RESEARCH ARTICLE

Effectiveness of Fundoplication or Gastrojejunal Feeding in Children With Neurologic Impairment

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ABSTRACT

BACKGROUND AND OBJECTIVES: Gastroesophageal reflux (GER), aspiration, and secondary complications lead to morbidity and mortality in children with neurologic impairment (NI), dysphagia, and gastrostomy feeding. Fundoplication and gastrojejunal (GJ) feeding can reduce risk. We compared GJ to fundoplication using first-year postprocedure reflux-related hospitalization (RRH) rates.

METHODS: We identified children with NI, dysphagia requiring gastrostomy tube feeding and GER undergoing initial GJ placement or fundoplication from January 1, 2007 to December 31, 2012. Data came from the Pediatric Health Information Systems augmented by laboratory, microbiology, and radiology results. GJ placement was ascertained using radiology results and fundoplication by International Classification of Diseases, Ninth Revision, Clinical Modification codes. Subjects were matched within hospital using propensity scores. The primary outcome was first-year postprocedure RRH rate (hospitalization for GER disease, other esophagitis, aspiration pneumonia, other pneumonia, asthma, or mechanical ventilation). Secondary outcomes included failure to thrive, death, repeated initial intervention, crossover intervention, and procedural complications.

RESULTS: We identified 1178 children with fundoplication and 163 with GJ placement, matching 114 per group. Matched sample RRH incident rate per child-year (95% confidence interval) for GJ was 2.07 (1.62–2.64) and for fundoplication 1.67 (1.28–2.18), $P = .19$. Odds of death were similar between groups. Failure to thrive, repeat of initial intervention, and crossover intervention were more common in the GJ group.

CONCLUSIONS: In children with NI, GER, and dysphagia: fundoplication and GJ feeding have similar RRH outcomes. Either intervention can reduce future aspiration risk; the choice can reflect non-RRH-related complication risks, caregiver preference, and clinician recommendation.

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Dr Stone assisted with conceptualizing the study, collected data, validated data, assisted with data analysis, and drafted the initial manuscript; Drs Hester and Jackson assisted with data collection instrument design, collected data, and reviewed and revised the manuscript; Mr Gouripeddi and Mr Butcher designed the data collection instrument, collected data, were instrumental in data preparation for analysis, and reviewed and revised the manuscript; Drs Richardson and Hall planned the data analysis, acquired the data from PHIS+, completed the analysis and reviewed and revised the manuscript; they had full access to the data and take responsibility for the integrity of the data and the accuracy of the analysis; Drs Keren and Srivastava conceptualized the study, provided oversight and advice during data acquisition and analysis, and critically reviewed the manuscript; and all authors approved the final manuscript as submitted and agree to be accountable for all aspects of the work.

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Children with severe neurologic impairment (NI) often have failure to thrive due to nutritional deficiency and aspiration of pharyngoesophageal contents due to dysphagia and gastroesophageal reflux (GER).[1–4] Primary and secondary aspiration from oral intake and GER may lead to development of acute and chronic lung disease and subsequent respiratory-related death.[5–7] In this population, nutrition and primary aspiration risk are often addressed with gastrostomy tube (GT) placement for feeding.[4,8] Children with GER remain at significant risk for secondary aspiration of refluxed material with related morbidity and mortality.[4] These children are then offered either a fundoplication with continued GT feeding or a change to transpyloric gastrojejunal (GJ) tube feedings.[9,10]

Previous research has addressed the effectiveness of fundoplication in this clinical scenario.[9,11–14] Although generally favorable, studies report subjective outcomes, have few patients enrolled, and are largely retrospective in design. A large cohort study of children with NI demonstrated a reduction in hospitalizations for aspiration pneumonia, gastroesophageal reflux disease, and mechanical ventilation after fundoplication.[15] There are fewer published studies evaluating the effectiveness of GJ feedings to reduce secondary aspiration risk.[16] One single-center study comparing GJ placement and fundoplication found more frequent hospitalizations associated with GJ feeding, largely due to admission for tube replacements, with no difference in time to aspiration pneumonia admission or mortality.[17,18] The conduct of a prospective randomized comparative effectiveness study has been hampered by a lack of clinical equipoise between the 2 treatment arms as expressed by parents and the limited number of patients in a single center.

The Pediatric Research in Inpatient Settings Network in partnership with the Children's Hospital Association developed the Pediatric Health Information Systems—plus (PHIS+) database, which includes data present in the PHIS database from 6 free-standing children's hospitals augmented by laboratory, microbiology, and radiology results data.[19–21] We used the PHIS+ database to compare the effectiveness of GJ tube feeding to fundoplication plus GT feeding in reducing reflux-related hospitalizations (RRH) in children with NI and GER.

METHODS

This study was approved by the Institutional Review Boards of the University of Utah and the 6 PHIS+ sites with a waiver of informed consent.

Data Sources

Data were obtained from the Children's Hospital Association PHIS+ database.[20] PHIS+ includes all PHIS components: patient abstract (demographics, total charges, etc), diagnoses, procedures, and detailed Clinical Transaction Classification (CTC) codes for laboratory studies, pharmacy, imaging, clinical, supply, and other charge events. In PHIS, patients are assigned a unique ID number to permit tracking over multiple hospitalizations. PHIS undergoes prescribed data quality and validation processes. PHIS+ is augmented by values for harmonized laboratory tests and microbiology studies, as well as radiology results text. Radiology results text is deidentified in bulk using De-ID software (De-ID Corp, Richboro, PA; www.de-idata.com) and includes examination title, report text, and impression reported in free-text format. PHIS+ underwent careful validation using random chart review at the 6 participating hospitals.

Study Design and Participants

We conducted a retrospective observational 1-to-1 propensity score matched comparative effectiveness study of children admitted to a children's hospital participating in PHIS+ between January 1, 2007, and December 31, 2012, with NI, GT feeding, and GER who underwent a first intervention to control GER. The interventions for GER were simultaneous or subsequent addition to GT feeding of fundoplication or GJ tube feeding. To minimize treatment misclassification, we followed 2 strategies: (1) we enrolled younger children for whom we had hospitalization information in PHIS from birth and could identify their first intervention to control GER, and (2) we enrolled older children meeting inclusion criteria who had data present in PHIS for a minimum of 4 years preceding study entry to validate their first intervention for GER during the study years. International Classification of Diseases, Ninth Revision, Clinical Modification (ICD-9-CM) inclusive diagnosis codes were used to identify and group children with NI.[22] GT placement or presence was identified by ICD-9-CM procedure codes 4300, 4311, 4319, 9702 and diagnostic codes v441, v551, 536.4×. We validated ICD-9-CM diagnosis and procedure code identification of initial GT placement with chart review of 780 random charts at the 6 participating hospitals (see Supplementary Table 6). The diagnosis of GER was ascertained using ICD-9-CM diagnostic codes 530.11 and 530.81, in combination with CTC codes for GER medications (histamine 2 receptor blockers, proton pump inhibitors, and antacids; see Supplementary Table 7 for codes). The fundoplication intervention group was identified using ICD-9-CM procedure codes (44.66, 44.67) and the GJ group through manual review of radiology reports in PHIS+ (identified using Current Procedural Terminology [CPT] codes listed in Supplementary Table 8). After validating the process, radiology report data extraction was completed by 6 trained reviewers using Research Electronic Data Capture (REDCap) tools hosted at the University of Utah (see Supplementary Fig 2).[23] Data for inclusion and independent variables were present in the record at the time of the index procedure but did not have to be listed as discharge diagnoses for that specific hospital admission.

Outcome Measures and Other Variables

The primary outcome measure was the rate of RRH that occurred during the first year after the initial intervention. RRH is a composite measure of hospitalization for gastroesophageal reflux disease (GERD), other esophagitis, aspiration pneumonia, other pneumonia, asthma, and mechanical ventilation (see Supplementary Table 7 for ICD-9-CM codes).[15] Hospitalization for

esophagitis, GERD, and aspiration pneumonia represent likely complications of persisting GER. Hospitalization for other pneumonia and asthma were included because distinguishing aspiration pneumonia or aspiration/GER-associated asthma[24,25] from other pneumonia or asthma can be difficult as a subjective diagnosis in this medically complex population unless clinically obvious, such as with a witnessed aspiration event, and, if unrelated to GER, should not associate with either GJ or fundoplication and not introduce bias.[26,27] We chose mechanical ventilation because unlike the preceding diagnoses, it is an objective measure of serious respiratory disease that, again, would not be expected to differ between the 2 groups if unrelated to GER.

Secondary outcomes for the 2 intervention groups were also measured over 1 year and included a discharge diagnosis of failure to thrive, death during hospitalization (recorded in PHIS), a second intervention for unresolved GER (subsequent fundoplication if GJ was first, or GJ placement if fundoplication was first), repeat of the initial intervention (GJ replacement or fundoplication redo), procedural complications for GJ or fundoplication (early: ≤30 days, late: >30 days) and gastrostomy complications in each group. Procedural complications for both procedures were derived from the Agency for Healthcare Research and Quality Patient Safety Indicators including bleeding, peritonitis, reoperation, shock, hematoma/seroma (± infection), other infection, accidental puncture, wound dehiscence, nonhealing wound, foreign body left, postoperative sepsis, postoperative pulmonary embolus, postoperative respiratory failure, anesthesia complications, other/unspecified complications, late complications, and E-codes for abnormal outcome of surgery.[28] Complications of gastrostomy based on ICD-9 codes were persistent vomiting (suggesting nonresolution of GER or gastric/enteral obstruction), gastrostomy complication unspecified, infection of gastrostomy, and mechanical complication of gastrostomy. All secondary outcomes were identified using ICD-9-CM codes augmented when helpful with CTC codes and Current Procedural Terminology codes (see Supplementary Table 7).

Variables potentially influencing intervention choice were collected including complex chronic conditions,[29–32] technology dependencies,[33–35] tracheostomy,[36,37] upper airway anomalies,[38] previous aspiration pneumonia, chronic lung disease, swallow study or known dysphagia, and contraindications for fundoplication (microgastria, Barrett esophagus, peptic stricture, esophageal dysmotility, short esophagus, gastric or intestinal motility disorders, and gastric outlet obstruction).

Statistical Analyses

Categorical variables were described using frequencies and percentages; continuous variables using median and interquartile range. χ^2 tests compared categorical variables and the Wilcoxon rank-sum test compared medians.

We used propensity score matching to account for potential confounding between treatment groups by observed baseline covariates instead of multivariable modeling because the number of covariates was large and could create unreliable estimates.[39–41] We created a propensity score using multivariable logistic regression to estimate the likelihood of GJ tube feeding in children with NI, GT feeding, and GER using the following significantly associated variables: previous swallow study; gastrointestinal (GI) tech dependency; race; meningitis, encephalitis, or abscess; cerebral palsy; intracranial hemorrhage or injury; GI motility disorder; or peptic stricture. The propensity score was used to perform a 1-to-1 match between patients with a GJ tube and patients with a fundoplication using the SAS Greedy match algorithm.[42] Balance of covariates between groups was assessed both before and after matching. Patients without a match were removed from the analysis. The calculated C-statistic for the propensity match was 0.87, indicating the model provided a better estimate than expected by chance alone (ie, a C statistic equal to 0.5), eliminating concern for nonoverlapping propensity score distributions between groups.[43]

The primary analysis compared RRH rates per child-year, defined as 365 days starting with the date of the first intervention (fundoplication or GJ placement). Secondary analyses compared rates of repeated first intervention and failure to thrive, and odds of second intervention (GJ if fundoplication first, fundoplication if GJ first) and death. Rates per child-year of RRH and rates/odds of secondary outcomes were calculated directly. Rate ratios and odds ratios were used to compare results and generate P values. The percentage of patients experiencing surgical and gastrostomy complications within 1 year were compared using a χ^2 test for association.

Outcomes except death and second intervention were modeled using a multivariable generalized linear mixed model (GLMM) assuming an underlying Poisson distribution. GLMMs were assessed for overdispersion, and if present, the GLMM was refit assuming an underlying negative binomial distribution. Death and second intervention were modeled using logistic regression. All models included a random hospital clustering effect to account for hospital-to-hospital variability.[44,45]

A priori power calculation using previously published studies [15] supported an estimated minimum 1 year outcomes data on 200 children with fundoplication and 120 with GJ tubes. Assuming fundoplication RRH admission rates per child-year would range from 0.6 to 1.6, detectable changes in GJ RRH rates per child-year would range from >0.90 to >2.06 with 80% power and from >0.96 to >2.14 with 90% power to detect a difference. Calculations were performed using PASS 2008, implementing the methodology of Signorini.[46]

RESULTS

We identified 78 914 neurologically impaired children with initial GT placement in 7544 (9.6%), and a GER diagnosis in 4733 (62.7%). Of these, 3392 had no intervention, 1178 had an initial fundoplication, and 163 had an initial GJ tube placement (Fig 1). Table 1 lists characteristics of the participating hospitals in relation to annual admissions, annual NI admissions, overall procedures to treat GER in NI children, and each

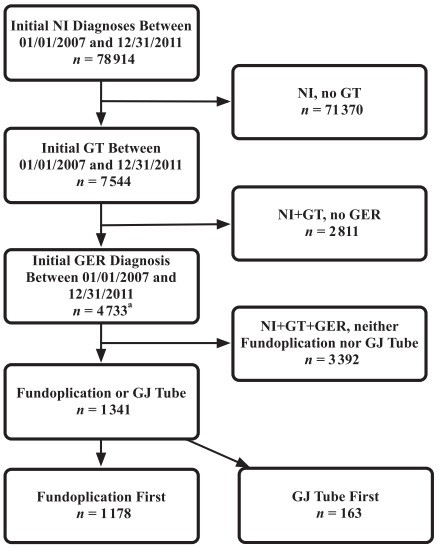

FIGURE 1 Cohort selection within the 6 PHIS+ participating hospitals. [a] To verify GJ tubes for the 4733 patients with NI, GT, and GER, we identified and reviewed all 507 of their GJ-related radiology studies and identified 163 original GJ placements (1 of our treatment groups).

hospital's contribution to the study population. Table 2 lists patient characteristics of the 2 intervention groups before and after propensity score matching. The study cohort was young, equal male and female, near 50% government insurance, had a high degree of complexity, frequent technological dependency, and multiple reasons for neurologic impairment. Within hospital 1:1 matching of GJ and fundoplication subjects resulted in 114 children in each arm. We observed a GER intervention preference accounted for by using within hospital matching, with fundoplication percentages of 99%, 99%, 97%, 89%, 85%, and 35% across the 6 sites. The 114 matched subjects were similar across observed variables.

There were no differences between groups in our primary outcome of RRH rate per child-year in the unmatched cohort, with an incidence rate of 2.97 (95% confidence interval 2.47–3.58) for GJ and 2.68 (2.41–2.98) for fundoplication; $P = .292$. Similarly, in the matched cohort, the incidence rate for RRH in the GJ group was 2.07 (1.62–2.64) and in the fundoplication group 1.67 (1.28–2.18); $P = .19$. There were no differences in the rates of hospitalization for the individual components of RRH, specifically esophagitis, GERD, aspiration pneumonia, other pneumonia, asthma, and mechanical ventilation in the unmatched or matched cohorts (Table 3).

In the propensity score matched sample, the odds of mortality were similar: 0.07 (0.04–0.13) for GJ and 0.04 (0.01–0.09) for fundoplication; $P = .25$. The odds of crossover from the GJ treatment arm to fundoplication were 0.10 (0.05–0.17), and from fundoplication to GJ were 0.03 (0.01–0.08); $P = .04$. More children with an initial GJ tube placement had repeat interventions (incidence rate per child-year for GJ 0.97 [0.63–1.51]) than for fundoplication (0.02 [0.01–0.07]; $P < 0.001$), as was clinically expected. Children treated with an initial GJ placement were almost twice as likely to have a diagnosis of failure to thrive in the subsequent year (incidence rate 0.53 [0.33–0.85]), compared with initial fundoplication (0.26 [0.15–0.45]); $P = .02$ (Table 3). Early and late procedural complications of wound dehiscence, bleeding, and peritonitis in the unmatched cohort were between 0 and 7.6 per 1000 procedures per year, and similar between groups (Table 4). Unspecified GT complications were similar in the 2 groups; however, persistent vomiting, gastrostomy infection, and mechanical complication of GT were more common in the GJ group.

TABLE 1 Hospital Comparison by Total Discharges, NI Discharges, and Interventions for GER

Hospital (Ordered by Fundoplication %)	A	B	C	D	E	F
Annual discharges	87 613	95 271	184 077	111 435	61 143	53 783
NI discharges, % of annual	9.2	8.0	5.0	7.4	10.6	8.6
GER intervention % of NI discharges	0.9	2.4	1.5	2.9	2.5	2.1
Fundoplication % of GER interventions	99.3	98.0	95.8	86.2	82.1	40.3
Study population count	108	262	201	409	253	108
Fundoplication	107	259	195	363	216	38
GJ	1	3	6	46	37	70
Fundoplication %	99.1	98.9	97.0	88.8	85.4	35.2

DISCUSSION

In this comparative effectiveness study of a propensity-matched sample of children with neurologic impairment, gastrostomy feedings, and GER, we were unable to demonstrate a difference in RRH in the first year after treatment with an initial fundoplication versus an initial GJ tube. In addition, there were no differences between the 2 treatment groups for individual components of RRH including hospitalizations for esophagitis, GERD, aspiration pneumonia, other pneumonia, asthma, or mechanical ventilation. Overall there were between 1 and 3 RRH events per child-year in each group. Mortality was rare in either group. Treatment with fundoplication and GT feeding had approximately one-third the need to change treatment arms, 1 in 50 as many repeat procedures, and half as many hospitalizations associated with a diagnosis of failure to thrive compared with an initial GJ feeding tube.

There is sparse literature advising the choice between GJ and fundoplication in this population. A retrospective single-center study by Srivastava et al[18] addressed this question using propensity score matching and found no difference in time to next hospitalization for aspiration pneumonia or mortality by initial intervention choice, with average follow-up of 3.4 years. Our study focused on RRH admission incidence rates per child-year between treatment arms and found no statistically significant difference in the point estimates: 2.07 (1.62–2.64) for GJ versus 1.67 (1.28–2.18) for fundoplication (ratio 1.24, $P = .19$). Our a priori power calculations support ~80% power to identify a difference between treatment groups had a true difference existed. Post hoc power analysis using *t* test comparison of 2 independent means supports 85.3% power to detect a true difference between study groups. Both analyses support our

TABLE 2 Patient Characteristics Pre– and Post–Propensity Score Matching

	Prematch			Postmatch		
	GJ First $N = 163$	Fundo First $N = 1178$	P	GJ First $N = 114$	Fundo First $N = 114$	P
Median age, mo (Q1, Q3)	4 (0, 32)	2 (0, 9)	<.01	3 (0, 17)	2 (0, 17)	.39
Age group, *n* (%)						
<3 mo	73 (44.8)	670 (56.9)		54 (47.4)	60 (52.6)	
3 to <6 mo	17 (10.4)	149 (12.6)		13 (11.4)	10 (8.8)	
6 mo to <1 y	13 (8.0)	87 (7.4)	<.01	13 (11.4)	13 (11.4)	.76
1 to <3 y	21 (12.9)	112 (9.5)		13 (11.4)	16 (14.1)	
3 to <12 y	21 (12.9)	106 (9.0)		14 (12.2)	9 (7.9)	
12 to 17+ y	18 (11.0)	54 (4.6)		7 (6.1)	6 (5.3)	
Female sex, *n* (%)	80 (49.1)	522 (44.3)	.25	54 (47.4)	55 (48.2)	.90
Race, *n* (%)						
Non-Hispanic white	92 (56.4)	749 (63.6)		65 (57.0)	76 (66.7)	
Non-Hispanic black	14 (8.6)	164 (13.9)		11 (9.6)	8 (7.0)	
Hispanic	28 (17.2)	96 (8.1)	<.01	20 (17.5)	16 (14.0)	.66
Asian	3 (1.8)	20 (1.7)		3 (2.6)	3 (2.6)	
Other	26 (16.0)	149 (12.6)		15 (13.2)	11 (9.6)	
Insurance, *n* (%)						
Government	91 (55.8)	563 (47.8)		65 (57.0)	61 (53.5)	
Private	61 (37.4)	503 (42.7)	.13	46 (40.4)	49 (43.0)	.83
Other	11 (6.7)	112 (9.5)		3 (2.6)	4 (3.5)	
Complex chronic conditions, *n* (%)						
Cardiovascular	40 (24.5)	247 (21.0)	.30	30 (26.3)	31 (27.2)	.88
Respiratory	25 (15.3)	195 (16.6)	.69	17 (14.9)	20 (17.5)	.59
Renal	3 (1.8)	44 (3.7)	.22	2 (1.8)	7 (6.1)	.17
Gastrointestinal	4 (2.5)	27 (2.3)	.78	3 (2.6)	1 (0.9)	.62
Hematological or immunological	7 (4.3)	34 (2.9)	.33	5 (4.4)	4 (3.5)	.99
Metabolic	8 (4.9)	15 (1.3)	<.01	4 (3.5)	1 (0.9)	.37
Congenital or genetic	42 (25.8)	325 (27.6)	.63	34 (29.8)	38 (33.3)	.57
Malignancy	7 (4.3)	23 (2.0)	.08	5 (4.4)	0 (0.0)	.06
Specific characteristics, *n* (%)						
Tracheostomy, any time	31 (19.0)	301 (25.6)	.07	23 (20.2)	17 (14.9)	.30
Upper airway anomaly	67 (41.1)	585 (49.7)	.04	57 (50.0)	52 (45.6)	.51
Previous aspiration pneumonia	17 (10.4)	108 (9.2)	.60	13 (11.4)	15 (13.2)	.69
Previous swallow study	36 (22.1)	96 (8.1)	<.01	26 (22.8)	20 (17.5)	.32
CSF shunt	18 (11.0)	108 (9.2)	.44	11 (9.6)	14 (12.3)	.53
Chronic lung disease	43 (26.4)	366 (31.1)	.22	29 (25.4)	41 (36.0)	.09
Contraindications, *n* (%)						
Microgastria	5 (3.1)	14 (1.2)	.07	5 (4.4)	1 (0.9)	.21
Barrett esophagus	1 (0.6)	4 (0.3)	.48	0 (0.0)	0 (0.0)	.99
Peptic stricture	5 (3.1)	57 (4.8)	.31	4 (3.5)	3 (2.6)	.99
Esophageal dysmotility	3 (1.8)	29 (2.5)	.79	3 (2.6)	2 (1.8)	.99
Short esophagus	0 (0.0)	10 (0.8)	.62	0 (0.0)	0 (0.0)	.99
GI motility disorder	18 (11.0)	36 (3.1)	<.01	9 (7.9)	4 (3.5)	.15
Gastric outlet obstruction	3 (1.8)	12 (1.0)	.41	0 (0.0)	3 (2.6)	.25
Technology dependencies, *n* (%)						
Respiratory	48 (29.4)	438 (37.2)	.05	39 (34.2)	30 (26.3)	.19
Renal	21 (12.9)	66 (5.6)	<.01	16 (14.0)	14 (12.3)	.70

TABLE 2 Continued

	Prematch			Postmatch		
	GJ First $N = 163$	Fundo First $N = 1178$	P	GJ First $N = 114$	Fundo First $N = 114$	P
Brain and spinal cord	49 (30.1)	350 (29.7)	.93	30 (26.3)	32 (28.1)	.77
Gastrointestinal	163 (100)	1178 (100)	.99	114 (100)	114 (100)	.99
Cardiac	0 (0.0)	10 (0.8)	.62	0 (0.0)	0 (0.0)	.99
Medication infusion	4 (2.5)	25 (2.1)	.77	4 (3.5)	4 (3.5)	.99
Clinical NI groupings, *n* **(%)**						
Asphyxia, anoxia, arrest	75 (46.0)	497 (42.2)	.36	53 (46.5)	50 (43.9)	.69
Brain/spinal cord abnormalities	69 (42.3)	447 (37.9)	.28	51 (44.7)	47 (41.2)	.59
Cerebral palsy	44 (27.0)	288 (24.4)	.48	32 (28.1)	25 (21.9)	.28
Cerebrovascular disease	20 (12.3)	111 (9.4)	.25	11 (9.6)	8 (7.0)	.47
Encephalopathy	44 (27.0)	210 (17.8)	.01	30 (26.3)	27 (23.7)	.65
Genetic conditions	66 (40.5)	442 (37.5)	.46	50 (43.9)	50 (43.9)	.99
Hydrocephalus	24 (14.7)	174 (14.8)	.99	16 (14.0)	16 (14.0)	.99
Intracranial hemorrhage/injury	11 (6.7)	169 (14.3)	.01	10 (8.8)	9 (7.9)	.81
Optic atrophy and other visual	49 (30.1)	308 (26.1)	.29	39 (34.2)	31 (27.2)	.25
Seizures	86 (52.8)	499 (42.4)	.01	57 (50.0)	55 (48.2)	.79
Spina bifida	3 (1.8)	31 (2.6)	.79	3 (2.6)	4 (3.5)	.99
Other CNS injury[a]	8 (4.9)	77 (6.5)	.42	4 (3.5)	3 (2.6)	.99
Other CNS[a]	60 (36.8)	372 (31.6)	.18	37 (32.5)	36 (31.6)	.89
Other PNS[a]	31 (19.0)	192 (16.3)	.38	20 (17.5)	21 (18.4)	.86
NI diagnoses						
Single diagnosis	40 (24.5)	304 (25.8)	.73	27 (23.7)	27 (23.7)	.99
2+ diagnoses	123 (75.5)	874 (74.2)		87 (76.3)	87 (76.3)	
Single grouping	49 (30.1)	364 (30.9)	.83	34 (29.8)	32 (28.1)	.77
2+ groupings	114 (69.9)	814 (69.1)		80 (70.2)	82 (71.9)	

CNS, central nervous system; CSF, cerebrospinal fluid; fundo, fundoplication; PNS, peripheral nervous system.
[a] See Supplemental Table 5.

conclusion of equivalence in relation to RRH of the 2 treatment approaches. When considering medically equivalent procedures, other issues including procedural expertise at the local institution and family preference can appropriately have greater influence on decision-making. Mahant et al[47] completed a qualitative study of 16 families of children with NI, GT, and

TABLE 3 Comparative Effectiveness of GJ Tube Placement Versus Fundoplication

Rate of outcome per Child-Year	Unmatched			Matched		
	GJ Tube, $n = 163$	Fundo, $n = 1178$	P	GJ Tube, $n = 114$	Fundo, $n = 114$	P
RRH composite	2.97 (2.47–3.58)	2.68 (2.41–2.98)	.292	2.07 (1.62–2.64)	1.67 (1.28–2.18)	.188
Esophagitis	0.00 (0.00–0.07)	0.01 (0.00–0.05)	.324	0.01 (0.00–0.06)	0.01 (0.00–0.06)	.999
GERD	2.56 (2.09–3.13)	2.36 (2.11–2.65)	.452	1.68 (1.26–2.24)	1.41 (1.03–1.92)	.317
Aspiration pneumonia	0.19 (0.09–0.40)	0.40 (0.31–0.52)	.060	0.13 (0.07–0.24)	0.11 (0.06–0.21)	.743
Pneumonia	0.45 (0.26–0.79)	0.61 (0.47–0.78)	.340	0.26 (0.17–0.41)	0.21 (0.13–0.34)	.508
Mechanical ventilation	0.76 (0.47–1.21)	0.73 (0.57–0.92)	.881	0.38 (0.24–0.60)	0.43 (0.27–0.68)	.696
Asthma exacerbation	0.61 (0.34–1.10)	0.61 (0.44–0.84)	.982	0.33 (0.19–0.58)	0.16 (0.08–0.30)	.083
Failure to thrive	1.06 (0.71–1.57)	0.82 (0.66–1.01)	.225	0.53 (0.33–0.85)	0.26 (0.15–0.45)	.017
Death (odds)	0.06 (0.03–0.11)	0.03 (0.02–0.05)	.077	0.07 (0.04–0.13)	0.04 (0.01–0.09)	.246
Repeat first intervention[a]	1.20 (0.91–1.59)	0.03 (0.02–0.04)	<.001	0.97 (0.63–1.51)	0.02 (0.01–0.07)	<.001
Second intervention (odds)[a]	0.07 (0.03–0.14)	0.01 (0.00–0.02)	<.001	0.10 (0.05–0.17)	0.03 (0.01–0.08)	.040

Fundo, fundoplication.
[a] First intervention is the initial intervention which defined treatment groups, and second intervention is crossover to the alternate treatment of persisting GER symptoms.

TABLE 4 Procedural Complications Per 1000 Procedures Per Year, Unmatched Cohort

	GJ Tube First (n = 163)	Fundo First (n = 1178)	P
Early complications (≤30 d)			
Wound infection/dehiscence	6.1	7.6	0.99
Bleeding	0	0.8	0.99
Peritonitis	0	2.5	0.99
Late complications (>30 d)			
Peritonitis	6.1	5.1	.60
Gastrostomy complications			
Persistent vomiting	24.5	5.9	.04
Gastrostomy complication, unspecified or other	116.6	87.4	.23
Infection of gastrostomy	66.5	28.9	.01
Mechanical complication of gastrostomy	190.2	109.5	<.01

Fundo, fundoplication.

GER who received either GJ feeding or fundoplication with GT feeding. They developed a conceptual model addressing the choice of intervention that included issues around feeding, caregiving, and health care utilization within a generalized model of quality of life and well-being of the child, parent/caregiver, and family. Our findings support equivalence of the 2 interventions in the health care utilization domain of their model, thereby emphasizing feeding and caregiving issues within the larger frames of quality of life and overall well-being as important components of the discussion when choosing between GJ feeding and fundoplication with GT feeding in this population. Using the Mahant model, our findings favoring fundoplication/GT feeding with regard to repeating the initial procedure, resorting to a second procedure, and admission for failure to thrive, can add to the discussion of intervention choice in the shared decision-making process.

The PHIS+ radiology report database allowed us to identify patients undergoing initial GJ placement for intervention group assignment and also identified subsequent GJ interventions as secondary outcomes. Studies addressing feeding strategies for this population have been hampered by the lack of a reliable methodology for identifying GJ placement using administrative data. We were able to assemble an adequately powered propensity score–matched study population that exceeds the largest study currently published addressing this question. Although not part of the current study, we also identified a population with NI, GT placement, and GER who received no intervention, a population of interest for future study.

Limitations

Comparative effectiveness studies using retrospective methodologies suffer from limitations of selection bias, including possible confounding by indication as fundoplication is considered by some to be "permanent" and GJ "temporary," may be routinely done for any GT placement indication in the NI population, may carry more upfront surgical risk leading to a preference for GJ placement in higher risk children, and may be preferred in children at higher risk from reflux and aspiration because GJ tubes can displace to the stomach increasing reflux and aspiration, suggesting subject disease characteristics might influence intervention choice. Examination of the prematch characteristics of the 2 groups (Table 2) shows that a GJ placement was more likely in children with metabolic disorders, GI motility disorders, renal technology dependency, encephalopathy, and seizure, whereas those having intracranial hemorrhage or injury were more likely to receive fundoplication. GJ placement was more likely if a swallow study had been completed and the age at placement was slightly older (4 vs 2 months). These data do not support a selection bias for surgical risk or risk from reflux/aspiration; there may be a tendency, however, to choose GJ placement in diagnoses/conditions felt to be less "permanent." To address selection bias, we looked at a broad array of variables defining patient characteristics including demographics, underlying diagnoses, and surrogates for severity such as number of complex chronic conditions and technology dependencies, using propensity score matching estimating the likelihood of a GJ tube placement to simulate a randomized trial methodology. The excellent matching supports mitigation of confounding by indication despite the limitations inherent to the design. We anticipated within PHIS+ a more balanced use of fundoplication/GJ placement in treating GER in children with NI. We discovered, however, that the hospitals often favored one or the other approach, with fundoplication greatly outnumbering GJ placement, despite similar experience with NI admissions and intervention rates for GER risks (Table 1). To address this possible source of postmatch bias, introduced by potential differences in study population risks, severity of disease, and local procedural and care practices by facility, we chose to match only within hospital, and included treating hospital as a random effects variable in our models. Despite our efforts to address both pre- and postmatch selection bias, we cannot be certain that all potential sources of bias were eliminated.

Uncertainty around the diagnosis of GER based on ICD-9-CM coding or in clinical practice is widely recognized. Confirming diagnostic studies are rare, as are severity measures, leaving us unable to validate GER diagnosis or severity, although the choice by clinicians and families to proceed with a procedural intervention to mitigate GER risks supports both diagnosis and disease severity. We could not access other measures of differences between GJ and GT fundoplication for dysphagia and aspiration risk, such as quality of life and success of safe feeding. We measured repeat procedures occurring during a hospitalization, crossover to the other procedure, and occurrence of admission for failure to thrive in an attempt to estimate these concerns. Our matching methodology

would leave unmatched outliers, such as patients with absolute indications/contraindications for one procedure or the other, excluded from the study analysis, not allowing us to address these less common circumstances. The participating hospitals are freestanding tertiary care children's hospitals that may see more and sicker children with NI, limiting generalizability to other settings. We reported repeat interventions occurring during hospitalizations, underestimating the actual frequency of GJ replacement procedures, which often occur in the outpatient setting. We did not capture termination of GJ feeding, or reversal or unaddressed failure of fundoplication that might occur as a subject's GER status improves. Our study relies heavily on accurate ICD-9-CM coding and is limited by the accuracy and detail of the available data. Although we could not do individual chart review or validate each code used, we noted the distribution of NI diagnoses to be similar to published studies.[23] We did validated the codes for initial GT placement as mentioned and found a 1:1 correlation between ICD-9-CM codes for GER and PHIS CTC codes for GER medications. We used previously published ICD-9-CM–based strategies to identify covariables and outcomes whenever available to strengthen our findings.

CONCLUSIONS

In the population of children with severe neurologic impairment who receive gastrostomy feedings and have GER, treatment with an initial fundoplication with continued GT feeding or converting to GJ tube feeding are viable approaches to reduce GER-related hospitalization risk, with similar 1-year outcomes. Given similar impact on subsequent hospitalization for GER in this population it is reasonable, following the Mahant model, to allow findings favoring fundoplication/GT feeding with regard to repeating the initial procedure, resorting to a second procedure, and admission for failure to thrive, greater emphasis in shared decision-making with families.

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