procedure being studied. This topic requires additional study.

Length of Stay

Reduced LOS following stoma closure surgery relative to prior year procedure volume, especially in the infant population, is a significant finding of this study. This study empirically demonstrates that ***the number of days an infant can expect to remain admitted decreases by approximately 25% for every ten additional stoma closure surgeries a hospital performed in the previous year*** while adjusting for race, gender, and the number of comorbidities. The bar graph in Figure 5 is a striking exhibit showing the effect of prior-year hospital procedure volume on predicted LOS for both infants and non-infants undergoing stoma closure surgery. As expected, the incremental improvement (decrease) in LOS shrinks as the number of cases increases in both groups. However, the magnitude of the improvement is much larger in the infant population.

Other studies have identified comorbid conditions and hospital volume to be significant predictors of longer LOS (Pucciarelli et al., 2017). When comparing expected LOS at the highest volume hospitals compared with the lowest volume hospitals, after controlling for comorbid conditions, infants undergoing stoma closure surgery should expect to be hospitalized 66% fewer days at a hospital that performs the surgery 50 or more times per year versus a hospital performing the procedure less than ten times per year. Non-infant patients' expected hospital stay is 50% less at high-volume hospitals than low-volume hospitals.

Other possible reasons for the lower LOS at higher-volume hospitals might have little to do with the surgery itself. Higher volume hospitals may be academic institutions with more resources, greater availability of sub-specialist physicians, or more experienced inpatient nursing staff. Surgeons at higher-volume hospitals may also be more comfortable discharging a patient sooner due to more significant experience managing this group of postoperative patients.

Whatever the cause, reduced LOS brings several clinical, administrative, and patient-focused benefits. Noted benefits of reduced LOS include reduced utilization of resources, reduced opportunity for a hospital-acquired condition or infection, reduced time away from work or school for the patient and their family, and increased patient and family satisfaction. A significant additional benefit to reduced LOS is cost. A significant portion of the medical cost for admission is the hospital room and board, which can be thousands of dollars per day. LOS reduction can reduce the total cost for a stoma closure surgery by tens of thousands of dollars. Further study related to higher volume, specialized centers, is required to assess if they may be less costly.

Significance of these Findings

These findings suggest that complex patients, or those requiring complex procedures, may best be treated in high volume centers. These results are not generalizable to all patient phonotypes or all surgical procedures; however, they are generalizable to pediatric patients nationwide and infants in particular. Pediatric patients of any age requiring stoma closure surgery are likely to have a shorter length of stay if treated at a high-volume center. Additionally, infant patients are less likely to be readmitted when treated at a high-volume center.

Both readmissions for postoperative complications and LOS contribute to the overall cost of an episode of care. The financial burden associated with inpatient surgical care can lessen if either readmission rates or LOS decrease. These findings suggest that pediatric patients' costs associated with surgical treatment of certain bowel anomalies could be reduced substantially by directing them to high-volume centers.

This study's findings are relevant to parents of children facing stoma closure surgery. As a parent with a child, especially if that child is an infant, one should ask a potential surgeon, *"How many of these surgical procedures has this hospital done in the past two years?"* The second task is to determine if this hospital has performed this surgery often enough to reduce the odds of readmission or to reduce the expected postoperative LOS enough to care for their child. The third and final task is to choose a hospital where the child has the best chance of a quality outcome.

This study's findings are relevant to the health insurance industry. Medical claim payers should note the reduced readmission and LOS achieved by higher volume hospitals. Both characteristics indicate that both lower cost and higher value treatment are associated with higher volume centers and they should be considered preferred hospitals, even if they are in another state. Find the ***Best in Class*** medical programs throughout the United States and include those programs in the preferred network. Doing so might reduce cost significantly for those services.

This study's findings are also relevant to government healthcare policymakers. The quest for value in healthcare spending should be a universally accepted goal. Higher volume hospitals can offer better value in some circumstances and, when those circumstances exist, policymakers should remove any barriers patients or families face, which prevent them from seeking care at those institutions.

Conclusion

This study's findings indicate that hospital prior-year procedure volume exhibits a relationship to quality surgical outcomes of readmission and LOS in infant patients following stoma closure surgery. It does not definitively show this relationship to be causal. Are quality indicators better because the volume is high or are volumes high because of better quality? Regardless, the relationship exists, and it is significant.

Limitations of this Study

A primary limitation of this study is the assumption that postoperative readmission is due to a complication of the stoma closure surgery. While the overwhelming majority of 30-day postoperative readmissions are the result of complications resulting from the surgery rather than exacerbation of medical issues existing prior to surgery (Merkow et al, 2015), the possibility exists that the cause of readmission is unrelated to the surgery. Administrative data is insufficient to rule out the possibility that readmission was due to a comorbid condition unrelated to the surgery.

Another limitation of this study is the reliance on archival billing data as a surrogate for a quality outcome. While readmission is a generally accepted surrogate measure of quality, it only identifies surgery complications significant enough to warrant readmission. Many other, less catastrophic complications are possible but will not appear in billing data. Complications such as constipation or infection addressed during the index admission may not be identified in archival billing data yet are necessary quality of care measures. Therefore, patient LOS is a reasonable surrogate measure of minor complications or unexpected events resulting from surgery or postoperative care.

Lastly, studying only hospital volume while not examining surgeon volume may provide misleading information. Surgeon-specific volume is not available in the current study data. A low-volume surgeon in a high-volume hospital may have a volume-outcome association quite different than that of the hospital. Further study is required relating to a surgeon-specific volume-outcome association.

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