Securing Nasogastric Tubes in Children

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SECURING NASOGASTRIC TUBES IN CHILDREN

by

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A Dissertation submitted to the Faculty of the Graduate School,
Marquette University,
in Partial Fulfillment of the Requirements for
the Degree of Doctor of Philosophy

Milwaukee, Wisconsin
August 2021

Abstract

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Marquette University, Spring 2021

Nasogastric tubes (NGTs) are commonly placed in children at risk for malnutrition in order to provide temporary nutrition support until the child achieves independent oral feedings or requires durable tube placement. Accurate securement of NGTs is necessary to safely provide nutrition, particularly in infants and toddlers who are at highest risk for dislodging their NGT. Dislodgement of an NGT has a cascade effect on the medical management, requiring increased exposure to the healthcare system with every replacement. Nasal bridles are widely used to secure NGTs in adults but are not widely used with children. The purpose of this retrospective, correlational study is to compare NGT-related outcomes for children with standard tape securement of an NGT with those that have had a nasal bridle to secure the NGT.

Lewin's Theory of Planned Change provides a framework to motivate the adoption of new medical techniques. Lewin's theory posits several components: analysis of environment components that both push change forward and prevent change from occurring; preparing stakeholders for change to come; the period of actual change; and achieving sustainable change. This framework was used to implement a nasal bridle program across one pediatric tertiary medical center. The bridle program was implemented incrementally across departments through institutional credentialing of providers, education of nurses, and instruction for families. Patient outcomes, both with and without bridle placement, were tracked via the electronic health record at the time of NGT placement until the child achieved full oral feeds or obtained a durable tube. Outcomes of Interest included NGT dislodgements, length of stay, number of unplanned clinical encounters, radiographic exposure, adverse skin outcomes, and transition to oral feeding versus placement of a durable tube for ongoing nutrition support.

Results/Conclusions:

Between March 2018-August 2020, 582 children received NGTs secured traditionally (with facial tape) and 173 received nasal bridles to secure the tube in place. The mean initial hospital length of stay post placement of the NGT was 28 days in the bridle group and 54 in the standard care group ($p<0.001$). Bridled NGT children were 1.49 times less likely to have one more unplanned medical encounter than their non-bridled NGT counterpart (OR=0.67, 95% CI 0.40, 1.14). Dislodgements were more frequent in the unbridled NGT group compared to the bridled NGT group, respectively (M=4.73, 0.33; $p<0.001$). Within this cohort, 62.4% (n=108/173) children with bridled NGTs and 77.1% (449/582) children with unbridled NGTs progressed on to achieve sustained oral feedings and required no further therapy. Children with a bridled NGT were 4.76 times less likely to require one more radiographic exposure than an unbridled child (OR=0.21, 95% CI 0.14, 0.33). Adverse skin outcomes were rare in both groups.

Keywords: nasogastric bridle, pediatric, dislodgements, length of stay, gastrostomy tube, radiographic exposure

ACKNOWLEDGMENTS

I approached my Dissertation Qualifying Exam much like I approach everything in life: with passion, an insatiable thirst for learning and very little understanding of how to balance writing, pediatric medicine, course work, motherhood, marriage and stress. Without a very special cohort of people in my life that I affectionately refer to as my “1% club” this would have not been survivable.

Professionally, Dr. Christine Schindler is the reason I found the strength to pursue both my acute care pediatric nurse practitioner certificate and my PhD at the very same time. A single line in the acknowledgement section of a dissertation will never properly address the lifelong indebtedness I feel for my mentor. Although a simple thank you is vastly inadequate, it must be said: thank you Chris for your unwavering belief that this mountain was something I could climb.

Praveen, I feel like we started this journey 15 years ago when you hired me at Children’s. You have been a steady force my entire career, gently nudging me in the right direction. I can only hope that when this part of the journey is over that we find a way to continue to work together again and make a difference in the lives of the children we serve. Thank you for never giving up on me and always being my advocate, cheerleader and mentor. It would be a great oversight if I did not take the time to thank Dr. Donna McCarthy for carrying me to the finish line. She is undoubtedly the best editor I have ever had the pleasure of working with. Dr. G, although you were invited later into this process, I have admired your teaching style and your incredible intelligence since the day I met you as a nursing student. Your thoughtful insights into this dissertation were invaluable. Dr. Mau, in the last leg of this marathon I have met more often with you than anyone else on this committee. I will certainly never look at a p-value the same ever again, but more than that, I enjoyed our weekly stats conversations from across the globe. You are sincerely one of the most intelligent humans I have ever met, and I feel blessed to call you a mentor and a friend.

Personally, God blessed me with a husband and daughter who have brought more joy into my life than I thought was possible. Thank you, Brandon and Colette Lavoie for the countless hours you allowed me to quietly spend writing, and for the persistent cadence of your cheerleading over the course of this very long journey.

For those that know me well, they know that I am not concise by any stretch of the imagination. The temptation to write a verbose narrative thanking the many friends and family that influenced my path and helped me succeed academically, professionally and personally is strong. I will suffice to say to my 1% club, you know who you are, your support throughout my very long and winding academic journey has given me the liberty to pursue knowledge and learning in a way that satisfies my soul and quenches my thirst for the ultimate academic pursuit: A degree as a Doctor of Philosophy.

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CHAPTER ONE
INTRODUCTION

Significance

Nasogastric tubes (NGTs) are commonly used to provide temporary nutrition support prior to transitioning to full oral feeding or placement of a durable tube (Cannaby et al., 2002; Chen et al., 2014; Dias et al., 2017; Halloran et al., 2011; Parker et al., 2018). Children with complex medical concerns may have NGTs for weeks or months while they are managed across a variety of disciplines (Ellett et al., 2012, 2014; Halloran et al., 2011; Khilnani, 2007; Parker et al., 2018). Children that are discharged home with NGTs often experience tube dislodgement (Kang et al., 2018; Khilnani, 2007; Newton et al., 2016; Taylor et al., 2015), requiring families to seek medical assistance for accurate replacement, which involves additional radiological exposure and increased healthcare costs. Children requiring enteral nutrition support through NGTs pose specific challenges to prevent the tube from being dislodged (Society of Pediatric Nurses (SPN) Clinical Practice Committee, SPN Research Committee, & Longo, 2011; Khilnani, 2007; Taylor et al., 2015). Aggregate data published on 255,140 hospital discharges in the United States reported that 25% of all patients receiving enteral nutrition were children (Irving et al., 2018) and that 6% of that pediatric subgroup were less than 12 months of age (Irving et al., 2018). Lyman et al. (2016) reported that 25% of all hospitalized children required temporary feeding tube placement (Lyman et al., 2016). The incidence of NGT dislodgement across all age groups, including adults has been reported to be 40-68%.

NGT placement is usually performed at the bedside with a low incidence of complications (Chen et al., 2014; Dias et al., 2017; Hanson, 1979; Parker et al., 2018; Quandt et al., 2009). However, improper placement results in morbidities such as aspiration, pneumonia and pneumothorax, and in the worst cases, death (Baskin, 2006;

Beckstrand et al., 2007; Chen et al., 2014; Cirgin Ellett et al., 2011; Ellett et al., 2005; Parker et al., 2018; Quandt et al., 2009). Procedures for confirmation of accurate placement of NGTs can easily be done in the hospital, but not after discharge to home (Beckstrand et al., 2007; Boeykens et al., 2014; Cannaby et al., 2002; Gilbertson et al., 2011; Stock et al., 2008; Parker et al., 2018). The gold standard for confirming proper placement is a chest x-ray with the inherent risks of radiological exposure (Boeykens et al., 2014; Parker et al., 2018). pH testing of gastric aspirate is also an acceptable method of confirming proper tube placement (ASPEN, 2018; Boeykens et al., 2014). Auscultation of breath sounds and measurement of the NGT are unreliable and therefore deemed unacceptable methods for confirming placement (ASPEN, 2018; Wilkes-Holmes, 2006; Huffman et al., 2004; Farrington et al., 2009).

Enteral nutrition is a safe and effective method to meet the nutritional needs of children (Cannaby et al., 2002; Yi, 2018). Children are at particular risk of undernutrition as their growing bodies and developing brains require uninterrupted nutrition to achieve proper development; without proper nutrition, children are at risk for developmental delay, wasting and stunting (Yi, 2018). Unlike adults, infants and toddlers have little reserve and may decompensate quickly without daily provision of appropriate nutrition and hydration. Hospitals are often hesitant to send infants home with NGTs due to the 40-50% likelihood of inadvertent removal (Allan et al., 2019; Meer, 1989; Taylor et al., 2018;) resulting in increased gastrostomy tube (GT) placement or longer length of hospital stay for patients working on achieving full oral intake. Nasal bridles may provide a safe method to secure the placement of the NGT in children, allowing patients to be discharged home with less concern for tube removal or dislodgement (Kang et al., 2018).

The nasal bridle was developed in the 1980's as a method to secure NGTs. A string-like material is passed through the vomer bone in the anterior aspect of the skull and tied to the NGT through a clip that matches the diameter of the tube, securing it in place (Figure 1) (Barrocas, 1982; Levensen et al., 1985). This method did not initially gain popularity due to the difficulty of placement; however, improvements have been made in bridle design, including magnetic end points to improve the ease of placement and tubing materials that allow for smoother placement across the vomer bone (Figure 2) (della Faille et al., 1996). An animal model study conducted on sheep heads tested the sustainability of bridled tubes, finding that 15.5kg of weight could be applied to the tube before damage to the anterior or posterior septum occurred (Carey et al., 2014).

Figure 1

Placement Technique for Nasal Bridles

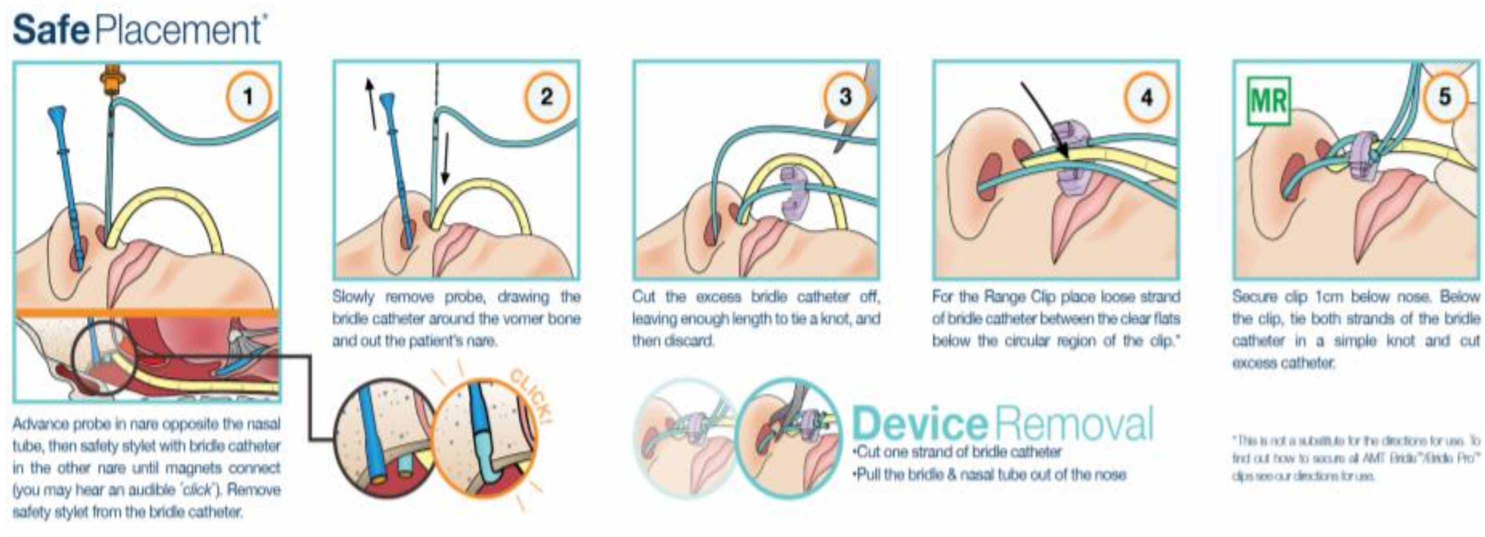
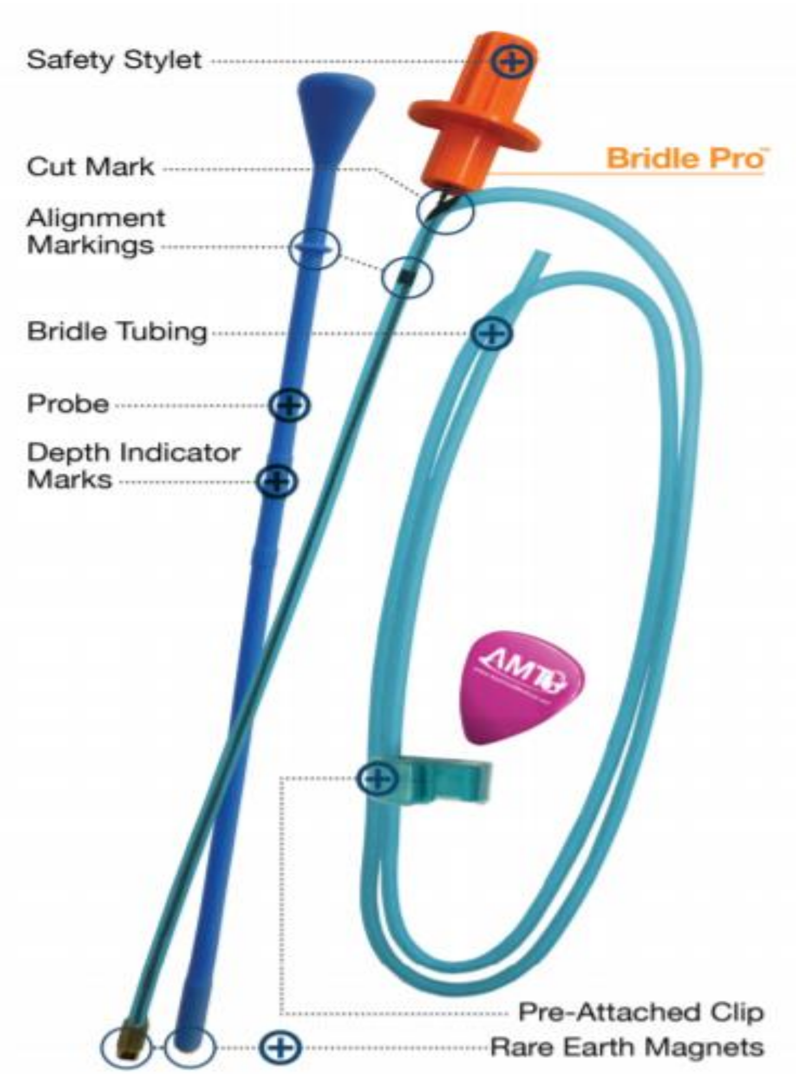


Figure 2.

Nasal Bridle Kit



Statement of the Problem

NGTs are often needed to deliver enteral nutrition on a short-term basis. Adequate enteral nutrition is of particular importance in children to facilitate recovery from illness and promote adequate growth and development in children with complex medical conditions (Yi, 2018). While proper placement is imperative (SPN committee, 2011), NGTs are frequently dislodged. Nasal bridling to secure NGTs is widely used in adults requiring enteral feeding, but is not often used in children, likely due to lack of studies documenting their efficacy. Bridling of NGTs in infants and toddlers should allow those children more time at home to develop oral feeding skills and potentially avoid GT placement.

Purpose

The purpose of this study was to determine whether nasal bridling improves NGT-relevant outcomes in children requiring NGT placement. Data were extracted from medical records of patients receiving a NGT at a large Midwestern regional children's hospital over a two-year period. Data analysis compared NGT-relevant outcomes in patients with NGTs secured with bridles or traditional methods such as taping (Figure 3). Specifically, this study compared length of inpatient hospital stay (LOS), end point of gastrostomy tube (GT) placement, episodes of tube dislodgement/replacement, unplanned clinical encounters, radiographic exposure and reported adverse effects on nasal and skin integrity.

Figure 3.

Securement Method of Tape vs. Bridle

Specific Aims

The primary aim of this study is to determine whether nasal bridling of NGTs is superior to unbridled methods to secure NGTs in children. Outcomes relevant to NGT placement include hospital length of stay, insertions of GTs post placement of the NGT, number of NGT-related unplanned clinical encounters, number of X-rays related to NGT placement confirmation, as well as occurrence of infections and/or skin breakdown in patients with nasal bridles vs traditional methods to secure NGT tube placement.

Hypothesis

Current research supports nasal bridling as an effective method to secure NGTs in adults (Allan et al., 2019; Bechtold et al., 2014; Gupta et al., 2010; Stabler et al., 2018), though only two small studies have demonstrated the efficacy of nasal bridles to secure NGTs in children (Kang et al., 2018; Newton et al., 2016). Lewin's Theory of Planned change was used to guide staff buy-in for nasal bridling of NGTs and training of providers and nurses to insert bridles appropriately and document placement in the electronic health record. Patient outcomes related to securement of NGTs were compared to evaluate the efficacy of nasal bridling compared to the standard practice of facial taping. Data supporting the effectiveness of bridling in children is needed to achieve sustainable change in clinical practice in this vulnerable population.

Research Questions

1. Is there a difference in the number of dislodgements of NGTs in children with nasal bridles compared to children using standard methods of securing the NGT?
2. Is there a difference in length of stay in children with nasal bridles compared to children using standard methods of securing the NGT?
3. How did bridles affect GT insertion in children at a single pediatric tertiary medical center?
4. How did NGT-related unplanned clinical encounters (readmissions, unplanned clinic visits and emergency department visits) differ in children with bridled NGTs compared to children with unbridled NGTs?
5. How did bridles affect the number of NGT-related nasal and facial skin integrity issues at a single pediatric tertiary medical center?
6. Is there a difference in number of radiographic exposures in children with bridled NGTs compared to children with unbridled NGTs?

Theoretical Framework

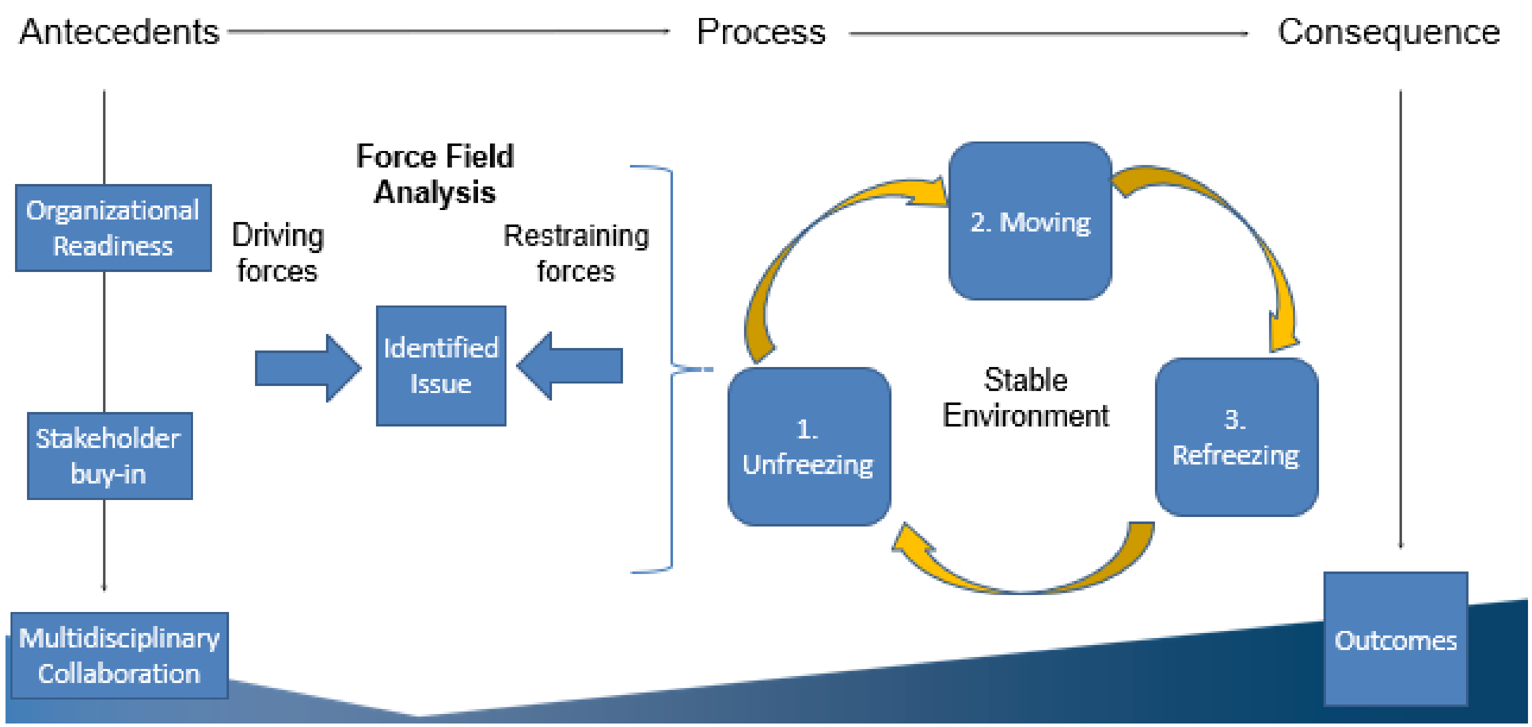
Since the year 2000, the Institute of Medicine has made the American public aware that hospitals are not always safe (Institute of Medicine, 1999); an alarming 98,000 deaths occur annually from medical errors in America. In 2003, James revised that number using the same data, stating that the number was closer to 400,000 deaths annually (Institute of Medicine, 1999; James, 2003). While hospitals have expended much effort to improve those numbers, Lewis, and colleagues (2011) reported that efforts to achieve sustainable change fail 40-80% of the time (Barrow & Toney-Butler, 2017; Lewis, 2011).

In 2001, the Institute of Medicine (IOM) called on nurses as transformative leaders to provide a safe, accessible, and affordable health care environment (Institute of Medicine, 2011). The American Organization of Nurses identified five executive competencies, noting leadership as a key competency for change management in the workplace (Shirey, 2013). Others have called on nurses to provide evidence-based care for their children (Mitchell, 2013) which requires continual revisions in practice based on the latest credible evidence. While the bridling of NGTs has been shown to improve patient care outcomes in adults (Yardley & Donaldson, 2010) there is a dearth of evidence to determine if nasal bridling of NGTs would improve outcomes of children requiring enteral nutrition to promote healing, growth, and development.

Lewin's Theory of Planned Change (TPC) was used as a framework to organize the change process, evaluate clinical outcomes of the implemented change in practice, and produce sustainable change in management of NGTs in one large pediatric tertiary medical center (Figure 4). Lewin's TPC was used to guide the implementation of nasal bridling to secure NGTs across multiple disciplines in the medical center (Lewin, 1951). The groundwork for this study focused on the training of providers and nurses to place nasal bridles appropriately and to document the care for patients with bridled NGTs. Evaluation of patient outcomes after implementing the change in practice provided the evidence needed to support a sustainable change in management of NGTs throughout the hospital (Figure 4).

Figure 4.

Lewin's Theory of Planned Change



A description of Lewin's TPC was first published in 1951, and the theory has subsequently been used to implement effective and sustainable change in medical environments (Evans et al., 2016; Manchester et al., 2014; Wojciechowski et al., 2016). Lewin's TPC involves three linear phases: Unfreeze, Move, and Refreeze. According to Lewin's theory, change is an iterative process, not a linear one. This idea is especially relevant to implementing change in a hospital setting where patient care across the continuum is not linear, but circumferential in nature (Evans et al., 2016; Lewin, 1951; Manchester et al., 2014; Wojciechowski et al., 2016).

In Lewin's TPC, antecedents to successful change include stakeholder buy-in, organizational readiness, and multidisciplinary collaboration. Based on increased interest in employing nasal bridles to secure NGTs, organizational stakeholders from a variety of hospital departments came together to decide upon the best approach to enhance clinician adoption of nasal bridles to secure NGTs in this pediatric acute care hospital. A force-field analysis (Mitchell, 2013; Shirey, 2013) was conducted, looking carefully at restraining, and driving forces that would 'unfreeze' the environment and affect the eventual success of the plan for increasing nasal bridle insertion. A business plan accounting for the financial expenses, including personnel costs, to support implementation of this practice change was prepared. Experts in placement of nasal bridles were identified, and educational modules were developed to help key stakeholders consider moving from the traditional method of securing NGTs towards using nasal bridles, a new option for securing NGTs in their patients. The planning team met with groups of clinicians, answering questions, and arranging for training and credentialing in bridle placement for nurses and providers. Departmental silos were dismantled though multidisciplinary work groups, frequent meetings, and mentoring.

The “change” phase of Lewin’s model took place as the nasal bridling procedure was implemented across the hospital. Potential super users underwent training sessions with device representatives. Proficient super users then trained colleagues to place nasal bridles. Training was optional and included observation of placement, assistance with placement and finally supervised independent placement. On-site instruction covered troubleshooting, documentation, education of families and follow-up care. The final phase of change incorporated teams to develop policies and procedures for NGT management across subspecialties, and a multidisciplinary team to oversee nutritional management of children post discharge.

The final “refreeze” stage in Lewin’s TPC was based on data that indicate a positive change in patient care outcomes after implementation of nasal bridles to secure NGTs. As such, careful consideration was made when determining the specific outcomes to evaluate the possible benefits of this change in practice. If positive effects are seen, a sustainable change in practice for securing NGTs may be achieved.

Summary

Chapter one described the significance of proper placement and securing of NGTs for delivery of adequate enteral nutrition in children. Chapter one also described nasal bridles as a novel means to secure NGTs. The conceptual framework used to guide implementation and evaluation of this new approach to securing NGTs is based on Lewin’s Theory of Planned Change. The process used to support adoption of nasal bridles in the clinical setting and the training of providers across multiple disciplines and departments within the hospital was described. This study addresses a gap in the literature on nasal bridling as a method for securing NGTs in children.

CHAPTER TWO
REVIEW OF THE LITERATURE

Critical Review of the Literature

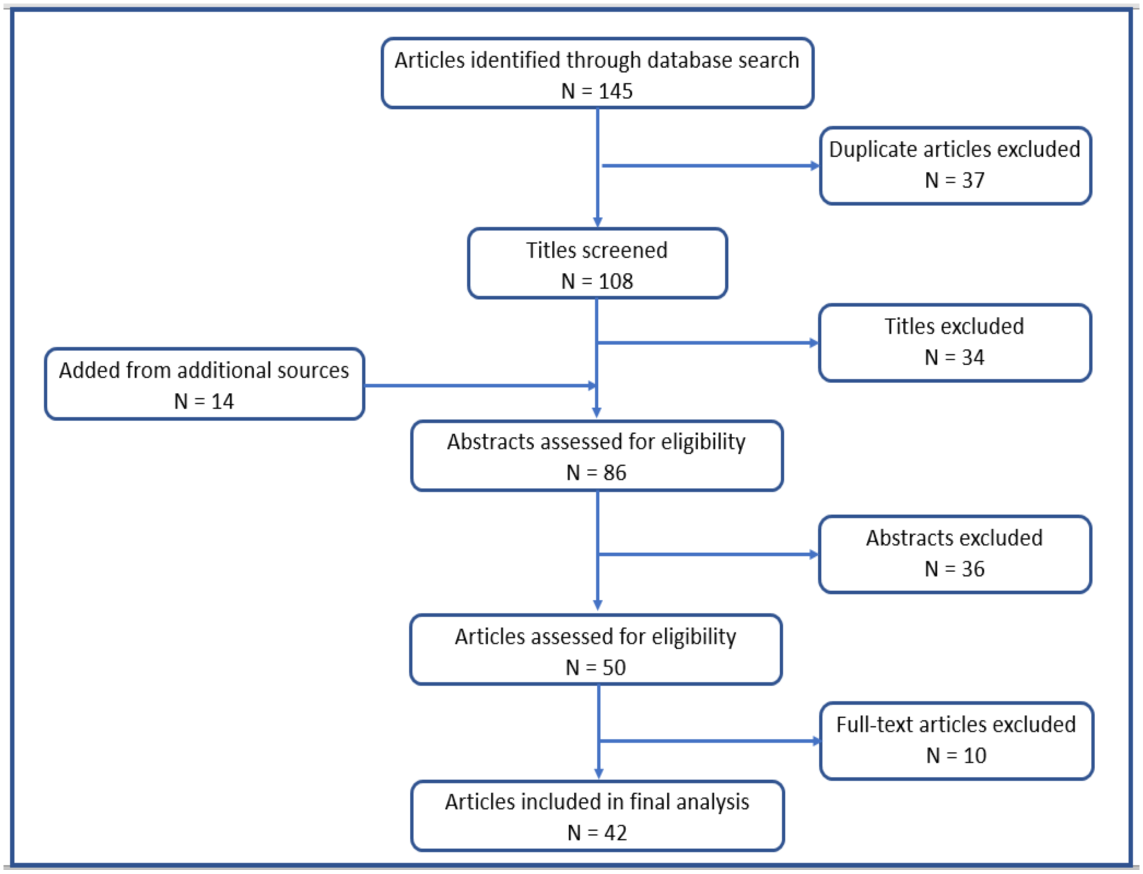
Chapter one addressed the importance of NGTs for temporary delivery of enteral nutrition in children, including accurate placement and risks associated with inadvertent, albeit common dislodgement. Chapter two presents the current literature on nasal bridles to reduce the risk of dislodgement of NGTs. Due to the limited number of studies of nasal bridles in children, studies conducted with adult patients were incorporated into this review. The review of literature describes the efficacy of the nasal bridle as a securement device across a wide range of age groups and subjects in the acute care or hospital setting. However, there were no published studies demonstrating the benefits of NGT bridles to secure NGT placement post discharge from the acute care setting, until March of 2021 when a new pediatric study emerged in the literature, as a direct result of collaboration between the author of this dissertation and NICU colleagues at the affiliated institution (Lagatta et al. 2021). This study is discussed in detail in the pediatric literature review section. Because patients with nasojejunal tubes were not included in the proposed study, the literature on nasojejunal tubes was not described in this review. This review informed the design of the study to address identified gaps in the literature on nasal bridling to secure NGTs in children.

An extensive literature search was performed using the CINAHL, Web of Science and PubMed databases. Key terms included: enteral nutrition/instrumentation, enteral nutrition/methods, nose, nasal bridle, enteral nutrition, and securement or secure, taping and strapping, equipment, or supplies. MeSH terms were employed across each search engine and only articles published in English were included. Years were not restricted in the initial search to include work published prior to the creation of the modern bridle device and allow for relevant hallmark articles. Reference lists in retrieved articles were also used to expand the number of studies considered for this review of literature. Articles were excluded if they were focused solely on bridling of nasojejunal tubes. Articles published in other fields such as sociology and psychology were included if they were relevant to implementing nasal bridling of NGTs in a hospital setting. Children requiring enteral nutrition therapy are often medically complex. Their care often requires the support of multiple disciplines, creating an environment that is high risk for frequent medical touch points, increased healthcare costs and resource utilization. No articles proposed the use of NGT bridles to lessen these tenants, collectively described as the healthcare burden, when caring for complex, enterally fed pediatric children.

The initial search resulted in 57 articles via CINAHL, 25 articles via Web of Science, and 63 articles via PubMed for a total of 145 articles. Duplicate articles were excluded, and 14 articles were added from additional sources. In the initial screen, articles with titles discussing irrelevant topics were excluded leaving 86 articles for review. A secondary screen was done, reviewing abstracts in detail, which reduced the number of articles to 50. The remaining 50 articles were reviewed in their entirety and ten more were discarded for their content. Of the final 42 relevant articles, eight were published before 1998, 30 (three editorials, three case studies and 24 research studies) addressed nasal bridles in adult patients, and two studies addressed nasal bridles in children. Since the initiation of this dissertation, the author has collaborated with colleagues at the institution where this study took place and published one study and one programmatic development paper that have contributed to scientific knowledge concerning children with bridled NGTs. Both papers are included in this doctoral work (Figure 5).

Figure 5.

PRISMA Chart of Literature Review for Nasal Bridles



Historic literature

Eight articles published between 1972 and 1998 describe the early use of nasal bridles to secure NGTs (Pourquier & Combres, 1972; Barrocas 1982, Levensen et al., 1985, Taylor, 1988; Lewis & Wachsman, 1992; della Faille et al., 1996, 1998; Meer, 1989; Porquier, 1972). The authors noted that the incidence of inadvertent enteral tube dislodgement was 40-60% and that dislodgment posed a cascade of undesirable results including delayed feeding, increased use of staff and provider resources, risk of aspiration, waste of enteral formula, longer hospital stays, and use of invasive nutrition support through parenteral nutrition or gastrostomy tube placement (Meer, 1989).

Prior to the use of magnetic strings that would easily clasp behind the vomer bone, a fine-bore polyurethane tube was attached by plugging a rounded tip of the bridle into the opposite hollow end of the tube (Meer, 1989), called a nasal-septal loop. An adhesive-backed polyurethane tape was positioned inside the patient’s nose (Meer, 1989). Placement was described as difficult, but effective in securing enteral tubes (della Faille et al., 1996, 1998). Meer (1989) advocated use of the novel bridle device as an effective method for securing NGTs for delivery of enteral nutrition rather than costly parenteral nutrition or medically complicated gastrostomies (Meer, 1989). della Faille et al. (1996, 1998) published two studies in 1996 and 1998, respectively. Both studies were conducted in a single medical center and both reported the nasal septal loop to be an effective method of securing NGTs in uncooperative or agitated patients requiring short-term enteral nutrition (della Faille et al., 1996, 1998). The difficulty of bridle placement and patient discomfort were the main reasons this early type of nasal bridle method was not widely used at this time.

Bridling in Adult Patients

Nasal bridles became easier to place behind the vomer bone with the addition of tiny magnets placed at the end of each probe, allowing the bridle to circumnavigate the nasal septum (Popovich, 2010). The use of umbilical tape in the bridle was reportedly more comfortable for patients (Popovich, 2010). Nasal bridles were further updated and are now comprised of a soft and smooth microfilament tubing (Applied Medical Technology, 2018) that is more comfortable for the patient both during and after bridle placement (AMT, 2018). Lubricant for placement is no longer necessary and there is a 60% decrease in surface area of the bridle loop.

As technical aspects of nasal bridling had improved, there was an uptick in the number of published studies of nasal bridling to secure NGTs in adult patients. Three editorials discussed current studies on the efficacy of nasal bridling of NGTs and endorsed its safety and effectiveness of nasal bridles in preventing tube dislodgement (Popovich, 2010; Gurram, 2011; McGinnis, 2011). Mahoney et al. (2015) conducted a survey of 528 registered nurses affiliated with the Scottish National Stroke Nursing Forums to assess common strategies for management of NGTs in stroke patients. The survey response rate was 59% (314/528) and nurses reported tape to be the most common method to secure NGTs. Bridles were used least often, and taping was seen as safer but not as effective. Aspiration of gastric contents and x-ray were commonly reported methods of confirming NGT placement (Mahoney et al., 2015). Other authors agree that facial taping is the standard way to secure NGTs but is not always effective (Popovich, 2010; Gurram, 2011; McGinnis, 2011). Radiographic confirmation of NGT placement is the gold standard of care but exposes patients to additional radiation if the tube must be replaced (Irving et al., 2018). Enteral nutrition is interrupted when NGTs are dislodged. Bridles are discussed as a possible method to ameliorate dislodgement, minimize radiation exposure, and improve enteral nutrition intake (Popovich, 2010; Gurram, 2011).

Studies of nasal bridles in adult patients examined the efficacy of the nasal bridle as a method to improve the longevity of enteral tube placement, reduce risks associated with tube replacement, or avoiding invasive forms of nutrition support such as parenteral nutrition and percutaneous endoscopic gastrostomy (PEG) placement (Christian et al., 2018). Findings are synthesized below and organized by outcomes relevant to this study: dislodgement, tube duration, impact on enteral nutrition (PEG, enteral delivery), radiographic exposure, and bridle-associated adverse events.

Systematic reviews that include multiple outcomes in adult bridle patients are discussed at the end of this section.

Dislodgement

Several studies reported the incidence of dislodgement of taped NGTs to range from 40-73% (Allan et al., 2019; Anderson et al., 2004, Gunn et al., 2009; Taylor et al., 2018; Brazier et al., 2017). Brazier et al. (2017) noted that the removal rate climbs even higher (82%) in stroke patients with neurological impairment. Studies conducted in a variety of hospital settings associate bridle usage with a marked decrease in tube dislodgement, with reduction of tube dislodgements ranging from 9-20% (Allan et al., 2019; Bechtold et al., 2014; Gunn et al., Gupta et al., 2010; 2009; Li et al., 2018; Power et al., 2010; Seder et al., 2010; Taylor et al., 2018; Allan et al., 2019). A quality improvement initiative to reduce dislodgement of NGTs in an adult burn unit was described by Parks and colleagues (2013). They found the nasal bridle to be clinically superior over traditional adhesive tape in reducing the number of NGT dislodgements (Parks et al., 2013). Gupta et al. (2010) studied the safety of nasal bridles placed in 38 elderly patients (mean age 72 years). Patients in this study qualified for a bridle once they had dislodged their NGT three times. Prior to bridle placement an additional 147 x-rays were conducted to confirm proper placement of the NGT. Only one additional x-ray was conducted post-bridle placement (Gupta et al., 2010). Authors concluded bridles are safe and effective in reducing the number of NGT reinsertions as well as the number of repeated radiation exposures to confirm proper NGT placement (Gupta et al., 2010).

Power et al. (2010) conducted a prospective trial of NGT bridles in a cohort of 28 patients with a history of frequent tube dislodgement. Post-bridle placement, 24 patients experienced no further tube dislodgement. Authors concluded bridles were safe and cost effective compared to traditional securement methods (Power et al., 2010). A large retrospective, single-center study reviewed data on ‘device loss’ from October 2014 through December 2017 for both NGTs and nasojejunal tubes. They found that prior to the use of bridles, 53% of enteral tubes were dislodged; after bridle placement, only 9% of tubes were dislodged (Taylor et al., 2018). One prospective study of 74 adult burn patients with NGTs found that 33 taped NGTs were dislodged more frequently per 10 feeding days (0.9+/-0.2) than the 41 bridled NGTs (0.2+/-0.1). A Kaplan Meier analysis demonstrated a longer tube life for bridled NGTs compared to taped NGTs (Hazard Ratio 0.35; p=0.01). Fewer x-ray studies were performed to confirm proper NGT placement in the nasal bridle cohort compared to non-bridled patients (1.48+/-0.13 vs. 2.21+/-0.21; p=0.003, respectively) (Li et al., 2018).

Allan et al. (2019) and colleagues recently examined the effect of nasal bridles on inadvertent tube loss in a single center adult intensive care unit (ICU) over a three-month period. This was an observational study in which a total of 205 tubes were inserted in 109 patients, 77 of which were bridled. Authors reported the life of the tube in situ was significantly longer when patients were bridled on day 1 (p<0.0011). Tubes secured with tape were significantly more likely to become dislodged than those secured by bridles (p<0.0011) (Allan et al., 2019). Another study looked solely at NGTs secured by tape and did not have a bridle cohort. Over 200 tubes were placed in 75 patients and 59% required three or more NGT replacements (Brazier et al., 2017).

Adverse Events

No study specifically studied adverse events associated with bridled NGTs, though most anecdotally reported that the prevalence of skin integrity issues, sinusitis or epistaxis was minimal (Seder et al., 2010; Stabler et al., 2018; Guram, 2011). Three case studies of adult patients that underwent nasal bridling described unusual complications, including two cases of an avulsed magnet and a retained stylet from a bridle-insertion kit (Smith et al., 2016; Puricelli et al., 2016 & Jackson & Sharma, 2015). Studies comparing nasal bridles to standard practice using facial tape to secure NGTs reported minimal risk for nasal erosion or sinusitis (Seder et al., 2010; Gunn et al., 2009; Gupta et al., 2010; Griffin, 2015). An adult ICU in Canada implemented a training program for bridle insertions. Post training, nurses were asked to complete a survey. Three of the sixteen nurses who placed bridles reported bridle placement was “difficult” (Stabler et al., 2018). No skin erosion or epistaxis occurred in the 16 patients and only one NGT was dislodged post bridle placement (Stabler et al., 2018).

Enteral Nutrition Delivery

The goal of any system to replace oral intake is to provide adequate nutritional support with minimal risks. Unbridled NGTs are frequently dislodged, interrupting the enteral delivery of calories. Several of the studies reviewed reported improvement in the delivery of adequate enteral nutrition when bridles were used (Bennell, 2009; Cheung et al., 2009; Donaldson et al., 2007; Anderson et al., 2004; Young & Leedham, 2011). Seder et al. (2010) conducted a randomized controlled trial of 80 surgical ICU patients requiring enteral nutrition. The 40 patients in the bridled group received a higher percentage of their enteral nutrition goal than the non-bridled patient cohort (78% vs. 62%, $p=0.016$) likely related to lower need for tube replacements in the bridled group (Seder et al., 2010).

In a small retrospective study of 50 intensive care patients, Allan found that patients with the use of nasal bridles to secure NGTs attained 78% of goal calories while those with taped NGTs received 69% (Allan et al., 2018). Donaldson et al. (2007) prospectively monitored 96 stroke and dementia patients with unbridled NGTs and found that prior to bridle placement, only 20% of the prescribed caloric goal was met. After bridle placement, enteral intake rose to 98% of the nutrition prescription (Donaldson, et al., 2007). Cheung et al. (2009) monitored caloric intake in 48 adult ICU patients with unbridled NGTs for seven days prior to bridle placement versus 30 days after bridle placement (Cheung et al., 2009). Authors found that 67% of patients received less than half of their caloric intake goals in the period before bridle placement. Conversely, 86.6% of patients met caloric intake goals post bridle placement (Cheung et al., 2009).

Percutaneous Endoscopic Gastrostomy Prevention

NGTs were designed to provide short-term delivery of enteral nutrition. However, frequent dislodgement of NGTs often influences a clinician's decision to place a PEG tube in patients who are expected to need nutritional support for a longer period. PEG tube placement is invasive and is associated with morbidities and possible mortality (Popovich, 2010; Gurram, 2011; Young & Leedham, 2011; Christian et al., 2018). Donaldson reported 30-day mortality post PEG insertion fell from 16% in historic controls to 6% after the routine use of nasal bridles for patients who would have previously received PEG placements (Donaldson et al., 2007). Young & Leedham (2011) reported that the majority of 170 patients with bridled NGTs recovered full oral intake (115; 67.6%) or died from their underlying illness (24; 14%), thus avoiding an unnecessary and invasive PEG placement (Young & Leedham, 2011). Similarly, in a prospective study of 14 adult patients on a single stroke unit, all were offered a bridled NGT due to frequent dislodgements. Of the 14 patients, 28.57% went on to recover full oral intake within a median of 15 days, indicating that rapid progression towards placement of a PEG tube within the first 28 days of a neurological event may be unwarranted (Anderson et al., 2004). The findings of these studies imply that bridling may circumvent PEG placement if adult patients are given a period of time to re-develop oral motor skills (Anderson et al., 2004; Donaldson et al., 2007).

Webb et al. (2012) followed a cohort of 140 critically ill elderly patients referred for bridle placement due to frequent dislodgement of their NGT and acutely impaired swallowing over a 36-month period. In that time, 52% of them recovered adequate swallowing within 28 days, negating the need for PEG placement. The mortality rate was high for the entire cohort (35.3%), which might also negate the need for an invasive PEG tube placement in critically ill elder patients (Webb et al., 2012). For patients at high risk of mortality, PEG placement may be avoided by placing a bridled NGT until end of life (Webb et al., 2012; Donaldson et al., 2007).

Systematic Reviews

One integrative review of 7 studies of nasal bridles in adult stroke patients concluded that evidence for the efficacy of nasal bridle loops is sparse and methodologically impaired. The authors concluded that bridle placement depends on patient acceptance of nasal bridles and that further research is required to demonstrate bridle efficacy (Mahoney & Veitch, 2018).

Brugnolli et al. (2014) conducted a systematic review of 5 studies that compared methods of securing NGTs in adult patients; four studies included nasal bridles and demonstrated lower rates of tube dislodgement. Two of 3 studies demonstrated a longer time to tube failure in bridled patients, and 1 reported greater caloric intake in the bridled patients compared to taping or other methods of securing the NGT. Three of the five studies also compared adverse events in bridled and unbridled patients and found conflicting results. The authors concluded there is a need for more well-designed studies in a variety of settings to support one NGT securement method over another (Brugnolli et al., 2014).

One meta-analysis of six studies with 544 patients found a significant reduction in tube dislodgement with bridles (14%) compared with the standard method of adhesive tape (40%) (OR 0.16, 95% CI 0.10-0.27; $p<0.01$). Occurrence of skin complications and sinusitis were not different between the two groups (Bechtold et al., 2014).

Lynch et al. (2018) conducted a systematic review of 18 studies of nasal bridles that examined the rate of tube dislodgement, rate of tube replacement, tube dwelling time, quantified enteral nutrition, cost, complications and PEG-related morbidity/mortality (Lynch et al., 2018). The authors concluded that nasal bridling is associated with less NGT dislodgement, a decreased NGT replacement rate, and a longer tube life compared to traditional methods (Lynch et al., 2018). They also concluded that bridled nasoenteric tubes resulted in a higher proportion of enteral feeding delivery (Lynch et al., 2018).

Summary

In summary, multiple studies of nasal bridles in adult patients have demonstrated that the bridle is an effective medical device to prevent NGT dislodgement, resulting in reduced radiographic exposure, improved delivery of enteral nutrition, reduced PEG tube placement and extended life of the NGT tube (Gurram, 2011). Indirect cost savings, noted in several studies, included more efficient delivery of enteral nutrition, less use of medical equipment and less staff resources (Popovich, 2010; Gunn et al., 2009; Seder et al., 2010). Minimal adverse events have been reported with NGT bridle use. Gaps in the literature remain, as no study examined whether use of nasal bridles to secure the NGT in the acute care settings affected length of stay or outcomes in patients discharged home with an NGTs. All studies took place at a single-center, and the cohorts studied were small. Further research is needed to determine the efficacy of nasal bridles to secure NGTs and improve nutritional outcomes.

Pediatric Literature

A total of four studies comprised the literature review of nasal bridles in pediatric patients. Two of the published papers were authored by this writer in direct collaboration with the program built at the affiliated institution. The first focused on describing the programmatic development of a pediatric bridle program at this institution (Lavoie et al., 2021). The second paper focused on a subset of infants bridled in the NICU and then discharged home (Lagatta et al., 2021). The remaining two published reports of nasal bridles in children were small, single center studies looking at the impact of nasal bridling on dislodgment of NGTs in their setting (Kang et al., 2018; Newton et al., 2016). Newton et al. (2016) examined whether routine bridling of NGTs decreased tube dislodgement in a cohort of 30 children from November 2012 through June 2015. Data were compared to two control groups: (1) 33 children who underwent tracheoesophageal fistula (TEF) repair from 2001 to 2012 and (2) 20 children who had their NGTs placed under fluoroscopy from February 2012 to July 2013. In both control groups, NGTs were secured using the traditional method of taping the tube to the cheek. Comparisons included differences in total number of tube dislodgements as well as tube dislodgements per 100 tube days. Across 1553 total tube days, only three of the 30 children with nasal bridles experienced tube dislodgements compared to 18 of 33 TEF children ($p<0.0016$) and nine of 20 fluoroscopically placed tube children ($p=0.021$) (Newton et al., 2016), with a significant difference in the number of dislodgements per 100 tube days between groups ($p<0.0001$). One incidence of nasal erosion was noted in the bridle group. Authors concluded that bridling NGTs in children was a safe and effective method for limiting tube dislodgement (Newton et al., 2016). However, it is of concern that the historic cohort spanned 11 years of time prior to use of nasal bridles in this setting. Over that period, the infrastructure of patient care may have changed, confounding comparisons on children who received nasal bridles. This study did not examine nutritional intake or other patient outcomes.

Kang et al. (2018) conducted a pilot test of bridle placement in children under one year of age which was overseen by the pediatric surgical service in a single setting. Fourteen bridle systems were in place over 444 patient days for an average duration of bridling of 31.7 days per patient (Kang et al., 2018). Only one tube dislodgement was noted amongst the 14 bridles (Kang et al., 2018). Authors concluded that bridles are safe and effective for securing tubes in infants (Kang et al., 2018).

Lagatta et al. (2021) conducted a prospective single-center study that compared healthcare utilization and parent health-related quality of life (HRQL) in three groups of infants who had NGTs while in the NICU and were discharged home orally fed (n=80), GT fed (n=65) and NGT fed (n=35), the majority of whom (n=31) were bridled. Each infant was tracked for three months post discharge, at which time acute healthcare utilization and HRQL scores were compared between groups. Infants with GTs experienced more readmissions and emergency department encounters (OR=3.97, 95% CI 0.1, 1.7, p=0.02). The bridle group experienced only one bridle-related emergency department encounter and 19 infants in the GT group experienced emergency department encounters related to GT dislodgement, bleeding, or complications with their durable tube. The study found that infants discharged home with NGTs were associated with a reduced NICU stay without increased post-discharge healthcare utilization or decreased parent HRQL (Lagatta et al., 2021). Of the 35 infants discharged home with NGTs, 31 were bridled and 27/35 (77%) progressed to achieve full oral feeds and the median use of the NGT was 29 days. Given the small number of NGTs without bridles, no comparison of the effects of bridling on outcomes was possible.

In summary, use of nasal bridles to secure NGTs in children has been shown to reduce the incidence of enteral tube dislodgement in small numbers of children at two single centers. Neither study addressed patient outcomes post hospital discharge. One recent study, conducted by this author and colleagues at the affiliated institution, found that NICU infants discharged home on NGT feeds did not experience increased post-discharge healthcare utilization or decreased parent HRQL compared to orally fed and GT fed infants (Lagatta et al. 2021). Lagatta et al. (2021) did not address tube dislodgement. This recent study serves to address an important gap in the literature of children being discharged home with bridled NGTs. Given the frequent use of NGTs across pediatric care, additional data are needed to track children's transition to oral feeds. Further research with a larger sample size across the continuum of inpatient and outpatient care is needed.

Gaps in the Literature

There are significant gaps in the literature pertaining to nasal bridles to secure NGTs in children/pediatric children. The studies available to date are conducted on small sample sizes at single centers with limited control groups. Of the three published studies of nasal bridles in children, the collective number of children was 73. Each of these studies occurred at single institutions and one had a comparison cohort and that cohort spanned 11 years prior to when nasal bridles were placed in children at this institution (Newton et al., 2016).

Kang et al. (2018) and Newton et al. (2016) collected data retrospectively and were therefore limited to the data in the medical record. Both studies were conducted in the acute care setting, and neither addressed the efficacy of bridling in the ambulatory or community setting. Lagatta et al. (2021) prospectively collected data in 31 children with bridled NGTs and assessed acute healthcare utilization post discharge from the NICU. Dislodgement, as well as the specifics of outpatient management were not discussed in detail for this cohort.

The purpose of this study is to close this gap by 1) describing NGT-relevant outcomes of nasal bridling of NGTs compared to current method for securing NGTs in children, and 2) describing NGT-relevant outcomes after discharge from the hospital setting.

Philosophical Underpinnings

Florence Nightingale, a British social reformer, statistician, and iconic figure of nursing, wrote volumes about nursing the sick and bridged the gap between art and science. This created a foundation for nursing as a discipline that still serves this modern era. Nightingale wrote,

> I use the word nursing for want of a better. It has been limited to signify little more than the administration of medicines and the application of poultices. It ought to signify the proper use of fresh air, light, warmth, cleanliness, quiet and the proper selection and administration of diet – all at the least expense of vital power to the patient. (Florence Nightingale's Notes on Nursing, 2010, p. 64-65)

Her words from 1860 can be directly applied to much of nursing research. This dissertation focuses on improving the nutritional intake and overall well-being of patients best served by sending them home safely with their families.

All nursing theory is derived from or leads us to the underpinnings of philosophy (Silva, 1977). The melding of philosophy, science and theory allows nurse scientists to take an integrative approach to their work (Benner et al., 1997). The philosophy-science-theory triad evokes a more holistic approach to the development of nursing knowledge; research without philosophical introspection is research without truth (Silva, 1977). This was a bold statement at the time, as other scholars described science as closed to intuition (Riehl & Roy, 1974; Gortner, 1974). According to Benner et al. (1997) critical thinking and pluralism have been incorporated into the fabric of nursing science. Nursing research is an integrative approach to science beyond the realm of traditional scientific methods, inclusive of mind, body, environment, ethics, and health (Benner et al., 1997). These diverse ways of knowing require diverse methods for scientific inquiry and lend themselves to the expansion of scientific knowledge underpinning nursing practice (Fawcett, 1999).

The philosophical underpinnings chosen for this dissertation are post-positivism and constructivism. These philosophical underpinnings help guide the research methods, assist in evaluation of possible methodologies, and encourage creativity and innovation within the scientific construct (Easterby-Smith, 1997). Any discussion of post-positivism warrants a brief understanding of positivism for contextual purposes.

In the 18th and 19th century, philosophers John Locke and David Hume wrote about positivism as a phenomenon of observation and experience. In the early 20th century, positivist philosophers emphasized the importance of establishing laws for inquiry. By the 1960's positivism had grown into a phenomenon focused on deductive reasoning, leading to a logical conclusion (Allmark, 2003; Crossan, 2003). Ontologically, positivism is described as a knowable reality, existing for all to access, measure and comprehend, driven by unchangeable laws (Guba, 1990). Under a positivist paradigm, the purpose of science is to predict and control natural phenomena (Guba, 1990). Positivism is known for excluding subjective meaning from the research process, promoting objectivity and reductionism (Playle, 1995), which has been rejected by some nurse scientists (Clark, 1998, Guba & Lincoln, 1994).

The discipline of Nursing is built upon holistic perspectives on the human experience of health and illness, making the stringent, law-centered scientific philosophy of positivism inherently challenging in nursing research. Popper, Kuhn and Brownowski were the first to promote post-positivist philosophy as an alternative to the positivist ideals of discipline and rigidity (Brownowski, 2956; Popper, 1959). These theorists did not seek universal truths, but rather an approximation of the truth (Clark, 2998). Popper (1974) described the post-positivist research approach in which hypotheses should be predicted and attempts to falsify them through empirical tests should be conducted.

Kuhn offered a new lens through which the world views scientific discovery. Kuhn believed that culture, values, and even societal events play a role in the dynamic process of what he referred to as "normal science" -- an iterative process that twists and changes direction causing growth within a discipline. Scientists work within a paradigm built through a unique combination of ontology, epistemology and methodology striving to find solutions to legitimate problems (Kuhn, 1970).

Ontology, Epistemology and Methodology

Ontology describes the nature of reality (Guba, 1990). The ontology of post-positivism states that there is a reality that exists but can never fully be explained or understood because reality is ever-changing and progressing (Guba, 1990). Under this reality, researchers are not seen as being detached from their research (Clark, 1998). Post-positivism assumes reality is subjective and research is an iterative process (Monti & Tingen, 1999). Scientific knowledge is based on theories that have not been disproven in our current reality and not upon an absolute and undeniable truth (Popper, 1974). For the post-positivist, reality is context dependent and not a steady path towards ultimate truth (Kuhn, 1970). The ontology of constructivism states that reality is mentally constructed, and a different reality occurs for each individual with each interaction because it is based upon social interaction and experiences (Guba, 1990).

Epistemology describes the nature of the relationship between the researcher and the study participant (Guba, 1990). The epistemological perspective of post-positivism states that the researcher cannot be without bias, and they are merely a “modified objectivist” (Guba, 1990, p.23). From a post-positivism standpoint, one would argue that objectivity is ideal, but difficult to achieve, as a researcher is never unbiased about their subject of research (Guba, 1990). The goal of the researcher is to look at multiple ways of observing and acknowledging their biases. The epistemology of constructivism states that knowledge emerges as it is created, and both the researcher and the study participant partake in the creation of that knowledge collectively (Guba, 1990).

Guba posits that methodology is defined by how the researcher obtains knowledge to address their question. The methods utilized in post-positivism is a mixed-methods approach. Data gathering in a natural environment is encouraged. Constructivism methodology states that the goal is to generate additional constructions to add to the knowledge base. This is done by testing hypotheses in which single constructions are compared and contrasted and a consensus is then reached (Guba, 1990).

This research study adheres to the ontology of post-positivism in that the investigator does not seek an absolute truth about bridled NGTs. The context of the patient’s medical complexities, age, family dynamics and providers of care all change the context under which the nasal bridle is used to manage care of patients requiring NGTs for delivery of enteral nutrition. The design of nasal bridles has changed over the years, which may have changed the outcomes achieved with their use as well as their applicability in patient care. From the perspective of constructivism, nasal bridles are experienced differently by each patient and could therefore produce different results.

Certainly, the researcher tries to maintain objectivity during the research process, but is ultimately, as Kahn describes: a modified realist (Kahn, 1970). The role of the researcher is to observe multiple factors related to bridling outcomes and describe them, leaving the results for others to either verify or refute. There are no qualitative or subjective data in this study, and therefore the epistemology of constructivism is not fully met. However, the emerging knowledge gained from this study is a co-creation between the researcher studying and observing and the participants experiencing the bridle in different ways. Methodologically, this study spans over time and the longitudinal nature of the data fits into the paradigm of ever-changing reality.

The design of this study reflects Popper's four-phase approach to building scientific theory (Allmark, 2003). First, Lewin's TPC was chosen as a framework for mobilizing the efforts of training and implementing bridles at the site of the study (Lewin, 1951). Second, hypotheses were developed after identifying gaps in the literature related to use of bridles in children across the continuum of care. Third, these hypotheses were subjected to rigorous testing through analysis of retrospective data gathered at the study site and finally, in phase four, the findings were collated to reveal an approximation of the truth on the efficacy of nasal bridles to secure NGTs in children framed by the experiences of those involved in the study. Philosophically, the overall goal of this study is to contribute to the existing body of nursing knowledge by utilizing ontological, epistemological, and methodological underpinnings.

Summary

Chapter two describes the post-positivist and constructivist philosophical underpinnings of this research study as well as the literature on nasal bridling to secure NGTs. Several studies have examined the use of nasal bridles to secure NGTs in adult patients compared to the traditional use of tape (Allan et al., 2019; Gunn et al., 2009; Gupta et al., 2010; Gurram, 2011; Newton et al., 2016; Seder et al., 2010; Taylor et al., 2018) reporting a significant reduction in dislodgement of tubes, rare incidence of minor nasal complications, (Levensen et al., 1985; Meer, 1989; Westhus, 2004) and a significant increase in percentage of enteral calories received by patients with bridled NGTs (Hegazi et al., 2008; Meer, 1989). Only three studies examined the use of nasal bridles in children; all were conducted with a small sample of subjects in a single hospital setting. However, two of the studies suggest that nasal bridles reduce dislodgment of NGTs in children (Newton et al., 2016; Kang et al., 2018). Any reduction in tube dislodgement will reduce risks of repeated exposure to radiation and sedation with tube reinsertion and reduces utilization of clinical resources while increasing the amount of enteral nutrition received by this vulnerable population (Seder, 2010; Allan et al., 2018; Donaldson et al., 2007; Gurram, 2011; Lynch et al., 2018). The third study demonstrated safe and effective use of bridled NGTs post discharge in infants (Lagatta, et al., 2021).

CHAPTER THREE
RESEARCH DESIGN AND METHODS

Chapter three provides a detailed description of the research methods and study design to address the aims and hypotheses for this dissertation. This chapter describes the population of interest, sample, data collection methods, and statistical analyses. Strategies to limit threats to validity are discussed and rationale for the design and methods of the study are described.

Research Design

The purpose of nursing research is to advance nursing science through identification, description, exploration, explanation, prediction, and control of nursing phenomena (Polit & Beck, 2004). For the purposes of this dissertation, a retrospective, correlational study design was used. Data were collected from the medical records of children with bridled NGTs and a concurrent group of children with unbridled NGTs. Data were analyzed using inferential statistical methods. The primary aim of this study was to determine if nasal bridles reduce the number of dislodgements of NGTs compared to standard facial taping of tubes in children served at this single setting. Additional outcomes of interest include length of stay, end point of GT placement, unplanned medical encounters, radiographic exposures, and skin integrity issues in these two cohorts of children.

The period of data collection is March 2018 through August 2020, after the introduction of nasal bridling as a method to secure NGTs in children. Children with NGTs secured with tape served as concurrent controls to minimize variation in medical management. Any patient receiving either a bridled or unbridled NGT for longer than seven days were considered for the study. Data on several covariates affecting placement and securement of NGTs in children were collected and included in the statistical model to control for variables that cannot be manipulated. These variables are discussed in detail in the methods section below.

This study contributes to the very small body of literature evaluating the efficacy of nasal bridles to secure NGTs in children. These findings are useful to clinicians caring for children that require NGTs to provide adequate enteral nutrition to this vulnerable population.

Hypotheses

1. There will be a lower number of dislodgements of NGTs in children with nasal bridles compared to children using standard methods of securing the NGT.
2. There will be a shorter length of stay in children with nasal bridles compared to children using standard methods of securing the NGT.
3. There will be a lower number of GT insertions in children with bridled NGTs compared to children with unbridled NGTs.
4. There will be a lower number of NGT-related unplanned clinical encounters (readmissions, unplanned clinic visits and emergency department visits) in children with bridled NGTs compared to children with unbridled NGTs.
5. There will not be a higher number of documented skin integrity issues for children with bridled NGTs compared to children with unbridled NGTs.
6. There will be a lower number of radiographic exposures in children with bridled NGTs compared to children with unbridled NGTs.

Setting

This research study took place at one large, pediatric tertiary medical center in the Midwest. This facility is a 306-bed free-standing children's hospital. Potential subjects received care in one of 13 inpatient units, or in the ambulatory setting. In 2019, there were 14,539 admissions to the inpatient wards and 3,644 unique children followed in the outpatient gastroenterology clinic that cares for children with bridled and unbridled NGTs. The principal investigator had access to both the inpatient and outpatient setting as an employee of the hospital.

Study Sample

Children with NGTs are seen across the inpatient hospital and outpatient ambulatory setting. The sample for this study included children with NGTs with and without nasal bridles, age zero to six years. The choice between placement of a bridled versus unbridled NGT for each patient was decided upon by the primary medical team with input from subspecialists in gastroenterology, nutrition and speech and language pathology, and the patient's family. Exclusion criteria for placement of the nasal bridle adhered to the recommendations of the manufacturer of the bridle as well as the standards set by the enteral feeding program at the site of the study. The exclusion criteria for this study include age greater than six years, facial trauma, or post septoplasty. Families could decline bridle placement for any reason. There are no exclusion criteria for bridled NGTs specific to gender, underlying medical condition, mortality risk, palliative care status, or medical complexity. Lavoie et al. (2021) described the enteral feeding bridle program in detail at this center.

Per hospital policy, children in both groups had their NGT changed every 30 days. The planned reinsertion took place in either the inpatient or outpatient setting.

Children with bridled NGTs had their bridle device changed at this same time. Neonatal intensive care unit (NICU) patients had their NGT changed weekly if it is not bridled to ensure proper placement given the risks associated with dislodgement or misalignment (Patel et al. 2014). Children that required NGTs beyond 90 days were potential candidates for a durable tube. Children that received nutrition support through an NGT for less than seven days were excluded from the study. All children in both groups were tracked until their NGT was permanently removed for either placement of a permanent tube or the patient had advanced to full oral feedings. As the study was a retrospective chart review in nature, participants were not approached for study enrollment. All data were retrieved from medical records de-identified for entry into an encrypted database. A power analysis was not required for the purpose of sample size prediction, as this is a retrospective, correlational study design using a convenience sample of subjects. While the results are informative, they will be limited in generalizability.

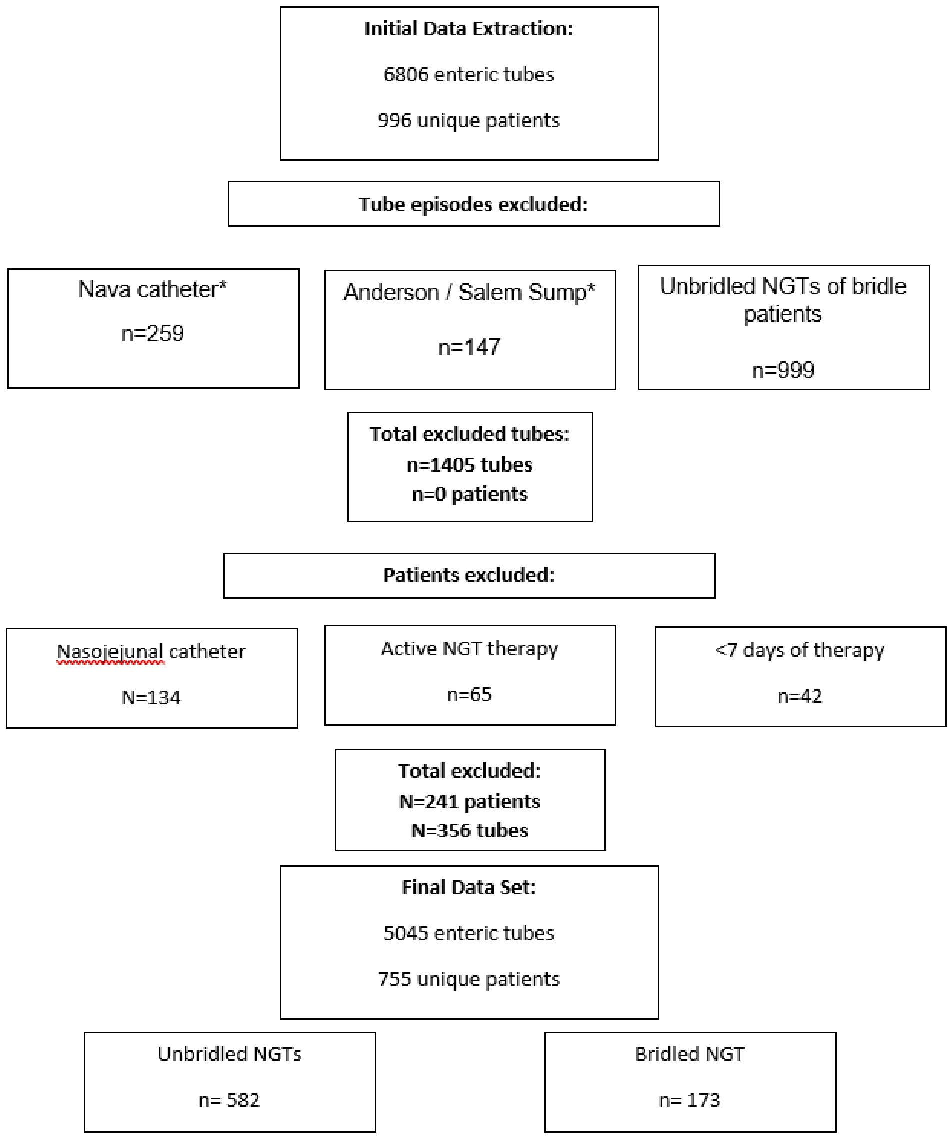
Data Collection Methods

The data for this study were gathered from the electronic medical record (EMR) and a coded data query that accessed subject area marts from a variety of clinical data repositories used by the hospital. Data were collected by the principal investigator. One senior data analyst was used to write a proper code to identify children with bridled and unbridled NGTs in the health record and provide a list of children for each group as well as their demographic characteristics and tube placement dates. Data abstracted from these sources included the following demographic characteristics: chronological age, gender, weight, length, as well as weight-for-age z-score from Fenton growth chart (premature infants), WHO weight-for-length z-score (0-24 months), BMI weight-for-age z-score (24 – 60 months) at the time of NGT placement, zip code, insurance status, and primary diagnoses at the time of enteral nutrition therapy initiation. Data that was difficult to extract through an automated process was gathered through manual chart review. Data were stored in the cloud, in an excel spreadsheet that was encrypted. All encrypted data were also backed up on an external hard drive.

Children were separated into two groups: the study group with bridled NGTs or the concurrent control group with unbridled NGTs. Information about each episode of care was carefully gathered. Both groups received their care at one tertiary pediatric medical center between March 2018 – August 2020. Data collection began for each child upon the initiation of their enteral nutrition therapy via NGT and ended upon completion of temporary enteral nutrition therapy. The end point for each child was either achievement of 100% oral feeds, or transition to a permanent GT. Children were excluded if they did not reach an endpoint at or before August 30th, 2020. Children with tubes used for purposes other than nutrition, such as Anderson Sump, Salem Sump and Nava catheters were excluded from the study. These tubes are typically used for surgical procedures or as a mechanism for mechanical ventilation. All children that had a nasojejunal tube as part of their nutrition therapy were excluded from the study. Additionally, any child that did not receive supplemental nutrition via their NGT for at least seven days was excluded from the study (Figure 6).

Figure 6

Algorithm of Patient Selection



*Several Nava catheters and Anderson/Salem Sump tubes were bridled, but excluded for the purposes of this study

Categorical or binary data included gender (male/female), insurance status (combination, commercial or Medicaid), primary service at the time of therapy initiation (critical care, NICU, acute care, ambulatory or other). The services included in “other” for the purposes of this study included hematology/oncology, emergency department, operating room, transport, interventional radiology, and outside hospital. Primary diagnosis at the time of therapy initiation was divided into the following categories: cardiac, congenital anomaly, GI/nutrition, prematurity, respiratory or other. Diagnoses grouped into the category “other” included trauma, infection, neurological, hematological, renal, and oncological.

Continuous variables included age (weeks) upon initiation of therapy as well as at the time of final tube removal, weight (kg) at the time of first tube insertion and final tube removal as well as anthropometric z-score at the time of NGT therapy initiation. The Z-score is regarded as the most relevant indicator of malnutrition for each population (Becker et al., 2015; Goldberg et al., 2018, 2019). For premature infants, the Fenton growth chart is used to assess weight-for-age z-score. For term infants, age 0 months through 24 months, the WHO growth chart is used to assess weight-for-length z-score. Finally, for children age >24 months, the CDC growth chart is used to assess BMI-for-age z-score. Each type of growth chart measures a series of standard deviations from the mean, giving each child a specific z-score that correlates to their nutritional status. The raw z-score was used in several regression models as a predictor of the outcomes of interest. The z-score was also used to define malnutrition status of each child (Becker et al., 2015; Goldberg et al., 2018, 2019). Z-scores < -3.0 = severe malnutrition, z-scores </= -2 = moderate malnutrition, z-scores </= -1.0 = mild malnutrition and z-scores >-1.0 = not at risk for malnutrition.

Initial hospital length of stay was collected for all children upon initiation of NGT therapy. For children that did not have a hospital stay associated with their initial NGT therapy, their hospital length of stay was zero. The total duration of a patient's NGT episode for enteral nutrition began upon initial NGT placement, where feeding lasted >/= seven days, and ended either when the child achieved full oral intake or transitioned to a GT. Each tube removal was tracked and labeled as a dislodgement, purposeful removal, trial by-mouth or final tube removal. A tube was coded as a dislodgement if the child inadvertently or intentionally pulled out their tube. A Purposeful removal was defined as a provider decision to remove the tube. This occurred in the NICU every seven days per institutional policy to replace tubes once weekly to mitigate the risk of necrotizing enteric colitis and infection (Patel et al. 2014). In every other unit, purposeful removals occur, on average, every 30 days. Additional reasons for purposeful removals included changing an NGT due to surgery or mechanical ventilation, in which another type of enteric tube was inserted. Therapies classified as trials-by-mouth included tubes that were purposefully removed and not replaced immediately to allow the infant or child to demonstrate their oral-motor skills and attempt to eat all required enteral nutrition by mouth. Each final tube removal was also tracked as the end of NGT therapy. At this time, the tube either remained out and the child ate all their feedings by mouth, or a gastrostomy surgery was performed. Each child was then coded as a yes=1, 0=no for gastrostomy. Additionally, the total number of days that each child had an NGT in place was calculated. The total number of tubes for each child was comprised into a total throughout the duration of their NGT therapy. The number of unplanned medical encounters was determined by adding the number of ED visits, unplanned GI clinic visits and readmissions together for each unique patient. Readmissions were counted only if they were relevant to NGT concerns or malnutrition. ED visits were also counted and treated as an independent variable of interest. Skin integrity concerns were counted using hospital incident report software for each child with an NGT, age zero to six years, within the specified time frame of the study. Outpatient days of therapy were calculated by subtracting the first hospital length of stay discharge date when therapy began from the final NGT removal date. This variable accounts for time each child spent outside of the hospital throughout the duration of their NGT therapy episode. Finally, every NGT placement in which an abdominal x-ray was ordered to confirm placement, was counted rom the electronic health record to gather a total number of x-rays throughout the entire duration of an NGT episode.

All regression models for each hypothesis were initially tested using the outcome variable of interest comparing only the two groups: bridled NGTs compared to unbridled NGTs. Each hypothesis was then tested by adding clinically relevant predictors into each regression model. Clinically significant covariates relevant to the enteral feeding program remained in the model whether or not the p-value was <0.05.

Research Procedures

Prior to the initiation of this study, great effort went into developing protocols for implementing use of nasal bridles to secure NGTs at this institution. As previously discussed, Lewin's Theory of Planned Change was employed as the framework to support the dissemination of training throughout the institution. Educational modules, and seminars on policies and procedures were conducted in preparation for caring for children with bridled NGTs. Infrastructure support was required by key stakeholders and multidisciplinary meetings addressed and resolved challenges. The principal investigator partnered with clinical nurse specialists and advanced practice providers to identify super users and ensure proper training occurred. Education about bridle placement, documentation of care, and trouble shooting was essential for success of bridle implementation across the clinical settings.

Methodological Rigor

The aims of this study are to determine if bridling of NGTs are superior to standard taping methods for securing NGTs in terms of dislodgements, total number of tubes, length of stay, outcome of GT insertion, number of radiographic exposures, number of unplanned clinical encounters, emergency department visits and skin integrity issues. Data were reported as number of events per patient, per group. Cofactors specific to these outcomes were collected upon initiation of NGT therapy and included: gender, age, weight, appropriate z-score, insurance status, primary location, and primary medical service. The initial hospital length of stay was also collected for any patient that was in the hospital at the time of initial therapy. At the time of final NGT removal, weight and age were collected again. The number of days a patient spent out of the hospital during therapy was also calculated for each patient.

Internal validity

Threats to internal validity were present in this study design. Although clinicians received similar training on placement of the NGT bridle device, it is likely that clinicians varied, to some degree, in techniques for bridle placement, which may have affected outcomes. To control for this, specific training competencies were identified, and providers were required to be credentialed for the bridle procedure before placing them in children. Clinicians may have exhibited selection bias in deciding who was and who was not an appropriate bridle candidate, which could potentially cause differences between the two groups. To control for this limitation, comparisons of demographic characteristics were made between groups during data analysis and controlled for in the statistical modeling of the data.

Additionally, the reliability of data were a threat to internal validity. Data collection included hospital and ambulatory care settings. Each patient chart is a conglomeration of thousands of data points charted on by multiple care providers. Each clinician that documents in the chart may have documented differently and this also affected the internal validity of the data. This threat was mitigated by training staff in proper documentation so that in the future, accurate data may be extrapolated from the medical record. Over time, changes in use of bridles or methods of placement may affect data from NGT children as they coincide with the institutional implementation of bridled NGTs. The use of bridles became more prevalent as the study continued and clinicians increased their awareness and became more comfortable with their placement. The requirement of 30-day ambulatory clinic follow-up visits may have resulted in missed appointments and therefore missing data. Reasons for missed appointments are multifactorial and include transportation difficulty, noncompliance, or circumstances outside the family's control. Data on children with missed appointments were collected for the data that is available in the chart.

External validity

The factors affecting external validity include the limited generalizability of the results due to the retrospective nature of the study design and use of a single hospital center to collect data. Additionally, institutional criteria for who gets a bridle versus who does not may differ from children selected for bridling in other institutions. This is the first known study to document patient outcomes from the inpatient to ambulatory setting; as such, there is little to compare it to in the realm of previously published work.

Statistical Procedures and Rationale

The data were analyzed using IBM SPSS Statistics for Windows (Version 27) predictive analytics software. Descriptive statistics were used to describe demographic characteristics of the two groups. Categorical and dichotomous variables were expressed as number and percentage. Continuous variables were expressed by depicting mean, standard deviation, minimum, median and maximum values. Analysis of outcome data were conducted using the Generalized Linear Models (GLM) family of analyses. This allows for adjustment of the predictive model for different types of outcomes. Specifically, it allows the use of logistic and negative binomial regressions (Agresti, 2007; Darlington & Hayes, 2017). This series of predictive models predicted the score of an observed outcome for the subjects, based on selected, clinically relevant, predictors. Through evaluating the relevance of the overall model and each predictor based on null hypothesis tests and effect size measures, both elements were considered in determining if a predictor has a relevant impact on the outcome. For the null hypothesis test of each predictor, we used a significance level of 0.05 as a threshold to reject the null hypothesis.

Logistic regression is a type of GLM analysis used for binary (0, 1) outcomes. This statistical test specifies a model to predict binary data by the addition of the logit link function; this way it predicts the increase/decrease in log-odds to score 1 in the binary outcome. The logit link function transforms continuous predicted values to the range of probabilities [0, 1]. These log-odds are later transformed into odds ratio (OR) and probabilities for interpretation and presentation as effect sizes. The OR represents the multiplicative change in the odds of scoring 1 in the binary outcome variable. The results are presented as OR and probability increase or decrease of answering 1 for each outcome as multiple interpretations of the effect sizes, and with plots representing the expected change in probability in function the predictors (Agresti, 2007; Gelman, & Hill, 2007). The overall model was evaluated by its overall predictive accuracy with Tjur pseudo-R^2 (Tjur, 2009), which evaluates the discriminant quality of the probability of answering 1.

Negative binomial regression was also used in this data analysis. This type of GLM is needed when the outcome is a variable count of integers without negative values. Linear regression would not be appropriate in this scenario because it allows prediction of negative values for the outcome. Negative binomial regression is a generalized version of Poisson regression, by account for over-dispersion. The relation between the outcome and predictors is evaluated by the log-count change in function of the predictors. This type of model predicts the likelihood of answering a higher or lower count on the respective outcome. As a GLM, the overall model would be evaluated with a pseudo-R^2 method, and each of the predictors were evaluated with a null hypothesis test. The exponent of the slopes presents the incident rate ratios (IRR), representing the ratio change that can be transformed into probability change for interpretation (Lindsey & Jones, 1998; Agresti, 2007).

Of the 755 children in the study, there were minimal missing variables. There was one missing value for insurance status and 5 missing anthropometric z-score values. The remainder of the variables for both groups were complete. No imputation was necessary for the data set. The covariates chosen for each research question vary slightly. These predictors were carefully selected based on their clinical significance and relevance to the specific research question.

Negative binomial regression was used for the outcome of the number of dislodgements, starting at zero and advancing from there by whole numbers. For research question one (RQ1), the predictor of interest was whether or not a patient has an NGT secured with a bridle. This regression model was first run solely with that predictor. A second regression analysis was run adding in covariates including: age at initial placement, gender, anthropometric z-score, and primary service at initial placement.

Research question two (RQ2) focused on quantifying the impact that type of NGT securement method (bridled NGT vs. unbridled NGT) had upon length of stay through negative binomial regression. Again, the model was initially run using bridled NGT vs. unbridled NGT as the only predictor. A second analysis was run adding in the following covariates: primary diagnosis at time of placement, insurance status, anthropometric z-score and age, in weeks, upon initial NGT placement.

Research question three (RQ3) focused on predicting whether children with NGTs undergo GT placement and if GT placement differs by type of securement method (bridled NGT versus non-bridled NGT). Logistic regression was used for the outcome variables of hospital practices (0 = no GT placement, 1 = GT placement). By accounting for covariates, we can state if these differences are above and beyond measured confounding variables. In the initial model, bridled NGT vs. unbridled NGT was the sole predictor. In a second model, the following three covariates were added: primary service at the time of initial placement, initial hospital length of stay and age at the time of final NGT removal.

Negative binomial regression was also used for research question four (RQ4), the outcome of number of unplanned encounters, starting at zero and advancing from there by whole numbers. For RQ4, the predictors of interest are whether or not a patient has an NGT secured with a bridle. This model was tested first. A second model was then tested with the following clinically relevant covariates added to the model: number of outpatient days during therapy, insurance status, anthropometric z-score, and age at time of initial therapy.

Research question five (RQ5) focused on predicting if children with NGTs experienced skin integrity concerns and if these differ by type of securement method (bridled NGT versus non-bridled NGT). This research question was eliminated due to the infrequency of skin integrity concerns in both groups, making regression modeling impossible to perform.

Negative binomial regression was used for the outcome of the number of radiographic exposures, starting at zero and advancing from there by whole numbers. For research question six (RQ6), the predictors of interest were whether or not a child had an NGT secured with a bridle. This model was run first. A second regression model was run using the following covariates of clinical relevance: age at initial placement, outpatient days during therapy, initial hospital length of stay and primary service at initiation of enteral nutrition therapy.

All research questions were controlled by a series of clinically relevant covariates to identify relevant third variables that might affect the relation between predictors of interest and outcomes. The covariates vary amongst research questions and are defined in detail below. Each covariate was evaluated for unique predictive contribution towards the outcome, however, despite predictive statistical significance, clinically relevant covariates remained in the models.

Table 1
Research Question Analysis Plan

	Question	**Level and unit of measurement**
Research Question 1	**Negative Binomial**	
Dependent		
RQ1D	How many times was the NGT dislodged?	Count: integers 0, 1, 2, 3, etc.
Independent		
RQ1I	Bridled NGT	Categorical: binary 1. Yes

		2. No
Covariates		
RQ1Co	Age upon initiation of NGT enteral nutrition therapy	Continuous, weeks
	Initial anthropometric z-score at time of first placement	Continuous, z-score
	Gender	Binary 1. Female 2. Male
	Primary service at time of first placement	Categorical 3. Acute care 4. Ambulatory 5. Critical care 6. NICU 7. Other
Research Question 2	**Negative Binomial**	
Dependent		
RQ2D	What is the initial hospital length of stay, in days, for children receiving enteral nutrition therapy through a NGT?	Count: integers 0, 1, 2, 3, etc.
Independent		
RQ2I	Bridled NGT	Categorical: binary 1.Yes 2.No
Covariates		
RQ2Co	Age upon initiation of NGT enteral nutrition therapy	Continuous, weeks
	Initial anthropometric z-score at time of first placement	Continuous, z-score
	Insurance Status	Categorical 1.Combination 2.Commercial 3. Medicaid
	Primary diagnosis upon initiation of enteral nutrition therapy through a NGT	Categorical 1.Cardiac 2.Congenital 3.GI/Nutrition 4.Prematurity 5.Respiratory 6.Other
Research Question 3	**Logistic Regression**	

Dependent		
RQ3D	Did the child receive a GT at the end of their NGT experience?	Categorical: binary 1. Yes 2. No
Independent		
RQ3I	Bridled NGT	Categorical: binary 1. Yes 2. No
Covariates		
RQ3Co	Age upon completion of NGT enteral nutrition therapy	Continuous, weeks
	Primary service at time of first placement	Categorical 1.Acute care 2.Ambulatory 3.Critical care 4.NICU 5.Other
	Initial hospital length of stay	Count: integers 0, 1, 2, 3, etc.
Research Question 4	**Negative Binomial**	
Dependent		
RQ4D	How many times did a child experience an unplanned medical encounter?	Count: integers 0, 1, 2, 3, etc.
Independent		
RQ4I	Bridled NGT	Categorical: binary 1.Yes 2.No
Covariates		
RQ4Co	Outpatient days during therapy	Count: integers 0, 1, 2, 3, etc.
	Age upon initiation of NGT enteral nutrition therapy	Continuous, weeks
	Initial anthropometric z-score at time of first placement	Continuous, z-score
	Insurance Status	Categorical 1. Combination 2. Commercial 3. Medicaid
Research Question 5	**Relinquished based on data results**	
Dependent		

RQ5D	Is there an episode of documented skin integrity concerns in the electronic medical record during related to the bridle and/or NGT?	Categorical: binary 1.Yes 2.No
Independent		
RQ5I	Bridled NGT	Categorical: binary 1.Yes 2. No
Research Question 6	**Negative Binomial**	
Dependent		
RQ6D	How many times was the child exposed to radiation for NGT replacement confirmation?	Count: integers 0, 1, 2, 3, etc.
Independent		
RQ6I	Bridled NGT	Categorical: binary 1.Yes 2.No
Covariates		
RQCo	Initial Age at time of first NGT placement	Continuous, weeks
	Initial hospital length of stay	Continuous, days
	Primary service at time of first placement	Categorical 1.Acute care 2.Ambulatory 3.Critical care 4.NICU 5.Other
	Outpatient days during therapy	Count, integers 0, 1, 2, 3, etc.

Human Subjects Protection

This proposal was submitted and approved the Institutional Review Board (IRB) at the primary institution of record for an expedited review based on the use of de-identified data in December of 2020. The site where the data were being collected also reviewed the proposal. IRB approval was obtained prior to the collection of any data. Throughout the study, no changes in methods of data retrieval were required and no amendments were submitted. Parental consent and patient ascent are not required for the purposes of this retrospective, correlational study design.

Summary

Chapter three provided a detailed description of the research design and methods that were used to address the 6 research questions for this study. Data extraction was explained, and statistical procedures and rationale were illustrated, for each of the six research questions. Human subject's protection was also addressed. This study compared the outcomes of bridled NGTs compared to traditional methods of taping NGTs. This study also assessed NG-relevant outcomes in children after discharge from the hospital, something no other study has done. As such, these findings make a unique contribution to the literature on management of NGTs to provide adequate nutrition in infants and toddlers. The implications of improved outcomes for children with bridled NGTs will increase the use of nasal bridles as means to bridge care of these infants to home, to work on feeding and growing with their families while reducing their length of stay in the hospital and potentially avoiding premature surgical placement of a GT. Additionally, there is a possible cost benefit to the NGT Bridle Program, with reduced length of stay and less radiation exposure that would conventionally be required with frequent NGT dislodgements. Emergency department visits for NGT dislodgements would also decline with an NGT bridle securement device in place.

CHAPTER FOUR
FINDINGS

Findings

In this chapter, results of the research study are reported. The distinct aim of this study was to determine whether nasal bridling of NGTs is superior to traditional methods to secure NGTs in children by comparing outcomes relevant to NGT placement between two groups. In this study, outcomes included hospital length of stay, number of NGT-related unplanned clinical encounters, number of X-rays related to NGT placement confirmation, insertions of GTs post NGT therapy, as well as occurrence of infections and/or skin breakdown in children with nasal bridles vs. unbridled NGTs. Additionally, total number of nasogastric tubes throughout the duration of enteral nutrition therapy were analyzed.

Descriptive and Comparative Statistics

There was a total of 755 unique children enrolled in the study with 582 children enrolled in the concurrent control group and 173 children enrolled in the experimental group. Demographic comparisons can be seen in Table 2 & 3. For each categorical variable, “n”, percent, odds ratio, and p-value is depicted in Table 2. For each continuous variable, Table 3 depicts the mean, standard deviation, minimum, median, and maximum value for each variable by group.

Table 2

Participant Characteristics: Categorical

Characteristic	Bridled NG N (%)	Unbridled NG N (%)	Total N (%)	OR (p-value)
Gender				0.61 (p=0.004)
Female	96(55.5)	251(43.1)	347(46.0)	
Male	77(44.5)	331(56.9)	408(54.0)	
Insurance Status				0.76 (p=0.105)
Commercial	70(40.5)	242(41.6)	312(41.3)	
Medicaid	79(45.7)	293(50.3)	372(49.3)	
Combo	24(13.9)	46(7.9)	70(9.3)	
Primary Service[a]				0.25 (p<0.001)
Critical Care	8(4.6)	100(17.2)	108(14.3)	
NICU	77(44.5)	411(70.6)	488(64.6)	

Acute Care	58(33.5)	42(7.2)	100(13.2)	
Ambulatory	22(12.7)	3(0.5)	25(3.3)	
Other	8(4.6)	26(4.5)	34(4.5)	
Primary Diagnosis[b]				0.62 (p=0.002)
Cardiac	11(6.4)	81(13.9)	92(12.2)	
Respiratory	12(6.9)	52(8.9)	64(8.5)	
GI/nutrition	55(31.8)	27(4.6)	82(10.9)	
Prematurity	50(28.9)	298(51.2)	348(46.1)	
Congenital anomaly	24(13.9)	73(12.5)	97(12.8)	
Other	21(12.1)	51(8.8)	72(9.5)	
Final Mode of Nutrition				2.03 (p<0.001)
GT[c]	65(37.6)	133(22.9)	198(26.2)	
Oral	108(62.4)	449(77.1)	557(73.8)	

Note. [a]Other Primary Service includes: interventional radiology, transport, at home, emergency department, operating room. [b]Other Primary Diagnoses include: hematology, oncology, infection, neurological and trauma. [c]GT, gastrostomy tube.

Table 3

Participant Characteristics: Continuous

Characteristic	Bridled NGT	Unbridled NGT	Total	
	M(SD) Range (min, median, max)	M(SD) Range (min, median, max)	M(SD) Range (min, median, max)	Cohen's d (p-value)
Age, therapy initiation (weeks)	36.45(51.15) 0.29, 15.57, 238.00	11.41(35.30) 0.00, 0.14, 273.14	17.15(40.87) 0.00, 1.29, 273.14	39.52 (<0.001)
Age, therapy completion (weeks)	46.42 (52.38) 2.86, 26.71, 276.29	19.83 (37.73) 1.14, 8.71, 284.29	25.92 (42.99) 1.14, 11.14, 284.29	41.54 (<0.001)
Weight, therapy initiation (kg)	5.75 (3.02) 2.17, 4.79, 17.00	3.24 (3.26) 0.43, 2.28, 26.50	3.81 (3.38) 0.43, 2.84, 26.5	3.21 (<0.001)
Weight, therapy completion (kg)	6.94 (3.01) 2.46, 6.30, 17.20	4.39 (3.23) 1.04, 3.40, 28.60	4.97 (3.35) 1.04, 3.93, 28.60	3.18 (<0.001)
Anthropometric z-score	-0.46 (1.44) -3.77, -0.36, 3.25	-0.35(1.36) -6.91. -0.37, 3.96	-0.37 (1.38) -6.91, -0.37, 3.96	1.38 (0.357)
Total tube days (n)	62.88 (54.08) 4, 50, 312	45.35 (42.28) 0, 32, 375	49.37 (45.81) 0, 35, 375	45.24 (<0.001)
Length of Stay (days)	28.40 (40.34) 0, 16, 328	53.92 (52.79) 0, 37, 383	48.07 (51.32) 0, 32, 383	50.22 (<0.001)

Dislodgements (n)	0.33 (0.62) 0, 0, 3	4.73 (4.76) 0, 3, 29	3.72 (4.58) 0, 2, 29	4.20 (<0.001)
Total number of tubes (n)	2.36 (1.71) 1, 2, 10	7.99(6.27) 1, 6, 37	6.70 (6.05) 1, 5, 37	5.57 (<0.001)
Unplanned medical encounters (n)	0.19 (0.47) 0, 0, 2	0.14(0.75) 0, 0, 8	0.15 (0.69) 0, 0, 8	0.69 (0.391)
Skin integrity concerns (n)	0.01 (0.11) 0, 0, 1	0.00 (0.00) 0, 0, 0	0.00 (0.05) 0, 0, 1	0.05 (0.009)
Radiographic exposures (n)	0.20 (0.44) 0, 0, 2	1.00 (1.23) 0, 1, 14	0.82 (1.15) 0, 1, 14	1.11 (<0.001)
Outpatient days of therapy (n)	82.89 (94.19) 0.00, 53, 586	15.26 (56.07) 0, 0, 652	30.75 (72.50) 0, 0, 652	66.73 (<0.001)
Emergency department encounters (n)	0.08 (0.29) 0, 0, 2	0.09 (0.54) 0, 0, 8	0.09 (0.49) 0, 0, 8	0.49 (0.707)

Of the 173 bridled NGT children in the study, 55.5% (n=96) were female. The mean weight and age of the bridle cohort upon initiation of NGT therapy was 5.75 kg and 8.38 months, respectively. The final NGT removal mean weight and age of this cohort was 6.94 kg and 10.68 months, respectively. The mean anthropometric z-score for the bridle cohort was -0.46 at the time of therapy initiation. The average number of days with a bridled NGT in place was 63 and the cohort had an initial hospital length of stay of 28 days. The mean number of outpatient therapy days for this group was 83. On average, the children in this group experienced 0.33 tube dislodgements (range, 0-3; median 0) over the duration of their enteral nutrition therapy with a mean number of 2.36 (range 1-10; median 2) tubes per child. The group had, on average, less than one unplanned medical encounter or radiographic exposure per child. Only one child in the cohort of 173 experienced a reported skin integrity concern.

Most of the population of bridled NGT children in this study initiated their enteral nutrition support via bridled NGT in the NICU (n=77, 44.5%). The second most common service managing this population was the acute care hospitalist team (n=58, 33.5%). The most common diagnoses in the bridle population were prematurity (n=50, 28.9%) and GI/nutrition concerns (n=55, 31.8%). The insurance status of this cohort was comprised of 45.7% Medicaid (n=79).

Of the 582 unbridled NGT children in the study, 43.1% (n=251) were female. The mean weight and age of the unbridled cohort upon initiation of NGT therapy was 3.24 kg and 2.63 months, respectively. This is substantially lower than the bridled NGT cohort, likely due to the fact that bridles are customarily not placed until 36 weeks gestation, or until just prior to discharge home. The final NGT removal mean weight and age of this cohort were 4.39 kg and 4.56 months, respectively. These metrics are substantially lower than the bridled NGT cohort likely because unbridled NGTs are used primarily in the inpatient setting for children who are expected to gain oral motor skills quickly and before discharge home. The bridled NGT children are primarily managed outpatient and require additional tube days to gain sustainable oral motor skills. The average number of days with an unbridled NGT in place was 45, substantially lower than the bridle group, and the cohort had an initial hospital length of stay of 54 days, which is substantially longer than the bridled NGT group. The mean number of outpatient therapy days for this group was 15. This again, is likely because the customary model for unbridled NGTs is to remain inpatient during therapy. On average, the children in this group experienced 4.73 tube dislodgements over the duration of their enteral nutrition therapy with a mean number of 8 tubes per child. The group had, on average, less than one unplanned medical encounter and 1 radiographic exposure per patient. None of the 582 children in this cohort experienced a reported skin integrity concern.

The majority of the population of children with unbridled NGTs in this study also initiated their enteral nutrition support in the NICU (n=411, 70.6%). The second most common service managing this population was the critical care team (n=100, 17.2%). This is consistent with the teams of the hospital that utilize nutrition support to manage their critically ill children. The most common diagnoses in the unbridled NGT population were also prematurity (n=298, 51.2%), followed by cardiac (n=81, 13.9%) and congenital anomalies (n=73, 12.5%), respectively. The insurance status of this cohort was comprised of 50.3% Medicaid (n=293), also consistent with the bridled NGT group.

There were 128 children that received both unbridled NGT that was then converted, based on clinician preference, to a bridled NGT. A methodological decision was made to analyze only the bridled NGT portion of their therapy to maintain two mutually exclusive groups for analysis.

Of the 755 children in the complete data set, five children had missing z-scores because one or more anthropometric measurements were not obtained during the clinical encounter. Even though this creates missing data, we inferred that using a deletion method would only affect the standard errors of the estimates, most likely decreasing power, while unlikely to present bias in the parameters of interest. The effect of the missing z-score data is also attenuated for the generally large sample in the study (N > 500) (Enders, 2010).

Anthropometric z-score was used as a surrogate for nutritional status (Becker et al., 2015; Goldberg et al., 2018, 2019). Each z-score value was categorized into a malnutrition status as previously described in methods (z-scores < -3.0 = severe malnutrition, z-scores ≤ -2 = moderate malnutrition, z-scores ≤ -1.0 = mild malnutrition and z-scores >-1.0 = not at risk for malnutrition). Based on these categories, 4.09% (n=7/171) of children with bridled NGTs were severely malnourished at the time of initiation of enteral nutrition therapy, compared to 2.25% (n=13/579) of children with unbridled NGTs. The majority of both cohorts were not found to be at risk for malnutrition at the time of enteral nutrition therapy initiation (66.67% bridled NGT, 69.94% unbridled NGT).

Three of the outcome variables were analyzed by securement group per 100 days. Children in the bridled NGT group had a collective total of 10,878 days with a tube. Children with unbridled NGTs had a total of 26,395 tube days. Children with bridled NGTs exhibited 0.52 dislodgements per 100 days compared to children with unbridled NGTs who exhibited 10.43 dislodgements per 100 days. The number of unplanned clinical encounters per 100 days for children with bridled NGTs and unbridled NGTs was the same (0.30 per 100 days). Finally, the number of ED visits per 100 days by group was 0.12 ED visits per 100 days in children with bridled NGTs and 0.20 visits per 100 days in the children with unbridled NGTs.

Negative Binomial Regression Models

Dislodgements

A negative binomial regression analysis was used to test for associations between type of NGT securement method (bridled vs. unbridled method) and the outcome variable of number of dislodgements per child. Initially, securement type was the only predictor entered into the model. For this analysis, we rejected the null hypothesis that bridled, and non-bridled groups had equal numbers of dislodgements (X^2 (1) =279.39, p <0.001). Children with a bridled NGT were 14.3 times less likely to have one more dislodgement than an unbridled NGT child (OR=0.07, 95% CI = 0.05, 1.00). The bridled NGT group demonstrated a mean of 0.33 dislodgements (95% CI 0.24-0.44) and the unbridled NGT group demonstrated a mean of 4.73 dislodgements (95% CI 4.33-5.17).

In a secondary analysis, additional predictors were added into the model. For this model we rejected the null hypothesis that bridled, and non-bridled groups had equal numbers of dislodgements (X^2 (1) =232.04, p <0.001) when controlling for anthropometric z-score (OR =1.00, p=0.927), age at initial placement (OR=1.00, p=0.962), gender (OR_{female}=1.01, p=0.940) and primary service at time of initial placement ($OR_{acute\ care}$=1.06, p=0.817; $OR_{ambulatory}$= 1.49, p=0.359; $OR_{critical\ care}$= 0.39, p<0.001; OR_{NICU}=1.13, p=0.570) compared to children classified as being cared for by ‘other’ primary services. Children with a bridled NGT were 16.67 times less likely to have one more dislodgement than an unbridled NGT child (OR=0.06, 95% CI 0.04, 0.09). Children cared for under the critical care service were 2.56 times less likely to experience one more dislodgement than those cared for under other services including emergency department, transport, at home or in the operating room. The bridled NGT group demonstrated a mean of 0.28 dislodgements, 95% CI [0.20, 0.38] and the unbridled NGT group demonstrated a mean of 4.39 dislodgements, 95% CI [3.58, 5.38] when controlling for the aforementioned predictors in the model (Table 4).

Table 4

Negative Binomial Regression Model: Tube Dislodgements

Dependent variable: number of NGT dislodgements per child (N=750)					
Covariate		Coefficient (β)	SE	p-value	OR(95% CI)
Intercept		1.55	0.21	<0.001	4.72 [3.10, 7.21]
Bridle		-2.77	0.18	<0.001	0.06 [0.04, 0.09]
Primary service[a]					
	Acute care	0.62	0.27	0.817	1.06 [0.63, 1.81]
	Ambulatory	0.40	0.43	0.359	1.49 [0.64, 3.45)]
	Critical Care	-0.95	0.25	<0.001	0.39 [0.24, 0.63]
	NICU	0.12	0.22	0.570	1.13 [0.74, 1.73]
Gender[b]		0.01	0.09	0.940	1.01 [0.84, 1.20]
Anthropometric z-score[c]		0.00	0.03	0.927	1.00 [0.93, 1.07]
Age[d]		-7.19	0.00	0.962	1.00 [1.00, 1.00]

Goodness-of-fit $X^2(10) = 399.80$, $p<0.001$

Note. Outcome of testing association between numbers of NGT dislodgements based on securement method when controlling for primary service, gender, anthropometric z-score, and age. [a]Primary service is compared to other (interventional radiology, transport, at home, emergency department, operating room). [b]Gender is for females compared to males.

[c]Anthropometric z-score was recorded upon initiation of NGT therapy. [d]Age, in weeks, at the time of NGT therapy initiation.

Initial Hospital Length of Stay

A negative binomial regression analysis was used to test for associations between type of NGT securement method (bridled vs. unbridled method) and the outcome variable of initial days in the hospital per child. Initially, securement type was the only predictor entered into the model. We rejected the null hypothesis that bridled, and non-bridled groups had equal numbers of days for initial hospital length of stay (X^2 (1) =53.14, $p<0.001$). Children with a bridled NGT are 1.90 times less likely to have one more day in the hospital than an unbridled NGT child. (OR=0.53, 95% CI 0.44, 0.63). The bridled NGT group demonstrated a mean initial hospital length of stay of 28.40 days (95% CI 24.40, 33.05) and the unbridled NGT group had a mean hospital length of stay of 53.92 days (95% CI 49.67, 58.52).

Additional predictors were added into the model for a secondary analysis. This model also rejected the null hypothesis that bridled, and non-bridled groups had equal numbers of days for initial hospital length of stay (X^2 (1) =20.79, $p<0.001$) when controlling for anthropometric z-score (OR=1.06, p=0.042), age at initial placement (OR=1.00, p=0.182) primary diagnosis ($OR_{cardiac}$=2.20 p<0.001; $OR_{congenital}$=1.63, p=0.004; $OR_{GI/nutrition}$=0.44, p<0.001; $OR_{prematurity}$=1.80, p<0.001; OR_{other}=1.10, p=0.583) compared to respiratory diagnosis and when controlling for insurance status ($OR_{combination}$=0.90, p=0.423; $OR_{commercial}$=0.85, p=0.053) compared to Medicaid. Children with a bridled NGT are 1.54 times less likely to have one more day in the hospital than an unbridled NGT child when all predictors remained in the model [OR=0.65, 95% CI 0.54, 0.78]. Children with a primary cardiac diagnosis are 2.2 times more likely to have one more additional day in their hospital length of stay than children with a primary respiratory diagnosis (Table 5). The bridled NGT group demonstrated a mean initial hospital length of stay of 25.44 days (95% CI 24.19, 39.72) and the unbridled NGT group had a mean hospital length of stay of 39.31 days (95% CI 34.81, 44.38) when controlling for the previously described co-variates in the model.

Table 5

Negative Binomial Regression Model: Inpatient Length of Stay

Dependent variable: number of days spent in the hospital per child (N=749)					
Covariate		Coefficient (β)	SE	p-value	OR(95% CI)
Intercept		3.62	0.13	<0.001	37.16 [28.63, 48.23]
Bridle		-0.44	0.10	<0.001	0.65 [0.54, 0.78]
Primary diagnosis[a]					
	Cardiac	0.79	0.17	<0.001	2.20 [1.59, 3.07]
	Congenital	0.49	0.17	0.004	1.63 [1.18, 2.27]
	GI/nutrition	-0.83	0.18	<0.001	0.44 [0.31, 0.62]
	Prematurity	0.59	0.14	<0.001	1.80 [1.36, 2.39]
	Other[b]	0.99	0.18	0.583	1.10 [0.78, 1.58]
Insurance status[c]					
	Combination	-0.11	0.13	0.423	0.90 [0.69, 1.17]
	Commercial	-0.16	0.08	0.053	0.85 [0.73, 1.00]
Anthropometric z-score[d]		0.05	0.03	0.042	1.06 [1.00, 1.11]
Age[e]		-0.00	0.00	0.182	1.00 [1.00, 1.00]

Goodness-of-fit $X^2(10)$ =180.29 (p=<0.001)

Note. Outcome of testing association between numbers of days in hospital upon therapy initiation based on securement method when controlling for primary diagnosis, insurance status, anthropometric z-score and age. [a]Primary diagnosis is compared to respiratory disease. [b]Other diagnoses include: hematology, oncology, infection, neurological and trauma. [c]Insurance type is compared to Medicaid. [d]Anthropometric z-score was recorded upon initiation of NGT therapy [e]Age, in weeks, at the time of NGT therapy initiation.

Unplanned Medical Encounters

A negative binomial regression analysis was used to test for associations between type of NGT securement method (bridled vs. unbridled method) and the outcome variable of total number of unplanned medical encounters. Unplanned medical encounters included emergency department visits, unplanned GI clinic visits and readmissions associated with the NGT. Initially, securement type was the only predictor entered into the model. We fail to reject the null hypothesis that bridled and non-bridled groups had equal numbers of unplanned medical encounters (X^2 (1) =1.98, p=0.159). Children with a bridled NGT are 1.37 times more likely to have one more unplanned medical encounter than an unbridled NGT child (OR=1.37, 95% CI 0.88, 2.13). The bridled NGT group demonstrated a mean of 0.19 unplanned medical encounters during therapy, 95% CI [0.13, 0.28] and the unbridled NGT group had a mean of 0.17 unplanned medical encounters, 95% CI, [0.11, 0.18].

Additional predictors were added into the model for a secondary analysis. This model also failed to reject the null hypothesis that bridled and non-bridled groups had equal numbers of unplanned medical encounters (X^2 (1) =2.20, p=0.138) when controlling for all covariates including: anthropometric z-score (OR=0.86, p=0.070), outpatient days (OR=1.01, p<0.001) age at initial placement (OR=1.01, p<0.001) and insurance status ($OR_{combination}$=2.03, p=0.036; $OR_{commercial}$=1.07, p=0.783;) compared to Medicaid (Table 6). Children with a bridled NGT are 1.49 times less likely to have one more unplanned medical touch point than an unbridled NGT child (OR=0.67, 95% CI 0.40, 1.14). Both groups demonstrated a mean of zero with covariates appearing in the model at the following fixed values: Age at initial placement 17.08 weeks, anthropometric z-score -0.37 and outpatient therapy days 30.86.

Table 6

Negative Binomial Regression Model: Unplanned Medical Encounters

Dependent variable: number of unplanned medical encounters per child (N=749)				
Covariate	Coefficient (β)	SE	p-value	OR(95% CI)
Intercept	-2.99	0.22	<0.001	0.05 [0.03, 0.08]
Bridle	-0.40	0.27	0.138	0.67 [0.40, 1.14]
Insurance status[a]				
Combination	0.71	0.33	0.036	2.03 [1.05, 3.94]
Commercial	0.71	0.26	0.783	1.07 [0.65, 1.79]
Anthropometric z-score[b]	-0.15	0.08	0.070	0.86 [0.74, 1.01]
Age[c]	0.01	0.00	<0.001	1.01 [1.00, 1.01]
Outpatient days[d]	0.01	0.00	<0.001	1.01 [1.01, 1.01]

Goodness-of-fit $X^2(6)$= 156.13 (p=<0.001)

Note. Outcome of testing association between numbers of unplanned medical encounters based on securement method when controlling for insurance status, anthropometric z-score, age, and outpatient days. [a]Insurance type is compared to Medicaid. [b]Anthropometric z-score was recorded upon initiation of NGT therapy [c]Age, in weeks, at the time of NGT therapy initiation. [d]Outpatient days are number of days of therapy spent outside of the hospital during treatment.

Next, a negative binomial regression model was run by separating out emergency department visits from total number of unplanned medical encounters and testing this count integer in the model, as visit types are the most clinically significant relative to cost, exposure and resource intensity. This model rejected the null hypothesis that bridled, and non-bridled groups had equal numbers of emergency department encounters (X^2 (2) = 61.27, p<0.001) when controlling for number of outpatient days (OR=1.01, p<0.001). Children with a bridled NGT are 2.5 times less likely to have one more emergency department encounter than an unbridled NGT child when number of outpatient therapy days remained in the model (Table 7). The bridled NG group demonstrated a mean of 0.03 ED visits, 95% CI, [0.02, 0.06] and the unbridled NGT group had a mean of 0.08 ED visits, 95% CI [0.06, 0.11].

Table 7

Negative Binomial Regression Model: Emergency Department Encounters

Dependent variable: number of emergency department visits per child (N=755)				
Covariate	Coefficient (β)	SE	p-value	OR(95% CI)
Intercept	-2.83	0.17	<0.001	0.06 [0.04, 0.08]
Bridle	-0.92	0.37	0.013	0.40 [0.19, 0.82]
Outpatient days[a]	0.01	0.00	<0.001	1.01 [1.01, 1.01]

Goodness-of-fit $X^2(2)$= 61.27 (p=<0.001)

Note. Outcome of testing association between numbers of emergency department encounters based on securement method when controlling for number of outpatient days. [a]Outpatient days are number of days of therapy spent outside of the hospital during treatment.

Skin Integrity Concerns

Regression models were not run to compare skin integrity concerns between groups. The bridled NGT group had x documented skin integrity concerns and the unbridled NGT group had x documented skin integrity concerns. The incidence of these events was marginal, and therefore statistical analysis between groups was unnecessary.

Radiographic Exposure

A negative binomial regression analysis was used to test for associations between type of NGT securement method (bridled vs. unbridled method) and the outcome variable of number of X-rays performed to confirm accurate NGT placement per child. Initially, securement type was the only predictor entered into the model. We rejected the null hypothesis that bridled, and non-bridled groups had equal numbers of X-rays taken during NGT therapy (X^2 (1) =67.42, p <0.001). Children with a bridled NGT are 4.93 times less likely to have one more X-ray than an unbridled NGT child (OR=0.20, 95% CI 0.14, -0.30). The bridled NGT group had a mean of 0.2 X-rays, 95% CI [0.14, 0.29] and the unbridled NGT group demonstrated a mean of 1.0 X-rays, 95% CI [0.89, 1.12].

A second analysis was run, adding additional clinically relevant predictors into the model. This model was also rejected for the null hypothesis that bridled, and non-bridled groups had equal numbers of X-rays taken during NGT therapy (X^2 (8) =141.47, p <0.001) when controlling for age at initial placement (OR=1.01, p=0.700), initial hospital length of stay (OR=1.01, p<0.001), outpatient therapy days (OR=1.01, p<0.001) and primary service at time of initial NGT placement ($OR_{\text{acute care}}$=0.57, p=0.077; $OR_{\text{ambulatory}}$= 0.21, p=0.022; $OR_{\text{critical care}}$= 0.63, p=0.093; OR_{NICU}=0.51, p=0.008) compared to children classified as being cared for by ‘other’. Children with a bridled NGT are 4.67 times less likely to have one more X-ray than an unbridled NGT child (OR=0.21, 95% CI 0.14, 0.33). Children under the primary service of critical care were 1.6 times less likely to have one more X-ray compared to children under the care of other services. (Table 8).

The bridled NGT group had a mean of 0.19 X-rays, 95% [CI 0.12, 0.29] and the unbridled NGT group demonstrated a mean of 0.89 X-rays, 95% CI [0.65, 1.19].

Table 8

Negative Binomial Regression Model: Radiographic Exposure

Dependent variable: number of radiographic exposures related to NGT placement per child (N=755)				
Covariate	Coefficient (β)	SE	p-value	OR(95% CI)
Intercept	0.17	0.25	0.50	1.18 [0.72, 1.94]
Bridle	-1.54	0.21`	<0.001	0.21 [0.14, 0.33]
Primary service[a]				
Acute care	-0.56	0.32	0.077	0.57 [0.31, 1.06]
Ambulatory	-1.57	0.69	0.022	0.21 [0.05, 0.80]
Critical Care	-0.47	0.28	0.093	0.63 [0.36, 1.08]
NICU	-0.67	0.25	0.008	0.51 [0.31, 0.84]
Outpatient days[b]	0.00	0.00	<0.001	1.00 [1.00, 1.01]
Length of stay[c]	0.00	0.00	<0.001	1.01 [1.00, 1.01]
Age[d]	0.00	0.00	0.70	1.01 [1.00, 1.01]

Goodness-of-fit $X^2(8) = 141.47$ (p=<0.001)

Note. Outcome of testing association between numbers of x-rays taken to confirm proper NGT placement during therapy based on securement method when controlling for primary service, outpatient days, length of stay, and age. [a]Primary service is compared to other (interventional radiology, transport, at home, emergency department, operating room). [b]Outpatient days are number of days of therapy spent outside of the hospital during treatment. [c]Length of stay is the number of inpatient hospital days at the time of initial NGT placement. [d]Age, in weeks, at the time of NGT therapy initiation.

Total Number of Tubes

An additional negative binomial regression analysis was used to test for associations between type of NGT securement (bridled vs. unbridled method) and the outcome variable of total number of NGTs throughout therapy. We rejected the null hypothesis that bridled, and non-bridled groups had equal numbers of NGTs (X^2 (1) =144.71, $p<0.001$). Children with a bridled NGT are 3.36 times less likely to have one more tube than an unbridled NGT child. (OR=0.30, 95% CI 0.24, 0.36). The bridled NGT group demonstrated a mean of 2.38 tubes during therapy, 95% CI [1.99, 2.84] and the unbridled NGT group demonstrated a mean of 7.98 tubes during therapy, 95% CI [7.32, 8.70].

A second model with clinically relevant predictors was run and the null hypothesis that bridled, and non-bridled groups had equal numbers of NGTs was also rejected with a (X^2 (8) =181.74, $p<0.001$) when controlling for anthropometric z-score (OR=1.01, p=0.771), age at initial placement (OR=0.99, p=0.444), gender (OR=0.98, p=0.823). Primary service ($OR_{\text{acute care}}$=1.01, p=0.961; $OR_{\text{ambulatory}}$= 1.15, p=0.671; $OR_{\text{critical care}}$= 0.44, $p<0.001$; OR_{NICU}=1.13, p=0.539) compared to children classified as being cared for by ‘other’. In this model, children with a bridled NGT are 3.33 times less likely to have one more tube than an unbridled NGT child (OR=0.30, 95% CI 0.24, 0.38) (Table 9). The bridled NGT group demonstrated a mean of 2.10 tubes, 95% CI [1.71, 2.58] and the unbridled NGT group demonstrated a mean of 7.05 tubes, 95% CI [5.98, 8.32] when controlling for the aforementioned predictors in the model.

Table 9

Negative Binomial Regression Model: Total Tube Days

Dependent variable: number of tube days for therapy duration per child (N=750)				
Covariate	Coefficient (β)	SE	p-value	OR(95% CI)
Intercept	2.09	0.19	<0.001	8.08 [5.50, 11.87]
Bridle	-1.21	0.12	<0.001	0.30 [0.24, 0.38]
Primary service[a]				
Acute care	0.01	0.23	0.961	1.01 [0.64, 1.59]
Ambulatory	0.14	0.32	0.671	1.15 [0.61, 2.14]
Critical Care	-0.81	0.22	<0.001	0.44 [0.29, 0.69]
NICU	0.12	0.20	0.539	1.13 [0.77, 1.66]
Gender[b]	-0.18	0.08	0.823	0.98 [0.84, 1.15]
Anthropometric z-score[c]	0.01	0.03	0.771	1.01 [0.95, 1.07]
Age[d]	-0.00	0.00	0.444	0.99 [1.00, 1.00]

Goodness-of-fit $X^2(8)$= 181.74 (p=<0.001)

Note. Outcome of testing association between total numbers of NGTs throughout therapy based on securement method when controlling for primary service, anthropometric z-score, gender and age. [a]Primary service is compared to other (interventional radiology, transport, at home, emergency department, and operating room). [b]Gender is for females compared to males. [c]Anthropometric z-score was recorded upon initiation of NGT therapy. [d]Age, in weeks, at the time of NGT therapy initiation.

Binary Logistic Regression

Gastrostomy Tube Placement

A binary logistic regression analysis was performed to examine the effect of securement type on the likelihood that study participants would receive a GT. Initially, securement type was the only predictor entered into the model. Overall, the statistical significance of the model was $p<0.001$ describing how well the model predicts the likelihood of GT placement. The logistic regression model was statistically significant, $X^2(1) = 14.935$, $p<0.001$. The model's overall fit improved by 2.7% (Nagelkerke pseudo-R^2) in comparison to a model with no predictors in gastrostomy tube placement, and correctly classified 73.8% of cases overall. Measuring sensitivity of the model, 0% of children who received a GT were predicted to receive a GT. In this model, 100% of children who did not receive a GT were correctly predicted by the model not to receive a GT. The positive predictive value is zero. The negative predictive value is 73.7%. The odds of having a GT placed is 2.03 times higher when a child is bridled compared to the unbridled groups.

A binary logistic regression analysis was also performed to ascertain the effects of securement type, length of stay, age at the time of final NGT removal and primary service on the likelihood that study participants would undergo gastrostomy tube placement. The overall statistical significance of the model is $p<0.001$, namely, how well the model predicts likelihood of gastrostomy placement compared to no independent variables. The logistic regression model was statistically significant, $X^2(7) = 145.47$, $p<0.001$. The model's overall fit improved by 25.6% (Nagelkerke pseudo-R^2) in comparison to a model with no predictors in gastrostomy tube placement, and correctly classified 78.1% of cases overall. Measuring sensitivity of the model, 32.8% of children who received a GT were predicted to receive a GT. In this model, 94.3% of children who did not receive a GT were correctly predicted by the model not to receive a GT. The positive predictive value of the model is 67%. The negative predictive value is 79.7%. In this model, securement status, primary service caring for the child upon initiation of NGT therapy and length of stay significantly added to the model. The odds of requiring a GT is 2.34 times higher when a child is bridled compared to the unbridled counterparts. As LOS increases by one day, the odds of requiring a GT are 1.02 times higher. The model found that children cared for on the ambulatory service were 4.23 times more likely to require GT placement than those cared for on the ‘other’ care service. Children cared for by the acute care service were 2.24 times more likely to undergo gastrostomy placement than those cared for on the ‘other’ care service. Age at the time of final NGT removal did not contribute significantly to the model (Table 10).

Table 10

Logistic Regression Model: Gastrostomy Tube Placement

Dependent variable: gastrostomy placement (1=yes) (N=755)				
Covariate	Coefficient (β)	SE	p-value	OR(95% CI)
Bridle	0.85	0.24	<0.001	2.34 [1.47, 3.72]
Primary service[a]				
Acute care	0.80	0.50	0.102	2.24 [0.85, 5.87]
Ambulatory	1.44	0.61	0.019	4.23 [1.27. 14.04]
Critical Care	0.02	0.50	0.976	1.02 [0.38, 2.70]
NICU	-0.64	0.46	0.162	0.53 [0.22, 1.29]
Length of stay[b]	0.02	0.00	<0.001	1.02 [1.02, 1.03]
Age[c]	-0.00	0.00	0.578	1.00 [0.99, 1.00]

Goodness-of-fit X^2 (7) =145.47 ($p<0.001$)

Note. Outcome of predicting GT placement based on securement method when controlling for primary service, length of stay and age. [a]Primary service is compared to other (interventional radiology, transport, at home, emergency department, and operating room). [b]Length of stay is number of hospital days at the time of therapy initiation. [c]Age, in weeks, at the time of final removal of NGT.

Summary

In summary, there were several statistically significant differences in outcomes for children with bridled NGTs and children with unbridled NGTs in this cohort of 755 infants and children. Negative binomial regression models validated the hypotheses that bridled NGT children experienced a statistically significant lower number of dislodgements, total NGTs, radiographic exposures and emergency department visits compared to children with unbridled NGTs. Bridled NGT children had 5 fewer tubes and were more than 4 times less likely to receive one more x-ray during therapy than the children with an unbridled NGT. The initial hospital LOS for a child with a bridled NGTs was 26 days shorter than a child with an unbridled tube without controlling for clinically relevant predictors, and 14 days shorter when controlling collectively for anthropometric z-score, age at the time of initial NGT placement, insurance status and primary diagnosis. Binary logistic regression models predicting the occurrence of GT placement in this cohort found bridled NGT children 2.3 times more likely to undergo gastrostomy placement than a child with an unbridled NGT. Skin integrity concerns were not prevalent in either group throughout the course of NGT therapy.

CHAPTER FIVE
CONCLUSIONS, DISCUSSION & FUTURE CONSIDERATIONS

Chapter four described the negative binomial and binary logistic regression modeling used to analyze the results of the study. Several covariates were found to be predictive for the outcomes of interest. This chapter will summarize the findings, present a discussion on the topic of bridled NGTs in children and suggest areas for future research.

Summary of Findings

In summary, the largest percentage of children in both the bridled NGT group and the concurrent control group initiated their enteral nutrition therapy in the NICU (44.5%, 70.6%, respectively). Additionally, a common primary diagnosis in both groups was prematurity (28.9% bridled NGT, 51.2% unbridled NGT). The payer mix was roughly half Medicaid for both groups (45.7% bridled NGT, 50.3% unbridled NGT). Children with bridled NGTs exhibited a longer total number of tube days for enteral nutrition therapy (M= 62.88, SD = 54.08) compared to the concurrent controls of children with unbridled NGTs (M=45.35, SD=42.28). Children with bridled NGTs had substantially fewer dislodgements (M=0.33, SD=0.62) and total number of tubes (M=2.36, SD=1.71) compared to the concurrent controls with unbridled NGTs ($M_{\text{dislodgements}}$=4.73, SD=4.76 & $M_{\text{total number of tubes}}$=7.99, SD=6.27), respectively. Children with unbridled NGTs experienced more X-rays (M=1.00, SD=1.23) than their bridled NGT counterparts (M=0.20, SD= 0.44). Due to the shorter length of stay in the children with bridled NGTs, the mean number of outpatient days of therapy was longer (M=82.89, SD=94.19) than the concurrent controls with unbridled NGTs (M=15.26, SD=56.07). Overall, the mean number of emergency department visits was low in both the bridled NGT and unbridled NGT cohorts (M=0.08, M=0.09), respectively.

Conclusions

While the two groups of children with NGTs in this study had similar demographic characteristics, they differed significantly in post discharge outcomes. The conclusions of the study are presented below for each hypothesis.

Dislodgements

Children with bridled NGTs had a significantly lower number of tube dislodgements compared to children with unbridled NGTs during a course of enteral nutrition therapy. Those with bridled NGTs were 16.67 times less likely to experience one more dislodgement than their unbridled NGT counterparts when tested in a negative binomial regression model controlling for primary clinical service, gender, anthropometric z-score, and age upon initiation of therapy. The covariates that were statistically significant in the model were a bridle and critical care service (Table 4).

Hospital Length of Stay

Children with bridled NGTs were found to have a significantly lower number of initial hospital length of stay days compared to the unbridled NGT group. Children with a bridled NGT were 1.54 times less likely to have an additional day in the hospital during the initiation of their enteral nutrition therapy when tested in a negative binomial regression model controlling for primary diagnosis, insurance status, anthropometric z-score and age upon initiation of NGT therapy. The predictors in the model that were significant were securement type, primary diagnosis, and anthropometric z-score (Table 5).

Unplanned Clinical Encounters

The hypothesis that there would be a lower number of NGT-related unplanned clinical encounters (readmissions, unplanned clinic visits and emergency department visits) in children with bridled NGTs compared to children with unbridled NGTs was not supported (Table 6). However, in the negative binomial regression model, controlling for insurance status, anthropometric z-score, age at time of NGT therapy initiation, and number of outpatient therapy days for children with bridled NGT were 1.49 times less likely to have one more unplanned medical encounter compared to the unbridled NGT group ($p=0.138$). Only age ($p<0.001$) and number of outpatient days of therapy ($p<0.001$) were statistically significant in this model. The cohort of unbridled NGT children had a longer hospital length of stay and spent less of their time out of the hospital, therefore affecting the number of possible unplanned medical touch points post discharge. Additionally, emergency department visits are an important sub-type of unplanned clinical encounters. As such, they were separated from the aggregate variable and tested independently. When number of ED visits was tested in a negative binomial regression model, controlling for number of outpatient therapy days, the model was significant (Table 7). Bridled NGT children were 2.50 times less likely to have one more ED visit than their unbridled NGT counterparts. Figures 7 & 8 depict the data over time by 6-month increments by percentage. The percentage of children with bridled NGTs that experience an emergency department visit exponentially declined every six-month time-period since the inception of the enteral feeding program.

Skin Integrity Concerns

The hypothesis of skin integrity concerns not being higher in the bridled NGT group was not tested because there was only one documented skin integrity concern reported in the data in the bridled NGT group and none in the unbridled NGT group.

Radiographic Exposure

Children with bridled NGTs experienced less radiation exposure than their unbridled counterparts. Negative binomial regression modeling was used to analyze if there was an association between number of x-rays taken to confirm accurate NGT placement during therapy based on the type of securement method when controlling for primary service at the time of initial NGT insertion, outpatient therapy days, initial hospital length of stay, and age at the time of therapy initiation (Table 8). Children with bridled NGTs were found to be 4.76 times less likely to have one more x-ray than their unbridled NGT counterparts. The model was significant for the following predictors: Ambulatory primary service compared to other (OR=0.21, p=0.022), NICU primary service compared to other (OR=0.51, p=0.008), outpatient therapy days (OR= 1.01, p<0.001), and initial inpatient hospital length of stay (OR=1.01, p<0.001).

Total Number of Tubes

An additional analysis was conducted to test the association between total number of NGTs throughout enteral nutrition therapy based on securement method when controlling for primary service, anthropometric z-score, gender, and age, in weeks, at the time of NGT therapy initiation (Table 9). Bridled NGT children were found to be 3.33 times less likely to have one more additional tube than the unbridled control group. Being cared for by the critical care service resulted in a child being 2.27 times less likely to have an additional tube compared to those cared for in the ‘other’ service category.

Gastrostomy Tube Placement

The data demonstrated a lower number in GTs in the unbridled population compared to the children with bridled NGTs. Children with bridled NGTs were 2.3 times more likely to undergo gastrostomy placement than children with unbridled NGTs when controlling for initial hospital length of stay, primary service, and age (Table 10). In this model, securement type (bridle) was significant in the model (OR=2.34, p<0.001), as was length of stay (OR 1.02, p<0.001) and primary service of ambulatory setting compared to other service lines (OR=4.23, p=0.019). Age and other primary care service lines were not significant in this logistic regression model.

Discussion

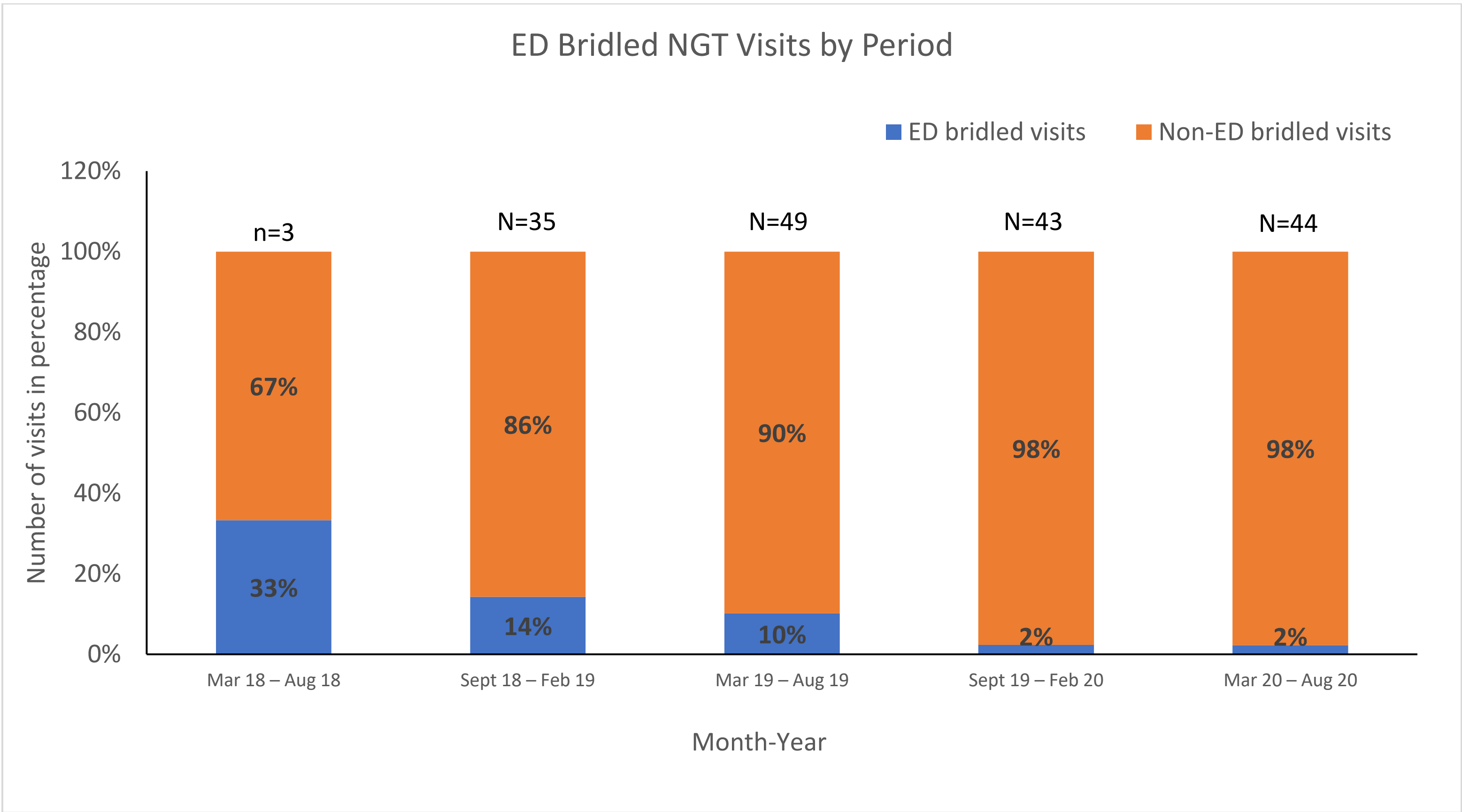
The data obtained in the present study suggests that the use of bridled NGTs in infants and children up to age five years is safe and effective. This study offers a new perspective on bridled NGTs in the pediatric population and is the largest study to date. Bridled NGTs in this population were found to be effective at minimizing the number of NGT dislodgements and total number of tubes in this population. The length of stay for children with bridled NGTs was significantly less than children with unbridled NGTs. Skin integrity concerns were noncontributory in either group and therefore did not require analysis. Number of x-rays were significantly less in the children with bridled NGTs as well, resulting in significantly lower levels of radiation exposure. This in turn should reduce expenses associated with replacement of the NGT.

The number of unplanned clinical encounters (sum of emergency department visits, unplanned GI clinic visits and readmissions) was higher in the bridled NGT group. One possible explanation for this is that the visits collected for this study were limited to enteral feeding team and gastroenterology visits. It is entirely possible additional ambulatory visits occurred and were not recorded. It should be noted that children with unbridled NGTs remained in the hospital significantly longer than their bridled NGT counterparts, reducing the number of days in which an unplanned medical encounter could occur. To address this possibility, the number of days of therapy spent outside of the hospital was noted for each child and was found to be significantly lower in the unbridled group (M=15.26 vs 82.89, respectively). Also, only unplanned GI clinic visits were counted as part of the unplanned clinical encounters.

Emergency department visits are more costly and resource intensive than an ambulatory clinic visit. These visits were isolated and run in a separate regression model to account for their difference from other types of unplanned clinical encounters. The number of ED visits per 6-month period for both children with and without bridled NGTs are presented in Figures 7 & 8, respectively. These charts depict five, six-month periods of time in which number of ED visits were tracked for children in both groups. The percent of children with bridled NGTs that had an ED encounter over time has decreased by 93.9% since March of 2018 (Figure 7).

Figure 7

Emergency Department Visits for Children with Bridled NGT

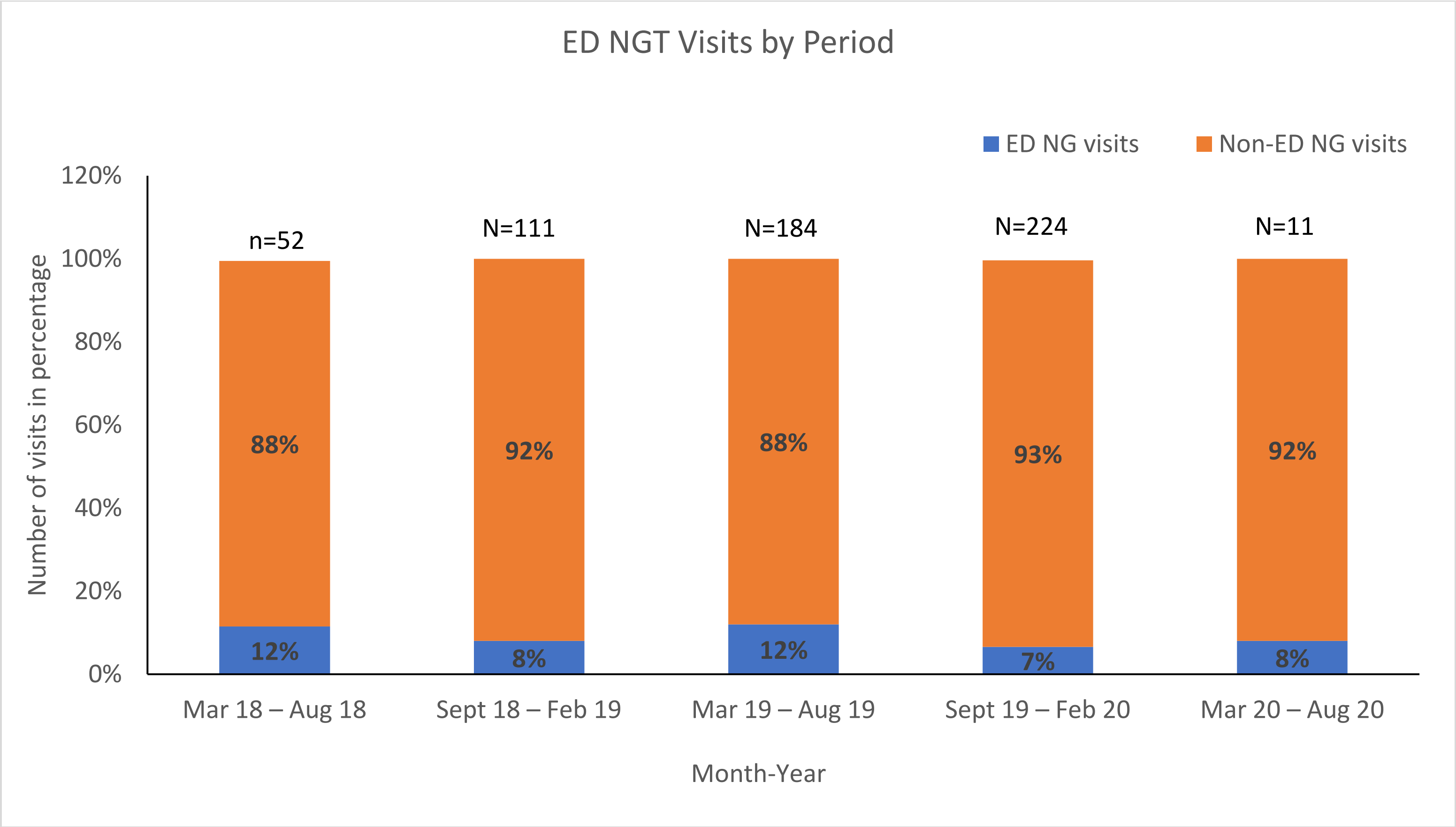


As the bridle program became fully operational and expanded throughout the medical center, families were better supported, additional providers became credentialed in the procedure and educational materials were more robust. Additionally, as the program expanded to a 24/7 on-call model, providers could access the team for questions and prevent unnecessary ED visits. Another change that occurred during this time was that clinic days expanded to five days per week instead of the previous three days per week. Children with unbridled NGTs receive care system-wide, allowing them equal access to 5-day per week ambulatory care. This also contributed to keeping families out of the ED. Families could access the enteral feeding team clinic during normal business hours, resulting in expert care at a lower cost. Although total unplanned medical encounters were not predicted to be lower in the regression model, when the variable was reduced to account only for ED visits, and the number of outpatient therapy days was added into the model, it showed that bridled children were 2.50 times less likely to have one more ED visit than an unbridled NGT child.

Conversely, the percent of children with unbridled NGTs that had an ED encounter over time has not drastically decreased (Figure 8). The percent of children with unbridled NGTs that visit the emergency department consistently ranged from 7-12% throughout the duration of the study. Children with unbridled NGTs have equal access to outpatient clinic appointments either through Gastroenterology or their primary specialty service.

Figure 8

Emergency Department Visits for Children with Unbridled NGT



One consideration for why children with bridled NGTs more often undergo gastrostomy placement is due to their clinical presentation. In this retrospective study, all patients received either a bridled or unbridled tube based on their primary care team's clinical decision. There were basic guidelines for bridling, however, the clinical team ultimately made the choice of which securement method was most appropriate for each child. Children that receive a bridled NGT are often selected for this therapy because they are identified seen as a viable candidate for achieving slow but steady progression towards oral motor skill development. Prior to the initiation of this program, many of these children would have remained in the hospital or received GTs earlier and with a higher frequency. As such, it remains standard clinical practice to discuss the possibility of a GT when the bridle is presented as an option for these families. It is impossible to know how many of these children with bridled NGTs would have had a GT placed if the bridle program did not exist. For the current cohort of 173 bridled children, 63% (N=109) went on to achieve full oral feeds and left the hospital, on average, 14 days earlier than children with unbridled NGTs when accounting for clinically relevant predictors in the model. It is also important to understand that the NGT (bridled or unbridled) has no direct association with whether a GT needs to be placed or not. This decision is made based upon the ability of the child to feed and grow without additional supplementation. The role of the bridled NGT is to provide stable enteral access during the period of time that the child is given the opportunity to achieve feeding goals. Based on our data, the children with bridled NGTs did have that opportunity but needed GTs more often than their unbridled counterparts based upon intrinsic factors such as overall development including maturity of their feeding skills.

It is known that rashes, redness, and dryness can be a common concern for infants and children using tape on their face to secure enteric tubes or oxygen tubing of any kind. In a retrospective study, it is nearly impossible to find this documented in the record. For the purposes of this study, incident reports and skin integrity documentation in the electronic health record was used to uncover these concerns. As reported, only one of the 755 children had a documented skin integrity concern. It is likely that additional children experienced less critical skin issues. It is important to recognize that these skin concerns may go undocumented or even untreated in this population. The recommendation for all bridled NGTs is to not use facial tape and therefore preserve the integrity of delicate skin. Conversely, the monofilament tube of the bridle has been known to erode through the nasal cartilage and cause significant injury as well. Consulting the Pressure Ulcer Prevention (PUP) Team upon placement of any NGT could be deployed across this institution to improve the awareness and documentation of skin integrity concerns related to NGT placement, for both bridled and unbridled tubes.

As many hospitals move towards a value-based care model and strive to provide higher quality care at a lower cost, many pediatric hospitals are seeking new strategies for providing care. Discharging patients' home with temporary feeding tubes allow children to work on oral-motor skill development in their home environment and avoid the high cost of an inpatient hospital stay. The average cost for one inpatient day in the hospital on a critical care unit is ~$10,000.00. Based on the current predictive model, children with bridled NGTs were sent home, on average, 13.87 days earlier than their unbridled NGT counterparts when controlling for primary diagnosis, insurance status, anthropometric z-score, and age at the time of enteral nutrition therapy initiation. This reduction in inpatient length of stay results in a potential savings of $138,700.00 per patient.

Limitations

There were several limitations to this study. The retrospective nature of the study design exhibits an inferior level of evidence when compared to prospective study designs. Retrospective studies are also prone to misclassification bias as the data is not reported or collected in real-time. There was no purposeful selection or randomization between groups, therefore the ability to create a homogenous demographic sample between groups was not feasible. Data abstracted from the medical record could be incomplete or incorrect. For this data set, there were 5 missing data points for anthropometric z-score. However, a large portion of the data had to be extracted manually. Automated data extraction was not efficient as several of the variables were embedded in the medical record in a way that made them difficult to procure. Additionally, multiple notes for each patient had to be reviewed to gather the precise variable that was needed. The inherent difference between the hospital record and the ambulatory record for each patient created additional complications as many of these children transitioned across care venues multiple times throughout their enteral nutrition therapy. As a result, data validation and cleaning took four months longer than expected. The difficulty of automated data extraction is not unique to this study and is something many academic medical centers must manage when pulling data from medical records. Big Data offers a nearly infinite number of variables to the researcher, however, drilling down on unique data variables and efficiently extracting them is difficult and often requires the expertise of a senior data analyst familiar with code. Frequently, data analysts do not possess the clinical acumen required to differentiate between specific variables. A clinician / analyst dyad contributed to the eventual success of both automated and manual data extraction.

For the purposes of this study, the only unplanned clinical encounters that were tracked were ambulatory clinic visits to the enteral feeding program and

Gastroenterology, ED visits, and readmissions related to the tube. It is possible that children followed-up in additional ambulatory clinics for NGT-related concerns and this was not tracked. Additionally, it is feasible that readmissions or ED visits were coded for something other than NGT concerns, when indeed the NGT was manipulated or changed. Finally, it is also possible that patients sought out care at other facilities that were not available in the electronic medical record. These data elements were then also unavailable to the researcher.

Another limitation of this study is that 128 children experienced both an unbridled NGT and a bridled NGT during their enteral nutrition therapy. For each of these children, only the bridled NGT portion of their care was entered into the final data set. Classifying the children that experienced both types of securement methods as only bridle therapy for their entire episode would introduce confounding variables amongst that group. It is a limitation that the length of therapy is the time that they had a specific type of therapy with a bridled NGT OR without bridled NGT and not the length of the entire treatment. To analyze this properly a separate analysis that accounts for the dependence of different treatments within the same subject, such as a multilevel analysis, would be required. That type of analysis is outside of the scope of this project. That said, it is rare that a bridle and NGT are initiated on the same day. It is routine practice at this center to place an NGT in the hospital and to place a bridle just prior to discharge in children that have been clinically identified as appropriate bridle candidates. Therefore, nearly every bridle patient was an unbridled patient at some point during their episode of enteral nutrition therapy.

Suggestions for Future Research

The opportunities for further research on the use of pediatric bridles is substantial. In preparing the data for the purposes of this dissertation, several new research questions emerged. The algorithm depicting the number of excluded tubes and children for this study offers an excellent sample for future studies (Figure 6).

At the institution where this study was conducted, the bridle program has expanded and made several advancements in both tube type and patient characteristics for which bridles are being utilized. Nava catheters are used in the intensive care unit as a mechanism of sensitive mechanical ventilation. The Nava catheter is dual purpose and can simultaneously be used for enteral feeding. Several Nava catheters have been bridled at this institution to secure the tube. Evaluating the effectiveness of Nava catheter securement using bridles would be a novel research endeavor. Additionally, Salem Sump and Anderson tubes are often used in the operating room to maintain patency of the GI tract after a trauma. At this single institution, bridles are now routinely used in the operating room to secure these tubes. Surgeons anecdotally report bridles to be an effective securement method in the trauma population. Children often wake post anesthesia from their trauma incident and try to pull out their tube. Bridles offer a way to safely maintain tube securement. Investigating the use of bridles to secure these tube types would expand upon the current use of bridles in this institution. In the current study, children with bridled NGTs used them solely to maintain an enteral feeding tube. The tubes described above are dual-purpose, as they maintain surgical repair or provide ventilatory support, as well as provide a modality for enteral nutrition. The securement of these tubes is perhaps more critical than tubes used only for the provision of enteral nutrition. Investigating the practice of bridle utilization on Nava, Salem Sump and Anderson tubes may uncover additional uses for bridles. Assessing the health care costs associated with dislodgement of these tube types and the critical risk to the patient may add efficacy to the importance of properly securing these tubes.

Nasojejunal tubes are also frequently bridled at this institution but were excluded from this study. However, additional research may indicate the effectiveness of bridles maintaining nasojejunal securement. Nasojejunal tubes are often required in complex children that experience prolonged feeding intolerance. It would be interesting to study the nutritional status of children with bridled NJ tubes vs. unbridled NJ tubes. Children with NJ tubes are often experiencing significant feeding intolerance and often present with vomiting and a history of malnutrition. NJ tubes are more expensive and require a specialized technique for accurate placement. Outcome measures of dislodgements, number of tubes, radiographic exposure, and length of stay outcomes could be duplicated for this population. Each time a NJ tube is dislodged at home, a child must come into the hospital's interventional radiology department to have it replaced, increasing the healthcare burden. Performing a cost-analysis and resource utilization study on this population would also contribute to the literature in this area.

For the purposes of this study, there were 128 children who received unbridled NGT securement prior to switching to a bridled NGT. To maintain mutual exclusivity between groups, those tubes were eliminated from this study. It would be interesting to conduct a direct comparison on that cohort of 128 children who received both types of therapy and analyze the outcomes addressed in this study including number of dislodgements, number of tubes before bridle vs. after bridle.

Looking at this population through the lens of a qualitative study would contribute novel perspective to this area of research. Assessing child / family satisfaction scores for those participating in the NGT bridle program may help providers and organizations understand how to improve the care of children with bridled NGTs. A survey assessing family comfort level with care of bridles in the home would also be interesting and contribute to improved patient and family outcomes.

A prospective study detailing the nutrition progress of children with bridled NGTs in the home setting would enrich the body of literature contributing to the nutritional management of at-risk pediatric children.

Finally, expanding the use of pediatric bridles and partnering with other pediatric academic medical centers would broaden the generalizability of this research. Studying the effectiveness of bridles in securing enteric tubes across centers would strengthen the external validity / generalizability of this area of research. Several programs have reached out since the publication of this institution's first manuscript inquiring about starting a pediatric bridle program. Studying the effectiveness of bridles in securing enteric tubes across centers would strengthen the research and broaden the scope of this program.

Conclusion

Based on the results from this retrospective, correlational study conducted using medical records at one tertiary academic medical center, the bridling the NGTs of pediatric patients were found to be a safe and effective method of securing NGTs. Bridling NGTs resulted in a decrease in the number of dislodgements, total number of tubes, emergency department visits and radiographic exposures. In a field in which value-based medicine is likely to become increasingly important, this medical device supports the efficacy and safety of nasogastric tube management in the pediatric population. More research needs to be conducted in a larger sample size, involving other institutions and other pediatric patient populations to continue to determine the generalizability of the findings of this study.

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