



## Response to the author on “*Percutaneous Ultrasound Gastrostomy (PUG) overview updates*” in response to our review on “*An overview of percutaneous endoscopic gastrostomy (PEG) tube placement in the intensive care unit (ICU)*”

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This letter is in response to the letter to the editor by Dr. Tropello on “*Percutaneous Ultrasound Gastrostomy (PUG) overview updates*” in response to our review on “*An overview of percutaneous endoscopic gastrostomy (PEG) tube placement in the intensive care unit (ICU)*”.

While we applaud and congratulate Dr. Tropello and colleagues for developing this new innovative PUG, we have to respectfully disagree with their statement that it is a safe technique compared to traditional PEG technique. PUG is a relatively new technique and there are no good prospective randomized trials comparing the two techniques or good long term outcomes data and several issues need to be addressed before PUG can be deemed as a safe technique which we will discuss below.

The authors mention the possibility of visceral injury with PEG as “unavoidable risk” which was described in the 1980s when there was no wide spread use of ultrasound in the intensive care units (1). With ultrasounds readily available in ICU and endoscopy units, in addition to transillumination and one-to-one finger indentation a quick examination of the trans illuminated insertion area with ultrasound adds to the safety profile of PEG and prevents any visceral injury in the current era. We term this technique a “Three-point Verification Technique” while performing PEG. This further adds to the safety profile of PEG technique.

Gastrostomy tubes are sometimes placed in inappropriate or not so ideal locations and this can lead to long term

complications down the line which may or may not be immediately noticed while the patient is still in the intensive care unit or hospital. The ideal anatomic location of placing a gastrostomy is in the body or antrum of the stomach. Endoscopically, we can always ensure that it is placed in an ideal anatomic location by direct visualization. The PUG technique is a blind technique without endoscopic or fluoroscopic visualization and we can never be sure of the ideal anatomic positioning of the gastrostomy in the body or antrum of the stomach. With PUG, how can we ensure that the magnetic gastropexy is not too close to the pyloric sphincter in the pyloric canal or too high in the fundus or too close to the lesser curvature which are not ideal positions for gastrostomy placement? A gastrostomy placed too close to the pyloric canal can cause gastric outlet obstruction (2). This can be a problem in the absence of endoscopic or fluoroscopic visualization especially in J shaped anatomy of the stomach or in the presence of hiatal and Para esophageal hernias.

In the published studies of PUG, they had to use fluoroscopy as a bail out in significant number of patients. Furthermore, majority of the procedures were done in the interventional radiology (IR) suite and only a small number of patients underwent a true bedside gastrostomy in ICU (3-6). Given the low number of PUG procedures performed in the ICU we cannot comment or extrapolate the conclusions on ICU-specific outcomes. This disputes the whole purpose of the concept of combined tracheostomy

and gastrostomy in a single setting in ICU. In addition, PUG was performed by interventional radiologists with extensive expertise and experience in diagnostic ultrasound and percutaneous ultrasound-guided procedures (5,6). The study quoted by the authors on critical care physicians performing PUG is a very small study of five patients and cannot be used as a generalized measure without robust data and outcomes study with large patient population (7). The safety and success of the PUG procedure in the hands of non-IR operators should not be taken for granted (6). In the PUG study by Cool *et al.*, fluoroscopy was used in two of five procedures to localize the orogastric balloon position within the stomach to achieve magnetic gastropexy (3). The same issue was encountered in another study by Dhiman *et al.* where they had to use fluoroscopy 95% of the time (4).

In support of their letter the author also quotes a more recent prospective, observational, non-randomized cohort trial by Reis *et al.* looking at 25 patients who underwent PUG placement over a 5-month period between April 2020 to August 2020 with 25 consecutive patients who underwent Percutaneous Radiological Gastrostomy (PRG) placement over a 2-month period between February 2020 to March 2020 (5). In that study, 23 of 25 (92% of patients) were admitted to the ICU at the time of planned gastrostomy. Patients who underwent PUG placement had a mean BMI of 24.8 kg/m<sup>2</sup>. They report a success rate for PUG placement of 96% (24 of 25). However, only Eight procedures (n=8, 32%) were performed bedside in the ICU and majority of procedures (n=17, 68%) were performed in the IR suite. Success rate of bedside PUG placement was 88.9% (8 of 9). It must be noted that these are a small number of patients that underwent successful “bedside procedure” and majority of them had to be transported to IR suite for the procedure. The one patient that had an unsuccessful bedside procedure in ICU underwent PUG placement in IR without fluoroscopic assistance but needed confirmation of nasogastric tube location in the stomach with a chest radiograph. Technical success rates of PUG procedures performed in IR was 94.1% (16 of 17). One attempt was stopped due to difficulty passing the orogastric balloon past the tracheostomy tube. It is also important to note that in this study as well, an additional 4% required fluoroscopic assistance for insufflation of the stomach below the ribs. One PUG patient had bleeding following the start of anticoagulation therapy and another patient had bleeding at the skin incision site.

The author in his letter quotes another prospective, industry-sponsored single-arm study of PUG insertion

performed in 25 adult patients under investigational device exemption by Accorsi *et al.* (6). In this study they report a practical success rate of 100% (25/25) for both PUG and PRG. Again, only three (3/25) PUG procedures were performed bedside in the ICU (12%) and 22/25 in the IR suite (88%). No PUG procedures (n= only 3) performed within the ICU needed fluoroscopic assistance for achieving magnetic gastropexy. However, Fluoroscopy was used in 8/25 (32%) PUG insertions to assist in locating and coapting the orogastric balloon for magnetic gastropexy. Three (12%) mild procedure-related adverse events were reported after PUG insertion, one aspiration and two stoma site infections, managed with antibiotics. One (4%) moderate adverse event occurred, an abdominal wall abscess near the gastrostomy site needing percutaneous drainage. One mortality was also observed in the PUG group, 12 days’ post-gastrostomy tube insertion secondary to aspiration pneumonia which they mention was unrelated to the procedure. However, the exact anatomic location of the tube in the stomach of this particular patient was not reported in the study.

Bleeding can also be an issue if the gastrostomy is placed too high in the fundus close to short gastric vessels or too close to lesser curvature from branches of the left gastric artery not just immediately following the gastrostomy insertion but also long term if there is ulceration in these areas. Furthermore, we also need to think about pyloric obstruction after long term tube exchange of the initial gastrostomy tube to a balloon gastrostomy tube if the gastrostomy is placed too close to the sphincter in the pyloric canal. These complications may not be seen immediately in the ICU post placement but certainly can happen down the line due to malposition or not so ideal site of insertions are chosen during initial placement (2). With PUG technique we can never be sure of the actual anatomic location of the gastrostomy during initial placement. Hence, we need long term multi-center prospective comparison and follow up studies with large patient population before we can say PUG is a safe technique compared to existing techniques.

Due to aforementioned reasons, we think that the safety of PUG is unsure at this time especially if the operator is inexperienced and has unrealistic understanding of the anatomy and limitations of what they can accomplish. Therefore, its unsafe for an untrained non-interventional operator to have access to performing bedside PUG at this time. Insufficiently studied equipment and techniques leading to unsafe practices in future serves no benefit to

our patients. Due to the reasons we discussed in this letter, we recommend further long term multi-center prospective comparison and follow up studies with large patient population before we can say PUG is a safe technique compared to existing techniques.

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