Electromagnetic Versus Blind Guidance of a Postpyloric Feeding Tube in Critically Ill Children

Prashant Jha, MD,[a,b] Lisa Rupp, RN, BSN, CCRN,[c] Lorraine Bonilla, RN,[c] Jonathan Gelfond, MD, PhD,[d] Jay N. Shah, DO, MPH,[c,e] Andrew D. Meyer, MD, MS[c,f]

abstract

BACKGROUND AND OBJECTIVES: Postpyloric feeding tube placement is a time-consuming procedure associated with multiple attempts and radiation exposure. Our objective with this study is to compare the time, attempts, and radiation exposure using the electromagnetic versus blind method to place a postpyloric feeding tube in critically ill children. Our hypothesis is that using electromagnetic guidance decreases the procedure time, number of x-rays, and number of attempts, compared to the blind method.

METHODS: Eleven pediatric nurses participated in a randomized controlled intention-to-treat study at an academic pediatric medical, surgical, and congenital cardiac ICU. University of Texas Health Epidemiology and Biostatistics generated a randomization sequence with sealed envelopes. A standard (2-sided) F-test of association between the electromagnetic and blind method yielded 40 subjects with 86% power. Data were analyzed with Fisher's exact test for categorical variables and the Wilcoxon rank test for continuous variables, with data documented as median (interquartile range [IQR]).

RESULTS: We randomly assigned 52 patients to either the electromagnetic (n = 28) or blind method (n = 24). The number of attempts and radiographs was at a median of 2 (IQR: 1–2.25) using the blind method, compared to the electromagnetic method at a median of 1 (IQR: 1.0–1.0; P = .001). Successful guidance was 96.4% with the electromagnetic method, compared to only 66.7% with the blind technique (P = .008). The total time required was 2.5 minutes (IQR: 2.0–7.25) with the electromagnetic method, compared to 19 minutes (IQR: 9.25–27.0) for the blind method (P = .001).

CONCLUSIONS: Electromagnetic guidance is a superior, faster, and overall safer method to place a postpyloric feeding tube in critically ill children.

[a]*Division of Critical Care, Department of Pediatrics, Children's Hospital of Nevada at University Medical Center, Las Vegas, Nevada;* [b]*Department of Pediatrics, University of Nevada Las Vegas School of Medicine, Las Vegas, Nevada;* [c]*Pediatric Services, University Health System, San Antonio, Texas; and* [e]*Divisions of Pediatric Gastroenterology and* [f]*Pediatric Critical Care, Department of Pediatrics and* [d]*Department of Epidemiology and Biostatistics, University of Texas Health San Antonio, San Antonio, Texas*

Drs Jha and Meyer conceptualized and designed the study and data collection instrument, drafted the initial manuscript, and reviewed and revised the manuscript for important intellectual content; Dr Shah has contributed to the conception of the study design and reviewed and revised manuscript; Dr Gelfond provided support with study design in terms of guiding through the randomization technique and statistical analysis of study results; Ms Rupp and Ms Bonilla helped with collecting the data and nursing education and training for the study and have reviewed and revised the manuscript; and all authors approved the final manuscript as submitted and agree to be accountable for all aspects of the work.

WHAT'S KNOWN ON THIS SUBJECT: Routine placement of a postpyloric feeding tube in a critically ill children using the standard blind technique is time consuming and challenging. This lengthy process can lead to a delay in the initiation of enteral nutritional support.

WHAT THIS STUDY ADDS: This is the first randomized controlled trial in pediatrics documenting that electromagnetic guidance of a postpyloric feeding tube will decrease harm by significantly decreasing radiation exposure, time, and attempts to successful placement.

To cite: Jha P, Rupp L, Bonilla L, et al. Electromagnetic Versus Blind Guidance of a Postpyloric Feeding Tube in Critically Ill Children. *Pediatrics.* 2020;146(4):e20193773

Acquired malnutrition in a PICU is common.[1–5] Up to 55% of children have acute or chronic malnutrition on admission that worsens because of critical illness–related metabolic stress, gastrointestinal dysmotility, and inaccessibility to enteral nutrition.[6] Numerous studies report that the enteral route is the most optimal to provide nutrition.[7] Although sometime necessary, the parenteral route is not optimal because of common side effects including central line infection and hepatic cholestasis.[7] For critically ill children who are medically unable to feed by mouth, a feeding tube provides enteral nutrition. Nurses place a tube through the nose into the stomach or past the pylorus into the duodenum. Postpyloric tube feeding improves feeding tolerance and nutrition by decreasing gastric residual volume, emesis, and risk of pneumonia in comparison to stomach feeding in critically ill patients.[8,9] However, traditional methods to place a postpyloric feeding tube include surgery or interventional radiology, which are expensive, time consuming, associated with radiation exposure, and have a higher risk of complications. Therefore, it is common for pediatric intensive care units to place a postpyloric feeding tube at the bedside using traditional methods, including manipulating patient position, medications to induce gastric motility, and weighted tip tubes. By using this approach, confirmation of tube placement can be inconsistent or time consuming because the methods to confirm are unreliable. These methods include the inability to aspirate air, color of aspiration fluid (ie, yellow color refers to bile), and the alkaline pH of aspiration fluid (pH $>$ 6). Therefore, postpyloric feeding tube guidance may require multiple attempts that prolong the time until successful placement.[10–12] Therefore, there is an essential need to establish new methods that will decrease the time and radiation exposure necessary to place a postpyloric feeding tube.

The CORTRAK* 2 Enteral Access System uses electromagnetic detection to provide real-time location of a metal stylet to help in placement of a postpyloric feeding tube. Previous before and after studies have documented that this visualization using the CORTRAK*2 reduced postpyloric feeding tube misguidance, time to guidance, and cost.[10] In retrospective trials, by using electromagnetic guidance of a postpyloric feeding tube, a high success rate for initial placement compared to the standard-of-care blind method was also documented.[11,12] Therefore, we designed a randomized controlled trial to define the efficacy of electromagnetic compared to traditional blind guidance. Our hypothesis is that electromagnetic guidance decreases the procedure time, number of radiographs, and number of attempts compared to the blind method. Because biomedical devices require only safety approval from the Food and Drug Administration, independent controlled trials are necessary to define their efficacy in patient outcomes.

METHODS

Study Design and Selection of Patients

A prospective, randomized controlled clinical trial was conducted in the Pediatric Medical and Surgical ICU and Pediatric Congenital Cardiac Care Unit located at University Hospital in San Antonio, TX. Avanos Medical, formerly known as Halyard Health, supported the investigators with a small grant to defray costs and supplied a CORTRAK* 2 Enteral Access System (Avanos, Alpharetta, GA). The University of Texas Health San Antonio Institutional Review Board and the University Health System approved the study design. The study team confirmed verbal consent (parental permission) with each participant before enrollment, all parents had the opportunity to decline, and an information sheet was provided to all parents. The study team requested a waiver of written consent because enteral feeding tube placement by using a blind or electromagnetic technique is routine and standard of care. Because the procedures were deemed minimal risk, obtaining written consent may cause misunderstanding, leading the parents to deny necessary care that would be regularly performed. Participants were randomly assigned to the electromagnetic (compared to blind guidance) method from February 2018 to September 2018. The inclusion criteria was a $>$37-week postgestational age, a need for postpyloric feeding tube, and being an inpatient at University Health System. The exclusion criteria were a weight $<$3 kg or patients who currently had an open surgical abdomen or open surgical chest (n = 30). Please see the Consolidated Standards of Reporting Trials (CONSORT) flow diagram for the study design in Fig 1.

Postpyloric Tube Guidance Procedures

Blind guidance of a small-bowel tube was performed, as described previously.[13] Briefly, the tube was measured from the tip of the nose or mouth to the earlobe and then a routine distance past the xiphoid process. After confirming that the tube had reached the stomach, nurses placed the patient on their right side and, using only tactile feel, carefully advanced the tube a measured distance past the pylorus. The confirmation of the placement of the postpyloric placement was a decrease in the return of a bolus of air and abdominal radiograph documenting the crossing of the midline of the patient. The US Food and Drug Administration approved CORTRAK* 2 Enteral Access System to use real-time navigation to direct the bedside

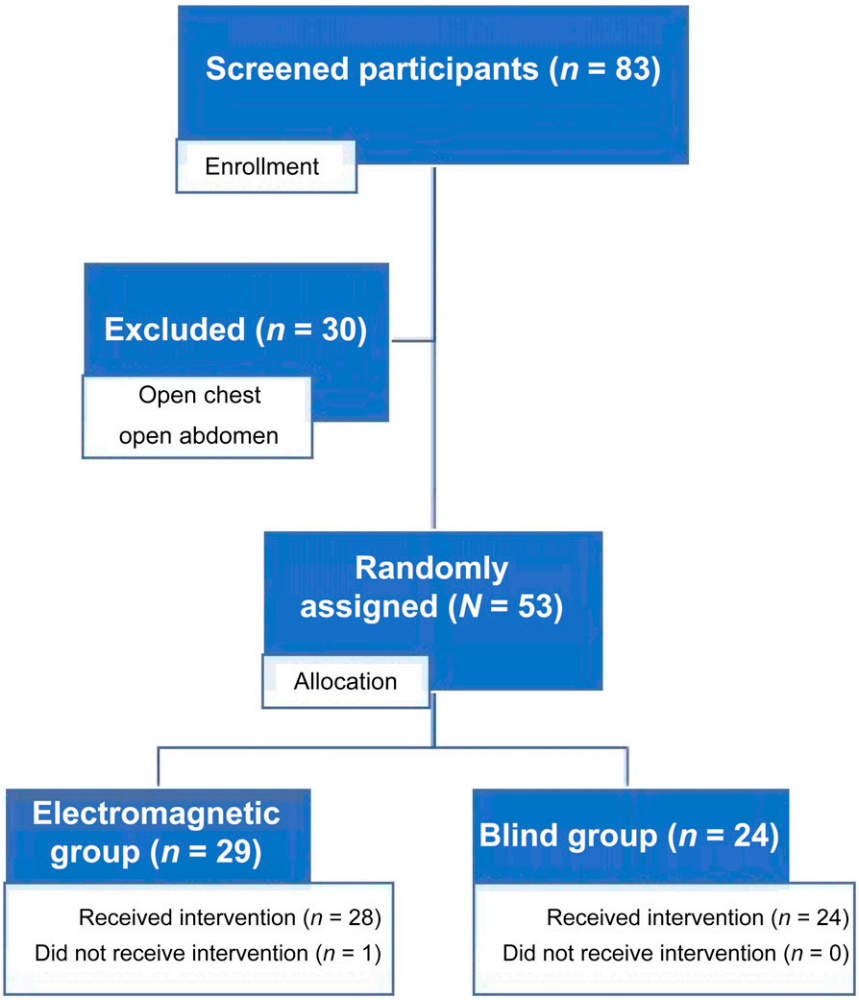

FIGURE 1
CONSORT flow diagram.

guidance of the feeding tube past the pylorus. The location of the tube is captured by an electromagnetic signal detected by the tip of the feeding tube stylet. This signal is tracked in real-time by using a receiver unit placed on the patient's xyphoid process. The CORTRAK* 2 system displays the anterior and cross-section guidance of the tube through the esophagus, stomach, and small bowel. A multidisciplinary team, which included pediatric critical care physicians, a pediatric gastroenterology physician, and 11 experienced pediatric critical care nurses conducted the trial. Initial classroom training was conducted for all study personnel by the Avanos study team. Classroom training consisted of PowerPoint presentations of the basics of functioning of the CORTRAK* 2 equipment, hands-on practice with the equipment on an artificial human gastrointestinal system model, and troubleshooting maneuvers for patients with anatomic variation of pylorus location. The training was 8 hours long in total, divided into 4 sessions, with each session being 2 hours long. After the successful completion of the classroom training, each nurse was supervised by Avanos study team for the real patient postpyloric feeding tube placement for up to 3 correct placements before being involved actively in the study and doing placements independently.

Clinical Trial Procedures

The University of Texas Health San Antonio Department of Epidemiology and Biostatistics prepared the sealed envelopes for randomization (1:1) in a locked box. The primary ICU team notified the study team of the need for a postpyloric feeding tube. A study team member picked a card from the randomization box that decided the method of postpyloric feeding tube guidance to perform. A data collection tool (Supplemental Fig 4) collected the time, attempts, and number of radiographs performed during guidance and other outcomes related to the hospital stay. For the patients who required >1 attempt for guidance, the time required for each attempt was added to calculate the total time for that guidance. The primary clinical and study team confirmed the appropriate placement for both procedures with an abdominal radiograph. The data collection tool was stored in a locked cabinet until study personnel entered the data into a Research Electronic Data Capture database. Participants were followed for the duration of their hospital stay to determine any adverse effects and the effect on clinical outcomes.

Study Outcomes

In addition to demographic information, the following variables were collected: admission diagnosis, pediatric risk of mortality (PRISM) score, weight (in kilograms), type of the tube used, total time for guidance (in minutes), time from end of guidance to radiograph arrival (in minutes), number of attempts, number of radiographs for each guidance, and time from beginning of guidance to beginning of feeding.

Statistical Analysis

Before starting the trial, investigators completed a retrospective chart review to define the incidence of postpyloric feeding tube placement at our institution. We reviewed all the

charts with all enteric feeding tube guidance identified from the nursing flowsheet for the period between August 2016 and January 2017. To determine the difference between the 2 methods we performed a power analysis on our hypothesis that electromagnetic guidance method would decrease the time to placement, number of attempts, and radiation exposure compared to the standard blind method. The standard (2-sided) F-test of association between electromagnetic and standard technique guidance would yield a power of 86%, given 40 subjects with a type I error of 0.05. We made this power calculation using PASS 2008 (NCSS, LLC, Kaysville, UT). For final data analysis after data collection, Fisher's exact test was used for categorical variables, and, for count and continuous variables, the Wilcoxon rank test was used. All statistical testing was 2-sided with a *P* value threshold of .05. Statistical analysis was conducted in R version 3 by using an accountable data analysis process. The values are counts (percent) for categorical variables and median with interquartile range (IQR) for counts (eg, number of attempts and/or radiographs) and continuous variables. Cumulative incidence curves were created for the number of attempts or providers needed to successfully place a postpyloric tube. Graphs and log-rank (Mantel-Cox) analysis were performed on Prism 8.3 (GraphPad Software, San Diego, CA).

RESULTS

Eighty-three patients were screened during the study period from February to September 2018 for the guidance of a postpyloric feeding tube. Of the 30 patients who were not eligible for the study, 12 were <3 kg, 15 were with an open chest, and 3 were with an open abdomen. Fifty-three were enrolled for the study, with 29 randomly assigned to the electromagnetic guidance group and 24 to the blind standard group. One patient was retracted from the electromagnetic group because of screen failure. After pulling the card for randomization, the 1 screen failure had worsening clinical status, requiring the primary ICU team to cancel the need for a feeding tube. Indications for the postpyloric feeding tube placement were not recorded. The electromagnetic and blind groups' participants were similar for age, weight, race, sex, and severity of illness (Table 1). Participants in each group ranged in age from 8 days to 17 years old, weighed from 3.3 to 84 kg, and had PRISM scores from 1 to 14; a majority were male (61%), and ~67% of them were of Hispanic ethnicity. More than one-third of the patients were postoperative from a congenital heart surgery (n = 18), with 1 patient having pacing wires during guidance.

Successful guidance of a postpyloric feeding tube was 96.4% using the electromagnetic method, compared to only 66.7% using the standard blind technique (P = .008). The total time required for a successful guidance was 2.5 minutes (2.0–7.25) with the electromagnetic method, compared to 19 minutes (9.25–27.0) for the standard blind approach (P = .001; Fig 2). The standard blind method needed significantly more radiographs (median of 2 [IQR: 1–2.25]) to confirm placement, compared to the electromagnetic method (median of 1 [IQR: 1–1]; P =.001). The mean time for arrival of the radiograph after guidance was 25 minutes, taking into account all the methods, both electromagnetic and standard. We did not encounter any complications during the placement of any tube or during the hospital stay. We also compared the results in terms of total mechanical ventilation days, length of stay in ICU, and total hospital days, documenting no significant difference. None of the patients received prokinetic agents to assist in placing the feeding tube postpyloric. None of the patients experienced any adverse events in terms of misplacement into respiratory tract, pneumothorax, or gastrointestinal perforation. Lastly, a comparison of cumulative incidence curves of the number of attempts and providers was completed (Fig 3).

Using the electromagnetic method, we were able to successfully place a postpyloric tube after 1 attempt at 89%, compared to 43% for the blind method (P = .0006). Moreover, using the electromagnetic method, we were able to successfully place a postpyloric tube with 1 provider at 96%, compared to 54% (P = .002).

DISCUSSION

Enteral nutrition by using a postpyloric feeding tube is a common procedure in critically ill children, with or without the need for mechanical ventilation. Several centers report that using blind approach for the guidance of postpyloric tubes is difficult and time

TABLE 1 Comparison of Demographic Characteristics and PRISM Scores Between Two Groups

Category	Electromagnetic (n = 28)	Blind (n = 24)	P
Age at tube placement, mo, median (IQR)	17.35 (5.10–59.77)	9.55 (5.00–66.05)	.818
Wt, kg, median (IQR)	9.18 (6.67–22.00)	7.75 (6.23–14.52)	.550
Race, *n* (%)			.429
Asian	2 (7.1)	0 (0.0)	
Black or African American	1 (3.6)	3 (12.5)	
Hispanic	19 (67.9)	16 (66.7)	
Not specified	0 (0.0)	1 (4.2)	
White	6 (21.4)	4 (16.7)	
Sex (male), *n* (%)	17 (60.7)	13 (54.2)	.779
PRISM score, median (IQR)	6.00 (4.00–14.00)	5.00 (1.00–13.00)	.215

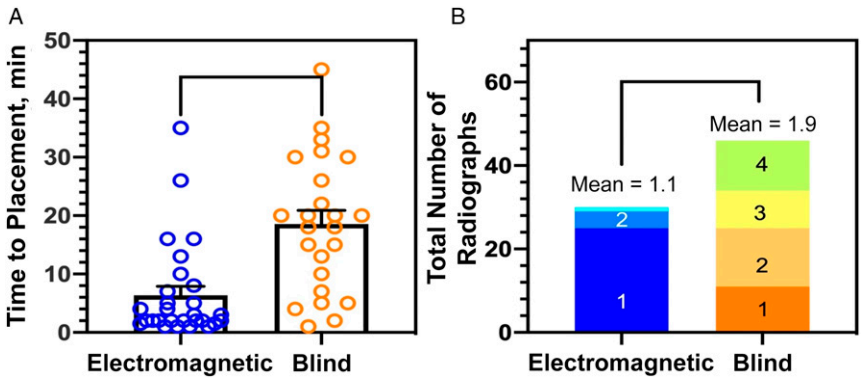

FIGURE 2

The time and number of radiographs needed to place a postpyloric tube. All data are represented as mean ± SE of mean. Electromagnetic guidance using CORTRAK® 2 Enteral Access System and blind is the routine bedside approach. A, The total time required for guidance of individuals randomly assigned to the electromagnetic group compared to the standard group. B, The number of radiographs needed to confirm guidance of the postpyloric feeding tube in the electromagnetic group compared to the standard group. The mean of the number of radiographs needed to place the tube is above each bar graph. Children who received 1, 2, 3, and 4 radiographs are represented as a stacked bar graph.

consuming.[7–9,13,14] Viana et al[13] documented, in a randomized controlled trials with adults, that electromagnetic guidance improved the chance of successful guidance and decreased the time to placement, compared to the standard blind method. Achievement of postpyloric location is based on the anatomic fact that the pylorus is located anteriorly in our gastrointestinal system. This anatomy confirms that the feeding tube is across the pylorus when a drop in the tip of the tube is visible in lateral and cross-sectional view.

Electromagnetic guidance decreased a significant amount of nursing time because the real-time feedback from the device decreased the guidance time, number of attempts, and abdominal radiographs. Powers et al[14] completed a prospective study at a quaternary referral center with >900 electromagnetic postpyloric guidance, documenting a 92% decrease in radiographic confirmation necessary for blind guidance. With our study, we confirm and extend this finding in a randomized controlled trial in children. This is impactful because placement of the feeding tube in children is difficult on the basis of their anatomy and size.

The electromagnetic group required significantly fewer radiographs to confirm placement compared to the traditional method, and this decreased the amount of radiation exposure. A case control study published by Bartley et al[15] in children <14 years revealed that diagnostic radiographs have been associated with increased childhood leukemia risk. Also, an additional radiograph adds 25 minutes' delay from guidance to radiograph arrival, which can delay enteral feeding. The mean delay in radiographic confirmation of the postpyloric guidance in Powers et al's[14] study was 78.8 minutes. Apart from radiation exposure, obtaining a chest radiograph also puts a child at a risk of potential invasive device dislodgement events because it requires moving the child to place the radiograph plate underneath.

In a previous retrospective study, researchers performed a cost analysis for electromagnetic compared to the standard approach enteral feeding tube guidance, documenting a saving of $55.46 per electromagnetic enteric tube guidance.[7] Complications associated with a blind guidance of a feeding tube can be common and life-threatening. Review of articles published from 1993 through 2012 documented misguidance of a feeding tube into the respiratory tract in 15 cases in pediatrics, with 4 deaths and 5 complications of a pneumothorax.[7] The Pennsylvania Patient Safety Advisory reviewed data on all tube malposition over a 6-year period from January 1, 2011, to December 31, 2016, documenting feeding tube misguidance into the respiratory tract for infants (age 0–11 months) as high as 1 in 15 attempts (6.6%).[16] Gilbert and Burns[17] documented that tube guidance at a single center had malposition into respiratory tract as high as 5% or 3 of 60 patients. We

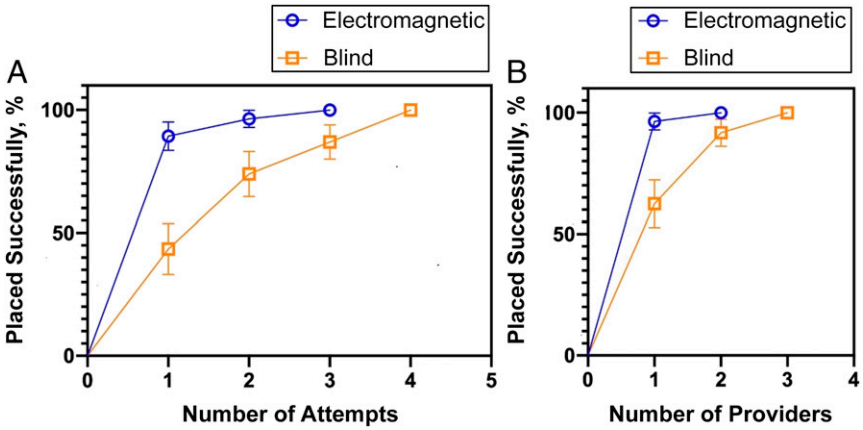

FIGURE 3

The attempts and number of personnel needed to place a postpyloric tube. A, Cumulative incidence curve of the number of attempts necessary to place a postpyloric tube. B, Cumulative incidence curve of the number of individual personnel necessary to place a postpyloric tube.

came across one study in adults in which researchers looked at adverse events from electromagnetic guidance of feeding tube placement from the Manufacturer and User Facility Device Experience database between 2013 and 2015 and reported 25 events of misplacement into respiratory tract, 17 of them resulting in pneumothorax.[18] This highlights failure of clinicians to recognize misplacement. We did not encounter any misplacement during our study, and we believe that with the real-time image feedback electromagnetic guidance can prevent misguidance into the tracheobronchial tree, eliminating this avoidable and deadly complication. The only downside we came across was nonavailability of compatible feeding tubes in sizes less than 8F. For smaller children, it was either difficult to insert through the nostrils or would have completely occluded the nostrils, which could have a negative impact on ventilation. Also, for some children requiring noninvasive ventilation, it would be difficult to insert both the 8F feeding tube and interface for noninvasive ventilation, be it a high-flow nasal cannula or a noninvasive positive pressure ventilation. This is the first randomized controlled trial designed to determine if the electromagnetic system decreased time, harm from radiation, and complications for guidance and placement of a postpyloric feeding tube.

Our study has several limitations, including it being a single center study, the use of only experienced nurses, and our inability to blind the participants to the intervention. We did not collect and compare the data regarding difference in placement outcome by individual study personnel. This creates a potential for bias due to difference in interindividual expertise, but, at the same time, all the study personnel were new to this equipment and everyone received an equal amount of training before being enrolled into the study, so the effect of the bias is possibly limited. Each of these limitations increases our potential bias, including site selection, expertise in feeding tube placement, and lack of an external control group. As the manufacturer, Avanos Medical had no participation in study design, analysis, or conclusions reached by the investigators. Moreover, in our study, we did not have enough power to determine if the method of tube guidance decreased the time to goal feeds. Despite these limitations, the electromagnetic technique was new to our nurses, and they quickly grew to appreciate the method, especially the real-time visual feedback in the guidance of the tubes. A brief survey of all the study nurses after the study completion documented increased confidence in using electromagnetic guidance compared to the standard blind guidance in placing postpyloric feeding tube.

CONCLUSIONS

Bedside electromagnetic guidance is an effective and safe method of placing a postpyloric feeding tube in critically ill children as young as 8 days and with 3.3 kg weight, compared to the traditional blind approach. Moreover, the use of an electromagnetic enteral access system can confirm proper placement past the pylorus reducing time and radiation exposure for the patient and ICU staff.

ACKNOWLEDGMENTS

We thank the group of our study nurses who voluntarily participated in the study: Lorraine Bonilla, Lisa Rupp, Kristen Phoenix, Michelle Guajardo, Shawna Velez, Kristy Mendoza, Sandra Goss, Lana Benavidez, Patricia Banner, Jennifer Davis, and Barbara Martinez.

ABBREVIATIONS

CONSORT: Consolidated Standards of Reporting Trials
IQR: interquartile range
PRISM: pediatric risk of mortality

This trial has been registered at www.clinicaltrials.gov after completing data collection (identifier NCT04241146).

The presented work was conducted at the University Health System, San Antonio, Texas, where the first author was affiliated with. The affiliation has changed since as noted.

DOI: https://doi.org/10.1542/peds.2019-3773

Accepted for publication Jul 30, 2020

Address correspondence to Prashant Jha, MD, Pediatric Critical Care Medicine, Children's Hospital of Nevada at University Medical Center and School of Medicine, University of Nevada Las Vegas, 1800 W Charleston Blvd, Las Vegas, NV 89102. E-mail: prashant.jha@umcsn.com

PEDIATRICS (ISSN Numbers: Print, 0031-4005; Online, 1098-4275).

FINANCIAL DISCLOSURE: The authors have indicated they have no financial relationships relevant to this article to disclose.

FUNDING: Avanos Medical, formerly known as Halyard Health, supported the investigators with a small grant to defray costs and supplied a CORTRAK* 2 Enteral Access System (Avanos Medical, Alpharetta, GA). There are no open access requirements.

POTENTIAL CONFLICT OF INTEREST: The authors have indicated they have no potential conflicts of interest to disclose.

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Pediatrics 2020;146;
DOI: 10.1542/peds.2019-3773 originally published online September 29, 2020;

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DOI: 10.1542/peds.2019-3773 originally published online September 29, 2020;