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Concomitant fundoplication increases morbidity of gastrostomy tube placement☆,☆☆,★,★★

Loren Berman [a,*], Iman Sharif [a], David Rothstein [b], Jobayer Hossain [a], Charles Vinocur [a]

[a] Nemours-A.I. duPont Hospital for Children, Wilmington, DE
[b] Division of Pediatric Surgery, Women and Children's Hospital of Buffalo, Buffalo, NY

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ABSTRACT

Background: Fundoplication is often performed in conjunction with gastrostomy tube (GT) placement in children, but there is a great deal of variation in rates of and indications for this procedure. Little is known about the impact of fundoplication on peri-operative outcomes. This study examines a national cohort of pediatric patients to compare risk-adjusted surgical outcomes in patients undergoing GT placement with or without concomitant fundoplication.

Methods: We identified all patients undergoing GT placement in the 2012 National Surgical Quality Improvement Program – Pediatric. We evaluated demographics, comorbidities, complications, and length of stay for GT with fundoplication versus GT alone. We defined composite morbidity as a dichotomous variable for the presence of any complication. Logistic regression was performed to identify predictors of morbidity after adjusting for covariates.

Results: 1289 GT patients were identified, and 148 (11.5%) underwent concurrent fundoplication. The fundoplication patients were more likely to be younger, have cardiac risk factors, and be on respiratory support. They also had higher rates of surgical site infection (7.4% vs 3.7%, $p = 0.03$) and composite morbidity (16.9% vs 8.7%, $p = 0.001$), and longer LOS (median 5 vs 3 days, $p = <0.0001$) compared to GT only. After adjusting for covariates, fundoplication was a predictor of composite morbidity and increased LOS.

Conclusion: Concomitant fundoplication is an independent risk factor for 30-day post-operative morbidity in patients undergoing GT placement. These findings do not negate the value of fundoplication but underscore the importance of careful patient selection, and should be taken into consideration when discussing risks and benefits with families.

About 14,400 gastrostomy tubes (GT) were placed in children in the United States in 2009, making it one of the most common elective operations performed on the alimentary tract in children [1]. Gastrostomy tube placement is an operation plagued by complications ranging from insertion site granulation tissue to intra-abdominal leakage requiring reoperation, with published complication rates ranging from 2% to 20% [2–6]. It is difficult to compare results of single institution series, however, because of the lack of a uniform definition of complications and varied methods of data collection and case selection. Whether or not to perform fundoplication at time of GT placement is a difficult decision in some cases, and the added morbidity of concurrent fundoplication is not well understood.

In order to describe outcomes of GT placement and identify predictors of morbidity in a generalizable fashion it would be ideal to use a national database, but administrative databases are limited in their ability to provide reliable data because of inconsistent definitions and data entry of comorbidities and outcomes [7]. The American College of Surgeons National Surgical Quality Improvement Program – Pediatric (NSQIP-P) contains validated outcomes data from 50 children's hospitals across the country and can be used to describe complication rates and identify risk factors for these complications. This dataset provides a unique opportunity to evaluate risk-adjusted outcomes at children's hospitals for children undergoing GT placement with or without fundoplication.

Failure of medical therapy for gastro-esophageal reflux disease (GERD) is perhaps the most common indication for fundoplication, but some practitioners recommend prophylactic fundoplication for patients with certain comorbidities who may be prone to developing reflux or are at risk for complications such as aspiration pneumonia [8]. Multiple single institution series have reported extremely low complication rates after fundoplication, and especially laparoscopic

Abbreviations: ASA, American Society of Anesthesiologists; GT, gastrostomy tube; GERD, gastro-esophageal reflux disease; LOS, length of stay; NSQIP-P, National Surgical Quality Improvement Program - Pediatric; PUF, participant user file; SSI, surgical site infection.

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* Corresponding author at: Department of Surgery, A.I. duPont Hospital for Children, 1600 Rockland Rd., Wilmington, DE 19803. Tel.: +1 302 651 5888.
E-mail address: loren.berman@nemours.org (L. Berman).

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fundoplication [9–11], but these low rates have never been validated in a large dataset. In addition, there is a great degree of variation in the rate of fundoplications in children's hospitals across the country [12]. Having a better understanding of the outcomes of GT placement in general, as well as the potential impact of fundoplication on morbidity, would help to inform decision-making about which patients should have a fundoplication along with gastrostomy tube placement.

1. Patients and methods

1.1. Data source

The 2012 NSQIP-P participant use data file (PUF) consists of 327 data points, including preoperative risk factors, intraoperative variables, and 30-day postoperative morbidity and mortality for patients undergoing major surgical procedures in both the inpatient and outpatient setting. Each of the 50 participating children's hospitals has a trained and certified surgical clinical reviewer who reviews charts and follows up with patients when necessary in order to enter information in the database. Data at collecting sites is routinely audited to ensure appropriate case selection and accurate assignment of variables. If the inter-rater reliability audit disagreement is greater than 5% or the 30-day follow-up rate is less than 80% then the data is excluded from the PUF. [13] The study protocol was evaluated by our IRB and deemed to be exempt from review.

1.2. Case selection

Using the 2012 NSQIP-P PUF, we identified all patients with primary Current Procedural Terminology (CPT) 2011 codes for GT placement or fundoplication (43830, 43653, 43831, 43324, 43280, 43325, 43327). We then identified concurrent procedures in order to determine which patients were undergoing GT placement alone and GT placement with fundoplication. We did not include patients undergoing fundoplication without GT placement. We also did not include patients undergoing GT placement as a secondary procedure.

1.3. Variables

The primary independent variable was type of operation: GT only versus GT with fundoplication. We evaluated demographic characteristics (age, gender, race, ethnicity), comorbidities, inpatient versus outpatient status, surgical approach (laparoscopic versus open), and post-operative complications and length of stay. Age was converted to a categorical variable: less than 1 year, 1–5 years, 6–12 years and 13–18 years. For the race variable, the numbers of Asian, Native American, and Native Hawaiian were small so these were grouped into a single category called "other race." There were 173 observations for which race was unknown, and we performed the analysis with "unknown" as its own race category and with "unknown" included in the "other" category. Results of these two analyses were similar, so we grouped unknown/other together. Ethnicity was treated as a category separate from race, with patients classified as Hispanic, non-Hispanic or unknown. American Society of Anesthesiologists (ASA) class was grouped into 1 or 2, 3 and 4 or 5 because there were so few patients in ASA class 1 or 5 categories.

In order to describe outcomes, a composite surgical site infection (SSI) variable was created by grouping together the NSQIP variables superficial, deep and organ space SSI. A composite morbidity variable was created by grouping together SSI, wound disruption, pneumonia, unplanned intubation, pulmonary embolism, renal failure/insufficiency, urinary tract infection, coma, stroke, seizure, nerve injury, intraventricular hemorrhage, cardiac arrest, transfusion greater than 25 cc/kg in first 72 hours, ventricular tachycardia, sepsis, and central line associated bloodstream infection. Reoperation and readmission were not included in composite morbidity according to NSQIP-P convention [14,15]. In addition to the composite morbidity analysis, the likelihood of unplanned intubation, transfusion >25 cc/kg, and sepsis were assessed since these were the most common complications other than SSI. Detailed definitions of all variables are available in the NSQIP-P PUF user guide [13].

1.4. Statistical analysis

Study variables including demographic and clinical characteristics were summarized by group (GT with and without fundoplication). Categorical variables were described using frequencies and percentages. A chi-square or Fisher's exact test was used to compare the distribution of demographic and clinical variables between the two groups. Frequencies and percentages of composite morbidity were described by groups of study variables, and univariable logistic regression was used to examine the association of fundoplication and other study variables with composite morbidity. All tests were two-tailed at the overall level of significance of 0.05. The distribution of the length of hospital stay (LOS) was right skewed, so median and interquartile range were used to summarize this variable. The Mann-Whitney U test or Kruskal-Wallis test, whichever appropriate, was used to compare the median LOS between groups of study variables.

Multivariable logistic regression with stepwise backward variable selection was used to select variables that were significantly associated with composite morbidity. We included all variables that were significant at the 0.05 level on univariable regression for composite morbidity and that were significantly different between the GT only versus GT fundoplication groups in the initial model, along with demographics. A p-value of 0.05 was set as the criterion for keeping a variable in the model, but all demographics were kept in the model. To evaluate LOS, we performed a Box-Cox transformation with power parameter $\lambda = -0.4$ to change the shape of the distribution. A multiple regression analysis with stepwise backward variable selection was used to identify the variables significantly associated with LOS. Model assumptions were checked before statistical analyses. All statistical analyses were performed using SAS Enterprise Guide 4.2 (Cary, NC).

2. Results

A total of 1289 patients who underwent GT placement were identified, and 148 of these (11.5%) had concurrent fundoplication. Patients aged less than one year were more likely to have fundoplication compared to other age groups. Fundoplication patients were also more likely to be inpatient, have esophageal, gastric or intestinal disease (this category includes GERD), have cardiac risk factors, require inotropic or oxygen support, be on a ventilator at time of surgery, or have pneumonia at the time of surgery (Table 1). A higher proportion of fundoplication patients had laparoscopic surgery compared to GT alone (82% vs 72%, $p = 0.006$). There was no difference in rate of neurologic impairment, seizure disorder, cerebral palsy, neuromuscular disorder, or chronic lung disease between the two groups. About 50% of the sample (649 patients) had a diagnosis of failure to thrive or had experienced 10% weight loss in the six months preceding surgery, but there was no significant difference in the proportion of these patients in the GT group versus the GT and fundoplication group (50.8% versus 46.6%, $p = 0.34$).

Fundoplication was significantly associated with composite morbidity (16.9% vs 8.7%, $p = 0.001$) on univariable logistic regression. Several variables were associated with composite morbidity, including age less than one year, higher ASA class, preoperative sepsis, chronic lung disease, esophageal/gastric/intestinal disease, cardiac risk factors, hematologic disorders, preoperative oxygen support or ventilator dependence, preoperative steroid use or weight loss, and