

Percutaneous Ultrasound Guided Gastrostomy Tube Placement: A Prospective Cohort Trial

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Stephen P. Reis, MD, MBA, FSIR¹ , Sidney Z. Brejt, MD¹,
Joseph R. Weintraub, (Student)², Noor Ahmad, MD¹,
Jonathan Susman, MD, FSIR¹, and David G. Mobley, MD¹

Abstract

Background: To compare the safety and efficacy of percutaneous ultrasound guided gastrostomy (PUG) tube placement with traditional fluoroscopic guided percutaneous gastrostomy tube placement (PRG). **Methods:** A prospective, observational, non-randomized cohort trial was performed comparing 25 consecutive patients who underwent PUG placement between April 2020 and August 2020 with 25 consecutive patients who underwent PRG placement between February 2020 and March 2020. Procedure time, sedation, analgesia requirements, and complications were compared between the two groups in non-inferiority analysis. **Results:** Technical success rates were 96% in both groups (24/25) of procedures. Ninety-two percent of patients in the PUG cohort were admitted to the ICU at the time of G-tube request. Aside from significantly more COVID-19 patients in the PUG group ($P < .001$), there was no other statistically significant difference in patient demographics. Intra-procedure pain medication requirements were the same for both groups, 50 micrograms of IV fentanyl ($P = 1.0$). Intra-procedure sedation with IV midazolam was insignificantly higher in the PUG group 1.12 mg vs 0.8 mg ($P = .355$). Procedure time trended toward statistical significance ($P = .076$), with PRG being shorter than PUG (30.5 ± 14.1 minutes vs 39.7 ± 17.9 minutes). There were 2 non-device related major complications in the PUG group and 1 major and 1 minor complication in the PRG group. **Conclusion:** PUG is similar in terms of complications to PRG gastrostomy tube placement and a safe method for gastrostomy tube placement in the critically ill with the added benefits of bedside placement, elimination of radiation exposure, and expanded and improved access to care.

Keywords

percutaneous gastrostomy, ultrasound guidance, bedside, enteral feeding

Introduction

Approximately 250,000 Gastrostomy tubes (g-tubes) are placed annually in the U.S. to provide patients with a pathway for enteral nutrition via a tract formed by puncture through the abdominal and stomach walls, bypassing the mouth and esophagus.^{1,2} Approximately 50% of all gastrostomy procedures in the US are performed in the critically ill.³ The most common methods for G-tube placement are transoral and transabdominal.⁴ Image guidance varies among institutions and providers with endoscopic (PEG), fluoroscopic, and surgical (primarily laparoscopic) (LAG) guidance being the most common. Percutaneous Endoscopic Gastrostomy (PEG) uses endoscopic guidance to visualize the inside of the stomach, as well as to transilluminate the intended puncture path. PEG tubes can be placed in the endoscopy suite, operating room or at the bedside using a mobile endoscopy tower. The second most common minimally-invasive alternative is the fluoroscopically guided transabdominal approach or percutaneous radiologic gastrostomy (PRG).

Fluoroscopically guided g-tubes are typically placed in interventional radiology suites with moderate sedation. Fluoroscopy incurs the risk of ionizing radiation, which can theoretically lead to an increased risk of cancer in the long term.^{5,6} Surgically placed procedures can be open or laparoscopic and tend to be reserved for patients who are not candidates for either PEG or PRG due to their anatomy or other factors. These are routinely

¹ Division of Interventional Radiology, Columbia University Irving Medical Center, New York, NY, USA

² Columbia University, Vagelos College of Physicians and Surgeons, New York, NY, USA

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Corresponding Author:

Stephen P. Reis, Division of Interventional Radiology, Columbia University Irving Medical Center, 630 West 168th Street, New York, NY 10032, USA.
Email: sr3321@cumc.columbia.edu

Table 1. Inclusion/Exclusion Criteria for PUG Cohort Recruitment.

| Inclusion criteria | Exclusion criteria |
|---|---|
| <ul style="list-style-type: none"> • Patients ≥ 18 years of age • BMI >20 and <30 kg/m² • Systolic BP >100 and <180 mmHg • Heart Rate >50 and <140 bpm | <ul style="list-style-type: none"> • Contraindications to being near magnet • Prior history of gastric or major upper abdominal surgery • Hematocrit less than 25 or transfusion within 48 hrs prior to surgery • History of GI bleed |

performed under general anesthesia in the operative room and have associated increased risk and cost.

Percutaneous ultrasound guided gastrostomy (PUG) is an alternative to traditional methods of feeding tube placement which utilizes solely ultrasound imaging to guide gastrostomy placement. PUG may be performed at the bedside in the ICU by physicians trained in the use of ultrasound without the requirement for ionizing radiation, endoscopy, or general anesthesia.⁷ Because the critically ill often require continuous monitoring, ventilatory support, and multiple intravenous medication drips, bedside procedures avoid hospital transportation which poses potential risk to patients and caregivers.⁸⁻¹¹ Importantly, current COVID-19 guidelines recommend limiting movement of patients to avoid hospital cross-contamination.^{12,13} At our institution, interventional radiologists skilled in ultrasound and credentialed in gastrostomy adopted the PUG procedure as an option for bedside performance.

While both interventional radiologists and intensivists have reported experience performing PUG in the literature,^{7,14} to our knowledge, an analysis of its safety profile has not yet been published. The objective of this study is to prospectively evaluate whether PUG placement using the Point-of-care Ultrasound Magnet Aligned Gastrostomy (PUMA-G) System (Coaptech, Baltimore, MD) has a non-inferior safety profile compared to traditional PRG.

Methods

Institutional review board approval was obtained for this prospective, observational, non-randomized cohort trial comparing the safety and efficacy of percutaneous ultrasound guided gastrostomy tube placement with traditional fluoroscopic guided gastrostomy tube placement. Enrollment began in April 2020 and concluded in August 2020. All requests for gastrostomy tube placement by interventional radiology (IR) during this period were screened using inclusion and exclusion criteria (Table 1). To avoid potential bias, the first consecutive 25 patients who met the inclusion and exclusion criteria and gave consent to be included in the study were enrolled in the PUG group. Results of the PUG group were compared to 25 consecutive patients who underwent G-tube placement between February and March 2020. A sample size of 25 was chosen for this non-inferiority study because it forms the basis for safety in a small sample. This sample size provides an 80% chance of seeing at least one serious device-related event assuming the event rate is at least 6.3% and a 90% chance of seeing at least one event if the true event rate is at least 8.8%.¹⁵

When the patient could consent for themselves, written consent for enrolment in the study was obtained from the patient, otherwise consent was obtained from the patient's health care proxy as approved by our IRB.

PUG Procedure

PUG procedures were performed at the bedside or in the IR suite depending on patient clinical status, IR suite availability and the logistics of transporting ventilated patients in isolation (often with COVID-19) to IR. Patients were routinely sedated with midazolam and fentanyl for intraprocedural pain control. All patients were required to have a nasogastric tube prior to the procedure for air insufflation of the stomach. Glucagon (1 mg IV) was used to transiently decrease the peristalsis of smooth muscle in the gastrointestinal tract prior to gastric distention with air. The stomach was inflated with enough air to approximate the stomach to the anterior abdominal wall. The PUMA-G balloon orogastric tube (OGT) was then advanced into the stomach. A gauss meter was used to identify the position of the magnet on the end of the OGT over the abdomen. Using the proprietary external magnet, the balloon and stomach were coapted to the anterior abdominal wall forming a temporary magnetic gastropexy. The OGT balloon was then inflated with 30 ml of water with a drop of methylene blue and balloon position was confirmed with ultrasound. With continued magnet-balloon apposition and under direct ultrasound guidance, an 18-gauge needle was advanced through the abdominal wall into the balloon (Figure 1). After aspiration of sterile saline stained with methylene blue, the specialized PUMA-G pigtail wire was then passed through the needle into the OGT balloon. The balloon was deflated, ensnaring the guidewire which was then pulled up the esophagus in tandem with the deflated balloon and out through the mouth. A 20-French pushable mushroom retained gastrostomy tube (Boston Scientific, Minneapolis, MN, USA) was advanced over the wire and pulled through a dermatotomy in the abdominal wall (Figure 2). The tube was then trimmed to the appropriate length and contrast was injected through the tube to confirm location within the stomach with a portable x-ray or fluoroscopic image. The tubes were left to gravity drainage for 6 hours prior to use for decompression and monitoring for bleeding.

PRG Procedure

All PRG procedures were performed in the IR suite with fluoroscopy. All patients were required to have a nasogastric

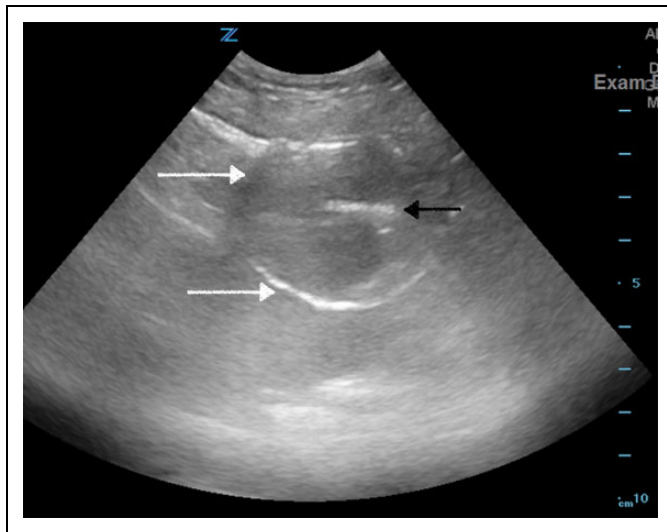


Figure 1. Ultrasound image demonstrates the OGT balloon (white arrows) with magnets (black arrow) in a patient with an abdominal wall to stomach depth of 2 cm.

tube (NGT) prior to the procedure and receive oral contrast (50 ml Omnipaque (GE Healthcare, Wauwatosa, WI) diluted with 500 ml water) the night prior to the procedure to opacify the transverse colon. Most procedures were performed with moderate sedation supervised by the interventional radiologists. For a subset of PRG patients who have amyotrophic lateral sclerosis patients (ALS), institutional guidelines require the presence of an anesthesiologist secondary to their tenuous respiratory status although no patients required intubation. An outline of the left lateral edge of the liver was marked using ultrasound evaluation. As described previously, 1 milligram glucagon IV was routinely used as a smooth muscle relaxant prior to gastric distension. Local anesthesia was achieved with 1% lidocaine at skin entry sites. Under fluoroscopic guidance, the distended stomach was punctured with 3 T-fasteners (Halyard Health, Alpharetta, Georgia, USA). After each puncture, contrast was injected through each fastener to confirm its location within the gastric lumen. The T-fasteners were each deployed within the gastric lumen and retracted and locked, pulling the anterior wall of the stomach up against the anterior abdominal wall to create a gastropexy.

A dermatotomy was created at the center of the T-fasteners and a 19-gauge needle was used to puncture the anterior wall of the stomach central to the fasteners. Contrast injection confirmed intraluminal location. The tract was then dilated to 22 French over a stiff 0.035 guidewire and an 18 French balloon retention gastrostomy tube (MIC G Feeding Tube, Halyard Health, Alpharetta, Georgia, USA) was placed into the gastric lumen through a peel-away sheath. The peel-away sheath was removed, and the balloon was inflated with 8-10 ml of sterile water. Contrast injection confirmed proper intragastric location using fluoroscopy. The tubes were left to gravity drainage for 6 hours prior to use for decompression and monitoring for bleeding.

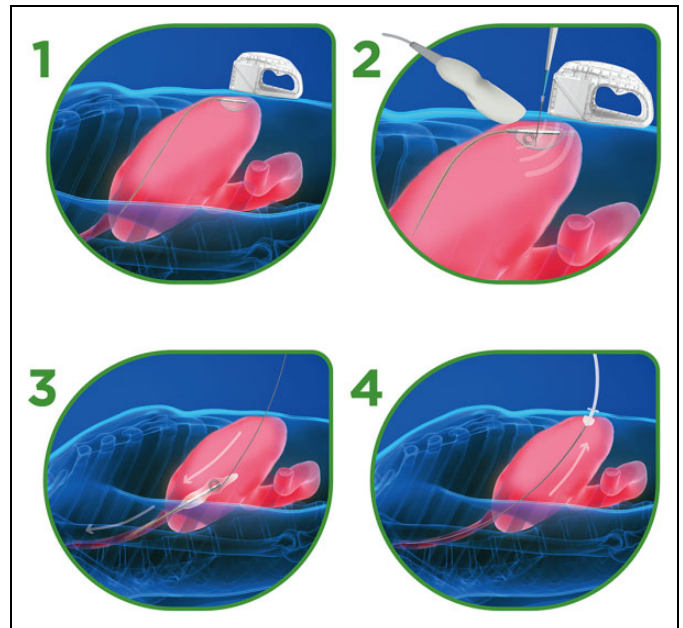


Figure 2. Diagram of percutaneous ultrasound gastrostomy procedural steps. Panel 1: Magnetic orogastric balloon catheter is fed into an air insufflated stomach and magnetically pexied to the anterior stomach wall by an External Magnet placed on the abdomen. Panel 2: Upon inflation with methylene blue dyed fluid, an ultrasound probe is used to positively identify the balloon catheter and a safe tract for percutaneous needle access is chosen. Percutaneous needle entry into the balloon is visualized under ultrasound, confirmed by blue fluid aspirant, and a pigtailed guidewire is inserted. Panel 3: The balloon catheter is deflated, ensnaring the pigtail guidewire within the balloon before slowly retracting the coupled balloon-guidewire from the mouth. Panel 4: A pushable mushroom bumper style gastrostomy tube is fed over the wire, completing the procedure.

Data Collection and Statistical Analysis

All data were collected and stored in a secure, HIPAA compliant database. Statistical analysis was performed using IBM SPSS software (Armonk, New York, USA). Multivariate linear regression was performed to evaluate for factors affecting procedure time for PUG procedures (BMI, height, weight, stomach depth, location, sedation requirement). Independent sample T-tests were used to compare characteristics of PRG patients to PUG patients (Age, height, weight, BMI, sedation requirements, procedure length, and COVID-19 status).

Results

PUG Patients

Seven female patients (28%) and 18 male patients (72%) underwent PUG placement (Table 2). Twenty-three of 25 (92%) of patients were admitted to the ICU at the time of G-tube request. Patients who underwent PUG placement had a mean BMI of 24.8 kg/m² (ranging from 18.7 to 34 kg/m²). Technical success rate for PUG placement was 96% (24 of 25). Eight procedures (32%) were performed bedside in the ICU and 17 procedures (68%) were performed in the IR suite

Table 2. Patient Demographics by Study Cohort.

| | PUG | PRG |
|--------------------------------------|----------------|------------------|
| Gender (N) | | |
| Female | 18 | 15 |
| Male | 7 | 10 |
| Race (N) | | |
| White | 7 | 12 |
| Hispanic | 16 | 8 |
| African American | 2 | 3 |
| Asian | 0 | 1 |
| Other | 0 | 1 |
| Age (years) | | |
| Mean (range) | 70.2 (54-86) | 65.9 (21-91) |
| BMI (kg/m²) | | |
| Mean (range) | 24.8 (18.7-34) | 25.8 (15.9-54.8) |
| Clinical indication (N) | | |
| Prolonged intubation due to COVID-19 | 17 | 0 |
| Stroke | 4 | 4 |
| Dementia | 0 | 4 |
| Glioblastoma | 1 | 0 |
| Lung transplant | 0 | 2 |
| Amyotrophic lateral sclerosis | 1 | 3 |
| Encephalopathy | 1 | 0 |
| Failure to thrive | 1 | 2 |
| Head and neck cancer | 0 | 2 |
| Multiple sclerosis | 0 | 1 |
| ARDS | 0 | 1 |
| Anoxic brain injury | 0 | 1 |
| Neck abscess | 0 | 1 |
| Aspiration pneumonia | 0 | 1 |
| STEMI | 0 | 1 |
| Malignant bowel obstruction | 0 | 1 |
| Leukoencephalopathy | 0 | 1 |
| Ventilation status (N) | | |
| Intubated | 12 | 3 |
| Tracheostomy | 5 | 0 |

without the aid of fluoroscopy. Technical success rate of bedside PUG placement was 88.9% (8 of 9). The patient that had an unsuccessful bedside procedure underwent successful PUG placement in IR without the aid of fluoroscopy after confirmation of NGT location in the stomach on pre-procedure chest radiograph. Technical success rates of PUG procedures performed in IR was 94.1% (16 of 17). One attempt was aborted due to difficulty passing the orogastric balloon past the tracheostomy tube. An additional procedure (4%) required the use of fluoroscopy for insufflation of the stomach below the ribs. Patients received a mean of 1.1 mg of intravenous (IV) midazolam, with a range between (0 and 5 mg). Patients who received no procedural sedation were intubated and sedated and required no additional sedation for the procedure. PUG patients received a mean of 50 micrograms (mcg) of IV fentanyl range (0 to 100 mcg). All patients received pre-procedure antibiotics.

PUG procedures took a mean of 39 ± 17.9 minutes. Neither gastrostomy tract depth, patient weight, height nor BMI were associated with procedure time using a linear regression model.

Two major complications occurred following PUG procedure. One patient became hypotensive with systolic blood pressure in the 80 s after being restarted on therapeutic lovenox for pulmonary embolism 24 hours post procedure. He had coffee ground emesis aspirated from the PUG and was noted to have a 2 gram drop in hemoglobin, which required transfusion with 2 units of packed red blood cells (PRBC). There was no further evidence of bleeding after lovenox was discontinued. The second patient was found to have a blood-soaked dressing and sheets by the nursing staff. This patient also had a 2 gram drop in hemoglobin and required 2 units of PRBC. Bleeding stopped when pressure was applied to the gastrostomy skin exit site with no further bleeding noted.

PRG Patients

Fifteen female patients (60%) and 10 male patients (40%) underwent PRG placement (Table 2). Patients who underwent G-tube placement had a mean BMI of 25.8 (ranging from 15.9 to 54.8 kg/m²). Technical success rate was 96% (24 of 25). One procedure was unsuccessful due to lack of a safe percutaneous access window to the stomach free from intervening bowel on fluoroscopy. Twenty-five PRG attempts (100%) were performed in IR with fluoroscopic guidance. PRG procedures lasted a mean of 30.5 ± 14.1 minutes. Mean fluoroscopy time was 3.2 minutes (ranging from 0.8 to 14 minutes). Radiation skin dose averaged 32 mGy (ranging from 0.6 to 374 mGy). Patients received a mean of 0.8 mg of intravenous (IV) midazolam, with a range between (0 and 2 mg). PRG patients received a mean of 50 mcg of IV fentanyl range (0 to 100 mcg). Fifteen patients received pre-procedure antibiotics (60%). Fourteen patients (93.3%) received 1 or 2 grams of ancef depending on body weight. One patient received levofloxacin 500 mg IV.

One major and one minor complication occurred following PRG placement. One patient's tube pulled back into the subcutaneous tract resulting in subcutaneous abscess formation requiring antibiotics and tube removal 18 days after placement. Another patient developed a subcutaneous abscess around the tube that was successfully treated with vancomycin. This patient did not receive periprocedural antibiotics. A third patient with dementia pulled their tube out on post procedure day 2 and a new tube was placed on day 3.

Comparison

Aside from significantly more COVID-19 patients in the PUG group ($P < .001$), there was no other statistically significant difference between the patient populations. Of note, BMI was similar between groups, 25.8 m²/kg for PRG patients and 24.8 m²/kg for PUG patients ($P = .588$). Intra-procedure pain medication use was the same for both groups, 50 mcg ($P = 1.0$). Intra-procedure sedation with midazolam was insignificantly higher in the PUG group 1.12 mg vs 0.8 mg ($P = .355$). Procedure length trended toward statistical

significance ($P = .076$), with PRG being shorter than PUG (30.5 ± 14.1 minutes vs 39.7 ± 17.9 minutes).

Technical success rates were 96% in each group. Complication rates were 8% in each group. One PUG patient had bleeding following initiation of anticoagulation therapy. Another had bleeding at the skin incision site. While both patients required RBC transfusion, neither required surgical or endoscopic treatment. Both PRG patients with complications developed subcutaneous abscesses which were treated with antibiotics. One abscess failed antibiotic therapy alone and the tube was removed.

Discussion

In this study, we prospectively observed inpatients receiving the PUG for 30 days post-procedure and compared outcomes to a retrospective cohort of patients who received PRG. Complications of the PUG procedure were insignificantly different from that of PRG despite the overall higher acuity of the PUG cohort. There were two major non-device related bleeding complications in the PUG group. One was related to early restarting of anticoagulation for pulmonary embolism and the other was cutaneous bleeding that may occur following any percutaneous procedure. Bleeding complications are reported to occur in up to 1% of gastrostomy tube placements¹⁶⁻¹⁸ and anticoagulation is a known risk for bleeding following PEG placement.¹⁹ There were two access site infections in the PRG group which required treatment. Access site infection is a known complication of G-tube placement and can occur in up to 30% of cases.⁴ It is reported in the literature that most access site infections are minor and only 1.6% require aggressive intervention.²⁰

Both PUG and PRG methods of gastrostomy tube placement were similar with respect to local anesthesia and procedural sedation. PRG procedures were insignificantly shorter than PUG procedures, however, the cause for increased procedure time could not be accounted for by objective patient related factors. Subjectively, the most time-consuming portion of the PUG procedure was identifying the OGT with ultrasound. The authors suggest evaluation of a pre-procedural chest x-ray or CT, if available, to identify the location of the stomach and to consider PRG in patients with stomachs positioned high under the ribs as fluoroscopy is necessary to identify gastric inflation below the ribs.

Though each technique had high technical success rates (96%), there are important advantages of PUG over PRG. While the radiation dose to patients from PRG is low, PUG eliminates a source of radiation to chronically ill patients who already receive greater than average radiation compared to the general hospital population.²¹ PUG enables bedside placement in the ICU, eliminating the need for transporting critically ill patients to specialty suites and the related complexities and risks to the patient and staff. Bedside placement during the COVID-19 pandemic enabled procedures to be performed within negative pressure rooms without requiring additional

preparation and decontamination of an operating or angiography suite.

To further limit patient transport from the ICU for procedures, bedside tracheostomy and PUG has been performed in tandem by critical care physicians.²² Other authors have reported on the feasibility and safety of concomitant bedside tracheostomy and PEG tube placement by interventional pulmonologists.²³ Concomitant procedural events improve efficiencies in workflow and patient care by minimizing interruptions (e.g. feeding and anticoagulation) and anesthesia over utilization. Further, bedside placement avoids expensive operating and specialty suites. PUG can be performed when endoscopy towers are unavailable or by physicians who are more comfortable with ultrasound than endoscopic techniques. Widespread adoption of PUG by ultrasound trained physicians, such as intensivists and interventional pulmonologists, may address ICU care coordination challenges in locations without readily available interventional radiologists and endoscopists. Delays in proceduralist availability are associated with increased ICU length of stay and overall hospital costs.²⁴

Limitations of this study include differences in clinical operations and underlying disease processes, given that the COVID-19 pandemic began shortly after identification of the PRG cohort and before PUG recruitment. No patients in the PRG cohort had COVID-19. Importantly, while a significant number of the PUG cohort ($n = 17$) received gastrostomy tubes within the IR suite due to its availability while hospital elective procedures were canceled, 92% of the PUG cohort were admitted to the ICU at the time of g-tube placement. Of note, PUG helped our institution address critical bed shortages by preparing chronically ventilated patients with COVID-19 for discharge to available nursing homes. A further limitation of this study is that the cohort of performing physicians were only interventional radiologists and results may not be generalizable to all providers. Future studies would need to evaluate the procedure in the hands of intensivists, surgeons and gastroenterologists.

In conclusion, PUG is similar to PRG gastrostomy tube placement with respect to complications and is a safe method for gastrostomy tube placement in the critically ill with the added benefits of bedside placement, elimination of radiation exposure, and expanded and improved access to care. PUG should be further evaluated in large scale studies by ultrasound trained physicians to evaluate its safety and impact on patient outcomes in the critically ill population.

Authors' Note

S.P. Reis and S.Z. Brejt equally contributed to the conception and design of the research; D.G. Mobley contributed to the design of the research; S.P. Reis and J.R. Weintraub equally contributed to the acquisition and analysis of the data; J Susman, S.P. Reis, N. Ahmad, S.Z. Brejt, and D.G. Mobley contributed to the interpretation of the data; and S. P. Reis 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. Traditionally, placement of gastrostomy enteral feeding

tubes has been performed by specially trained physicians using endoscopy (PEG), fluoroscopy (PRG), or surgical techniques. A relatively new method for placing gastrostomy tubes, Percutaneous Ultrasound Gastrostomy (PUG), enables a bedside approach by using only portable, inexpensive, and readily available ultrasound imaging technology. This study demonstrates that PUG has is similar to PRG in terms of complication rates. Importantly, PUG may be safely performed by physicians skilled in ultrasound at the bedside. Thus, PUG eliminates the requirement for transport of the critically ill, preventing cross contamination during COVID, and reduces the coordination burden that may delay patients receiving adequate nutrition.

Declaration of Conflicting Interests

The author(s) declared no potential conflicts of interest with respect to the research, authorship, and/or publication of this article.

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ORCID iD

Stephen P. Reis, MD, MBA, FSIR  <https://orcid.org/0000-0002-8924-1286>

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