



Published in final edited form as:

*J Perinatol.* 2018 September ; 38(9): 1270–1276. doi:10.1038/s41372-018-0145-4.

## National and Regional Trends in Gastrostomy in Very Low Birth Weight Infants in the US: 2000-2012

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### Abstract

**Objective**—To determine rates of gastrostomy (GT) in very low birth weight (VLBW) infants.

**Study Design**—Retrospective, cross-sectional analysis of the Kids' Inpatient Database for the years 2000, 2003, 2006, 2009 and 2012. We identified VLBW births and infants undergoing a gastrostomy (GT), with and without fundoplication, using ICD-9-CM codes.

**Result**—National rates (per 1000 VLBW births) of GT increased from 11.5 GT (95% CI, 10-13) in 2000 to 22.9 (95% CI, 20-25) in 2012 ( $p < 0.001$ ). Gastrostomy with and without fundoplication increased during the study period ( $p < 0.001$  in both groups). VLBW survival also increased from 78.5% in 2000 to 81.1% in 2012 ( $p < 0.001$ ). In all study years, the Northeast census region had the lowest GT rates; while, the West had the highest rates in four of the five study years.

**Conclusion**—Between 2000 and 2012, the incidence of GT in VLBW infants doubled, associated with improvements in survival in this population.

### Introduction

Advances in antenatal maternal and neonatal care in the last several decades have led to marked improvements in survival of premature infants.<sup>1–4</sup> Very low birth weight (VLBW) infant in-hospital mortality in US centers participating in the Vermont Oxford Network (representing 756 centers in 2014) nearly halved from 18.1% in 1991<sup>1</sup> to 10.9% in 2014.<sup>3</sup> Among VLBW infants, the largest relative increase in survival has come in infants at the

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**Financial Disclosure:** The authors have no financial relationships relevant to this article to disclose.

**Conflict of Interest:** The authors have no conflicts of interest relevant to this article to disclose.

limits of viability (23-25 weeks).<sup>2, 4</sup> Despite national improvements in morbidities in VLBW infants,<sup>3</sup> improved rates of survival have led to more infants surviving with major morbidities of prematurity, particularly in infants at the limits of viability.<sup>2</sup>

Very low birth weight infants, especially those born at the limits of viability or with significant respiratory disease, are at risk for feeding/swallowing dysfunction and postnatal growth failure.<sup>5-8</sup> Approximately 50% of extremely low birth weight infants require assistance with feeding at 18 months of age.<sup>7</sup> Surgical placement of a gastrostomy (GT) tube is often used in infants with neurologic impairment, feeding dysfunction and growth failure to ensure adequate long-term nutrition.<sup>9, 10</sup> Although GT is the most common gastrointestinal operation performed in neonates,<sup>11</sup> the impact of increasing survival of VLBW infants on the national utilization of GT has not been reported. Furthermore, the safety and efficacy of GT placement, including which infants would benefit from this therapy, is unknown.

We hypothesized that coincident with improving national VLBW survival, GT placement also increased. The main objective of our study was to describe the national trends in the utilization of GT as a long-term feeding modality in VLBW infants in a nationally representative sample of all VLBW births. Secondly, we evaluated the regional variation in the use of GT in this population.

## Methods

### Study Design and Data Sources

We performed a retrospective, cross-sectional analysis of pediatric discharge data from 2000, 2003, 2006, 2009, and 2012 (the most recent year available), from the Healthcare Cost and Utilization Project's (HCUP) Kids' Inpatient Database (KID), compiled by the Agency for Healthcare Research and Quality (AHRQ). The KID is a nationally representative dataset that samples 80% of pediatric inpatient discharges and 10% of uncomplicated in-hospital births to allow evaluations of rare diseases or treatments in children.<sup>12-14</sup> Each patient record contains a discharge weight to allow calculation of national and regional rates of diagnoses and procedures using a specified sampling method. Because our study utilized de-identified data it was deemed exempt by the Vanderbilt University Medical Center Institutional Review Board.

### Identification of Study Population

We identified VLBW infants using a combination of *International Classification of Diseases, Ninth Revision, Clinical Modification (ICD-9-CM)* diagnosis codes<sup>15</sup> (Appendix 1) and *All-Payer Severity-Adjusted Diagnosis Related Groups (DRG), version 18 or 24*, depending on the study year.<sup>16</sup> Infants who had an *ICD-9-CM* code for a birth weight less than 1500 grams and did not have a *DRG* code (389-391) associated with term birth or normal neonates were included in the study cohort. We did not exclude infants based upon postnatal age at the time of hospital admission. We used the hospital birth variable to identify the number of VLBW infants born per study year since some VLBW infants would have been

born at one facility, transferred to another hospital for Neonatal Intensive Care Unit (NICU) care and thus potentially be represented twice in the KID.

### Demographics and Comorbidities

We utilized patient, payer and hospital characteristics provided by the KID to describe the study population. Primary payers were grouped into three categories: public sources (Medicaid and Medicare), private insurance, and other (includes self-pay, no charge and other sources). The KID contains hospital information including region, teaching status and urban vs. rural location that were included in the data collection. Multiple infant comorbidities including bronchopulmonary dysplasia (BPD), severe intraventricular hemorrhage (IVH)- Grade 3 or 4, and severe retinopathy of prematurity (ROP)- grades 3-5 were evaluated. Further, we assessed infants for one of the neuromuscular complex chronic conditions (CCC) as described by Feudtner et al.<sup>17</sup>

### Study Outcomes

The primary outcome of the study was the receipt of a GT. Gastrostomy placement was identified using *ICD-9-CM* procedure codes 43.11 (Percutaneous [endoscopic] gastrostomy) and 43.19 (other gastrostomy).<sup>18</sup> We further classified infants according to whether they had received a fundoplication (*ICD-9-CM* procedure codes 44.66 [other procedures for creation of esophagogastric sphincteric competence] and 44.67 [laparoscopic procedures for creation of esophagogastric sphincteric competence]) during the same hospitalization as their GT.<sup>11</sup> As Current Procedural Terminology (CPT) codes are not available in the KID, we used *ICD-9-CM* procedure codes alone to identify the procedures and thus could not reliably identify open versus laparoscopic GT.

### Statistical Analysis

We utilized survey weights in the KID to calculate national rates of GT, GT only and GT with fundoplication (GTF) for all study years. We used the number of infants with procedure codes for the respective procedures as the numerator and the number of in-hospital VLBW infant live births for each study year as the denominator. Rates were described per 1000 VLBW live births. In addition to national rates, we calculated regional and birth weight specific rates of GT. To evaluate potential explanations for trends in GT utilization over time, we calculated national and birth weight specific survival for all study years. We evaluated statistical significance of secular trends for all rates over time by assessing *P* for trend using variance weighted least squares regression with study year as the independent variable in the models.<sup>14</sup>

We calculated descriptive statistics for the populations of infants discharged during 2012 who received no GT, GT only or GTF. We compared differences in characteristics of infants who received GT only versus GTF using Pearson's chi-square test. To evaluate for changes in the population of infants who received GT over the study period, we calculated descriptive statistics for infants who received GT during each of the study years and assessed *P* for trend using variance weighted least squares regression with study year as the independent variable in the models.<sup>14</sup>

Finally, using data from 2012, we built a multivariable logistic regression model to identify factors associated with GT in VLBW infants. The dependent variable for the model was a GT placement and the a priori chosen independent variables included sex, birth weight, neonatal comorbidities (severe IVH, surgically-ligated patent ductus arteriosus, BPD, aspiration and chromosomal anomalies), payer, hospital characteristics and census region. Variables were chosen a priori to preserve the Type 1 error of the model.<sup>19</sup> Since the KID is de-identified, it is impossible to follow infants who were transferred across multiple hospitalizations. Therefore, to construct our regression model, we used all 2012 VLBW hospitalizations instead of all 2012 VLBW births, as some infants would not have received their GT at their birth hospital. All analyses were completed with STATA version 14.1 (StataCorp LP, College Station, TX) using discharge survey weights provided in the datasets by the AHRQ.<sup>20</sup> P-values less than 0.05 were considered significant.

## Results

During the five study years, a total of 253 117 VLBW infants were born in the US with 4060 (1.6%) infants receiving a GT. A total of 2397/4060 (59%) infants received GT only and 1663/4060 (41%) received GTF. National rates (per 1000 VLBW births) increased significantly over the study period from 11.5 GT in 2000 to 22.9 in 2012 ( $p<0.001$ ) (Figure 1). Rates for all study years are shown in Table 1. In all study years, the lowest GT rates occurred in the Northeast Census Region while the highest rates in four of the five study years occurred in the West (Figure 2).

When stratified by birth weight, infants less than 500 grams showed the largest relative increase in GT (4.9 GT/1000 births in 2000 to 14.1 GT/1000 births in 2012), however the rates of GT in all three birth weight strata increased significantly ( $p<0.001$ ). Infants with birth weight 500-999 grams were the primary factor in the national increase in the rate of GT placement (17.9 GT/1000 births in 2000 to 39.2 GT/1000 births in 2012). In parallel with the GT rates, survival for all three birth weight strata increased significantly over the study years ( $p<0.001$ ) (Table 2).

The rates of VLBW infants receiving GT only and GTF increased over the study years ( $p<0.001$ ). The population of infants who received GT only and those who received GTF were relatively similar (Supplemental Table 1, Online Appendix). In univariate analysis, infants who received GTF had lower gestational age at birth ( $p<0.04$ ) and were more likely to have a diagnosis of gastroesophageal reflux at time of discharge ( $p<0.001$ ). Death prior to discharge was higher in the GT only infants (6% versus <1%,  $p=0.02$ ).

Characteristics of infants receiving a GT changed over the study period (Supplemental Table 2, Online Appendix). Compared to infants who received a GT in 2000, infants who received a GT in 2012 were more likely to receive public insurance ( $p<0.001$ ) and to receive their GT in an urban teaching hospital versus an urban non-teaching hospital ( $p<0.001$ ). The rate of tracheostomy in infants receiving a GT declined over the study period (23% in 2000 to 13% in 2012,  $p<0.001$ ), as did the in-hospital mortality of infants receiving a GT (11% in 2000 to 4% in 2012,  $p<0.001$ ). The percentages of infants with a neuromuscular CCC and

chromosomal anomalies increased significantly over the study years. The incidences of BPD, severe IVH and PVL in infants receiving a GT did not significantly change.

After accounting for potential confounders, infants with significant comorbidities including surgically ligated PDA (adjusted odds ratio [aOR] 2.1, 95% confidence intervals [CI] 1.7-2.6) and BPD (aOR 4.1, 95% CI 3.3-5.1) were more likely to have received a GT. Furthermore, significant differences in regional utilization of GT existed even after adjustment for potential confounders with infants hospitalized in the South (aOR 1.6, 95% CI 1.1- 2.4) and West (aOR 1.6, 95% 1.0-2.5) regions more likely to receive a GT (Supplemental Table 3, Online Appendix).

## Discussion

Our study demonstrates increasing use of GT, both with and without fundoplication, for long-term feeding of VLBW infants in the US. From 2000-2012, the national rate of GT placement in VLBW infants doubled. Although the increase was most prominent in infants <500 grams, we found significant increases among all VLBW infants. We speculate that the improving rate of survival for VLBW infants resulted in a greater proportion of infants with dysphagia due to immaturity or neurologic injury and may partially explain the increase in GT placement. We also demonstrated significant regional practice variation, even after adjustment for multiple infant characteristics and comorbidities, with the lowest rates of GT consistently found in the Northeast region.

Though our study is the first to characterize the epidemiology of GT in VLBW infants, our findings are consistent with previous work that showed an increase in the national use of GT in children. Using the KID, Fox et al. showed that the rate of GT placement in pediatric patients (<18 years of age) increased from 16.6 GT/100,000 children in 1997 to 18.5 GT/100,000 children in 2009. Children <1 year of age primarily accounted for the overall increase in GT (136.6 GT/100,000 children <1 year in 1997 to 173 GT/100,000 children <1 year in 2009). Also consistent with our results, these authors found that children born prematurely made up a larger percentage of the total GT population over time (11.5% in 1997 to 15% in 2009,  $p<0.001$ ).<sup>21</sup> Berry et al. used the KID to show similar findings of increased rates of GT in pediatric patients (<18 years of age) from 1997-2006 for children with and without a diagnosis associated with neurologic impairment.<sup>22</sup>

From our data, we are unable to determine with certainty the cause of the increasing rate of GT in VLBW infants. We suggest, based on the available data (Table 2), that improved survival of VLBW infants over the study period may be a key driver of this increase. In support of this proposal, we found the largest increases in GT rates were seen in the birth strata with the highest relative improvements in survival (<500 grams and 500-999 grams). During the study period, no consensus guidelines or studies were published to change clinical practice for GT placement in VLBW infants. In 2006, the North American Society for Pediatric Gastroenterology, Hepatology, and Nutrition published a national guideline that advocated consideration for earlier placement of GT in neurologically impaired children.<sup>23</sup> However, our data show increases in GT prior to the publication of this guideline. Other potential explanations for the increase in GT include more availability of pediatric surgical

specialists (supply-sensitive care), advances in the use of laparoscopic GT surgery making GT a potentially less invasive procedure, earlier placement of GT due to payer pressures/ shorter hospitalizations and/or changes in provider bias/preference in recommending GT.

Interventions for long-term nutrition in former preterm infants with feeding dysfunction include home nasogastric (NG) tubes, GT placement or GTF. The long-term safety and efficacy of each of these interventions in preterm infants are not well known. Home NG feeding, in association with home nursing support, has been shown to be safe and allow earlier discharge of preterm infants;<sup>24</sup> however, NG feeds as a long-term home feeding modality in preterm infants is not well-studied. Gastrostomy feeding has been shown to improve growth<sup>9, 25, 26</sup> and decrease caregiver stress<sup>27</sup> in older children, but has also been associated with increased emergency department visits and re-hospitalizations.<sup>28</sup> Given limitations of the dataset, we were unable to assess how the epidemiology of home NG tubes changed over the course of the study years as the use of GT increased. This is an important area for future prospective study.

Developing evidence and guidelines to guide decision-making for GT is especially important for VLBW infants, as surgical procedures themselves have been independently associated with poorer long-term outcomes in preterm infants.<sup>29</sup> Currently, data to inform which neonates would benefit from GT placement or GTF are limited. Likely as a result of this limited evidence, we found significant regional practice variation even after accounting for patient-level factors (Table 1). Given the data structure of the KID, we were not able to reliably define variation at the hospital level. It is possible that the regional variation in GT rates is explained by home NG tube use or increased rates of GT after discharge in the Northeast region. Given the importance of postnatal growth on neurodevelopmental outcomes<sup>30</sup> and cardiovascular and metabolic risk profiles later in life,<sup>31</sup> well-designed prospective studies assessing growth, neurodevelopmental outcomes, feeding trajectories and complications (both surgical and medical) of these therapies are essential.

Although our study provides the first understanding of the national epidemiology of GT in VLBW infants, it also has some important limitations. Due to the de-identified data structure of the KID,<sup>20</sup> we were unable to follow infants that were transferred from one center to another. This makes it difficult to determine the timing of GT during the hospitalization in many infants as well as the age of the infant at the time of the procedure. As these administrative data were collected at discharge, we are also unable to determine temporality with other acquired morbidities such as IVH during the hospitalization. This complicates the interpretation of our regression analysis because some of the comorbidities that were used as covariates may not have been present at the time of GT, or even resulted from the actual procedure itself. We also observed a difference in mortality in the GT and GTF groups that likely represents selection bias and not a consequence of the operative procedures themselves. Infants with higher pre-operative morbidity may have preferentially received GT versus GTF due to the more invasive nature of GTF and the additional operative risks. As with all studies utilizing administrative data we are unable to determine causality for the temporal increase in GT, only hypothesize about possible causes for the associations seen. Lastly, the potential exists for misclassification of outcomes due to coding errors.

In summary, the national rate of GT placement in VLBW infants doubled from 2000-2012, associated with improving rates of survival in this population. Given the paucity of data regarding safety, efficacy and long-term outcomes of preterm infants treated with GT, prospective studies to determine the optimal long-term feeding strategies for preterm infants after NICU discharge are essential. As preterm survival continues to improve and the absolute number of preterm infants with significant morbidity including feeding dysfunction increases these investigations will become increasingly important.

## Supplementary Material

Refer to Web version on PubMed Central for supplementary material.

## Acknowledgments

We would like to acknowledge and thank Ann R. Stark, MD for her editorial assistance with the writing of this manuscript.

**Funding Source:** Research reported in this publication was supported by the Katherine Dodd Faculty Scholars program (Hatch) and the National Institute On Drug Abuse of the National Institutes of Health under award number K23DA038720 (Patrick). The content is solely the responsibility of the authors and does not necessarily represent the official views of the National Institutes of Health

## Abbreviations

<b>AHRQ</b>	Agency for Healthcare Research and Quality
<b>DRG</b>	Diagnosis Related Groups
<b>BPD</b>	bronchopulmonary dysplasia
<b>CCC</b>	complex chronic conditions
<b>GT</b>	gastrostomy
<b>HCUP</b>	Healthcare Cost and Utilization Project
<b>ICD-9-CM</b>	International Classification of Diseases, Ninth Revision, Clinical Modification
<b>IVH</b>	intraventricular hemorrhage
<b>KID</b>	Kids' Inpatient Database
<b>NG</b>	nasogastric
<b>NICU</b>	Neonatal Intensive Care Units
<b>ROP</b>	retinopathy of prematurity
<b>VLBW</b>	very low birth weight

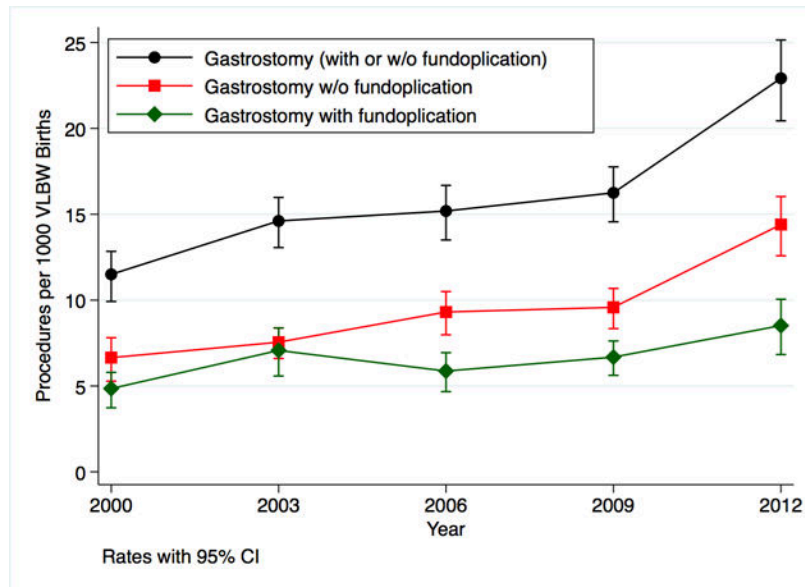


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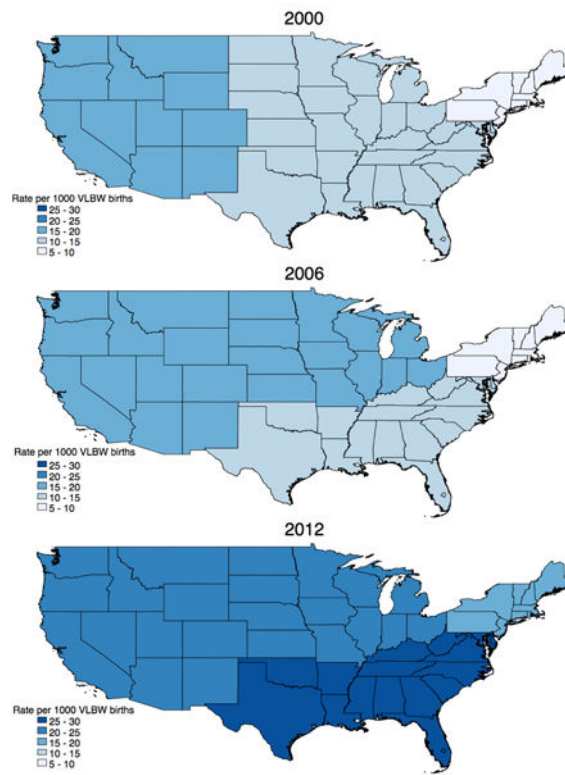
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**Figure 1.** Nationally representative rates of all gastrostomy (black), gastrostomy only (red) and gastrostomy with fundoplication (green) per 1000 very low birth weight (VLBW) infants using weighted estimates of procedures and VLBW live births in the Kids' Inpatient Database 2000, 2003, 2006, 2009 and 2012.



**Figure 2.** Changes in the rate of gastrostomy per 1000 very low birth weight (VLBW) births by US Census Regions, using weighted estimates in the Kids' Inpatient Database 2000, 2006 and 2012

Estimated National and Regional Rates of Gastrostomy and Gastrostomy/Fundoplication<sup>1</sup>

Table 1

	2000	2003	2006	2009	2012	P for trend
VLBW births	49561 (45253–53868)	48736 (45777–51695)	54279 (51055–57503)	52623 (49686–55561)	47918 (45358–50479)	–
Gastrostomy procedures	570 (449–692)	712 (598–826)	824 (689–959)	855 (724–987)	1098 (927–1270)	–
Rate of procedure(s) per 1000 VLBW live births (95% confidence intervals)						
Gastrostomy (all)	11.5 (10–13)	14.6 (13–16)	15.2 (14–17)	16.3 (15–18)	22.9 (20–25)	<0.001
Gastrostomy only	6.7 (5–8)	7.6 (7–8)	9.3 (8–10)	9.6 (8–11)	14.4 (13–16)	<0.001
Gastrostomy with fundoplication	4.8 (4–6)	7.1 (6–8)	5.9 (5–7)	6.7 (6–8)	8.5 (7–10)	<0.001
Rates of gastrostomy (95% CI) by census region						
Northeast	7.9 (6–10)	7.7 (5.6–9.3)	9.3 (7–11)	11.8 (9–14)	16 (11–20)	<0.001
Midwest	12.5 (8–15)	15.4 (13–17.6)	16.6 (12–20)	19.2 (15–22)	24.1 (19–28)	<0.001
South	10.6 (8–13)	15.7 (13–18)	15 (12–17)	14.1 (11–17)	25.5 (21–29)	<0.001
West	15.4 (11–19)	18.1 (14–22)	19.3 (15–23)	21.5 (17–25)	22.3 (17–7)	<0.001

<sup>1</sup>For all the rates in the table, the numerator is the number procedures (either nationally or in the respective regions) and the denominator is the number of very low birth weight (VLBW) infants (either nationally or in the respective regions).

Table 2

## Gastrostomy Status and Survival by Birth Weight

	2000	2003	2006	2009	2012	P for trend
All VLBW Infants						
In-hospital live births	49561	48736	54279	52623	47918	–
In-hospital deaths	10643	10924	11513	10554	9052	–
Survival to hospital discharge (%)	78.5	77.6	78.8	79.9	81.1	<0.001
Gastrostomies	570	712	824	855	1098	–
Gastrostomies/1000 births	11.5	14.6	15.2	16.3	22.9	<0.001
< 500 grams						
In-hospital live births	4511	4599	4854	4799	4455	–
In-hospital deaths	4077	4166	4433	4293	3874	–
Survival to hospital discharge (%)	9.6	9.4	8.7	10.5	13	<0.001
Gastrostomies	22	19	39	41	63	–
Gastrostomies/1000 births	4.9	4.1	8.0	8.5	14.1	<0.001
500–999 grams						
In-hospital live births	19259	18550	20323	19408	17925	–
In-hospital deaths	5437	5674	5827	5052	4198	–
Survival to hospital discharge (%)	71.8	69.4	71.3	74	76.6	<0.001
Gastrostomies	344	455	519	546	702	–
Gastrostomies/1000 births	17.9	24.5	25.5	28.1	39.2	<0.001
1000–1499 grams						
In-hospital live births	25791	25587	29102	28416	25539	–
In-hospital deaths	1135	1084	1253	1209	981	–
Survival to hospital discharge (%)	95.6	95.8	95.7	95.7	96.2	0.004
Gastrostomies	203	238	266	268	334	–
Gastrostomies/1000 births	7.9	9.3	9.1	9.4	13.1	<0.001