Successful Identification of Anatomical Markers and Placement of Feeding Tubes in Critically Ill Patients via **Camera-Assisted Technology with Real-Time Video Guidance**

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Abstract

Background: Enteral feeding via feeding tube (FT) provides essential nutrition support to critically ill patients or those who cannot intake adequate nutrition via the oral route. Unfortunately, 1%-2% of FTs placed blindly at bedside enter the airway undetected (as confirmed by x-ray), where they could result in adverse events. Misplaced FTs can cause complications including pneumothorax, vocal cord injury, bronchopleural fistula, pneumonia, and death. X-ray is typically performed to confirm FT placement before feeding, but may delay nutrition intake, may not universally identify misplacement, and adds cost and radiation exposure. Methods: A prospective case series was conducted to evaluate a novel FT with a camera to provide real-time visualization, guiding placement. The primary end point was the clinician's ability to identify anatomical markers in the gastrointestinal tract and/or airway using the camera. Results: The Kangaroo Feeding Tube with IRIS Technology tube was placed in 45 subjects with 1 misplaced tube; 3 placements were postpyloric, with the remainder gastric. Clinicians correctly identified the stomach in 44 of 45 placements at a median depth of 60.0 cm (range 45.0–85.0 cm). A stomach image was obtained in 42 subjects (93.3%). Agreement between camera image and radiographic confirmation of placement was 93% (P = .014) with small deviations in recognizing stomach vs small bowel. No device-related adverse events occurred. Conclusions: Direct visualization of the stomach using a camera-equipped FT can assist with FT placement, help avoid misplacements, and with further studies to evaluate the safety of eliminating confirmatory x-ray before feeding, could potentially preclude the need for radiographic confirmation. (JPEN J Parenter Enteral Nutr. 2019;43:118-

Keywords

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critical care; enteral access; enteral feeding; enteral nutrition; feeding tube; malnutrition; postpyloric; safety

Clinical Relevancy Statement

Use and placement of enteral feeding tubes (FTs) are essential to provide nutrition support to patients in the intensive care unit and other hospital settings. Unfortunately, 1%-2% of FTs placed blindly at the bedside are found on x-ray confirmation to have entered the airway undetected. These FT misplacements have been shown to result in serious complications including pneumothorax, vocal cord injury, bronchopleural fistula, and death. Inadvertent insertion of FTs into the tracheopulmonary system during placement is not predictable from clinical signs and auscultation in highrisk patients with the following associated factors: altered mental status, preexisting endotracheal tube, critical illness,

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older adults, and abdominal distention. In the high-risk patient, alternatives to blind FT insertion are needed to improve patient safety. This study examined the role of a novel enteral FT with a camera to assist with safe FT placement. The results of this study suggest that use of an FT with a camera can assist with FT placement via direct visualization of the stomach, may allow for improved safety and ease of FT placement, and may help avoid misplacements.

Introduction

Enteral nutrition (EN) provides nutrition support to critically ill patients or those who cannot intake food via the oral route. Proactive nutrition therapy attenuates the metabolic response to stress, prevents oxidative cellular injury, and favorably modulates immune responses in the critically ill patient.¹ Conversely, malnutrition is associated with poor outcomes in patients in the intensive care unit (ICU) and in those recovering from surgery.^{2,3} Delivering early nutrition via the enteral route is thereby seen as a proactive therapeutic strategy that may reduce disease severity, diminish complications, decrease length of ICU stay, and improve patient outcomes.⁴⁻⁶ Current Society of Critical Care Medicine and American Society for Parenteral and Enteral Nutrition guidelines recommend that EN be initiated within 24-48 hours in a critically ill patient who is unable to maintain volitional nutrition intake.¹

Accurate feeding tube (FT) placement is essential to optimize delivery of EN and prevent adverse outcomes. Tube misplacement can lead to the distal tip lying in the esophagus, trachea, or bronchial tree. Risks of tube misplacement include pneumothorax, vocal cord injury (nasogastric tube syndrome), bronchopleural fistula, aspiration pneumonia, perforation of the membranous trachea or pleural parenchyma, hydrothorax, mediastinitis atelectasis, plural effusions, and death.7 Inadvertent insertion of enteral FTs into the tracheopulmonary system during placement is not predictable from clinical signs and auscultation in highrisk patients with the following associated factors: altered mental status, preexisting endotracheal tube, critical illness, older adults, and abdominal distention.⁸ In the high-risk patient, alternatives to blind FT insertion are needed to improve patient safety.

Clinicians are routinely confronted with challenges when inserting and placing enteral FTs, especially in unconscious patients or those with impaired cognition who cannot assist in passage of the tube. Between 1% and 2% of smallbore FTs placed blindly at the bedside enter the airway undetected, and a proportion of these misplacements result in pulmonary injury that is not preventable and may remain undetected, even after confirmatory radiograph.⁹ Given that approximately 1.2 million small-bore FTs are placed annually in the United States alone, a substantial number of 119

misplacements are known to occur.¹⁰ Studies have estimated that mortality rate from tracheobronchial malpositioning is >20%.¹¹ Taken together, these statistics suggest that blindly placed FTs could cause 3600–8400 pulmonary injuries and 1200–3600 deaths in the United States annually.

Mechanically ventilated patients are at increased risk for having a nasogastric tube misplaced because of reduced consciousness and weakened cough reflex.¹² Because enteral FTs are commonly inserted at the bedside and are associated with the aforementioned risks (including patient discomfort), many methods have been developed to increase firstattempt success of FT placement. These range from patient positioning to tactile methods, and several techniques are currently available to confirm that the distal tip of the tube is in the correct position. This includes an increasing number of ICU patients being sent to interventional radiology for FT placement, which adds significant cost and the risk of transporting a critically ill patient. Blind bedside placement methods use techniques such as auscultation, aspiration of gastric contents, measurement of pH in aspirate, and capnometry to assist in placement.¹² Aspiration of gastric contents, auscultation of insufflated air over the stomach, absence of patient coughing or choking, among others, suggests, but cannot ensure, correct tube placement.¹³ In 2006, Pennsylvania Patient Safety Authority¹⁴ wrote an article, "Confirming Feeding Tube Placement: Old Habits Die Hard," where they concluded that none of these methods are 100% effective and because "it's always been done this way" is not a good reason for healthcare workers to continue using less reliable methods to confirm FT placement. The authors further state that implementing improved evidencebased methods for FT placement will promote a safer environment of patient care.14

Regardless of placement method or location, x-ray/ radiographic verification is considered the gold standard to confirm the correct final position of enteral FTs inserted blindly at the bedside.¹⁵ Upper gastrointestinal (GI) endoscopy and fluoroscopically guided placement methods have higher success rates; however, procedures are costly, technically challenging, time-consuming, and can delay access to enteral feeding because of limited availability.¹⁶

Technological advances have resulted in FTs that facilitate insertion by providing visual cues to the FT location during insertion.^{7,17} The goal of such devices is to minimize the injury associated with misplaced tubes and provide ease of use for the clinician, thereby reducing risk and discomfort to the patient. A multicenter study showed that small-bowel FT placement using a bedside electromagnetic placement device (EMPD) was 99.5% accurate, with authors concluding that the use of a confirmatory radiograph in the setting of FT placement with EMPD technology was unnecessary.¹⁸

Even though EMPD and camera-guided technology FTs are subject to the same likelihood of initially entering the

bronchus as those placed blindly, camera-guided tubes allow immediate visualization of bronchial structures, and thus instant FT removal. In contrast, both blind FT placement and EMPD technology may delay recognition of incorrect FT placement and lead to continued inappropriate advancement of FT before confirmatory imaging.

The Kangaroo Feeding Tube with IRIS Technology (hereafter referred to as "IRIS"; Cardinal Health, Mansfield, MA, USA) is a single-use device designed with a camera embedded in the distal end to aid in tube placement. It is composed of a Dobbhoff-type, small-bore, nasogastric FT with a distal tip-mounted miniature camera that connects to an external image display monitor. This advanced enteral FT placement system allows visualization from the distal end of a nasogastric FT and allows clinicians to identify anatomical markers during the placement procedure.

The primary objective of this prospective case series was to provide additional data on the visualization capabilities, specifically targeting the identification of the esophagus and the stomach, while using the IRIS during a bedside FT placement procedure.

Methods

The study protocol was approved by the Western Institutional Review Board before conduct, and each subject provided informed consent to participate in the study.

Subjects

Eligible subjects were hospitalized adults in the ICU or step-down unit who were anticipated to require enteral feeding for a minimum of 3 days. Major exclusion criteria included hemodynamic instability, pregnancy, known basal skull fractures, GI perforation or leak, GI bleeding sufficient to obscure images, or known obstruction or lesions of the GI tract.

Device Information and Placement Procedure

Three clinicians with previous experience in small-bore enteral FT placement received training on the use of the tube and performed a total of 12 training cases on enrolled and consenting subjects. Two clinicians completed the training phase with the minimum of 5 cases each; the third clinician did not complete the training phase with only 2 placements performed before study enrollment completed. Each clinician selected the appropriate diameter (8, 10, or 12 Fr) FT for the subject. To estimate insertion depth, the clinician used the tube to measure the distance from the tip of the subject's nose to the earlobe and from the earlobe to the xiphoid process for gastric placement. The clinician positioned and prepared the subject in accordance with the usual protocol for FT placement at his or her facility. The FT was placed in the most patent naris using a stylet. While inserting the IRIS FT, the clinician used the console screen to identify anatomical markers to visualize the placement of the distal tip of the tube. The manual air insufflation device was used to introduce small bursts of room air through the tube's distal end for better visualization at the discretion of the investigator. Still images of anatomical markers were captured during the procedure. For anatomical markers noted during the placement procedure, the approximate depth of the FT's distal tip was recorded. Still images of the vocal cords, trachea, and carina were captured if visualized on the console during the procedure.

If signs of the airway were not visible while pausing during the advancement of the FT at a depth of approximately 25 cm, and if the clinician was confident that the tube was in the esophagus based on the real-time images on the console, the clinician continued to advance the tube down the GI tract. When the distal tip of the tube reached the desired final location in the stomach, still images of the rugal folds of the gastric mucosa were captured. The qualified physician reviewed the images and determined the final tube location. An initial abdominal radiograph of the kidneys, ureters, and bladder (KUB), including the diaphragm, was obtained and interpreted by an in-house radiologist or qualified clinician. Additional views were obtained if needed to confirm agreement between the KUB and IRIS-determined tip placement.

End Points and Statistical Analysis

Because this was a case series, no formal sample size calculation was performed. For continuous end points, number of available observations, mean, SD, and median, minimum, and maximum values were provided. For categorical end points, the frequency and percentage of subjects in each category were displayed, including the anatomical landmarks visualized. Statistical analyses were performed using SAS Version 9.4. Analyses were performed on the intentto-treat (ITT) and the per protocol (PP) populations. The ITT population consisted of all subjects who consented, enrolled, and met the eligibility criteria. The ITT population served as the primary population for the primary end point of the study and for safety. The PP population consisted of all subjects in the ITT population without a major protocol violation who had an IRIS FT placed with final IRIS location obtained and underwent the required abdominal radiograph for confirmation of FT placement. Subjects considered as "training cases" were excluded from the PP population.

Results

Study Population

Forty-nine subjects (37 males, 12 females) were determined to be initially eligible and consented to participate in the



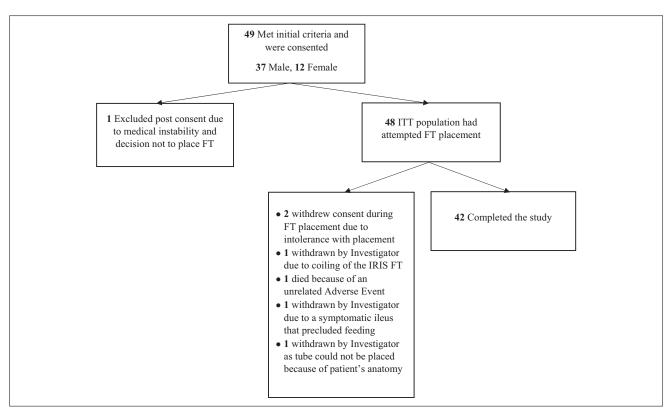


Figure 1. Distribution of eligible and enrolled subjects. FT, feeding tube; IRIS, Kangaroo Feeding Tube with IRIS Technology; ITT, intent-to-treat.

study, although 1 subject was later excluded because of medical instability and a decision not to place a FT. See Figure 1 for details of the enrolled and evaluated patient population. The demographics and baseline characteristics of the ITT population are included in Table 1.

Placement Details

Forty-four subjects (91.7%) in the ITT population had successful placement of the IRIS FT into the stomach or small bowel. In 3 cases (6.3%), the FT could not be placed either because of the subjects' anatomy or their intolerance to the placement procedure. During the initial training cases period, 1 additional subject's FT was discovered to be coiled in the pharynx (2.1%) on x-ray, and the subject was removed from the study as another tube was placed. The median time between initial insertion start and final placement was 8.0 minutes in both the ITT and PP populations. See Table 2 for details of the IRIS placement procedure and final tip location.

Within the ITT population, there was 1 subject who did who did not undergo a KUB because of an adverse event (unrelated to FT placement) that led to death before the image could be obtained. No subjects' radiographs were inconclusive as to the final placement location; therefore, no subjects underwent radiograph with contrast media. Agreement between the IRIS placement location and KUB confirmation occurred in 40 instances (93.0%), which was statistically significant (Cohen's $\kappa = 0.3645$; P = .014). As stated, during the initial training cases period, 1 subject's FT was discovered to be coiled in the pharynx (2.1%) on x-ray. In the other cases of disagreement, 2 cases were read as in "stomach" via camera visualization but were determined to be "small bowel" via x-ray. These tubes also may have migrated to the small bowel before confirmatory x-ray. Finally, 1 tube was read as "postpyloric" via camera visualization; however, subsequent confirmatory x-ray was read as "downstream antrum/proximal pylorus," which may have also occurred because of tube movement after placement.

The primary end point was to evaluate the clinician's ability to identify anatomical markers in the GI tract and/or airway using the IRIS FT. In the ITT population, the esophagus was identified in 36 subjects (80.0%) and not identified in 9 subjects (20.0%) at a median tube depth of 30.0 cm (range 25.0–35.0 cm). An image of the esophagus was obtained in 34 subjects (75.6%) and was not obtained in 11 (24.4%). Clinicians placing the tube interpreted the tip to be in the stomach in all 45 placements at a median tube depth of 60.0 cm (range 45.0–85.0); however, 1 was

Characteristics	Value
Age, y	
Mean + SD	53.6 ± 17.05
Median	56.0
Minimum-maximum	21.0-81.0
Gender, n (%)	
Female	12 (25.0)
Male	36 (75.0)
Race, n (%)	
Black/African American	2 (4.2)
White	46 (95.8)
Ethnicity, n (%)	
Hispanic or Latino	5 (10.4)
Not Hispanic or Latino	43 (89.6)
Body mass index, kg/m ²	
Mean + SD	28.0 ± 6.92
Median	27.4
Minimum–maximum	17.4-45.1
State of consciousness, n (%)	
Awake and alert	10 (20.8)
Mildly sedated	28 (58.3)
Deeply sedated	7 (14.6)
Comatose	3 (6.3)
Type of intensive care unit or	
step-down unit, n (%)	
Burn/Trauma	7 (14.6)
Cardiothoracic surgical	21 (43.8)
Neurological	14 (29.2)
Surgical	6 (12.5)
Mechanical ventilation required,	
n (%)	
No	28 (58.3)
Yes	20 (41.7)

Table 1. Demographics and Baseline Characteristics of the Intent-to-Treat Population (N = 48).

Table 2. Kangaroo Feeding Tube With IRIS Technology Placement Details in the Intent-to-Treat Population (N = 48).

Tube Placement Details	N (%)
Number (%) of times IRIS could not be placed	3 (6.3)
Number (%) of misplaced IRIS tubes	1 (2.1)
Number (%) with successfully placed IRIS tube	44 (91.7)
Feeding tube size	
10 Fr	22 (48.9)
12 Fr	22 (48.9)
8 Fr	1 (2.2)
Feeding tube length	
43 in	33 (73.3)
55 in	12 (26.7)
Time between insertion start and final placement	
Mean \pm SD	11.0 ± 9.40
Median	8.0
Minimum-maximum	2.0-52.0
Final tip location based on KUB	
interpretation in 44 subjects who	
underwent KUB	
Postpyloric	3 (6.8)
Stomach	40 (90.9)
Other (not identified)	1 (2.3)

IRIS, Kangaroo Feeding Tube with IRIS Technology; KUB, kidney, ureter, and bladder x-ray.

Table 3. Clinician Interpretation of Anatomical MarkersDuring Feeding Tube Insertion in the Intent-to-TreatPopulation (N = 45).

Anatomical Area	Visualized by Camera During Placement	n (%)
Trachea	No	37 (82.2)
	Yes	8 (17.8)
Carina	No	44 (97.8)
	Yes	1 (2.2)
Esophagus	No	9 (20.0)
	Yes	36 (80.0)
Stomach	Yes	45 (100.0) ^a
Other markers	Small intestine at 70 cm	1 (2.2)
identified	Vocal cords at 20 cm	1 (2.2)
	Vocal cords at 25 cm	1 (2.2)

^aClinicians interpreted the tip of the feeding tube (FT) to be in the stomach in all placements; 1 tube was confirmed by x-ray to be coiled in the pharynx.

able to consent for the study. Blind placement had been attempted on this individual before attempted placement of the IRIS FT without success.

After informed consent was obtained, the subject was seated in a 90-degree upright position with the chin down and placement with camera guidance attempted. Initial visualization of the oropharynx was made. However, vocal

discovered to be coiled in the pharynx on x-ray. An image of the stomach was obtained in 42 subjects (93.3%) and not obtained in 3 (6.7%). In the 3 patients without a stomach image, 1 occurred during the initial training cases period, where 1 tube was discovered to be coiled in the pharynx (2.1%) on x-ray and no stomach image was obtained. In the other 2 cases, the stomach was visualized per the investigator, but because of other clinical timing constraints and patient intolerance of ongoing procedure there was not sufficient time to capture an image with the camera (both cases were confirmed to be in the stomach by x-ray). The anatomical structures identified in the ITT population are displayed in Table 3 and Figure 2.

An Important Clinical Case and Considerations for Clinical Practice

One clinical case was notable due to the impact of the IRIS camera on the subject's course of treatment. The subject was a 73-year-old man hospitalized for an ascending aortic dissection and aortic graft procedure. He was awake and

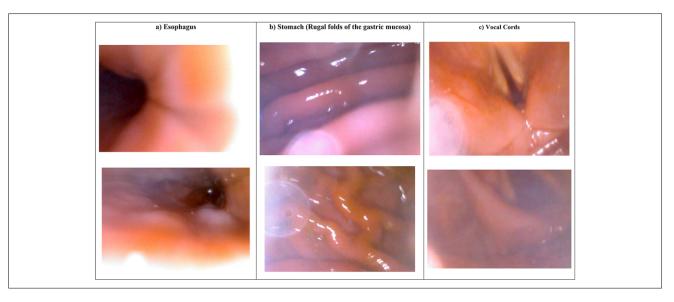


Figure 2. Representative images captured during placement with Kangaroo Feeding Tube with IRIS Technology. (a) The esophagus appears smooth, pale pink, with visible submucosal blood vessels. (b) The stomach is characterized by the appearance of rugal folds. (c) Vocal cords as visualized by the IRIS device.

cords were not seen due to edema. The airway was immediately visualized, although the subject experienced no coughing or gagging, despite being conscious, even when the tube was near the carina. Anecdotally, the nurses who had attempted prior placement indicated that the tube would not move past 35-40 cm because of resistance, suggesting these prior placements were in the airway. The patient was repositioned and after receiving patient agreement to continue, the patient was instructed to swallow ice chips and water during placement to attempt to further facilitate movement of tip into the esophagus. Again, with slow advancement initial views of the airway came into view, including the carina, which did not lead to any patient discomfort, coughing, or gag reflex response. The decision was made to abandon the FT placement procedure in this case for both patient comfort reasons and because the ICU care team concluded the subject's lack of cough and gag reflex, even with stimulation at the carina, put him at a very high risk for aspiration with EN. After presenting the case and the evidence obtained by the IRIS device, the ICU team agreed that the patient should receive a speech and swallow evaluation and parenteral nutrition was a more appropriate nutrition option. The ICU team felt the use of a cameraguided FT placement technique in this case not only saved the patient from a potential complication of airway and lung injury, but also may have prevented aspiration if EN had been initiated.

Discussion

This prospective case series is the largest study to date on the real-time visualization of anatomical landmarks during FT

placements using the IRIS. In this study, the investigators found that after training cases to ensure proficiency with the IRIS system, placement of this device was simple and safe in critically ill patients and provided identification of the esophagus and stomach to aid in accurate placement. Our experience revealed that optimal positioning of the patient, asking them to maintain a chin-down position while swallowing, and avoiding oral topicalization allowed for expeditious placement of the tube. Intubated patients are more difficult at times to place in optimal chin-down position; however, this did not impair expeditious placement of IRIS in intubated patients. The direct camera visualization of the ETT tube and other landmarks improved safe and efficient FT placement. Interestingly, topicalization with local anesthetic agents often led to initial airway visualization and a more difficult entry of the tip into the esophagus. It was the opinion of this investigator (P.W.) that this surprisingly often increased patient discomfort, rather than reducing it.

Entrance into the airway was noted by clear identification of the trachea and carina in 17.8% and 2.2% of subjects, respectively. Notably, this was higher than the study clinicians had expected would occur. The vocal cords were visualized in 4.4% of placements. Visualization of the trachea confirms a significant risk for airway misplacement in this population. This is an important risk to address because approximately 40% of the subjects enrolled were sedated and mechanically ventilated, and thus often unable to respond to misplacement. Use of IRIS visualization allowed the clinician to retract and redirect the tube down the GI tract, thus avoiding further advancement into the airway and the resulting potential injury and complications. This is a key safety measure that the IRIS appears to address because recent data on blind FT malpositioning demonstrate that 13%–32% of FTs are also misplaced on subsequent repositioning attempts. These data show after an initial misplaced FT, when subsequent FT placements are required, this patient population is exposed to a cumulative mortality rate from tracheobronchial malpositioning approaching >20%.¹¹

In this study, agreement between the IRIS image and radiographic confirmation was 93%. These results suggest that with further study, direct visualization of the gastric mucosa by the IRIS camera could potentially preclude the need for radiographic confirmation in almost all patients but may require some improvements to the camera to identify other anatomical markers. Our results and clinical experience in this study were similar to a recently published case series by Mizzi et al¹⁹ using IRIS to confirm bedside FT placement in patients in the ICU. In that study, 20 unconscious patients underwent FT placement using the device, and the gastric mucosa was identified in 90% of the cases and airway misplacement was avoided in approximately one-third of patients.^{16,19} In both the Mizzi et al's study¹⁹ and our own, there was some difficulty with image quality. The manufacturer has since improved the device design to increase the quality of the camera's visualization. In some patients who were quite anxious about the FT placement procedure, the tube was quickly passed through the esophagus and to the stomach, where this was the first landmark able to be photographed due to desire to minimize procedure time and patient anxiety from FT placement. It should be noted that all FTs were planned to be gastric in location; in some patients, the investigators noted the pylorus was easily identified and the tube was passed into the small bowel (postpyloric) after discussion with the primary care team as to appropriateness of postpyloric tube placement.

Translating these results into the expected impact on clinical practice, radiographic confirmation of correct FT placement could potentially be avoided by accurate IRIS visualization of the gastric mucosa, thus saving time and money, avoiding radiation exposure, and offsetting the cost of the camera technology.

Strengths of this study include the enrolment of patients with a variety of diagnoses as eligible subjects from all ICU and step-down units at the facility. This improves the generalizability of these results. Shortcomings of this study include the single-center design. Also, only 3 individuals (MD, RN, and PA credentials) placed all the tubes, somewhat limiting the generalizability of the placement experience. The clinicians also completed training cases and were therefore well practiced on the use of IRIS during this study. The learning curve in general clinicians must be determined in further studies. Only 3 of the tubes placed were in the postpyloric space. Because postpyloric tubes are generally harder to place, further investigation is warranted to determine the feasibility and success rates of postpyloric tube placement. These patients may, in fact, represent an ideal opportunity to use anatomical markers to guide the more challenging postpyloric placement.

Conclusions

The results of this series support the ability of IRIS to provide direct visualization of anatomic markers to assist with bedside placement and avoid FT misplacements. Further studies are needed to evaluate the safety of using IRIS alone to confirm tube location before feeding in clinical practice.

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Statement of Authorship

P. Wischmeyer and E. J. Dye contributed to the conception and design of the research; M. M. McMoon contributed to the acquisition of the data; P. Wischmeyer, M. M. McMoon, N. H. Waldron, and E. J. Dye contributed to the analysis and interpretation of data; P. Wischmeyer, M. M. McMoon, N. H. Waldron, and E. J. Dye drafted the manuscript. All authors critically revised the manuscript, agree to be fully accountable for ensuring the integrity and accuracy of the work, and read and approved the final manuscript.

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