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Bedside electromagnetic-guided placement of nasoenteral feeding tubes among critically Ill patients: A single-centre randomized controlled trial

Xuejin Gao [a,1], Li Zhang [a,1], Jie Zhao [b], Feng Tian [a], Haifeng Sun [a], Peng Wang [a], Jiwei Wang [a], Zhiming Wang [a,*], Xinying Wang [a,*]

[a] Research Institute of General Surgery, Jinling Hospital, Medical School of Nanjing University, Nanjing, Jiangsu Province, China
[b] Department of Neurosurgery, Jinling Hospital, Medical School of Nanjing University, Nanjing, Jiangsu Province, China

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ABSTRACT

Purpose: We aimed to compare the effectiveness of EM-guided and endoscopic nasoenteral feeding tube placement among critically ill patients.
Materials and methods: We performed a single-center, randomized controlled trial among 161 adult patients admitted to intensive care units (ICUs) requiring nasoenteral feeding. Patients were randomly assigned to EM-guided or endoscopic nasoenteral feeding tube placement (1:1). The primary end point was the total success rate of correct jejunal placement.
Results: This was achieved in 74/81 and 76/80 patients who underwent EM-guided and endoscopic jejunal tube placements, respectively (91.4% vs. 95%; relative risk, 0.556; [CI], 0.156–1.980; P = 0.360). The EM-guided group had more placement attempts, longer placement time, and shorter inserted nasal intestinal tube length. However, they had shorter total placement procedure duration and physician's order–tube placement and order–start of feeding intervals. The EM-guided group had higher discomfort level and recommendation scores and lesser patient costs. This trial is registered at Chinese Clinical Trials Registry (ChiCTR-IOR-17011737).
Conclusion: Bedside EM-guided placement is as fast, safe, and successful as endoscopic placement and may be considered the preferred technique in critically ill patients.

1. Introduction

Enteral nutrition is increasingly being recognized as an integral component in the management of critically ill patients, with a major effect on morbidity and outcome [1]. Early enteral nutrition has been shown to be better than total parenteral nutrition in terms of nitrogen balance, wound healing, and host immune function improvements; gut integrity preservation, infectious complication reduction, and patient outcome improvement [2-7]. However, numerous studies have shown that early enteral nutrition is not frequently used or is associated with inadequate calorie delivery [8-10]. Gastrointestinal intolerance is the main reason, which occurs in 8.2%–53% of critically ill patients [11-14]. In particular, in patients suffering abdominal surgery or trauma and given intragastric nutrition, delayed gastric emptying is common and associated with large gastric residual volumes, emesis and pneumonia [15,16]. The American Society for Parenteral and Enteral Nutrition (ASPEN) and European Society for Clinical Nutrition and Metabolism (ESPEN) guidelines recommend intestinal feeding to facilitate an adequate nutritional supply among patients who are intolerant of intragastric nutrition [5,16].

However, jejunal tube placement poses an obstacle for many healthcare providers in the ICU, which often leads to rare or even non-use of intestinal feeding at all in patients, depriving them of the benefits of enteral nutrition. Several methods exist for the positioning of nasointestinal tubes. Consequently, of the different endoscopic and radiologic techniques, the bedside electromagnetic (EM)-guided technique has been developed for the placement of jejunal feeding tubes. However, no large-sample randomized trial comparisons between endoscopic and EM-guided tube placement have been conducted among critically ill surgical and medical patients.

Accordingly, we compared the success rates of correct jejunal placement between the new EM-guided and endoscopic jejunal tube placement techniques through a prospective, randomized trial among critically ill patients.

* Corresponding authors.
E-mail addresses: drwangzhiming@126.com (Z. Wang), wxinying@263.net (X. Wang).
[1] These authors contributed equally to this work.

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2. Materials and methods

2.1. Study design

We performed an investigator-initiated, single-center, randomized trial. The study protocol conformed to the ethical guidelines of the Declaration of Helsinki and was approved by the Research Ethics Committee of the Jinling Hospital. In accordance with the Austrian law and Research Ethics Committee guidelines, written informed consent was obtained from all participating patients prior to randomization.

2.2. Patients and setting

The study was performed in the ICUs (including the medical and surgical ICUs) of Jinling Hospital. The data were collected from June 2017 to December 2017.

Patients were eligible for inclusion in the study if they were older than 18 years of age and had intolerance to intragastric enteral nutrition. Intolerance is defined as high gastric residual volumes (250 mL for 24 h) and/or repeated emesis [17,18]. The gastric residual volume was evaluated twice within 24 h through enteral nutrition interruption for at least 0.5 h and connection of the tube to a gastric content exchange bag [18]. Gastric content exchange bags were placed at the same height as the stomach to guarantee that nasogastric tubes served only as an overflow outlet.The patients were not enrolled in the study if any of the following criteria were present: contraindications for enteral nutrition or upper gastrointestinal endoscopy or EM-guided placement, previous upper gastrointestinal surgery, signs of active upper gastrointestinal bleeding, severe nasopharyngeal stenosis, and inability or unwillingness to provide informed consent. Standardized enteral nutrition was prescribed in accordance with a nutritional protocol. Energy requirements were calculated with the goal of 25 and 30–35 kcal/kg of body mass/day for ICU and burn patients, respectively. For every patient included, age, sex, admission reason, and comorbidities, as well as laboratory data, were documented.

2.3. Randomization and blinding

Eligible patients were randomly allocated in a 1:1 ratio to undergo either EM-guided or endoscopic placement of a nasoenteral feeding tube (EM-guided or endoscopy group, respectively). Randomization and concealment were achieved using a secure, computer generated system. Blinding of patients, care providers, and outcome assessors was considered impossible given the obvious differences between the two tube placement methods.

2.4. Tube placement procedures

The endoscopic nasoenteral feeding tube placement method was performed at the endoscopy department by a trained gastroenterologist who is assisted by one or two endoscopy nurses and one anesthesiologist, in accordance with the standard operating procedure. Initially, the patients fasted for 4–6 h, but clear fluids were allowed up to 3 h before the procedure. Subsequently, formal endoscopic evaluations of the esophagus, stomach, and duodenum were performed. The procedures were performed with the patients in a supine position using a fiber optic endoscope (GIF-Q 260; Evis Exera II, Olympus, Tokyo, Japan). A 140 cm single-lumen jejunal tube (enteral lumen, 10 French) was used for all patients who were randomized to the endoscopic guided group after the administration of intravenous anesthesia using propofol. The timing of the procedure started when the jejunal feeding tube entered the nostrils. The tube was slowly advanced to the back wall of the throat and then into the esophagus and stomach. The flexible tube tip was grasped in the stomach using endoscopic forceps and passed into the pylorus under endoscopic control. Subsequently, the tip of the tube was then placed at the ligament of Treitz under endoscopic vision. The endoscope was withdrawn into the stomach while the tip of the tube was kept in the jejunal position by advancing the endoscopic forceps in the opposite direction. The correct course of the tube through the pylorus was visually verified before the endoscope was withdrawn from the stomach. In case a tube tip was accidentally retracted into the stomach, the flexible tip was recaptured and jejunal positioning was repeated. Finally, the correct jejunal tube position was verified through radiography after careful retraction of the guide wire. The tube was then fixed with nasal adhesive tape or thread and needle.

EM-guided nasoenteral feeding tube placement was performed at the patient's bedside by an experienced member of the nutritional support team for all participants. Prior to participation in the trial, the nutritional support team member performed at least ten EM-guided nasoenteral feeding tube placements before initiation of the study to gain an experience.

The CORTRAK Enteral Access System (CORPAK Med-Systems, Wheeling, IL) aids the feeding tube placement by showing the relative location of the feeding tube tip during placement. The tip of the feeding tube stylet is an EM transmitter. A non-invasive receiver unit is placed at the patient's xiphoid process, which acquires the signal from the stylet as it moves through the patient during the placement procedure. The track of the tube is shown on the computer monitor.

The procedure was performed based on the manufacturer's instructions. The CORFLO enteral feeding tube(CEAS, Corpak MedSystems, Buffalo Grove, IL) is a 10 Fr, 140 cm-long single-lumen tube. Initially, the distal tip of the tube was lubricated. The timing of the procedure started when the jejunal feeding tube entered the nostrils. The tube was manually advanced based on the track shown on the computer monitor. The tube was removed for a few centimeters in case of curling. In cases of reoccurring curling, the patients were moved onto either their right or left side. If the tube was stuck, 10–20 mL of air was insufflated into the stomach. The procedure was finished when the track of the tube reached the position of the ligament of Treitz, as shown on the computer monitor. Failure was defined as a time limit of 20 min for every placement. In this case, a second trail was performed after 6 h. If placement was still not achieved, enteral feeding tube placement was performed through radioscopy.

To improve peristalsis, 10 mg of intravenous metoclopramide was routinely administered 10 min before the procedure. A radiograph was used to verify position.

The functional capability and patency of jejunal feeding tubes were checked by flushing the tubes with 20 mL 0.9% sodium chloride eight times per day in all patients.

The clinical data, with regard to the baseline characteristics and outcomes, were collected during hospital admission by the treating physician using written standardized case report forms. The study coordinators crosschecked the case report forms with the source data. After each (re)placement procedure, the patients were asked to complete a short questionnaire consisting of a Visual Analogue Scale scoring sheet for five dimensions, that is, discomfort (nausea and vomiting), pain, social embarrassment, anxiety, and total burden, which was similar to a previous study [19]. Furthermore, the participants were also asked whether they would recommend the procedure to a family member, friend, or colleague in the same situation [19]. Patients were followed up for as long as they were hospitalized, when they were discharged with a nasoenteral feeding tube in situ, and during outpatient clinic or day-care visits until removal of the feeding tube.

2.5. Outcomes

The primary outcome was the total success rate of feeding tube placement. Meanwhile, the secondary outcomes included the duration of the tube placement procedure; intervals between the physician's order and tube placement, start of feeding, feeding goal achievement;